Working Report No. 23, 2002
Arbejdsrapport fra Miljøstyrelsen

Workshop on the New Approach, Copenhagen, 29-30 Nov. 2001

Appendices

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Danish Ministry of the Environment

The Danish Environmental Protection Agency will, when opportunity offers, publish reports and contributions relating to environmental research and development projects financed via the Danish EPA.

Please note that publication does not signify that the contents of the reports necessarily reflect the views of the Danish EPA.

The reports are, however, published because the Danish EPA finds that the studies represent a valuable contribution to the debate on environmental policy in Denmark.

Content

Preface

This report, The New Approach in setting product standards for safety, environmental protection and human health: Speakers' presentations, is one of two complementary reports published by the Danish Environmental Protection Agency (DEPA) as follow-up to a 29-30 November 2001 workshop that took place in Copenhagen.

The workshop, sponsored jointly by DEPA and the Danish Ministry of Trade and Industry, aimed to bring stakeholders together to discuss potential solutions for various issues with respect to the use of the New Approach in European legislation. Participants included officials from eleven Member States as well as representatives from standards-setting organisations, industry and non-governmental organisations. The workshop was organised around two central themes:

- Is the New Approach concept able to ensure high levels of protection for humankind and the environment?

- Can the standardisation process under the New be a useful element for stimulating environmental product innovation in an integrated product policy (IPP)?

The report at hand, available in electronic format only, is part of the DEPA Arbejdsrapport series. It includes the written contributions of those who made formal presentations at the workshop, whether as full text, overheads or other supplementary reading material. These materials are organised in the order of the workshop agenda, which is also included, along with a list of workshop participants. A detailed list of background reading for better understanding of the issues discussed at the workshop is included as an annex.

The second report, The New Approach in setting product standards for safety, environmental protection and human health: Directions for the future, has been published as a bound volume in the Miljønyt series (Miljønyt No. 66/2002). It provides summaries of the presentations and the subsequent discussions, and general conclusions on the use of the New Approach for securing environmental and (long-term) health protection. It also provides three background papers prepared before the workshop by the consultant Milieu Ltd explaining inter alia the history of the New Approach, the role of standardisation in ensuring product safety, and regulatory tools aimed at achieving environmental innovation. This report can be obtained from Miljøbutikken in Copenhagen or freely downloaded from DEPA's web site (the publication's database) at www.mst.dk.

The Danish Environmental Protection Agency hopes that the two reports will contribute to current discussions at European level on the review of the New Approach, and to the preparation of a White Paper on an Integrated Product Policy. For further information, contact DEPA, Division for Cleaner Products.

Forord

Ny Metode til opstilling af produktstandarder for sikkerhed, miljøbeskyttelse og menneskers sundhed: Oplæg er en af to supplerende rapporter, der udgives af Miljøstyrelsen som en opfølgning på en workshop, der blev afholdt 29.- 30. november 2001 i København.

Workshoppen blev sponsoreret af både Miljøstyrelsen og Erhvervsministeriet og skulle samle interessenter til en diskussion om mulige løsninger på forskellige problemer ved anvendelse af den Ny Metode i europæisk lovgivning. Deltagerne var embedsmænd fra 11 medlemsstater og repræsentanter fra standardiseringsorganisationer, industrien og NGO'er. Workshoppen havde fokus på to centrale temaer:

- Kan den Ny Metode sikre høj beskyttelse af mennesker og miljø?
- Kan den Ny Metodes standardiseringsproces anvendes til at stimulere miljørigtig produktudvikling i en integreret produktpolitik (IPP)?

Denne rapport, som kun findes i elektronisk form, indgår i Miljøstyrelsens Arbejdsrapport-serie. Den omfatter de skriftlige bidrag fra workshoppens oplægsholdere, enten som fuld tekst, overheadpræsentation eller yderligere supplerede materiale. Materialet er systematiseret i overensstemmelse med workshoppens dagsorden, som også indgår i rapporten sammen med en deltagerliste. En udførlig liste over baggrundslitteratur, der kan give en bedre forståelse af de behandlede emner, findes i et bilag til rapporten.

Den anden rapport, Ny Metode til opstilling af produktstandarder for sikkerhed, miljøbeskyttelse og menneskers sundhed: Vejledning til fremtiden, er udgivet som et bind i Miljønyt-serien (Miljønyt nr. 66/2002). Den indeholder resumeer af præsentationerne og de efterfølgende diskussioner sammen med generelle konklusioner om, hvor den Ny Metode skal anvendes for at sikre miljømæssig og (på langt sigt) sundhedsmæssig beskyttelse. Rapporten indeholder også 3 baggrundsoplæg, skrevet inden workshoppen af konsulentvirksomheden Milieu Ltd. Oplæggene beskriver bl.a. den Ny Metodes historie, standardiseringens rolle i forbindelse med produktsikkerhed og styringsværktøjer, der støtter miljømæssig nyudvikling. Rapporten kan bestilles hos Miljøbutikken eller hentes under publikationer på www.mst.dk.

Miljøstyrelsen håber, at de to rapporter vil kunne bidrage til den aktuelle diskussion på europæisk niveau om evalueringen af den Ny Metode og til udfærdigelsen af en hvidbog om en integreret produktpolitik. Yderligere oplysninger kan fås ved henvendelse til Miljøstyrelsen, Kontoret for renere produkter.

1 Agenda of the Workshop

Thursday 29 November 2001

10:00 Welcome; Purpose of the Workshop
Preben Kristensen, Head of Cleaner Products Division, Danish Environmental Protection Agency

Session I: The New Approach: Background and issues

Facilitator: ***Helge Andreasen, Deputy Director General, Danish Environmental Protection Agency***

10:15 The New Approach: History of a success story
Evangelos Vardakas, Director, European Commission, DG Enterprise G

10:40 Formulating New Approach Directives for Safety, Environmental Protection and Human Health
Michail Papadoyannakis, European Commission, DG Enterprise E.1

11:00 Coffee

11:15 Preparing standards for essential requirements by CEN/CENELEC/ETSI
David Perchard, CEN Consultant on Packaging, Perchards Consulting

11:30 The challenge of verifying compliance with essential requirements
Richard Lawson, Deputy Director of Standards and Technical Regulations, UK Department of Trade and Industry

11:45 The wider international issues: Interface between European and international standards-setting
Jacob Holmblad, Vice President, CEN

Session II: The New Approach: Ensuring a high level of protection for the environment and human health[1]

Facilitator: ***Claus Jensen, Danish Agency for Trade and Industry***

13:15 Experience with the New Approach from an

[1] *e.g.*, long term exposures.

environmental point of view
John Hontelez, Secretary General,
European Environmental Bureau (EEB)

13:35 The New Approach: Can it ensure a high level of protection for the environment and human health?
Helge Andreasen, Deputy Director General, Danish Environmental Protection Agency

14:00 Panel on experience with the New Approach

Experience with the Toys Directive
Aage Stevns Hillersborg, LEGO

Experience with the Medical Devices Directive
Peter Thompson, CEN consultant on medical devices

Experience from a consumer's point of view
Franz Fiala, Vice President, ANEC

Standardisation in other forums
Herman Köeter, OECD

Discussion with Panel and Plenary

15:50 Presentation on options for consideration
Christian Fischer, Danish Environmental Protection Agency

16:00 Breakout sessions

17:30 Reports from Session II break-out discussions

18:00 End of session

Friday 30 November 2001

Session III: What is the role of the New Approach in promoting environmental innovation?

Facilitator: ***Eckert Meyer-Rutz. German Federal Ministry of the Environment***

9:30 The proposed use of the New Approach in Integrated Product Policy
Otto Linher, European Commission,
DG Environment, A.2

10:00 Panel on environmental innovation

Dynamism in the standardisation process: Guiding or delaying innovation?
Eva Schmincke, Büro für Ökologische Studien

Eco-labelling, benchmarking, environmental

product declarations, and other tools for promoting environmental innovation
Nicola Breier, European Commission, DG Environment D.3

Management standards versus product standards
Hugues Plissart, CEN Management Centre

Environmental innovation in product design: The industry point of view
Viktor Sundberg, Electrolux

Innovation in product design: The environmental point of view
Karola Taschner, European Environmental Bureau

Discussion

11.30 Presentation on options for consideration
Preben Kristensen, Head of Cleaner Products Division Danish Environmental Protection Agency

11:40 Break-out discussion

14:00 Reports from Session III break-out discussions

Session IV: General Plenary Discussion

Facilitator: ***Preben Kristensen, Head of Cleaner Products Division, Danish Environmental Protection Agency***

14:30 Rapporteurs' conclusions from Day I & Day II

15:00 General discussion on conclusions & next steps

15:30 End of workshop

2 Speaker notes

2.1 The New Approach: background and issues (Session I)

2.1.1 The New Approach: History of a success story.

Evangelos Vardakas, Director, European Commission, DG ENTR. G

Structure of the presentation

1 - The New Approach
2 - Market surveillance
3 - The international dimension
4 - Conclusions

The New Approach 2

Why a "success story"?

Council Resolution 28-10-1999:

"…the New Approach created for the completion of the internal market, which combines the official instrument of the Directive with voluntarily applied European standards, has proved itself and should be further applied, and invites the Commission to examine systematically whether the New Approach principle can be applied to sectors not yet covered as a means of improving and simplifying legislation wherever possible."

New Approach Directives

1 - The New Approach

Free movement of goods

1. Mutual recognition principle:
   - Article 28 (ex-30) of the Treaty
   - Case law "Cassis de Dijon" (120/78)

2. Community legislation (harmonised)
   - Article 95 (ex-100A) of the Treaty

⇓

Directives

New Approach Directives

31-12-1992 Completion of the **Single Market**

1985:

- **White Paper** on achieving the single market (nearly 300 legislative proposals envisaged)
- Council Resolution on "A **New Approach** to technical harmonisation and standards"(7 May)

1989:

- Council Resolution on "A **Global Approach** to conformity assessment"

Old Approach

- **Detailed technical specifications** for specific products
  - deadlocks in the Council
  - need of frequent update to adapt to technical progress
- **Control of public authorities prior** to the placing on the market of products
  - need to integrate modern techniques used by enterprises ("quality assurance systems")

Guiding Principles of the New Approach

Principles (1)

- Legislative harmonisation limited to **essential requirements** (safety, health, consumer protection and environmental protection)
- Manufacturers are free to use **any technical solution** provided the product complies with the essential requirements
- When applied, **harmonised European standards** give presumption of conformity

Guiding Principles of the New Approach

Principles (2)

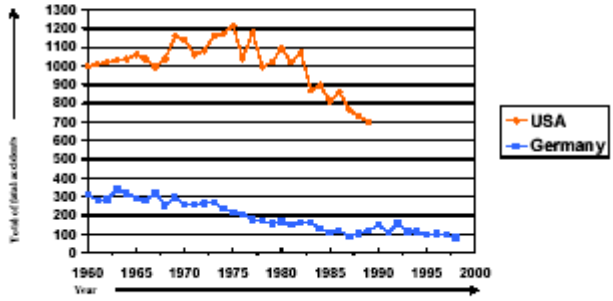
- Choices offered to manufacturers as to the **conformity assessment** procedures to evaluate the compliance with directives
- Only those products complying with directives can be placed on the EC market and bear the **CE marking**
- Member States have the duty to control that only complying products are placed on the market (**market surveillance**)

The results

- First "New Approach" Directive in 1987
- Since then more than 20 broad areas of products or risks are covered, including:
  - *Machines, Lifts, Pressure equipment, Pleasure boats*
  - *Medical Devices, in vitro diagnostic equipment*
  - *Personal Protection Equipment, Toys, RTT equipment*
  - *Gas appliances, Low Voltage Equipment, EMC*

A proof of the success...

Total Number of Fatal, electricity related accidents (incl. High-voltage) in the USA and Germany



Elements of the New & Global Approaches

Concepts

1. Essential requirements (ERs)
2. Harmonised standards
3. Conformity assessment
4. CE marking =====>
5. Market surveillance

Essential requirements

- Objectives which are **essential** to guarantee a high level of protection for the public interest at issue
- **Technology neutral**, no technical solution prescribed
- Written in such terms to ensure **binding** obligations which can be **uniformly** enforced

Harmonised Standards

- Technical specifications adopted by the **European Standardisation Bodies** (CEN, CENELEC, ETSI) through a consensus building process = not defined by public authorities, but by stakeholders
- One means to comply with the ERs = remain **voluntary**

Harmonised Standards (2)

- A **mandate** is given by the Commission and once adopted, references to standards are published in the **Official Journal**
- **Presumption of conformity** with the ERs = burden of the proof lies with public authorities
- **Safeguard clause** mechanism against standards not fulfilling ERs (EC procedure)

New Approach Directives

2 - Market Surveillance

Market Surveillance

The guarantee of:

- equal protection for citizens
- level playing field for enterprises

Goal: a uniformly high level of enforcement of Internal Market legislation

… is a national responsibility

Subsidiarity applies

- Carried out by government officials, in the marketplace : administrative co-operation is essential
- Few explicit requirements in the Directives, but implicit requirements in Treaties

New Approach Directives

3 - The International Dimension

The International Dimension

- European Economic Area
- EU - Turkey Customs Union
- PECAs under the Europe Agreements
- Mutual Recognition Agreements (MRAs)
- WTO TBT

New Approach Directives

4 - Conclusions

Goal of European approach:

To complete the Single Market

- enhancing safety, environmental friendliness and performance of products
- offering a flexible technology-neutral legal environment
- reducing undue burdens for enterprises

...the resulting successful structures are a consequence of this effort.

The New Approach & Global Approach

For more information:

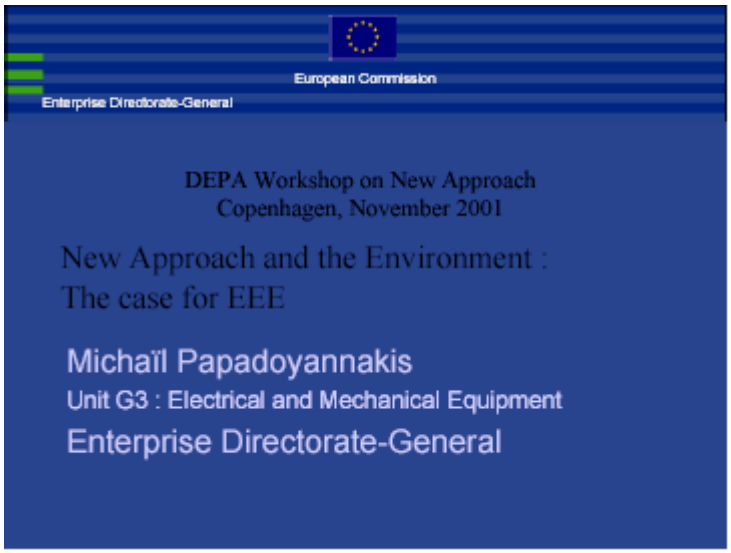
« *Guide to the implementation of directives based on the New Approach and the Global Approach* »

(11 languages)

http://europa.eu.int/comm/enterprise/newapproach/index.htm

2.1.2 Formulating New Approach Directives for Safety, Environmental Protection and Human Health.

Michail Papadoyannakis, European Commission, DG ENTR. E.1



- Amsterdam Treaty
- European Councils of Cardiff, Helsinki, Gotheburg
- Integrated Product Policy (IPP)

November 2001

EEE related proposals

- Directive on management of waste from EEE based on Article 175
- Separate Directive on the restriction of certain hazardous substances in EEE based on Article 95
- Product design requirements of EEE to be addressed via a *New Approach* Directive

November 2001

Application of New Approach for environment I

- Legislators define "essential requirements"
- European Standards Bodies are requested to develop standards through "Mandates"
- "Harmonised" European standards give a presumption of conformity, if published in OJ, yet remain voluntary
- Conforming products are marked
- Member states carry out market surveillance

November 2001

Application of New Approach for environment II

- *New Approach* is a possible tool for IPP
- Many useful standards and guidelines already exist (ISO, IEC, CENELEC, and ECMA eco-declaration)
- Provides incentive to incorporate environmental dimension into technical product standards
- Allows environmental concerns to be integrated without compromising competitiveness or free circulation

November 2001

Standards for the environment

- Environment is a highly political domain
  - standardisation should only deal with technical solutions
  - institutional mechanism is required to handle political questions
- Involvement of NGO stakeholders
  - in the standardisation process
  - in an advisory capacity
- Cultural change takes time

November 2001

EEE Objective

To ***harmonise requirements concerning the design of electrical and electronic equipment*** to ensure the free movement of these products within the internal market, aiming to improve their overall impact on the environment, and thus providing an efficient use of resources and a high level of environmental protection compatible with sustainable development

November 2001

EEE Features : Scope

Definition based on voltage requirements *and* specific PRODCOM list categories

- Electric domestic appliances
- Office machinery and computers
- Electrical machinery and apparatus
- Radio, television and communication equipment
- Medical, precision and optical instruments
- Games and toys

- Components and sub-assemblies are covered

November 2001

EEE Features : Essential Requirements

- Identify and assess the magnitude of the significant environmental impacts of the product at each stage of its lifecycle to develop its environmental profile
- Use this profile to design products to ensure a high level of environmental protection in balance with technical and economic requirements, taking into account key principles
- Provide information on environmental characteristics of the product throughout its lifecycle

November 2001

EEE Features : Conformity assessment

- Conformity assessment
  - internal design control
  - environmental assurance system
- Presumption of conformity
  - harmonised standards
  - Ecolabel
  - EMAS
  - Community Environmental Agreement

November 2001

EEE Features : Market Surveillance

- Co-operation between Member States and with the Commission will be essential
- Restriction clause
  - non-compliant equipment should be made to comply by the manufacturer
  - if it becomes necessary to prohibit or withdraw equipment from the market, then the Commission will become involved in the consultation process
  - Commission may draw upon technical advice from independent experts

November 2001

EEE Features : Committee

- Regulatory role
  - Adapt scope and the essential requirements to reflect evolution of technical knowledge or provide more detailed specification of the requirements
- Advisory role
  - Review standardisation mandates and implementation issues
  - Stakeholder participation

November 2001

EEE Features : Timeframe

- Many large companies are nearly ready, small companies will need help
- Suggested 5 year transition period
- Review proposed within 5 years

November 2001

EEE Benefits

- Reduced environmental impact
- Reduced risk of fragmentation to the Internal Market and possible barriers to trade
- Integration of environmental aspects into enterprise policy without compromising competitiveness
- Development of new standards for the environment
- First concrete example of IPP
- Acceleration of ecological solutions, advantaging EU competitiveness in global trade
- Greater availability/exchange of environmental information in the public domain

November 2001

EEE : Next Steps

- Text published on web in February 2001
- Impact assessment study launched
- Preliminary results in Spring 02
- Final EEE draft ready by end 02

November 2001

EEE : Website

http://europa.eu.int/comm/enterprise/electr_equipment/eee/index.htm

November 2001

2.1.3 Preparing standards for essential requirements by CEN/CENELEC/ETSI.

David Perchard, CEN Consultant on Packaging, Perchards

The Directive

The Packaging and Packaging Waste Directive (94/62/EC) came into force on 31 December 1994. It covers all packaging marketed in the EU and all household, commercial and industrial packaging waste.

The aims of the Directive are to:

- harmonise national measures so as to prevent or reduce the impacts of packaging on the environment of all member states and of third countries, and to remove obstacles to trade and distortion and restriction of competition; and to

- prevent the production of packaging waste, and reduce the amount of waste for final disposal through packaging reuse, recycling and other forms of recovery.

Member states ***must***

- take action to reduce the quantity and the harmfulness to the environment of materials and substances used and in general promote 'clean' products and technology;

- ensure other preventive measures are taken, such as 'collecting and taking advantage of' packaging waste prevention initiatives being taken;

- set up systems to recover at least 50% of packaging waste and no more than 65% by July 2001 and to recycle at least 25% and no more than 45% of packaging materials, with no material recycled at less than 15%;

- notify the Commission of measures adopted or to be adopted;

- report on progress and set up national databases so implementation can be monitored;

- 'where appropriate', encourage the use of materials recovered from recycled packaging waste in the production of new packaging and other products;

- ensure that by January 1998, packaging is allowed on the market only if it complies with certain 'essential requirements', which include minimisation of packaging weight and volume to the amount needed for safety and consumer acceptance of the packed product, and suitability for reuse, material recycling, energy recovery or composting;

- limit heavy metals content to 600 ppm by July 1998, 250 ppm by July 1999 and 100 ppm by July 2001;

- allow free access to packaging complying with the Directive.

Use of recovery capacity outside a member state counts towards achievement of that member state's targets, provided this takes place on the basis of agreements and within EC rules.

Member states ***may***

- encourage reuse systems for packaging 'which can be reused in an environmentally sound manner', provided they do not conflict with the EC Treaty;

- introduce economic instruments to implement the objectives of the Directive provided they are in accordance with the principles governing Community environmental policy;

- set themselves targets higher than 65% recovery, 45% recycling and a minimum of 15% recycling for each material, but only if they have appropriate recycling/recovery capacity and provided the measures taken do not distort the internal market or hinder other member states' ability to comply with the Directive. However they must pre-notify the Commission, which must verify that the proposals will not constitute arbitrary discrimination or a disguised restriction to trade.

Greece, Ireland and Portugal may decide to set lower targets than those required for the other member states, but must achieve at least 25% recovery by mid-2001. By the end of 2005 they must however meet the targets laid down for the other member states to achieve by mid-2001.

The 'Article 21 Committee' – a committee of national civil servants, chaired by a Commission official – was to decide how to deal with any problems in applying the Directive to particular products or packs; exemptions from the heavy metal limits (e.g. for recycled materials and materials in closed loops); and any adaptations to scientific and technical progress needed.

The committee would later examine member states' practical experience in implementing the targets and the findings of scientific research and evaluation and fix targets for the second five-year phase, which, it was envisaged, would be substantially higher than the present targets.

The Commission was to promote new European standards on criteria and methodologies for packaging LCAs; methods for measuring and verifying the presence and release into the environment of heavy metals and other dangerous substances in packaging and packaging waste; criteria for minimum recycled content in appropriate types of packaging; criteria for recycling methods; criteria for composting methods and produced compost; and criteria for the marking of packaging ***(see section on the Essential Requirements and the CEN standards)***.

The proposed revision

Progress

The Directive requires the Council to set targets for the second five-year phase (i.e. from 1 July 2001) by the beginning of 2001. To meet this timetable, the Commission would have needed to publish its proposal early in 2000.

This was indeed DG Environment's intention, but because of the late transposition of the Directive into national law and the need to evaluate experiences and the costs and benefits of potential revised targets, it was eventually decided to delay. DG Environment explains that the timing of its proposal is a compromise between the availability of analytical information and the wish to adopt the new targets as early as possible to give member states maximum time to make legislation to allow achievement of the targets by 2006.

DG Environment's proposal entered Interservice consultation within the Commission on 5 July but at the time of writing, internal agreement has not yet been reached. It will be well into 2002 before a revised Directive can be adopted.

As expected, DG Environment proposes to limit the revision to targets and definitions. However, the explanatory memorandum says that there are other important issues which must be addressed 'in the near future'. One of these issues related to the standards and the New Approach.

In its proposal, DG Environment commented that the Packaging and Packaging Waste Directive was the first application of the ***New Approach*** to legislation on the environmental characteristics of products. There had been intensive debate about the drafting of Article 9 and Annex II of the present Directive and about whether the CEN standards should give presumption of conformity with the Essential Requirements. More analysis and debate was needed, and this was foreseen for the Communication/White Paper on IPP and the Thematic Strategy on Recycling. Ideas may also emerge from the planned Directive on Electrical and Electronic Equipment.

DG Environment's latest thoughts were set out in a ***Working document on aspects related to the Packaging and Packaging Waste Directive to be reviewed after the current revision proposal***, dated 27 August 2001:

"The experience with the existing system of Article 9 and Annex II of the Directive and the related standards produced by CEN has shown a number of difficulties. In particular, the following issues need to be addressed:

There is a need to clarify whether and how the New Approach technique should continue to be the basis for defining environmental requirements for packaging. Within the current application of the new Approach, the Essential Requirements may not be drafted clearly enough to guarantee a harmonised application throughout the Community. Therefore, it will be necessary to define whether the current elements of Annex II should be maintained or changed. If they are maintained, it will be necessary to define how the various elements should relate to each other (cf. CEN umbrella standard). There may also be a need to separate more clearly political issues such as the

definition of minimum calorific values, weight percentages to be recycled, rotation number etc, from technical issues and/or ensure a better co-ordination between the political levels and standardisation. Finally, it needs to be seen how the current work by CEN can be integrated into a New Approach framework and/or how the standards the references to which have not been published can be finalised.

The Commission has understood the wish by member states to move forward as rapidly as possible with this issue. Due to the fundamental impacts of potential changes to the current approach, an in-depth debate (on the basis of options still to be identified) will be necessary. This may also be an important precedent for other fields of product-related environmental policy. As the issue of the application of the New Approach technique for environmental design of products will also be addressed in the White Paper on Integrated Product Policy (to be adopted end 2001/beginning 2002), it seems appropriate to build upon the elements that will be identified there. Nevertheless, preparation work could start in parallel and first thoughts on concrete options could be laid down in a working document for the next meeting of the Committee."

The Essential Requirements

The Packaging and Packaging Waste Directive says that member states must ensure that by January 1998, packaging is allowed on the market only if it complies with certain 'essential requirements':

- 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 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 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.

Where packaging is claimed to be ***reusable***, 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 and thus becomes waste.

All packaging must be recoverable in one or more of the following ways:

- ***Packaging recoverable 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.

- ***Packaging recoverable 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.

- ***Packaging recoverable 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.

- ***Biodegradable packaging:*** Biodegradable packaging waste 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.

The Directive also limits the heavy metals content of packaging, to 250 ppm by July 1999 and 100 ppm by July 2001.

The Commission's Mandate

The European Commission mandated CEN, the European Committee for Standardisation, to prepare a set of standards to give effect to the Essential Requirements. The intention was that their references would be published in the Official Journal as recognition of their status as 'harmonised standards'. Once the references have been published, packaging in compliance with the harmonised standards would be deemed to be in conformity with the Essential Requirements, and could not be denied access to any country in the European Economic Area on grounds of non-conformity with the Directive.

The six principal standards have all been adopted by a large majority and they are now being published by CEN's 19 members (the national standards bodies) as harmonised national standards.

- ***EN 13427,*** Packaging – Requirements for the use of European Standards in the field of packaging and packaging waste ***(88% of the votes cast were in favour, with Austria, Denmark and Ireland voting against and Belgium abstaining);***

- ***EN 13428,*** Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction ***(again, 88% of the votes cast were in favour, Austria, Denmark and Ireland voted against and Belgium abstained);***

- ***EN 13429, Packaging – R***equirements for relevant materials and types of reusable packaging (***86% of the votes cast were in favour, Austria and Spain voted against and Belgium, Denmark and Portugal abstained);***

- ***EN 13430,*** Packaging – Requirements for packaging recoverable by material recycling ***(92% of the votes cast were in favour, with Denmark and Ireland against and Belgium abstaining);***

- EN 13431, ***Packaging – Requirements for packaging recoverable in the form of energy recovery, including specification of minimum interior calorific value*** (96% of the votes cast were in favour, with Denmark against and Switzerland abstaining);

- ***EN 13432,*** Requirements for packaging recoverable through composting and biodegradation – Test scheme and evaluation criteria for the final acceptance of packaging ***(all votes cast were in favour, but the Czech Republic and Greece abstained).***

Standards can be adopted when (i) an absolute number of members is in favour and (ii) at least 71% of the votes cast are affirmative. As in the EU voting system, national votes are weighted according to the population of the countries concerned.

CEN submitted the complete package of texts to the Commission, with a request for publication of the references in the Official Journal. Belgium and Denmark lodged objections, and DG Environment's Waste Management Unit issued an appraisal which was highly critical of the standards. The Article 21 Committee considered the Waste Management Unit's comments and held a lengthy question-and-answer session with the CEN Consultant on Packaging and the Environment on 6 October 2000, and it examined conformity of the standards with the Essential Requirements at its meeting on 16 January; however the committee remained divided.

The Commission submitted a draft Decision to the Committee on Standards and Technical Regulations set up under Directive 98/34. The '98/34 Committee' met on 15 March, and was also divided. Very unusually, the Commission took a vote, and concluded from this that it had sufficient support to proceed. After a further discussion at the 98/34 Committee on 27 June, Decision 2001/524/EC was adopted by the Commission the following day.

The Decision records the Commission's intention to publish only two of the references to the harmonised CEN standards in the Official Journal:

- EN 13428, the standard on prevention by source reduction (but with a warning that it does not take adequate account of noxious and hazardous substances and so does not fully comply with the Essential Requirements in the Packaging and Packaging Waste Directive); and

- EN 13432, the standard on organic recovery.

Standards whose references have not been published still exist as harmonised CEN standards, and individual member states are free to accept compliance with them as evidence of conformity with the Essential Requirements. However, there is no presumption of conformity, so member states are not obliged to grant market access to packaged products which meet the

requirements of these standards. Member states choosing not to recognise the validity of the CEN standards for this purpose will have to find another way of testing conformity with the Essential Requirements.

DG Enterprise and DG Environment have drafted a 'second standardisation mandate' to revise the prevention, reuse, material recycling and energy recovery standards and to incorporate the 'umbrella standard' in the new mandate. The draft has been circulated to the member states for comment and the Commission submitted a further draft to the 98/34 Committee on 11 October. The Commission hopes that CEN can adopt amended standards as quickly as possible, but it may take some time to reach a consensus among the stakeholders.

The CEN approach

In view of the enormous range of packaging types and recovery and disposal situations which have to be taken into account, CEN Technical Committee TC261/SC4 on Packaging and the Environment opted for a management system approach aimed at ensuring a continuous effort to improve the environmental profile of the packaging placed on the market. To comply with the standards, packaging designers and specifiers will have to work methodically through a checklist to ensure that their decisions take account of the often conflicting social, environmental and economic factors affecting the choice of packaging, and find a solution that is right for the product, for the distribution system and for how it will eventually be stored and used.

The texts consist of six principal standards and a series of supporting standards, as well as reports on heavy metals and other dangerous substances and on avoiding substances and materials which might present a sustained impediment to recycling.

In addition to the five mandated standards (on prevention, reuse, material recovery, energy recovery and organic recovery), the CEN experts have prepared a standard on requirements for the use of European standards in the field of packaging and packaging waste, the so-called 'umbrella standard'. This is the key document which explains how the interlocking mandated standards and reports are to be used.

The CEN thinking is that by providing practical guidelines on how the Essential Requirements can be interpreted and implemented, the new standards will ensure that packaging designers and specifiers keep potential environmental improvements under continuous scrutiny, as well as giving added value in developing the European Single Market for packaging and packaged goods.

CEN 'umbrella standard' (EN 13427)

The Standard on Requirements for Use of European Standards in the Field of Packaging and Packaging Waste (the 'umbrella standard') guides users through the texts, indicating which standards are applicable to each type of pack.

Compliance with the Essential Requirements will involve the supplier in the detailed consideration of up to five mandated standards and one mandated report (in two parts) before placing the packaging or packed product on the

market. They are all potentially capable of reducing the environmental impact of packaging disposed of as waste but they can be mutually exclusive in some combinations and circumstances. Thus the 'umbrella standard' has been introduced to establish an overall methodology:

- ***all packs must be assessed against the standard on prevention (which includes both source reduction and the methodology for minimising noxious and other dangerous substances), and with reference to the report on minimisation of heavy metals;***

- ***where reuse is claimed, packs must be assessed against the standard on reuse; and***

- ***packs must be assessed against at least one and if appropriate all of the standards on material recovery, energy recovery, and organic recovery.***

Usually a number of components will be brought together to form a functional unit of packaging and these may in turn be brought together in a complete packaging system which could comprise primary, secondary and tertiary packaging:

- Packaging at the component level should be assessed for minimisation of heavy metals and noxious and hazardous substances;

- Packaging at the level of the functional unit should be assessed for reuse, material recovery, energy recovery and/or organic recovery (as appropriate);

- Any complete packaging system should be assessed for prevention by source reduction.

Having identified the appropriate standards, suppliers must then work through a series of checklists to ensure that all relevant factors have been taken into account in the design of the packaging system. For instance in terms of product protection there may be trade-offs between the primary packaging and the transport packaging (outer cases and wrappings, pallets etc).

The supplier is to apply the requirements of the selected standards to packaging he places on the market, so as to ensure that

- the packaging system contains the minimum adequate amount of the chosen material (EN 13428);

- the packaging components contain less than the maximum permitted levels of heavy metals and only the minimum amount when used for functional purposes (CR 13695-1);

- the packaging components have been assessed to minimise the presence of noxious and other hazardous substances (EN 13428 and prCR 13695-2); and

- the functional packaging is reusable if reuse is claimed (EN 13429), and recoverable by material recycling, recoverable in the form of energy and/or compostable or biodegradable in accordance with the relevant standards (EN 13430, 13431 and 13432).

A summary of the assessment results must be prepared. Records of the assessments and supporting documents must be retained by the supplier for at least two years after the relevant packaging has been placed on the market for the last time. These records must be available for inspection.

The 'umbrella standard' recognises that optimisation of the effect of one procedure may require moderation in the application of others. A significant element of selecting and applying the standards will be to determine the most appropriate balance between them for any particular application.

The supplier is recommended to apply these principles as an integral part of his formal management system, for example by incorporating the procedures into an existing EN ISO 9000 / 14000 scheme, so as to improve the environmental performance of his operation and to provide the opportunity for continuous improvement.

CEN standard on prevention by source reduction (EN 13428)

'Prevention by source reduction' is defined as 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.'

The standard 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.

The substitution of one material for another is not a basis for source reduction.

The standard is based on a self-assessment approach similar to the approach in systems standards such as the EN ISO 9000 and EN ISO 14000 series. It could be used by any producer, user or distributor as a methodology for demonstrating that the minimum amount of weight and/or volume of the finished packaging has been reached taking into account the relevant performance criteria.

The basis for complying with the standard is identification of the 'critical area' which governs the achievable limit for source reduction. That is to say, if the packaging is reduced further, it will fail to meet the listed performance criteria:

- product protection;
- packaging manufacturing process;
- packing/filling process;
- logistics (including transport, warehousing and handling);

- product presentation and marketing;
- user/consumer acceptance;
- information;
- safety;
- legislation;
- other issues.

If no critical area is identified, the packaging is not in compliance with the standard and the potential for (further) source reduction is to be investigated. If on the other hand tests show that further source reduction will result in an unacceptable increase in the packaging failure rate, the critical point has already been reached.

[An 'unacceptable' failure rate must be a matter of commercial judgement – it may be different for a high-value product than a low-value item, and for products where leakage could endanger people or property – and this judgement must be shared between the producer, the customer and possibly the end-user.

The packaging manufacturing or packing/filling process also has to be taken into account. It may be possible for the producer to reduce his packaging further, but only by purchasing new machinery. This may not be economically practicable, and it may not be environmentally desirable for the existing equipment to be scrapped before it reaches the end of its life.

If the packaging is source reduced to the point where the product is unacceptable to the consumer, it will not sell, and there is no point producing it. Consumer acceptability is listed among the Essential Requirements.]

An Annex sets out guidelines on the use of the standard. It can be used in the assessment of existing packaging or as an aid in the normal dialogue between supplier and customer in agreeing a specification for new packaging. The Annex

- describes the different phases of the assessment process;

- reviews the ten specific performance criteria and lists typical requirements in order to help users of the standard identify the important and decisive requirements applicable to the packaging under assessment; and

- gives examples of completed assessment checklists and their supporting reports together with explanatory documents which support the completion of the checklists.

The company responsible for compliance must prepare a statement of conformity with the assessment procedures and determination of critical area, together with supporting documentation, based either on their internal documentation or on a checklist. In either case all listed performance criteria must be covered.

The enforcement authorities can verify compliance with the standard by asking the producer to demonstrate the steps that have been taken to identify the 'critical area'. If this cannot be done, the packaging fails the standard.

The supplier must also be able to demonstrate that only the minimum adequate amount of any substance dangerous to the environment has been used in the packaging or packaging component, with a view to minimising its presence in ash, emissions or leachate from landfills. The methodology for this is fully explained in the draft CEN report prCR 13695-2 (***Packaging – Requirements for measuring and verifying 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***).

The evaluations to be undertaken are as follows:

- Have such substances been intentionally added? If not, or if they are used but only in concentrations below trace level, minimisation is not applicable.

- Are any of the substances identified likely to be released into the environment from ash, emissions or leachate resulting from incineration or landfilling of the packaging or any packaging component after use? If not, minimisation is not applicable.

- If any of these substances are likely to be released into the environment, the supplier must ensure minimisation and document the results of the procedure.

CEN standard on requirements for relevant materials and types of reusable packaging (EN 13429)

This standard contains a checklist by which the packer or filler can assess 'reusability'. If the pack fails any of these three tests, it is deemed unfit for reuse:

- packer/fillers must ***intend*** to reuse the pack for its original purpose (i.e. a pallet which can be used for grocery products or house bricks is 'reuse for the same purpose'; a mustard container intended for a secondary life as a drinking glass is not 'reuse for the same purpose'; the refilling with home-made jam of jars originally containing commercially-made jam is not 'reuse for the same purpose');

- it must be ***possible*** to clean, wash and/or repair the pack after emptying and to refill or reload it;

- a system which supports reuse of the pack must be available. This may be a 'closed loop' system (in which reusable packaging is circulated by a company or an organised group of companies; an 'open loop' system (in which reusable packaging circulates amongst unspecified companies) or a 'hybrid' system (in which reusable packaging stays with the end-user and is replenished by means of one-way packaging which is used as an auxiliary product to transport the contents to the reusable packaging).

Auxiliary products (e.g. a detergent pouch) are one-way products and are not covered by this standard, but non-reusable items which support the reusable

packaging in its function (e.g. labels or closures) are considered part of that packaging.

CEN standard on material recycling (EN 13430)

The standard covers all forms of packaging and types of packaging material, and all collection and sorting arrangements and recycling facilities. It formalises a procedure by which design, production and use of packaging can be checked against the requirements of various material recycling systems.

Those responsible for placing packaging and/or packaged products on the market must be able to demonstrate that the procedures defined have been followed in arriving at the final design of the finished packaging such that a certain percentage of material can be recycled.

For material recyclability to be claimed, they must

- ensure that packaging design takes account of the recyclability of the materials from which it is produced;

- control selection of raw materials used in production/ packing/filling operations and where practicable collection/sorting operations to ensure that they do not adversely affect recycling processes;

- ensure that the design of packaging makes use of materials or combinations of materials which are compatible with known and relevant recycling technologies whilst also recognising the interrelationship of the various standards supporting Directive 94/62

  (The standard recognises that it takes time to develop and expand processes to recycle new packaging materials and systems, and it says that provided such development is being demonstrably pursued, it may be appropriate for such innovative packaging to be classified as recyclable during this period);

- establish a system to ensure that new developments in relevant recycling technologies are monitored and recorded and that such records are made available to the design function; and

- take account of the potential change in releases to the environment that will result from introducing the used packaging to the recycling process.

The procedure for assessing recyclability criteria is as follows:

Design should ensure that the packaging is compatible with the specifications of related recycling technologies, enables a certain percentage by weight of materials to be recycled, and takes into account

- substances or materials liable to create technical problems in the recycling process (see CR 13688, a CEN report on ***Requirements for substances and materials to prevent a sustained impediment to recycling***);

- materials, combinations of materials or designs of packaging liable to create problems in collecting and sorting before material recycling; and

- the presence of substances or materials liable to have a negative influence on the quality of the recycled material.

As regards ***production criteria,***

- ensure that any changes in packaging raw material sourcing / manufacture, conversion and filling can be managed so that they cannot adversely affect the compatibility of the packaging with the recycling process;

- ensure that materials selected in the design stage as causing no significant problems for recycling technologies, are not changed during the process so as to adversely affect compatibility with the specification of the recycling process (this also applies to changes in other constituents such as adhesives, inks and coatings and to components such as labels, closures and other sealing materials).

Utilisation criteria are to

- ensure that the construction is without prejudice to the conformance with other Essential Requirements, and the requirement that it meets the safety, hygiene and consumer needs of the packaging;

- ensure that the design of the primary packaging (e.g. its shape, design and location of the opening, etc) will enable emptying of the packaging so that the used packaging is compatible with the recycling process;

- ensure that where the packaging comprises more than one material component which need to be separated to be compatible with the collection system linked to the recycling process, the packaging is constructed so that the end-user can carry out the separation under normal and foreseeable circumstances;

- ensure, as far as practicable, that information has been sought regarding any particular requirements of the expected and relevant collection and sorting process and that the design and construction of the packaging takes these into account. (The standard recognises that this may be impracticable if the packaging does not have a specific destination, since there are significant differences in systems available within and between the member states).

The standard also explains that the CEN report, ***Packaging – Marking and material identification system***, recommends that any material identification should be recognisable to its target groups, so as to facilitate clear and unambiguous identification of the predominant material. Identification of the predominant material may help the packaging user by indicating a disposal option, or may facilitate collection and sorting, or the aggregation of materials into recycling streams. However the nature of some materials is clear without the need for applied identification, and recognition may also be assisted by means such as colour or container shape.

CEN standard on energy recovery (EN 13431)

This standard specifies the requirements for packaging to be considered as suitable for energy recovery and identifies the necessary procedures for a supplier placing packaging on the market to claim conformity with these requirements. The scope is limited to factors under the control of the supplier.

Packaging claimed to be suitable for energy recovery must be combustible and capable of providing calorific gain, as determined by the method specified. In addition,

- packaging composed of over 50% by weight of organic materials (e.g. wood, cardboard, paper and other organic fibres, starch, plastics) provides calorific gain and ***shall be*** considered recoverable in the form of energy;

- packaging composed of over 50% by weight of inorganic material (e.g. ceramic, glass, clay, metals) ***may be*** declared recoverable in the form of energy when supported by evidence of the calorific gain;

- thin gauge aluminium foil (up to 50 μm thick) ***shall be*** considered recoverable in the form of energy.

Calorific gain is assumed to be fulfilled when the net heat of combustion exceeds the amount of energy required to raise the temperature of the post-combustion substances from ambient temperature to the specified final temperature, without heat entering or leaving the system. The standard provides a formula for calculating the net calorific value of a packaging consisting of different constituents.

Compliance assessment by the supplier shall be supported by records, providing as and when required the following information as a minimum:

- composition by main materials with particular reference to whether it may be considered organic or inorganic; and

- the calorific gain, when appropriate.

CEN standard on organic recovery (EN 13432)

This standard defines the requirements for packaging to be considered as recoverable through composting and biodegradation.

A pack is deemed organically recoverable when each pack, packaging material or packaging component fulfils the following criteria:

- they are inherently and ultimately biodegradable as demonstrated in laboratory tests, and to the criteria and pass levels laid down; and

- they disintegrate in a biological waste treatment process to the criteria and pass levels laid down, without any observable negative effect on the process; and

- when submitted to a biological waste treatment process, no negative effect on the quality of the resulting compost is recorded.

Packaging or packaging components intended for the biowaste stream must be recognisable by the end-user as compostable or biodegradable.

The standard covers the compostability of the packaging itself but does not address regulations that may exist regarding the compostability of any residual contents.

The standard is only intended to obtain information on the processing of packaging in controlled waste treatment plants, and does not take into account packaging waste which may end up in the environment through littering or other uncontrolled means.

Each packaging material under investigation must be identified and characterised prior to testing, including at least

- information on, and identification of, the constituents of the packaging materials;

- determination of the presence of hazardous substances (e.g. heavy metals); and

- determination of the organic carbon content, total dry solids and volatile solids of the packaging material used for biodegradation and disintegration tests.

Constituents known to be or expected to be harmful to the environment during the biological treatment process, in excess of the limits laid down, may not be introduced into packaging or packaging materials intended to be designated as suitable for organic recovery.

If a packaging material is demonstrated to be organically recoverable in a particular form, the same packaging material in another form, having a smaller mass to surface ratio or wall thickness, is also regarded as organically recoverable. Chemically unmodified packaging materials of natural origin (e.g. wood, wood fibre, cotton fibre, paper pulp or jute) can be accepted as biodegradable without testing, but have to be chemically characterised and must fulfil the criteria for disintegration and compost quality.

The results of each assessment or test undertaken must be recorded on an assessment checklist and their combined outcome used to determine whether a packaging material or a pack is biologically treatable and therefore suitable for organic recovery. The checklist, together with any externally sourced data or other information needed to support the conclusions reached in the assessments, must be retained and made available for inspection as required. The standard includes a recommended format for a conformity assessment checklist.

The evaluation criteria laid down include pass levels for Zn, Cu, Ni, Cd, Pb, Hg, Cr, Mo, Se, As and F. It is assumed that 50% of the original weight of the packaging or packaging material will remain in compost after biological treatment together with 100% of the original amount of hazardous substances.

CEN report on requirements for measuring and verifying heavy metals and other dangerous substances present in packaging, and their release into the environment (CR 13695-1 and prCR 13691-2)

Part 1 of the report, which deals with the four heavy metals controlled by the Directive, was published in March 2000. Part 2, which covers other dangerous substances, will be available shortly.

Part 1 notes that very few examples of the intentional introduction of heavy metals into packaging and packaging materials have been identified. These are listed in the report.

Two ways of assessing heavy metals content are possible:

- The preferred method is through calculation (the so-called 'upstream approach'). The manufacturer of the packaging component asks the suppliers of each constituent to provide him with information on its heavy metals content, and aggregates this information. If the heavy metals content exceeds the limits – having regard to any derogations – he must ensure that this is corrected before he issues his statement of conformity. Similarly, packaging convertors and packer/fillers assemble information from their suppliers and calculate the total heavy metals content reported.

- If information on the heavy metals content is not available, the statement of conformity must be based on the results of tests on a representative sample, carried out by a qualified laboratory.

Part 2 of the report will enable the component and/or packaging manufacturer to demonstrate that the introduction of substances dangerous to the environment has been minimised. These substances are those

- classified as dangerous by Directive 67/548/EC and its amendments;

- intentionally introduced for functional purposes;

- present in individual concentrations equal to or above trace level (0.1% by weight); and

- liable to be released into the environment during incineration or after landfilling.

Where all four of these conditions apply, the component and/or packaging manufacturer must ensure and be able to demonstrate that he has added only the minimum amount of the substance(s) needed for the functional purpose.

The draft report says that there are no general standardised methods for the systematic measurement of the presence of these substances in ash, emissions or leachate, so the 'upstream approach' is again recommended.

2.1.4 The challenge of verifying compliance with essential requirements.

Richard Lawson, Deputy Director of Standards and Technical Regulations, UK Department of Trade and Industry

THE CHALLENGE OF VERIFYING COMPLIANCE WITH ESSENTIAL REQUIREMENTS

Richard Lawson, Deputy Director of Standards and Technical Regulations, Department of Trade and industry

Synopsis of Presentation

The presentation will begin with a brief explanation of the UK's legislative traditions in the field of product safety and how it has coped with the transition to harmonisation on the basis of the New Approach. It will go on to consider some of the benefits that the New Approach has brought about. It will give practical examples in the field of Machinery safety together a reference to our more limited experience in the field of Packaging and Packaging Waste. It will then try to illustrate how the Essential Requirements approach can be hampered. It will do this by giving an example of holding onto a more prescriptive approach while ostensibly doing the opposite. It will - again briefly – consider the respective roles of product standards and management standards in current safety-related New Approach legislation. It will conclude by listing some of the overall benefits we have found with the New Approach.

STANDARDS & TECHNICAL REGULATIONS DIRECTORATE

Benefits from the essential requirements approach

- Changing legislation itself heightens awareness of issues
- Three principles of safety integration: design, safeguarding, warning
- Driving force for innovatory design
- More focus on health requirements
- More focus on installing and maintenance

2

STANDARDS & TECHNICAL REGULATIONS DIRECTORATE

Examples of helpful essential health and safety requirements (EHSRs)

- EHSR on all round operator visibility - basis of life-saving market surveillance for mobile machinery in stone quarries– standard less clear
- Two successful enforcements of essential requirements under P&PW

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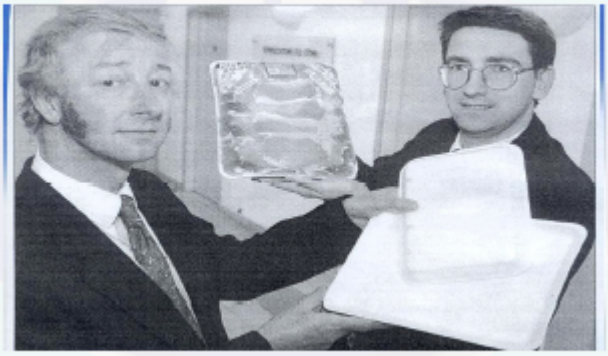

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STANDARDS & TECHNICAL REGULATIONS DIRECTORATE

Essential requirements – problems

- Lifts Directive EHSR 2.2 to prevent crushing at top & bottom of shafts insists on spatial protection
- Contrary to goals based New Approach EHSRs
- Impedes development of technological solutions
- Industry confusion over roles of ER and standard
- Mitigated by individual member States initiatives – undermines harmonisation (see www.dti.gov.uk/strd/ladmin2.pdf)

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STANDARDS & TECHNICAL REGULATIONS DIRECTORATE
Product standards or management standards?
• In "our" sectors – Machinery, Lifts, LVD, PPE, Pressure Equipment, EHSRs are supported by specific product standards e.g. Machinery "C" standards
• ISO 9000 an OPTION in several Directives (in various forms) to demonstrate conformity
• Good balance of roles


STANDARDS & TECHNICAL REGULATIONS DIRECTORATE
Some conclusions
In TBT/ H&S Sector, N.A. based on EHSRs:
• effective for a wide range of products
• stimulates industry, legislators and regulators to seek design based solutions
• confirms standards role in Europe's technical infrastructure, competitiveness and innovation

2.1.5 The wider international issues: interface between European and international standards-setting.

Jacob Holmblad, Vice President, CEN

Workshop on New Approach

Being CEN's vice-president, I note with great pleasure that standardization along with the New Approach have created success for the internal market in Europe.

However, the subject I wish to introduce today is 'The Interface between European and International Standards-setting' and **not** the internal market. This has become a live issue due to the fact that globalisation has increased the need to find an international solution on global trade. This solution should be based on the European success.

Until the mid-eighties standardization was primarily a tool for industry in the pursuit of achieving rational production and trade. The political relations were few and the national standardization bodies manifested a great degree of stability.

The change came around the mid-eighties, and was demonstrated by the ratification of the New Approach, which was one of the main elements in creating a new Europe with an internal market. Standards gained a role in relation to the directives, and by adding this legal dimension a growth generator for the standardization work had been initiated.

The work behind the establishment of the internal market was now well on its way. The future challenges are maintenance, the application of the new approach in new areas, co-regulation and international solutions.

International trade is to become the focus of attention. The philosophy behind the internal market should be put into a global perspective. The technical trade barriers throughout the world are to be removed.

The International Standards are ascribed the same role standards had in Europe before the introduction of the New Approach. In Europe the importance of standards were more far-reaching. The introduction of the New Approach launched a brave and far-sighted process within a political framework. The process itself laid down the responsibility of the parties involved – them being the manufacturers, the consumers, the authorities or whom else might be involved – in order to contribute to the creation of the internal market. There are not many other places in the world where such a confidence was shown towards the citizens' self-regulation. But it turned out to be a success, which the Commission wishes to carry on with within the

framework of co-regulation. We can be very proud of this process of thought. I believe it is highly unique and it has caught considerable attention outside of Europe.
The American central administration has studied the European model for a while now – and it has been found very appealing. However, the conclusion is that the USA most likely will use it as a source of inspiration rather than an actual implementation.

The extent to which standards are used within a legislative framework is rather unique for Europe. In the rest of the world traditions and codes of practise in certain sectors are given higher priority. Therefore, it is often seen that trade-specific de facto standards regulate a certain sector.

Another important difference is that in Europe, it is a requirement to withdraw national standards for the benefit of a national implementation of European Standards. This is quite a decisive factor for the existence of the internal market. Nevertheless, this results in an imbalance in relation with whom we trade outside of Europe, as existing national standards do not have to be withdrawn as a result of the approval of ISO- and IEC-standards. If only we could achieve this, we would have achieved a lot.

The question is whether we can agree on an international model resulting in a huge global internal market? It won't be easy. In Europe there are 20 somewhat homogeneous countries while there are 150 countries in ISO, which are at different stages of development.

One possibility would be to divide the world into regions. And we already have several of them – Pacific Rim, ACEAN, EU, NAFTA etc. At first the thought would be to promote trade among countries within the regions and then afterwards start promoting trade among the regions. But this model would not work seen in the perspective of creating a larger and more equally shared wealth among countries.

As mentioned earlier, I do not believe in the popularisation of the European model. The internal market was born as a political vision. I think that the global vision will emerge as a wish to simplify and harmonize within the global market and the source of inspiration could very well be the “world standards”. There is a need for worldwide-accepted standards. Present examples of worldwide-accepted standards are ISO Standard for codes for foreign exchange currency as well as ISO 9000 and ISO 14000.

We are witnessing the beginning of a shift towards international focus on certain areas. One could hope that the increased focus on health, safety, environment and also soon ethical aspects - which all are terms transcending barriers – would have an encouraging effect towards an international

orientation. The value of international standards within these areas would benefit international society and trade.

Being inspired by the European model one could imagine an umbrella-standard corresponding to the requirements in the directives. This would conform to the role of the directives in the internal market. On a regional level, regional standards could be elaborated and with respect to regional differences, the standards would fulfil the requirements laid down in the umbrella-standard.

The umbrella-standard could be an intermediate stage on the journey towards harmonized international standards. The world of standardization is able to propose several solutions on an international level, but the chances of going through with them will to a great extent depend on negotiations in other international co-operating fora such as WTO.

2.2 The New Approach: ensuring a high level of protection for environment and human health (Session II)

2.2.1 Experience with the New Approach from an environmental point of view.

John Hontelez, Secretary General, European Environmental Bureau (EEB)

The New Approach in Setting Product Standards for Safety, Environmental Protection and Human Health: Directions for the Future
29-30 November 2001, Copenhagen
sponsored by
Danish Ministry of Industry and Trade
Danish Environmental Protection Agency

EXPERIENCE WITH THE NEW APPROACH
- FROM AN ENVIRONMENTAL POINT OF VIEW-

By John Hontelez, Secretary General, European Environmental Bureau

Involvement of the EEB
The European Environmental Bureau consists of 140 member organisations in 27 countries and with more than 14 million members/direct supporters in these countries. The EEB works on many different environmental issues with a European perspective, including standardisation. The work with standardisation has been part of the EEB's work for ten years, so far without any specific financial support, so on a very limited scale. Logically, the focus has been the impact of standards to the environment.

On the initiative of the EEB, this year, a group of large European Environmental Organisations and several national organisations, including the Danish Society for Nature Conservation (DN), founded ECOS, the European Environmental Citizens Organisation for Standardisation). ECOS

is to support and develop standardisation work in and for the environmental movement in the consciousness that standards have a huge impact on Europe's environment. ECOS has so far no financial support for its work, but we are waiting for the Commissions answer to an application we sent in August.

The evolution of environmental policy making

The environmental policy simultaneously exploded and imploded throughout the 90s. With the explosion the environmental policy decisions are diffused to new forums. Environmental policy is not determined in the demarcated national parliamentary process alone but in complex interactions and battles between private as well as public national, European, and international actors. These actors include the European Commission, WTO, ISO, CEN, CENELEC and civil society organisations like the EEB. Ofcourse they also include very much powerful business organisations, in Brussels more in particular UNICE.

With the implosion of the environmental policy I mean that environmental policy processes are narrowed down and are of an increasingly closed nature. Environmental policy decisions increasingly are being determined as being technical and transferred to relatively closed forums of experts, such as technical standardisation working groups in CEN or committees within the European Commission, often with involvement of the Member State governments, but not of the European Parliament and with a very imbalanced involvement of non-governmental players.

The risks of the New Approach

Standards are no longer simply a voluntary option amongst others, but have become ***the*** way to comply with New Approach legislation. From a strictly legal point of view, such standards may still be regarded voluntary, however ***in practice they have become binding***. In other words, the New Approach has transformed technical standards into ***soft law***. This in return may pose a problem for the legitimacy of the New Approach, as this legitimacy rests on the voluntary nature of standards. For us the main question then is, whether it is posing a problem from an environmental point of view. The answer is that **it depends**:

The standardisation bodies are private and autonomous organisations, in which the voluntary effort of industry is the driving force. It was exactly this voluntary effort which the EU wanted to draw on in the New Approach. However, industry pursues its own interests - unfortunately - and these interests are not necessarily those of the EU's citizens or the environmental movement. ***Hence it should not be expected that standardisation organisations by themselves realise the aims of EU's environmental policy, nor of any national integrated product policy.***

The need for a clear environmental framework

This means that the Commission and the political system have to develop tools and procedures to ensure that standards indeed have a high environmental quality, that they support and reinforce EU's environmental legislation and objectives.

For the general legal basis for such a revision we refer to article 6 of the EU Treaty, which obliges the EU Institutions to ensure the integration of

environmental concerns in all policy areas. This article needs to be elaborated into some much more concrete decisions for the standardisation process.

So our first demand is a **framework directive on environmental demands to products**, similar to the product safety-directive. It should lay down a structural and specified obligation that environmental objectives and safeguards are part of the essential requirements and that no other essential requirements can complicate the achievement of such requirements.

Secondly, the requirements of the framework directive should be **specified in each New Approach directive** that, but setting concrete environmental benchmarks for the standards.

- These front end requirements need to be complemented with some improvements in the standardisation process:
- Firstly, it is necessary that the Commissions develop tools for an **ongoing evaluation** of standards to examine if they are living up to the environmental essential requirements.
- Also effective **repeal and sanctioning mechanisms** for the political level to control the standardisation bodies must be established to be able to address non-compliance.
- Furthermore, New Approach standards should be **explicitly** recognised or refused as harmonised standards by the EU Authorities, and a way of ensuring this would be by having a Unit in DG Environment dealing with standardisation and the environment horizontally.
- In the standardisation process, participation of organisations defending environmental interests should be made possible.
- Finally, **minority opinions** of organisation involved in the standardisation process but do not agree with the result, should be communicated to the Commission as part of the report, so that the Commission and Member States can take account of their arguments.

Our recommendations are not developed without a context – as said, our experience is limited as so far we do not have been given the means to get involved on a substantial scale. But we have reason to be concerned, given the lack of interest for environmental performance we have often seen in the main European standardisation body. There are a few concrete examples that we have come across where the environmental performance is clearly unacceptable.

One example are the standards for **heating appliances**. These appeared to be violating national legislation from Austria and Germany with regards to NOx, CO2 and volatile organic compounds for several appliances up. Acceptance levels of the standards exceed these national laws with between 100% and 900%. While they may not have violated law in other countries, nor the EU regulations, it shows clearly that the EU standards are not at all state-of-the-art or with a particular environmental ambition.

Another example are the standards on **construction materials**, where we are concerned in particular about the tolerance towards hazardous substances.

But the case we have been engaged in most is, paradoxically, the standards developed for the only New Approach Directive with an environmental origin, the **Packaging Directive.** Here we clearly see the weakness of the system:

- The Directive's does have essential environmental requirements, but they are formulated in VERY general terms. Furthermore the targets of the Directive are weak seen from an environmentalist point of view.
- Despite this, the adopted standards still do not fulfil the essential requirements.
- The minority groups in the standardisation committees didn't have any possibility to influence the process. The minority groups were in this case, not only the environment movement, but also the Danish Government and the Danish Standards Association.
- On various occasions the Commission showed its strong discontent with the standards and informed CEN that the draft standards did not comply with the mandate. CEN didn't change anything!

Currently, there is discussion to rely on CEN to assist in the implementation of the **Electric and Electronic Equipment Directive,** in particular to set standards for management systems. It is essential that the mistakes of the Packaging Directive won't be repeated.

Attempts to find solutions

The Environmental Help Desk and Environmental guidelines are two attempts from the standardisation bodies to try to integrate environmental concerns. Both are instruments developed inside the standardisation system, and they do not have to live up to the requirements of the European Treaty or European Institutions, neither do their have the possibility to change the fundament of the system.

The initiatives of the standardisation bodies can not replace the political responsibility, and therefore the main focus has to be on changing the method in a way that raises the political influence on the process and thereby make politicians and public authorities accountable again.

TO CONCLUDE:

The EEB can not support use of the New Approach in the environmental field without some major changes. We call on the EU Institutions to ensure that the New Approach is transformed into a one that safeguards and promotes environmental interests.

CEN AT WORK:
HOW THE REQUIREMENTS OF THE EUROPEAN PACKAGING AND PACKAGING WASTE DIRECTIVE (94/62) ARE BYPASSED BY CEN STANDARDS

(September 2000)
A legal analysis for The European Environmental Bureau (EEB)
by Susanna Paleari

EEB Publication 2000/15

The European Environmental Bureau (EEB)

The EEB is a federation of 135 environmental citizens organisations based in all EU Member Countries as well as in several other countries and around Europe. It was established in 1974 to provide a focal point for environmental groups in Brussels to monitor and respond to the emerging EU environmental policy. It lobbies to improve and protect the environment of Europe and to enable the citizens of Europe to play their part in achieving that goal. The EEB is active both at the EU institutions level and in each Member State.

Environmental organisations throughout the EU play a rich and important role in protecting and sustaining Europe's environment. We are responsible for representing public opinion and galvanising support for better environmental protection. We also deliver a huge amount of environmental protection - whether directly, as managers of land and buildings, or indirectly, through paid and voluntary work for the environment of all kinds. We are proud of our work and achievements, and see ourselves as partners in the search for more sustainable lifestyles and better environmental policies.

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Foreword

The present paper analyses the implementation of the European Packaging and Packaging Waste Directive (94/62/EC) through five standards elaborated by the European Committee for Standardisation (CEN):

- EN 13428 "Requirements on prevention by "source reduction",
- prEN 13429 "Packaging suitable for reuse",
- EN 13430 "Requirements on packaging recoverable by material recycling",

- EN 13431 "Requirements on packaging recoverable in the form of energy recovery",
- EN 13432 "Requirements on packaging recoverable through composting and biodegradation".

It also considers two standards, EN 13193 – on terminology – and the so-called "umbrella standard" EN 13427, which are frequently mentioned by all mandated standards, although they were not the subject of a mandate from the Commission.

This analysis, prepared by Susanna Paleari, of the EEB, concludes that the standards mentioned are not consistent with the general requirements of the Directive. Consequently, the mandate conferred by the Commission to CEN was not properly implemented.

In fact, CEN did not seem to take the legal requirements of the Directive seriously and chose a different approach. Instead of the expected thresholds and quantitative criteria, CEN opted for a management system approach, which, along with the flexible and generic criteria provided for in the standards, cannot guarantee that packaging to be placed on the market complies with the essential requirements of the Directive.

Moreover, CEN has consistently ignored and bypassed the critical comments made by environmental NGOs, (whose involvement in the standardisation process was clearly required by the Commission mandate), DG Environment and other participants in this process. The same criticism applies to the comments on CEN standards drawn up by the Waste Management Unit of the Directorate-General for the Environment (DG ENV-E.3).

These standards therefore have to be rejected. They should not be granted official approval by being published in the Official Journal. Official approval would set a disastrous precedent, with democratically legitimated institutions conferring a mandate for implementation to a private body, which then reshapes it according to its personal preferences. This would encourage CEN, and hence industry, to ignore and bypass environmental legislation and write out its own in the future. This would raise a question about environmental governance in Europe: is it governed by politics or by business? The EEB is convinced that politics should have the last word, even if tasks are assigned to private bodies.

CEN could have refused to work on the mandate, if it felt it impossible to implement, instead of which it opted for an independent reinterpretation of its tasks. By so doing, CEN has gone beyond the terms of reference and hence beyond its rights.

The failure of CEN to deliver what is required by the Packaging Directive implies additional tasks for the forthcoming revision of the Directive itself. We believe that safeguards need to be introduced to avoid a repetition of the CEN failure, which has caused considerable delay in implementing the Packaging Directive. A major change of approach in implementing its essential requirements is therefore needed.

Dr. Christian Hey, EU Policy Director, EEB

1 A short history: the preparation of the EC Directive 94/62

In 1990, the Directorate General of the Environment elaborated a first Outline Proposal, in order to draft a Directive addressing all packaging wastes, which focused on three basic measures:

a) The member countries should ensure that within five years the amount of packaging waste per head of population did not exceed the EC average;

b) The member countries should ensure that within five years at least 60% of the packaging waste was recycled and another 30% incinerated with energy recovery, while not more than 10% should be disposed untreated;

c) The member countries should ensure within five years that market packaging met certain standards as to its content of heavy metals and other dangerous substances.

The first internal draft of the Directive retained the main requirements of the Outline, adding some auxiliary obligations, but it was rejected by the chefs de cabinets, a steering body immediately below the colleague of Commissioners. In the following years three other internal drafts were elaborated, introducing important changes, even if, during the political decision making process, the ambitious recycling goals proposed by the Commission were defeated by the countries with a low standard in the sector. As a consequence, the Council fixed the requirement to recover to 50% of the packaging waste and the target to recycling to 25% of the total amount and to only 15% of each material. This target was further weakened by a temporary exemption for some low standard countries (Greece, Ireland and Portugal). Here we have to note that the definition of recovery includes energy recovery and recycling, while recycling can be defined as the reprocessing in a production process of the waste materials for the original purposes including organic recycling but excluding energy recovery.

The Council added to the mentioned minimum goals a cap, limiting recovery at a maximum of 65% and recycling at 45% of the total amount of packaging waste, aimed at regulating the faculty of the member states to go beyond the harmonised standards.

2 The contents of the Directive

The European Packaging and Packaging Waste Directive (94/62/EC), adopted under Art. 100A of the Treaty, is aimed at preventing or reducing the environmental impact of packaging, ensuring at the same time the functioning of the internal market (Art. 1). It applies to all packaging placed on the market in the Community and all packaging waste, as defined by Art. 3 par. 1 and 2.

The Directive lays down provisions for, "…as first priority, prevention of packaging waste and, as additional fundamental principles, reuse of packaging, recycling and other forms of recovering packaging waste and, hence, reduction of the final disposal of such waste". In particular the member states are required to take such measures that could be necessary:

to prevent the formation of packaging waste and to promote other preventive actions; (Art. 4 and 9)
to attain the recovering and recycling targets established by Art. 6, (while particularly relaxed targets have been decided with reference to Greece, Ireland and Portugal, because of their specific situation);
to ensure the creation of return, collection and recovery systems (Art. 7);
to limit the presence and the concentration in packaging of noxious and hazardous substances, including four heavy metals, (cadmium, mercury, lead and hexavalent chromium), (Art. 11).

Besides, Art. 9 and Annex II of the Directive set out essential requirements for packaging standards. The principles underlying the essential requirements are that:
packaging weight and volume should be minimised to the amount needed for safety and for acceptance of the packed product;
noxious and other hazardous constituents of packaging should have minimum impact on the environment when the packaging reaches its end of life;
packaging should be suitable for material recycling, energy recovery or composting, or for reuse if reuse is claimed.

Member states shall ensure that three years from the date of the entry into force of the Directive, packaging may be placed on the market only if it complies with all essential requirements defined by the Directive itself, including Annex II (Art. 9).

Art. 15 authorises member states to introduce national economic instruments (taxes or levies) to achieve the Directive's objectives, provided any such instruments are consistent with the Treaty, i.e. provided they do not create barriers to trade.

3 The Mandate of the Commission to CEN

Although the Directive introduces important requirements, it doesn't tell how packaging producers and importers can demonstrate compliance with these requirements. In other words, it doesn't say anything about how to design and specify packaging which will meet these legal obligations. Consequently, the Commission charged CEN with the following Mandate (M 200 Rev. 3):

The Commission requests CEN to draw up standards for packaging and packaging waste useful for the application of the Directive, covering all environmental aspects of all kinds of packaging and packaging materials and reflecting the objectives of the Directive, i.e. to prevent waste of packaging and to promote reuse of packaging and recovery, including recycling, of packaging waste.

Apart from this Mandate and some informal experts advices, no other guidance or constraints were available to CEN because national standards on the subject were non-existent.

According to this Mandate, three groups of standards are to be developed:
standards intended to give presumption of conformity with the essential requirements of the Directive (Art 9, Annex II);
standards in support of the environmental objectives of the Directive;
reports on particular areas, including where appropriate proposal for the elaboration of further standards in such areas.

In the context of standards permitting presumption of conformity with the Directive, the following standards are to be prepared:
- (EN 13428) Requirements on prevention by source reduction;
- (prEN 13429) Packaging suitable for reuse;
- (EN 13430) Requirements on packaging recoverable by material recycling;
- (EN 13431) Requirements on packaging recoverable in the form of energy recovery;
- (EN 13432) Requirements on packaging recoverable through composting and biodegradation.

All these standards were adopted by CEN in April 2000, except for the one concerning reuse (prEN 13429), which is currently being prepared for final vote. Beside these, CEN elaborated two non-mandated standards: the so called "umbrella guidance document" (EN 13427) which is a horizontal standard that should show the links among the different mandated standards and the standard concerning terminology (EN13193).

The Mandate requires the preparation of the standards to be carried out in association with industrial and commercial organisations, particularly in the field of packaging and waste management; with regulatory bodies; with representatives of consumers groups and with environmental and scientific organisations.

4 The organisation of the work on packaging and packaging waste standards in CEN

Members of the European standards institutes (CEN/CENELEC) are the respective national standardisation institutes, which are predominantly constituted from national industry and industry associations, even if in some countries there are various models for the participation of public interests and in fewer countries (Germany, France, Denmark and Finland) also for the occasional or regular participation of environmental groups. Standardisation is dominated by the principle of territorial representation, according to which, each national standardisation institute only represents at European level positions agreed nationally. As a consequence, even if environmental groups have participated at national level, their voice is filtered at European level by national consensus. Besides, environmental organisations can participate in CEN work as observers, but, in this case, they have not the right to vote.

The European Standardisation Committee for Packaging (CEN/TC261), created in 1990, has the purpose of preparing standards on terminology, dimensions, capacities, labelling, test methods and functional and performance requirements related to packaging and loading units. Each member state can participate in each Technical Committee with a delegation of three persons, which has one vote and is thus expected to represent national interests.

The standardisation work is organised in four pillars managed by Subcommittees (SC's), even if TC 261 retains full responsibility for the activity of these SC's. In particular, SC4 was charged to develop the standards related to the Packaging and Packaging Waste Directive.

In principle, TC's shall operate through Working Groups (WG's), in order to prepare the individual standards. WG's usually consist of people with detailed

technical knowledge and shall work in consensus. If it is not possible to come to a consensus, the discussion and the vote shall take place at the SC or at the TC level. The task of drafting the mandated standards was given to 5 WG's dealing with:
WG1: Terminology, symbols and criteria for life cycle analysis of packaging (three mandated reports);
WG2: Degradability of packaging and packaging materials (five mandated standards);
WG3: Material recovery (three mandated standards);
WG4: Energy recovery (one mandated standard);
WG6: Prevention (one mandated standard).

The convenors of these groups participate in a WG drafting a non-mandated umbrella standard, intended as a user's guide to the set of CEN packaging standards. A joint WG, comprising members from SC2, SC3 and SC4, working on requirements for relevant materials and types of reusable packaging has also been established (one mandated standard).

In April 2000, at the TC level,
EN 13427 and EN 13428 were adopted by a 88% weighted majority with Austria, Denmark and Ireland voting against and Belgium abstaining;
EN 13430 was adopted by a 92% majority with Denmark and Ireland against and Belgium abstaining.
EN 13431 was adopted by a 96% majority with Denmark rejecting and Switzerland abstaining;
EN 13432 was adopted by 100 % of expressed votes, (the Czech Republic and Greece did not vote).

Besides that, a series of supporting standards were prepared, as well as reports on "heavy metals and other dangerous substances present in packaging" and on "requirements for substances and materials to prevent a sustained impediment to recycling".

To become harmonised, CEN mandated standards have: 1) to be adopted through a voting procedure by national standards organisations and 2) to be published in the Official Journal of the European Communities, the act which confers on them the status of EU Harmonised Standards. If mandated standards do not satisfy the basic requirements, the Commission can refuse publication in the mentioned Journal. However, we have to observe that, in the past, the usual practise was that all mandated standards were published without further control. From the moment of their publication, all packaging that complies with the standards will be deemed to be in conformity with the essential requirements of the Packaging Directive and will be guaranteed free circulation throughout the European Union.

5 Analysis of two non-mandated standards: EN 13193, concerning terminology and EN 13427, the so-called "umbrella standard"

In April 2000, two non-mandated standards were adopted by CEN: EN 13193, concerning terminology, and EN 13427, the so-called "umbrella standard". Mandate 200 Rev. 3 neither mandates these standards nor allows for implicit mandates. All the five mandated standards contain references to these two non-mandated ones.

EN 13193 “defines terms used in the field of Packaging and the Environment” (par. 1 “Scope”), with the aim “to provide a comprehensive glossary which uses the applicable Directive’s definitions providing when appropriate additional notes to make these definitions understandable without reference to other documents”, (“Introduction”). The terms are divided into three clauses: - clause 3 refers to terms which are specifically related to packaging and the environment; - clause 4 refers to terms relating to degradability and – clause 5 refers to terms relating to energy recovery.

EN 13427 “specifies requirements and a procedure by which a person or organisation responsible for placing packaging or packed product on the market (the supplier) may combine the application of five (mandated) packaging standards and one (mandated) CEN report (in two parts)”, (par. 1 “Scope”). In other words, the “umbrella standard” should represent an instrument in order to co-ordinate the application of the five mandated-standards.

As we have already said, the non-mandated standards, which are not published in the Official Journal of the European Communities, cannot be considered harmonised. Consequently, the references of the mandated standards to EN 13193 and to EN 13427 prevent them to be considered as harmonised standards too. An advisable solution to face this problem would be to delete these non-mandated standards, shifting their contents into the mandated ones.

Moreover we have to notice that the non-mandated standards are characterised by some substantial inconsistencies with the Directive 94/62. With this respect, our comments concern especially the incorrect use of various terms and expressions by both EN 13193 and EN 13427. In fact the non-mandated standards do not take into account some terms and expressions defined by the Directive, replacing them with other ones. As the latter have not exactly the same meaning of the former, there are concrete risks of a misunderstanding or of a narrow interpretation of the Directive. Consequently, in order to avoid all these problems, if the Directive contains and defines some terms and expressions, the same should be used in the standards too.

1) EN 13193, as well as EN 13427, defines the “packaging component” as a “part of packaging that can be separated by hand or by using simple physical means” (see respectively par. 3.1.1 and par. 3.2). This concept is linked to the one of “packaging constituent”, defined by EN 13193 par. 3.1.2 as following: “part from which packaging or its components are made and which cannot be separated by hand or by using simple physical means”. EN 13427 specifies that “the smallest part of a packaging considered in this standard is a component. Usually a number of components will be brought together to form a functional unit of packaging and these may in turn be brought together in a complete packaging system which could comprise primary, secondary and tertiary packaging”. The Directive 94/62 speaks only about “primary, secondary and tertiary packaging” and doesn’t refer to “packaging component”, except for Art. 11 which concerns the “Concentration of heavy metals present in packaging”. Therefore, the latter expression has to be deleted and the former, that is the only correct and legal one, to be introduced in the standard.

2) EN 13193 defines the “used packaging” as “packaging or packaging component remaining after the removal of the product it contained, protected or carried” (par. 3.3.3). Also this expression, that we find in all the mandated standards, is unknown to the Directive 94/62, which instead speaks about “packaging waste”, that is the only correct and legal term. In particular, we want to underline that the Directive is going to be undermined by resorting to the expression “used packaging” for two main reasons:

the calculation of the recycling and recovery rates could be highly manipulated;
in most member states the waste is under strict control by law, while used packaging not, as it is a matter of industrial raw material, (hence out of official control).

3) EN 13427 in Annex Z speaks about par. 9 and 11 of the Directive 94/62, instead of using the correct term “Articles”, which should be introduced.

4) EN 13427, contrary to all other standards, (mandated or not), has no bibliography. It would be of advantage to introduce it.

6 Analysis of the mandated standards intended to give presumption of conformity with the essential requirements of the Directive

Introduction

The following paragraphs contain an analysis of the “mandated standards intended to give presumption of conformity with the essential requirements of the Directive 94/62”. This analysis focuses on the comparison between the mentioned standards, elaborated by CEN, and the Mandate and the Directive, prepared within the EC.

Here we want to make some general considerations, which will be then closely examined. All the standards, (EN 13428, prEN 13429, EN 13430, EN 13431 and EN 13432), are based on a self-assessment system similar to that of systems standards such as the EN ISO 9000 and EN ISO 14000 series. Neither the Directive, nor the Mandate, (which, more in general, speaks about “assessment”), specifically provide for this kind of approach. However, the main problem, as far as the implementation of the Mandate and the Directive is concerned, is related to the character of the standards. In fact, directives are juridical acts that on the one hand bind to determinate results and, on the other hand, give freedom to choose the instruments in order to achieve such results. The self-assessment systems, lined out by CEN standards, are instruments too generic and too flexible to guarantee that the essential requirements of the Directive are fulfilled. They are founded on concepts and expressions often defined in a very evasive way or, sometimes, not defined at all. Besides, as we have already said, most of these terms are defined by a non-mandated standard, (EN 13193), as well as the co-ordination and the application of these standards is specified by a non-mandated standard (EN 13427). As these non-mandated standards will not be published in the Official Journal of the European Communities, (the act which confers the status of EU Harmonised Standards), and have not force in law, these references prevent the mandated-standard to “stand-alone” and to be considered a harmonised standard. This result is clearly in contrast with the first aim of the Directive, that is to “harmonise national measures” (Art. 1).

Procedural inconsistencies common to the five mandated standards

The Mandate of the Commission establishes that "The preparation of the standards shall be carried out in association with industrial and commercial organisations, particularly in the field of packaging and waste management; with regulatory bodies; with representatives of consumer groups and with ***environmental*** and scientific organisations".

This means that the Mandate requires environmental organisations to take part, ("in association with"), in the standardisation process at European level. However we have to notice that:

- environmental organisations have participated directly in the standardisation process via national delegations only in the case of Germany, thanks to governmental financing;
- environmental organisations have participated directly in the standardisation process as observers, (i.e. without the right to vote), only for short periods, because of the lack of funds. In particular, as long as the standardisation process within CEN is not streamlined, the participation of the environmental NGO's will always be difficult. For example, the work on standard 13430 started in summer 1991, took 10 years to be finished and brought a result which is really of little use for the implementation of the Directive 94/62. Hence the real problem is that CEN often wastes time and money and this situation represents a clear strategy of industrial actors in order to keep environmental NGO's away from the standardisation process.

We can conclude that the Mandate hasn't been fulfilled.

EN 13428 Requirements on the prevention by source reduction

Substantial inconsistencies, lack of provisions, generic provisions and advisable improvements

1) EN 13428 contains several references to two non mandated-standards, that is to say to EN 13427 and EN 13193, (see "foreword", "introduction", "scope", "normative references", "terms and definition", "terms and definitions-supplier", "requirements-application"). As a non-mandated standard is not published in the Official Journal of the European Communities, (the act which confers the status of EU Harmonised Standards), and hasn't force in law, these references prevent EN 13428 to "stand-alone" and to be considered a harmonised standard. This result is clearly in contrast with the first aim of the Directive, that is to "harmonise national measures" (Art. 1).

2) EN 13428 focuses only on source reduction, without containing any reference to the other wider and more environmentally beneficial meanings of the term "prevention", as defined by the Directive 94/62.

This omission is clearly in contrast with the Mandate which, although it declares that "a standard is necessary to set criteria for the assessment and measurement of source reduction", speaks more in general about the prevention of packaging and packaging waste. In fact it states that: "the standard containing the requirements regarding prevention shall be in line with articles 1, 3 par. 4, 4 and 9 and Annex II par. 1 indents 1, 2 and 3 of the Directive. Prevention of packaging waste and any impact thereof on the environment are key objectives of the Directive ...".

The Directive 94/62, as we have already told, defines a concept of prevention that includes measures and actions that do not consist only of source reduction. Thus, Art. 3 par. 4 states that "prevention shall mean the reduction of the quantity and of the harmfulness for the environment of: - materials and substances contained in packaging and packaging waste, - packaging and packaging waste at production process level and at the marketing, distribution, utilisation and elimination stages, in particular by developing clean products and technology". Art. 4 par. 1 states that "Member States shall ensure that, in addition to the measures to prevent the formation of packaging waste taken in accordance with Art. 9, other preventive measures are implemented. Such other measures may consist of national programmes or similar actions adopted, if appropriate, in consultation with economic operators, and designed to collect and take advantage of the many initiatives taken within Member States as regards prevention. They shall comply with the objectives of this Directive as defined in Art. 1".

We can conclude that the Mandate and the Directive have not been fulfilled.

3) The Mandate states that "the assessment and measurement is necessary to put the packaging on the market and to be in accordance with the essential requirements of the Directive 94/62".

The standard prepared by CEN reduces the scope of the Mandate as it provides just for "a procedure for assessment of packaging", (par. 1), without any mention of measurement, and, consequently, it cannot assure that packaging on the market is in accordance with the essential requirements of the Directive.

4) The definition of "prevention" in Article 3 par. 4 of the Directive 94/62 states that "prevention shall mean the reduction of the quantity and the harmfulness for the environment of:

- materials and substances contained in packaging and packaging waste,
- packaging and packaging waste at the production process level and at the marketing, distribution, utilisation and elimination stages, in particular by developing clean products and technology".

Besides that, Annex II point 1 of the Directive, "Requirements specific to the manufacturing and composition of packaging" states that:

- 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 minimise 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 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.

Prevention by source reduction is defined by EN 13428 par. 3.1 as follows: "process for the achievement of a minimum adequate weight and/or volume for identical requirements, of primary, secondary and/or tertiary packaging,

when performance and user acceptability remain unchanged and/or adequate, thereby minimising the impact on the environment".
The Directive, (Art. 3 par. 4), refers the word "reduction" to qualitative (decreasing the harmfulness) and quantitative (diminishing of quantity) aspects. Instead, there is evidence of the fact that the meaning of "prevention by source reduction", as defined by the Directive, has been limited by EN 13428 to a procedure of weight and/or volume reduction, which corresponds only to the first indent in Annex II, whereas ignoring the second and the third indents. In other words, the definition given by EN 13428 doesn't fully take into account the Mandate where it states that "the requirements regarding prevention shall be in line with articles…3 par. 4…and Annex II 1, indents 1, 2 and 3 of the Directive" and therefore it is at the same time in contrast with the Directive itself.

We have to notice that in the final version of EN 13428 an Annex dealing with dangerous substances has been introduced (Annex C), so that it is difficult to argue that decreasing the harmfulness has been entirely omitted. However, we have to underline that:

a) This Annex is an inadequate instrument for the assessment of dangerous substances. In fact, as it is very generic and imprecise, (see in particular n. 6), it makes it impossible to verify if the supplier has used in the packaging only the minimum adequate amount of any substance dangerous to the environment.

b) The qualitative meaning of the world "reduction" should be mentioned in the definition of "prevention by source reduction" (par. 3.1).

5) The standard elaborated by CEN lists (par. 5) some performance criteria for packaging that basically are of equal importance in comparison with the environmental one. They are the following:
- product protection;
- packaging manufacturing process;
- packing/filling process;
- logistics (including transport, warehousing and handling);
- product presentation and marketing;
- consumer acceptance;
- information
- safety;
- legislation
- any other relevant issue.

Individuals or organisations placing the packaging on the market shall establish the priority ranking of the criteria and the eventual evaluation of a criterion as "critical". The mentioned standard describes a critical area for source reduction as a "specific performance criterion, which prevents further reduction of weight and/or volume of the packaging without endangering functional performance, safety and user/consumer acceptability" (par. 3.2). Hence, if a criterion is evaluated as "critical area", this means that no reduction of the packaging weight and/or packaging volume is required under this criterion. As a consequence, emphasis is put on all other functions that packaging has to comply with and that the environmental side appears as marginal as to be let to the discretion of the producer.

This liberty of evaluating and determining (see "other relevant issue") the "critical area" doesn't comply with the Directive for two main reasons:

a) It makes these criteria completely subjective, without any possibility of control by the authorities. In other words, when all performance criteria are given preference over prevention, there is no way for an enforcement-authority to prove non-compliance. In conclusion, the performance criteria of EN 13428 are something totally different from the "necessary level of safety, hygiene and acceptance for the packed product and for the consumer" mentioned by the Directive, (Annex II, point 1, par. 1).

b) It makes it impossible to speak about the creation of harmonised measures, which represent the first objective of the Directive, (Art. 1). In fact, according to the Danish EPA, a harmonised standard should contain precise and unambiguous requirements in order, in first place, to allow the authorities to have at their disposal objective assessment criteria and, secondly, in order to be administered in the same way in different countries.

6) In Annex C.2 of EN 13428 "Determination of the substances to be minimised", step 1, we read: "If no substances are intentionally added, or if any are used but in concentrations below the ***trace level***, conclude the procedure". The "trace level" in a harmonised standard should be quantified or at least specified. In fact, the procedure described in the mentioned Annex is based on this concept, as, if substances dangerous to the environment are used in concentrations below the "trace level", minimisation is not applicable. Moreover, the fact that the reduction of substances hazardous to the environment finally depends on the intention of the supplier, (as described by CR 13695-2), cannot be considered in line with the Directive, which in general terms calls for the minimisation of the mentioned substances.

7) More in general, the third par. of the introduction of EN 13428 states that "This European Standard presents a framework for assessment to determine whether the requirements of this standard have been met. Its approach is similar to that of systems standards such as the EN ISO 9000 and EN ISO 14000 series".

The Mandate simply asks the creation of criteria for the assessment of source reduction, without specifying if they could consist of a self-assessment system. However, we think that the Directive doesn't line out any self-control system as flexible as this one, because it guarantees neither the implementation of the essential requirements of the Directive, nor the harmonisation of the internal market.

6.4 prEN 13429 Packaging suitable for reuse

Substantial inconsistencies, lack of provisions, generic provisions and advisable improvements

1) prEN 13429 contains several references to two non mandated-standards, that is to say to EN 13427 and EN 13193, (see "foreword", "introduction", "scope", "normative references", "terms and definition", "requirements-application"). As a non-mandated standard is not published in the Official Journal of the European Communities, (the act which confers the status of

EU Harmonised Standards), and hasn't force in law, these references prevent prEN 13429 to "stand-alone" and to be considered a harmonised standard. This result is clearly in contrast with the first aim of the Directive, that is to "harmonise national measures" (Art. 1).

2) This standard (par. 4) contains a checklist by which the packer or the filler can asses "reusability". If the pack fails any of these three tests, it is deemed unfit for reuse:
packerfillers must intend to reuse the pack for its original purpose;
it must be possible to clean, wash and/or repair the pack after emptying and to refill or reload it;
a system which supports reuse of the pack must be available. This may be a "closed loop" system (in which reusable packaging is circulated by a company or an organised group of companies), an "open loop" system (in which reusable packaging circulates amongst unspecified companies) or a "hybrid system" (in which reusable packaging stays with the end-user and is replenished by means of one-way packaging which is used as an auxiliary product to transport the contents to the reusable packaging).

The inclusion of the "hybrid system" among the systems in place for reuse has to be criticised for the following reasons:

1) The standard doesn't require the reusable packaging to be refilled by the consumers and doesn't establish the ratio between the number of refillable packaging and the one of auxiliary products that can be used, (i.e. detergent pouches used to refill a container at home). As a consequence, reuse cannot be guaranteed by such a system and, what is more, it could be carried out with an excessive use of auxiliary products.

2) The mentioned inclusion doesn't make clear that the one way packaging used as auxiliary product is not part of the reuse system. In fact, if we say that:

hybrid system = reusable packaging + one way packaging

and that:

hybrid system = reuse system,

then we have to work out that:

reusable packaging + one way packaging = reuse system.

However we have to notice that, on this point, not only the standard, (see number 3) but also the Directive 94/62 is ambiguous. In fact, the latter states that: "reuse shall mean any operation by which packaging has been conceived and designed to accomplish within its life cycle a minimum number of trips or rotations, is refilled or reused 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". The meaning of the expression "support of auxiliary product" hasn't been enough clarified.

3) The meaning of the expression "auxiliary product", as defined by "terms and definition" par. 3.10 "auxiliary product" is not clear and could cause different interpretations, so that it would be better to re-define it.

4) The Mandate of the Commission states that “the requirements shall take into account: - requirements to guarantee a minimum number of trips or rotations under normally predictable conditions of use including test methods for the demonstration of this”. As these instructions are only partially taken into account and clarified in the draft standard, this one, firstly, doesn’t fulfil the Mandate and, secondly, as it cannot be considered as a harmonised standard, is in contrast with the objectives of the Directive, (Art. 1). In particular, with reference to “terms and definitions”, par. 3.1 “reuse” and par. 3.2 “reusable packaging”, it would be useful and more precise to specify how often a packaging should be reused to be classified as reusable. If this is not possible at a general level, (that is to say for all reuses systems), at least it should be possible to elaborate a concept or a procedure in order to analyse and calculate the number of trips.

5) The procedure drawn by par. 5.1 and the related Annex B (that has only an informative value) is too much generic and need to be specified, if EN 13429 wants to be considered as a harmonised standard. (see for example the following passages: “... the packaging can be emptied/unloaded without ***significant damage***, beyond that which can be ***viably*** repaired” or “... any reconditioning process within its control is managed ***in a manner that minimises its impact*** on the environment”).

6) The third par. of the introduction of EN 13429 states that “This European Standard presents a framework for assessment to determine whether the requirements of this standard have been met. Its approach is similar to that of systems standards such as the EN ISO 9000 and EN ISO 14000 series”.

With this respect, we think that the Directive does not line out any self-control system as flexible as this one, because it guarantees neither the implementation of the essential requirements of the Directive, nor the harmonisation of the internal market.

6.5 EN 13430 Requirements on packaging recoverable by material recycling

Substantial inconsistencies, lack of provisions, generic provisions and advisable improvements

1) EN 13430 contains several references to two non mandated-standards, that is to say to EN 13427 and EN 13193, (see “foreword”, “introduction”, “scope”, “normative references”, “terms and definition”, “requirements-application”). As a non-mandated standard is not published in the Official Journal of the European Communities, (the act which confers the status of EU Harmonised Standards), and hasn’t force in law, these references prevent EN 13430 to “stand-alone” and to be considered a harmonised standard. This result is clearly in contrast with the first aim of the Directive, that is to “harmonise national measures” (Art. 1).

2) The Directive Annex II point 1, indent 3 states that “packaging shall be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimised with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled”.

In the same line, the Mandate asks the requirements to take into consideration:
"substances or materials that are liable to have a negative influence on the energy recovery process";
"materials, combinations of materials or designs of packaging that are liable to create problems in collecting and sorting before energy recovery".

These instructions are nowhere taken into account or clarified in the draft standard. In fact, in EN 13430 we cannot find any identification of substances, materials or designs that are liable to create problems during collection, sorting or recycling. Therefore the standard doesn't fulfil the Mandate and, besides that, as it cannot be considered as a harmonised standard, it is in contrast with the objectives of the Directive, (Art. 1).

3) With reference to "Terms and definitions", par. 3.1 "Empty packaging", on the one hand, the standard defines "empty packaging" as follows: "a packaging is empty if (under normal and foreseeable circumstances) all product residues that can be removed by the emptier have been removed using practices commonly employed for that type of packaging".

On the other hand, the Directive only regulates the recycling of "packaging waste", which is defined with reference to the Directive 75/442. It has to be specified that an "empty packaging", that is to say a packaging that has been emptied, is a packaging waste. In the same way, the expression "packaging after use" (Annex A 4 of the standard) is unknown to the Directive and has to be substituted with "packaging waste".

In fact, the Directive is going to be undermined by resorting to these expressions, as in most member states only waste is under strict control by law, while empty or used packaging not, as they are a matter of industrial raw material, (hence out of official control).

4) The definition of "recycling process" given by "Terms and definitions" par. 3.4, ("physical and chemical process which converts collected and sorted used packaging and scrap, together in some instances with other material, into secondary raw material or products") doesn't exactly correspond to the definition of "recycling" given by the Directive Art. 3 par. 7, ("recycling shall mean the reprocessing in a production process of the waste materials for the original purposes including organic recycling but excluding energy recovery").

5) EN 13430 includes so many examples of unclear words/concepts, which, on the whole, make it impossible to finally decide when packaging is recoverable by material recycling. In particular the procedure for assessing recyclability criteria that are described in Annex A, B and C needs considerable improvements by way of specification before these are suitable in order to elaborate or assess recyclability. Thus, for example, what does it mean that operations shall be controlled to such an extent that the recycling processes are not ***negatively affected***? (A.2.2). This expression could refer to the explosion of the recycling plant (safety), to the increase of the amount of waste resulting from not recyclable packaging (environment), or to the fall in market price for mixed qualities under the level where a recycling of the packaging does no longer bring profit and therefore no longer is bought by the recycling industry (economy). The same considerations have to be made with

regard to other expressions such as: “ensure that the design of packaging includes consideration of ***aspects significant*** for the recycling of the materials from which it is produced” (A. 2.1), “ensure that the design of packaging makes use of ***materials or combination of materials which are compatible*** with the known, relevant and industrially available recycling technologies...” (A. 3.1), “design the packaging ... so as to ensure that it ... enables a ***certain percentage*** by weight of materials to be recycled ...” (B. 2), “the presence of the amount of substances or materials that are liable to have a ***negative influence*** on the quality of the recycled material” (B. 2), “ensure that the production operations ... can be managed such that any changes or deviations cannot ***adversely affect*** the compatibility of the packaging with the specification of the recycling process” (B. 3.1), “ensure that materials selected in the design stage as causing no ***significant problems*** in recycling technologies...” (B 3.2), “ensure that the construction is ***without prejudice*** to the conformance with other essential requirements” (B.4.1), “ensure that the design of the primary packaging ... will enable emptying of the packaging using common practices as defined in 3.1 such that the used packaging is ***compatible*** with the recycling process” (B 4.2), etc.

We can conclude that the Mandate that asks the standard to “give presumption of conformity with the essential requirements for packaging recoverable in the form of material recycling” hasn’t been fulfilled by this standard.

6) The third par. of the introduction of EN 13429 states that “This European Standard presents a framework for assessment to determine whether the requirements of this standard have been met. Its approach is similar to that of systems standards such as the EN ISO 9000 and EN ISO 14000 series”.

With this respect, we think that the Directive doesn’t line out any self-control system as flexible as this one, because it guarantees neither the implementation of the essential requirements of the Directive, nor the harmonisation of the internal market**.**

6.6 EN 13431 Requirements on packaging recoverable in the form of energy recovery

Substantial inconsistencies, lack of provisions, generic provisions and advisable improvements

1) EN 13431 contains several references to two non mandated-standards, that is to say to EN 13427 and EN 13193, (see “foreword”, “introduction”, “scope”, “normative references”, “terms and definition”, “terms and definitions-recycling process, -secondary raw material, -supplier”, “requirements-application”). As a non-mandated standard is not published in the Official Journal of the European Communities, (the act which confers the status of EU Harmonised Standards), and hasn’t force in law, these references prevent EN 13431 to “stand-alone” and to be considered a harmonised standard. This result is clearly in contrast with the first aim of the Directive, that is to “harmonise national measures” (Art. 1).

2) The Mandate asks the requirements to take account of:
- “substances or materials that are liable to have a negative influence on the energy recovery process”;

- “materials, combinations of materials or designs of packaging that are liable to create problems in collecting and sorting before energy recovery”.

These instructions are nowhere taken into account or clarified in the draft standard. In fact, in EN 13431 we cannot find any identification of substances, materials or designs that are liable to create problems during collection, sorting or recovery. Therefore the standard doesn’t fulfil the Mandate and, besides that, as it cannot be considered as a harmonised standard, it is in contrast with the objectives of the Directive, (Art. 1).

As far as collecting and sorting are concerned, combustible packaging waste, that can contain bacterial pollution or sporogenics from microbiological activity, represents a hazard during these prior to energy-recovery phases. The standard should mention this problem too.

3) It would be important to make a reference to the existing Directive 94/67 EC on the incineration of hazardous waste as well as to Directive 89/369 EC on the prevention of air pollution from new municipal waste incineration plants and compliance with the emission limits of these Directives must be assured (both Directives are going to be replaced by a new one on incineration of waste that is going to be adopted). In fact, the energy recovery of packaging waste is acceptable only if the pollutant emissions originated by this process are not higher than the ones of modern MSW-incinerators with dust elimination, scrupping and catalyst. This means that the plants have to apply Best Available Techniques and at least comply with the emission limit values of the new waste incineration directive.

Besides that, as the emission of acid forming substances, heavy metals and other hazardous components are only regulated in an environmentally satisfying way with reference to modern MSW incineration plants, but not with reference to coal fired or bio-fuel-plants or to cement plants, which use PDF or RDF as fuel, a precise distinction between the MSW-incineration and other incineration plants has to be introduced by the standard.

4) Annex II point 3 of the Directive, “Requirements specific to the recoverable nature of packaging”, letter b), “Packaging recoverable in the form of energy recovery” states that “Packaging waste processed for the purpose of energy recovery shall have a minimum inferior calorific value to allow optimisation of energy recovery”.

Also the Mandate of the Commission asks for a specification of the minimum inferior calorific value: “The standard shall contain a specification of the minimum inferior calorific value”.

The standard specifies the minimum inferior calorific value through the technical concept of calorific gain (see par. 3, par. 4 and Annex A). In fact, it establishes that calorific gain is assumed to be fulfilled when the net heat of combustion exceeds the amount of energy required to adiabatically raise the temperature of the post-combustion substances from ambient temperature to the specified final temperature. However, even through the concept of calorific gain it is desirable to set higher targets for the calorific gain than “> 0”. In fact, we think that energy recovery is useful and makes sense from both economic and environmental points of view only if the energy obtained by this process is significantly positive. This result cannot be guaranteed simply fixing a target for the calorific gain “> 0”.

Moreover, as for PVC the net energy balance with energy recovery is likely to be negative (Moller and Jeske 1995, Pohle 1997), the refusal to give a numerical dimension to the minimum inferior calorific value could lead to consider PVC recoverable through direct incineration with all the consequent problems concerning the formation of dioxin and other toxic substances and their release into the environment. In this regard, the Green Paper on environmental issues of PVC, adopted by the European Commission on 26th July 2000, states that: "Upon incineration, PVC waste generates hydrochloric acid (HCI) in the flue gas, which needs to be neutralised, except when a special technology is employed where HCI is reused. At the moment, this specific technology is used only in 5 plants in Germany and 3 plants are in construction… The potential influence of incineration of PVC waste on the emissions of dioxins has been at the centre of a major scientific debate since PVC is currently the largest contributor of chlorine into incinerators… Whilst at the current levels of chlorine in municipal waste, there does not seem to be a direct quantitative relationship between chlorine content and dioxin formation, it is possible that an increase of chlorine content in the waste stream above a certain threshold could contribute to an increase of the dioxin formation in incinerators".

5) The requirement of par. 6.1 of the standard, which states that "packaging composed of more than 50% (by weight) of organic materials… shall be considered recoverable in the form of energy", shall be integrated by a calculation of the calorific gain by analogy with what is established in par. 6.2.

6) The second par. of the introduction of EN 13431 states that "This European Standard presents a framework for assessment to determine whether the requirements of this standard have been met. Its approach is similar to that of systems standards such as the EN ISO 9000 and EN ISO 14000 series".

With this respect, we think that the Directive does not line out any self-control system as flexible as this one, because it guarantees neither the implementation of the essential requirements of the Directive, nor the harmonisation of the internal market.

6.7 EN 13432 Requirements on packaging recoverable through composting and biodegradation

Substantial inconsistencies, lack of provisions, generic provisions and advisable improvements

1) EN 13432 contains several references to two non mandated-standards, that is to say to EN 13427 and EN 13193, (see "foreword", "introduction", "scope", "normative references", "terms and definition", "requirements-application"). As a non-mandated standard is not published in the Official Journal of the European Communities, (the act which confers the status of EU Harmonised Standards), and hasn't force in law, these references prevent EN 13428 to "stand-alone" and to be considered a harmonised standard. This result is clearly in contrast with the first aim of the Directive, that is to "harmonise national measures" (Art. 1).

2) The Mandate asks the requirements to take account of:

“substances or materials that are liable to create problems in the composting or biodegradation process”;
“materials, combinations of materials or designs of packaging that are liable to create problems in collecting and sorting before composting or biodegradation”;
“the presence of substances or materials that are liable to have a negative influence on the quality of the product from the composting or biodegradation process”.

These instructions are only partially taken into account by EN 13432 in Annex A.1.2. Therefore the standard doesn’t fulfil the Mandate and, besides that, as it cannot be considered as a harmonised standard, it is in contrast with the objectives of the Directive, (Art. 1).

3) EN 13432 allows three different biodegradation tests to be considered for determining the biodegradation rate of packaging material, (see par. 6 “laboratory tests on biodegradability”). These tests are meant to demonstrate the fundamental biodegradability of a packaging material, as par. 6 states: “Only biodegradation tests that provide unequivocal information on the inherent and ultimate biodegradability of a packaging material or its significant organic constituents shall be used”.

Two of these tests (ISO 14851:oxygen consumption, and ISO 14852: Sturm test) do not stimulate composting conditions because the degradation happens in a liquid medium with mesophilic conditions. In fact, if the packaging material does not completely biodegrade during the composting process it should be demonstrated that it eventually degrades in the soil where the temperature is in the psychrophilic range and the medium is the soil.

As a consequence, EN 13432 fails its objective, that was to demonstrate the fundamental biodegradability of packaging material, and doesn’t fulfil the requirements of the Mandate and the Directive, (see in particular Annex II point 3 letters c) and d)).

4) Annex A par. 2.2 of EN 13432 “Aerobic biodegradation tests” establishes that “The period of application for the test specified in the test methods shall be a maximum of 6 months”. Six months for a test on compostability is a much too long period which is not reflected in common practices and may present risks of pollutant accumulation in soil. It is suggested that a 90% biodegradation rate in a time span of two to three months would give better guarantees as regards complete biodegradability.

5) As far as heavy metals are concerned, the assumption made in the standard that “50% of the original weight of the packaging or packaging material will remain in compost after biological treatment” is not contested. However, as potentially compostable packaging materials, already on the market, have heavy metal concentrations much lower than foreseen in the standard, the level of heavy metals in products should be kept as low as possible in order to prevent their spreading into the environment. Packaging deemed to be compostable should not impair the quality of the best compost which is possible to produce. As a consequence, it would be better to lower the heavy metal concentration indicated by the standard.

6) The third par. of the introduction of EN 13432 states that “The European Standard presents a framework for assessment to determine whether the

requirements of this standard have been met. Its approach is similar to that of systems standards such as the EN ISO 9000 and EN ISO 14000 series".

With this respect, we think that the Directive doesn't line out any self-control system as flexible as this one, because it guarantees neither the implementation of the essential requirements of the Directive, nor the harmonisation of the internal market.

7 Conclusion

The Commission requested CEN to draw up standards for packaging and packaging waste, useful for the implementation of Directive 94/62, covering all environmental aspects for all kinds of packaging and packaging materials and reflecting the objectives of the Directive itself.

EN 13428, prEN 13429, EN 13430, EN 13431 and EN 13432 (along with the two non-mandated standards EN 13193 and EN 13427) are the fruit of CEN work.

As we have already underlined in this paper, some elements of these standards do not comply with the mandate and the Directive from the legal point of view. Firstly, at a procedural level, the mandate, which establishes that "the preparation of the standards shall be carried out in association…. with representatives of consumer groups and with environmental and scientific organisations", has not been fulfilled. Secondly, all the standards show substantial inconsistencies with the Directive and/or the mandate, even if they are not all of the same relevance.

Starting with the two non-mandated standards (EN 13193 and EN 13427), we have to note that they play a central role in the standards system elaborated by CEN, as the former defines many terms used in these standards and the latter guarantees a certain co-ordination among them. We focused on a number of substantial inconsistencies of these standards, such as avoiding legally defined terminology, but added that their main problem is that they are not harmonised, so that we suggested their incorporation into the mandated standards after they have been adjusted to the terminology of the packaging directive.

As far as the mandated standards are concerned, our major criticism refers to EN 13428, prEN 13429 and EN 13430 for the following reasons:

a) EN 13428 does not fulfil the mandate as it reduces the scope of the concept of "prevention", (speaking only about "source reduction", not about clean products), it limits the meaning of the expression "source reduction" (addressing its definition only to minimisation of weight and volume, and not to minimisation of noxious and other hazardous substances), and it lists a number of performance criteria which are so flexible that the environmental aspect is left to the discretion of the producer.

b) PrEN 13429 does not fulfil the requirements of the mandate, as it neither specifies nor determines a method for establishing how often packaging should be reused in order to be classified as reusable and, besides, as it includes the "hybrid system" among the systems in place for reuse.

c) EN 13430 uses such imprecise and generic terminology that it makes it impossible to finally decide when packaging is recoverable by material recycling

EN 13431 contains some effective packaging requirements, even if it does not comply with the Directive as it does not take into account the instructions concerning "substances or materials that are liable to have a negative influence on the energy recovery process" and "materials, combination of materials or designs of packaging that are liable to create problems in collecting and sorting before energy recovery". Moreover, this standard insufficiently specifies the minimum lower calorific value through too low a demand for "calorific gain".

Finally, although EN 13432 is not completely consistent with the Directive, it seems to be of good quality since it states in its final version that the biodegradation level must reach at least 90%. Some changes should be introduced, however, especially with regard to the biodegradation maximum period of 180 days, biodegradation tests and dangerous substances targets.

A common problem for all the standards consists in the fact that they are based on self-control systems along with a high rate of flexibility and a terminology that is often vague and imprecise. This situation has two important consequences: a) it makes CEN standards inadequate instruments in order to guarantee that the essential requirements of the Directive are fulfilled; b) it deprives the enforcement authority of the means to prove non-compliance with the standards and to ensure their respect. As we have already underlined in this, although the Commission mandate simply asks for the establishment of assessment criteria, without specifying if they could consist of a self-assessment system, the systems that emerge from the standards are not in line with the Directive. It is aimed at fixing requirements and rules to regulate and curb packaging waste, while the standards side-step this purpose.

We can conclude that the Commission mandate is not fulfilled by the standards, which therefore should not be published in the Official Journal of the European Communities.
The failure of CEN to deliver what is required by the Packaging Directive implies additional tasks for the forthcoming revision of the Directive itself. We believe that safeguards have to be introduced to avoid a repetition of the CEN failure, which has caused considerable delay in implementing Directive 94/62. A major change of approach in implementing its essential requirements is needed.

Two options have to be discussed: the EEB prefers another institutional framework for implementing the mandate (e.g. mixed Committee consisting of Member States and Stakeholders; or an Information Exchange Process according to the IPPC model or according the model of the air quality steering group).

A second attempt to co-operate with CEN would require the following major changes:

1) The mandate should be written out in a much more precise way, clearly indicating the level of ambition and the criteria to be met, if possible by numerical indications.

2) Member States should invest considerably more in order to participate in the CEN process.
3) The requirement of Mandate 200 to consult environmental and consumer organisations should be implemented by giving them the means to do so on a continuous and professional basis both at national and EU levels.
4) Within the Technical Committees of CEN, minority opinions should not be ignored or bypassed, but require discussion at higher levels.
5) In co-operation with the Art. 21 Committee of the Packaging Directive, the Commission should decide and assess, if the then revised standards comply with the mandate.

List of EEB Publications 2000

2000/001 2000/001/Fr 2000/002 2000/003 2000/004 2000/005 2000/006 2000/007 2000/008 2000/009 2000/010 2000/011 2000/012 2000/012/Fr 2000/013 2000/014 2000/014/Fr 2000/015	❑ EEB **Memorandum to the Portuguese Presidency** and the EU Member States – January 2000 ♦ **Mémorandum** du BEE **à la Présidence portugaise** et aux Etats membres de l'UE – janvier 2000 ❑ **The Freedom of Access to Information on the Environment** Directive, EEB Comments on the DG Environment Working Paper on the Revision of Dir. 90/313/EEC on – 9 February 2000 ❑ EEB and the **6th Environmental Action Programme** – Response to the Global Assessment of the 5th Environmental Action Programme – 25 February 2000 ❑ **White Paper on Environmental Liability,** EEB Analysis of Com (2000) 66 final – 7 March 2000 ❑ **Precautionary Principle**, EEB Assessment of the Communication from the Commission of February 2, 2000, COM (2000) 1 – 7 March 2000 ❑ **Water Framework Directive,** The European Parliament's 2nd Reading – Analysis of key principles – 12 March 2000 ❑ **Public access to documents of the European Parliament, the Council and the Commission,** EEB Comments on the European Commission's Proposal for a Regulation – 17 March 2000 ❑ Assessment of **Plastic Recovery Options** – March 2000 ❑ EEB Open **Seminar on Water and Chemicals** – December 1999 – Reader – March 2000 ❑ **Towards Balancing Participation** – A report on devolution, technical committees and the New Approach in EU environmental policies : the cases of standardisation, chemicals control, IPPC and clean air policies in a comparative perspective – April 2000 ❑ **Construction and Demolition Waste**, EEB Position paper – June 2000 ❑ ~~Shaping the New Europe – Working towards sustainable development ...~~ see 2000 / G (joint publications) ♦ ~~Donner forme à la nouvelle Europe – Un rôle de leader pour la Commission européenne ...~~ see 2000 / G (joint publications) ❑ **1999 Activity Report – 2000 Programme of Activities** – a combined presentation – June 2000 ❑ EEB **Memorandum to the French Presidency** and the EU Member States – July 2000 ♦ **Mémorandum** du BEE à la **Présidence française** et aux Etats membres de l'UE – juillet 2000 ❑ CEN at Work: How the Requirements of the European **Packaging and Packaging Waste Directive** (94/62) are Bypassed by CEN Standards
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Joint Publications

2000 / A 2000 / B 2000 / C 2000 / D 2000 / E 2000 / F 2000 / G	❑ Getting More for Less – An alternative assessment of the proposed **National Emission Ceilings** Directive – January 2000 ❑ **Greening the Treaty III** : Institutional Reform, Citizen's Rights and Sustainable Development – February 2000 ♦ **Verdir le Traité III** : Réforme institutionnelle, droit des citoyens et développement durable – février 2000 ➢ Die **« Ökologisierung der EU-Verträge III »** : Institutionelle Reform, Bürgerrechte und Nachhaltige Entwickelung – Februar 2000 ✓ **Rinverdire il Trattato III** : Riforme istituzionali, diritti dei cittadine e sviluppo sostenibile – febbraio 2000 ❑ **Chemicals under the spotlight** – From awareness to action – April 2000 ♦ **Les Produits chimiques sur la sellette** – De la sensibilisation à l'action – avril 2000 ❑ **Strategic Environmental Assessment** – Comments by CPRE, EEB, Birdlife International, WWF, T&E to the Common position on an *Amended proposal for a Council Directive on the assessment of the effects of certain plans and programmes on the environment* – May 2000 ❑ **What is the Aarhus Convention** ? – June 2000 ❑ **The Dubrovnik Declaration** – July 2000 ❑ **Shaping the New Europe** – Working towards **sustainable development** – A leading role for the European Commission – Discussion paper – September 2000
Joint News-letters	❑ **Chemicals Awareness**, ass. ed. Danish Soc. for the Conservation of Nature, Danish Ecological Council, Danish Consumer Council, EEB, European Consumers Organisation ❑ **Participate**, ed. EEB, co-ed.: Public Participation Campaign Committee ❑ **Sustainable Mediterranean**, ed. and co-ordination MIO-ECSDE, Athens; co-ed.: RAED and EEB

2.2.2 The New Approach: can it ensure a high level of protection for the environment and human health?

Helge Andreasen, Deputy Director General, Danish Environmental Protection Agency

New Approach workshop in Copenhagen on 29-30 November

The New Approach: can it ensure a high level for the environment and human health?
Helge Andreasen, Deputy Director General, Danish Environmental Protection Agency

Opening	I'm very pleased to have this opportunity to talk about the New Approach as a tool both for harmonisation of product requirements and for ensuring a high level of protection in relation to safety, health and environment. When the Council Resolution on the New Approach was adopted in 1985 it only referred to safety, but at the same time it was stated that the New Approach could also be applied to protection of public health, environment etc. However, in the Resolution itself, reference is only made to safety on practical and editorial grounds.
New Approach in relation to different spheres of application	In my presentation, I will try to analyse the possibilities of applying the New Approach to different areas: Safety, health and environment. Within each area, I will focus on three key issues. 1. The possibility of establishing precise, essential requirements. 2. Development of standards based on essential requirements. 3. Demonstration of compliance with the essential requirements. The possibility of establishing precise essential requirements takes up the central position in the assessment of the application of New Approach. The essential requirements must meet three requirements in particular. 1. They must provide a high level of protection. 2. They must be suffi-

	ciently exact to create legally binding obligations. 3. They must be so precise that they represent a real harmonisation.
Safety	
	The well-developed purpose of the concept of the "New Approach" has been to harmonise safety requirements, in other words to ensure the personal safety of the consumer when using a product.
Establishment of essential requirements	Generally speaking, safety is a qualitative parameter and a close link exists between product, risk and responsibility.
Conversion of requirements into standards	Thus, it is a fairly simple matter to establish precise substantial requirements for safety, e.g. to prevent children from being choked by toys. The exact level of safety may be hard to determine precisely, but it is of minor concern, since industry has a direct interest in ensuring a high level of safety.
Compliance with and documentation of requirements	The development of the standards based on the essential requirements is working well. Industry has a direct interest in not being discredited by the individual product's safety. Furthermore, industry has a substantial technical capability and knowledge of safety issues.

It is in the interest of the individual companies to comply with and document the requirements. If something goes wrong they will see their own product as a smoking gun at the scene of crime.

My conclusion as regards safety is that the New Approach is working well as it is possible to establish precise essential requirements for safety, and industry has a substantial interest in complying with the requirements.

Health effects

Protection of health must also be recognised as a qualitative parameter – and the requirement will be that the product should not contribute to any negative health effects. But health is much less unambiguous than safety. Health impacts may be acutely caused by a product, e.g. toxic or caustic exposure. However, avoiding long-term effects when using a product, including carcinogenic, mutagenic and reproduction toxic effects may also be included in the evaluation of health effects.

Generally, it is technically complicated to establish precise requirements for health effects. How can both short-term and long-term health effects be taken into account? Comparatively speaking, it is easy to agree on the fact that a high level of protection must be obtained. But it is difficult to establish essential requirements which ensure a

high level of protection precisely, unambiguously and exhaustively.

Establishment of essential requirements	The existing essential requirements as described in e.g. the Toys Directive are far from being exhaustive. The essential requirements of the Toys Directive include eight elements. These requirements establish the maximum daily exposure of children to dangerous substances in toys . These limit values have been calculated as a percentage of the children's allowed total exposure to the elements. Thus, a political choice has been made as to which extent the exposure to the element may originate from toys No specific essential requirements have been specified in the Toys Directive regarding all other elements and chemical substances, even though many of these substances could be very relevant, e.g. nickel and solvents. Indeed, it would also be relevant to state the quantity of the total exposure from e.g. nickel that was allowed to originate from toys. This is considered a major shortcoming in the Toys Directive. In case limit values for all relevant chemical substances were to be established to rectify this situation, the annex would be so extensive that it would be impractical to establish and maintain.

But could we not just draft criteria for the principles to establish limit values for the individual substances? In my experience, an issue as simple as rules on classification of chemicals in the 8th revision of Directive (67/548) has shown us that this will not be precise enough to secure harmonisation. The criteria document on classification is rather exhaustive.

We also know that the precautionary principle may have to be applied to some types of substances (e.g. phthalates), and in accordance with the Treaty of Nice this must be made at a political level and not in the standardisation committees.

My conclusion is therefore that, in practice, it is not possible to establish exhaustive essential requirements for safeguarding the consumers especially against chronic damage caused by chemical substances.

Conversion of requirements into standards

As regards the development of standards based on the requirements within the health area, it will only be possible if the essential requirements are exhaustive and described precisely. Experience gained from the drafting of a standard for organic chemicals in toys has demonstrated that industry has not shown adequate professional expertise/interest in the health area.

Compliance and documentation	The toy industry has not had the necessary knowledge of the fact that certain chemical substances may migrate from their products, or knowledge of what substances they use in their products. This applies to flame retardants, for instance. Despite this fact, the standard has not been changed for many years. Compliance with and documentation of requirements are limited by the fact that the incitement of industry is non-existent. It is impossible to demonstrate a connection between a product and a chronic damage occurring 5 – 20 years later.
Environmental impact	The environmental impact caused by a product is a multidimensional parameter. What should be prioritised? The environmental impacts on water, air or soil? Should the local, regional or global impact be prioritised? Should focus be on production resources consumption or environmental impact from waste handling? This means that the linkage between the concrete product and the environmental risk is far less unambiguous.
Political prioritisation	The assessment of the environmental risk is therefore also a question of political prioritisation.
Drafting of essential requirements	As regards the essential requirements in the safety and health area, the requirement will be that a product is safe and does not involve a

health risk. But of course, it is absurd to demand that the environmental impact of a product is zero. Thus, the essential requirements laid down in a directive regulating the environmental impact must include quantitative requirements. For certain products, this may be laid down as a maximum requirement.

However, such an approach is as a general approach not recommendable. The wording of the requirement of the Packaging Directive is "as low as possible". Is this as low as technically possible, and for whom and when? Experience shows that products cause less environmental impact due to the technological development.

The conclusion is that a requirement worded "as low as possible" will be a relative requirement determined by the one who assesses, and will be based on a known technology. This cannot be an applicable tool to harmonise product requirements.

Another characteristic feature of environmental requirements is that there will always be different ways of producing a product meant to solve the same problem. Thus, during the construction phase it will be possible to reduce one type of environmental impact at the expense of another.

In any circumstances, the drafting of the essential requirements therefore include how certain types of environmental impacts are to be measured and weighed against each other.

This emphasis is solely a political decision.

In case it is not possible to establish precise, emphasized prioritisation and requirements, the whole concept of the New Approach will fall on the floor. If the New Approach is to be applied to the environmental field huge efforts are required to value and describe the essential requirements precisely. In this connection, it is important to remember that the emphasized prioritisation may change in step with the technological development.

Packaging Directive

The Packaging Directive, which specifically establishes requirements for environmental protection, is the only New Approach Directive to be adopted so far. The essential requirements of the Directive have not contributed to reducing the environmental impact from packaging. The basic problem is that the essential requirements laid down in the Directive are formulated in a vague and imprecise manner. Those who have followed this lecture will know why!!!

But it is interesting that the Council and the Commission realised that the essential requirements were imprecise when the Directive was adopted in 1994. In the statement of the reasons for the Common Position on 4 March 1994, the Council declares: "The Council found that most of the essential requirements to be laid down for the manufacture and composition of packaging could be only very general at this stage, when there were very few standards and criteria and very little practical experience available for most kinds of packaging."

This is directly in contradiction with the requirements to the essential requirements in a

New Approach directive. One of the main principles is that the essential requirements have to be worded precisely.

This statement was given 9 years after it was stated in the Council Resolution that the New Approach was also applicable to environmental aspects.

Electronics Directive

In 2000, the Commission submitted a proposal for an EEE Directive on electric and electronic products. The Commission proposal tried to solve the problem with on the one hand many different product types having to comply with the same environmental requirements, and on the other hand environmental requirements to the products having to be precise and unambiguous. The Commission proposes that the products have to go through the same procedure in order comply with the Directive. For instance it is proposed to apply the EMAS scheme in connection with product development. The Directive is proposed as a harmonisation Directive. The draft Directive will indeed harmonise the procedure, but as described above it will not harmonise the requirements to the environmental impact from EE products.

In my opinion, the current proposal does not have a future – but some of the ideas inherent in the proposal may be useful as a basis for further work in this area.

During the work on developing an IPP strategy, tools like ecolabelling, EMAS and green procurement have been brought forward.

An additional tool which could ensure that the

producer assesses and documents his product's environmental performance seems interesting for two reasons.

Firstly, it would ensure that the producer carries out the assessment – and thus implements improvements to the best of his ability.

Secondly, it would provide private and public procurement with a real option of assessing the environmental performance of the product before purchase.

Conclusion

During the 80's, the whole concept of the New Approach was developed in relation to safety requirements. The 1985 Council Decision mentions in a footnote that the principle can be applied in the environmental field. However, it has never been analysed whether the New Approach is suited to include environmental requirements.

The application of the New Approach Directives in the environmental and health fields is not a realistic possibility. Drafting exhaustive descriptions of the essential requirements will be so comprehensive that it will prove much less demanding to regulate the environmental requirements through traditional regulation.

The tests that have now been carried out, applying the New Approach within the environmental and health fields, have far from lived up to being a real New Approach Directive.

Therefore, the New Approach has proved to be difficult in these areas and has not ensured harmonisation. It would be quite interesting to make a cost-benefit analysis of the costs of achieving the minimum environmental improvement by applying e.g. the packaging standards.

New Approach Directives are not well suited to ensure a high level of environmental and health protection. The New Approach cannot act as a substitute for environmental directives. These directives ensure the level of protection within the environmental and health areas in the EU.

It may be sensible to introduce environmental management system requirements for products marketed in the EU. This may increase the environmental conscience of the individual companies. However, this requirement must be a general requirement. Not a requirement which via the New Approach is used to allow all products to be marketed in the EU, no matter their environmental impact.

There is a demand on instruments to ensure further development on IPP. Standardisation is an interesting and perhaps unavoidable instrument. Denmark will be open to discuss ideas based on some instruments in the draft EEE Directive as I explained before.

We sea large problems in using the New Approach covering environmental impacts from products. But we also see large possibilities in using some of the principles from the New Approach. I have outlined these ideas above.

I foresee a fruitful discussion on how we can move on in developing an IPP, using the best from the New Approach.

Thank you for your attention.

2.2.3 Panel on experience with the New Approach

2.2.3.1 Experience with the New Approach: the Toys Directive.
Aage Stevns Hillersborg, LEGO

The New Approach – Experiences within the Toy Safety Directive

Aage S. Hillersborg, Director, LEGO Company & Chairman, CEN TC 52 Toy Safety

The New Approach has been a proven success within the directive on toy safety. The directive was approved in 1998 and is supported by a number of harmonised CEN and CENELEC standards. Every year, thousands of new toys are brought on the European market, almost all of them based on the harmonised standards and only very few are approved via EC type examination.

The standardisation process and products have been dynamic. Revision of the standards and implementation of amendments have been executed as new products and knowledge has been introduced.

Benefits

A number of benefits have been identified
The legislation has been simplified, as the directive in itself concentrates on the essential requirements. This gives increased flexibility in developing solutions and setting up the technical details to meet the requirements. Accordingly, the New Approach opens up for innovation and continuous improvements.
Expertise and practical experience have been available as all stakeholders have been given access to the work
Involvement of the best expertise in Europe is possible and achievable.
The decision process is based on consensus and all stakeholder experts have equal right to express their opinion.
Active involvement in the standards development process ensures practical use of the finished standards. Within the toy area, thousands of different products are every year designed and manufactured according to the harmonised standards. The ration of non-complying products identified by market surveillance authorities is in the level of parts per million (ppm).
The standards developed are ***per se*** relevant and needed from the market as they are based on justifications from the stakeholders.

Obstacles

Standardisation as such is not always easy and standardisation in relation to mandates under New Approach directives has special obstacles.

- The mandates may not reflect entirely the real work as the final scope may be expanded due to inputs from the participants in the standardisation groups.

- The financial support from the Commission does not reflect the total work and is often insufficient.
- The financial support of the Commission is given at European level, but the standardization work at national level is widely covered by the stakeholders, especially the industry. For product specific standards, it is normally possible to find interested companies, but for general issues – like environmental aspects – it proves difficult to ensure wide participation.
- Single events – incidents – tend to call for initiation of standardisation, although a robust background is missing. This may lead to inefficiency and it may also be difficult to keep the standards away from a too specific product orientation.
- The open and transparent process of standardisation with encouragement of involving all experts should guarantee the quality of the products and accordingly make the publication in the Official Journal a formality. However, this is mechanism has not functioned perfectly in all cases.
- The input from some national members within the standardisation process differs from time to another from the opinion expressed by the same Member States officials.
- Integration of product related environmental aspects are traditionally addressed to a minor extent only as the focus is on the immediate safety for the user. This is in line with the normal drafting of mandates, but expectations from participants may go further than the mandate.

Future challenges

The standardisation process under the New Approach is a continuously developing process and new fields have to be investigated.

- It should be possible to move from the traditionally product based focus to a more generic approach e.g. specifying management procedures and tools to be used in assessing and ensuring compliance with essential requirements.
- The width of the expectations for standardisation under New Approach mandates must be clear. If environmental aspects are to be addressed it must be defined within the mandates – toy safety has traditionally originated from the immediate safety of the individual user, and neither addressed long term effects of the compounds nor the environmental effects of the manufacturing process.
- Enforcing standards with process orientated aspects – environmental, social etc. – becomes difficult and may be difficult to perform equally for European manufactures and importers from e.g. the Far East
- A truly international – beyond Europe – perspective must be applied. This will require improved relations between the European standards bodies (CEN, CENELEC) and the international organisations (ISO, IEC). More importantly, it will require an acceptance of that the levelling of requirement may lower the level in some regions whilst elevating in other regions – with a global improvement.
- Addressing environmental aspects along with safety and health aspects has immanent conflicts. If the standardisation bodies are to work within this context, clear political directions must be given on beforehand if standardisation is to remain a technical process.

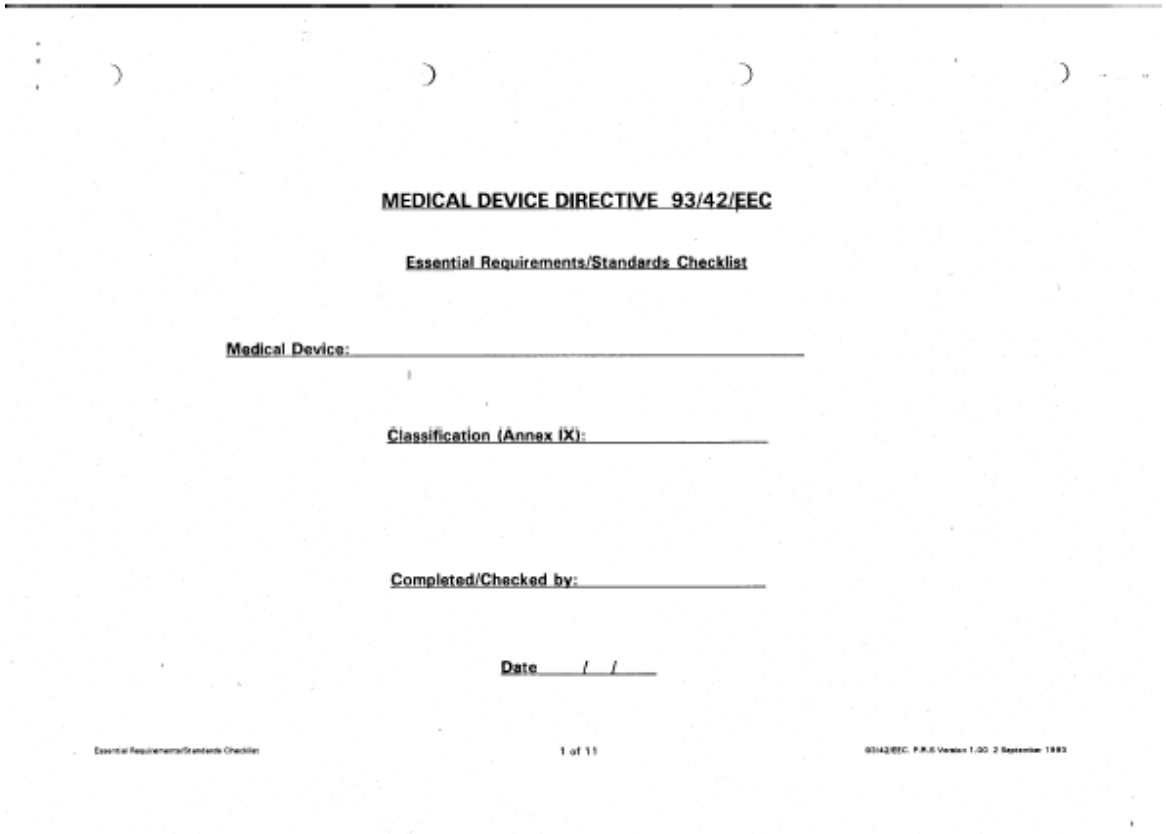
Conclusion

Toy safety was the first area to be regulated via the New Approach. It has over more than a decade proved to be an efficient and dynamic legislative

means. The changing focus with increasing demand for the integration of new elements – like environmental aspects – sets challenges for the future development to be met by legislators as well as standardisers. The concept – the New Approach – is deemed still to be appropriate for this.

Aage S. Hillersborg
LEGO Company

2.2.3.2 Experience with the Medical Devices Directive.
Peter Thompson, CEN



MEDICAL DEVICE DIRECTIVE 93/42/EEC

Essential Requirements/Standards Checklist

Medical Device: _____

Classification (Annex IX): _____

Completed/Checked by: _____

Date ___/___/___

Essential Requirements/Standards Checklist 1 of 11 93/42/EEC: P.R.S Version 1.00 2 September 1993

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
I.	GENERAL REQUIREMENTS						
1.	The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.						
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction) - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, - inform users of the residual risks due to any shortcomings of the protection methods adopted.						
3.	The devices must achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(2) (a) as specified by the manufacturer.						
4.	The characteristics and performances referred to in sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.						
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.						
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended.						

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
II.	REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION						
7.	Chemical, physical and biological properties						
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the "General requirements". Particular attention must be paid to: - the choice of materials used, particularly as regards toxicity and, where appropriate flammability; - the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device;						
7.2	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure.						
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use.						
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC.						
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.						
7.6	The devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.						
8.	Infection and microbial contamination						
8.1.	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as is possible the risk of infection to the patient, user and third parties. the design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.						

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified Bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferrable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.						
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.						
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method.						
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.						
8.6	Packaging systems for non-sterile devices must keep the product without deterioration in the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.						
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.						
9.	Construction and environmental properties						
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performance of the devices. Any restrictions on use must be indicated on the label or in the instruction for use.						

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as possible: - the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features, - risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, - the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, - risks arising where maintenance or calibration are not possible (as with implants) from ageing of the materials used or loss of accuracy of any measuring or control mechanism.						
9.3	Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substance which could cause combustion.						
10.	Devices with a measuring function.						
10.1.	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.						
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.						
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC, as last amended by Directive 89/617/EEC.						
11.	Protection against radiation						
11.1	General						
11.1.1	Devices shall be designed and manufacturer such that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.						
11.2	Intended radiation						
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.						

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.						
11.3	Unintended radiation						
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation must be reduced as far as possible.						
11.4	Instructions						
11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.						
11.5	Ionising radiation						
11.5.1	Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking account of the intended uses.						
11.5.2	Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way, as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.						
11.5.3	Devices emitting ionising radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of the radiation.						
12.	Requirements for medical devices connected to or equipped with an energy source						
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.						
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.						
12.3	Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.						
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.						

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.						
12.6	Protection against electrical risks Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly.						
12.7	Protection against mechanical and thermal risks						
12.7.1	The devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.						
12.7.2	The devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generation by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.						
12.7.3	The devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.						
12.7.4	The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimise all possible risks.						
12.7.5	Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.						
12.8	Protection against the risks posed to the patient by energy supplies or substances						
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and the user.						
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.						

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
12.9	The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.						
13.	Information supplied by the manufacturer.						
13.1	Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential user. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions.						
13.2	Where appropriate this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.						

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
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Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
13.3	The label must bear the following particulars: a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or the instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14.2 or of the authorised representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate; b) the details strictly necessary for the user to identify the device and the contents of the packaging; c) where appropriate the word "STERILE"; d) where appropriate, the batch code, preceded by the word "LOT" or the serial number. e) where appropriate an indication of the date by which the device should be used, in safety, expressed as the year and month; f) where appropriate, an indication that the device is for single use; g) if the device is custom-made, the words "custom made device"; h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations"; i) any special storage and/or handling conditions; j) any special operating instructions; k) any warnings and/or precautions to take; l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number; m) where applicable, method of sterilisation.						
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instruction leaflet.						
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.						

Essential Requirement	NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
13.6 Where appropriate, the instructions for use must contain the following particulars: a) the details referred to in 13.3 with the exception of d) and e); b) the performances referred to in section 3 and any undesirable side effects; c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; e) where appropriate, information to avoid certain risks in connection with implantation of the device; f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation; h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the device to be re-sterilised, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilised before use, the instructions for cleaning and sterilisation must be such that, if correctly followed, the device will still comply with the requirements in section 1; i) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.); j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instruction for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: k) precautions to be taken in the event of changes in the performance of the device; l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc. m) adequate information regarding the medicinal products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; n) precautions to be taken against any special unusual risks related to the disposal of the device. o) medicinal substances incorporated into the device as an integral part in accordance with section 7.4; p) degree of accuracy claimed for devices with a measuring function;						

Essential Requirement		NA	Standard	Requirement Clause/s	Test Clause/s	Comments	Change
14	Where conformity with the essential requirements must be based on clinical data, as in section 1 (6), such data must be established in accordance with Annex X.						

2.2.3.3 Experience with the New Approach from a consumer's point of view. Franz Fiala, Vice President, ANEC

Council Resolution of 28/10/99 on Standardisation in Europe

March 2001

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ANEC 2001/GA/007

Executive Summary

Following the *Council Resolution on Standardisation in Europe* of 1999 the European Commission is to report in June 2001 to the Council and the European Parliament on its political answers to fundamental issues and challenges standardisation is facing in Europe. The ANEC Position Paper addresses major concerns and requests consumers have with respect to the principles of standardisation, greater involvement of public authorities, efficiency, financing and international standardisation.

Provided that the standardisation process is transparent and open to participation of all concerned parties, European standards (EN) complementing in many areas European legislation are useful means of consumer protection and consumer safety. The recent crisis in the food sector has once again demonstrated the crucial importance of transparency to ensure that consumers have faith in the power of the internal market to benefit them as much as it does business.

To ensure democratic structures, ANEC calls for a reform of the European standardisation system that in its current shape primarily serves industry needs. Representatives of the public interest such as consumers or other non-industrial stakeholders are not able to participate in the process in an adequate manner to guarantee a high level of protection.

Such a revision of the European standardisation system is even more vital in the light of the wider discussion on alternative regulatory models (so called co-regulation). To protect the public interest, the European Commission proposes alternative regulatory models bridging between legislation and its binding nature and the more flexible self-regulatory approach. The success of alternative regulatory models like traditional and new standardisation, however, depends on effective monitoring, open access for consumers and effective dispute settlement procedures.

Therefore, ANEC urges the European Commission, the European Parliament and Member States to take actions on the basis of the following recommendations to ensure a high level of consumer protection and transparent and democratic procedures in future European and international standardisation.

ANEC RECOMMENDATIONS ON STANDARDISATION IN EUROPE

I. Principles of Standardisation

1. The European standards bodies shall develop a policy to ensure transparency, access of all stakeholders and balanced representation in the standardisation process.

2. A dispute settlement procedure open to European stakeholder organisations active in standardisation shall be implemented.

3. Industry agreements and *specifications* (e.g. *new deliverables*) other than European standards shall not be used to complement European legislation in the field of health, safety, environment and basic legal and economic interests of consumers.

II. Greater Involvement of Public Authorities in European Standardisation

4. To ensure that European standards are consensus-based and reflect the needs of all stakeholders including consumers, the establishment of a European standards monitoring system outside the standards bodies could be considered.

5. To ensure uniform application of European standards across Europe, ANEC calls for improved market surveillance and a single European certification mark.

6. Due to a negative experience in the field of environmental standardisation, ANEC cautions the application of the *New Approach* for environmental requirements of products, services and processes unless there exist adequate precautionary measures.

III. Efficiency

7. Whenever the European Commission launches mandates for standards of public interest, consultation of stakeholders has to be guaranteed.

8. The European standards bodies shall improve the transparency of decision-making by publishing the affiliation of the participants in their Technical Committees.
A transparent procedure for the recruitment and evaluation of consultants of the European standards bodies shall be established to ensure neutral and independent conformity checks of standards.

IV. Financing

9. To enable consumer involvement in European standardisation at all relevant stages, adequate resources are needed. The European Commission and the Council should reiterate and strengthen their recommendations addressed to EU Member States to provide sufficient financial support for consumer representation in standardisation.
At the European level, the European Commission should provide increased and stable funding for consumer participation in European standardisation.

10. Candidate countries in Central and Eastern Europe should be invited by the EU to ensure adequate funding at the national level for consumer representation in standardisation.

V. International Standardisation

11. ANEC calls upon the European public authorities and national standards bodies to take the necessary actions to introduce the principles of balanced representation, openness and transparency into international standardisation.
To ensure a better representation of consumers in international standardisation additional financial support has to be provided.

12. Safeguards have to be developed in order to ensure that European public policy issues are adequately taken into consideration in international standardisation, e.g. through a European mirror committee.

Introduction

Since 1995, ANEC represents and defends consumer interests in the European standardisation process. ANEC provides technical expertise based on a network of more than 170 experts in EU Member States, EFTA countries and the Czech Republic. These experts representing consumers participate in Technical Committees of the three European standards bodies CEN, CENELEC and ETSI. Areas of priority are child safety, safety of domestic appliances, information society, consumers with special needs, environment, and traffic safety.

Based on its experience in European standardisation work, ANEC calls for a reform of the European standardisation process along with the following recommendations in order to ensure transparent and democratic procedures. The latter are prerequisites to build and maintain consumer confidence in the Internal Market and the European integration process.

I. Principles of Standardisation

I.A. Balanced Representation of Interested and Concerned Parties in the Standardisation Process and Committees

In theory, standardisation at the European level is an open, transparent and consensus-driven process, which allows all stakeholders to participate and to safeguard their interests. Reality, however, is different. Industry representatives dominate many standardisation committees of the three European standards bodies. Thus, real balanced representation of all stakeholders is rather the exception in the standardisation world. As a consequence, standards do often not meet consumer requirements. In some cases, European standards had even been adopted against sustained opposition of consumer representatives.

Openness and transparency are important principles, to which the European standards bodies have committed themselves. These principles must be complemented by the principle of balanced representation of all interested parties in the standardisation process as far as public interests are concerned.

The standards bodies shall develop a policy to ensure balance in co-operation with public interest groups such as consumer organisations. This may include a set of measures, e.g. establishment of balanced project teams to draft standards,

obligatory written evidence of input and support by consumers for a standard and, a formal dispute settlement procedure.

ANEC Recommendation 1

The European standards bodies shall develop a policy to ensure transparency, access of all stakeholders and balanced representation in the standardisation process.

I.B. Dispute Settlement Procedure

In the current European standardisation system, consumers do not have adequate access to initiate and carry through new standardisation work, which we deem necessary and vital for consumer protection, but which might not be a priority for industry.

Therefore, ANEC calls for a mechanism at the European level in terms of a mediation procedure providing consumers and European stakeholder organisations active in standardisation with an instrument to articulate their proposals for standardisation.

At the same time, such a procedure should serve as an arbitration board both for conflicts arising from procedural issues and conflicts occurring as a result of a standardisation work. The composition of the body should be pluralistic and balanced in numbers and not only in terms of interested parties. In general, the standards bodies shall develop the terms of reference of such a dispute settlement in co-operation with the European stakeholder organisations.

ANEC Recommendation 2

A dispute settlement procedure open to European stakeholder organisations active in standardisation shall be implemented.

I.C. The Use of *New Deliverables* and *Specifications* in EU Policies

ANEC is concerned about the use of European Community documents other than standards to support European policies and legislation. This relates to both the so-called *new deliverables* of the three standards bodies and to *specifications* developed by industry or industry consortia. We believe that the use of such other documents in Community policy should be the exception and not the rule. In the very exceptional case that it is deemed necessary to refer to documents other than standards, specification-producing bodies should meet strict requirements to guarantee the transparency of the process and the involvement of consumers. Moreover, the lifetime of such documents should be restricted to a time period not exceeding three to five years, followed by an evaluation including the option of a formal European standard, with the latter involving the full consultation process.

As a matter of principle, documents or *specifications*, which do not comply with the criteria of a European standard, shall not be used in sectors covered by the New Approach and other legislation such as the General Product Safety Directive dealing with aspects of health, safety, environment and basic legal and economic interest of consumers. The recognition of *specifications* produced by pure industry fora would undermine the credibility of consumer protection policy in Europe.

ANEC Recommendation 3

Industry agreements and *specifications* (e.g. *new deliverables*) other than European standards shall not be used to complement European legislation in the field of health, safety, environment and basic legal and economic interests of consumers.

II. Greater Involvement of Public Authorities in European Standardisation

II.A. European Standardisation Monitoring System

In the European standardisation system as it is today, public authorities have to wait until a standard is completed before being able to trigger the safeguard clause if a standard is deemed insufficient and does not comply with the technical requirements set out in the respective directive. Interventions, however, should be made possible at an earlier stage, e.g. during the enquiry stage of the standards-making process.

For this purpose, the European Commission and Member States might consider the establishment of a European standardisation monitoring system outside the standards bodies providing evaluation of a mandated standard. Such a monitoring system could be based on a two-step approach. Whilst the first check would be carried out as soon as the draft standards are available, a second check would be involved once the standards have been finalised, but before their references are published in the Official Journal of the EU. Both steps would ensure that the (draft) standards are consensus-based, i.e. consumers or other groups representing the public interest do not fundamentally disagree with the standards. The standards bodies would be obliged to respect any decisions of the European Commission and the EU Member States resulting from the monitoring system.

In the same context, ANEC calls for free access of consumers to the various fora, which are already involved in monitoring the European standardisation process. Most notably, this applies to the European Commission's Committee on Standards and Technical Regulations, Committee 98/34, but also to the standing committees pertaining to the various directives, e.g. for toys and construction products.

Moreover, in some cases the European standards bodies failed to elaborate adequate standards in compliance with the essential requirements of directives. As a result Member States had to intervene by making use of the safeguard clause. Nonetheless, Technical Committees of the standards bodies were reluctant to revise the standards in an appropriate manner even though the European Commission supported Member States. Therefore, instruments are needed allowing for an alternative to standards as a last resort.

ANEC Recommendation 4

To ensure that European standards are consensus-based and reflect the needs of all stakeholders including consumers, the establishment of a European standards monitoring system outside the standards bodies could be considered.

II.B. Application of standards

The most stringent standards in the world serve no purpose unless they are applied in practice. Many elements help ensure that standards are respected. Market surveillance, market forces stimulated by the publication of consumer information, certification and labelling schemes all play their part. Developments at the European level are increasingly important to ensure that there is a uniform application of the European standards throughout the EU.

ANEC calls for improved market surveillance in the internal market and strongly supports a single European quality mark, which has to fulfil specific requirements such as third party testing and precise information in order to provide transparency on safety, performance and environmental aspects of the product.

ANEC Recommendation 5

To ensure a uniform application of the European standards across Europe, ANEC calls for improved market surveillance and a single European certification mark.

II.C. Caution with respect to wider application of the *New Approach*

ANEC sounds a note of caution with respect to wider application of the *New Approach*, as there are certain sectors where it would not be appropriate to apply the *New Approach*. Due to a negative experience with environment related standardisation[1], ANEC cautions the extension of the *New Approach* to environmental requirements for products, services and processes unless there are precautionary measures established. Unfortunately, the CEN Environmental Helpdesk (EHD), a forum intended to promote the integration of environmental aspects in product standards, does not seem to be an adequate instrument to significantly improve the situation.

As there is a fundamental difference between the areas of safety of products and of environmental requirements[2], it is deemed necessary to undertake preparatory measures such as feasibility studies and pilot projects before launching any *New Approach* directive in the environmental area. A permanent external monitoring, involving the European Commission, Member States and stakeholders should be implemented. Moreover, the European Commission and Member States should discuss what changes have to be introduced in order to enable the existing standardisation system to deal with environmental requirements in an appropriate manner.

ANEC Recommendation 6

Due to a negative experience in the field of environmental standardisation, ANEC cautions the application of the *New Approach* for environmental requirements of products, services and processes unless there exist adequate precautionary measures.

1 For example: CEN standards in the field of packaging and environment including prevention, re-use, recycling and energy recovery of packaging and packaging waste.

2 Whilst product liability legislation might be very cost intensive for the manufacturer in case of injuries or fatalities and thus seems to be an incentive to take safety issues into account, comparable incentives do not exist in the environmental sector.

III. Efficiency

III.A. Consumer Involvement in Drafting Mandates for Standardisation issued by the European Commission

A mandate is a political request by the EU and EFTA to develop voluntary standards based on consensus amongst all parties involved. In many cases, a mandate is given to support European legislation and to develop the technical specifications of the essential safety requirements. Mandates are mainly issued in the area of *New Approach* legislation, but may also be given for the elaboration of standards in other areas e.g. biotechnology.

ANEC is convinced that the drafting of standardisation mandates of public interest should be done in consultation with all stakeholders, especially consumer representatives and experts from consumer organisations across Europe.

ANEC Recommendation 7

Whenever the European Commission launches mandates for standards of public interest, consultation of stakeholders has to be guaranteed.

III.B. Transparency

As highlighted by the European Parliament and by the European Commission in a recently published report on the legal aspects of standardisation, ANEC is convinced that greater efforts could be made to provide more information on the opinions the various stakeholders elaborate during the standardisation process.

To improve transparency, ANEC suggests a listing of the participants of a Technical Committee and their affiliation. For this purpose, an attendance form could be used, in which participants indicate their affiliation and the interest group they belong to (i.e. industry, standards bodies, scientific community, test laboratories, consumer or environmental organisations). The lists of participants should be available for consultation by all stakeholders.

Moreover, ANEC would like to stress the importance of external consultants whom European standards bodies employ in order to verify the conformity of elaborated standards with the relevant directives. In general, these consultants have positively contributed to the work. Nonetheless, ANEC wishes to stress the importance of involving neutral and independent experts who critically review standards. It would be beneficial to establish a transparent and harmonised procedure for recruitment and evaluation of external consultants.

ANEC Recommendation 8

The European standards bodies shall improve the transparency of decision-making by publishing the affiliation of the participants in Technical Committees.
A transparent procedure for the recruitment and evaluation of consultants of the European standards bodies shall be established to ensure neutral and independent conformity checks of standards.

III.C. Training

Existing rights and rules must be known and respected. Inaccurate application of rules and procedures undermine standardisation work. Training and project management might contribute to render the standardisation process more efficient. Training for the secretariat of Technical Committees and Working Groups of the European standards bodies might be useful to improve the support provided to the group.

IV. Financing

IV.A. No Membership Fees for Consumer Organisations

In many countries, consumer organisations are confronted with the request to pay fees in order to be able to participate in the standardisation process. ANEC totally rejects demands that consumer organisations pay fees for participating in standards bodies as this represents a barrier to effective and comprehensive involvement of consumers in standardisation.

IV.B. Financial Support for Consumer Representation in Standardisation

ANEC welcomes the Council position that consumers and other interest groups should be fully involved in the standardisation process at all relevant stages. A prerequisite for such an involvement is adequate and stable funding – both at national and European level. The current situation, in particular in the southern European countries and Ireland, is far from being satisfactory and has to be improved.

The lack of adequate consumer representation in many EU Member States undermines the credibility of the consensus that should be a fundamental characteristic of the European standardisation process. ANEC calls on the Commission and the Council to reiterate and strengthen their recommendations addressed to the Member States to actively encourage consumer representation in standardisation through the provision of resources and financial support (88/41/EEC and 88/C 293/01).

As consumer organisations already suffer at national level from a lack of financial resources to represent their interests in standardisation, it is obvious that at the European level, ANEC is only able to play the role it is supposed to play as long as the European Commission provides a reliable source for funding.

ANEC Recommendation 9

To enable consumer involvement in European standardisation at all relevant stages, adequate resources are needed. The European Commission and the Council should reiterate and strengthen their recommendations addressed to EU Member States to provide sufficient financial support for consumer representation in standardisation.
At the European level, the European Commission should provide increased and stable funding for consumer participation in European standardisation.

ANEC also calls for continued support initiatives to improve consumer representation in standardisation in the Central and Eastern European countries. In particular, ANEC suggests that the candidates for EU membership are requested to provide adequate funding for consumer representation in standardisation and to ensure that national consensus building arrangements are respected.

ANEC Recommendation 10

Candidate countries in Central and Eastern Europe should be invited by the EU to ensure adequate funding at the national level for consumer representation in standardisation.

V. International Standardisation

V.A. Need for Balance, Transparency and Openness

Many standards used to be made at the European level, but are more and more subject to international standardisation in ISO and IEC. Whilst ANEC recognises the importance of international standardisation, we have to highlight the substantial difference between European and international standardisation as regards the participation of stakeholders, in particular the participation of consumers.

ANEC therefore calls upon the European public authorities and national standards bodies to take the necessary actions to introduce the principles of balanced representation, openness and transparency into international standardisation.

Consumer representation in international standards bodies is limited to participation in a few technical committees. *Consumers' International* is actually not allowed to participate in the political work of international standards bodies, which are thus highly industry dominated. Furthermore, consumer participation at the technical level is considerably hampered by a lack of financial resources. Participation in the standards making process of ISO and IEC involves considerable financial resources due to travels around the world.

In order to establish adequate consumer representation at the international level, and thus legitimacy of the international standardisation process, it is vital that additional funding is provided to the consumer movement.

ANEC Recommendation 11

ANEC calls upon the European public authorities and national standards bodies to take the necessary actions to introduce the principles of balanced representation, openness and transparency into international standardisation. To ensure a better representation of consumers in international standardisation, additional financial support has to be provided.

V.B. Safeguarding Objectives of European Public Policy

As already mentioned, European public authorities have the possibility to directly intervene in the European standardisation process if it is deemed necessary in the interest of the market or consumers. This possibility does not exist in international standardisation, where there are no procedures for national administrations to challenge international standards that insufficiently address consumer protection.

ANEC advocates that the European Commission reinforces its efforts to control and monitor the standardisation work complementing European legislation, which is a difficult task when standardisation is shifted to the international level. Moreover, non-European standards bodies will not always be prepared to take full account of the essential requirements of European Community legislation.

National and European standards bodies, as well as European public authorities should be aware of these drawbacks of international standardisation in comparison to European standardisation. Safeguards have to be developed in order to ensure that public policy issues are adequately taken into consideration in international standards. Whenever standardisation tasks linked to a standardisation mandate are transferred to an international standards committee, a European mirror committee should be set up. This group should elaborate a European view and ensure that European public policy, consumer, health and safety issues are taken into account.

As long as there are no safeguards in international standardisation, it may therefore be advisable to give priority to European standardisation whenever European public policy issues are at stake.

ANEC Recommendation 12

Safeguards have to be developed in order to ensure that European public policy issues are adequately taken into consideration in international standardisation, e.g. through a European mirror committee.

Annex I

Examples of Inadequate European Standards

Machine-readable cards

Smart or machine-readable cards are of major importance to consumers. They are used by all consumers, with or without disabilities, for purposes of identification and for payment in all types of applications. Standardisation did address the issue of tactile identifiers, which help consumers with visual impairments to introduce the card into the reader in the right direction. Unfortunately, two different standards were produced, one by CEN and one by ETSI, specifying the location and shape/size of these notches. In addition, the standard elaborated by CEN (primarily for banking cards) offers four options of which only one is considered suitable. ANEC calls for a practical solution.

Exclusion Clause in Standards in Electro-technical Products

For several years already, ANEC has expressed concerns about the degree to which child safety is addressed in electro-technical products, which are not specifically produced for children, but with which children inevitably come into contact like microwave ovens. Some of these standards for electro-technical products have an exclusion clause. Due to the exclusion clause, the standard does not take into account the use of the appliance by young children. It equally does not take into account the needs of older people or people with disabilities – thus excluding large parts of the society from using the appliances. ANEC feels that it is not acceptable to have such exclusion clauses in the standards.

Packaging

In 2000, CEN finished work on several standards concerning the manufacturing and the composition of packaging as well as their re-use or recycling. Unfortunately, the elaborated draft standards provide no clear-cut and product specific requirements and are thus of little use for enforcement. For instance, the standard dealing with prevention allows for excessive packaging if the manufacturer considers it necessary for marketing reasons. The standard on re-use does not even define a minimum number of trips or rotations and the standard on material recycling only requires compatibility with "known and relevant recycling technologies". ANEC has asked the European Commission not to recognise these draft standards.

High Chairs

At the moment, there is a draft European standard on high chairs for children out for vote, which was prepared by the CEN Technical Committee on Furniture. ANEC believes that the standard is inadequate and in contradiction to its counterpart on convertible highchairs developed by the CEN Technical Committee on Child Care Articles. Whereas the draft standard on convertible highchairs is acceptable to consumers' organisations, the draft standard developed by the Technical Committee on Furniture shows severe deficiencies. It also fails to meet the provisions of the Commission mandate M 264 related to the safety of child-care articles with respect to barriers and the restraint system. The requirements do not sufficiently prevent children from falling off the chair. The work item should be deleted from the work programme of the CEN Technical Committee on Furniture and the scope of the draft standard on convertible highchairs should be expanded to cover all types of highchairs.

Noise limits for toys

Impulsive sounds e.g. produced by toys using percussion caps such as cap pistols are of particular concern to consumers. Exposure to just one impulse can lead to an irreversible damage of the hearing capacity or to tinnitus (buzzing in the ears). Nonetheless, the CEN Committee on Toys set a threshold exceeding the one allowed at the workplace if one takes into account that children sometimes fire these toys very close to their ears. Consequently, Austria and Germany triggered the safeguard clause in accordance with article 6 (1) of the Toys Directive claiming that the standard did not comply with the essential requirements of the directive. Finally, the European Commission did not recognize the relevant part of the toys standard and recommended to fix limits "which are deemed to be safe during normal or foreseeable abusive use of sound-emitting toys".

Child Restraints

If correctly installed, child restraints can reduce child mortality by 75% and the number of seriously injured children by 67%. However, several studies show that 50-70% of child restraints are badly installed. ISOFIX – a universal mounting system - was originally developed to reduce the possibilities for incorrectly installed child restraint seats. In order to offer the best possible protection to children, ISOFIX should consist of two lower anchorages and a top tether. Industry favours, however, a two-stage process. The ISOFIX standard defines at present only the two lower anchorages of the child restraint system. Consumers are opposed to such a two-stage process, which first introduces the two lower anchorages and then at a later stage a top tether. The latest EuroNCAP car crash tests showed that there was a total ejection of a child from a VW ISOFIX seat, which consisted of the two lower anchorages only. The test illustrated that the two point, forward facing, shield type child restraint seats do not offer the best possible protection to children.

Annex II: Definitions

ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation
CEN	European Committee for Standardisation whose main objective is to elaborate voluntary technical standards at the European level and for this purpose co-operates with its national counterparts and with international standards bodies.
CENELEC	European Committee for Electro-technical Standardisation, similar to CEN in purposes, membership, constitution and activity whilst the main difference is that CENELEC deals only with electrical products and services.
Co-Regulation	Alternative regulatory model bridging between legislation and its binding character and the more flexible self-regulation by industry
ETSI	European Telecommunications Standards Institute whose mission is to determine and produce the telecommunications standards. It is an open forum that unites more than 600 members from more than 40 countries, representing administrations, network operators, manufacturers, service providers, and users.
ISO	International Organisation for Standardisation: worldwide federation of national standards bodies from some 130 countries, one from each country. Its mission is to promote the development of global standardisation and related activities in order to facilitate international exchange of goods and services, and to develop co-operation in the spheres of intellectual, scientific, technological and economic activity. ISO work results in international agreements that are published as International Standards.
IEC	International Electro-technical Commission is the world organisation that prepares and publishes international standards for all electrical, electronic and related technologies. The membership consists of more than 50 participating countries.
New Approach	The introduction of the *New Approach to product regulation* is linked to the completion of the European Internal Market. In *New Approach* directives, the European legislator restricts himself to harmonise the essential safety requirements whereas the technical solutions are delegated to the three European standards bodies.
Standard	Standards affect the daily life of every citizen. Standards help to make the use of products safer and to prevent accidents (e.g. due to a technical standard, washing machines cannot be opened during operation). A standard is defined as a written document approved by a recognised body. It is available to the public and drawn up on a consensus basis involving all interested parties. The application of a standard, however, is voluntary.

2.2.3.4 Standardisation in other forums.
Herman Köeter, OECD

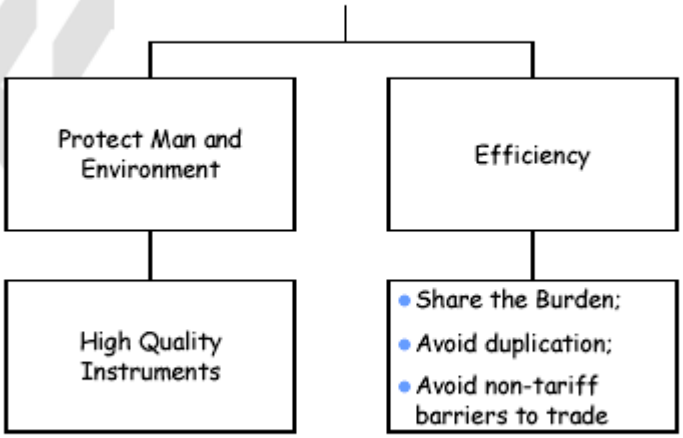
OECD
(Organisation for Economic Co-operation and Development)

International Organisation grouping 30 industrialised countries:

Australia	Hungary	Poland
Austria	Iceland	Portugal
Belgium	Ireland	Slovak Republic
Canada	Italy	South Korea
Czech Republic	Japan	Spain
Denmark	Luxembourg	Sweden
Finland	Mexico	Switzerland
France	The Netherlands	Turkey
Germany	New Zealand	United Kingdom
Greece	Norway	United States

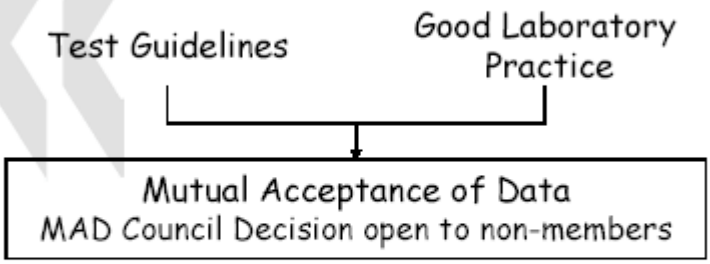
OECD 1 OCDE

Objectives



OECD 2 OCDE

Data Quality Ensured By:



Avoid: → duplication of testing by industry
→ non-tariff trade barriers

MAD and Non-Member Countries

- Accept data from OECD countries (GLP, TG)
- Assistance in developing compliance system
- Participate in OECD work
- OECD countries accept data from non-OECD countries (GLP, TG)

MAD: international standard open to all interested WTO members

OECD Test Guideline Development Process

OECD 6 OCDE

Procedure for the Development of OECD Test Guidelines

- Submission of the Proposal
- Completion of the Standard Project Submission Form (SPSF)
- Priority Setting by National Co-ordinators
- "Conducting the Work: Reaching Scientific Consensus"
- Adoption of New Guideline

OECD 7 OCDE

Procedure for the Development of OECD Test Guidelines

1. Submission of the Proposal by:

- Member country
- BIAC
- TUAC
- International Scientific Society
- Secretariat

Procedure for the Development of OECD Test Guidelines

2. Completion of the Standard Project Submission Form (SPSF):

- http://www.oecd.org/ehs/test
- Essential Criteria
- Desirable Criteria

Procedure for the Development of OECD Test Guidelines

- Desirable Criteria to be met before considering a Proposal:
  - Guideline intended for general/broad use
  - Scientifically valid, reliable, relevant
  - Addresses endpoints not yet covered
  - Existing national/regional protocols as a basis

Procedure for the Development of OECD Test Guidelines (2)

- Desirable Criteria to be met before considering a Proposal:
  - Animal welfare concerns are addressed
  - Contributes to saving resources
  - For guidance documents:essential or helpful
  - For guidance documents: linked to a
  - Specific TG or for general guidance

Procedure for the Development of OECD Test Guidelines

3. Priority Setting by National Co-ordinators

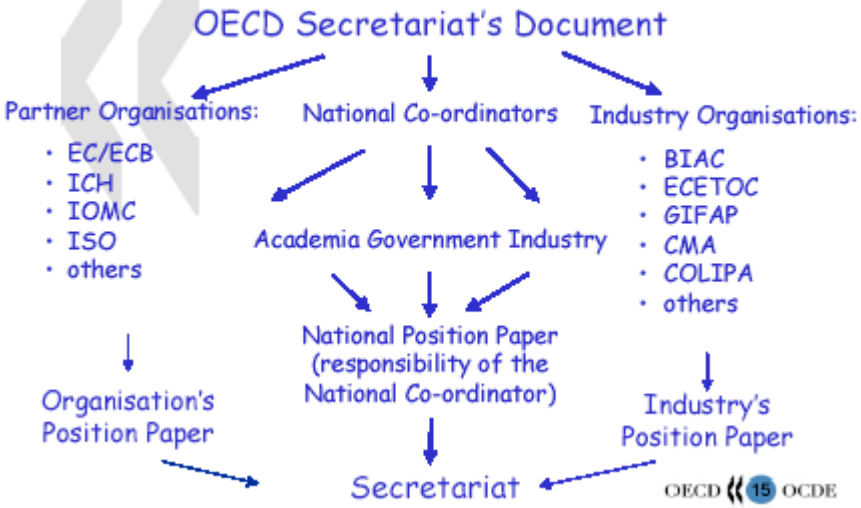
- By written procedure
- High,Medium,Low ranking priorities
- Proposal for the Annual Workplan
- Endorsement by Joint Meeting

Subject Areas For Which Member Countries Have Nominated National Experts

- Physical-Chemical Properties
- Aquatic Ecotoxicity
- TerrestrialEcotoxicity
- Abiotic Degradation
- Biodegradation
- Bioaccumulation
- Health Effects
- Exposure
- Data Analysis
- Animal Welfare

Total number of Experts in the data base: 6,000

Test Guidelines Programme
Expert Review Of Draft Documents



Procedure for the Development of OECD Test Guidelines

7. Adoption of New Guideline

- Reaching scientific consensus
- Approval by National co-ordinators
- Endorsement by Joint Meeting
- EPOC Approval for Submission to Council
- Council Endorsement

OECD 16 OCDE

2.3 What is the role of the New Approach in promoting environmental innovation? (Session III)

2.3.1 The proposed use of the New Approach in Integrated Product Policy.

Otto Linher, European Commission, DG ENV, A.2

European Commission
DG Environment
Sustainable Resources, Consumption and Waste

How does it relate to the main EU Strategies and other environmental policies?

- *Sustainable Development Strategy*
- *Sixth Environment Action Programme*
- *Thematic Strategies on Resources and Recycling*

- *Chemicals Policy*
- *Waste Policy*

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Life Cycle Thinking: The Basic Philosophy of IPP

- *Every actor should consider the life cycle environmental performance of products as an element in taking his/her decisions on products*

- **Prioritisation on:**
  - **Where are the biggest environmental impacts?**
  - **Where can we do most to reduce them?**

- **Depth of analysis/use of LCA will depend on:**
  - **Importance of issue to be considered**
  - **Degree of clarity from the outset**
  - **Resources of concerned actor**

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The three main pillars of IPP

- **Using the price mechanism**
  - **more fundamental changes on the market are only likely if the consumer can see the advantage in his/her pocket**
- **Designing and marketing the products of the future**
  - **once a product is sold, there is relatively little that can be done to change its environmental performance**
- **Creating consumer demand**
  - **all design improvements will be in vain if the consumer does not buy greener products**

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Why a focus on the design of products (1)?

➪ *Public action should concentrate on reducing environmental impacts where it is most efficient*

- **The most important decisions on the life cycle environmental performance of products are taken at the design table and in purchase decisions.**
- **All other phases may also play a role but are in general either rather minor in importance or cannot be controlled easily**

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What can public authorities do to influence product design (1)?

- **Command-and-control legislation:**
  - **Clear on results, including the way they have to be achieved**
    - ★ Can deal with high risk and high cost issues
    - ★ Needs a lot of resources by public authorities (legislation, administration, enforcement)
    - ★ Will we ever be able to regulate the bulk of issues needed to reinforce the environmental design of products (Where shall we start and how long will it take us?)?
    - ★ Should public authorities at all determine technical details of environmental design of products?

➪ *Heavy procedure but needed whenever high risks and high costs are involved*

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What can public authorities do to influence product design (2)?

- **Enabling legislation**
  - **Should be clear on objective but leaves the ways how to achieve the objective to businesses and technical bodies**
    - ★ Not necessarily as clear and predictable as command and control
    - ★ However, allows to address a larger range of environmental impacts which in summary may allow to achieve more for the environment with less government-regulation
    - ★ Appropriate for low risk, low cost but high volume issues

➪ *If well designed, it can be faster and more efficient to cover „mainstream" environmental impacts*

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What can public authorities do to influence product design (3)?

- **Other supporting instruments**
  - **Encourage the availability of life cycle management instruments (LCA databases, eco-design guidelines, environmental management tools, tools to enable information flow)**
    - ★ Is the bottleneck availability of tools or the absence of drivers to apply them?
  - **Education and training**
    - ★ Large need for education/training on eco-design (schools/universities)
    - ★ However, will education on environmental design be ever more than a cherry on the cake if businesses cannot make money with it?
  - ➪ ***Where can authorities achieve most with available resources?***

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The New Approach in the IPP Green Paper

- **The New Approach is put to the discussion as one of possible elements to influence product design**
- **However, the failure of the experience with the Packaging Directive shows the need to adopt innovative approaches to address the specificity of environmental issues**
  - ➪ ***It is relatively easy to determine safety and fitness for use but very difficult to specify the right balance between functionality of a product and its environmental characteristics***

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The IPP Green Paper: Options for the dealing with the New Approach

- **Eco-design guidelines and use of the enforcement system to identify options how to improve products**
- **"New Deliverables"**
- **Eco-labels as giving presumption of conformity**
- **Key performance indicators**
- **Combining various elements**

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Insights developed from the stakeholder debate (1)

- *If a large range of product-related environmental impacts is to be tackled, there is no other way than putting responsibility to designers and managers*
  - Environmental management systems (EMAS, management standards such as ISO 14062 etc.) can play a key role!
- *Putting the responsibility to industry without accompanying the process will not work*
  - There need to be incentives andchecks to make sure that the obligations for environmental management are taken seriously

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Insights developed from the stakeholder debate (2)

- *The key to the making the New Approach work for the environment is not in choosing one or the other option of instruments but setting up an intelligent mechanism how various elements can be combined to create a clear and credible framework*
- *Maybe such a framework should not be limited to the New Approach but be rather a combination of various instruments based on setting clear political objectives and delegating technical issues to businesses and technical bodies and keeping the option of command and control if necessary*

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How could enabling legislation for the environmental design of products look like (1)?

- *For the moment, these are only preliminary ideas and no decisions have been taken!!!*
- **Setting essential requirements for environmental design of products in the form of framework legislation (general or product-specific)**
  - Producers could be obliged to use the state of art of environmental design on their products
  - Obligation to use life cycle thinking/environmental management systems in the design of their products (e.g. inspired by ISO 14062 or the packaging prevention standards)

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Details of possible essential requirements on eco-design (1):

- Producers could be obliged:
  - to use the state of art of environmental design on their products
  - to use life cycle thinking/environmental management systems in the design of their products (e.g. inspired by ISO 14062 or the packaging prevention standards)
  - to provide evidence that environmental aspects have been appropriately taken into account
  - to make key information on the environmental balance of their products available

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Details of possible essential requirements on eco-design (2):

- Obligations to use the state of art on eco-design and life cycle thinking could be general
- However, the degree to which this would require written evidence, partial or full Life Cycle Assessment will have to be differentiated according to (e.g.:)
  - size of company
  - level of environmental impacts associated to product life cycle
  - volume of products sold
  - degree of clarity from the outset on the scientific evaluation

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How could enabling legislation for the environmental design of products look like (2)?

- The essential requirements need to be completed by:
  - appropriate enforcement/market surveillance
  - the further definition of key requirements via various possible mechanisms

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The possible role of enforcement and market surveillance

- To check whether basic obligations (e.g. use of environmental management system) have been fulfilled
- To discuss with designers and managers whether and where further improvements could be made
- To collect and provide information to public authorities on possible areas for improving product environmental performance

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The further definition of key requirements (1)

- Wherever substantial environmental improvements can be made that are not carried by the market alone, more detailed requirements could be set via:
  - informal or formal discussions or agreements with businesses and industry associations
  - standardisation (i.e. the use of the New Approach technique)
  - working groups following the model of the IPPC Directive
  - product panels
  - introducing command and control elements on specific issues into the framework directive
  - targets on the basis of key performance indicators

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The further definition of key requirements (2)

- Prioritisation should be made on importance of issues and on the basis of information by enforcement authorities, technical experts, NGOs etc.
- There should be a „ladder of preference“ towards the more informal instruments with the more stringent tools only used if necessary
- The further development of key requirements would need to take into account the duration of design cycles to provide a clear and predictable framework for industry

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Possible fields of application for enabling legislation

- The most obvious candidates are packaging and electrical and electronic equipment as test cases
- Possible later extension to further product categories and/or to a general product design framework directive

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The Greening of Standardisation

- "Environmental soundness" should become a feature of all European standards
  - To be addressed in a Communication on Standardisation and the Environment
  - Strengthen participation of civil society actors
  - CEN environmental help desk
  - Possible mechanisms to strengthen the co-ordination between political and technical bodies

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Related Policy Instruments

- IPPC could serve as an inspiration: definition of the state of art on product eco-design similarly to BAT for installations
- Eco-labelling: "pull-strategy" whereas "New Approach" is "push-strategy"; eco-label criteria could inspire instruments to define the state of art of eco-design
- EMAS:option to demonstrate conformity with the environmental management obligation (if product-related aspects are considered)

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Enabling legislation and innovation

- Cementing the existing state of art or driver for environmental innovation?
  - Level of ambition and clarity of essential requirements
  - Enforcement and control
  - "Feedback" from implementation will be crucial
  - Continuous further development of detailed requirements
  - "Create tension" to reward early movers in environmental design
  - Good co-ordination between technical and political levels of decision making

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The next steps:

- Discuss possible ideas within the Commission and agree on the main elements to be described in the IPP White Paper (spring 2002) and invite stakeholders and the European institutions to react.
- Discuss possible adaptations of the New Approach elements of the Packaging Directive with Member States and determine a timetable
- Active participation in the preparation of the planned Directive on Electrical and Electronic Equipment (EEE)

2.3.2 Panel on environmental innovation

2.3.2.1 Dynamism in the standardisation process: guiding or delaying innovation?

Eva Schmincke, University of Tubingen

Dynamism in the standardisation Process:

guiding or delaying innovation

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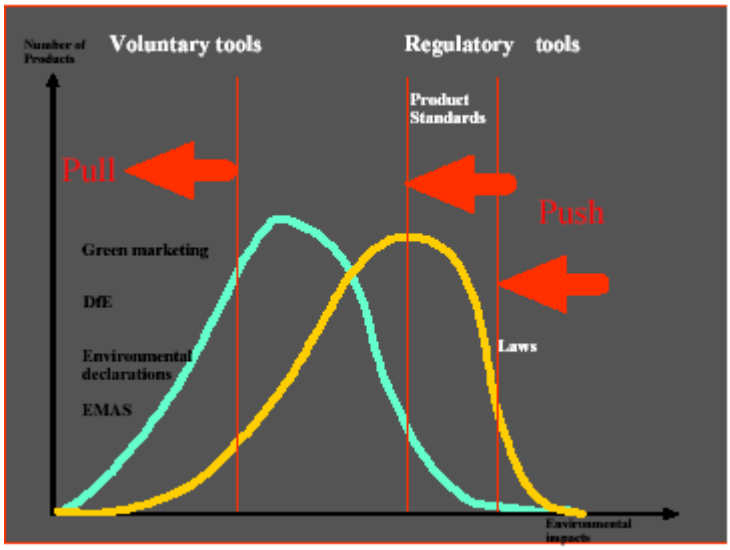
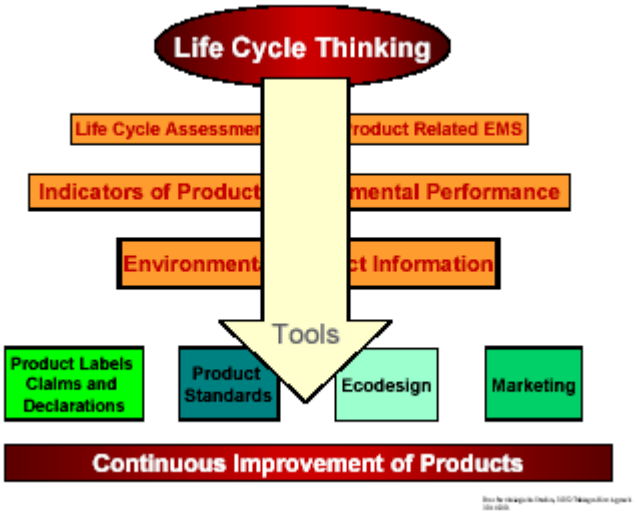




Discussion points

- How can management standards encourage environmental thinking in product design?

ISO DTR 14062

- Is a typical guidance document, encouraging environmental thinking in product development and design
- a generic document, not developed for certification
- Has the potential for sector specific adaptation, e.g. EEE, focussing on :
  - Relevant phases of life cycle, e.g.use phase
  - Main impacts, e.g. energy demand, hazardous substances
  - Relevant design strategies e.g.design for disassembly

ISO DTR 14062

- Environmental management - Integrating environmental aspects into product design and development
- Scope:
  - Describes concepts and current practices..
  - for all those involved in design and development,
  - Stakeholders,
  - All types of goods and services, all sizes of enterprise
- Final draft finished in October 2001, voting spring 2002

Contents of ISO DTR 14064

- Goals and potential benefits
- Strategic considerations
- Management considerations
- Product considerations
- Product design and development process

What you can get from the report

- Description of broad consensus: industrialised and developing countries
- Comprehensive concept: Strategy, Organisation, Product
- Definition of terms and setting concepts into context
- Practical help boxes, e.g.for treating trade-offs
- Road map through the development process and where to integrate environmental aspects
- Bibliography and web sites

Product Considerations:

- Goods and services, picks service examples
- Continuous product development, Product redesign, System Innovation
- Life Cycle Thinking /Multi-Criteria
- Early Integration
- Functionality/Economy/Environment: Trade-Offs
- Strategic product related environmental objectives

Discussion points

- Is there a need to develop operational, product area specific methodologies for LCA and how can this be done?

Information management

- Basic for introducing environmental aspects into product standards and product design.
- Prerequisites already exist:
  - Standardised methodology for information input (LCA methodology)
  - Standardised procedures for processing and managing information (declaration programs)

- Existing standardised LCA methodology is becoming widely accepted,
  - Competition between softwares
  - Standardised data formates
  - In curricula at universities and schools

- Further development needed:
  - Public, easily accessible data bases
  - Experience with screening applications
  - Revision of practice for critical review for communicating LCA information

Discussion points

- What elements would need to be in place to enable the New Approach to be used effectively to encourage innovation?
  - Minimum requirements
  - Criteria
  - Verification
  - Stakeholder consultation

Existing Life Cycle Based Schemes

	Life Cycle Assessment	Compara-bility	Continuous Improvement	Environment Excellence	Third party validation
Type I	optional	medium	Not intended	intended	required
Type II	optional	low	possible	possible	optional
Type III	required	high	intended	Not intended	required

Main Element Needed: Credibility

- Stakeholder participation,
  - At early stages to enable stakeholders owning the process and building up responsibility for it
- Transparency of procedures
  - To allow for sufficient public control
- Effective revision procedures
  - To provide guidance e.g. on BAT without being prescriptive
  - To check guidance in terms of real environ-mental improvement

2.3.2.2 Management standards versus product standard. Hugues Plissart, CEN

The New Approach in Setting Product Standards for Safety, Environmental Protection and Human Health : Directions for the Future

29/30 November 2001, Copenhagen

Session III : What is the role of the New Approach in promoting environmental innovation ?

Panel on environmental innovation:

Management standards versus product standards,
H.Plissart, CEN Management Centre

The title « Management standards versus product standards » suggests an antagonism. But is there an antagonism between both ?

We are accustomed to deal with product standards. Traditionnally products standards complemented by measurement standards (test methods) were used in the area of voluntary standardization. A great number of products and services as well as cross sectorial fields as environment are covered by standards. They were also an ideal tool in support of legislation at national and at European level. Their use in support of New Approach Directives (with the « harmonized » standards) and in support of other EC legislation and policies have proven successful in many areas.

But more and more there is a tendency to make use of system standards, of management standards, in the non-regulatory area. Such standards are used also in the regulatory area, even in the New Approach area.

Already in the classic field of machinery safety, when CEN was faced with the challenge of producing safety standards in support of the directive for 55.000 different types of machines (EC figures), the solution found organised the work in basic safety standards dealing with concepts, principles for design and general aspects, and generic safety standards on the one hand. Typical product standards would only be developed for a limited number of machines or group of machines on the other hand.

Some of these standards were in fact already management standards (risk management standards, environmental standards).

Management standards can be found in other New Approach and non New Approach areas : medical equipment standards, space project management standards, system standards in the railway applications area,... Quality management standards are used in the Global Approach.

Management standards versus product standards

Product standards define objective criteria, requirements expressed in precise terms for individual products or families of products. A more modern approach is the product standard defining performance criteria rather than design criteria. These widely used types of standards allow verification of the products against their requirements.

With these types of standards the requirements for the product, the level(s) of performance will be maintained for a certain time pending a revision or an amendment.

Morevover product standards are a too restricted tool when one aims at improving a wide spectrum of products on a greater scale and simultanuously introduce e.g. the concept « environment ».

It is also not affordable, nor possible to produce product standards for a huge number of products and for all aspects including health, safety and environment.

It is then that one should think in terms of management standards, system standards, procedure standards.This kind of standards make manufacturers think from the design stage. The purpose of this type of standards is to ensure that the manufacturer gives full consideration to the issues covered in the document be they of health, safety (risk management standards) or environmental nature. These standards bring in iterative processes aiming at permanent improvement of the products, be it their quality, the aspects relating to safety, health or environment etc.. They are really incentives for improvement. They are more efficient for improving the performances than the previous type of standards.
Management standards also provide a means to anticipate the evolution, the improvement, whatever the product.
Management and system standards can in some cases be the only possible solution especially today with the fast changing technologies.

Verification for these types of standards will not aim at ensuring that a product is in compliance with a standard but that the procedure is in compliance, or that the process in the standard will have been followed. They cannot give a pass/fail system for individual products.

In fact both types, the management standards and the products standards are not antagonistic. They are different tools which can be used together to cover a field or an issue. The management standard will cover the whole field or an aspect for the whole field. The product standard will be developed when the need will be justified for specific types of products, of risks, ..in comparison to the cost and the consequences etc… Management standards can also be used as a first step when the product standard cannot yet be produced e.g. when there is a need for more research.

The standards vis-à-vis the legislation.

Standards have been used for decades and decades in support of national, later of European legislation. Originally the method of direct reference to a specific standard was used (Old Approach). This had its weak sides as for example it cast the requirements in concrete for a long time hampering thus progress. Moreover the technical part of this Old Approach legislation often was obsolete at the time of enforcing. The solution was the introduction of the "New Approach" which gave an important role to "mandated" European Standards. Other types of legislation made use of standards too: Public Procurement directives, Transport of Dangerous Goods, etc…

The New Approach was successfully used in more than 15 different fields. As said earlier, mainly but not only product standards have been used in support of the

"essential requirements" of these directives. Management standards have also been used (risk management standards, quality management standards,.).

The New Approach, which offered a quite broader perspective than the previous one, introduced a kind of co-operation between the legislator and the standardizer. It separated the "legal" part from the "technical" part allowing the technical part to adapt fast to technical progress and to develop whilst safeguarding what is essential and remains under the authorities' responsibility. It introduced a kind of co-operation between the legislation and the standardization that has a potential for development. This relation is defined in the "mandates" given by the European Commission to the European Standardization Organisations and accepted by them.

Experience has shown that it is very important that scope and aims of the work allocated to the standardizer in the mandates are well understood and understood in the same way by all partners. It is evident that the standardizer is neither able nor willing to take over pure responsibility of the legislator. It is therefore important that a partnership is developed between the European Commission and the European Standardization organisations, but also at national level between the National Standards Bodies and the National Authorities and that all stakeholders are involved in the development of the standardization mandates and in the development of the standards.

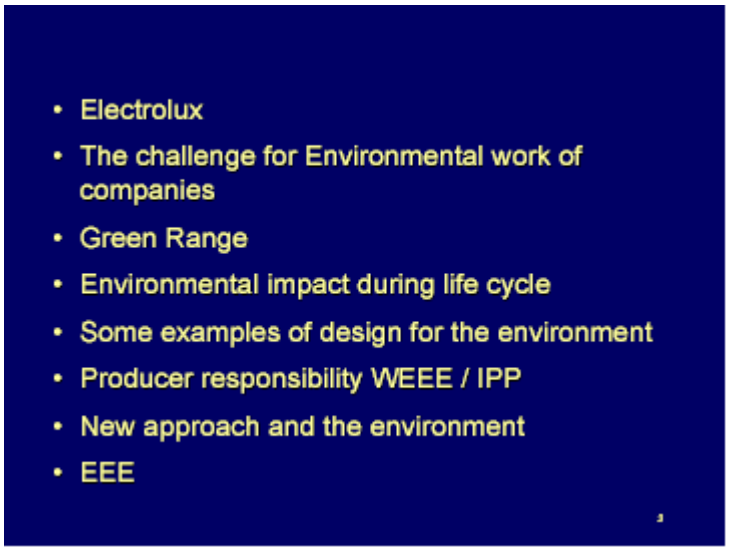
In this role of the standards vis-à-vis de legislation the main question is: "What should remain "legislation"; what can be dealt with by the standard; where is the border?" The next question: "To what level of detail the "essential requirements" have to go?" defines the possible scope for the standard and the types of standards.
The question whether or not product standards should be the answer, or whether or not management standards can be a solution can best be examined together with the standardizer. There are advantages and disadvantages for both types. It is clear however that in case management standards are the answer, the requirements of the legislation have to envisage this possibility and be drafted with this in mind (example: require that procedures e.g. for risk management, for assessment procedures, etc.. are followed.
The verification of compliance will thus be different but possible for both types of standards.

It shall be noted that CEN supports the IPP's consideration to use standardisation to provide specific tools to support European environmental legislation and policy which is in agreement with its own policy. Moreover the aspects of the IPP which encourage the inclusion of environmental aspects into product standards across CEN sectors are also in line with steps already undertaken by CEN

Concluding:

There is potential for development of standardization also in the environmental field; there is potential for both product and management standards developed in support of policies and legislation but such developments shall be realised in co-operation and partnership between legislator and standardizer, on the basis of clear boundaries of reciprocal responsibilities defined in unambiguous mandates.

2.3.2.3 Environmental innovation in product design: The industry point of view
Viktor Sundberg, Electrolux

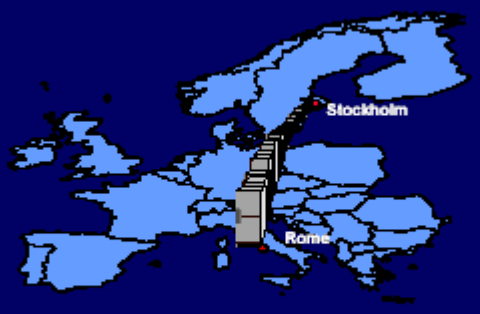



ELECTROLUX
at home everywhere
• Sales SEK 124,500m
• 55 million products sold every year
• Approx. 87,000 team members


Consumer Durables
Indoor
&
Outdoor
• White goods
• Vacuum cleaners
• Air-conditioners
• Light-duty chain saws
• Garden equipment


Professional Products
Indoor
&
Outdoor
• Food-service equipment
• Laundry equipment
• Components
• Chain saws
• Trimmers etc.
• Turf-care equipment
• Power cutters

Impact of Products ?



If you take all the cold products (refrigerators/freezers) Electrolux produces during one year and put them in a row ...
..... then the line would stretch from Stockholm to Rome - 2 250 km.

Improving products for the environment must become part of business thinking & competition

Electrolux Green Range
an Internal Measurement Tool

What gets measured gets done

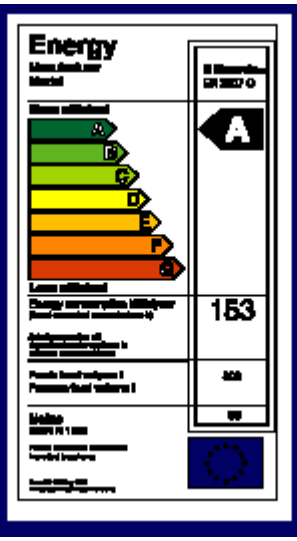
Electrolux Green Range
an Internal Measurement Tool

Why ?

- Are "green products" profitable for the company ?
- How does the "green segment" of our range develop ?
- To justify further efforts for "green products".

Green Range was introduced 1996

- Criteria are revised (sharpened) yearly



Green Range Criteria 2000

Refrigerators / Freezers

Energy consumption
Energy class A or B

Insulation & refrigerant
Hydro Carbons
(low GWP, no ODP)

Noise level
Max 40 dB(A)

Washing Machines

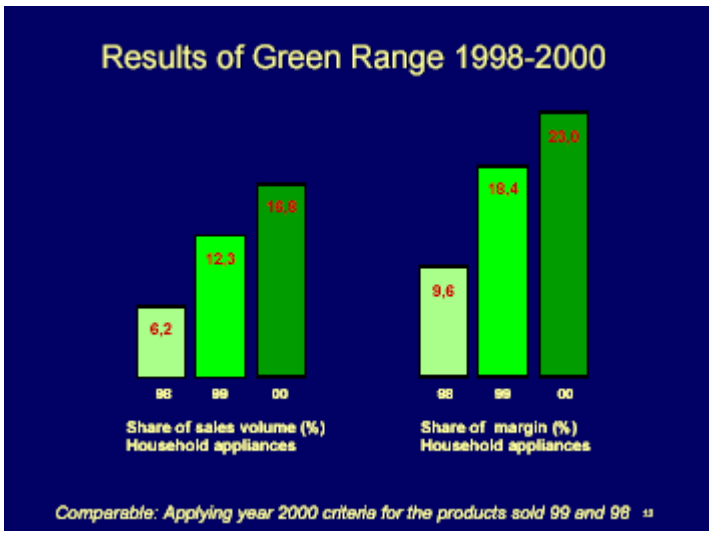
Energy consumption
Energy class A and B

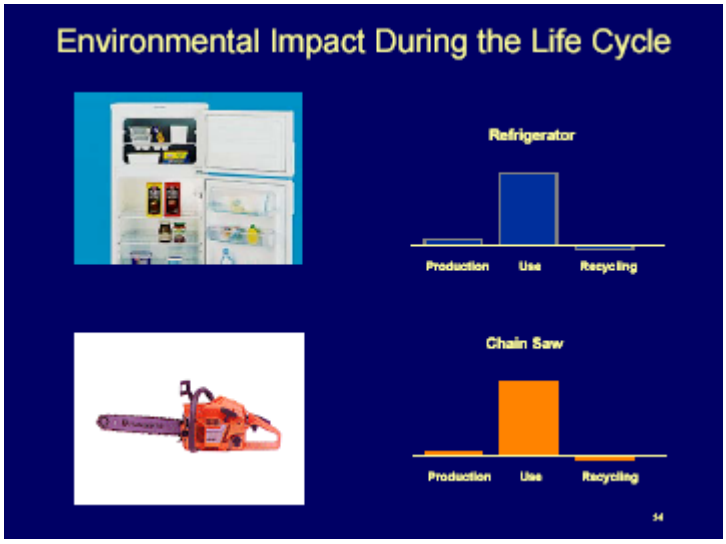
Water consumption
Max 56 litres for 4.5-5 kg

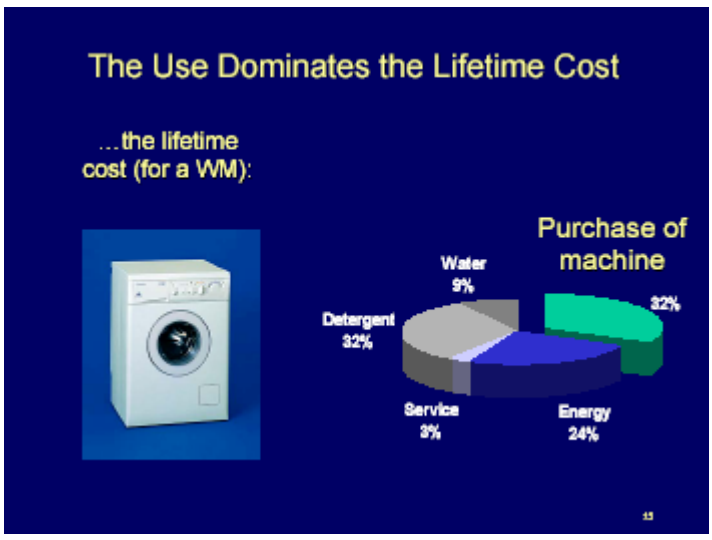
Detergent losses
0% losses of detergent

Washing efficiency
Class A and B

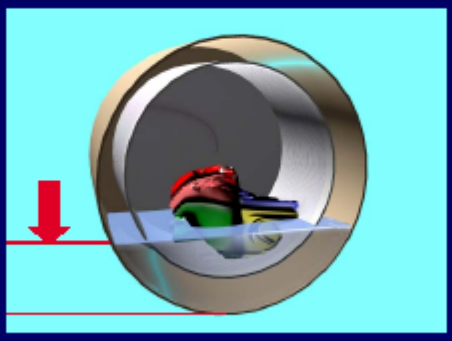
Noise level
Washing - max 59 dB(A)
Spinning - max 72 dB(A)


Results of Green Range 1998-2000
6,2
12,3
9,6
18,4
98
99
00
Share of sales volume (%)
Household appliances
Share of margin (%)
Household appliances
Comparable: Applying year 2000 criteria for the products sold 99 and 98

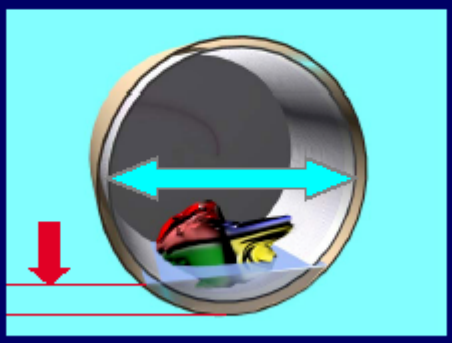

Environmental Impact During the Life Cycle
Refrigerator
Production
Use
Recycling
Chain Saw
Production
Use
Recycling


The Use Dominates the Lifetime Cost
...the lifetime
cost (for a WM):
Purchase of
machine
32%
Water
9%
Detergent
32%
Service
3%
Energy
24%

Water Level of Washing Machine



Save Water & Energy by Reduced Tub/Drum clearance



Cadmium free batteries
- All Cd batteries phased out in Sweden and Norway in 1996
- Nordic eco label

PVC free products
- Introduced in Sweden in 1997 for professional customers
- Introduced in general product range in 2001

Most efficient refrigerators/freezers in Europe
- Best product in the Energy+ competition in 2001

Design for Recycling & Reuse

Two possible Refrigerants
Choice at design ?

HFC
R134a

- No ODP
- GWP (Kyoto)
- Recovery Requirements
- Less expensive to produce

HC
Isobutane
"Greenfreeze"

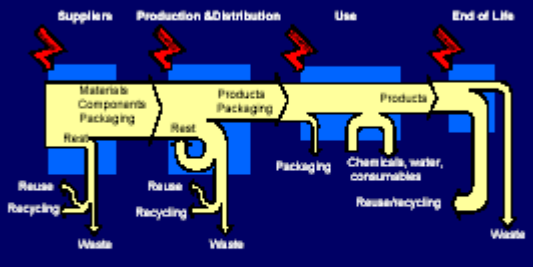
- No ODP
- Very low GWP
- No recovery necessary
- More expensive to produce, safety measures

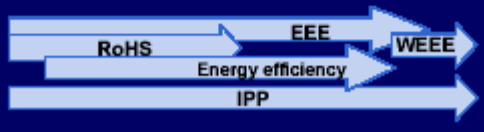
Design for Recycling & Reuse

- Reuse
- Mechanical recycling
- Disassembly
- Labelling
- Compatibility
- Material substitution
  (Concrete balancing weight in washing machines ?)

The Recycling Process

Regulation During the Product's Life Cycle





IPP and the Transformation to a Greener Market

- "Integrated Product Policy offers the opportunity to bring in their (industry and retailers) experience to **promote a business-oriented approach** towards greener markets"
- "In the context of the proposed strategy, promotion of environmental quality of goods and services means **using market forces to the largest possible extent"**
- "These cover instruments that **encourage firms to apply a life cycle approach** for their products"
- "The most powerful instrument to transform the market … is .. by ensuring that **the true environmental cost during the life cycle of products is integrated into the product price"**

Will the WEEE directive be compatible with IPP ?

IPP Green Paper

Page 11:
*"The concept of **producer responsibility** relates to the integration of costs occurring once the product has been sold into the price of new products.*

***This encourages prevention at the design stage** and allows consumers to bring back end-of-life products free of charge.*

***It has recently been integrated into** the Directive on End-of-Life Vehicles and **the Commission Proposal for a Directive on Waste Electrical and Electronic Equipment.** "*

?

Council Position for Producer Responsibility WEEE

*"...**producers provide** ...for the financing of the collection, the treatment, recovery and environmentally sound disposal of WEEE..."*

*"The management of WEEE coming from producers that are **no longer present on the market or which can no longer be identified** at the time when the costs occur **shall also be financed by producers**..."*

Does this give the incentives called for in IPP ?

- No, contradiction with IPP

This is reducing producer responsibility to a waste tax!

Each actor needs to be legally responsible for his activities, i.e.

a producer should be responsible for the products he has produced

Collective activities are necessary to handle the waste in practice

There is no contradiction between a individual producer responsibility and collective recycling operations

EU Parliament Proposal for Producer Responsibility WEEE

*"... **the financing ... is provided on an individual basis**... ensure that producers **make provision for appropriate guarantees** for the financing of the management of WEEE."*

Does this give the incentives called for in IPP ?

- Gives each actor a clear signal that his activities at the design stage will influence his future recycling cost.
- Compatible with IPP

Where is the incentive if you become responsible for your neighbour's waste ?

Producer Responsibility must not become a waste tax !

New approach

- Proven efficient for product safety, low voltage directive, machinery directive, etc
- Provides the tools and details, e.g. measurement
- Can be fast, flexible and tailor made
- Goals set by political decision makers

Voluntary agreements Energy efficiency

- Washing machines 1997
- Dish washers 2000
- Water heaters 2000

- Refrigerators / Freezers ?
- Tumble dryers ?
- Air conditioners ?

EEE initiative

+ Objective to ensure the functioning of the internal market by harmonising country initiatives on eco design.
– Compliance and enforcement can not be secured
– LCA is not a precise science. It can not used as a tool within legislation.
– Risk for widespread interpretation. Could lead to deviating enforcement in Member States.
– Increase cost and administrative burden Corresponding environmental benefit ?
– There is a need for legislative tools due to IPP, but lets first conclude the IPP debate

- *The IPP green paper contains several good intentions*
- *Using New Approach for environmental legislation can not be ruled out, but is far from straight forward.*
- *"EEE" in its draft formats is not feasible*
- *Don't use the WEEE directive to transfer the waste tax collection to manufacturers*

2.3.2.4 Innovation in product design: The environmental point of view Karola Taschner, European Environment Bureau

European Environmental Bureau

Innovation in product design: The environmental point of view

Copenhagen, 30 November 2001
By Dr. Karola Taschner
Scientific Advisor

Introduction:
The Community has invented the New Approach in order to avoid that government official were in charge of product standardisation because this was regarded to be an extremely inefficient way to deal with technical details. Governments have to stipulate the societal needs. That is their task according to the New Approach.
It cannot be the business of legislation to prescribe industry every single step on how to design a product. They will not do it because they do it differently. Governments should set clear target and timetables. This will necessarily trigger innovation.

Approaches to product innovation
There are very different points to start with product innovation. There are mainly four steps:

1. Product improvement
2. Refining improvement
3. Redesigning products
4. System innovation

Product innovation through standardisation

It is asked too much from standardisers to make them responsible for ecological product innovation. They have a brief to defend the market share of their company. If there is a producer of a green product, the others will jointly try to prevent the green producer to gain market shares. It would mean to turn market forces upside down if one expects sacrifices for the environment where competition is so hard.

Example: EEE-Directive

WEEE and ROHS sets clear targets and timetables.

What is the objective of the EEE-Directive?

EEE-Directive to implement the demands of WEEE and ROHS and present a framework that enable surveillance as to whether a product in question is meeting the requirements of WEEE and RoHS directive. This would be a kind of mandate having gone through the democratic decision making procedure. In the end it has to provide a scheme that delivers evidence for the presumption on conformity. This will have a push effect on all producers.

1

The last working document on EEE is focussing on introducing life-cycle thinking for eco-design and describes a detailed management system for that purpose. Such a directive could be useful under the condition that it is not aiming to provide for the presumption of conformity for the WEEE and RoHS directives because it cannot deliver in that case. It will be an incentive for some manufacturers but not all of them.

At the time, the Danish Government has criticised the packaging standards because they were management standards that left it absolutely to the discretion of producers how much reuse, recycling etc. they built into their products. The packaging standards did not provide for any measurable indicators. If the last draft EEE proposal would come into force, the implementation of WEEE and RoHS directive could not be monitored because the recycling targets cannot be measured. So the lack of implementation will take away for the innovative effects of the WEEE and RHS directives.

To set these targets and timetables a review of the state of art and science, of best practice, of the main problems not addressed by other directives, serious back-up work are needed to set a credible framework for producers that helps them and provides a framework for them how to plan their investments and so steer it inot innovation.

The way forward to efficiently trigger product innovation into the good direction

We imagine an EEE framework directive with daughter directives.

More than eighty different product groups are listed in the annex of the WEEE directive. They cannot be approached jointly and therefore schould be dealt with separately in clusters.

The following parameters will have to be developed

- Minimum performance levels to be achieved
- Orientations for the dimension of improvement needed (e.g. energy efficiency targets)
- Priorities for improvement (e.g. hazardous substances beyond the ROHS directive, energy efficiency, water use) on the basis of the 6th Environmental Action Programme and a screening of the most relevant environmental aspects of different groups of electronics.
- Key issues to be addressed (e.g. an obligatory switch off function – in addition to stand-by for IT equipment)

Harmonisation of chemicals regulations and a better and more restrictive chemicals policy in Europe will be more purposeful rather than a directive dealing with environmental design requirements for EEE

The directive should establish the following requirements:

- Benchmarking according to best practice and state of the art, e.g.
  requirements for using a certain level of recycled material,
  levels of energy efficiency,
  restrictions on emissions,
- Establishing grades (or classes) of performance
- Making a choice on which standards are needed

Preconditions for the good functioning of the system is among others the good environmental management of the producing company

- As the burden of proof for compliance with minimisation objectives is imposed upon producers
- Transparent decision-making (e.g. by documenting assessment of different options and justification requirement, why not the best performing option has been chosen).
- obligation to carry out a lifecycle assessment of products
- product oriented environmental management (POEM)
- environmental product information be forwarded

One thing for certain: Participation of NGOs in the standardisation process can make the difference in some cases but not in many due to restricted resources.

Discussion points:

- How can management standards encourage environmental thinking in product design?

Not at all. One bad example (packaging standards) should be sufficient. Management standards can be an add-on to document that benchmarking standards have been met.

- Is there a need to develop operational, product area specific methodology(s) for LCA, and how can this be done?

(EU) Ecolabels are not based on full blown LCAs but on life cycle inventories. The most important environmental impacts are then selected.

- Would it stimulate innovation if there were benchmarks starting from minimum requirements that could be used for a system of verifiable environmental product declarations? If so, how could these benchmarks be developed?

This can be a very effective system. In principle this is what the Commission has developed for the energy label which is not limited to only one parameter. Also the binding vehicle emission standards are progressing in a two step approach where Member States can grant tax incentives in case they introduce stricter limit values in advance. The criteria for benchmarking and the quantitative values have to be well studied and prepared.

- What "push strategies" should these be at EU or national level?

Announcing that the minimum requirement will after a while creep up the matrix,
eco-labels although for consumer goods only, best equipped with VAT reduction,
create markets for products with high environmental performance. Public Procurement is the other demand side tool that has a large potential to create markets: About 14% of the EU BIP are spent in public purchasing.

- What elements would need to be in place to enable the New Approach to be used effectively to encourage environmental innovation, e.g. mandatory minimum requirements; criteria based on LCA methodologies, methods of verification, stakeholder consultation

All of them.

Nobody has ever said that IPP would be cheap for EU and Governments. They will have to organise meetings similar to the working group meetings under the EU Eco-label for experts from MSs and interested parties. Member States and/or EU should be in charge of the studies, preparing for benchmark definitions, chair the meetings, write the minutes and make proposals.

NGOs believe that a lot of freedom has to be left to industry but the objectives, i.e. environmental requirements, have to be set by democratic decisions. Afterwards industry needs support and guidance how to reach these objectives. It is important that the valuable economic investments are paying back and have some gains for first movers in stock.

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4 List of New Approach directives

4.1 Product areas covered by New Approach Directives[2]

Directive	Product Area	Mandated Standards 2000[3]
90/396/EEC (amendment 93/68/EEC)	Appliances burning gaseous fuels	95
2000/9/EC	Cableway installations designed to carry persons	
89/106/EEC (amendment 93/68/EEC)	Construction products	1004
89/336/EEC (amendments 92/31/EEC, 93/68/EEC)	Electromagnetic compatibility	40
94/9/EC	Equipment and protective systems in potentially explosive atmospheres (ATEX)	96
93/15/EEC	Explosives for civil use	19
92/42/EEC (amendment 93/68/EEC)	Hot water boilers	
95/16/EC	Lifts	19
73/23/EEC (amendment 93/68/EEC)	Low voltage equipment	
90/385/EEC (amendments 93/442/EEC, 93/68/EEC).	Medical devices: Active implantable	49
93/42/EEC (amendment 98/79/EC)	Medical devices: General	215
98/79/EC	Medical devices: In vitro diagnostic	19
90/384/EEC (amendment 93/68/EEC)	Non-automatic weighing instruments	
89/686/EEC (amendments 93/68/EEC, 93/95/EEC, 96/58/EC)	Personal protective equipment	327
97/23/EC	Pressure equipment	766
99/5/EC	Radio and telecommunications	

[2] Updated version of Annex 1 in "Guide to the implementation of directives based on the New Approach and the Global Approach.
[3] Personal communication, Claus Jensen, based on CEN reporting to 98/34 Committee.

Directive	Product Area	Mandated Standards 2000[3]
	terminal equipment	
94/25/EC (proposed amendment COM(2000)639 final)	Recreational craft	49
96/57/EC	Refrigeration appliances	
98/37/EC (amendment 98/79/EEC, proposed amendment COM(2000/899 final))	Safety of machinery	734
88/378/EEC (amendment 93/68/EEC)	Safety of toys	11
87/404/EEC (amendments 90/488/EEC & 93/68/EEC)	Simple pressure vessels	47
98/13/EC	Telecommunications terminal and satellite earth station equipment	

4.2 Product areas covered by New Approach Directives, but which do not provide for the CE marking

Directive	Product Area	Mandated Standards 2000[4]
96/98/EC	Marine Equipment	
94/62/EC	Packaging and packaging waste (for marking see table below)	15
2001/16/EC	Rail systems, Conventional	
96/48/EC	Rail systems, High speed	

4.3 Product areas covered by proposals for New Approach Directives

Directive	Product Area
Proposal in preparation	Electrical and electronic equipment
COM(2000)566 final	Measuring Instruments
COM(96)191 final	Packaging, marking of
COM(93)322final COM(94)267 final	Precious metals

[4] Personal communication, Claus Jensen, based on CEN reporting to 98/34 Committee.

5 Abbreviations

ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation
ASEAN	Association of South East Asian Nations
B	Belgium
BAT	Best Available Techniques
BIAC	Business and Industry Advisory Committee
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
CD	Compact Disc
CMA	Canadian Marketing Association
CO_2	Carbon Dioxide
COLIPA	European Cosmetic Toiletry and Perfumery Association
COM	Commission
DG	Directorate General
DK	Denmark
DN	Danish Society for Nature Conservation
EC	European Communities
ECB	European Central Bank
ECETOC	European Center for Ecotoxicology and Toxicology of Chemicals
ECMA	European Computer Manufacturing Organisation
ECOS	European Environmental Citizens Organisation for Standardisation
EEB	European Environmental Bureau
EEE	Electrical and Electronic Equipment
EFTA	European Free Trade Area
EHSRS	Essential Health and safety Requirements
EMAS	Environmental Management Standards
EMC	Electromagnetic Compatibility
EPOC	Environmental Policy Committee
ER	Essential Requirement
ETSI	European Telecommunications Standards Institute
EU	European Union
EuroNCAP	European New Car Assessment Programme
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques
GLP	Good Laboratory Practice
GWP	Global Warming Potential
HFC	Hydrofluorocarbon
H&S	Health and Safety
ICH	International Conference on Harmonisation
IEC	International Electrotechnical Commission
IOMC	Inter-organisation Programme for the Sound Management for Chemicals
IPP	Integrated Product Policy
IPPC	Integrated Pollution Prevention and Control
ISO	International Standards Organisation
IT	Information Technology
JM	Joint Meeting

LCA	Life Cycle Assessment
LVD	Low Voltage Differential
MAD	Mutual Acceptance of Data
MRA	Mutual Recognition Agreement
NA	New Approach
NAFTA	North American Free Trade Agreement
NGOs	Non Governmental Organisations
NO_x	Oxides of Nitrogen
ODP	Ozone Depletion Potential
OECD	Organisation for Economic Cooperation and Development
OJ	Official Journal
P&PW	Packaging and Packaging Waste
PECAs	Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products
POEM	Product Oriented Environmental Management
Ppm	Parts per million
PRODCOM	Nomenclature for Industrial Statistics
PVC	Polyvinyl Chloride
RoHS	Restriction of Hazardous Substances
RTT	Regional Technology Transfer
SEK	Swedish Kroner
SMEs	Small and Medium Enterprises
SPSF	Standard Project Submission Form
TC	Technical Committee
TG	Test Guidelines
TUAC	Trade Union Advisory Committee
UK	United Kingdom
UNICE	Union of Industrial and Employer's Confederations of Europe
VAT	Value Added Tax
WEE	Waste Electrical and Electronic Equipment
WNT	Working Group of National Coordinators of the Test Guidelines Programme
WTO	World Trade Organisation

Appendix A: List of background reading

The New Approach in Setting Product Standards for Safety, Environmental Protection and Human Health: Directions for the Future.

Documents related to the Workshop

The following documents and links can provide additional information about a number of the topics discussed at the Workshop.

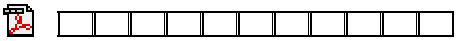
The New Approach

The European Commission has a website related to Standards Policy. This can be found at:

Standards policy

There are a number of documents of particular interest. These include:

Report of the Commission of 2001-09-26 to the Council and the European Parliament on "Actions taken following the Resolutions on European Standardisation adopted by the Council and the European Parliament in 1999" - COM (2001) 527 final This report from the Commission aims to set out the most relevant developments since 1999, as requested by the Council and the Parliament. It basically takes a horizontal view on European standardisation matters.



Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations
Official Journal L 204 , 21/07/1998 P. 0037 - 0048
CONSLEG - 98L0034 - 05/08/1998 - 33 P.

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31998L0034&model=guichett

Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards
Official Journal C 136 , 04/06/1985 p. 0001 - 0009
Spanish special edition...: Chapter 16 Volume 1 p. 248
Portuguese special edition Chapter 16 Volume 1 p. 248

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31985Y0604(01)&model=guichett

Guide to the Implementation of Directives Based on New Approach and Global Approach. This Guide is intended to contribute to better understanding of Directives based on the New

Approach and the Global Approach, and to their more uniform and coherent application across different sectors and throughout the Single Market.

http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm

Standards and innovation

http://www.dti.gov.uk/strd/fundingo.htm#swannrep

Other sites related to standardisation

CEN Strategic Advisory Body on Environment (SABE):
http://www.cenorm.be/sectors/sabe.htm

EOTC - European Organisation for Conformity Assessment
This website is an interactive learning tool designed to provide an intuitive understanding of the principles of the New and Global Approach.

http://www.eotc.be/newapproach/cdrom/index.htm

Integrated Product Policy

The Commission's web page on Integrated Product Policy:

http://europa.eu.int/comm/environment/ipp/home.htm

The Green Paper on Integrated Product Policy: Press release

Green Paper on Integrated Product Policy COM(2001)68

(pdf ~150K; except el 1.3M)

The Challenge of an Integrated Product Policy in Europe
Brussels, 18 th of October in the European Parliament. Minutes of the hearing are available in pdf format.

http://www.garciaorcoyen.org/conclusiones_ingles.htm

The IPP Conference: Launching the Stakeholder debate
Brussels, 8-9 March 2001. Summaries of the workshops are available in pdf format.

http://europa.eu.int/comm/environment/ipp/stakeholder_events.htm

Proposals for Electrical and Electronic Equipment legislation:

WEEE proposal (amended text)

COM/2001/0315

RoHS proposal (amended text)

COM/2001/0316

EEE Working Document

http://europa.eu.int/comm/enterprise/electr_equipment/eee/workdoc.pdf

http://europa.eu.int/comm/enterprise/electr_equipment/eee/faq.htm

Other Commission Documents:

Commission White paper on governance

http://europa.eu.int/comm/governance/index_en.htm

Environmental governance

http://europa.eu.int/comm/environment/governance/index_en.htm

Commission White paper on a future chemicals policy.

http://europa.eu.int/comm/environment/chemicals/whitepaper.htm

Other Relevant Documents:

The Nordic Council of Ministers Working Group on product-oriented environmental strategy
Workshop report: Integrated Product Policy and the New Approach, October 2, 2001. Stockholm

<indsæt dokumentet NordicWSreport.pdf herefter>

Workshop report

Integrated Product Policy and the New Approach

October 2, 2001
Stockholm

The Nordic Council of Ministers Working Group
on product-oriented environmental strategy

TABLE OF CONTENTS

PREFACE

Integrated Product Policy (IPP) is a public policy that aims at continuous reduction of the environmental impacts that arise along the life cycle of products. In 2001 the Nordic Council of Ministers (NCM) adopted a Nordic product oriented environmental strategy. Its objective is to save resources and decrease environmental impacts of products. The implementation is highly dependent on the development in Europe and globally.

It is often claimed that environmental measures are in conflict with international trade regulations. In 1999, the Nordic environmental sector IPP working group initiated a project to investigate this further. The aim was to review the relationship between international trade rules and IPP. A study was carried out to give an overview of international trade rules, primarily rules of the European Union (EU) and the World Trade Organisation (WTO). The purpose was to identify regulative obstacles to product-oriented environmental protection measures.[1]

As a follow-up to the study, the Nordic environmental sector IPP working group initiated a workshop that was held in Stockholm on October 2, 2001. Representative from all Nordic countries participated. The aim of the workshop was to identify possibilities to reduce environmental impacts of products within the framework of the EU and WTO. It also aimed at promotion of the discussion between environmental experts and trade experts in the Nordic region.

This report will be used as background documentation for the European workshop on the New Approach, which will be held in Copenhagen in November 2001. It may be useful for various experts who are working with product-oriented environmental policy. The IPP-working group and the Nordic Council of Ministers are not committed by the conclusions of the workshop.

November 2001

The NCM environmental-sector working group on product-oriented environmental strategy

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Sigrun Gudmundsdottir, Icelandic Environmental Protection Agency

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1 Alanen (2000) *Trade Regulations and Product Environmental Measures.* TemaNord 2000:549

SUMMARY

On October 2, 2001 the Nordic Council of Ministers working group on product-oriented environmental strategy arranged a workshop on the possibilities to reduce environmental impacts of products. The purpose of the workshop was to develop a deeper, common Nordic understanding of how legislative measures can be applied in order to reduce the environmental impacts of products. The workshop also focused on possibilities to use New Approach legislation as an instrument to achieve greener products.

A conclusion from the workshop was that the New Approach clearly has potential as an instrument to achieve greener products. Especially as the New Approach process involves various stakeholders and third world countries.

Another important conclusion is that it is necessary to carefully select the products and product groups that could be appropriate to regulate with the New Approach. The Packaging and Packaging waste directive and the proposed EEE-directive, which in part include New Approach legislation, should be closely evaluated. The potential risks that are associated to use of the New Approach have to be taken into consideration. The success of the New Approach would be facilitated if the European Commission could define more detailed, environmental, essential requirements for products. In line with this, the mandate and instructions to CEN could be more detailed.

The workshop also concluded that it would be of interest to further analyse the possibilities to adopt a directive that puts a general obligation on producers to design products so that they protect human, animal or plant life or health and conserve exhaustible natural resources. Such a directive could, at least in theory, stimulate standardisation bodies to elaborate environmental standards for products.

1 Nordic Workshop about the possibilities to reduce environmental impacts of products within the framework of the EU and the WTO

The Nordic Council of Ministers working group on product-oriented environmental strategy arranged a workshop about the possibilities to reduce environmental impacts of products in Stockholm on October 2, 2001.

Representatives from all the Nordic countries participated in the workshop. The program for the workshop is enclosed in Annex 1 and a list of the participants is enclosed in Annex 2.

On the commission of the Nordic Council of Ministers IPP working group, Linklaters Lagerlöf law firm, prepared a background paper to the workshop. This background paper served as a starting point for the discussion and is integrated in this workshop report.

2 Introduction - Integrated Product Policy and New Approach

Integrated Product Policy (IPP) is an approach, which seeks to reduce the life cycle environmental impacts of products from the extraction of raw materials to production, distribution, use and waste management. The underlying idea is that integration of environmental impacts at each stage of the life cycle of the product is essential and should be reflected in decisions of stakeholders.[2]

The European Commission Green Paper on IPP states that the role of public authorities within the IPP approach in most cases should be one of facilitation rather than direct intervention. The general idea is that public policy should set the main objectives and provide different stakeholders with the means and incentives to achieve these.

The New Approach is a regulatory technique and strategy. New Approach directives define binding essential requirements from which standardisation bodies elaborate technical standards. New Approach legislation has mostly been used on health and safety aspects of product design.

In the Green Paper the New Approach is seen as a potential instrument to achieve greener products. Three questions that concern the New Approach are put forward in the Green paper:

(a) How can IPP contribute to greening the standardisation process and to use the potential of New Approach legislation optimally?

(b) How can environmental characteristics become an integral part of the standardisation process?

(c) How can the New Approach legislation contribute to the promotion of environmental characteristics of products?

The Workshop mainly focused on the third question (c).

The Green Paper only refers to the possibilities to use the New Approach for environmental protection. Potential risks for the protection of the environment, which are connected with the use of the New Approach, are not mentioned. They are however listed in this report.

Historically, trade issues and environmental issues have been two separate disciplines. Gradually, however, the link between the two has become more visible. The concern with regard to the implications of the connection between trade and environmental issues has consequently grown. When discussing IPP it is hence important to analyse the relationship between IPP and trade rules, both on the international and the European level. In theory, States are sovereign with regard

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to regulation within their own territories. They should subsequently be free to use whichever tools they want, including IPP, to achieve environmental protection. However, by entering into international or regional obligations, States have restricted their domestic policy options.

3 The international framework

This section provides a background with regard to the legislative international framework. It is divided into three parts. The first introduces three general principles that link trade and the environment. The second briefly describes the WTO framework for trade and the environment. The third part describes the corresponding framework of the EU. A more extensive review of international trade legislation, with a special focus on the rules of the World Trade Organisation (WTO) and the European Union (EU) can be found in the TemaNord report *"Trade Regulations and Product Oriented Measures" (2000:549)*.

3.1 Trade and the Environment

Questions that regard free trade and environmental protection have received increasing attention in recent years. One critical issue regards is if the growing interest in the connection between free trade and the environment should be viewed as a blooming of "sustainable development" or as "eco-protectionism". According to trade-oriented analysts, many environmental policies are covert means to protect domestic producers from international competition. Concerns have been raised with regard to the risk that protectionist ambitions masquerade as environmental protection. On the other hand, environmental analysts often regard trade policies as an important part of environmental policy.

Most analysts of both fields agree upon that trade policy and environmental policy interact. The opinions on the consequences of free trade however vary. Anti-globalisation groups claim that free trade endanger the environment. Their main argument is that requirements for environmental protection will be set by the lowest common denominator since stricter national standards could be regarded as unjustified barriers to trade. Spokesmen for free trade, on the other hand, assert that free trade is a prerequisite for improved environmental protection and raised living conditions in the Third World and elsewhere. This later view is confirmed in the Rio declaration, principle 12, which states:

> *"States should cooperate to promote a supportive and open international economic system that would lead to economic growth and sustainable development in all countries, to better address the problems of environmental degradation. Trade policy measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade.*
>
> *Unilateral actions to deal with environmental challenges outside the jurisdiction of the importing country should be avoided. Environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on an international consensus."*

In this second paragraph of principle 12 the principle of sovereignty is highlighted, and this principle is also confirmed in principle 2 of the Rio declaration, which states:

> *"States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction."*

States have the sole right to decide upon their environment. Another principle that is well established in international law stipulates that states have the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States. In the Rio declaration this principle has been further elaborated. States have not only the obligation to refrain from damaging other states; they also have an obligation to enact, from their environmental and development context, effective environmental legislation. This is manifested in principle 11 of the Rio declaration:

> *"States shall enact effective environmental legislation. Environmental standards, management objectives and priorities should reflect the environmental and development context to which they apply. Standards applied by some countries may be inappropriate and of unwarranted economic and social cost to other countries, in particular developing countries."*

If a state or the EU want environmental standards for products to be set the considerations above have to be taken into account.

3.2 The WTO Framework for Trade and the Environment

The WTO regulative framework for trade and the environment mainly consists of two parts: the GATT treaty and the TBT-agreement.

The Gatt Treaty

The original goal of the General Agreement on Tariffs and Trande (GATT) is to promote trade through the reduced tariffs and elimination of both non-tariff barriers and non discriminatory trade practises. Two central provisions of the GATT reflect this.

(1) Article 1, the Most Favored Nation (MFN) clause, articulates the general obligation of all WTO members to treat goods of one country no less favorably than goods of another country. What the Most Favored Nation Clause means is basically that countries normally cannot discriminate between their trading partners. If one country is granted favourable trading conditions, these must also be given to all other WTO members.

(2) Article III, the National Treatment clause, prohibits adverse discrimination against foreign products as compared to similar/"like" domestic products. This means that a state can implement an internal regulatory scheme under Art III provided that both domestic and foreign goods touched by the regulation are treated equally. In line with this, Article XI prohibits quantitative import and export restrictions that have a discriminatory effect on the entry or exit of foreign goods. A state can consequently generally not issue a regulation that bans qualitative trade of products. This restriction is however not absolute; it is subject to the exceptions in Article XX.

Article XX outlines general exceptions that permit WTO member states to enact public policy measures that are inconsistent with the general rules of GATT. In order to be placed within the ambit of Art XX, the measures, according to what is commonly called the "chapeau", must not "constitute arbitrary or unjustifiable discrimination on international trade" or a "disguised restriction on international trade". After these requirements are met, the contracting party must demonstrate that the measure falls into one of the policy objectives listed in Art XX. Even if environment is not specifically mentioned, two of the listed objectives relate to environmental protection and resource conservation:

Art XX (b) [measures] necessary to protect human, animal or plant life or health

Art XX (g) [measures] relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.

This paragraph illustrates the fear that a country may introduce an import ban in the name of environmental protection when the true purposes is protection of the local industry. A regulation can be justified with environmental protection as long as it is not "eco-protective".

The 1994 Agreement on technical barriers to trade ("TBT Agreement")

This agreement seeks to ensure that technical regulations, standards, testing and certification procedures do not create unnecessary obstacles to international trade. WTO member states shall ensure that the technical regulations for products that are imported from the territory of one state shall be treated no less favourable than products of national origin or like products that originate in any other country.

The agreement outlines a code of practise for preparation, adoption and application of standards to avoid creation of unnecessary obstacles to trade. Technical regulations should not restrict trade more than necessary to fulfil legitimate objectives. According to clause 2.2 these objectives include protection of human health of safety, animals or plant life of health or the environment.

Article 2.4 of the TBT agreement stipulates that members must use "relevant international standards" in establishing national technical regulations "except where such international standards or relevant parts of them would be an ineffective or inappropriate means for the fulfilment of the legitimate aim pursued". The term legitimate objective includes, as mentioned above, the protection of human health or safety, animal or plant life or health, or the environment. Reliance on international standards shall provide a rebuttable presumption that such regulations are not barriers to trade.

3.3 EU legislative trade and environment framework

In Annex 3 an attempt is made to clarify what power EU or Member States have to legislate for environmental protection. A more detailed description of the procedure is outlined below. The question is what possibilities a Member State has to regulate in relation to the EU. The answer would define the possibilities for Member States to regulate in order to reduce environmental impact from products. In this context a difference must be made between policy areas where the EU already has adopted regulation or directives ("harmonised areas") and areas where no such EU legislation exists ("non-harmonised areas").

Harmonised areas

Some leeway is given to Member States to maintain or adopt unilateral national legislation pursuant to harmonisation, mainly through Article 95 (4-9) (previously Article 100a (4)). To assess the possibilities for Member States to regulate for environmental protection, Article 176 (previously Article130 t) also is of importance. As a consequence, this section will also deal with Article 176.

Article 95 (1) regulates the possibilities for the EU to adopt harmonisation measures in order to achieve the internal market. When a harmonisation measure has been adopted on the basis of art 95 (1), Member States however still have some possibilities to maintain or adopt more stringent measures. If a Member State after adoption of a harmonisation measure deems it necessary to *apply* national provisions that relate to the environment or on grounds of major needs referred to in art 30, the Member State shall notify the Commission (95 (4)). Moreover, art 95 (5) states that if a Member State after the adoption of a harmonisation measure deems it necessary to *introduce*

national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that member state arising after the adoption of the harmonisation measure, it shall notify the Commission. The Commission is then obliged to within six months approve or reject the national provisions involved after having verified whether or not they are means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market. If the Commission does not decide otherwise, the measure is allowed.

Article 176 allows Member States that have adopted product-related environmental rules under Art 175, to introduce or maintain more stringent protective measures as long as these are compatible with the Treaty. The European Court of Justice (ECJ) has held that the consequences of taking more stringent measures are consistent with the objective pursued by the directive[3]. Hence, art 176 does not confer competence on Member States to adopt less stringent protective measures. It should also be noted that art 176 does not give a basis for adopting protective measures in connection with Community environmental legislation that has not been adopted pursuant to Article 175, but pursuant to other provisions in the Treaty, like Article 95, 133 or 37.

Member States may also have the possibility to take action if the EC measures contain a specific safeguard clause allowing Member States to take own protective measures. Such safeguard clauses, which allow Member States to take provisional measures even in harmonised areas, can be found in Article 95 (10) and Article 174 (2) (previously 130 r). Article 95 states that harmonisation measure shall, in appropriate cases, include a safeguard clause that enables the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure. Article 174 (2) states that harmonisation requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a Community inspection procedure.

Non-Harmonised areas

In the absence of harmonisation, the consistency of national environmental regulations with European community law mainly depends on their conformity with the free trade rules in Art 28 (previously Art 30). Art 28 of the Treaty prohibits quantitative restrictions on imports and all measures with equivalent effects between Member States. The European Court of Justice (ECJ) has interpreted "measures having equivalent effect" broadly and stated that it should include "all trading rules enacted by Member States which are capable of hindering directly or indirectly, actually or potentially, intra-Community trade".[4]

The principle of free movement of goods is however not absolute. Derogation to Art 28 may be made under Art 30 (previously Art 36) on the basis of, inter alia, the protection of health and life of humans, plants or animals, as long as such measures are not means of arbitrary discrimination or a disguised restriction to trade between Member States. Environmental protection is not expressly mentioned as a ground justifying derogation from Art 28. In its judgement in the Cassis de Dijon case[5] the ECJ however provided further grounds upon which derogation from Art 28 may be permitted. In this case it was held that in absence of Community measures, restrictions on the free movement of goods resulting from disparities between national laws "must be accepted in so far as those provisions may be recognised as being necessary in order to satisfy mandatory requirements [of the Treaty]…", commonly referred to as the *Rule of Reason*. Environmental

3 Case C 232/97 Nederhoff [1999] ECR I-6385, paragraph 8

4 Case 8/74, Procureur du Roi v. Benoit and Dassonville, [1974] ECR 837 at 852

5 Case 120/78, Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon) [1979] ECR 649.

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protection is now recognised as such a mandatory requirement. However, the Cassis doctrine can only be applied where the test of proportionality and non-discrimination are fulfilled.

3.4 Environmental Protection within the WTO and EU Frameworks

It is quite obvious that there is an imbalance between free trade and protection of the environment in the WTO legislative trade framework. The main objective in the GATT Treaty and the TBT Agreement is to create free trade. Products shall be able to circulate wherever they are produced, trade barriers are in principle forbidden. States have powers to regulate for environmental protection but these regulations could be considered as trade barriers and must therefore be justified in accordance with the GATT Treaty or the TBT Agreement, if questioned. This means that there is a presumption that products have the right to circulate within the WTO-area unless the individual state has not justified their environmental requirements in question.

This construction lays all the burden of environmental protection on the individual state, while producers have no obligations to take environmental considerations into account.

The same legal construction is found in Art 28 of the EC Treaty and the scope of Art 28 is wider than the scope of the corresponding provisions in the GATT Treaty and the TBT Agreement. There is, however, an important difference between the EU and the WTO. The EU has power to adopt legislation for environmental protection and the protection of environment is one of aims of the EU. WTO on the other hand has neither power to regulate for environmental protection, nor the aim to protect the environment, why imbalance between free trade and environmental protection arise.

This would in practise imply that products would have access to a free market, as long as a state has not justified the environmental requirements in accordance with the GATT treaty and the TBT Agreement, although the product itself does not fulfil essential environmental requirements. If one wants producers to take responsibility for the environmental impacts of the products one may say that there is a need to lay some basic obligations on the producer.

One way to achieve this is to turn the exception for environmental protection in the GATT Treaty (Art XX (b) and (c) and the TBT agreement (Art 2.2) in to a general rule for producers. In an EC directive for products it would be possible to direct that products have to be designed, so that they protect human, animal or plant life or health and conserve exhaustible natural resources.

It would then be possible to give the member states the possibility to prohibit products that are not regulated in another directive on the market that substantially diverge from this general rule. When the member states decide on this they have to take into account that the prohibition does not constitute an arbitrary or unjustifiable discrimination on international trade or a disguised restriction on international trade. They should probably also take principle 11 in the Rio Declaration into account when deciding if the products fulfil the requirements, which in practice would mean that products produced in developing countries would get lower standards. To avoid that member states abuse the powers laid upon them it would be possible to let the EC commission decide if the prohibition in question is in accordance with the directive.

The aim of such a directive would not be to prohibit as many products as possible on the ground that the products deviate from the requirements. The idea is to lay some burden on the producers to take environmental considerations into account when the product is designed. Such a burden would most certainly lead to a voluntary standardisation. It would work as an incentive for producers to elaborate standards for environmental protection since none of the producers would want to risk producing products that could later be banned.

3.5 Conclusions and considerations from the Workshop

- In his presentation, Jouni Alanen, the author of the TemaNord report 2000:549 Trade Regulations and product environmental measures, emphasised that actions to induce the "greening" of products should be taken at the European level. States are however, according to Alanen, free to set their level of protection as long as the principle of proportionality is observed.
- Alanen also pointed out that the TBT agreement forbids unnecessary trade barriers and that it is important to look at the applicability of the TBT agreement.
- Christian Poll delivered some comments from the Danish EPA on the TemaNord report 2000:549. The Danish EPA is of the opinion that the report was too focused on the problems with the EC-treaty and the WTO-rules. It would have been better to focus on the possibilities to work with the greening of products within the framework of the EC-treaty and the WTO-rules, exemplified by the concept of New Approach. According to Poll enterprises can, within a IPP framework, be sectioned into different environmental levels; at the bottom we find enterprises with a red profile (producing the worse products from an environmental point of view), then we find enterprises with a white profile (producing the average products from an environmental point of view) and at the top we find enterprises with a green profile (producing the best products from an environmental point of view). The concept of the IPP is to influence companies to produce green products instead of white products, and to influence consumers to buy green products instead of white products.
- There seemed to be a general approval of the ideas put forward in section 3.5. Several participants thought that it would be interesting to further examine if it would be possible to draft a directive that puts a general obligation on producers to design their products, so that they protect human, animal or plant life or health and conserve exhaustible natural resources. Such a directive could serve as motivation for the standardisation bodies to elaborate environmental standards for products.
- Would it be appropriate to more clearly point out the greening of products as one of the aims of an environmental policy for the EC in article 6 and/or article 174 in the EC treaty? The question was raised during the workshop, but not answered.

4 New Approach

This section is opened with a more extensive description of the New Approach. This is followed by a discussion of the use of New Approach within the WTO framework. The section is concluded with a summary of advantages and disadvantages of New approach.

4.1 What is the New Approach?

To fully understand the New Approach it is important to be familiar with the development that led up to the formulation of the policy. The development of the New Approach is based on the same policy concerns that underlie the Cassis de Dijon case. The cassis doctrine introduced the *Principle of Equivalence* and *Rule of Reason*. As long as a product is lawfully produced and marketed in one Member State of the EU it is entitled to access the markets of all other Member States. The Cassis doctrine raised concerns as free trade was promoted with little regulative control or guarantees. It was questioned if national removal of technical barriers to free trade on the basis of Article 28 and 30 was sufficient to secure the realisation of a true common market without simultaneous implementation of additional community-wide legislation.

Decisions by the ECJ based on Art 28 grants a certain amount of uniformity among Member States since no positive actions that are contrary to Art 28 are allowed. In fact, this can be seen as a form of negative harmonisation. However, restrictions to free movement of products, which may be acceptable under Art 28 and 30 of the EC Treaty and the Rule of Reason can only be avoided or eliminated through technical harmonisation on Community level, i.e. positive harmonisation.

The focus of the EC was then widened to include positive harmonisation, i.e. Community regulations. Initially, harmonisation was slow due to that the legislation became highly technical as it had the objective of meeting individual requirements of each product category. Another factor that slowed down the process was that the adoption of technical harmonisation directives was based on unanimity in the Council. It is in this context that the idea of the New Approach developed. In fact, New Approach conforms to the policy concerns that underlie the decision in Cassis.

The New Approach, which included a new regulatory technique and strategy, was laid down by the Council Resolution of 1985 on the New Approach to technical harmonisation and standardisation. "New Approach directives" are total harmonisation measures that define binding essential requirements. Below are outlined certain standard elements of New Approach directives.[6]

(a) Harmonisation is limited to essential requirements;

(b) For a product to be placed on the market and put into service it must fulfil the essential requirements;

(c) Harmonised standards that have been transposed into national standards are presumed to conform to the corresponding essential requirements. The reference number of these harmonised standards is published in the Official Journal;

(d) Producers are free to choose the means by which they demonstrate that products comply with the essential requirements. One way of doing so is by applying harmonised standards;

6 This compilation of elements is outlined in European Commission, Guide to the implementation of directives based on the New Approach and the Global Approach, 2000, p 8

(e) In the applicable directive are outlined different conformity assessment procedures, which the manufacturer may chose between.

As to date, the New Approach and standardisation has mostly been used in legislation on health and safety aspects of product design and manufacturing. The only experience of using New Approach Technique specifically for environmental design of products is made in the Packaging and Packaging Waste Directive[7]. It is also included in the planned directive on Electrical and Electronic Equipment (EEE) (Commission's working paper for a proposal for a directive on electrical and electronic equipment, Feb. 2001).

4.2 New Approach within the framework of the WTO

Since the powers for the EU to take actions to protect the environment are quite wide according to the EC Treaty, it is quite possible that EC-regulations concerning environmental requirements for products could get in conflict with Art III or Art XI of the GATT Treaty (see 2.3). The EC-regulations (measures) then have to be justified in accordance with Art XX (b) or (c) of the GATT Treaty.

Conflicts can also arise between EC provisions concerning environmental requirements for products and the TBT Agreement. If the product regulation in question falls under the scope of the TBT Agreement, the regulations shall not create unnecessary obstacles to international trade and the regulations shall not be more trade restrictive than necessary to protect human health, safety, animals or plant life or health, or the environment.

4.3 Advantages with the New Approach legislative technique

- New Approach directives might provide flexible and efficient means of promulgating EC wide product-related rules displacing a multiplicity of national measures, which possibly could undermine the internal market.[8] New Approach directives are more flexible for example because standards adopted in relation to a New Approach directives are more easily altered than a directive which aims at meeting individual requirements of each product category.
- New Approach can reduce the possible stifling effect of uniformity. The Parliament/the Council sets the basic rules governing health and safety of products but outside that area the Commission can permit flexibility.[9]
- The New Approach involves industry (mainly via standardisation).[10]
- The New Approach indirectly facilitates the process of enacting directives; the difficulties to reconcile interests of Member States in order to enact "regular" directives containing technical specifications is significant. New Approach forces the parties to agree and thus facilitates harmonisation.

7 The Packaging Directive (EC Directive 95/62)

8 Rod Hunter et al, "Legality of the Draft Directive on the Impact on Environment of Electrical and Electronic Equipment", Report from Hunton & Williams, p. 4. This is given as one of the reasons for the fact that the New Approach has gone unchallenged.

9 Stephen Wheatherill and Paul Beaumont, EC Law - the Essential Guide to the legal workings of the European Community, Penguin Books, 2nd edition, 1995 s 482 f.

10 Rod Hunter et al, "Legality of the Draft Directive on the Impact on Environment of Electrical and Electronic Equipment", Report from Hunton & Williams, p. 3. To involve industry was one of the objectives underlying the politically compromise that formed the New Approach.

4.4 Disadvantages with the New Approach legislative technique[11]:

- The New Approach is appropriate only where it is genuinely possible to distinguish between essential requirements and technical specifications
- Products has to be sufficiently homogenous or a horizontal hazard identifiable to allow common essential requirements. Where products vary their characteristics vary and it will be difficult to formulate "essential requirements".
- Product area or hazard must be suitable for standardisation Accordingly, the New Approach has not been used in sectors with a well formed structure of legislation adopted prior to 1985, or where provisions for finished products and hazards related to such products cannot be laid down. Areas where New Approach has not been utilised are for example, foodstuffs, chemical products, pharmaceuticals products, motor vehicles and tractors.
- "Reliance on the mutual recognition of national standards at the expense of positive harmonisation has a fashionable deregulatory flavour. In the long run, however, harmonisation is more apt to create uniform regulatory environment and produce the full advantages of the single market".[12]

5 Usefulness of the New Approach for Environmental Protection

This section deals with the possibilities to use the New Approach as legislative mean to achieve environmental protection. The below mentioned views originate mainly from written material provided by Swedish Environmental Protection Agency and from interviews made with people from different authorities and organisations.

5.1 Is the New Approach needed for environmental protection?

The need for the New Approach as an instrument for environmental protection has been questioned. Some people are of the opinion that the scope for states to regulate for environmental protection is wide enough and with the powers for the EU to legislate with ordinary directives for environmental protection, there is no need to use the New Approach. We have about 200 EC directives concerning environmental protection and all Member States have beside these, additional national regulations for environmental protection.

Others claim that these people do not fully understand the implications of art 28 in the EC-treaty. The scope for Member States to regulate is far more limited than opponents to the New Approach understand. Some also assert that new national regulation for environmental protection is undesired, since it will create new barriers to trade, which could have a negative impact on both the whole economy and the Third World companies since they will find it more difficult to compete.

Some in favour of the New Approach as an instrument for environmental protection believe that the New Approach will be a way of achieving a general greening of products. They argue that neither the EU nor individual Member States can regulate the environmental requirements for every product that is deemed to be in need of regulation. That process would be too time-consuming, too expensive and there are not enough experts. To achieve the greening of products, the EU and state administrations will need help from experts in the private sector. Additionally, it

11 The following arguments are collected from European Commission, Guide to the implementation of directives based on the New Approach and the Global Approach, 2000, p 8

12 In the Single European Act: a new Constitution for the Community?" [1989] Col. J. Transnat. L 529, 540 n. 44

will be difficult to achieve consensus regarding technical specifications that promotes environmental protection on a EU level. A standardisation body would facilitate the conclusion of standards.

5.2 Are technical regulations for environmental protection a real threat to international trade?

There has been doubt about the importance of regulations for environmental protection as a real threat to international trade. It is often said that these regulations will hinder free trade, but it is not shown that this is really a fact. Free trade needs some different regional and national regulations to become fully accepted by the majority of people. For example; their must be some room for France to keep certain regulations for cheese making even if other States might prohibit the method saying it is a health risk and consider the French regulation as a restriction to trade.

Others say that regulations for environmental protection are a threat to international trade. There are several examples of when its has been confirmed that the regulations for environmental protection are merely means to protect national industry and interests.

5.3 Will the New Approach have negative or positive effects for the protection of the environment?

There has been concern that the New Approach will hinder the EU and separate Member States to set stricter standards than the standards harmonised by the New Approach. This will especially be a serious problem if the standards that are set have a low ambition level.

Spokesmen for the New Approach believe that it would integrate a holistic approach to environmental thinking into the product development process. Environmental problem connected with products cannot solely be solved by the EU or state administrations, the questions regarding greening of products are too complicated and indistinct. The private sector has to be involved in the work on greening products and the New Approach will facilitate such involvement.

5.4 In which areas of environmental protection/for what products could a New Approach be appropriate?

To be able to use the New Approach for the greening of products, it is necessary that the products are sufficiently homogenous or that different products have the same identifiable hazards.[13] Otherwise it will be impossible to set the essential requirements.

There seems to be a general understanding that the New Approach should not be used to regulate hazardous chemicals. That is mainly because of the nature of hazardous chemicals. In all respects it is very important that hazardous chemicals are for example not used incorrectly. A traditional directive focused on meeting individual requirements of that product category offers greater security and protection. However, there are also certain areas that can be singled out as appropriate for New Approach. New Approach seem suited for regulation of certain aspects of the product life cycle that are not regulated in other pieces of legislation and where the effects of each product is less serious. These aspects would be possible to regulate on a product group basis or on effect basis. The question is then if it is possible for the EU to agree on the essential requirements. These requirements will also have to be sufficiently precise and distinct to elaborate further standards. If the EU cannot elaborate essential requirements, it is questionable if there really exist a need to elaborate standards or to regulate products and the environmental effects.

13 European Commission, Guide to the implementation of directives based on the New Approach and the Global Approach, 2000, p 8

5.5 Is it possible to ensure that standards are elaborated and will the environmental interest be sufficiently taken into account?

Standard of "essential requirements"

The question concerning if it is possible to ensure that standards are elaborated and then if they are, will the environmental interest be sufficiently taken into account relates to the problem mentioned above concerning if essential requirements will be sufficiently precise and distinct to elaborate further standards. The distinction of the essential requirements will also be of absolute importance for the environmental interest to be taken sufficiently into account. If the essential requirements will be sufficiently precise it will be easier to ensure that the environmental interest will be taken into account. If they, on the other hand, are indistinct and imprecise, the risk that the environmental interest is not taken into account is greater.

Environmental concerns in standards

Some people have expressed their concerns, based on the experience from the work in other standardisation projects, that the influence from the producers is far to great in the standardisation process. The publics interest of health, security and likewise, are not sufficiently taken into account. The environmental groups and state administrations have not the necessary means and experts to ensure that the public interests are observed in the standardisation process. They also state that the lack of interest to integrate environmental requirements in standards is proved by the fact that standard that have been elaborated to this point have not integrated environmental requirements.

Others say that the lack of environmental requirements in the present standards is explained by the fact that the neither EU or anybody else had environmental protection in mind when existing essential requirements were set. One cannot expect technical standards for environmental protection to develop if no one has been able to even set the essential requirements. It would also be easier for environmental groups (NGOs) and state administrations to monitor and ensure that the environmental interest will be taken into account if the essential requirements for a product group or type of effect are regulated. NGOs and state administrations would then know what standardisations groups to cover. Today NGOs and state administrations are trying to cover all groups of standardisation, without knowing which one of the standardisation groups that could be of interest - and none of the standardisation groups have a clear mandate to take environmental requirements into account.

5.6 Will the New Approach hamper international or national environmental regulations? Can this be avoided?

There is no explicit prohibition in the EC treaty that will hinder the EU to amend directives adopted in accordance with New Approach or adopt new legislation that replace the New Approach directive. In practise, however, it will be very difficult to remove a New Approach directive when standards have been elaborated.

The possibilities for the Member States to require stricter standards than the essential requirements and the adjoining standards will be difficult owing to the fact that the New Approach directives are adopted in accordance with Art 95 EC treaty (se 2.4). The New Approach directives do, however, usually include a safeguard clause. The possibilities for the Member States to use the safeguard clause are rather limited.

5.7 Conclusions and considerations from the Workshop

The questions in section 5.1-5.6 were discussed during the workshop. The participants' opinions diverged quit frequently in line with the discussion in 5.1-5.6. Most of the workshop participants however seemed to agree on the following matters:

- There is a risk that the standardisation process will create standards based the lowest common denominator. This risk has to be observed if the New Approach is to be used for the greening of products.
- The New Approach can be suitable for products that involve a lot of technical specifications.
- New Approach directives can, and should, add a life cycle perspective into the area regulated. This will be difficult to achieve in other ways.
- The success of the New Approach would be facilitated if the European Commission could define more detailed, environmental, essential requirements for products. In line with this, the mandate and instructions to CEN could be more detailed.
- The New Approach process involves other parties than the government. This will raise the level of consciousness of various stakeholders and lighten the burden on the public authorities.
- If New Approach directives are used, governments can focus on essential requirements and would then be able to handle more product categories without getting caught up in discussions of technical specifications.
- It is only advisable to use the New Approach in homogenous, well-defined areas. It was questioned if the area covered by the proposed EEE-directive is such a homogenous, well-defined area, or if it is homogenous but maybe too wide. The lack of success of the Packaging and packaging waste directive[14], could maybe be explained by this fact as it does not cover a homogenous, well-defined area.
- The essential requirements should not be used to eliminate differences in political opinions. These should be eliminated at the political level and not by standardisation bodies. The standardisation bodies can however sort out technical differences.
- The New Approach should not be used for products where the environmental impacts from the products are unambiguous. This applies for example for hazardous chemicals with chronic health or environmental effects.
- An advantage with the New Approach directives is that they involve third world countries through the Vienna Agreement where CEN and ISO adopt each other's standards by a short procedure.
- It would be interesting to examine if it is possible to introduce environmental requirements into already existing New Approach directives.

14 EC Directive 95/62

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6 Final conclusions from the workshop

The workshop participants seemed to agree upon that environmental requirement for products should be set on the European level. The pros and cons of using New Approach directives in the environmental field were vividly discussed. Some of the participants preferred "traditional" directives, while others referred to these directives as being "stone age" directives.

One obvious conclusion is that the concerns raised in connection with New Approach directives has to be taken into account. The Packaging and Packaging waste directive and the EEE-directive should be thoroughly evaluated.

It is however also quite obvious that the New Approach could have great advantages, for instance increased stakeholder involvement. Furthermore, it would be possible to develop standards including environmental requirements, much faster than ordinary directives can be adopted, while avoiding conflicts with the WTO-regulations. Most of the experiences of the work with standards under New Approach directives until now has however not shown impressing speed improvements, rather the opposite.

It is also in this context important to further analyse if it would be possible to adopt a general directive that puts oblige producers to design products that protect human, animal or plant life or health and conserve exhaustible natural resources. Such a directive could, at least in theory, stimulate the standardisation bodies to elaborate environmental standards for products.

Annex 1: Workshop Program

09.00	Coffee and registration
09.30	Presentation of the Nordic POMS-strategy *Eva Ahlner, Swedish EPA*
09.45	"Trade regulations and product-oriented environmental measures" A presentation of the conclusions of the report *Jouni Alanen, Environmental & Business Lawyers*
10.15	Comments on the conclusions of the report by the Danish EPA *Ditte Sakse, Miljöstyrelsen*
10.45	Identification of possibilities to take actions to reduce environmental impacts from products with regard to the trade rules of the WTO and the EU *A discussion lead by Magnus Fröberg at Lagerlöf & Leman Layers*
	Lunch
13.30	Presentation of the of the working paper on a proposed EEE directive- A pilot New Approach directive *Christian Poll, Miljöstyrelsen*
13.45	Comments on the directive from the Nordic countries
	Coffee
15.00	The potential of using the New Approach legislation to reduce the environmental impacts from products *A discussion lead by Magnus Fröberg at Lagerlöf & Leman Layers*
16.30	Concluding remarks

Annex 2: Participants

Name	*Country*	*Organisation*
Eva Ahlner	*Sweden*	Naturvårdsverket
Jouni Alanen	Finland	Attorneys House Ltd.
Christer Arvius	*Sweden*	Kommerskollegium
Karin Berkestad	*Sweden*	Linklaters Lagerlöf
Ilkka Cantell	Finland	Handels- och Industriministeriet
Inger-Grethe England	Norway	Norwegian Pollution Control Authority
Magnus Fröberg	*Sweden*	Linklaters Lagerlöf
Kerstin Grönman	*Sweden*	Miljödepartementet
Mikael Häggiöf	*Sweden*	Naturvårdsverket
Carsten Riis Fredriksen	Denmark	Dansk Standard
Inger Klöfver	*Sweden*	Naturvårdsverket
Camilla Lommi-Kippola	Finland	Miljödepartementet
Karin Nordström	*Sweden*	Utrikesdepartmentet
Christian Poll	Denmark	Miljöstyrelsen
Karin Thorán	*Sweden*	KEMI
Åsa Wiklund-Fredström	*Sweden*	Naturvårdsverket
Helén Ågren	*Sweden*	Naturvårdsverket
Bente Ågren	Norway	Norwegian Pollution Control Authority
Karin Öberg	*Sweden*	Naturvårdsverket

Annex 3: The possibilities to regulate for environmental protection