Swedish Code For Food Packaging Materials

NORMPACK

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http://normpack.packforsk.se/webdoc.asp

http://www.packforsk.se/normpack.asp

Materials and articles intended to come into contact with foods

1. Legislation on the EU market to protect Food from contamination by migration of chemicals.
2. Normpack – example of the Swedish solution of how to manage the legislation

The EU Market

Regulation L 1935/2004 of the EU Parliament and the Council

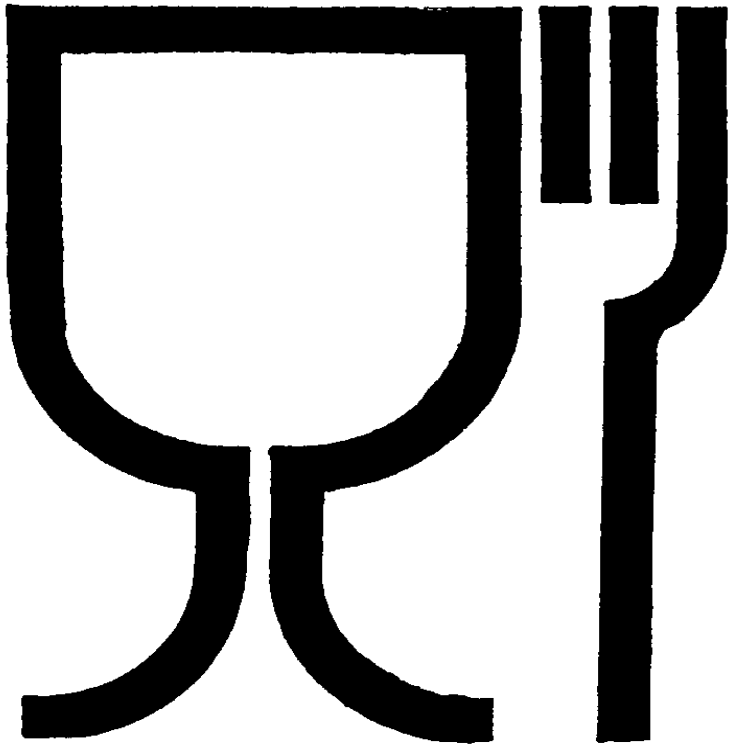
L 338/16 EN Official Journal of the European Union 13.11.2004

Principle of the regulation:

Materials or articles intended to come directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

In force since 3 December 2004

SYMBOL



2005 – 2006 - 2007

Existing Regulation L 1935/2004 for all materials and articles
Specific material regulations

Existing – coming

”Plastic”
Cellophane
Epoxy coatings
VCM in PVC
Rubber- Nitrosamine
Semi-carbamide
Recycled plastic
Active & intelligent packaging
Varnishes and coatings??

Missing

Cork
Glass
Ion-exchange resin??
Metals and alloys
Paper and board
Printing inks??
Silicones
Textiles
Waxes
Wood

National regulations = R
Recommendation = R

Examples:

Germany – BfR – all materials (no coatings)	R
The Netherlands – Warenwet – all materials	R
USA – 21 CFR – all materials	R
Italy – paper and board	R
Finland – paper and board	R
Belgium – coatings	R
France – all materials	
– specifically paper and rubber	R

Regulation L 1935 /2004

Chapter I : General Provisions

Article 1 : Subject matter

- General requirements
- Specific requirements
- Community procedure for the evaluation and authorisation of substances
- Rules for Labelling and Traceability
- Safeguard measures
- Community and national reference laboratories

Chapter I: General Provisions

Article 2 : Scope - Field of application

Provision for covering and coating substances

- A&I Systems covered by the Directive.
- The Regulation must apply without prejudice to the requirements for food contact materials or food laid down in other Community directives
- The Regulation shall not apply to materials and articles placed on the market before 1 January 1980 (to replace exemption of “Antiques”)

Chapter I: General Provisions

Article 3 : Definitions

- “active food contact material systems”: materials and articles intended to extend the self-life or to maintain or improve the condition of packaged foodstuffs. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged foodstuffs or the atmosphere surrounding these foodstuffs.
- “intelligent food contact materials systems”: materials and articles which monitor the condition of packaged foodstuffs

Chapter I: General Provisions

Article 4 : General use and safety requirements

- Active systems shall not release substances that could endanger human health
- Active systems may change the composition and/ or the organoleptic properties of food provided these changes comply with the provisions applicable to food.
- Active and intelligent systems shall not change the properties of food or give information that might mislead the consumer.

Chapter I: General Provisions

Article 5: Specific measures for groups of materials and articles

Specific directives

↳ **Specific measures**

Chapter III: Labelling and Traceability

Article 12 : Labelling requirements

- Consumers should always be informed when a material or article is “suitable for food contact”
- Labelling requirements for A&I food contact material systems (instructions on the permitted use(s) to enable the users of these systems to comply with any other relevant Community provisions or, in their absence, national provisions applicable to food)
- Declaration of compliance shall be supported by appropriate documentation to be made available to competent authorities on demand

Chapter III: Labelling (2004) and Traceability (2006)

Article 13: Traceability requirements

- Traceability at all stages of manufacture, processing and distribution.
- Businesses to have in place systems to identify the suppliers of materials and articles and where appropriate of starting materials to their businesses, and to whom they have supplied such materials and articles. Importers are equally affected (one step 'above' one step 'below' in the supply chain)
- Info to be supplied to the competent authorities on demand.
- Traceability by labelling or by product identification through documentation.
- Additional provisions for the specific groups may be adopted in specific measures.

Chapter IV : Common Provisions

Article 14 : Safeguard measures

Article 15 : Free trade

Article 16 : Public access

- Non-confidential info accessible to the public

Article 17 : Confidentiality

- Confidential data determined by EFSA in agreement with applicant
- Not confidential: name of the applicant and substance; info on the safety of the substance; analytical methods
- Confidential info may be made public in cases of problems with human health

New materials to be regulated by specific measures

- A&I Systems
- Ion-exchange Resins
- Adhesives
- Printing inks

Plastic regulation today

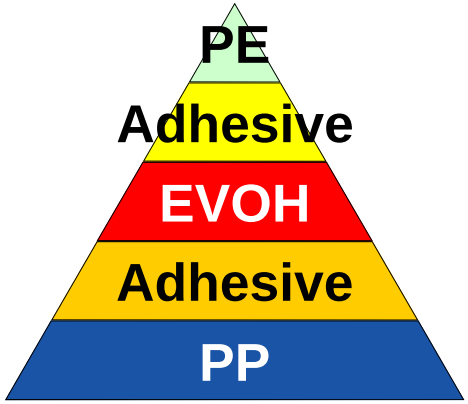
2002/72

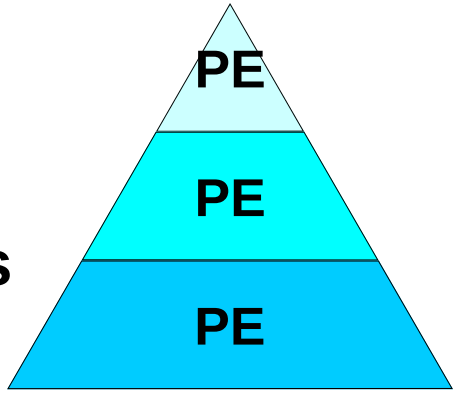
+ 2004/19

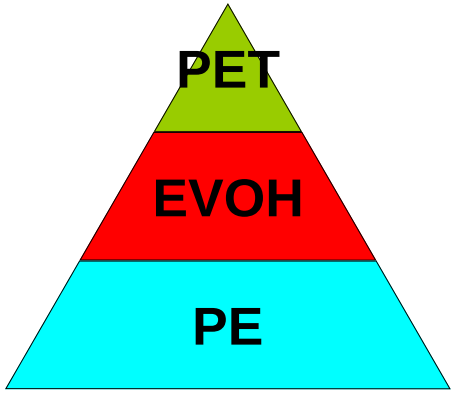
+ 2005/XX

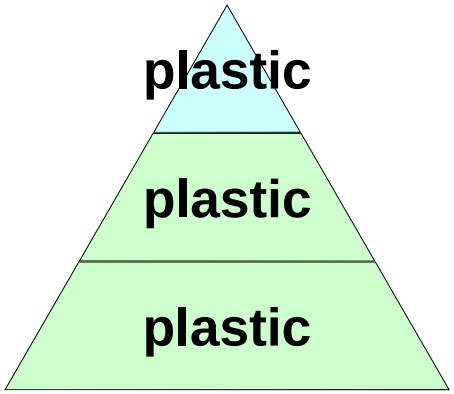
+ 87/109

+ plastic multilayers









“THE SUPER-REGULATION”

(130+ pages)

European Commission Health & Consumer Protection Directorate

General Directorate D – Food Safety: production and distribution chain

D3 - Chemical and physical risks; surveillance

THIS WORKING DOCUMENT DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Draft COMMISSION REGULATION …….. of…….. relating to plastic materials and articles intended to come into contact with foodstuffs

Brussels, 1 November *2004* DG SANCO/D3/LR *EMB/993-Rev. 6-3*

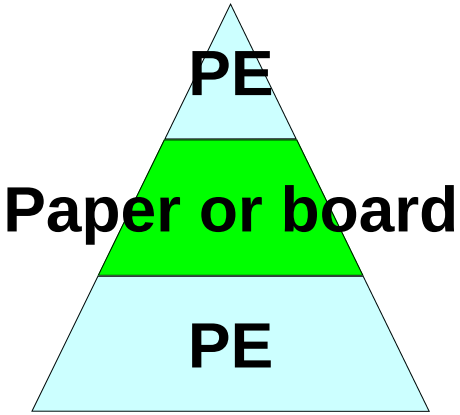
Coming ”Super Regulation”

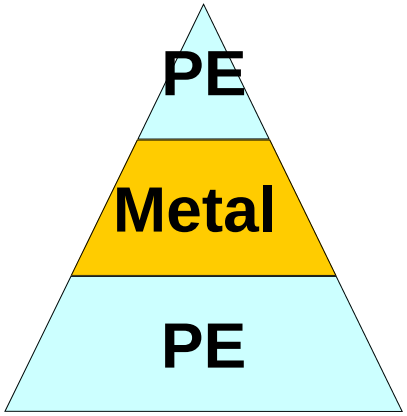
News 2005 - 2006

PLASTIC

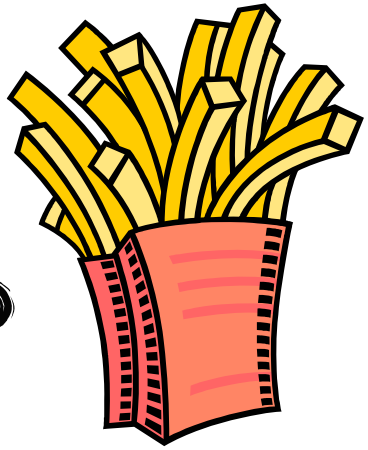
Extension of the rules to plastic multi-material multi-layer, i.e. articles composed of different materials, provided the material in contact with foods is plastic

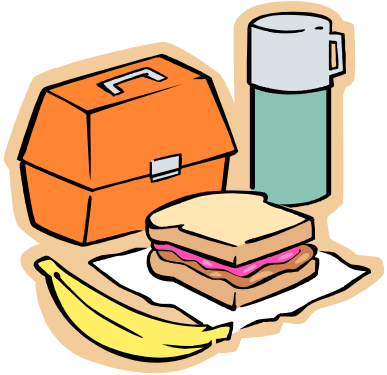
- plastic multilayers and
- multi-materials plastic multilayers





Super Regulation – ”plastic”





Super Regulation – ”plastic”

The scope is extended to multi-layer materials and articles made of plastics and materials other than plastics, such as metals and paper, provided the food contact layer or part of the food contact layer consists of plastic.

Food contact materials and articles whose direct food contact layer does not consist of plastic should not be covered by this Regulation

Concept of ”Funcional Barrier”

"Functional Barrier" is a barrier consisting of one or more layers which shall

a) ensure that the migration of authorised substances does not exceed the overall migration limit or their specific migration limits or the restriction applicable to them and that the migration of permitted substances is below a concentration that could endanger human health,

b) prevent transfer of the substances referred to in Article 13, paragraph 2, their reaction products and their impurities into food or food simulants;

Funcional Barrier

- Limit = 0,01 mg/kg food
- Threshold for migration considered ” non-detectable” = 10 ppb = 10^{-9} mg/kg food

Declaration of compliance

The written compliance declaration shall provide adequate and relevant information at each stage of the supply chain to help ensure the suitable use and safety of the materials and articles subject to the declaration and their compliance with relevant regulation.

The written declaration shall be reviewed **regularly and** whenever necessary.

Declaration of compliance

The declaration of compliance shall contain the following Information:

a) Name and address of the company in the European Union which manufactures or imports the finished material or article;

b) Product name;

c) Identity of the plastic materials and articles;

d) Date of the declaration;

e) Confirmation that the material or article complies with the requirements of EU Regulation and, when appropriate, of national law under the conditions of use identified under sub-paragraph hereunder. The references of these legislations and the specific provisions shall be quoted

Declaration of compliance

This compliance supporting documentation shall:

a) include, as is relevant for the products at stake and their place in the supply chain, the written declarations and other information received from suppliers, the results of testing, calculations, and other analysis, using internationally recognized scientific principles, including exposure assessments, carried out to demonstrate compliance, and any other pertinent legal, regulatory and scientific rationale;

Declaration of compliance

b) be made available to the Enforcement Authorities on request and be delivered without any unjustified delay;

c) be made available to the concerned business operators on request and be delivered without any unjustified delay under appropriate con-fidentiality agreements provided there is a documented risk of non-compliance with article 3 of L1935/2004 or a justified suspicion of non-compliance.

News

- Migration to dry food as rice - dry simulant
- Milk – simulant: water and 10% etanol
- Cheese containing less than 20% of fat - olive oil - X/5

Super Regulation

- Is very difficult from a technical point of view
- It takes an expert to manage it
- It is a very expensive regulation for both industry, retailers and consumers

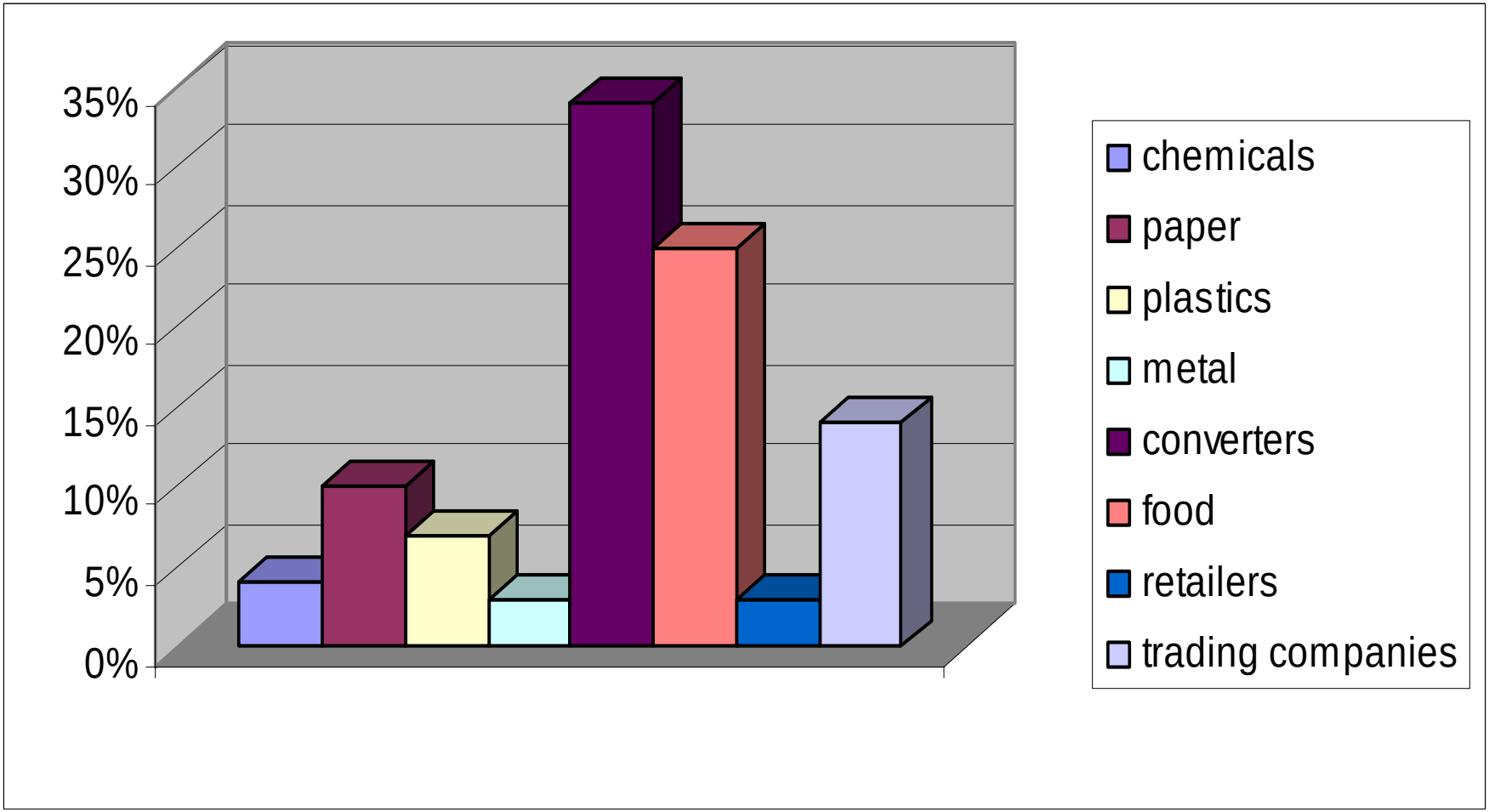
Normpack

Swedish Code for

Food Packaging Materials

- the Swedish way

160 members from
SE, NO, DK, Fl, D, UK, F, NL, It



Normpack (started 1981)

An agreement on a Swedish material norm to obtain product reliability for materials and products in contact with foodstuffs

The Normpack –Norm 2004
(will be changed 2005)

The paragraphs contain information about

§1 Swedish national regulation and LIV FS 2003:2 **and**

§2 Choice between Warenwet (NL) or BfR (DE)or FDA

§3 Cooperation regarding the use of material for foods throughout the whole chain

§ 4 Temporary Norm for PVC on DEHP (1984)

§ 5 Cellulose Based Materials (1997)

§ 6 Additives with limit values in plastic materials according to future amendments of 02/72/EEC (1997)

§ 7 BADGE, BFDGE and NOGE (2002)

§ 8 Elastomers and rubber (2001)

Aim

To further the interests of the industry, the trade and the consumer in product reliability as regards materials and products that are intended for use in contact with food, as well as to strengthen the position of the member companies on the Swedish and Scandinavian markets

Aim

Through a combination of product certificates and routine system for self-imposed control at the member companies it is ensured that materials and products meet the demands in both current Swedish legislation and ordinances as well as other regulations.

Activities

Advise and assist member companies to meet the demands in current legislation, both the Swedish and on export markets

Participate in international activities in this field

Acitivities

Continuous follow-up and information regarding current and coming legislation to members by education for the companies to help them find their way in current legislation and other regulations of importance to product reliability

Activities

Development of a routine system for the self-imposed control regarding product reliability. The routine system is implemented at the members companies to ensure that their products are inside the defined limits and pass the National Swedish Food Authority checks.

Principles

- Solve all ”problems” by agreement between the industry and the National Food Administration
- Avoid national regulation, wait for EEC regulation
- Normpack - economically advantageous to both industry & authorities
- ” Practical solution” - ”working” principles

Example of self-imposed control – BADGE

- EUREKA project
- Contamination results depend on the coating application technology as well as chemistry and the way in which a coating is tested, for example just the lid of a can, the can itself or closed packaging ready for use. Even the storage time of the contents (in this case, food) was covered in the project.

Example of self-imposed control

2003

Paper: DIPN, DEHA, BPA, BP ..

Various foodstuffs: sauce

Disposable gloves

2004

Primary Aromatic Amines in kitchen tools

EU commission meeting on March 22-23, 2005

The Norwegian Food Safety Authority sent an official remark to the EU commission and 24 EU countries giving Normpack as an example of a professional third party organisation which may be a good solution for fulfilling appropriate confidentiality agreements according to requests in L 1935/2004 and the coming Super Regulation.

The Swedish Authority supports the Norwegian Authority at this point.

The industry can manage L1935/2004 and the coming Super Regulation by self-imposed control systems

Industry self-control system

Normpack – economically advantageous to both industry and authorities in Sweden.