

TAKING INTO ACCOUNT ENVIRONMENTAL REQUIREMENTS IN THE DESIGN AND MANUFACTURE OF PACKAGING

***Application guide for
complying with the
compulsory packaging
regulations from the
European Directive
94/62/CE, modified by the
Directive 2004/62/CE,
transposed into French law
in the Environmental Code,
and in reference to the
harmonised standards,
published on February 19,
2005 in the OJEU¹***

FRENCH PACKAGING COUNCIL
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The third version of this practical guide, first published in May 2000 and then in May 2003, aims to help professional within the packaging chain (manufacturers of packaging materials and packaging, packers/fillers, brand owners, etc.) complying with the provisions which transpose, in our country, the European Directive related to packaging and packaging waste, and using the harmonised standards elaborated by the European Committee for Standardization (CEN). This reference document was prepared under the auspices of the **Conseil National de l'Emballage** (French Packaging Council)¹, at the request of **CLIFE**², **FCD**³, **ILEC**⁴, and **Interfilières Matériaux**⁵, in order to answer the questions asked by their member companies. Since 2003, the French and European statutory texts changed and the standards, still in the planning stage, were published.

Several professional members of the CNE wondered about what they should do after the repeal, by the decree 2007-1467, of the decree 98-638, which was transposing the European Directive 94/62/CE (itself amended in the meantime by the Directive 2004/12/CE).

The Directive 2004/12/CE amends 9 out of 25 articles from the Directive 94/62/CE and mainly Article 6 (establishing new recovery and recycling targets), without modifying significantly the prevention, reuse and recovery concepts, which are the subjects of this application guide. We shall always refer to the European Directive, which is the base for regulation issues.

The French decree of 1998, which transposed the European Directive of 1994, was repealed in 2007 in order to implement the Environmental Code whereof we have kept articles R543-42 to R543-52 about provisions relating to packaging (Book V, Title IV: Waste, Chapter III, Section V). Reference to the harmonised standards is constant in order to attest the packaging compliance with the essential requirements – which was not the case for the decree of 1998.

Our collective approach aims to help companies establishing procedures to ensure that packaging is manufactured and used in conformity with the essential requirements of the European Directive. Compliance guarantees the free movement of packaging and packaged products throughout the European Union.

Complying with the compulsory packaging regulations provides companies with an opportunity to be involved in an integrated prevention procedure. It is one of the objectives of the French Packaging Council to help them implementing this part of their sustainable development policy.

¹ Conseil National de l'Emballage or CNE, registered in Europe as the French Packaging Council ®

² Liaison Committee of French Packaging Industries

³ Federation of Trade and Retail

⁴ Institute of Consumer Goods Industries

⁵ Paper/cardboard, aluminium, steel, plastic and glass sectors

I Main statutory provisions

II How to ensure that packaging complies with the European directive?

1.1. Concentration levels of heavy metals present in packaging or its components (*Art.11 of Directive 94/62/CE and Art.R543-45 of the Environmental Code*)

Limit since June 30, 2001: 100 ppm

Note: "The concentration levels shall not apply to packaging entirely made of lead crystal glass which respect the approved standard NF B 30-004"

1.2. Essential requirements (Art. 10 and annex II of the Directive, and Art.R.543-44 of the Environmental Code) relating to:

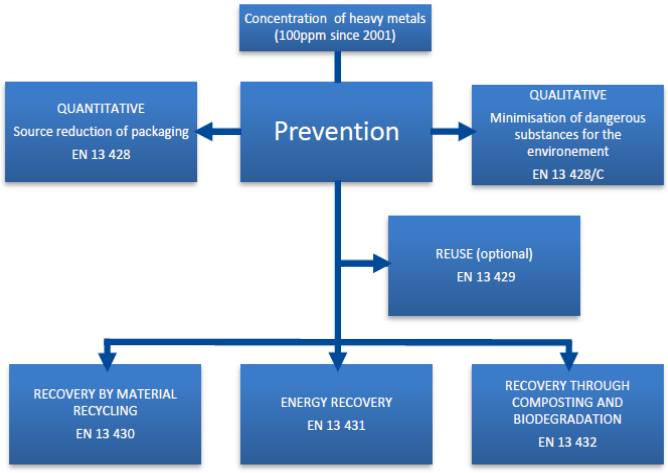
- o The design, manufacture and composition of the packaging:
 - Preventing by source reduction: "Packaging shall be so manufactured that the packaging volume and weight be limited to the minimum adequate amount to maintain the necessary level of safety, hygiene and acceptance for the packed product and for the consumer."⁶
 - Minimising the use of dangerous substances for the environment.
- o The reusable nature of packaging (for reusable packaging)
- o The recoverable nature of packaging (for all packaging) by at least one of the following forms of recovery:
 - Material recycling
 - Energy recovery
 - Composting
 - Biodegradation

The tree structure below puts into perspective these different essential requirements with the standards approved in 2004 and harmonised when published in the OJEU (Official Journal of the European Union) on February 19, 2005:

2.1 Heavy metals: The packaging or packaging constituents⁷ manufacturer must obtain declarations from his suppliers of raw materials confirming that the maximum concentration levels have not been exceeded. The declarations may refer to relevant scientific studies on the materials in question.

2.2 Essential requirements: A range of standards, published in the OJEU on February 19, 2005⁸ can be used to check whether the packaging complies with the essential requirements. The framework standard EN 13427 specifies the procedure on how to use the standards in order to produce technical documentation.

ESSENTIAL REQUIREMENTS	STANDARD	PUBLICATION IN THE OJEC	PUBLICATION IN THE OJEU	
Prevention	• By source reduction	EN 13428	12/07/01	19/02/2005
	• Minimisation of dangerous substances	EN 13428 (Annex C)		19/02/2005
Reuse (when relevant)	EN 13429			19/02/2005
Recovery (at least one form)	• By material recycling	EN 13430		19/02/2005
	• By energy recovery	EN 13431		19/02/2005
	• By composting or biodegradation	EN 13432	12/07/01	19/02/2005



The standard EN 13428, published in July 2004 before the set of standards, deals with the prevention of packaging waste by source reduction, priority principle in European Union texts.

⁷ Packaging constituent is defined as "a part of packaging that can be separated by hand or by using simple physical means". In the standards, the term used is packaging component (e.g. a cap). Each component must comply with the regulations on heavy metals.

⁸ The standards elaborated by the European Committee for Standardization (CEN) are now part of French national standards (NF-Afnor). Available at Afnor (reference 308 60 31 - Emballages et déchets d'emballages.) <http://www.afnor.org/>

⁶ European Directive 94/62/CE

The standards are for companies' internal use to implement the provisions of the Essential requirements.

These standards constitute a recognised reference guide for producing the technical documentation required by the Environmental Code, using an internal control procedure (self-assessment by the manufacturer).

Each standard includes its own procedure for assessing conformity.

3.1 Prevention

3.1.1 Prevention by source reduction (standard EN 13428)

○ Definitions

- *Prevention by source reduction*

"A process for the achievement of a minimum adequate weight and/or volume, for identical requirements, of primary and/or secondary and/or tertiary packaging, when performance and user acceptability remain unchanged and/or adequate, thereby minimising the impact on the environment."

Note: *"The substitution of one material by another is not a basis for source reduction."*

- *Designer*

We consider the packaging designer as the person who has drawn up a precise descriptive specification including technical drawings and who has (at the minimum) defined the weight and/or the volume of the packaging.

The user who transmits a functional specification or a design brief to a packaging manufacturer is not considered as a designer.

○ Methodology

Reduction at source is demonstrated by identifying "critical area/s". Identifying a "critical area" means demonstrating that, if the weight and/or volume of the packaging were further reduced, it would fail to fulfil one or more of its functions or "performance criteria". The standard suggests a list, which includes acceptance.

⇒ If the packaging manufacturer is also the designer, he should produce the technical documentation part related to prevention by source reduction. (In France, it is the packaging manufacturer's responsibility, except in particular cases; in the UK, it is the packer's responsibility).

⇒ If the packaging manufacturer is not the designer, and manufactures according to a descriptive specification, this specification may represent for him the critical area, from the moment he carries out his professional duty by offering advice to the designer. The designer (packer/filler or distributor for private label products) is responsible for using the standard to demonstrate compliance with the prevention procedure.

3.1.2 Minimisation of dangerous substances for the environment when packaging waste is disposed of⁹ (Standard EN 13428, annex C)

The annex C deals with the minimisation of dangerous substances or preparations in manufacturing and composition and conformity demonstration.

Dangerous substances are regulated by Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.¹⁰ Dangerous preparations are regulated by Directive 1999/45/CE.

The substances and preparations affected are those labelled as dangerous for the environment with the symbol "N", in accordance with Directive 67/548/CEE and its amendments, and with Directive 1999/45/CE.

The packaging manufacturer must obtain declarations from his suppliers confirming the absence or that no more than the minimum adequate amount of any dangerous substance for the environment has been intentionally added for technical reasons to the raw materials intended to be used to manufacture packaging.

If the packaging manufacturer is the producer of the raw materials used, he must be able to show that he has complied with the requirement to minimise the amount of dangerous substances for the environment intentionally added for technical reasons, if any such substances have been added.

3.2 Reuse (standard EN 13429)

○ Definition

"Any operation by which packaging, which has been conceived and designed to accomplish within its life cycle a minimum number of trips or rotations, is refilled or used for the same purpose for which it was conceived, with or without the support of auxiliary products present on the market enabling the packaging to be refilled; such reused packaging will become packaging waste when no longer subject to reuse." It is then subject to the same requirements as other packaging wastes when it comes to end-of-life recovery.

⁹ *"Packaging must be so designed and manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging materials 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."* Art. R.543-44 of Environmental Code

¹⁰ Directive 67/548/EC has been transposed into French law in the Labour Code, and in the Law of July 12, 1977 on chemical products and the Decree of April 20, 1994 relating to Declaration, Classification, Packaging and Labelling of Dangerous Substances.

○ Methodology

The requirements for reusable packaging are determined by a combination of requirements for the packaging itself and the reuse system in which it operates.

3.3 Recovery by material recycling (standard EN 13430)

○ Definitions

Material recycling: *"The reprocessing in a production process of the waste materials for the original purpose or for other purposes including organic recycling but excluding energy recovery."*

Recycling process: *"A physical and/or chemical process which converts collected and sorted used packaging and scrap, together in some instances with other material, into secondary raw material or products."*

○ Methodology

In order to demonstrate the suitability of packaging for material recycling, the manufacturer must *"ensure that the design of the packaging makes use of materials or combinations of materials which are compatible with the known, relevant and industrially available recycling technologies ..."*

A declaration from a recycling organisation will also be considered as an evidence of suitability for material recycling.

3.4 Energy recovery (standard EN 13431)

○ Definition

Packaging claimed to be suitable for energy recovery must be combustible and capable of providing a calorific gain.

○ Methodology

The standard makes the difference between organic materials and inorganic materials.

- Packaging composed of over 50% by weight of organic materials (e.g. wood, cardboard, paper and other organic fibres, starch, plastics) provide a calorific gain and shall be considered energy recoverable.
- Packaging composed of over 50% by weight of inorganic material (e.g. ceramic, glass, clay, metals) may be declared energy recoverable if the calculation of the calorific gain specified in Annex A of the standard EN 13431 provides evidence of this. Thin gauge aluminium foil up to 50 micrometres thick shall be counted as combustible and shall be considered energy recoverable.

3.5 Recovery through composting and biodegradation (standard EN 13432)

○ Definition of ultimate biodegradability

"Breakdown of an organic chemical compound by micro-organisms in the presence of oxygen to carbon dioxide, water and mineral salts of any other elements present (mineralisation) and new biomass or in the absence of oxygen to carbon dioxide, methane, mineral salts and new biomass."

○ Methodology

"To be designated as organically recoverable, each packaging, packaging material or packaging component shall disintegrate in a biological waste treatment process (according to the criteria and acceptance levels mentioned in the standard), without any observable negative effect on the process."

About packaging end-of-life, we draw the attention on the fact that everything which is compostable is biodegradable, but everything which is biodegradable is not automatically compostable according to the standard EN 13432. Moreover, this standard relative to the recovering through composting and biodegradation does apply only to the industrial composting. An industrial compostable packaging is not necessarily compostable at home (cf position paper of the CNE, of June 26, 2009).

IV Conformity assessments for packaging

4.1 Self-assessment by the packaging manufacturer

- The packaging manufacturer or his authorised representative located in a member state of the European Union or in another country which has an agreement with the European Economic Area, shall ensure and declare, according to internal manufacturing control procedures, that the packaging that he places on the market complies with the regulation provisions transposed in France in the articles R543-44 and R543-45 of the Environmental Code (*Art. R543-48*).
- Packaging in conformity with the harmonised European standards published in the Official Journal of the French Republic or, otherwise, with the French standards or with the standards of another member state of the European Union approved by the European Commission, and which references were published in the Official Journal of the French Republic, are deemed to meet the requirement of the articles R.543-44 and R.543-45 of the Environmental Code (*Art. R543-47*).

- The outcome of the self-assessment should be compiled in a **file** comprising a **written declaration of conformity** and **technical documentation**:
- **the written declaration** certifies the packaging conformity.¹¹ It may be sent to the packaging user.
- **the technical documentation** contains the elements needed to assess that the packaging meets the various requirements, such as: a description of the packaging and its composition, conception and manufacturing drawings with explanations, standards lists and self-assessment results, declaration on the concentration levels of heavy metals, declaration on the minimisation of dangerous substances for the environment, etc. The technical documentation is designed for enforcement officers as mentioned in paragraph 4.3.

To reduce the cost of compiling technical documentation, the packaging manufacturer may make reference to a type or a category of packaging, under certain conditions and according to relevant¹² pooling criteria (see explanatory note prepared by the French Industry Ministry dated February 16, 1999).

When neither the packaging manufacturer nor his authorised representative are located in a member state of the European Union or in another country approved by the European Economic Area, these obligations are incumbent upon the person responsible for marketing the manufactured packaging (Art. R543-48).

4.2 Certification by Packaging Users

Users designated here are packers/fillers or distributors of private label packaging, depending on the nature of their specification, or the importers of filled packaging, responsible for placing packaging on the market.

"The person responsible for placing filled packaging on the market, if he is not the manufacturer of that packaging, must be in a position [...] to present a written declaration of conformity for the packaging used from the place where they are filled to the place where they are sold to the final consumer" (Art. R543-51).

To do this, the user should collect from his suppliers the declarations of conformity (and not the technical documentation designed for officials from the administration in charge of enforcement) of the packaging or packaging constituents that he collates and which constitute his packaging system.

¹¹ See the suggested standard format widely used since 2000 in the Annex.

¹² The relevance of pooling criteria should be analysed for each of the essential requirements.

For packaging he designs, the user should ensure that the packaging complies with the requirements for prevention by source reduction by referring to the standard EN 13428.

4.3 Control by the authorities

Member states make sure that the packaging placed on the market complies with all essential requirements defined by the European Directive and assume that the packaging meets these requirements when it complies with the harmonized standards (Art. 9 of the European Directive 94/62/CE).

In France, the DGCCRF¹³ may check the conformity of packaging by verifying that the self-assessment procedures have been followed.

"In the event of an inspection during the two calendar years following the year when the packaging was first placed on the market, the packaging manufacturer, his authorised representative or otherwise the person responsible for placing packaging on the market, must be in a position to present the file within fifteen days to the enforcement officers. This file comprises the declaration of conformity and the technical documentation. (Art. R543-50 of the Environmental Code)

The user shall base his declaration of conformity on the declarations of conformity received from its suppliers, and on his self-assessment that the packaging complies with the requirement on prevention by source reduction when he is the designer of that packaging.

Publication available on the French Packaging Council website :

<http://www.conseil-emballage.org>

71, avenue Victor Hugo 75116 PARIS
Tel : 01.53.64.80.30. – Fax : 01.41.01.75.16.
e-mail : info@conseil-emballage.org

¹³ La Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes – Government body responsible inter alia for enforcing trading standards and competition laws in France.

DECLARATION OF CONFORMITY MODEL

Name and address of the company:

.....

Declares that the packaging¹ referenced below is in conformity with the provisions of the Directive 94/62/CE amended, and with the French Environmental Code (Regulation part, Book V, Articles R.543-42 to R.543.52).

The packaging(s) below has been designed and manufactured in accordance with the relevant and harmonized standards indicated below.

The company has available all information relevant to this declaration of conformity and can present them to the authorities within the prescribed timetable.

- Packaging references
-
- Prevention by source reduction (EN 13428) ²
- Reuse (EN 13429) if necessary
- Material recycling (EN 13430)
- Energy recovery (EN 13431) } at least one
- Recovery through composting and biodegradation (EN 13432)
- Dangerous substances: Declaration of minimisation (EN 13428/C)
- Heavy metals: Declaration that limits have not been exceeded

Signed in

Authorised signatory and company seal

¹ Packaging or packaging type

² ➤ If the packaging manufacturer is also the designer, he should produce the technical documentation part related to prevention by source reduction.

➤ If the packaging manufacturer is not the designer, and manufactures according to a descriptive specification, this specification may represent for him the critical area, from the moment he carries out his professional duty by offering advice to the designer. The designer (packer/filler or distributor for private label products) is responsible for using the standard to demonstrate compliance with the prevention procedure.

The person considered as the packaging designer is the person who has drawn up a precise descriptive specification including technical drawings and who has, at the minimum, defined the weight and/or volume of the packaging.

The user who gives a function specification or a design brief to a packaging manufacturer is not considered as the designer.

Model developed by CNE, in cooperation with CLIFE, FCD, ILEC and INTERFILIERES MATERIAUX.