

IOPP Packaging Summit 2008

Packaging Development in the Face of EU Regulations

Arno Melchior

Global Packaging Director

This document is not intended to give you legal advice.
Please consult your lawyer to make sure that you
fulfil all legal requirements

PACKAGING DEVELOPMENT . . . in the face of EU regulations

• **Agenda**

- ReckittBenckiser – a very short introduction
- Essential requirements according to 94/62/EC - Packaging waste regulation
- Packaging of dangerous preparations according to 2001/60/EC
- Child-resistant packaging
- REACH - Europe's approach to toxic materials
- Other important regulations which impact packaging development

Introduction to Reckitt Benckiser

- Reckitt Benckiser is a manufacturer of Household cleaning products and OTC pharmaceuticals
- Operations in 60+ countries
- Sales in 180 countries
- Packaging Development all over the world
- Turnover in 2007 ~ \$10bn

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Introduction to Reckitt Benckiser



- World No. 1 in:
- Surface Care
 - Personal Antiseptics
 - Fabric Treatment
 - Depilatories
 - Automatic Dishwashing
 - Sore Throat
 - Disinfectant Cleaning
 - Water Softeners
 - Lavatory Care

**RECKITT
BENCKISER**

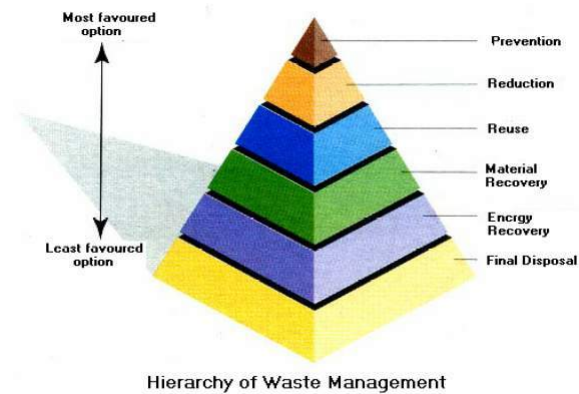
This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Packaging and Package waste directive 94/62/EC - Essential requirements

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Packaging and Package waste directive 94/62/EC

- The general objective:



This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Packaging and Package waste directive 94/62/EC

- The Directive covers three types of packaging with regards to waste:
 - sales or **primary packaging (WM: selling unit)** which is normally acquired by the purchaser or consumer;
 - grouping or **secondary packaging (WM: transport packaging)**, which is generally removed by the distributor or retailer at or near the point of sale;
 - **tertiary packaging**, which may be designed to facilitate bulk handling and transport.

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Packaging and Package waste directive 94/62/EC

- Key statements from 94/62/EC:
 - “Whereas the management of packaging and packaging waste requires the Member States to set up return, collection and recovery systems..... “
 - “Whereas the issue of Community marking of packaging requires further study, but should be decided by the Community in the near future;”
 - “Whereas, in order to minimize the impact of packaging and packaging waste on the environment and to avoid barriers to trade and distortion of competition, it is also necessary to define the **essential requirements** governing the composition and the reusable and recoverable (including recyclable) nature of packaging;”

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Packaging and Package waste directive 94/62/EC - Essential requirements

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Environmental Packaging Design and the Essential Requirements

- **The European Essential Requirements should be integrated into the new product development processes**
- **The Essential Requirements can be used as a basis for cost reduction and environmental improvement**
- **The Essential Requirements demand –**
 - **Minimal Packaging**
 - **Recyclable or Incineratable or Biodegradable packaging**
 - **Lowest possible levels of noxious/hazardous substances**
 - **Low Heavy metal content**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

94/62/EC - Annex II

Essential requirements on the composition and the reusable and recoverable, including recyclable, nature of packaging

Requirements specific to the manufacturing and composition of packaging:

- 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.
- Packaging shall be designed, produced and commercialised 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 waste management operations are disposed of.
- 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.

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

94/62/EC - Annex II

Essential requirements on the composition and the reusable and recoverable, including recyclable, nature of packaging

Requirements specific to the reusable nature of packaging

The following requirements must be simultaneously satisfied:

- **The physical properties and characteristics of the packaging shall enable a number of trips or rotations in normally predictable conditions of use**
- **Possibility of processing the used packaging in order to meet health and safety requirements for the workforce**
- **Fulfil the requirements specific to recoverable packaging when the packaging is no longer reused or thus becomes waste**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

94/62/EC - Annex II

Essential requirements on the composition and the reusable and recoverable, including recyclable, nature of packaging

Requirements specific to the recoverable nature of packaging in the form of material recycling:

- Packaging must be manufactured in such a way as to enable the recycling of a certain percentage by weight of the materials used into the manufacture of marketable products, in compliance with current standards in the Community. The establishment of this percentage may vary, depending on the type of material of which the packaging is composed

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

94/62/EC - Annex II

Essential requirements on the composition and the reusable and recoverable, including recyclable, nature of packaging

Requirements specific to the recoverable nature of packaging in the form of energy recovery:

- Packaging waste processed for the purpose of energy recovery shall have a minimum inferior calorific value to allow optimization of energy recovery

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

94/62/EC - Annex II

Essential requirements on the composition and the reusable and recoverable, including recyclable, nature of packaging

Requirements specific to the recoverable nature of packaging in the form of composting:

- **Packaging waste processed for the purpose of composting shall be of such a biodegradable nature that it should not hinder the separate collection and the composting process or activity into which it is introduced**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

94/62/EC - Annex II

Essential requirements on the composition and the reusable and recoverable, including recyclable, nature of packaging

Biodegradable packaging

- **Biodegradable packaging shall be of such a nature that it is capable of undergoing physical, chemical, thermal or biological decomposition such that most of the finished compost ultimately decomposes into carbon dioxide, biomass and water**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Essential Requirements

- **Transposed by all countries – only UK, France and Czech Republic have actively enforced ER in the past, but now all EU countries are starting to do so**
- **UK have increased enforcement in the last months considerably**
- **Series of CEN standards and reports to help companies comply**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Essential Requirements - CEN standards

Title	Reference
EN 13427	Packaging – Requirements for the use of European Standards in the field of packaging and packaging waste
EN 13428	Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction
EN 13429	Packaging – Reuse
EN 13430	Packaging – Requirements for packaging recoverable by material recycling
EN 13431	Packaging – Requirements for packaging recoverable in the form of energy recovery
EN 13432	Packaging – Requirements for packaging recoverable through composting and biodegradation – Test scheme and evaluation criteria for the final acceptance of packaging

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Heavy Metals Limits (Article 11 – 94/62/EC)

- **Aggregate heavy metals limits apply to cadmium, mercury, lead and hexavalent chromium. The total by weight should not exceed 100ppm after 30 June 2001**

**RECKITT
BENCKISER**

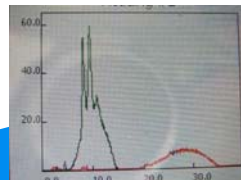
This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Heavy Metals Limits (Article 11 – 94/62/EC)

- Be aware: European authorities do check the heavy metal content!
- End of 2006 we had an issue. Although the two packaging suppliers have signed a declaration that they do not exceed the limit their products were well above the 100ppm limit
- As a result we have installed heavy metal testing equipment to monitor our suppliers



Detected	ppm	+/-
Tl	175	4
Not Detected	ppm	
Cr	ND < 3	
Hg	ND < 2	
Pb	ND < 2	
Cd	ND < 13	



This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Why should I be interested?

- **Packaging which complies with the Essential Requirements cannot be refused access to the market on grounds of non-conformity with the Directive.**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

What happens if I do not comply?

- **Packaging has to be changed to comply with ER**
- **Products could be removed from the marketplace**
- **Fines could be imposed on individuals/companies**
- **But by far the worst punishment:**
 - **Negative PR by NGO's**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Who is responsible?

- **Supplier – “the entity responsible for placing packaging or packed product on the market”**
 - Generally the packer/filler, brand owner or importer
- **Can comply in some respects by obtaining statements of compliance from upstream**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

What do I have to do?

- **Ensure that all packaging placed on the market is minimised and recoverable at the end of its life**
- **Be able to provide evidence of compliance backed up by technical documentation if requested to do so by regulatory authority – usually you have 28 days or so to produce documentation**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

What packaging is covered?

- **Essential Requirements relate to ALL packaging placed onto the market**

Assessment procedure	Reference	Applicability
Summary/umbrella	EN13427	All packaging
Source reduction	EN13428	All packaging
Heavy metals	CR13695-1	All packaging
Minimisation of dangerous substances	EN13428 and CR13695-2	All packaging
Reuse	EN13429	Where claimed
Recovery		All packaging must comply with at least one recovery method
Material recycling	EN13430	
Energy recovery	EN13431	
Organic recovery	EN13432	

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Umbrella standard – EN 13427

- “...specifies requirements and a procedure by which a person or organization responsible for placing packaging or packed products on the market may combine the application of five (mandated) packaging standards and one (mandated) CEN report (in two parts).”

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Umbrella standard – EN 13427

- “...shall ensure that the applicability of the relevant standards ...has been assessed in relation to packaging or packed product placed on the market”
- “...ensure that due consideration is given to limiting and if appropriate the further reduction of levels of heavy metals...”
- “...select.....a combination of Standards/Reports...with the objective of achieving a reduction in environmental impact of packaging waste whilst ensuring the maintenance of function, safety and consumer acceptance.”

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Minimisation / Prevention by source reduction EN 13428

- “...specifies a procedure for assessment of packaging to ensure that the weight and/or volume of its material content is at the minimum commensurate with the maintenance of:
 - Functionality throughout the supply and user chain
 - Safety and hygiene for both product and user/consumer
 - Acceptability of the packed product to the user/consumer

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Minimisation / Prevention by source reduction EN 13428

- **Includes a procedure for determining the presence of the four specified heavy metals**
- **Procedure for determining the presence and minimisation of any hazardous or noxious substances**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Minimisation / Prevention by source reduction EN 13428

- **Determine “critical area” preventing further minimisation**
 - **Note: substitution of one packaging material by another is not source reduction**
- **Demonstrate that substances classified as dangerous to the environment have been minimised**
- **Demonstration that any presence of the four heavy metals in packaging components does not exceed the specified limits**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Minimisation / Prevention by source reduction EN 13428

- **Performance criteria**

- **Product protection**
- **Packaging manufacturing process**
- **Packing/filling process**
- **Logistics (incl transport, warehousing)**
- **Product presentation and marketing**
- **User/consumer acceptance**
- **Information**
- **Safety**
- **Legislation**
- **Other issues**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Reuse EN13429

- **“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”**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Material recycling EN 13430

- **“The supplier shall be able to demonstrate that the procedures defined in normative Annexes A and B have been followed in arriving at the final design of the finished packaging such that a certain percentage of the packaging materials can be claimed to be recyclable.”**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Material recycling EN 13430

- **“packaging may use more than one material whose relative proportions may vary from small components and constituents, typically represented by labels and closures, to larger proportions in multi-material packaging.”**
- **“The supplier shall declare the percentage by weight of the functional unit of packaging available for recycling, identifying the intended material recycling stream(s)....”**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Material recycling EN 13430

- **Criteria relating to**
 - Design
 - Production
 - Utilisation
 - Emptying
 - Sorting
 - Collection
- **Declaration of percentage available for recycling**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Requirements for packaging recoverable in the form of energy recovery EN 13431

- **“To allow optimisation of energy recovery in a real industrial system, the theoretical calorific gain should be well above zero. To claim energy recovery q_{net} shall be equal to or greater than 5MJ/kg”**

q_{net} = net calorific value

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Requirements for packaging recoverable in the form of energy recovery EN 13431

- > 50% (by weight) organic content – assumed to comply
- > 50% (by weight) inorganic components – not energy recoverable
- > 50% (by weight) inorganic constituents can be energy recoverable if q_{net} is $\geq 5\text{MJ/kg}$

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Requirements for packaging recoverable through composting and biodegradation

• 5 assessment procedures

– Characterization

- Identification of constituents
- Determination of hazardous substances
- Determination of organic carbon content

– Biodegradability

- Each material or component must pass criteria

– Disintegration

- Each material or component must pass criteria

– Compost quality

- Must not have negative effect on compost quality

– Recognizability

- Must be recognisable to the end user

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Composting/biodegradation

- **“In the case of a packaging formed by different components, some of which are compostable and some other not, the packaging itself, as a whole is not compostable. However, if the components can be easily separated by hand before disposal, the compostable components can be effectively considered and treated as such, once separated from the non compostable components.**

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Essential Requirements – Reckitt Benckiser documents

- **How do we assess Compliance of Packaging with the EU Packaging and Packaging Waste Directive (94/62/EC) at ReckittBenckiser?**
 - A consultancy developed for us a “Compliance Documentation”
 - Target was to make the procedure as easy as possible
 - “Compliance Documentation” will be done by Packaging Development
 - The documentation will be kept in each factory on a public drive
 - On request this documentation will be send to the commercial units

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Packaging and Package waste directive 94/62/EC - Marking of Packaging in Europe

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Marking of Packaging in Europe

- Decision on Material Identification 97/129/EC
 - The system proposed is a detailed one, based on numbers and abbreviations, and covers paper, plastics, steel, aluminium and individual composite materials. With the exception of material identifiers for plastics, the Commission's material identification system does not recognise the existing, well established material identification systems already developed by the glass, aluminium and steel material sectors. The Commission system has not been used previously and **its use still remains voluntary.**



This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Marking of Packaging in Europe (97/129/EC)

Material	Abbrev.	#
Polyethylenterephthalate	PET	01
Polyethylene High Density	HDPE	02
Polyvinylchloride	PVC	03
Polyethylene Low Density	LDPE	04
Polypropylene	PP	05
Polystyrene	PS	06
Other Plastics	O	07
Corrugated	PAP	20
Carton-Solid board	PAP	21
Paper	PAP	22
Steel	FE	40
Aluminium	ALU	41
Wood	FOR	50
Cork	FOR	51
Cotton	TEX	60
Jute	TEX	61
Colourless glass	GL	70
Green Glass	GL	71
Brown Glass	GL	72
Paper and Carton/different metals		80
Paper and Carton/plastic		81
Paper and Carton/aluminium		82
Paper and Carton/tin-plate		83
Paper and Carton/plastic/aluminium		84
Paper and Carton/plastic/aluminium/tin-plate		85
Plast/aluminium		90
Plastic/tin-plate		91
Plastic/different metals		92
Glass/Plastic		95
Glass/aluminium		96
Glass/tin-plate		96
Glass/different metals		97

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

**RECKITT
BENCKISER**

Directive 2001/60/EC ...

... relating to the classification, packaging and labelling of dangerous preparations

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Directive 2001/60/EC - packaging and labelling of dangerous preparations

• Article 9 - Packaging

- 1. Member States shall take all necessary measures to ensure that:
- 1.1. preparations within the meaning of Article 1(2) and preparations covered by Annex IV pursuant to Article 1(3) cannot be placed on the market unless their packaging satisfies the following requirements:
 - it shall be so designed and constructed that **its contents cannot escape**; this requirement shall not apply where special safety devices are prescribed, **(i.e. leakage)**
 - the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents, **(i.e. stress cracks)**
 - packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling,
 - containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping;

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Directive 2001/60/EC - packaging and labelling of dangerous preparations

• Article 9 - Packaging

- 1.2. containers which contain preparations within the meaning of Article 1(2) and preparations covered by Annex IV pursuant to Article 1(3) offered or sold to the general public do not have:
 - **either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or**
 - **a presentation and/or a designation used for foodstuffs or animal feedingstuffs or medicinal or cosmetic products.**
- 1.3. containers which contain certain preparations offered or sold to the general public covered by Annex IV to this Directive:
 - **are fitted with child-resistant fastenings, and/or carry a tactile warning of danger.**
- The devices must conform to the technical specifications given in Parts A and B of Annex IX to Directive 67/548/EEC.

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Directive 2001/60/EC - packaging and labelling of dangerous preparations

- Article 9 - Packaging

- either a shape and/or graphic decoration likely to attract or arouse the active curiosity of children....

[011] 3 [111] 306 03 745.9 / 03
01, 05
[200] 19.01.2006 [151] 13.03.2006 [450] 13.04.2006
[540]



[531] 19.07.08; 29.01.12
[733] Henkel KGaA, Düsseldorf, DE
[750] Henkel KGaA, Markenabteilung - VJL - 40191 Düsseldorf
[510] 01: chemische Erzeugnisse für gewerbliche Zwecke.



RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Directive 2001/60/EC - packaging and labelling of dangerous preparations

- Article 10 - Labelling

- 2. The following information shall be clearly and indelibly marked on any package:
 - 2.1. the trade name or designation of the preparation;
 - 2.2. the name, full address and telephone number of the person established in the Community who is responsible for placing the preparation on the market, whether it be the manufacturer, the importer or the distributor;
 - 2.3. the chemical name of the substance or substances present in the preparation in accordance with the following detailed rules.....
 - 2.4. The danger symbol(s) and indication(s) of danger
- The symbol(s) shall be printed in black on an orange-yellow background



RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Child Resistant Packaging - CRP



This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Child Resistant Packaging - CRP

- **A short clarification:**
- A Child Resistant Closure CRC as such does not exist
- Neither a closure nor a bottle can be child-resistant alone
- It is always the whole pack (i.e. cap & bottle) which are child resistant and as such are certified
- If you use a cap which has already a certificate with another bottle (even similar shape, just different size) you have to do a full certification again
- Only if you have a family of bottles (i.e. 500ml,750ml,1000ml) with similar shape you can do a family certification. This means you test the smallest and the biggest bottle and all other bottles within this family are covered by the certificate as long as the shape is similar

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Child Resistant Packaging - CRP

- **Child Resistant Packaging is legally required in Europe under the following conditions:**



**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Child Resistant Packaging - CRP

- **Child Resistant Packaging is legally required in Europe under the following conditions:**
 - Preparations classified as corrosive, toxic, very toxic
 - Preparations classified as, harmful (R65): may cause lung damage if swallowed
 - Preparations containing more than 3% methanol or 1% dichloromethane
- In RB internally a CRP is required for preparations which present a risk of child ingress (due to attractive nature or appealing shape/colour) and/or present a hazard that would easily be realised under normal use.
- EU certificates are not valid in USA (and vice versa)

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Child Resistant Packaging - **CRP**

- **The applicable European Standards:**

- Child Resistant Closures ISO EN 8317:2004
- Child-resistant packaging – Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products; EN 862:2005
- Child-resistant packaging – Requirements and testing procedures for non-reclosable packages for pharmaceutical products; EN 14375:2004
- The certification has to be done by an institute which has an accreditation according to EN 45011. A certificate from such an institute is valid in the whole EU

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

**RECKITT
BENCKISER**

Tactile Warning of Danger - **TWD**



This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Tactile Warning of Danger - TWD

- Tactile warning of Danger (TWD) also called Tactile Danger warning (TDW) or Tactile warning device (TWD) is legally required in Europe under the following conditions:
- All chemicals sold to the public which are labelled “very toxic”, “corrosive”, “toxic”, “harmful” or “extremely flammable” must have a TWD to alert the blind or partially sighted that they are handling a dangerous product

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Tactile Warning of Danger - TWD

- **ISO 11683:1997 – Packaging: Tactile warnings of danger – Requirements**
 - This standard specifies a tactile warning which in its form is normally a raised equilateral triangle, reduced to 3 raised dots where there is not enough space on the package for the triangle.
 - For blind and visually handicapped persons, the tactile warning of danger is simple in its presentation, is as consistent as possible in its location, makes the teaching and learning process easy and provides a guarantee of recognition.

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Tactile Warning of Danger - TWD

- **ISO 11683:1997 – Packaging: Tactile warnings of danger – Requirements**

- **Symbol dimensions - General**

- The normal symbol (6.2) shall be used where physically possible. The reduced size 9 mm symbol shall be used only where application of the normal symbol is not physically possible. The 3 dots symbol shall be used only where application of the 9 mm symbol is not physically possible. The 3 mm symbol shall be used only where application of the 3 dots symbol is not physically possible.

- **Normal size**

- The symbol shall be an equilateral triangle with corners as sharp as possible (see figure 1). At the corners, the sides shall be joined where practicable, if not, no more than 1,0 mm apart. The **length L of the side shall be 18 mm ± 2 mm**. The triangle shall consist of a frame, of which the width B shall be 1,7 mm ± 0,2 mm. The height H of the frame cross section shall be between 0,25 mm and 0,5 mm. The minimum area of the cross section of the frame shall be 1/2 H x B, and the shape of the cross section may for example be rectangular (see section AA in figure 1) or curved.

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Tactile Warning of Danger - TWD

- **ISO 11683:1997 – Packaging: Tactile warnings of danger – Requirements**

- **Dimensions**

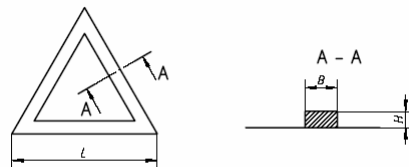


Figure 1 : Tactile symbol of warning

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Tactile Warning of Danger - TWD

- **ISO 11683:1997 – Packaging: Tactile warnings of danger – Requirements**

- **Reduced size**
- Three symbols of reduced dimensions, may be used:
- The 9mm symbol
- The 3 dot symbol
- For details please refer to ISO11683

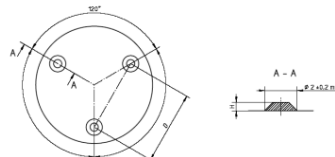


Figure 2 : 3 dot symbol for tactile warning of danger

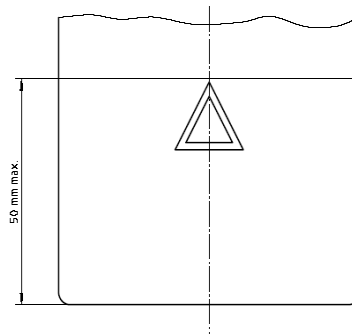
**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Tactile Warning of Danger - TWD

- **ISO 11683:1997 – Packaging: Tactile warnings of danger – Requirements**

- **Location of the tactile warning of danger – General case**
- Each entire symbol for tactile warning of danger shall be located on the upright handling surface near the edge within the range indicated in figure 3, such that the top of the triangle is not more than 50 mm from the bottom of the packaging
- For specific cases please refer to ISO 11683



**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

- **R** – Registration
- **E** – Evaluation
- **A** – Authorisation
- **CH** – of Chemicals
- Directive 1907/2006/EC



This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

• SCOPE

- Currently: Responsibility of the authorities to show that a chemical substance is unsafe
- Under REACH: Burden of proof transferred to industry
- Manufacturers, importers and users of chemical are required to **gather information on all their substances** and **prove that they are safe**

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

- REACH is a very detailed legislation which requires expert advice
- I will only scratch the surface of what REACH means to Packaging

<p>REACH</p> <p>Guidance for identification and naming of substances under REACH</p>  <p>June 2007</p> <p>Guidance for the implementation of REACH</p>	<p>LEGAL NOTICE</p> <p>This document contains guidance on REACH explaining the REACH obligations and how to fulfil them.</p> <p>However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice.</p> <p>The European Chemicals Agency does not accept any liability with regard to the contents of this document.</p>
---	---

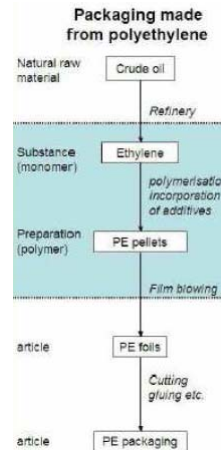
This document alone has ~7000pages

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

- REACH applies to
 - **Substances**
 - Single Chemicals
 - **Substances in Preparations**
 - Mixtures of Substances in Consumer and Industrial products
 - **Articles**
 - If intended to be released during normal or foreseeable conditions of use (e.g. anti-static additive, migration of printing inks)



**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

- Registration
 - If a substance is intended to be released registration is required unless it already exists for this type of use
 - All substances produced or imported > 1 ton/year
 - Content >0.1%
 - For specific and identified use
 - Producer or importer is required to register
 - Users are not required to register, but substance must be registered before use
 - Registration requires preparation and submission of a technical registration dossier
 - Substances listed in Annexes IV and V are excluded
 - ...

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

- Evaluation

- Technical dossier for registration
 - complete ?, all required information available?
- Substance
 - Member state can evaluate substance in case of suspicion
- Evaluation would be carried out by authorities
 - In coordination with European Chemicals Agency
-

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

- Authorization

- Substances which are of high concern independent from the tonnage
- Would be given by the European Commission
- Authorizations **cannot overrule** other restrictions or if prohibited by other Community legislation
- Authorization if **risk is appropriately controlled, if not authorization may** be granted when socio-economic benefits outweigh the risk to human health or the environment
-

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

- REACH - Summary

- Most Packaging will not fall under REACH legislation
- However you need to check if your supplier uses only registered articles
- You also need to check if your raw materials fall under REACH and if they are registered for your use
- Consider the Exposure Scenario (be aware of what is being released from products and packaging?)
- Your finished articles will generally not fall under REACH (except e. g. active packaging)

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

REACH - Europe's approach to toxic materials

- Expected cost per substance
 - Registration only +/- 15,000 €
 - Small scale testing +/- 30,000€
 - Large scale testing > 100,000€
- Expert advice is necessary to assess the risk
- Some useful links
 - http://ec.europa.eu/enterprise/reach/index_en.htm
 - <http://ec.europa.eu/environment/chemicals/reach/htm>
 - <http://ecb.jrc.it/REACH>

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Dangerous goods regulations

ADR/RID – Road/Railroad

**IMDG – International Maritime Dangerous
Goods Code**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

ADR & RID & IMDG Code

- If you ship products which are regarded as dangerous goods you need to consult an expert to get advice
- At Reckitt Benckiser we do the same

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Weights and measures regulations


This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Weights and measures regulations

- **The three Packers' Rules (UK)**
- **The Directives set out three Rules with which packers must comply:**
 - (a) that the actual contents of the packages should not be less, on average, than the nominal quantity;
 - (b) that the proportion of packages which are short of the stated quantity by a defined amount (the “tolerable negative error” or TNE) should be less than a defined limit; and
 - (c) that no package should be short by more than twice the TNE.

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Weights and measures regulations

- **E-marking** 
 - The use of the e-mark by packers or importers is voluntary but it acts as a metrological passport throughout the EU and as a guarantee that packages have been made up in accordance with the average system. Packages may display the e-mark if they are made up in accordance with the **three packers' rules** and have a nominal quantity of between 5 g or ml and 10 kg or L
 - The minimum height =3mm
 - The e-mark has to be placed next to the nominal volume



500g e

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Weights and measures regulations

- (UK): **Packers and importers must ensure that packages are marked in such a way as to be indelible (i.e. print has to be resistant), easily legible and visible on the package in normal conditions of presentation (on the outside or inside if the packaging is transparent) with the following:**
 - **the nominal quantity, expressed in kilograms or grams for solids and in litres, centilitres or millilitres for liquids;**

Nominal quantity in g or ml larger than: up to and including	Minimum height of figures
- 50	2mm
>50 - 200	3mm
>200 - 1000	4mm
>1000 - 10000	6mm

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Weights and measures regulations

- **Unit of measurement:**

Unit of measurement (metric)	abbreviation
kilogram	kg
gram	g
litre	l or L
centilitre	cl or cL
Millilitre	ml or mL

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Weights and measures regulations

- **Duty of packers and importers to mark outer containers (UK)**

- It shall be the duty of the packer of an outer container, to ensure that an outer container is marked, in such a manner as to be indelible, easily legible and visible in normal conditions of presentation, with the following-

- (a) the nominal quantity of the packages (i.e 500ml) contained in the outer container, being the predetermined constant quantity in which those packages were made up (including any additional quantity to which any statement on the package or outer container refers), or where the packages have different nominal quantities, each distinct nominal quantity, marked in accordance with regulation 8;
- (b) the number of packages contained in the outer container (i.e. 12 bottles), or where the packages have different nominal quantities, the number of packages corresponding to each nominal quantity; and
- (c) the name and address of a person established in the United Kingdom who is either the packer or the importer of the packages contained in the outer container

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Weights and measures regulations

- **According to German weights and measures regulation (Eichgesetz, §7 Absatz 2) there are rules about the design of packaging in order not to mislead consumers with regards to the relation of volume and content of the packaging**
 - The famous 70% rule (which has to be used very carefully) because if it is “state of technology” that you could fill for example up to 95% (because all your competitors are doing it) you are also required to comply with “state of technology”
- **Some types of packaging even need to be designed based on German DIN standards**
 - DIN 55540 calculation of fill level
 - Cartons for collapsible tubes according to DIN32, Part 3 (if the carton contains only tubes – i.e. tooth paste. Not valid for products which contain additional items like for example a spatula for a depilatory cream)

**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Weights and measures regulations

- **Even if you fulfil the 70% rule you could be marked by NGO's as somebody who cheats consumers**
- **The leading German consumer magazine “test” from the consumer group “Stiftung Warentest” has a section called “cheat pack of the month”**



**RECKITT
BENCKISER**

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

ADD – Aerosol Dispenser Directive

75/324/EEC (slightly updated by 94/1/EC)

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

ADD – Aerosol Dispenser Directive

- **ADD is a guideline to aerosols. It includes chapters about**
 - Construction & equipment
 - Capacity
 - Pressure
 - Filling
 - Etc.
 - I will cover only the **labelling** section

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

ADD – Aerosol Dispenser Directive

- Article 8
- 1. Without prejudice to other Community Directives, in particular to Directives on dangerous substances and preparations, each aerosol dispenser or, where particulars cannot be put on the aerosol dispenser due to its small dimensions (maximum capacity of 150 ml or less) a label attached thereto must bear the following particulars in visible, legible and indelible characters:
 - (a) the name and address or trade mark of the person responsible for marketing the aerosol dispenser,
 - (b) the symbol '3' (inverted epsilon, minimum height 3mm) certifying conformity with the requirements of this Directive,
 - (c) code markings enabling the filling batch to be identified,
 - (d) the details referred to in points 2.2 and 2.3 of the Annex,
 - (e) the net contents by weight and by volume.

3

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

ADD – Aerosol Dispenser Directive

- Annex 2.2
 - (a) Whatever its contents: 'Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use.';
 - (b) Where the contents are flammable within the meaning of point 1.8:
 - the flame symbol where appropriate, the indication that the substances and/or preparations contained in the aerosol dispenser, including the propellant, are flammable and the relevant risk phrases.....
- Annex 2.3
 - (a) Whatever its contents: the additional operating precautions which alert consumers to the specific dangers of the product;
 - (b) Where the contents are flammable, the following warnings:
 - 'Do not spray on a naked flame or any incandescent material.'
 - 'Keep away from sources of ignition — No smoking.'
 - 'Keep out of the reach of children'.

RECKITT
BENCKISER

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Cosmetics regulations

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements

Cosmetics regulation

- **German cosmetics regulation - § 8 Protection of health**

- It is not allowed ...
- 3. ...to produce, treat or market products which are no foodstuff but which could be confused as such (especially by children) because of their shape, their smell, their colour, their look, their appearance, their labelling, their size or their volume and therefore could pose a hazard to consumers esp. to children...



The tab wrapper on the left was forbidden by the regional government of Catalunya (Spain) because it “looks like a sweet” !
Now we use the one on the right.



Henkel had to stop the sales of this shower gel because it was too close to a drinks can!

This document is not intended to give you legal advice. Please consult your lawyer to make sure that you fulfil all legal requirements



Thank you!

REMEMBER:

This document is not intended to give you legal advice.
Please consult your lawyer to make sure that you
fulfil all legal requirements