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The New Approach in Setting Product Standards for Safety, Environmental Protection and Human Health

Directions for the Future

Milieu Ltd.

Danish Environmental Protection Agency
Danish Ministry of the Environment

Contents

Introduction

The use of the New Approach in European legislation as introduced in 1985 has given rise to concerns as to whether this approach is suitable or sufficient where the task for the standard setters includes securing environmental and (long-term) health protection. For example, only one of the five packaging standards produced by the European standardisation body CEN for the Packaging and Packaging Waste, that relating to composting, has been fully approved by the European Commission under the New Approach procedure.

In light of those concerns, the Danish Ministry of Trade and Industry and the Danish Environmental Protection Agency (Danish EPA) agreed to sponsor a Workshop that took place in Copenhagen on 29-30 November 2001. Participants included officials from Member State ministries of environment and industry as well as the European Commission, representatives from the European standardisation bodies, industries concerned, non-governmental organisations representing environmental and consumer interests, and academics. Appendix D of this Report provides a full list of participants.

The workshop was intended to provide an opportunity for sharing experiences and for focussed discussions aimed at developing recommendations for potential solutions at national and European levels. Two issues were regarded as central:

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

- Is the standardisation process able to provide a structure that furthers innovation, and, in particular, innovation that leads to more environmentally sustainable products and production forms? In other words, is the New Approach an applicable tool in an integrated product policy (IPP) for promoting environmental product innovation?

At the time of the workshop, the European Commission was in the process of preparing a White Paper on an Integrated Product Policy. The workshop was therefore also intended as a contribution to this European process.

These proceedings provide the workshop agenda, the background papers prepared before the workshop, and summaries of the presentations and the subsequent discussions.

Additional information, including speakers' presentations (overheads and other material) has been compiled into an online report (*Workshop on the New Approach, Copenhagen, 29-30 Nov. 2001, Working Report no. 23/2002*) published by the Danish EPA. This report is available on the Internet at the Danish EPA website: http://www.mst.dk/

The conclusions expressed in this document are those of the consultants and do not necessarily reflect the views of the Danish Ministry of Environment and the Danish EPA.

Sammenfatning og konklusion

Den Ny Metode har vist sig at være et effektivt og fleksibelt redskab i udviklingen af en række produktstandarder, der sigter mod et højt beskyttelsesniveau for offentligheden, specielt i forbindelse med produktsikkerhed. Samtidig er der dog rejst tvivl om anvendelsen af den Ny Metode i visse sammenhænge, specielt hvad angår langtidseffekter på menneskers sundhed og miljøbeskyttelse, og hvor politiske beslutninger vil være nødvendige.

I de senere år har debatten om den Ny Metodes rolle i udviklingen af standarder inden for sundhed og miljø for alvor skilt vandene. Dette var baggrunden for at organisere workshoppen om den Ny Metodes rolle i etableringen af produktstandarder for sikkerhed, miljøbeskyttelse og menneskers sundhed (København, 29.-30. november 2001). Formålet med workshoppen var at samle alle grupperinger til konstruktive diskussioner om mulige løsninger.

I workshoppens afsluttende plenumdiskussion beskrev en af deltagerne den traditionelle lovgivning som ikke blot den "Gamle Metode", men "Stenaldermetoden". Dette ordvalg i diskussionerne om den Ny Metode giver to associationer. Den ene handler om tingenes flygtighed: Forskellige metoder afløser efterhånden hinanden. Den anden er det underforståede billede af fremskridt: Hver ny metode er på et eller andet punkt den gamle overlegen.

På basis af diskussionerne på workshoppen i København kan det slås fast, at ingen af disse associationer er helt dækkende. Uanset hvordan man definerer "stenalder" og "gammel", har forskellige former for lovgivning stadig en naturlig rolle at spille, sideløbende med hinanden og relevante i egne, specielle sammenhænge. På områder med stor risiko, eller hvor begrænsninger vil medføre store omkostninger for visse dele af samfundet, kan det f.eks. være nødvendigt med vigtige politiske beslutninger. Der hersker generel enighed om, at sådanne beslutninger ikke kan uddelegeres til private standardiseringsorganisationer som CEN, CENELEC og ETSI. Samtidig er der også almindelig enighed om nødvendigheden af at

supplere traditionel lovgivning med andre mekanismer og finde en bedre balance mellem de forskellige former for lovgivning.

Det er vigtig at erkende de betydelige forskelle, der eksisterer mellem traditionel lovgivning og den Ny Metode. På de områder, hvor EU endnu ikke har vedtaget lovgivning, eller hvor EU-lovgivning er vedtaget i henhold til traktatens artikel 175, kan medlemsstater styrke den traditionelle lovgivning i overensstemmelse med nationale behov, specielt under henvisning til bekymring for miljøet. Men Ny Metode-direktiver er hidtil blevet vedtaget i henhold til traktatens artikel 95. Eftersom de sigter på at tilvejebringe det indre marked, har det ikke været tilladt for medlemsstaterne at vedtage mere restriktiv lovgivning på disse områder.

I visse tilfælde kan traditionel lovgivning med påbud og kontrol være påkrævet. Forslaget til direktiv om begrænsning af anvendelse af visse farlige stoffer i elektrisk og elektronisk affald er et meget aktuelt eksempel. I andre tilfælde fastlægges tekniske krav i mellemstatslige fora som f.eks. en arbejdsgruppe nedsat af EU eller en anden myndighed, hvor medlemsstater og andre interessenter er repræsenteret. Dette kan være en brugbar løsning i situationer, hvor det ikke er muligt at drage en fast grænse mellem politiske og tekniske emner.

Den Ny Metode er heller ikke et statisk, veldefineret koncept. En af Kommissionens embedsmænd har f. eks. foreslået, at emballagedirektivet – der beskrives som et Ny Metode-direktiv i Kommissionens officielle evaluering af den Ny Metode – nok ikke skal betragtes som et traditionelt Ny Metode-direktiv. Faktisk omhandler de centrale regler i dette direktiv slet ikke sikkerhed i traditionel forstand, men drejer sig i højere grad om emballagefremstilling og emballagesammensætning, mulighederne for genbrug og genindvinding af affaldet.

Samtidig har andre direktiver, der ikke betragtes som Ny Metode-direktiver, en række træk til fælles med disse. Der gives flere eksempler på dette i baggrundsmaterialet til workshoppens første samling.

Diskussionerne i workshoppen tyder kort sagt på, at opfattelsen af den Ny Metode som en veldefineret enhed, der erstatter og over-

flødiggør ældre udgaver af mindre fyldestgørende lovgivning, ikke kan opretholdes. Den Ny Metode er nærmere et vellykket lovgivningsmæssigt initiativ, der har fungeret godt i de mange år, det har været anvendt til at udvikle sikkerhedsstandarder for specifikke produktgrupper.

Den Ny Metode har udviklet sig, siden den blev introduceret for mere end 16 år siden, og en afgrænset definition af dette lovgivningsværktøj vil nok ikke være dækkende for de forskellige måder, hvorpå metoden har været anvendt til at indføre standardisering som en del af gældende EU-lovgivning. Det er sandsynligt, at der forsat vil ske udvikling på dette område.

Produktsikkerhed var et kontroversielt emne, da den Ny Metode i begyndelsen blev anvendt til at udvikle standarder på området, men emnet er blevet mindre kontroversielt med tiden og betragtes ikke længere som specielt problematisk. Det er ret sandsynligt, at etableringen af et teknisk forum, hvor alle relevante parter er aktivt involveret i at finde løsninger, som alle kan være enige om, har været befordrende for denne udvikling. Rammedirektivet om produktsikkerhed og produktansvarsdirektivet har også medvirket til udviklingen.

En tilsvarende udvikling kan også tænkes inden for områder som f.eks. menneskers sikkerhed og miljøbeskyttelse. Manglen på almindelig miljøansvarslovgivning og de vanskeligheder, som miljøgrupper har oplevet i forbindelse med at deltage i arbejdsgrupperne for standardisering og at øge hensynet til miljøet i udviklingen af standarder, kan dog betyde, at fremskridt i denne retning nok bliver vanskelig.

Da standardisering skulle anvendes i forbindelse med emballagedirektivet blev processen vanskeliggjort af en manglende forståelse for de to involverede parters forskellige roller: det lovgivende systems ansvar for at løse politiske problemer og standardiseringsudvalgenes ansvar for at løse tekniske problemer. Specielt udgjorde manglen på relevante feedback-kanaler mellem de to parter et problem.

Hvis standardiseringsudvalg i fremtiden skal anvendes til at opnå enighed om tekniske løsninger på områder med politisk uenighed, vil

det være nødvendigt med bedre systemer, der sikrer, at de forskellige spørgsmål bliver løst af den ansvarlige part.

Flere oplægsholdere understregede den stadig mere centrale rolle, som ISO (den internationale standardiseringsorganisation) indtager i standardiseringsprocessen. Denne tendens vil med sikkerhed blive yderligere forstærket i fremtiden, hvor Den europæiske Standardiseringsorganisation (CEN) vil komme til at spille en rolle som regional standardiseringsorganisation i brede, globale aftaler. Man må erkende dette i udviklingen af lovgivning, der omfatter standardisering, og sikre sig, at udviklingen i EU kan bidrage med brede løsninger, som ikke udgør tekniske handelshindringer.

"Stenaldermetoden", den "Gamle Metode" og den "Ny Metode" skal måske i højere grad ses som en udvikling, hvor det lovgivningsmæssige repertoire har udviklet sig og har fået mere og mere fintfølende værktøjer med egne styrker og svagheder. I dette perspektiv er kunsten ved at udvikle ny lovgivning at sikre sig, at man vælger det mest relevante værktøj.

Det store udvalg af mulige fremgangsmetoder blev fremhævet på den samling, der fokuserede på anvendelse af den Ny Metode til udvikling af innovative løsninger, som reducerer produkternes miljøbelastning. Dette emne drejede sig ikke om, hvorvidt lovgivningen skulle følge den Ny Metode til punkt og prikke for at styre nytænkning i retning af mere miljøvenlige produkter. Det drejede sig snarere om en erkendelse af, at de elementer, der allerede var taget i brug for at støtte miljømæssige forbedringer af produkter – lige fra forbud mod stoffer til markedsbaserede incitamenter som miljømærkning – kunne suppleres og forbedres med elementer fra den Ny Metode.

I forbindelse med Kommissionens arbejdsdokument, der omfattede et forslag til direktiv om elektrisk og elektronisk udstyr[1], blev det f.eks. fremført, at når det drejer sig om brede produktgrupper, hvor specielle miljøaspekter endnu ikke er klart afgrænsede, kan anvendelsen af den Ny Metode til opstillingen af præstationsstandarder (dvs.

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

ledelsesstandarder) spille en afgørende rolle, når man ønsker at fremme livscyklustanken i produktdesign. Gennemskuelige oplysninger og solid dokumentation kan være nogle af drivkræfterne bag ledelsessystemer, der fører til miljømæssig nytænkning. Efterhånden som man får mere viden og større erfaring, kan man så få mere specifikke produktstandarder og/eller lovmæssige krav på plads.

Flere deltagere fremhævede nødvendigheden af fortsat at opstille centrale krav som minimumsstandarder for markedsføring af et produkt på det indre marked. Andre slog til lyd for rammelovgivning, der lagde ansvaret for et produkts miljømæssige sikkerhed over på producenterne. De produktorienterede miljøledelsessystemer (POMS) blev rost som metoder, der kan anvendes til at fremme miljømæssig tænkemåde på design- og produktionsniveau.

Sammenlignelige og dokumenterbare kriterier for miljømæssig nytænkning inden for produktdesign, baseret på livscykluskriterier for specifikke produktgrupper og anvendt sammen med et system af miljøvaredeklarationer, kunne sætte forbrugerne i stand til at foretage bedre begrundede valg og forbedre producenternes miljømæssige nytænkning. De kriterier for miljømærkning, som EU's Miljømærkenævn er nået frem til, kunne anvendes som kriterier. Alternativt kunne kriterier blive defineret af standardiseringsgrupperne eller endog specielt nedsatte produktpaneler.

En af de visioner, der blev fremsat på workshoppen, var et koncept med rammelovgivning, som integrerer miljøvaredeklarationer med krav til minimumsbeskyttelse af sundhed og miljø, evt. som et Ny Metode-direktiv. De kriterier, der opstilles i et sådant system, skulle være mere vidtgående end kriterierne for miljømærkning, så man på denne måde kunne få producenterne til i højere grad at tænke i miljømæssige nyskabelser.

På baggrund af diskussionerne på workshoppen ser det ud til, at en kombination af de nedenstående elementer kunne gøre det muligt at nå længere med den Ny Metode og standardiseringen end med traditionel lovgivning. Samtidig kunne man stimulere miljømæssig nytænkning:

- lovpligtige minimumskrav om opstilling af definitioner, en fælles opfattelse og et minimumsniveau for miljøbeskyttelse (gerne inden for en produktgruppe);
- frivillige, men dokumenterbare ordninger som f.eks. opstilling af kriterier med henblik på at inspirere markedet til at konkurrere specifikt på miljømæssige parametre;
- et gensidigt anerkendt forskningsmæssigt grundlag for valget af kriterier baseret på en livscyklusanalysemetode;
- systemer som f.eks. miljøvaredeklarationer eller produktorienteret miljøledelse, der kan stimulere en tilgang af pålidelige data i hele produktkæden. Det vil sikre et minimumsniveau i datakvalitet, pålidelighed og åbenhed mellem interessenter på markedet;
- ekspertgrupper med repræsentanter fra forskellige interessenter, der skal evaluere og forbedre produktkriterierne på et teknisk fornuftigt grundlag. Dette vil sikre, at parametrene opstilles uafhængigt af særinteresser;
- høringsrunder blandt interessenter på alle relevante niveauer i standardiseringsprocessen;
- økonomiske værktøjer tilvejebragt på EU-plan eller nationalt plan, der sigter på at fremme nytænkning i den private sektor, herunder små og mellemstore virksomheder.

I denne sammenhæng fremstår den Ny Metode som et organisk lovgivningsværktøj. Metoden har vist sin berettigelse på de områder, hvor den traditionelt har været anvendt. Dens tilpasningsevne, der er demonstreret på de mange områder, hvor nogle af metodens elementer har været anvendt, er et bevis på dens anvendelighed – med eventuelle tilpasninger – i en større sammenhæng.

Nogle af de spørgsmål, der stilles i baggrundsmaterialet til workshoppen, antydede, at man må vælge mellem forskellige former for lovgivning, der gensidigt udelukker hinanden. Kunsten ved at finde de rigtige løsninger består måske i højere grad i at vælge passende kombinationer af værktøjer fra det eksisterende lovmæssige fundament og anvende dem på de forskellige spørgsmål uden at insistere på, at en bestemt lovgivning er den eneste anvendelige.

Summary and conclusions

The New Approach has proven an effective and flexible instrument for developing a number of product standards aimed at providing a high level of protection for the public, particularly with respect to product safety. At the same time, concerns have been raised with respect to certain applications of the New Approach, particularly where long-term impacts on human health and environmental protection may be in question and where political decisions may be required.

In recent years, the debate among stakeholders concerning the role of the New Approach to develop health or environment-related standards has become highly polarised. It is in this context that the Workshop on the New Approach in Setting Product Standards for Safety, Environmental Protection and Human Health (Copenhagen, 29-30 November 2001) was convened, with the aim of bringing all parties together for constructive discussions on possible solutions.

In the final plenary discussion of the Workshop, one participant described conventional legislation as not just the "Old" Approach, but as the "Stone Age" approach. Use of this imagery in New Approach discussions conveys two concepts. The first is one of transience: different forms succeeding each other as time progresses. The other is the implicit concept of progress: that each succeeding form is in some way superior to the form that it supersedes.

From the discussions that took place at the Copenhagen Workshop, it can be concluded that neither concept is valid. However "Stone Age" and "Old" are defined, there is still a natural role for different types of legislation, coexisting and relevant in their own context. For example, in areas where there is either a high risk or where restrictions could have high costs for certain sections of society, significant political decisions may be required. There is general agreement that such decisions should not be delegated to the private standardisation organisations such as CEN, CENELEC and ETSI. At the same time, there is general consensus concerning the need to

complement traditional regulation with other mechanisms, and to achieve more balance among the different forms of regulation.

It is important to recognise the significant differences that exist between conventional regulation and the New Approach. For those areas where the EU has not yet enacted legislation or where EU legislation has been adopted under Article 175 of the Treaty, Member States may strengthen conventional regulations according to national needs, in particular to address special concerns for the environment. But New Approach Directives have until now been adopted under Article 95 of the Treaty. Since they are aimed at achieving the internal market, they do not permit Member States to enact stronger national regulations in those areas.

In some cases, conventional "command and control" legislation may be required. A very recent example is the Restrictions on Hazardous Substances Directive proposed for the control of hazardous substances in electrical and electronic waste. In other cases, technical requirements may need to be developed in intergovernmental forums, such as an EU or other governmental working groups comprising Member States representatives together with other stakeholders. This can be a viable solution in situations where it is not possible to draw a clear line between political and technical issues.

Nor is the New Approach a static, well-defined concept. For example, one European Commission official suggested that the Packaging and Packaging Waste Directive – listed as a New Approach Directive in official Commission reviews of the New Approach — should not be regarded as a conventional New Approach Directive. Indeed, the essential requirements of this Directive do not address issues of safety in the conventional sense at all, but rather relate to the manufacturing and composition of packaging, its potential for reuse and the possibility of recovering the waste.

At the same time, other Directives not considered New Approach Directives share a number of characteristics of such Directives, as per several examples set forth in the background papers prepared for Session I of the Workshop.

In short, the image of the New Approach as a well-defined entity, replacing and superseding earlier forms of less satisfactory legislation, is not a conclusion that can be sustained on the basis of the Workshop discussions. Rather, the New Approach is a successful legislative initiative that has functioned well in the many years it has been used to develop safety standards for specific product groups.

The New Approach has evolved since its original introduction more than 16 years ago, and a narrow definition of this legislative instrument hardly does justice to the different ways in which it has led to the incorporation of standardisation as a part of current EU legislation. This evolution is likely to continue.

For example, although product safety issues were tendentious when the New Approach was first used to develop standards in this area, these issues have become less and less so with time, and are no longer regarded as especially problematic. The creation of a technical forum with all relevant parties actively involved in a process of finding consensus solutions has almost certainly helped to foster this development. The framework Product Safety Directive and the Product Liability Directive are also contributing factors.

Such a development could also occur with respect to human health and environmental protection concerns. However, the difficulties experienced by environmental interest groups in participating in standardisation working groups and in raising environmental awareness in the development of standards, together with the absence of general environmental liability legislation, would suggest that progress in this direction is unlikely to be easy.

In the application of standardisation with respect to the Packaging and Packaging Waste Directive, the process was complicated by an inadequate recognition of the different roles of the two parties involved — the legislative system's duty to find solutions to political issues, and the standardisation bodies' duty to find solutions to technical issues. A particular problem was the lack of appropriate feedback mechanisms between the two entities.

If standardisation bodies are to be used in future to agree technical solutions in areas of political polarisation, better mechanisms will need to be developed to ensure that the different issues are resolved in the appropriate context.

Several speakers underlined the increasingly important role of the International Organization for Standardisation (ISO) in the standardisation process. This is clearly a tendency that is likely to increase in the future, with the European Committee for Standardisation (CEN) playing a role as a regional standardisation organisation in wider, global agreements. Development of legislation involving standardisation needs to recognise this, and ensure that European Union developments can contribute to wider ranging solutions without becoming technical barriers to trade.

The "Stone Age" Approach, the "Old" Approach and the "New Approach" can perhaps be better seen as developments, where the legislative repertoire has evolved, and become enriched by more and more refined instruments, with their own particular strengths and weaknesses. Seen from this perspective, the art in developing new legislation is to ensure that the most relevant form of instrument is chosen.

The range of approaches available was highlighted in the session on the use of the New Approach in developing innovative solutions to reduce the environmental impacts of products. The issue was not whether legislation to encourage innovation towards environmentally more friendly products should strictly follow the New Approach. Rather, there was recognition that the elements already in use for encouraging environmental innovation in products – ranging from bans on substances to market-based incentives such as eco-labelling – could be supplemented and improved by elements of the New Approach.

For example, in the context of the Commission's working paper including a draft text for a directive on Electrical and Electronic Equipment (EEE)[2], it was argued that in the case of broad product

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

groups, where specific environmental concerns were not yet clearly defined, the use of the New Approach to set performance (*i.e.*, management) standards could play an important role in encouraging life cycle thinking in product design. Transparency of information and solid documentation could be driving forces for management-based systems that lead to environmental innovation. As knowledge and experience was gained, more definitive product standards and/or legislative requirements could then be set in place.

Several participants emphasised the need to continue to set essential requirements as minimum standards for placing a product on the Internal Market. Others called for framework legislation placing responsibility on producers for the environmental safety of their products. Product-oriented environmental management systems (POEMS) were applauded as a way to encourage environmental thinking at the design and production stages.

Development of comparable and verifiable benchmarks for environmental innovation in product design, based on LCA-derived criteria for specific product groups and linked to a system of environmental product declarations (EPDs), could enable consumers to make more informed choices and encourage producers towards more environmental innovation. The EU eco-labelling criteria agreed by the EU Eco-labelling Board (EUEB) could serve as benchmarks. Alternatively, benchmarks could be defined by standardisation working groups or even specially convened product panels.

One vision put forward at the Workshop was a system of EPDs within a legislative framework that minimum health and environmental protection requirements, perhaps via the "New Approach". The benchmarks set within this system would go even beyond eco-labelling criteria, thus helping to drive producers towards more environmental innovation.

From workshop discussions it emerged that the following elements in combination might enable the New Approach and standardisation to go beyond conventional regulation and to stimulate environmental innovation:

- mandatory minimum requirements to establish definitions, common understanding, and a minimum level of environmental protection (where possible, within a product group);
- voluntary but verifiable schemes such as benchmarking to inspire the market to compete specifically on environmental parameters;
- mutually agreed scientific fundament for identification of criteria based on an LCA methodology;
- systems such as EPDs and POEMS to stimulate a flow of reliable data throughout the product chain, thereby providing minimum data quality, reliability and openness between stakeholders in the market;
- groups of experts, comprising different stakeholders, to assess and refine product criteria on technically sound bases, so as to ensure independently set parameters;
- consultation among stakeholders at all relevant levels of the standard-setting process;
- economic instruments provided at EU and national level to encourage innovation in the private sector, including small and medium sized enterprises.

In this context, the "New Approach" can be seen as an organic legislative instrument. Its use in the areas where it has traditionally been applied has proved its usefulness. Its adaptability, as seen in the many areas where elements of the approach have been used, underlines its ability to be used, where necessarily modified, in a wider context.

In the background papers prepared for the Workshop, some of the questions raised for discussion suggested a choice to be made between alternative forms of legislation that were mutually exclusive. Perhaps the art of finding appropriate solutions lies rather in finding appropriate combinations of instruments in the existing legislative repertoire to be used to address the different issues, rather than insisting on the exclusive appropriateness of any one form of legislation.

1 Workshop programme

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[3]

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

13:15 Experience with the New Approach from an 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

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

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 The New Approach: Background and Issues (Session I)

This session aimed to give participants background information about the New Approach legislation. Examples to illustrate points were taken from existing or proposed New Approach legislation of particular interest in considering the issues central to the Workshop.

2.1 Background Document for Sessions I and II

2.1.1. Background

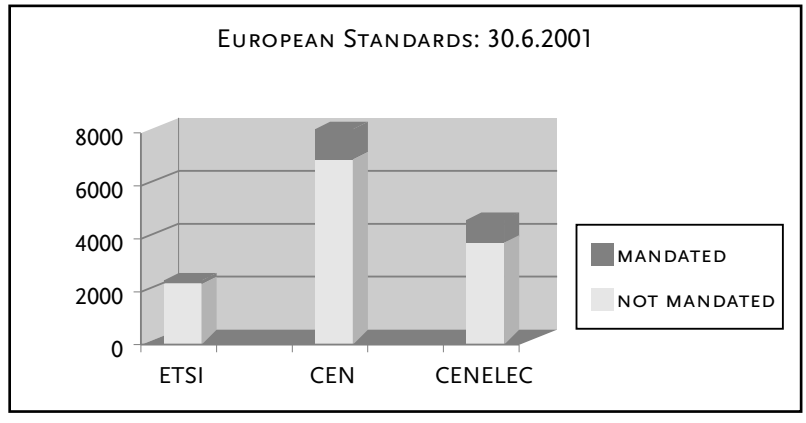
The New Approach was introduced in 1985 by the Council Resolution of 7 May 1985 on a New Approach to technical harmonisation and standardisation.[4] The Resolution emphasised "*the urgent need to resolve the present situation as regards technical barriers to trade …*", "*a high level of protection*" and "*the importance and desirability of the new approach which provides for references to standards – primarily European standards, but national ones if need be …*". This resolution was based on experience with the Low Voltage Directive from 1973.[5]

These three points were and remain the prime drivers for this approach. The New Approach was introduced to ensure that technical barriers to trade in the internal market due to the national use of standards was addressed as vigorously as the technical barriers to trade caused by Government regulation. The proposed solution was the active encouragement of a system of European standards. The New Approach has been successful in achieving these goals.

The figure below[6] shows the numbers of standards adopted by the

[4] Council Resolution on a New Approach to technical harmonization and standards. OJ C 136, 4.6.1985, p. 1.
[5] Council Directive 73/23/EEC on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits. OJ L 77, 26.3.1973, pp. 29-33.
[6] From Annex I to "Report from the Commission 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. Brussels, 26.9.2001.

three European standards bodies,[7] European Telecommunications Standards Institute (ETSI), European Committee for Standardisation (CEN), and European Committee for Electrotechnical Standardisation (CENELEC), at the end of the first half of 2001:



The growth in European standards has been considerable. In 1984 there were only 670 CEN and CENELEC standards. In the time the New Approach has been operating, a substantial body of European standards has been adopted. These European standards have replaced existing national standards as well as introduced new standards harmonised at a European level.

The New Approach has been used to ensure that harmonised standards have been developed for a series of product groups. A list of the product groups and the corresponding New Approach Directives regulating them is shown in Annex I of Appendix A of this report. The New Approach ensures a complete harmonisation of essential requirements to obtain a high level of protection and to avoid technical barriers to trade for each product group by ensuring simultaneous harmonisation of both the administrative regulations and the related technical standards.

[7] The European standards bodies are listed in Annex I to Directive 98/34/EC of the European Parliament and the Council laying down a procedure for the provision of information in the field of technical standards and regulations. OJ L 204, 21.7.1998, pp. 37-48.

Development of European standards is not of course limited to standards within these product groups. The chart above also shows that mandated standards directly related to the New Approach are only a small proportion of the total number of European standards.

The use of the New Approach also provided the Council with a solution to the problem of addressing detailed technical requirements, in what was hoped would be a more effective manner than could be attained by traditional legislation. It did so by establishing a system of co-regulation, where the work of developing the technical requirements is delegated to the three private European standards bodies.

The New Approach has been described extensively and numerous studies have been carried out about its efficiency, the legal aspects of the process, etc. Many of these reports are available from the Commission website on the New Approach and standardisation.[8] A report on experience with the New Approach is at present being prepared by the European Commission's services in DG Enterprise.[9]

2.1.2 Elements of the New Approach

The New Approach comprises the following elements:[10]

- ➤ *EU directives specify only essential requirements to ensure a high level of protection (health, safety, consumers, environment, etc.).*
- ➤ *Essential requirements worded so as to produce binding obligations that can be uniformly enforced by Member States.*
- ➤ *Directives deal with large families of products and/or hazards.*

The essential requirements form part of the main body of the New Approach Directive, and, as such, are drafted on the basis of a pro-

[8] http://europa.eu.int/comm/enterprise/newapproach/standardisation/ publicat.html. The European Commission has published a "Guide to the Implementation of Directives based on the New Approach and the Global Approach", available at http://europa.eu.int/comm/enterprise /newapproach/newapproach.thm.

[9] Erica Rydstrom, DG Environment D.3, personal communication.

[10] The separate bullet points shown in italics are taken from "Shaping standards for Enterprise Europe: Fifteen years of the New Approach", *Enterprise EUROPE No 1* 1. September 2000.

posal from the Commission, with the final text a result of discussions in the Council and in the Parliament. They are intended to stand alone. This is made clear in the 1985 Council Resolution: "*The essential safety requirements which must be met in the case of products which can be put on the market shall be worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced*". There is also an explicit requirement that the essential requirements "*be so formulated as to enable the certification bodies straight away to certify products as being in conformity, having regard to those requirements in the absence of standards*".

This is a necessary corollary of the fact that the technical specifications drawn up by "*organisations competent in the standardisation area … are not mandatory and maintain their status of voluntary standards.*"

In this, the drafting of essential requirements does not differ from drafting any other form of legislation. The scope of the essential requirements will depend on the area being regulated. The degree of technical detail required will again vary from case to case, depending on the political constraints involved. Where the group of products is well-defined and homogenous, formulation of the essential requirements is easier, since the group is more likely to share common characteristics. Where the requirements are related to properties being difficult to specify exactly, *e.g.*, ergonomics and long-term exposures, it is more difficult to formulate the essential requirements.

The distinction between the technical details that need to be included in the essential requirements and those that can be safely left to the subsequent standards can be difficult to draw. The ability of the standards bodies to fulfil any mandate is also determined by the way the essential requirements are formulated, and how these can be elaborated in relevant standards.

In addition, whilst in theory voluntary, the standards can in practice become effectively mandatory.[11] Proof of compliance with the essential requirements other than by the application of the standards "*is so burdensome that products not conforming with recognised standards*

are often rejected by distributors and other avenues of access to the EC market".[12]

The importance of the essential requirements and their central role in any New Approach Directive is clearly recognised by the 1985 Council Resolution, since this also states that amendment of the essential requirements "*can only be made by means of a new* (now Parliament and) *Council Directive under Article 100 (now Article 95) of the Treaty*".

Annex V in Appendix A to this report shows the essential requirements from three Directives. These are the Safety of Toys Directive (88/378/EEC), the Packaging and Packaging Waste Directive (94/62/EC), and the Low Voltage Directive (73/23/EEC). The difference in the extent of essential requirements is remarkable. Whilst the essential requirements in the Low Voltage Directive take up a single page of Directive text and are formulated in very broad terms, implementation of these essential requirements caused no more difficulties than implementation of the far more elaborate essential requirements of the Machinery Directive (98/37/EC) which fill roughly 20 times as much Directive text, and are formulated in considerable technical detail.[13]

- *Commission mandates European standardisation bodies to define the detailed technical solutions (harmonised standards), which manufacturers may apply on a voluntary basis.*
- *Manufacturers may choose whether they apply these harmonised standards (or other technical specifications), provided their products satisfy essential requirements.*

[11] In some cases. New Approach Directives to in fact make use of standards mandatory. An example of this is seen in the Safety of Toys Directive in the case of standards related to certain types of toys where the use of hazardous substances and preparations are essential to their functioning.

[12] R. Hunter and C. Garcia Molyneux, "The Draft EC Directive on Electronic Equipment: An Imprudent and Illegal Proposal", 23 (2000) *BNA International Environment Reporter* 924, at 926.

[13] For reference, the text of the Machinery Directive essential requirements are available in the complementary online *Arbejdsrapport* available on the Danish EPA web site.

The process of preparing mandates is the task of the relevant Commission service, following consultation with the Member States. This process is often initiated before the final adoption of the relevant legislation. The mandate is then transmitted to the European standards bodies, although, in practice, these may have been consulted informally at an earlier stage.

It should be underlined that, whilst these mandates are in effect service contracts, they are made between independent institutions, and the standards bodies are not bound to accept a particular mandate.

Whilst fully recognising the independence of the standards bodies, the mandate can contain provisions that ensure that the standards are prepared in a way that ensures appropriate consultation with all relevant stakeholders.

The development of the mandated standards is carried out by the relevant European standards body. The standards are produced by technical committees with participation of the national standards organisations. Membership of these technical committees can include government representatives, industry and relevant non-governmental organisations (NGOs). The numbers of government and NGO representatives are often limited. The work of these Technical Committees is followed by a Consultant appointed by the Commission whose job it is to ensure that the standards fulfil the requirements of the mandate and hence of the essential requirements.

Standards mandated under the New Approach are first adopted by the relevant standards body following their own procedures. The standards adopted by the European standards bodies do not become part of formal legislation, incorporated into a Directive with the explicit approval of the Member States, but are a type of "orphan legislation" recognised by the Commission in a Communication published in the *Official Journal*. The provisions of the underlying Directive presume that goods produced to the harmonised standards published in the *Official Journal* conform to the essential requirements of the Directive.

- *Where harmonised standards are complied with, a product is presumed to meet essential requirements (manufacturers are no longer required to obtain prior third party certification[14]). However, manufacturers[15] are legally responsible for ensuring that all products placed on the market comply with the directives.*
- *Member States must ensure that non-conforming products are withdrawn from the market (market surveillance).*
- *Directives also lay down conformity assessment procedures[16] for evaluating compliance with the Directives, taking into account identified potential risks.*
- *Conformity assessment is carried out by testing and certification bodies ('notified bodies'), designated by Member States within their jurisdictions and acting under their responsibility.*
- *CE mark symbolises conformity with all relevant Community rules — Member States recognise[17] that a CE marked product[18] placed on the market anywhere in the Community complies with their own national laws.*

If a Member State considers that the actual standard does not in fact provide a sufficient assurance that a particular product is in conformity with the essential requirements, the Member State informs the Commission. The concerns are discussed in a Committee established under the 98/34 Directive.[19] This Directive has replaced

[14] In some cases, third party certification is still required, *e.g.* for pancemakers.

[15] The rules apply both to manufacturers and importers.

[16] In 1989, the Council adopted a Resolution on a "Global Approach" to conformity assessment (OJ 10, 16.1.1990, p.1). In 1993, the Council adopted a Decision (Council Decision 93/465/EEC) concerning the modules for the various phases of the conformity assessment procedures and the rules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives. These aspects of conformity assessment, sometimes referred to generically as "the Global Approach", are not discussed in this background paper.

[17] The Member States shall presume that this is the case. However, it does not prevent the Member State from taking measures to confirm that this is in fact the case.

[18] The Packaging and Packaging Waste Directive does not provide for CE marking of packaging. CE marking of packaging is covered by a separate proposal. See Annex I in Appendix A of this report.

[19] Directive 98/34/EC of the European Parliament and the Council laying down a procedure for the provision of information in the field of technical standards and regulations. OJ L 204, 21.7.1998, pp. 37-48.

a Directive first adopted in 1983 (83/189/EEC) which is primarily intended to provide a mechanism for Member States to notify national standards and regulations. As such, the Directive covers the whole field of technical barriers to trade, and not merely standards related to the New Approach. A Standing Committee established under the Directive consisting of representatives of the Member States meets regularly. A reservation made by a Member State might result in the standard not being published, or being published with a reference to the fact that compliance with the standard does not guarantee compliance with the essential requirements.

The New Approach operates across three important boundaries.[20] These boundaries are between

- political decisions and technical solutions, through the formulation of essential requirements;
- public and private organisations, through mandates to the European standards bodies; and
- legislation and standards, through the passive adoption of the standards by publishing a Commission communication.

These boundaries are characteristic of New Approach Directives, but not restricted to them. The following section shows examples taken from outside the area of the list of product groups shown in Appendix A to this report. Experience from a wider range of Directives can potentially contribute to a better understanding of the difficulties, as well as to point to possible solutions that already form part of existing EU legislation.

2.1.3 Use of standardisation in EC legislation

As noted above, the development of European standards is not limited to areas covered by the New Approach. Nor is the use of standards and the delegation of the development of technical standards by these organisations in EC legislation limited to the product groups covered by the New Approach.

[20] Christian Frankel, Erik Højbjerg and Ove Kai Pedersen: EU Miljøpolitiske Potentialer i Europæiske Teknisk Standardisering. COS-arbejdspapir nr. 1-1998 (in Danish). ISSN 0903-6695.

In some cases, Directives are developed with requirements similar to "essential requirements" that require additional technical specifications to be operational in practice. Often when this occurs, the Commission mandates the European standards bodies to prepare standards to cover these technical specifications. The development of these mandated standards is often followed by a Consultant appointed by the Commission to ensure that the mandated standards are prepared in accordance with the needs of the Directive, and, after adoption by the relevant standards bodies, the Commission can publish the resulting standards in the *Official Journal*. Although the process of development of these standards differs perhaps only in minor detail from the standards produced under the New Approach for the product groups listed in Appendix A to this report, these Directives are not strictly speaking "New Approach" Directives. This type of Directive is not uncommon, and, as a result, there is a grey area of Directives similar to, but not regarded as part of the New Approach.

An example of a near-"New Approach" Directive is Directive 94/27/EC[21], the twelfth amendment of Council Directive 76/769/EEC on the marketing and use of certain dangerous substances and preparations. Directive 94/27/EC bans the use of nickel and its compounds in certain products. The Directive specifies "essential requirements" not in an Annex but in its Articles, standards to measure compliance (test methods) were prepared by CEN under a mandate, and, after adoption by the standards bodies, the standards were published in the Official Journal.[22] In spite of the obvious similarities, this Directive is not regarded as a "New Approach" Directive. A major difference from most New Approach Directives was the stipulation that the Directive would not come into

[21] European Parliament and Council Directive 94/27/EC anmending for the twelfth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative procisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. OJ L 188, 22.7.1994, pp. 1-2.

[22] Commission Communication C205(1999) in the framework of the implementation of Parliament and Council Directive 94/27/EC amending for the twelfth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. OJ C 205, 20.7.1999, p. 5.

force until the publication of the standards in the Official Journal. The essential requirements were not allowed to stand alone without harmonised test methods. As a result, the Directive, adopted in 1994 did not come into force until more than five years after its adoption. Technical details of this Directive are shown in Annex II of Appendix A to this report.

Experience with New Approach Directives that set essential requirements with regard to concerns for the environment for products is limited to the Packaging and Packaging Waste Directive. The Commission's working paper including a draft text for a directive on Electrical and Electronic Equipment (EEE) makes more wide-ranging proposals with regard to concerns for the environment.

There is however some additional experience with other product groups outside the New Approach. As an example, Technical Committees of European standards bodies have been established in order to further collaboration on the regulation of fertilisers and liming materials (CEN/TC 260) and soil improvers and growing media (CEN/TC 223). In particular, collaboration on methods to support eco-labelling of fertilisers is in progress. Extracts from the CEN Technical Board resolutions describing the scope of the work in these two Technical Committees are shown in Annex III of Appendix A to this report.

The European standards bodies are extensively involved in environmental legislation. There are a number of CEN Technical Committees where standards (including mandated standards) have been developed in support of a large number of EC Directives, many of which have their legal basis in Article 175. These TCs include CEN/TC 164 on water supply, CEN/TC 165 on waste water engineering, CEN/TC 230 on water analysis, CEN/TC 264 on air quality, CEN/TC 292 on characterisation of waste, and CEN/TC 308 on characterisation of sludge. Many of the standards developed in this context are analysis methods and methods for sampling. Several of the test methods have been adopted by the International Standards Organisation (ISO); a number of these ISO test methods are very similar to test methods developed by the OECD.

CEN has established a separate Committee regarding the environment, the Strategic Advisory Board on the Environment (SABE)[23], which reports directly to the Technical Board of CEN. CENELEC has a similar committee. In order to improve the quality of environmental competence in the individual technical committees, CEN/SABE has established an Environmental Help desk as part of the CEN Management Centre (CMC).

Finally, Annex IV of Appendix A to this report shows an example of a conventional Directive which includes technical Annexes developed by Commission Working Groups, as well as standards developed in several different fora. The symbols used in Council Directive 67/548/EEC are taken from the symbols developed in a UN Committee. Test methods are taken from the OECD Test Guidelines Programme. Many of these test guidelines are very similar to the ISO standards used in the environmental legislation mentioned above, as well as certain ISO standards used in support of the Medical Devices Directive. Performance of these test methods is controlled by Good Laboratory Practice, an OECD management standard. In addition, there are direct references to both CEN and ISO methodology for measurement of physical chemical effects, estimation of hazardous properties, certain labelling requirements, and on packaging requirements for child-resistant closures and for tactile warnings.

Agreements reached in connection with Agenda 2[24] have led to a global agreement on harmonised criteria for the definition of hazardous chemicals. This work, closely similar to that of other standardisation organisations, will be carried out by an international governmental body.

The example of Directive 67/548/EEC illustrates the use of standards that are directly incorporated into legislation, rather than passively adopted. It also illustrates the use of governmental rather than private standardisation bodies.

[23] http://www.cenorm.be/sectors/sabe.htm
[24] Agenda 21, Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil, 3-14 June 1992.

2.1.4 The use of the New Approach in relation to ensuring a high level of protection for human health and the environment

The New Approach has been successful in ensuring a high level of protection for safety and human health for a wide range of product groups.

Disagreements in relation to concerns on environment and human health after long term exposure (*e.g.* to chemical substances and noise) have mainly been seen in two out of the twenty six product areas[25] covered by New Approach Directives. These product areas are the Safety of Toys[26] and the Packaging and Packaging Waste Directives.[27] There are 26 mandated standards related to these two Directives out of a total of over 3,500 standards mandated under the New Approach[28] and after publication, less than five standards have not been accepted in full or in part as harmonised standards.

These two Directives differ in other ways from the other product areas. The Packaging and Packaging Waste Directive was the first to include essential requirements that actively addressed issues related to environmental protection. The Safety of Toys Directive addresses an area where particular concerns arise because of the special nature of the target group to be protected: children.

In the case of the Safety of Toys Directive, the concerns have mainly been linked to the presence of hazardous chemicals in toys. The concerns have been linked to low levels of exposure to chemicals with effects that are difficult to correlate to exposure to one particular object. There are often difficulties in getting data on the chemicals concerned, as well as difficulties in estimating exact exposure.

[25] For a list of these product areas, see Annex I in Appendix A to theis report.
[26] Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys, OJ L 187, 16.7.1988, pp. 1-13.
[27] European Parliament an Council Directive 94/62/EC on packaging and packaging waste. OJ L 365, 31.12.1994, pp. 10-23.
[28] For numbers of mandated standards related to each Directive, see Annex I of Appendix A to this report.

When assessing concerns for the environment, many of the same problems as are seen for human health also apply. Data on the environmental effects of different components can be limited, and estimates of release from products are often difficult to obtain. It is also difficult to correlate effects that are often first apparent some time after the event with the actual use of the product. These factors all contribute to the difficulty of making a scientifically based assessment.

But evaluation of the environmental effects of products is complicated by an additional aspect that is not seen with evaluation of the health effects. Children's exposure to toys occurs only as exposure to the products themselves. The effects of a product on the environment are not limited only to exposure from the actual product. In many cases the effects on the environment from the use of the actual product may be very limited. The environmental concerns for the use of a particular product are often more related to the processes used in the production of the product, as well as the consequences of disposal of the product at the end of its useful life. The need to evaluate the whole life cycle of a product complicates considerably the process from the preparation of essential requirements to the preparation of the standards and subsequent verification of compliance.

In both the evaluation of human health and in particular, the environment, there are often conflicting issues to be resolved at the same time. There may be short term concerns for the environment that are very different from the long term effects; parts of the production process may give rise to concerns for one environmental compartment (*e.g.*, the aquatic compartment), whilst other phases in the life of the product may give rise to concerns for another compartment (*e.g.*, the soil compartment in waste disposal). Whilst apparently technical in nature, these conflicting choices often require political choices to decide the weight to be put on the different concerns. These are often reflected in official policy concerning how to deal with these issues.

Finally, including issues related to production raises the additional complication that whilst the use of an imported article may be fall

within a particular jurisdiction, the production process will not. This in itself raises issues of compatibility with international trade agreements. These wider issues are not addressed specifically here, but it is important to recognise the need to ensure that any suggestions for improving or widening the application of the New Approach are made with due regard to the terms of these wider international agreements.[29]

2.2 Proceedings of Session I

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

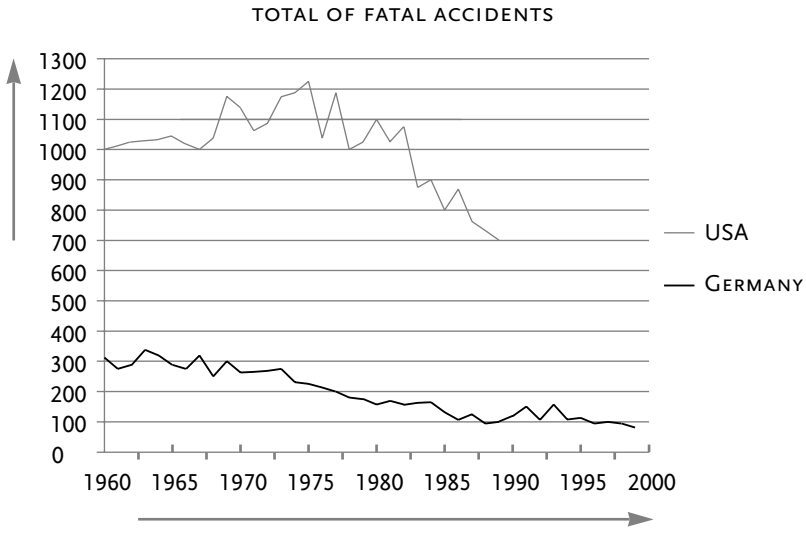
2.2.1 The New Approach: History of a success story

Evangelos Vardakas, Director, European Commission, DG Enterprise

The Council Resolution of 28th October 1999 states that: "…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 can be applied to sectors not yet covered as a means of improving and simplifying legislation whenever possible."

The Resolution recognises both the success of the Approach, and encourages its further use.

The New Approach legislation has been a success particularly in ensuring safety. This is demonstrated by the example of electricity related accidents in an EU Member State (Germany) and the US (see figure below). These figures are even more impressive when remembering that the standard voltage in the US is half that in Europe.



It is important to limit the legislative requirements to broad objectives essential to guarantee a high level of protection for the public health interest at issue. These objectives should be written in such a way that they could ensure binding obligations, uniformly enforceable. However, these essential requirements must also be framed so that manufacturers are free to use any appropriate technical solution.

Concerns with the workings of the New Approach Directives are more related to differences in the market surveillance carried out in the different Member States. This is an area where subsidiarity applies, and where a uniformly high level of enforcement is necessary to guarantee equal protection for the public and a level playing field for enterprises.

The New Approach can be used to complete the Single Market. It can enhance safety, environmental friendliness and performance of products, offer a flexible technology-neutral legal environment and reduce undue burdens for enterprises, but under two conditions: that the legislator will be able to define essential requirements while leaving space for standardisation to elaborate the appropriate solutions, and that matters considered "political" will not be given to standardisers for decision.

The Directives, and in particular the standards associated with them, are used widely outside the strict limits of the EU.

The New Approach has led to Europe having the strongest standards in the world. From this we stand to gain new markets in the world. This situation can be enhanced if we can create the conditions for standardisers to deal with the appropriate environmental aspects of products.

2.2.2 Formulating New Approach Directives for safety, environmental protection and human health

Michail Papadoyannakis,
European Commission, DG Enterprise

The Commission's working paper including a draft text for a directive on Electrical and Electronic Equipment (EEE) proposes the use of the New Approach to develop part of the Community's regulatory framework for this product group.

In discussing the use of the New Approach to address environmental concerns, it is important to recognise that the environment is a highly political domain. Standardisation should deal only with technical matters; an institutional mechanism is required to handle political questions. NGO stakeholders must be involved in the process. Whilst in time these issues might be expected to become less polarised, cultural change takes time.

The Commission's working paper including a draft text for a directive on EEE has elements intended to harmonise design requirements in relationship to the environmental performance of electrical and electronic equipment. This initiative, *i.e.* to create a comprehensive framework for addressing environmental aspects of EEE, would contribute to a continuous reduction of the environmental impact of these products and ensure free movement of compliant equipment in the internal market.

The Commission has launched an impact assessment study and the preliminary results will be available in mid 2002. A final draft proposal for an EEE Directive is expected by late 2002.

2.2.3 Preparing standards for essential requirements by CEN/CENELEC/ETSI

David Perchard, CEN Consultant on Packaging, Perchards Consulting

The process of preparing mandated standards to form the basis of a presumption of conformity with the essential requirements was followed in preparing standards for the Packaging and Packaging Waste Directive.

There is considerable background for the decision by the Commission not to publish the references to all of the standards developed under the mandate for the Packaging and Packaging Waste Directive. Whilst there had been considerable criticism of the process, the CEN members had voted in favour of the standards by an overwhelmingly majority and the views of the Member States on publication of the references were evenly balanced. Solutions to the difficulties have been discussed and the Commission is preparing a new mandate for amendment of those standards not deemed to be fully in line with the Directive's essential requirements.

Use of these standards will make a difference. They will change the balance of power in company decision making, as environment managers will have the support of legally recognised texts, rather than relying on purely commercial considerations. Unfortunately, the Commission's refusal to publish the references means that there will be no guarantee of compliance with the essential requirements until the references to the amended standards have been published or the legislators have agreed and implemented their own solution. It also means there is less chance to test whether the New Approach can be used successfully for environmental protection measures.

Many people had suggested that the difficulties arose because no clear distinction had been made between political issues (which were for the legislators to deal with) and the technical solutions. But the problem was less that the essential requirements had got the balance wrong, and more that certain Member States wanted to use the standards to take the legislation further.

Nevertheless, the essential requirements were not well drafted – vague wording had been used to disguise the lack of clear political direction – and the Commission's mandate had added new requirements rather than clarify ambiguities in the Directive. Finally, the long delay in issuing the mandate had put the CEN experts under great time pressure to complete the work on schedule.

2.2.4 The challenge of verifying compliance with essential requirements

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

The UK has a considerable legislative tradition in the field of product safety, which it has needed to take into account in coping with the transition to harmonisation on the basis of the New Approach. Changes in legislation have heightened awareness of the issues. The three principles of safety integration design, safeguarding and warning remain important. The benefits of the essential requirements include acting as a driving force for innovative design, with more focus on health requirements.

Whilst in many sectors mandated standards are product standards, management standards such as ISO 9000 are an option in many Directives. This can lead to a good balance in the roles of the two types of standards.

The New Approach is effective for a wide range of products, stimulates all involved parties to seek design based solutions and confirms the role of standards in Europe's technical infrastructure, competitiveness and innovation.

2.2.5 The wider international issues: Interface between European and international standards-setting

Jacob Holmblad, Vice President, CEN

It is noted with great pleasure that standardisation including the New Approach has created successful conditions for the internal market in Europe.

However, globalisation has increased the need to find an international solution on global trade. This solution should take the European success into account.

The introduction of the New Approach launched a process of self-regulation, which the Commission wishes to carry on within the framework of co-regulation. The extent to which standards are used within a legislative framework is rather unique to Europe. In the rest of the world, traditions and codes of practise in certain sectors are given higher priority, and trade-specific *de facto* standards often regulate a certain sector.

Another important difference is that in Europe, it is a requirement to withdraw national standards for the benefit of national implementation of European standards.

There is a need for worldwide-accepted standards. Present examples of worldwide-accepted standards are ISO standards for codes for foreign exchange currency as well as ISO 9000 and ISO 14000.

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 harmonised international standards. The world of standardisation 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.

3 The New Approach:

Ensuring a high level of protection for the environment and human health (Session II)

This session was intended to provide an opportunity for detailed discussion of the perceived successes and failures of the New Approach, in particular relating to problems of ensuring high levels of protection for human health (especially effects associated with long term exposure) and environmental protection.

3.1 Discussion Paper for Session II

3.1.1 When is the use of the New Approach appropriate or when is conventional legislation more appropriate?

The distinction between the use of the New Approach and conventional legislation is very closely linked to the issue of delegation, and therefore of governance.

The "Report from the Commission to the Council and the European Parliament on actions taken following the resolutions on European Standardisation adopted by the Council and the Parliament in 1999"[30] makes specific reference to the importance of governance and the focus on alternative forms of regulation and on democratic legitimacy.

The issue here is the delegation by New Approach Directives of the development of the technical requirements of legislation to private standards organisations. Much of the concern expressed in relation to ensuring a high level of protection for human health and the environment is related to the role of industry in the development of these standards. The role of industry in development of regulation is seen by some as problematic, by others as constructive cooperation with responsible partners committed to self-regulation. Industry is recognised as a stakeholder that can contribute much technical

[30] COM(2001)527 final. Brussels, 26.09.2001. See also the Commission's White Paper on Governance: COM(2001)428 final of 25.7.2001. OJ C 287, 12.10.2001, pp 1-29.

expertise. However, there is also a concern that other stakeholders, whose expertise is also valuable, such as NGOs, have only a marginal influence, and that therefore the result does not reflect a balanced societal solution. The issue of balanced representation is the topic of a Conference planned for 2002, and is not elaborated here.

There is widespread agreement that legislation to ensure high levels of protection for human health and the environment has to be fixed by conventional binding legislative instruments when there is

- high risk and/or
- high costs imposed by the regulation.

Concerns related to the high risks that may be associated with the use of hazardous chemicals are already regulated by a considerable body of Community legislation which includes worker protection legislation, and controls on the use of certain chemicals.[31]

There is therefore already a clear recognition that the use of co-regulation is not appropriate for certain areas.[32]

Conventional legislation may also be needed in the case where the consequences of the legislation may significantly increase the costs borne by the producer of the product. It is a considerable demand to make of an industry that they agree internally measures that potentially undermine their own competitiveness.

In addition, there may be Community policy that sets limits on the degrees of freedom within certain areas, *e.g.*, waste policy and the Commission White Paper on Chemicals Policy.[33] In both the evaluation of human health and in particular the environment, there are

[31] An example is Directive 76/769/EEC, which includes amendments that ban the sale of carcinogens, mutagens and reproductive toxins to the general public.

[32] The Danish Minister of Trade and Industry and Minister of Environment and Energy have recently written jointly to the European Commission concerning the revision of the Safety of Toys Directive indicating that they recommend use of positive/negative lists directly in the Directive.

[33] White Paper for a future chemicals policy. COM(2001)88 final. Brussels, 27.2.2001.

often conflicting issues to be resolved at the same time. Whilst apparently technical in nature, these conflicting choices often require political choices to decide the weight to be put on the different concerns.

It should be noted that even when conventional legislation is used, there may still be a need for the development of supplementary guidance, *e.g.*, for test methods to verify fulfilment of concentration limits, release rates or other values contained in conventional legislation.[34]

The Commission proposals for electrical and electronic equipment consist of three elements:

1. A Directive intended to encourage environmental friendly design of these products (the so-called EEE Directive; a draft text has not yet been adopted by the Commission)
2. A proposal for a Directive regulating the waste aspect of these products (the WEEE Directive; an amended proposal has been published[35] following discussion in the Council and European Parliament), and
3. A proposal for a Directive directly regulating certain hazardous chemicals as components of these products (the RoHS Directive; an amended proposal has been published[36] following discussion in the Council and European Parliament).

This is an example of a group of proposals that distinguish between areas where conventional legislation is seen as necessary and where the New Approach is seen as appropriate.

[34] Annex II of Appendix A of this report gives examples of conventional chemicals legislation, which nevertheless include many aspects of New Approach legislation.

[35] Amended proposal for a Directive of the European Parliament and of the Council on waste electrical and electronic equipment. COM(2001) 315 final. OJ C 240 E, 28.8.2001, p. 298

[36] Amended proposal for a Directive of the European Parliament and of the Council on the restriction on the use of certain hazardous substances in electrical and electronic equipment. COM(2001) 316 final. OJ C 240 E, 28.8.2001, p. 303.

Bans and other restrictions on the use of hazardous chemicals are normally regulated by conventional legislation for a number of reasons. Conventional legislation is considered more appropriate in situations where the potential risks are high, and where the industry concerned may face costs in substituting the chemicals concerned. In addition, chemicals, like a number of other product groups, were covered by a body of conventional legislation before the introduction of the New Approach, and where the introduction of this type of co-regulation was not considered appropriate. The proposal for the RoHS Directive is based on Article 95 (actions to establish the internal market), and is similar in nature to the conventional legislation (such as Directive 76/769/EEC) used for the control of hazardous chemicals.

The proposal for a Directive on Waste Electrical and Electronic Equipment (WEEE) is based on Article 175 of the Treaty (actions to achieve a high level of environmental protection). Since New Approach Directives are measures that are intended to ensure a harmonised internal market, this almost by definition means that the New Approach is not an appropriate model in this area. However, the different elements used in the New Approach (essential requirements, mandated standards, indirect adoption of standards) could perhaps be part of Directives based on other Articles of the Treaty than Article 95.[37]

The Commission has not yet agreed on a proposal for a New Approach Directive for the EEE product group, and therefore it is difficult to comment on this at the present time. However, much of the discussion up to now has focussed on essential requirements where conformity can be presumed by compliance with management standards[38] rather than specific product standards. Whilst management standards may be the most appropriate basis for achieving the goals of a projected EEE Directive, it is not clear to what extent the basic aims of the Directive can be seen as "essential requirements" in the conventional sense. This issue is dealt with at more length in Session III of the Workshop.

[37] For a further discussion of this point, see section 2.1.3.
[38] For a further discussion of management standards, see section 3.1.

Discussion points:

- ➤ Are there clear criteria that can be used to decide when conventional legislation is needed?
- ➤ Is the need for conventional legislation related to specific policy concerns (*e.g.*, control of hazardous chemicals) or is it related to the protection goals (environmental protection, concern for specific consumer groups)?
- ➤ Is the group of proposed EEE regulations with specific requirements for hazardous chemicals covered by conventional legislation a model for future development?

3.1.2 When the New Approach is appropriate, how can the different stages in the process be improved?

As indicated in the background document, difficulties have been experienced with the New Approach particularly with the Safety of Toys[39] and Packaging Waste Directives[40], where there are particular concerns for ensuring a high level of protection for human health (especially relating to long term exposure to *e.g.*, chemicals and noise) and the environment.

The criticisms of these two New Approach Directives relate to several of the different elements of the New Approach process. There is concern that the approach is inherently unsuited to ensure a high level of environmental protection. Some critics suggest that the difficulties are due to a variety of causes. These include insufficient care in the formulation of the essential requirements, inadequacies in the formulation of mandates, insufficient control by the Commission of the development of standards, and the nature of the standardisation process itself. There is little or no consensus that the difficulties experienced are related to any one specific phase in the process.

Possible options for discussion with respect to the different elements in the process are shown below.

[39] Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys, OJ No L 187/1, 6.7.1988, pp. 1-13.

[40] European Parliament and Council Directive 94/62/EC on Packaging and Packaging Waste. OJ L 365, 31.12.1994, pp. 10 – 23.

3.1.2.1 Essential requirements

Formulation of essential requirements is part of the work of drafting the relevant Directive. There is unlikely to be a common recipe for drafting these requirements, and the detail and technical complexity required may well vary from Directive to Directive. In general, the task of drafting good essential requirements is made easier when the product group under consideration is well defined and shares common elements that give rise to concern.

The argument has been put forward that the range of packaging falling within the scope of the Packaging and Packaging Waste Directive is too wide to be dealt with by product standards only. A more appropriate solution would be the development of management standards. However, this option is not possible in relation to the essential requirements as formulated in the Packaging and Packaging Waste Directive.

The task of drafting good essential requirements is also easier where the product group is intended to be used by industrial and professional users under limited, well defined conditions (as is the case for the Directives on Medical Devices[41]), rather than when the product group is used by a much wider target group including consumers and under many different conditions (as in the case of the Safety of Toys Directive).

It is difficult to suggest any general solution to the problems of formulating essential requirements. However, the importance of creating essential requirements which a) genuinely live up to the "stand alone" principle and b) can be supplemented appropriately by technical standards developed by others should be recognised in their preparation.

Discussion points:

➤ Are there special reasons why it is particularly difficult to formulate essential requirements for health and environmental

[41] Council Directive 93/42/EEC concerning Medical Devices. OJ L 169, 12.7.93, pp. 1-43.

concerns, as opposed to other safety requirements where few difficulties have been experienced?

- ➤ If there are special reasons, do they invalidate the use of the New Approach for addressing these concerns?
- ➤ Should essential requirements be formulated so that they can be supported as product standards, or is a formulation which can be supported by management standards also appropriate?
- ➤ Is a mixture of product standards and management standards a possible solution?
- ➤ Can the concepts reflected in management standards be included in a Directive as essential requirements in a way that ensures that they can stand alone and be enforceable?

3.1.2.2 Mandates

The process of formulating mandates is currently under discussion by the Senior Official Groups on Standardisation and Conformity Assessment Policy (SOGS) Committee, and a report is currently being drafted by the Commission services.[42]

When comparing mandates, it is obvious that there are major differences in the way they are drafted. Certain mandates stipulate only that a number of standards are to be drafted in accordance with the Directive, *e.g.*, the mandate for the standards for the mechanical and physical properties for toys. In other circumstances, the mandates are extremely specific, which was the case for the mandate for the revision of the toy standards.

The levels of detail of specification in the mandate have in some cases reached levels comparable with level of specifications in the actual standards. The reason for this high degree of specification is that the EC has had a particular need to achieve high and predetermined levels of safety. In some cases, the standardisation bodies have had their possibilities for creating their own interpretations of the essential requirements deliberately restricted by including a number of prerequisites in the mandate, which limited the freedom of the technical committees drafting the standards.

[42] Claus Jensen, Danish Agency for Trade and Industry. Personal communication.

The standardisation organisations must submit a deliverable which fulfils the essential requirements and the specifications in the mandate. But mandates which form the basis for tendering a task of developing a standard do not in general live up to the levels of detail common in other calls for tender. By ensuring that the mandates contain an adequate level of detail, the EC has great opportunity to determine the content of the standards. This is always relevant, and in some cases necessary, especially where it has traditionally proved difficult to achieve consensus between the parties on what constitutes an adequate level of protection.

The mandates are in some instances elaborated by the EC only and in other cases through a joint effort between the EC and the standardisation bodies. A joint effort in drafting the wording of the mandate has often resulted in the standardisation work being accepted immediately, since requirements and expectations were harmonised in advance.

The mandates have rarely been the object of reviews and renegotiations. When considering the fact that standardisation procedures change, an ongoing or step-by-step evaluation of the standardisation work in relation to the mandate would be appropriate. This could result in the mandate being followed more closely or taken up for review and possible revision.

The New Approach specifies that mandates may be given to three European standards organisations. However, there are many examples in Community legislation of technical standards developed by other organisations. These include the development of food standards by the UN Codex Alimentarius, the development of a range of standards and test methods governing the transport of dangerous goods by the United Nations Committee of Experts on the Transport of Dangerous Goods (UN CETDG), and the development of test methods for assessing the effects of hazardous chemicals as well as management standards for their assessment (Good Laboratory Practice) by the OECD.[43]

[43] See example of standardisation in Council Directive 67/548/EEC in Annex IV of Appendix A of this report.

Discussion points:

- ➤ Are the difficulties that have been seen related to problems in formulating and follow up of the mandates?
- ➤ If so, what lessons can be learnt by the Commission, the Member States and the standardisation organisations?
- ➤ Are there areas where development of standards should instead be mandated to governmental rather than private organisations (as is the practice in food regulation with the UN Codex Alimentarius)?

3.1.2.3 Development of standards

The way in which the European standardisation organisations develop standards is not considered in this discussion paper. However, it is appropriate to discuss the role of the Commission in supervising the work, and the possible ways in which the process of standards development and compatibility with the essential requirements can be controlled.

Here, the Commission consultants whose job it is to follow the process play a key role.

It should be noted that Member States also have the possibility to participate directly in the Technical Committees developing the draft standards, and hence to influence the result. It is important that Member States participate actively – at least at national level which will ensure that the viewpoints from Member States are presented and taken into consideration at an early stage of the work. Member States should not wait to present their viewpoints when the standards have to be accepted or rejected as harmonised standards.

The participation of other stakeholders is a matter of some contention. Whilst consumer and trade union participation in these discussions is supported by Commission funding, no comparable support is at present available for environmental NGOs.

The role of the CEN Environmental Help Desk in the development of standards is largely voluntary. Its role in supporting the development of standards mandated under New Approach Directives might be considered.

The New Approach recognises the importance of including concerns in related areas of Community policy in the preparation of standards in support of essential requirements. The point has been made by environmental organisations that there may be a need for an environmental liability Directive to cover products, amendments to the Product Safety Directive[44] to include an environmental chapter, and amendments to the Product Liability Directive to include environmental liability.[45]

Discussion points:

- Are the difficulties in setting standards to address health and environmental protection concerns related to problems in the way in which the mandate has been carried out?
- If so, what lessons can be learnt by the Commission, the Member States and the standards organisations?
- Is more participation and/or control by those directly associated with the parent New Approach legislation necessary?

3.1.2.4 Adoption of standards

The present procedure for adoption of standards under the New Approach is by publication of the adopted standards as a Commission communication in the *Official Journal*. If Member States consider that these standards do not fully provide proof of conformity with the essential requirements, these concerns are discussed by the Committee established under the 98/34 Directive (safeguard clause)[46]. The Committees established under the specific Directive concerned have no direct responsibility either for the approval of or for addressing any possible problems with the standards developed under the New Approach. Clearly close cooperation between the 98/34 Committee and the relevant Committee for the particular Directive is essential at both Commission and Member State level. However, the possibility of a closer relation between the process for

[44] Council Directive 92/59/EEC on General Product Safety . OJ L 228, 11.8.92, pp.24-32.

[45] Karola Taschner, EEB, at EEB Workshop on standardisation, 28.09.2001.

[46] European Parliament and Council Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations. OJ L 204, 21.7.98, pp. 37-48.

adoption of the standards and the relevant Committee under the Directive concerned might be considered.

Discussion points:

- ➤ Is this an appropriate way of adopting standards in all cases?
- ➤ If not, is there a case for a more active adoption process, such as inclusion of standards in an Annex to the specific Directive following a Commission proposal to the relevant Committee established under that Directive?

3.1.2.5 Feedback

Feedback of the effects and working of a Directive is essential for any efforts to assess the workings of a legislative instrument, and to provide a sound basis for its future improvement. This can be difficult in the best of circumstances. The development of the technical details in support of the essential requirements by a non-governmental organisation such as a standards organisation, taken in conjunction with a passive adoption process complicates the feedback process.

Discussion points: There are many possibilities for ensuring improved feedback, all of which have precedents in Community legislation:

- ➤ Is there a need to establish a forum where Member State representatives associated with the Directive can discuss the progress of the development of standards with the Commission consultant (if the Directive has provision for a Committee, this is the group that in an informal expert capacity would normally serve this function)?
- ➤ Is there a need to establish a forum where the results of verification and compliance experience can influence the process, *e.g.*, by enabling the consideration of possible revision of standards and / or essential requirements where necessary?
- ➤ Is there a need to establish a forum where stakeholders can discuss experience with the workings of the Directive?
- ➤ Is there a need to consider including in a New Approach Directive a requirement that the Commission prepare a formal report on the workings of the Directive, including the development of the relevant standards, at specified intervals?

3.1.3 Can the main principles of the New Approach be applied in cases where Member States are allowed to go further in protecting their environment than the measures described in Community legislation?

One of the fundamental intentions with application of the New Approach is to ensure a harmonised internal market for products. This precludes, almost as a matter of definition, national variations of a permanent nature in implementation of these Directives.[47]

As the New Approach is primarily aimed at ensuring both a high level of protection for all citizens in EU and as high a degree of harmonisation of the internal market as can be obtained, proposals for New Approach Directives are based on Article 95 of the EC Treaty, and adopted according to the co-decision procedure provided for in Article 251 of the EC Treaty.

There are however other Treaty obligations. The European Commission "Guide to the Implementation of Directives based on the New Approach and the Global Approach" (2000) makes this clear: "*New Approach Directives are generally designed to cover all hazards related to the public interest that the Directive intends to protect. Thus, compliance with Community legislation often requires simultaneous application of several New Approach Directives and, possibly, other Community legislation. This allows Member States to draw up national legislation in accordance with Articles 28 and 30 of the EC Treaty*".[48]

However, the different elements of the process (drafting essential requirements, mandating standards, development of standards by outside organisations, publication of the relevant standards in the *Official Journal*) are not necessarily limited to product regulation. In

[47] Austria has carried out research on the relationship between its national standards for chemicals and the New Approach standards developed for Council Directive 89/106/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products. OJ L 40, 11.2.98, pp. 12 –26. This study was aimed at considering whether it is possible to retain national legislation within the context of the New Approach Directive. Mr Martin Buchele, Federal Environmental Agency of Austria, personal communication.

[48] European Commission (2000): "Guide to the Implementation of Directives based on the New Approach and the Global Approach", available at http://europa.eu.int/comm/enterprise/newapproach /newapproach.htm.

theory, elements of the New Approach could be used when preparing proposals for Directives with a legal basis in other Articles of the Treaty than Article 95.

There is already a considerable body of environmental legislation based on Article 175 of the EC Treaty that makes extensive use of standards in support of this legislation. Whilst none of the Directives that these standards support are New Approach Directives, the process of development of these standards is in many ways very similar to the New Approach.

It should also be noted that the standards developed by ISO in support of much environmental legislation are in many cases very similar to or even identical to those developed by the OECD in support of chemicals legislation.

Discussion point:

➤ Are the elements of the New Approach appropriate when drafting non-product oriented legislation with a legal basis in other Articles of the Treaty, such as Article 175?

3.2 Proceedings of Session II

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

3.2.1 Experience with the New Approach from an environmental point of view

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

The EEB has more than 14 million members in 27 countries. This year, the EEB initiated the European Environmental Citizens Organisation for Standardisation (ECOS), a coalition of a number of European and national NGOs. The EEB work on standardisation so far has had very limited funding. ECOS applied for funding from the Commission in August 2001.

European environmental policy is determined via complex interactions among many different actors. Much of this policy is prepared and decided in selective expert fora, without the participation of the

European Parliament and with an imbalanced lack of participation of non-governmental organisations.

Whilst in theory voluntary, standards based on New Approach Directives have become legally binding in practice, and hence are a form of soft law. The standardisation organisations rely on industry input, and hence it is not possible to expect that these organisations are able to resolve the environmental issues involved.

An important tool to strengthen environmental considerations would be a framework Directive on environmental requirements for products, similar to the Product Safety Directive. These requirements should then be specified in each New Approach Directive. Moreover, these changes should be complemented by improvements in the standardisation process including an ongoing evaluation of standards, and a requirement that standards should be explicitly approved, the participation of environmental NGOs made possible, and minority opinions made public.

Problems have been seen with standards for heating appliances, construction materials and the Packaging and Packing Waste Directive. The essential requirements of the latter are framed in very general terms, and the targets are weak from an environmentalist viewpoint.

The EEB is unable to support the use of the New Approach in the environmental field without major changes, and it calls on the EU institutions to ensure that the New Approach is transformed so that it safeguards and promotes environmental interests.

3.2.2 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

The New Approach Directives work well in addressing concerns for safety, in part because industry has a substantial interest in complying with the requirements.

For health effects, it is technically complicated to establish precise requirements. It is also difficult to establish essential requirements which ensure a high level of protection precisely, unambiguously and exhaustively. For example, the essential requirements in the present Toys Directive are far from exhaustive.

It is difficult to draft criteria for establishing limit values for hazardous chemicals. Use of the Precautionary Principle as agreed in the Treaty of Nice has to be made at a political level and not at the level of standardisation Technical Committees.

Environmental impact is a multidimensional parameter, making the link between the specific product and effects on the environment difficult to establish. Agreeing on the level of a minimum risk is often complicated. Drafting of essential requirements must therefore include the way certain types of environmental impacts are measured and weighed against each other, since these decisions are political in nature rather than purely technical.

The essential requirements of the Packaging and Packaging Waste Directive were worded in very general terms, and this was in contradiction to the conditions for essential requirements set out in the 1985 Council Resolution on the New Approach. These uncertainties were reflected in the Council Common Position of 4 March 1994, which states "*The Council found that most of the essential requirements to be laid down for the manufacture and composition of packaging could only be very general; at this stage, when there were very few standards and criteria and very little experience available for most kinds of packaging.*"

The Commission's working paper for an EEE Directive puts forward a number of ideas that are problematic, but nonetheless would form a useful basis for further work in this area. In particular, tools like eco-labelling, EMAS and Green Procurement need to be included.

In conclusion, New Approach Directives are not well suited to ensure high levels of protection for human health or the environment, and this approach cannot act as a substitute for environmental Directives.

3.2.3 Panel on experience with the New Approach

Facilitator: Claus Jensen, Danish Agency for Trade and Industry

3.2.3.1 Experience with the the Toys Directive

Aage S. Hillersborg, LEGO, Chairman of CEN Committee on Toys

The New Approach has been a proven success with regard to the Toys Directive. Thousands of new toys are put on the European market annually, and the presumption of conformity for almost all of these is based on the harmonised standards rather than by direct proof of conformity with the essential requirements.

When a number of specific benefits and difficulties in the process are considered, a more generic approach including management standards has to be considered in the future. One possibility is a wider international context for the standards.

Clear political directions should be established for environmental aspects in advance, if standardisation is to remain a technical process. The changing focus with increasing demand for the integration of new elements sets challenges for both legislators and standardisers.

3.2.3.3 Experience with the Medical Devices Directive

Peter Thompson, CEN consultant on medical devices

In the development of standards in support of the Medical Devices Directives, the Technical Committees developed checklists making it possible to establish clearly the links between the essential requirements and the relevant sections of the different standards, thus ensuring a transparent method to ensure that the presumption of conformity is clearly demonstrable.

The sector was also one of the first to respond to the general CEN call to produce their own environmental guidance documents, to ensure a proper consideration of environmental concerns in the standards.

3.2.3.3 Experience with the New Approach from a consumer's point of view

Franz Fiala, Vice President, ANEC

The New Approach has contributed to consumer protection. However, both the first Workshop session and the recent Commission publications on the New Approach were unduly positive, ignoring negative aspects.

An example of the difficulties of addressing health-related problems via standardisation is the question of noise levels for cap pistols which has been discussed for over 10 years, without progress.

Closer monitoring of the workings of the Directives and associated standards is needed. There should be better possibilities for NGOs to take an active part in the process, as well as the need for a more active role for Regulatory Committees. The preparation of mandates should be discussed with a wide range of stakeholders. Failure to produce standards of sufficient quality should lead to the Commission withholding payment from the standards-setting bodies for the mandated work. The safeguard clause is inadequate. In the example of the standards related to emissions from heating appliances quoted by Mr. Hontelez, the resulting standards were set with requirements that enabled all existing apparatus to comply.

3.2.3.4 Standardisation in other forums[49]

Herman Köeter, OECD

There are similarities between the process of developing OECD Technical Guidance documents for chemicals testing and the development of standards in the European standardisation organisations. There are also international agreements on the mutual acceptance of data obtained in accordance with the procedures set forth in these documents, and management standards (Good Laboratory Practice) to ensure conformity with these procedures.

[49] See also Appendix B of this report.

The instruments used by the OECD to develop these internationally recognised procedures can be a part of the discussions concerning the New Approach with respect to health and environment-related standards.

3.2.4 Discussion

The discussion was at times heated with strong views expressed by both critics and supporters of the New Approach. Some of the panel contributions were interrupted by comments from the floor, and the differences in opinion were also reflected in the discussions that followed the plenary presentations.

Supporters of the New Approach felt that the many indirect positive aspects had been under-estimated by NGO representatives (ANEC and EEB). Development of standards led to improvements in many aspects of the process including material reuse. Active involvement of industry in the process led to a greater recognition of the importance of safety, health and environmental considerations. As regards the example of difficulties with setting noise levels for cap pistols, given the very wide range of potential problems associated with the very large numbers of different toys, this example could be used to argue the relative lack of problems in this area.

The argument put forward most strongly by the environmental NGOs reflected the relative weakness of environmental arguments compared to health and safety issues, due to the lack of formal legislation in this area. There is a greater understanding from industry for the importance of the health and safety aspects as there is framework legislation addressing these issues but not for environmental concerns.

There was a general recognition of the central importance of the drafting of the essential requirements. The question of setting essential requirements that required impacts to be "as low as possible" almost inevitably presupposes the development of standards to define these levels more precisely.

It was pointed out that whilst it was important that political difficulties be resolved before mandating the development of standards, the safety issues now seen as unproblematic were once considered highly contentious.

3.2.5 Presentation on options for consideration

Christian Fischer, Head of Household Waste Division, Danish Environmental Protection Agency, presented the topics for discussion in the breakout sessions, based on the Discussion document prepared in advance (see Section 3.1).

Groups I and II were asked to discuss the following two questions:

- When is the use of the New Approach appropriate and when is Conventional Legislation more appropriate?
- Can the main principles of the New Approach be applied in cases where Member States are allowed to go further in protecting their environment than the measures described in Community legislation?

Groups III and IV were asked to discuss questions related to the following issue:

- When the New Approach is appropriate, how can the different stages in the process be improved?

3.2.6 Plenary gathering, report-backs & discussion

The rapporteurs from Groups I (Birgitte Jørgensen Kjær, Danish Environmental Protection Agency, Household Waste Division) and II (Steve Andrews, UK Department of Trade and Industry) presented the conclusions of the first two breakout groups. The conclusions of the two groups were very similar.

It was clearly recognised that both New Approach and more conventional legislation are related, in that both are legislation designed to achieve clear political goals.

Use of New Approach legislation is seen as appropriate when

- the environmental aspects are clearly linked to the interest of the producer;
- the essential requirements can be clearly drafted; and
- the products covered by the legislation form homogenous groups.

Use of conventional legislation (rather than New Approach legislation) is seen as appropriate when

- the issues are political;
- the long term aspects are unclear (*e.g.*, climate change);
- there is no short-term interest for the producer.

Standardisation is seen as having advantages in situations where technological improvements occur rapidly. Conventional (command-and-control) legislation is seen as preferable for control of hazardous chemicals (bans, setting limits).

There was a general feeling that a discussion of whether the main principles of the New Approach should be applied in cases where Member States are allowed to go further in protecting their environment than the measures described in Community legislation was not relevant at the present time.

The rapporteurs from Groups III (Joakim Skottheim, Electrolux) and IV (David Perchard, Perchards) presented the conclusions of the second two breakout groups. The conclusions of the two groups were again similar and are combined below.

The main concerns discussed were related to drafting of the essential requirements.

- Separating the political and technical issues is difficult and needs to be guided, perhaps by including the relevant Regulatory Committee at an early stage in the discussions. Failure to draft clear essential requirements is not limited to the Packaging and Packaging Waste Directives.
- Drafting essential requirements for the environment is complicated by the fact that there is no tool for comparing different environmental aspects that is generally accepted by all

stakeholders. Evaluating environmental impact is complex and more experience is needed.

- There are concerns that safety aspects will be emphasised at the expense of environmental issues.
- There are arguments in favour of a wider use of management standards to ensure a general conformity that can later be supplemented by more detailed standards addressing specific problems. If this approach is considered appropriate, then the drafting of the essential requirements must reflect this intention.

Specific comments to the Commission's working paper on EEE included suggestions to

- focus the Directive on key product groups;
- clarify how management systems could encourage the manufacturer to consider environmental aspects in the design phase;
- recognise the importance of life cycle thinking; and
- emphasise the need for market surveillance and feedback to check and improve products.

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

4.1 Is the New Approach an appropriate means of encouraging innovation that will result in more environmentally friendly products? (Discussion paper for Session III)

4.1.1 Background

The *Green Paper on Integrated Product Policy*[50] proposes the use of the New Approach to promote the design and development of products with a reduced impact on the environment. It views New Approach directives as "total harmonisation measures that define binding essential requirements". Products in compliance with harmonised standards developed by the European standard-setting bodies under a mandate from the EU are presumed to conform to the essential requirements and may circulate freely within the internal market.

The New Approach has been applied for developing environmental product design standards only once to date, with respect to the Packaging and Packaging Waste Directive.[51] The Commission did not accept three out of five resulting standards, and hence compliance with the CEN-developed packaging standards may not be considered sufficient to meet the essential requirements set forth in that Directive.

The Commission working paper setting forth a draft text for a Directive on electrical and electronic equipment (EEE) also proposes the New Approach as a mechanism for encouraging innova-

[50] COM(2001) 68 final of 7.2.2001.
[51] European Parliament and Council Directive 94/62/EC on packaging and packaging waste. OJ L 365, 31.12.94, pp. 10 – 23.

tion in eco-design.[52] Annex II of the draft Directive sets certain essential requirements for manufacturers of EEE. These include mandatory life cycle assessment of each product's environmental impact, in order "to select the design solution for the product which represents an optimal balance between environmental factors and other appropriate considerations, such as technical and economic aspects, while complying with all relevant legislation." The manufacturer is to document the specific design choices and the reasons behind them, so as *inter alia* to be able to provide information on the environmental design characteristics for the EEE.

In this application, the New Approach would vary considerably from its prior role as a system for developing the regulatory details needed to verify compliance with essential requirements established by EU lawmakers. It ventures into new territory – the use of standardisation to develop a framework of procedures from which environmental innovation is expected to flow.

The relationship between innovation and standardisation is discussed in a recent report on the economics of standardisation.[53] The existence of a system of standards helps the customer to know what (s)he is getting, and encourages competition from producers who can apply the necessary technical knowledge from the codified standards. At the same time, it enables a subset of innovative producers to innovate away from the standard, so that they can raise their margins by price discrimination based on product differentiation. As the rate of innovation increases, customers face greater uncertainty and less understanding about the new products and services, and need greater reassurance before buying. Better standards can provide that reassurance. The report recognises that where health, safety or environmental concerns are present, regulation is needed to define a structure along which it is safe for innovation to proceed.

[52] The Commission working paper on a draft EEE Directive was issued in February 2001 by DG Enterprise, and is currently undergoing consultation among stakeholders.
http://europa.eu.int/comm/enterprise/electr_equipment/eee/index.htm

[53] G. M. Peter.Swann, "The Economics of Standardisation: Final Report for Standards and Technical Regulations Directorate, UK Department of Trade and Industry" (11 December 2000).
http://www.dti.gov.uk/strd/fundingo.htm#swannrep

A new consultation document released by DG Enterprise[54] confirms the link between innovation and standardisation, by pointing out that the New Approach was devised to facilitate the achievement of the internal market and to encourage flexible and technology-neutral legislation, thus promoting innovation and competitiveness.

In addition, standards can stimulate technology transfer by publishing guidance concerning what constitutes best available techniques (BAT) in an international context, thus raising technological levels generally.

This discussion paper focuses on (1) how environmentally innovative product design can be encouraged; and (2) how standard-setting under the New Approach might be used for encouraging innovation in product design.

4.1.2 Mechanisms for encouraging environmentally innovative product design

One definition of the term innovation is "the introduction of something new". But what is considered "new" depends on the perception of the observer. A technology or product may be innovative for one company, but state-of-the-art for another. This paper uses the term "innovation" to refer to a new technology or product that is not produced or marketed in Europe at present. A policy aimed at encouraging innovative technologies or products should therefore be prospective. It should consider what might be the likely outcome of existing or proposed scientific research projects, before a product emerges ready for the market.

In considering possibilities for encouraging more innovative ecodesign, it can be useful to review previous European regulatory interventions that have contributed to environment-related product innovation. These include:

Traditional restrictions and bans. The early EU environmental acquis were command-and-control measures, and some of these

[54] Draft consultation document on the review of the New Approach, 26 October 2001.

led to forced innovation in product design. The bans on specific substances and uses of those substances set in place under Directive 76/769/EEC[55] have led to substitution by less harmful substances in specific products. Similarly, the complex of EU legislation aimed at phasing out ozone depleting substances (ODS) in accordance with the Montreal Protocol has stimulated research and development on alternatives to ODS, including innovative technologies for refrigeration and substitution of non-ODS substances as cleaning agents.

It can be difficult to build the political agreement needed to enact a ban. Industries dependent on the use of a substance or activity that is targeted by the ban may not yet have a viable alternative. There is therefore sometimes a need for a warning or transition period to give sufficient time for innovation, production and marketing of alternative products before a proposed ban takes effect. Most often, a ban will not be adopted before alternatives are available at least at a scientific or pre-marketing level. The Danish chemical warning list may be considered as a notice from authorities to industry to look for alternatives and hence start innovation, in that a ban or other restrictions may be launched in the future.[56]

One of the sister Directives to the EEE — the proposed Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)[57] — is expected to bring about substitution by less environmentally harmful substances. Moreover, the proposed system of registration, evaluation and authorisation of chemicals (REACH) described in the *White Paper on a Strategy for a future Chemicals Policy*[58] may also lead to additional restrictions on chemicals, which would have an innovation-forcing effect.

[55] Council Directive 76/769/EEC on restrictions on the marketing and use of certain dangerous substances and preparations (as amended). OJ L 262, 27.9.76, pp. 201-203.

[56] List of Undesirable Substances (LOU) 2000, Environmental Review Nr.9 2000. An English version of this document is available at: http://www.mst.dk/homepage/default.asp?Sub=http://www.mst.dk/chemi/01040000.htm.

[57] Amended proposal for a Directive on the restriction on the use of certain hazardous substances in electrical and electronic equipment. COM(2001) 316 final. OJ C 240 E, 28.8.2001, p. 303.

[58] COM(2001) 88 final of 27.2.2001.

End-of-life requirements (extended producer responsibility). The EU waste management policy is progressively moving to make producers responsible for the environmental impacts of their products, once they have reached the end of their useful life-cycle. The principle of producer responsibility shifts part of the waste management burden from public authorities to private industry, and internalises waste management costs into product prices. Though the principle is directly addressed to the post-consumer stage, it also aims "upstream" at product design and material selection. If producers are required to pay at the end of the product's life cycle, they have a strong incentive to design products with lower end-of-life costs, *e.g.*, less material use and improved recyclability.

For example, Directive 91/157/EEC on Batteries and Accumulators (as amended by Directive 98/101/EC)[59] bans the marketing of batteries containing mercury, cadmium and lead, and aims to ensure separate collection of spent batteries and accumulators, with a view to their safe recovery or disposal. The Commission now aims to extend the requirements to cover nickel-cadmium batteries. The End of Life Vehicles Directive (2000/53/EC)[60] aims, as a first priority, at the prevention of waste from vehicles, including restrictions on the use of hazardous substances in new vehicles. The Directive obliges economic operators to set up systems for the collection of all end-of-life vehicles, and sets targets for re-use/recovery.

Similarly, Directive 94/62/EC on Packaging and Packaging Waste[61] obliges member states to set up waste collection and recycling systems. The Directive is silent concerning who should fund such systems. However, the Commission has recently proposed to amend the Directive to require packaging producers and traders to pay »in full or in part« the costs of collection and treatment and to relay such costs to consumers. This could be an incentive to producers and traders to develop packaging that would be less costly to collect and treat.

[59] Council Directive 91/157/EEC on batteries and accumulators. OJ L 78, 26.3.91, pp. 38-41.
[60] European Parliament and Council Directive 2000/53/EC on end of life vehicles. OJ L 269, 21.8.2000, OJ L 269, 21.10.200, pp. 34-43.
[61] European Parliament and Council Directive 94/62/EC on packaging and packaging waste. OJ L 365, 31.12.94, pp. 10 – 23.

Two new legislative proposals in this area were put forward by the European Commission in June 2000. The proposed Directive on waste electrical and electronic equipment (WEEE)[62] establishes producer responsibility for removing and recycling WEEE deposited by consumers at local collection points, including waste from equipment placed on the market prior to the entry into force of the WEEE proposal (historical waste). Producers can choose to pay for recycling individually or to share costs with others. The proposed Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)[63] obliges industry to find substitutes for certain substances that will be phased out within a given period, *i.e.*, lead, mercury, cadmium, hexavalent chromium, plus the brominated flame retardants PBB and PBDE.

Stakeholder consultations to identify BAT under the IPPC Directive. Council Directive 96/61/EC concerning integrated pollution prevention and control (IPPC)[64] aims to bring about an overall reduction of environmental impacts arising from the activities listed in the Directive's Annex I. The Directive requires operating permits for Annex I activities to be based on Best Available Techniques (BAT). The concept of BAT is defined broadly in the Directive. In order to assist licensing authorities to determine the conditions to set in IPPC permits, the European Commission has established a European IPPC Bureau in Seville, which is developing BAT Reference documents (BREF) for 30 different industry sectors listed in Annex I.[65]

A consultation process is used to develop the BREF documents, based on an exchange of information between experts from the EU Member States, industry and environmental organisations. This

[62] Proposal for a Directive of the European Parliament and the Council on Waste Electrical and Electronic Equipment. COM (2000) 347 final of 13.6.2000; 2000/0158 (COD).

[63] Proposal for a Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment COM (2000) 347 final of 13.6.2000; 2000/0159 (COD).

[64] Council Directive 96/61/EC concerning integrated pollution prevention and control. OJ L 257, 10.10.96, pp. 26 – 40.

[65] Plans to specify BREFs for specific sectors and already drafted BREF documents can be downloaded at the European IPPC Bureau's web page: http://eippcb.jrc.es.

consultation process has been successful in identifying often quite radical environmental improvements as BAT, thus providing a type of environmental benchmark for the various industries within the IPPC framework.

The Eco-Management and Audit Scheme (EMAS). Regulation 761/2001 on a voluntary eco-management and audit scheme (EMAS)[66], replacing the 1993 EMAS Regulation, establishes harmonised principles and procedures for environmental management systems in companies throughout the European Union and the European Economic Area (EEA). The objective of the scheme is to promote continuous environmental performance improvements of economic activities by committing organisations to evaluate and improve their environmental performance and provide relevant information to the public. Independent certified verifiers are used to confirm a company's compliance with EMAS. The EMAS scheme was originally open only to companies in industrial sectors but has now been extended to all sectors of economic activity including local authorities. The EMAS counterpart at international level is the ISO 14001 environmental management system standard.[67]

The incentive under the EMAS scheme is for an organisation to gain a marketplace advantage by improving stakeholder relations, enhancing the image of the company and its market share, conserving input materials and energy, fostering innovation, and sharing environmental solutions. While products are to be included in the scope of the EMAS review, the scheme does not cover product design *per se*.

An increasing number of EMAS registered or ISO-14001 certified companies request their suppliers to be ISO-14001 certified and/or to forward environmental product information. It is hoped that such product chain requests will lead to an Product Oriented Environmental Management focus (POEM) and thus lead to an increase of

[66] European Parliament and Council Regulation (EEC) No 761/2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS). OJ L 114, 24.4.2001, pp 1-29.
[67] ISO 14001:1996 on environmental management systems.

environmental aspects to be included in the design phase of products and their components.

Eco-labelling. The voluntary EU eco-labelling award scheme, first introduced in 1993, has been given new impetus with the recently adopted Regulation 1980/2000.[68] The eco-labelling scheme targets selected product groups for comprehensive studies of environmental impacts during their life cycles – from extraction of resources to disposal at the product's end of life. Criteria based on the life cycle assessment (LCA) are then developed. It should be noted that there are different approaches and methodologies for LCA, and the LCA methodology used for one product group may vary from that used for another. Development of a more standardised and transparent LCA procedure, perhaps building upon the ISO 14041 LCA standard, is therefore needed.

The newly established EU Eco-labelling Board (EUEB), where major stakeholders (industry, environmentalists, consumers, public authorities) are represented,[69] supervises the process of developing LCA-based criteria for specific product groups. When ready, the European Commission puts forward the new criteria for approval via a Regulatory Committee procedure. If accepted, the criteria are published as a Commission Decision.

Individual products must comply with all criteria for that product group in order to be awarded the EU eco-label. Criteria for a specific product group are established for a limited period (four to five years), to allow for upgrading reflecting technical improvements and changes in the market. The goal is to set the criteria at a level that allows only the best of the marketed products in that product group to comply. The incentive for producers is the increased marketability of products bearing the eco-label.

[68] European Parliament and Council Regulation (EC) No 1980/2000 on a revised Community eco-label award scheme. OJ L 237, 21.9.2000, pp. 1-12.

[69] The EUEB brings Member State representatives together with members of the (representatives of consumer and environment NGOs, trade unions, industry, SMEs and commerce).

Since all major stakeholders are involved in the selection of criteria subsequently adopted via a politically balanced procedure, this can be viewed as a type of "standardisation process". However, eco-labelling criteria have been developed to date for only a limited number of product groups, which has hindered its effectiveness as a mechanism for building a competitive market for goods with lower environmental impacts. More resources will need to be provided by both the Commission and the Member States, if the development of product group criteria and market penetration is to be speeded up.

Self verified environmental claims. Self-declared environmental claims (also known as "green claims") have been defined in ISO standard 14021 ("Type II" environmental labels)[70] as the "environmental claim that is made for one or more phases of the product's life cycle, without independent third-party certification, by manufacturers, importers, distributors, retailers or anyone else likely to benefit from such claims".

The European Commission's Directorate General for Health and Consumer Protection (DG SANCO) launched in 1998 a project aiming to assess the experience on green claims in Member States and to open a public debate on how the system could be improved to ensure consumer protection and enhance credibility of self-claims. Some of the possibilities that have been proposed by DG SANCO include:

- Amending Directive 84/450/EEC[71] concerning misleading advertising to introduce effective sanctions and essential requirements applicable to green claims, and to reverse the burden of the proof, so that it is the advertiser who has to prove the non-misleading character of the claim;
- Creating a specific European standard on green claims similar to ISO 14021;

[70] ISO/DIS 14021 on environmental labels and declarations. Self-declared environmental claims.

[71] Council Directive 84/450/EEC relating to the approximation of the laws, regulation and administrative provisions of the Member States concerning misleading advertising. OJ L 250, 19.9.84, pp. 17-20.

- Preparing guidelines for assessment of green claims that should be read as a code of good practice in establishing such claims, including use of life cycle analysis. These guidelines would assist both companies to draft self-declared claims, and public authorities and consumers to assess credibility of such claims;
- Monitoring of green claims at EU and national levels.

Whilst green claims might prove to be a flexible mechanism for providing wider information to consumers than eco-labels, there is concern that the lack of independent verification of such claims could foster misleading advertising. Environmental NGOs and consumers associations often criticise self-declared claims for the discretion that private companies have to state the environmental performance of their own products, and the lack of *ex-ante* controls to prevent misleading advertising. On the other hand, this would be the fastest option for small and medium enterprises to proclaim the environmental qualities of their products.

Environmental Product Declarations (EPDs). Environmental product declarations as defined in ISO Technical Report 14025 (ISO "Type III" labels)[72] are based on information from an LCA according to internationally accepted standards. They build on structured and quantitative data for a particular type of product group determined via product specific requirements (PSR). These are drawn up by industry in full consultation with stakeholders and competitors. The information is presented on a common format and then verified by a third-party source.

The ISO Type III EPD system is meant primarily as a way to pass life cycle-based environmental information from one company to another – a business-to-business information system. EPDs are expected to play an increasingly important role for companies adopting a POEM approach in their environmental management systems. Competition among suppliers to present the most favour-

[72] ISO/WD/TR 14025 on environmental labels and declarations – type III environmental declarations. Guiding principles and procedures.

able environmental profile of their products could therefore lead to product innovation.

An international network for EPD, *i.e.*, the Global Type III Environmental Declarations Network initiated in 1999, currently links Canada, Denmark, Germany, Italy, Japan, Norway, Sweden, and South Korea. The network is open to all participants working with Type III environmental declarations based on ISO Technical Report 14025. Its objective is to share practical experiences and seek mutual recognition outside of the ISO process.[73]

Other European experiences to advance in the area of EPD consist of the following:

- Nimbus project, initiated by industry (partly financed by the Nordic Industry Fund) to create a pan-Nordic (Denmark, Norway and Sweden) EPD by developing pilot projects for particular products .
- Italian and Swedish mutual recognition that EPD developed under one system will be valid under the other.

Discussion points:

- Is there still a need for traditional regulation, *e.g.*, restrictions on substances and end-of-life requirements, in stimulating environmentally innovative product design?
- Are there methods other than standardisation that might be considered for building stakeholder consensus concerning directions for product innovation, *e.g.*, the consultations to determine BAT under the IPPC Directive?
- How can the process of developing eco-labelling criteria to cover additional product groups be speeded up, and would this build the market for lower environmental impact goods?

[73] More information on the work developed under this network may be found at: http:/www.sms-standard.se/english/type3nw/index.htm.

4.1.3 Use of standard-setting under the New Approach to encourage innovation in product design

Management standards, as per the European Commission working paper including a draft text for an EEE Directive. Management standards, as opposed to product standards, have been suggested as one possibility for encouraging environmental thinking in product development in cases where product groups are defined too broadly to enable the development of product standards or where products are evolving quickly.

The manufacturing sector producing electrical and electronic equipment is experiencing rapid technological innovation. The draft EEE Directive, if adopted as put forward in the working paper, will become the first Directive to use the New Approach to develop management-type standards for environmental design The draft EEE Directive's approach represents an effort to set in place a flexible mechanism that can respond to market forces, and that establishes a self-monitoring process to ensure that environmental objectives are reached and maintained.

The Commission's working paper on an EEE Directive provides that EEE may be placed on the market only if they comply with the draft directive's provisions, including a number of essential requirements set forth in Annex II of the directive. Annex II sets essential requirements that would include mandatory life cycle assessment (LCA) of a product, and use of the results of that LCA for selecting the design solution for the product. Manufacturers would be given two options for demonstrating conformity with the essential requirements: (1) to follow procedures for applying internal design control, as per the draft Directive's Annex III; or (2) to follow procedures for applying an environmental assurance scheme, detailed in Annex IV. Conformity with essential requirements would be presumed if the EEE:

- had been awarded the EU eco-Label,
- was designed by an organisation registered according to the EMAS scheme,[74] or

[74] Christian Hey, Policy Director, EEB, at EEB Workshop on Standardisation, 28.9.01.

➤ complied with the provisions of a Community environmental agreement set up under an eventual Regulation.

Under the Commission's working paper on an EEE Directive, a Committee on impact on the environment of electric and electronic equipment (IMPEC) would be established. The IMPEC would comprise Member State representatives, and the Commission as chair. It would function as a regulatory committee *inter alia* to develop Annexes III and IV, in the light of evolution of technical knowledge and new scientific evidence, or to provide more detailed specification of the essential requirements, "as appropriate".

Though the overall framework set by the ISO standard for LCA could be used for the required life cycle assessment, it is considered not sufficiently detailed to serve as a foundation for the LCA foreseen in Annex II of the draft EEE Directive in the Commission's working paper. There will therefore be a need to develop and adopt specific guidelines on how to carry out LCA for electrical and electronic equipment.

The draft EEE Directive has been criticised by government officials, environmental NGOs and consumer associations as being too vague to ensure an adequate level of environmental protection. Much concern centers on the democratic deficit that may occur if the draft Directive is not amended to ensure more balanced representation of public interest, *e.g.*, via inclusion of other stakeholders in the proposed IMPEC. The European Environmental Bureau (EEB) has in particular pointed out that the introduction of management standards as one of the systems to assess conformity with essential requirements (environmental assurance system) does not necessarily determine good environmental performance.[75]

[75] The packaging CEN standards include: EN 13428 on Requirements on prevention by source reduction; EN 13429 on Packaging suitable for reuse; EN 13430 on Requirements on packaging recoverable by material recycling; EN 13431 on Requirements on packaging recoverable in the form of energy recovery; EN 13432 on Requirements on packaging recoverable through composting and biodegradation. The umbrella or guidance document is covered by EN 13427 on Requirements for the use of European Standards in the field of packaging and packaging waste.

The CEN working group charged with developing the standards to define the essential requirements set forth in the Packaging and Packaging Waste Directive also used a management standard approach for the five specifically mandated standards and one umbrella standard giving general guidance.[76]

One argument given for turning to management standards rather than product standards was that packaging was not a sufficiently homogenous product group to enable the development of highly technical and specific product standards. Moreover, the essential requirements set forth in the Directive were broadly defined, further increasing the difficulty of drawing up technical standards. The CEN working group used a management (procedural) standard approach in the end as the most likely option for delivering a unified standard covering such a wide typology of products.

The packaging standards have been strongly criticised by consumers and environmental organisations due to their lack of quantifiable criteria to assess compliance with essential requirements.[77] Moreover, only one of the packaging standards – that relating to waste composting — has been fully approved by the European Commission.[78]

"*Living Annexes*". There is a general concern that once essential requirements are laid out in a New Approach Directive, they become fixed provisions in the Directive. If new scientific or technological information emerged that indicated a need for upgraded essential requirements, the Directive would need to be amended via a full legislative process.

[76] Energy efficiency labelling programmes. COM(1999) 328 final. OJ C 274, 28.09.1999.

[77] European Parliament and Council Directive 1999/94/EC relating to the availability of consumer information on fuel economy and CO2 emissions in respect of the marketing of new passenger cars. OJ L 12, 18.1.2000, pp. 16 –23.

[78] Results from the project: "Energy Efficiency of Passenger Cars: Labelling and Its Impacts on Fuel Efficiency and CO2- Reduction", conducted within the framework of the European Commission's SAVE programme (DG Transport and Energy) and supported by the Austrian Ministry of Science and Transport, and the Dutch "Buy Eco-Wise, Drive Eco-Nice" programme.

One proposed solution might consist of the creation of independent technical working groups on innovation to advise committees set up under specific New Approach Directives. Any adaptations to essential requirements needed in light of scientific and technical progress could then be integrated into the Directive by means of "living Annexes".

This suggestion, apart from the more voluntary nature of the independent technical working group, is similar to the method used to develop the EU eco-labelling scheme, where criteria for each product group are revised every three to five years based on the most recent knowledge regarding BAT and market development. New criteria are voted in by Member State representatives through a regulatory committee procedure, and they then overlap one year with the former criteria. The aim is to ensure that only the best products on the market within a product group can meet the criteria, thus pushing innovation.

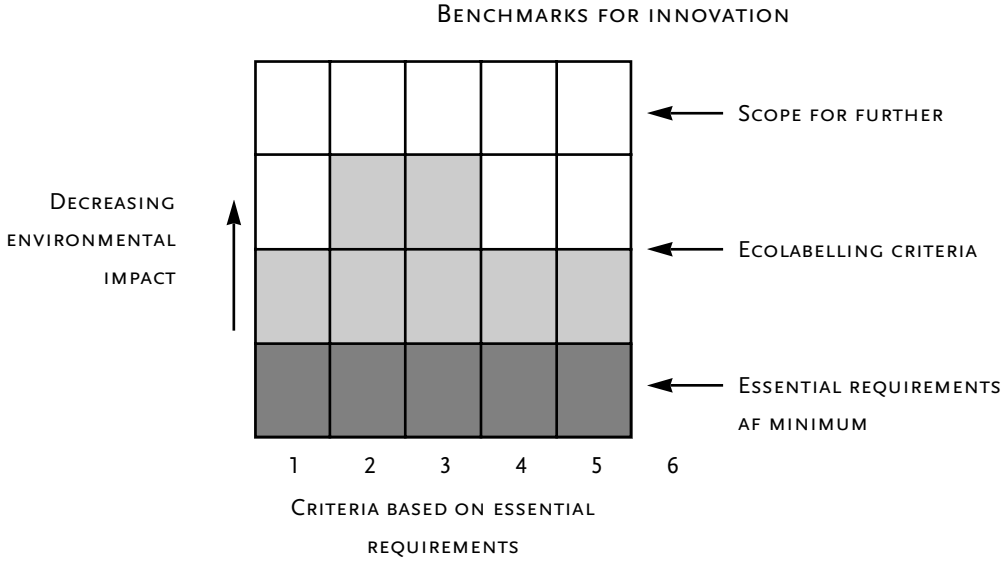
Similarly, the "living Annexes" could be adapted to keep abreast of new developments, so that the essential requirements would continue to serve as a minimum standard for protecting human health and the environment.

Benchmarking for specific product groups based on standardised LCA. Another proposal is to set up a transparent third party verifiable system that can give producers a way to demonstrate that their product is better than the essential requirements set forth in a New Approach Directive. The system would be based on the essential requirements as a core element but would not be limited to that. Rather, it would use benchmarks based on selected parameters establishing progressively more stringent environmental standards. These benchmarks could then be used to compare the environmental state of art of similar products and thus open up a market-based competition using relevant, documented and verified product information.

The benchmarks could be defined for specific product groups by specially convened product panels, industry workshop groups ("new deliverables"), standardisation working groups, or even the EUEB.

The method chosen would need to ensure independently set parameters while involving different stakeholders. One suggestion for ensuring independence is to create parallel committees: one composed of technical experts compensated for their work, and another of stakeholders voluntarily commenting on the work of the technical expert committee.

The proposed scheme may be represented as follows:



A framework of criteria would be developed for each product group, based on life cycle assessment and other requirements defined in the New Approach Directive. In the figure above, criterion 1 could be for concentrations of a hazardous substance, criterion 2 could be for energy efficiency, criterion 3 could refer to end-of-life considerations, and so on.

The essential requirements would serve as minimum standards for placing a product on the Internal Market. Progressively more environmentally stringent benchmarks would be then established for each criterion, provided that significant environmental improvements are possible. For product groups where eco-label criteria have been developed, the criteria could form the basis for defining additional benchmarks to be included in the list of parameters. For

product groups where a New Approach Directive is considered, the EUEB could be given a role in setting up LCA-based criteria, especially if the products are at least partly marketed to consumers.

For products containing chemicals posing high risk to man or environment or some risk in combination with serious (high cost) consequences for society, essential requirements would be needed as minimum requirements. If special circumstances (*e.g.*, development of new knowledge, identification of special vulnerable populations or environments) required strengthening of the criteria for such chemicals, adoption of mandatory legal measures would be indicated.

These benchmarks would represent scope for further environmental innovation. They would serve several important purposes:

1) they would enable companies to analyse and monitor their progress in innovation;
2) they would enable companies to make credible environmental product declarations concerning the environmental innovations they had achieved in product design;
3) they would provide a systematic scale for measuring and comparing the environmental impacts of similar products that could be used by business and in public procurement when taking purchase decisions;
4) they could form the basis for verification of EPDs if needed by the company in its marketing of products, especially to consumers (ISO type III labels); and
5) they could form the basis for green claims (ISO type II labels).

Such a scheme would by no means replace the need for legislation and for establishing clear-cut essential requirements that are able to stand alone. It would ideally work as a flexible system to encourage more pro-active companies to move ahead and to document the performance of their products in relation to the essential requirements, and could — at least for an initial period — be voluntary. The aim would be to foster the development of creative formulas involving innovation and cost-savings, and aimed at achieving win-win solutions.

The standardised European system for energy efficiency claims clearly illustrates how a benchmarking system can encourage manufacturers to bring out more efficient products and to showcase new technologies.[79] The energy label uses colours to depict graphically a series of categories ranging from "A: most efficient" (green arrow) to "G: least efficient" (red arrow). The energy label, which was originally voluntary, has become mandatory since 2000 for domestic refrigeration and freezing devices, washing machines, dryers, and dishwashers. The energy efficiency claims system is currently being supplemented via minimum efficiency standards and negotiated agreements with manufacturers for other products.

Similarly, Member States must introduce fuel economy labels for all passenger cars by 2001, under Directive 1999/94/EC on consumer information on fuel economy and CO_2 emissions for new passenger cars[80]. The introduction of this label is expected to lead to a 4-5% reduction in fuel consumption and CO_2 emissions per year for the entire European car fleet over the next ten to twenty years.[81] The fuel economy label is expected to not only influence consumer behaviour, but also to induce a market transformation by encouraging car manufacturers to produce vehicles that are more fuel efficient.

An environmental product declaration system as outlined above will need a credible third party verification system. Verification of compliance could be organised as at present under the New Approach, or in combination with the systems for verification of EMAS and eco-labelling. In both cases, the benchmarks would need to be linked to verifiable standards for testing the relevant parameters.

[79] Conference on Integrated Product Policy (IPP), Brussels, 8-9 March 2001. Workshop 1 on the Role of Economic Instruments in Integrated Product Policy.

[80] EEB response to the Commission Green Paper on Integrated Product Policy. EEB Document No. 2001/008. Brussels, April 2001.

[81] The views expressed in this document do not necessarily reflect those of the European Commission. Neither the Commission nor any person acting on behalf of the Commission is responsible for the use that could be made of the information given in this document.

There is also a need for a more operational life cycle assessment methodology that builds upon the existing ISO standard, as well as a European database for obtaining high quality generic LCA data.

Standards to be used in conjunction with market-based incentives ("pull" strategies). It has been argued, especially in the context of the eco-label, that the mechanisms to promote ("push") greening of products necessarily require some additional market-based incentives. Suggestions for such "pull" strategies include:

- *Environmental product declarations on Internet and point-of-sale labels*, as per the European energy efficiency claims system described above.

- *Public procurement as a driver.* Purchasing by public authorities represents around 12% of EU GDP. However, purchasing criteria, although taking into account environmental needs, typically give greater priority to economic matters. The EU is currently in the process of reviewing the Directives on Public Procurement. A shift in this policy should envisage the need for detailed guidelines for public authorities at central and local levels. In this respect, the European Commission has proposed a number of initiatives to enhance greening procurement at EU level, *e.g.*, to prepare an interpretative communication on public procurement and environment, a handbook on green procurement, and a web page containing a database of eco-product criteria that would enable public authorities to exchange best practices.

  Progress in greening of public procurement has been achieved in, *e.g.*, Austria and Denmark where it is obligatory to take into account environmental considerations while contracting goods and services. The city of Hanover in Germany is currently implementing EIA procedures in its procurement policy. In addition, the five Nordic countries have a common web site on greening of public procurement.

- P*roduct Oriented Environmental Management (POEM).* The product-oriented aspects of the revised EMAS Regulation

could be further elaborated (*e.g.*, practical guidelines) to facilitate possibilities for companies to request environmental information from suppliers. It can be particularly important, wherever modern production techniques rely on extensive upstream supply chains, to determine how to ensure that suppliers incorporate environmental thinking into their own design and production activities. The benchmark system outlined above could facilitate a uniform system for request of data in the supply chain for specific product groups. Incentives should be set in place, therefore, to promote the use of POEM by European companies.

➤ *Tax breaks for products that do better than minimum standards.* Reduced VAT schemes that would lead to price reductions would create incentives for consumers. Some options that have been suggested include[82]:

- lower VAT rates for products that lead to reduced emissions of greenhouse gases;
- lower VAT rates for repair services to encourage the fixing of broken products rather than replacing them;
- a car tax that is differentiated along environmental criteria.

The EEB has also suggested the following market mechanisms: virgin material taxes in order to promote recycling, tradable CO_2 credits to create incentives for lower CO_2 emissions, tax differentiation to phase out unwanted substances and promote safer substitutes (already existent for lead in petrol or packaging).[83]

Any market-based mechanisms introduced by national and EU authorities will however need to take into account the potential for collision with internal market provisions or international trade agreements in the context of WTO.

[82] COM(2001) 68 final of 7.2.2001.
[83] Commission Decision 2002/18/EC establishing the Community eco-label working plan. OJ L 27, 11.1.2002, p.28

Discussion points:

- How can management standards encourage environmental thinking in product design?
- Is there a need to develop operational, product-specific methodology(s) for LCA, and, if so, how can this be done?
- 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?
- What "pull strategies" should be considered to encourage the marketing of green products, and should these be at EU or national level?
- 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?

4.2 Proceedings of Session III

Facilitator: Eckert Meyer-Rutz, Ministry of Environment, Germany

4.2.1 The proposed use of the New Approach in Integrated Product Policy[84]

Otto Linher, European Commission, DG Environment

The Integrated Product Policy (IPP) as discussed in the *Green Paper*[85] does not constitute a single instrument, but rather an optimal mix of policies that in combination results in a strategy for improving the environmental performance of products and their markets. IPP consists of taking those elements that already exist in the market and combining them with new possibilities, when possible, to maximise the overall result.

[84] The views expressed in this dociment do not necessarily reflect those of the European Commission. Neither the Commission nor any person acting on behalf of the Commission is responsible for the use that could be made of the information given in this document.

[85] COM(2001) 68 final of 7.2.2001.

The IPP approach is to be understood within a more comprehensive framework based on the sustainable development strategy of the Sixth Environmental Action Programme, and relevant targets established via thematic strategies or specific policies, *e.g.*, chemicals and waste.

The basic philosophy behind the IPP approach relates to life cycle thinking and focuses on two main phases during the life cycle of products where environmental performance can be influenced, i.e, the design and the purchase stages. The IPP strategy is based on three pillars: stimulating the supply of greener products, greening of consumer demand, and price mechanisms.

Action during the design of products may well be the most efficient way to reduce environmental impacts of products. Eco-design becomes then the best procedure for progressively modifying the thinking of all economic actors on the supply as well as the demand side. This requires public authorities to take on a basic role in influencing product design. In addition, it is necessary to ensure that economic actors are sufficiently rewarded when applying life cycle thinking.

There are three main ways to channel public action:

- command and control legislation (where high risks and high costs are involved),
- enabling legislation establishing a clear objective but leaving the ways to achieve it to businesses and technical bodies (where the issues are low risk and low cost, but high volume is involved),
- other supporting instruments, *e.g.*, life cycle management instruments, education and training on eco-design, etc.

Traditional legislation may continue to play a very important role for regulating the so-called sensitive issues, *e.g.*, chemicals. However, it is a lengthy and highly costly procedure with legal, administrative and enforcement phases that may delay innovation. It is important also to provide a more flexible formula that ensures a clear distinction between political issues, which cannot be delegated, and tech-

nical requirements where decisions can be transferred to technical experts.

The *Green Paper on IPP* considers the logic of the New Approach as one of the possible elements for influencing product design. However, the failure of the experience with the Packaging and Packaging Waste Directive standards shows the need to adopt innovative approaches to address the specificity of environmental issues, and to find an appropriate balance between functionality of a product and its environmental characteristics. Moreover, the system will need to combine a sufficient degree of flexibility to permit the product to adapt to technical progress, and effective mechanisms for control and market surveillance once the product is placed on the internal market (feedback mechanisms). There should be in any case a clear and credible stick behind the market to ensure that economic actors are effectively pushed towards eco-design, and that a product might eventually be withdrawn from the market in the future if it does not incorporate environmental requirements.

Existing instruments, *e.g.*, eco-labels, key performance indicators such as the energy star label, environmental management standards, etc., need to be combined and their use prioritised. There should be a "ladder of preference" towards the more informal instruments with the more stringent tools used only if necessary. Such a system could be called New Approach, or enabling legislation, or any other term, but in any case, it needs to be an intelligent mechanism that combines different elements and provides for a new framework. The earlier such an approach is developed, the better.

The new system to tackle environmental performance of products needs to start by setting minimum mandatory essential requirements. It should be further developed by applying state-of-art eco-design and life cycle thinking (this formula will work in very similar terms to those currently used under the framework of the IPPC Directive when creating BREF documents). The definition of state-of-art of eco-design is to be formulated in the future via discussions taking place in the present and using available instruments. Such definition might be agreed via informal procedures, *e.g.*, discussions between enforcement authorities and producers or industry associa-

tions; formal environmental agreements with industry; or other mechanisms such as working groups to elaborate BREFs, product panels setting benchmarks, standardisation, command and control legislation, etc. In any case, further development of state-of-art of eco-design would need to take into account the duration of design cycles to provide a clear and predictable framework for industry. Ultimately, the IPP approach could be enshrined via a general framework Directive for broad product groups and/or product design.

The European Commission is currently discussing the main elements to be described in the IPP White Paper, which is to be released during Spring 2002. The Commission is also investigating how to apply the New Approach on the basis of the experience earned with the Packaging and Packaging Waste Directive.

4.2.2 Panel on environmental innovation

Facilitator: Eckert Meyer-Rutz, Ministry of Environment, Germany

4.2.2.1 Dynamism in the standardisation process: Guiding or delaying innovation?

Eva Schmincke, Büro für Ökologische Studien, Germany

Innovation can be enhanced via a combination of incentives and prescriptive requirements for companies. Dynamism may be pushed via already existing tools, which need to be adequately combined and integrated to maximise results.

Management standards and life cycle criteria prove to be two valid instruments to encourage environmental thinking in product design. More specifically, ISO has recently drafted a guidance document, ISO draft Technical Report 14062, which establishes a number of principles for integrating environmental aspects into product development. The guidance can be applied for all types of good and services, and different sized enterprises. Furthermore, this effort constitutes a joint initiative where broad consensus was achieved among industrialised and developing countries. The ISO draft

Technical Report 14062 focuses on relevant phases of life cycle and their main impacts, *e.g.*, energy demand or hazardous substances, and encourages environmental thinking via design strategies.

In any case, environmental thinking and innovation can only be developed effectively via credible and transparent procedures ensuring regular stakeholder participation, sufficient public control, and effective revision procedures.

4.2.2.2 Eco-label as a tool for promoting environmental innovation
Nicola Breier, European Commission, DG Environment

The Commission's working paper on an EEE Directive is not the first concrete example for the application of life cycle thinking as the EU eco-label has more than ten years of experience in developing and using life cycle criteria. Indeed, EU eco-labelling has most of the features laid out in the IPP strategy, *i.e.*, life cycle thinking, stakeholder involvement, information systems, and "push" strategies to place innovative green products in the market.

The eco-label is an EU-wide instrument, voluntary, selective and transparent, which covers all products of the non-food sector and services. It is multicriteria-based and takes into account the entire life cycle of a product when setting ecological criteria. It is independently awarded by a third party, which is a competent body of each Member State. In addition, the eco-label procedure brings together public authorities and other stakeholders to develop ecological criteria for targeted product groups. Such criteria are revised on a regular basis (three to five years) to provide for adaptations to technical improvements and market changes. So far, criteria have been set for 17 groups of products. Eco-label criteria are set in such a way that only the best products can meet the requirements.

The direct results of the eco-label have not been as successful as expected (although the label has made considerable progress during December 2001) due to the lack of resources with which the scheme is financed. However, its indirect and secondary effects offer considerable opportunities, especially for conceptualising the IPP stra-

tegy. Eco-label criteria are currently being used in public and private procurement (*e.g.*, Accor Hotels), or as benchmarks for energy rebate schemes (*e.g.*, in the Netherlands).

There are many other existing examples and possible options to benefit from the existing scheme:

- as benchmarks for a product group within the company,
- as targets to improve environmental performance of a product,
- as benchmarks for energy rebate schemes,
- as a basis to assess that companies have complied with essential requirements as suggested in the working paper on a possible EEE Directive,
- as a reference to create environmental product declarations (EPD) on the profile of marketed products,
- as a basis for certification procedures granted by eco-label competent bodies, which could share their role with EMAS verifiers,
- as criteria for benchmarking under the New Approach.

All these examples and options should be evaluated for their better use in the future, and further applied for those product groups to which the eco-label criteria have been established. Indeed, there is currently a newly established policy management group of the European Eco-Labelling Board (EUEB), which has been created under the recently adopted eco-label working plan[86], to look at the broader policy context of the instrument, and in particular its links to the IPP strategy. Eco-labelling has much to offer to identify environmental excellence among products, and the extensive expertise which has been developed under eco-labelling mechanisms, should be used more widely.

[86] Commission Decision 2002/18/EC establishing the community eco-label working plan. OJ L 27, 11.1.2002 p. 28.

4.2.2.3 Management standards versus product standards
Hugues Plissart, CEN Management Center

Standards have been used successfully as a tool to support legislation. However, the current system is to be improved via a clearer distinction between technical and political issues in standardisation, establishment of reciprocal responsibilities, and definition of unambiguous mandates.

The experience with the use of management standards (*e.g.*, medical equipment standards, space projects, railways, global approach, etc.) proves that they constitute a valid instrument to define performance criteria of a wide spectrum of products. Indeed, the relationship between product and management standards should be seen as complementary rather than antagonistic. Management standards would cover product categories, while product standards would address a specific type of products. Furthermore, management standards would be the first accomplishment in those cases where product standards have not yet been developed, and thus they would represent an appropriate instrument to enhance product innovation.

4.2.2.4 Environmental innovation in product design from the industry point of view
Viktor Sundberg, Electrolux

Environmental performance of products must become part of business thinking and competition of the company, and there should be some incentives to push companies in that direction. However, a reward system given by public authorities cannot be a sufficient guarantee as rewarding schemes might not exist for a long period of time. Moreover, internalisation of costs seems to be at this time the best and most simple option, both for producers and consumers.

Electrolux introduced in 1996 the so-called "green range" criteria for a number of products, including refrigerators, freezers, and washing machines. Since then, the volume of sales and margins of benefit for the company in those products designed following "green range" criteria have substantially increased.

Electrolux encourages private initiative to integrate environmental concerns in product design (*e.g.*, voluntary agreements on energy efficiency), but warns that there is a need to create an effective information mechanism so that consumers are aware of the costs and also the benefits of green products.

Following the *Green Paper on IPP*, environmental costs need to be fully integrated into the product price. Therefore, producer responsibility as described in the amended proposal for a Directive on waste of electrical and electronic equipment (WEEE) contradicts IPP principles and needs to be reformulated. The draft WEEE Directive reduces producer responsibility to a waste tax. Producers should be responsible for their end-of-life products only, and collective activities are necessary to handle "orphan" waste. Similarly, the Commission's working paper on a possible Directive on electrical and electronic equipment (EEE) is not feasible as it stands now.

The New Approach should not be considered as a tool to prescribe eco-design, but as an instrument to provide advice based on general guidelines and measurement tools to integrate environmental needs into marketed products. In any case, the New Approach will not be able to replace traditional environmental legislation where political goals need to be protected from market interests.

4.2.2.5 Innovation in product design from an environmental point of view

Karola Taschner, European Environmental Bureau

Integration of environmental issues in standardisation needs to be backed up by legislation defining general requirements and setting clear targets and timetables. According to the philosophy of the New Approach, there needs to be a clear separation between political issues, which have to be decided by the European legislator, and purely technical issues, which can be delegated to private standardisation bodies. Essential requirements need to be clear, unambiguous, and precise. In any case, delegation of rule-making should never be possible for sensitive sectors where there is a direct effect on public health and the environment, such as chemicals.

The proposed WEEE and RoHs Directives represent a good example by setting clear targets and timetables.

However, the system proposed for the current draft EEE Directive does not set clear and unambiguous targets and hence cannot be used to meet the presumption of conformity required under the New Approach. The draft EEE Directive proposes management standards, which do not provide for quantitative data or measurable indicators. This could endanger the implementation of the proposed RoHs and WEEE Directives, which would be difficult to monitor because recycling targets could not be measured.

It would probably be a better idea to draft an EEE framework Directive with daughter directives for specific product groups. Such directives will need to set minimum performance levels to be achieved and clear priorities for improvement according to the general targets and timetables set by the Sixth Environmental Action Programme. The Directive should establish a benchmarking system according to best available technology and best practice (European and national eco-label systems could be used to provide for criteria, quantitative thresholds, and performance levels). A precondition for the good functioning of the system would be, among many others, the good environmental management of the producing company. Producers' liabilility for environmental damage caused by their products could act as a powerful incentive for producers to improve the environmental performance of all products across the board.

Participation of a broad range of stakeholders in this process, including NGOs, and distribution of responsibility among all producers are also a precondition for the adequate functioning of the above-mentioned scheme.

4.2.3 Discussion

Due to a shortage of time, plenary discussion was postponed in favour of extended discussion time for breakout groups.

4.2.4 Presentation on options for consideration

Preben Kristensen, Head of Cleaner Products Division, Danish Environmental Protection Agency presented the topics for discussion in the Breakout sessions, based on the discussion document prepared in advance (see Section 4.1).

Group I was asked to discuss the need for traditional regulation, *e.g.*, restriction of substances and end-of-life requirements, in stimulating innovative product design.

Group II focused on "push" strategies to encourage the marketing of green products at national and EU level.

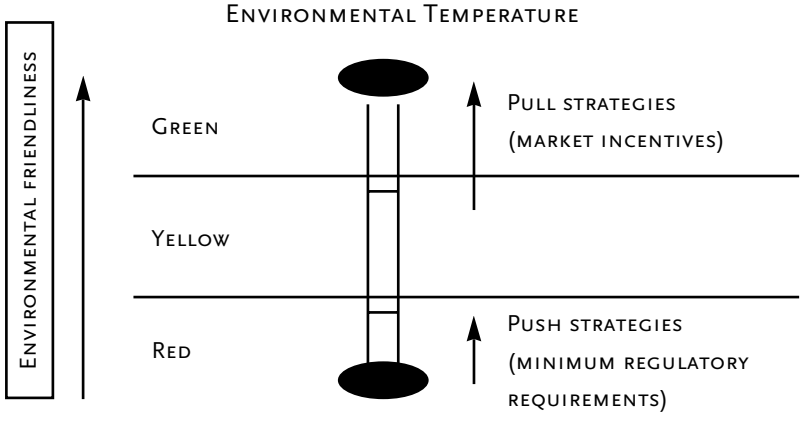
Group III addressed formulas to develop a system of benchmarks based on LCA methodologies.

Group IV discussed how management standards could encourage environmental thinking in product design.

4.2.5 Plenary gathering, report backs and discussion

The rapporteur from Group I (Annalisa Oddone, Orgalime) indicated that traditional regulation is still needed in some areas, as for instance chemicals. In addition, conventional legislation could potentially stimulate innovation as it sets rules that industry is necessarily bound to follow. It also guarantees adequate consultation among stakeholders, who at a later stage may decide by consensus that legislation is no longer needed for that particular matter which therefore could be relegated to more flexible mechanisms. However, traditional legislation still needs to be improved via effective enforcement systems and market surveillance. Special attention should be brought to the fact that legislation does not disguise taxation attempts (*e.g.*, the system of the proposed WEEE Directive). Finally, public authorities need to draw a borderline between the role of legislation and that of the New Approach; the New Approach could be used for environmental innovation but the ways and fields of its application need to be carefully assessed.

The rapporteur from Group II (Karin Öberg, Swedish Environmental Protection Agency) indicated that problems arose due to a lack of consensus on what could be defined as "push" and "pull" strategies. She showed a model based on a thermometer diagram to assess "environmental temperature" (see diagram below). Basic "push" strategies are the bottom line and constitute minimum legal requirements (usually related to safety issues). From there, the system may go further in moving to better integration of environmental requirements. Such environmental requirements would not necessarily be mandatory, but need to be encouraged via "pull" strategies. For such a system to move towards upper levels, consumer demand of green products needs to be enhanced via complete and transparent supply of information. Environmental quality of products cannot be totally regulated by public authorities, but it can be at least promoted. Finally, such a system should always keep in mind possible collision with WTO rules.



The rapporteur from Group III (Christian Poll, Danish Environmental Protection Agency) indicated the role of environmental product declarations (EPDs) to enhance innovation. EPDs would then be a flexible, clear and fair system based on life cycle thinking, which would constitute an effective means to provide information to consumers on the environmental characteristics of a specific product. EPDs need to be validated by an independent third party, and although the first aim of such a system would be to provide business-to-business communication, it should also ensure that all

stakeholders are involved in the process. Such a system should be built up slowly to guarantee that everyone could follow it. There might be a need for mandatory requirements in order to ensure effective application of EPDs and comparability of data for product categories marketed by different companies.
Finally, the rapporteur of Group IV (Hugues Plissart, CEN Management Centre) concluded that new management standards are needed to enable coverage of a wider number of products. Management standards and product standards are complementary, the linking element between both types of standards being the interest for continuous improvement. There is currently no common definition of EMAS (one could refer to EMASes, but not to a single approach) to guarantee that the fact that a company applies an environmental management system means that its products possess a high environmental performance. Some other issues that were discussed included the need for clarity when combining the different tools enumerated in the *Green Paper on IPP*; the limits of product information; incentives for consumers to purchase green products; limitations on the European Commission's capacity to exhaustively list technical specifications for thousands of products; and the need for uniform interpretation of essential requirements.

A more general discussion followed the rapporteurs' conclusions and especially focused on the role of EPDs. Frank Bill (Confederation of Danish Industries) indicated that in his opinion EPDs had to be exclusively voluntary to provide for effective flexibility, and did not need to be verified by third parties as such procedure would raise internal costs for the company. As EPDs are mostly used for business-to-business communication, their functioning should be regulated by market forces. Eva Schmincke (Büro für Ökologische Studien), Karola Taschner (EEB) and Philip Bennett (Council of European Producers of Materials for Construction) indicated that EPDs are currently considered independently validated systems, which indeed gives more credibility to the system. Viktor Sundberg (Electrolux) underlined the importance of providing for some voluntary schemes to enhance innovation, and noted that experience with the energy label proves that self-declaration from industry could be a valid instrument to speed up innovation.

5 General Plenary Discussion (Session IV)

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

5.1 Rapporteurs Conclusions

5.1.1 Day I: Session II

Christa Huygh (Federal Department of Environment, Belgium) found mainly two different positions during Session II, *i.e.*, either defending or questioning the use of the New Approach for setting health-or environment-related standards. This proves that there is certainly a need for dialogue among defendants of both positions.

The New Approach has proved to be a successful instrument for safety aspects, but certain problems concerning health protection have emerged. The complexity of environmental impacts indicates that changes might be needed in the current use of the New Approach to guarantee a high level of environmental protection. There were some fears that the application of the New Approach in the environmental arena might result in soft standards that would not always be met by all producers. This illustrates the need for a framework directive on environmental demands for products, similar to the Product Safety Directive.

Financial support is needed both for NGOs and industry to ensure balanced participation in the standards-setting process.

The New Approach is still an interesting tool in product policy. However, a number of issues are to be considered:

- Clear essential requirements
- Clear mandates and uniform interpretation
- Increased coordination between standardisation bodies and the political institutions.

- Strengthened safeguard mechanisms, including involvement of NGOs and other stakeholders at earlier stages of the process.

5.1.2 Day II: Session III

Jürgen Kühn (Ministry of Environment, Germany) indicated that, in part due to the very different use and understanding of terms and definitions, there were too many defending positions on the topics developed in the workshop and not enough discussion among stakeholders. Nevertheless, some consensus was reached concerning the fact that already a variety of methods, tools and measures are in place which could be used to enhance environmental innovation if adequately combined. The next step could be to investigate the advantages of the various instruments available, *e.g.*, environmental product declarations, BAT reference documents (BREFs), eco-labelling, EMAS, etc.

The New Approach has its merits in setting safety-related standards and partially in health issues, but it still needs to be improved in relation to environment. This does not mean that the New Approach necessarily needs to be discarded for environmental purposes. However, it will need to be adjusted and amended to guarantee sufficient protection of environmental goals.

Management standards may prove to be a valid instrument to enhance innovation for wide groups of products. However, as the Packaging and Packaging Waste Directive shows, essential requirements have to be unambiguous. Only if there is a clear political will when drafting such minimum requirements should delegation of technical specifications be transferred.

Green behaviour does not pay for itself; it needs a link to economic advantages for actors in the market, *i.e.*, both producers and consumers. Transparency of the process is essential for consumers.

The use of benchmarks may help to define the own position (producers) and the relative position (consumers) of the company.

If the New Approach, understood as a combination of political and legislative elements and standards, is to be applied on the basis of management standards, some changes might still be necessary:

- Standards will need to describe performance instead of technical solutions
- Essential requirements will have a more descriptive nature and relate to more than one product. They will be avoiding specific technical aspects in order to stay in pace with "moving targets".

5.2 General discussion

Michail Papadoyannakis (European Commission, DG Enterprise) remarked that the workshop concluded with a common sharing of opinions, although it was too early to reach any consensus.

Mario Calderón (AENOR, Spain) completely disagreed on the need to change the existing New Approach. It is clear that during the workshop some difficulties in applying the existing scheme were raised, but this proves only the need for improvement. Such improvement may occur via better monitoring of the system, better drafted essential requirements, or more guarantees to ensure that all interested parties are involved at relevant stages of the process. There is a need to differentiate what the process is and which results are obtained.

Eva Schmincke (Büro für Ökologische Studien) indicated that there are mainly two kinds of products to be delivered by standardisation, *i.e.*, product standards and management standards. Product standards are closely linked to legal aspects and should not be too soft, while management standards are "moving targets", which should focus on procedures rather than on performance.

Christer Arvius (National Board of Trade, Sweden) noted that discussion mainly focused in enumerating existing tools to promote environmental protection and innovation. However, there seemed to be no clear idea as of yet concerning what exactly needs to be built with such tools. There should be a clear definition of goals before

adjusting or/and combining existing tools. The New Approach does not need to be changed at this point, but differently applied.

5.3 Conclusions and next steps

Preben Kristensen, Head of Cleaner Products Division, Danish Environmental Protection Agency
The workshop has revealed the need to adjust and brush up the existing New Approach in order to better address environmental and health issues.

There should exist a more dynamic discussion between the people writing the essential requirements and those working in the standardisation bodies who are in charge of drafting technical specifications. This means that there should be a feedback mechanism where everybody is allowed to learn during the process.

If interest in management standards has increased and there is no available legislation to develop them, then it could be useful to look for "pull" mechanisms to enhance innovation via market mechanisms. But there is a need to ensure that if market mechanisms are used, the consumer will be informed and involved. The system needs to be flexible, but also credible.

Although no uniform conclusions were reached in this workshop, the sponsors' intention was to obtain a common understanding of the most important challenges in relation to the New Approach and its potential use for setting environmental standards. A number of potential options to follow when facing such challenges were actively addressed in the workshop.

It is thus too early to make specific proposals for the next stage of this process, but all stakeholders who attended this workshop are encouraged to continue the discussion in the future.

Annexes to Background Document for Sessions I and II

1.1 Annex I

1.1.1 Product areas covered by New Approach Directives[1]

Directive	Product Area	Mandated Standards 2000[2]
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	

[1] Updated version of Appex 1 in "Guide to the implementation of directives based on the New Approach and the Global Approach.

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

Directive	Product Area	Mandated Standards 2000[2]
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 telecom-munications terminal equipment	
94/25/EC (proposed amendment COM(2000)639 final)	Recreational craft	49
96/57/EC	Refrigeration appliances	

Directive	Product Area	Mandated Standards 2000[2]
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	

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

Directive	Product Area	Mandated Standards 2000[3]
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	

1,1,3 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

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

1.2 Annex II
Examples of standardisation in EU legislation

Parliament and Council Directive 94/27/EC: A Directive with many characteristics of a New Approach Directive

The Parliament and Council Directive 94/27/EC was adopted in 1994 as the twelfth amendment of Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. Directive 94/27 amends the Annex to Directive 76/769 by banning the use of nickel and its compounds in certain products.

The Annex describes the products covered by the Directive.

The first indent deals with nickel containing objects intended for pierced ears and other pierced parts of the body:

"*in post assemblies which are inserted into pierced ears and other pierced parts of the human body during epithelization of the wound caused by piercing, whether subsequently removed or not, unless such post assemblies are homogeneous and the concentration of nickel - expressed as mass of nickel to total mass - is less than 0,05 %*;"

This indent specifies the nickel concentration permitted in these assemblies. The method of analysis of nickel in these products is not specified.

The second indent deals with nickel products coming into direct and prolonged contact with the skin:

"*in products intended to come into direct and prolonged contact with the skin such as:*
- *earrings,*
- *necklaces, bracelets and chains, anklets, finger rings,*
- *wrist-watch cases, watch straps and tighteners,*
- *rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments*

if the rate of nickel release from the parts of these products coming into direct and prolonged contact with the skin is greater than 0.5 mg/cm_/week;"

This indent specifies the permitted nickel release rate, but does not specify how this should be measured.

The third indent deals with the same type of products as listed in the second indent, but which have been covered by a non-nickel containing layer:

"*in products such as those listed in point 2 where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such products coming into direct and prolonged contact with the skin will not exceed 0,5 ug/cm_/week for a period of at least two years of normal use of the product.*"

This indent addresses the expected life of the protective non-nickel containing coating layer, and specifies that this coating should last long enough to ensure that the nickel release rate is not exceeded for a period of at least two years. The indent does not specify how this should be measured.

The Directive makes a specific reference to policy related to consumer protection. The second "whereas" clause makes a direct reference a Council resolution on the subject:

"*Whereas work on the internal market should gradually improve the quality of life, health protection and consumer safety; whereas the measures proposed by this Directive are in line with the Council resolution of 9 November 1989 on future priorities for relaunching consumer protection policy;*"

As described above, the Parliament and Council Directive sets a clear cut-off value for the nickel release, but does not specify methods for measuring either the nickel release rate, or the methods to test whether products covered by a non-nickel layer will show an acceptable nickel release rate for at least two years of normal use. The Directive recognises that test methods are required for the

Directive to be operational and in the fourth "whereas" clause accepts the need for a European Standard:

"*Whereas the test methods to be used in demonstrating conformity with this Directive should be defined and published before the Directive is implemented; whereas these test methods should be the subject of a European standard;*"

The Directive makes no specific reference to the New Approach, although it is clearly the intention that the required standards should be developed by CEN under a mandate similar to those drawn up under the New Approach.

The Directive also makes implementation of the Directive dependent on the adoption of these standards:

"*Article 2*

1. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive not later than six months after publication by the Commission in the Official Journal of the European Communities, of the standards adopted by the European Committee for Standardization (CEN) on all the test methods used in demonstrating the conformity of the products with this Directive, or six months after the adoption of this Directive if that date is later than the former, so that:

- *six months after the expiry of one or other of those periods, whichever is applicable, no manufacturer or importer may place on the market products which fail to comply with this Directive,*
- *18 months after the expiry of one or other of those periods, whichever is applicable, products which fail to comply with this Directive cannot be sold or made available to the final consumer, unless they have been placed on the market before the expiry of the period in question.*

  They shall forthwith inform the Commission thereof."

This text sets a date for the Member States to adopt the necessary legislation not less than six months after publication by the Commis-

sion in the OJ of the CEN standards adopted. The additional, somewhat complicated text, deals with the possibility of these standards being adopted before the Directive itself comes into force.

In the event, there was a considerable delay in the adoption of the relevant standards, and the publication of these standards by the Commission in the Official Journal. The first standard EN 1810-1998, deals with the measurement of the nickel in piercing assemblies, the second EN 1811-1999 with measurement of the nickel release rate, and the third EN 12472-1999 with the accelerated wear and corrosion to be used for the detection of nickel release from coated items.

Reference to these standards was published as a Commission Communication in the Official Journal, C205, on 20th. July, 1999, page 5, over five years after the publication of the Parliament and Council Directive.

This is an example of the use of standardisation in a Directive, with many of the characteristics of the New Approach, but with significant differences.

Firstly, whilst the Directive makes a specific reference to Consumer policy, the New Approach is not specifically mentioned, even though the method is closely followed.

The "essential requirements" are clearly formulated in the Directive, as the three indents in the Annex. In particular, the cut-off limits for nickel content and nickel release, which many might consider as politically sensitive decisions are specified.

In a conventional New Approach Directive, there is the possibility of producers having a choice between demonstrating compliance with the essential requirements directly, or by reference to a standard. Here there is no such choice.

Since in a conventional New Approach Directive, there is the possibility of producers having a choice between demonstrating compliance with the essential requirements directly, or by reference to a

standard, implementation of the Directive does not formally need to be linked to the adoption of the relevant standards (although clearly any Directive would be clearly more operational with the appropriate standards in place). The requirements of this Directive, that standards should be adopted before implementation was possible, has lead to a delay of rather more than five years between publication of the Directive in the Official Journal, and the obligation on the Member States to implement its provisions. Delay in the adoption, for whatever reason, has therefore considerable consequences for the implementation of the measure. A delay that is moreover effectively out of the control of those responsible for the primary legislation.

1.3 Annex III

Examples of standardisation in EU legislation

Product groups outside the New Approach where standardisation addressing environmental aspects of these product groups has been developed

Two product groups are supported by CEN Technical Committees (TCs): CEN/TC 223 on Soil improvers and growing media, and CEN TC 260 on Fertilizers and liming materials.

The following extracts are taken from the BT Resolutions4 on the Market, environment and objectives of these TCs.

➤ *CEN/TC 223-Soil improvers and growing media*

Whilst the work of CEN/TC 223 is not mandated, the standards will assist in compliance with certain EU directives i.e.,

– most transactions in soil improvers and growing media refer to quantity, some being controlled by Council directive 211/76/EEC.
– WI 0022300[4] 'Quantity determination' was established to produce a method that could be used for all of this type of

[4] As posted on the CEN SABE (Strategiec Advisory Body for the Environment) website. Note that some of these resolutions refer to measures that have since been adopted.

product and that would enable the quantity declaration made comply with the issues regarding labelling stated in council Resolution 93/C 110/01 in the Annex.

– The EU Regulatory Committee which prepared Council Regulation (EEC) No. 880/92 of 23 March 1992 on a Community Eco-label award scheme, agreed once CEN/TC 223 methods had been produced on soil improvers and growing media they should be adopted for the purpose of ecolabelling.
– The EU is considering a Directive on 'Composting', which will require standards to support it. A liaison has been established with the EU officer responsible for the development of the directive so those TC 223 standards could be used in support of the directive.

➤ *CEN/TC 260- Fertilizers and liming materials*

This context is very strong in the field of fertilizers and exchange of information is important between standardisation and regulatory bodies such as Commission's DG Enterprise or national governments. The TC observership fulfils this role with respect to DG Enterprise.

At the present time, DG Enterprise revises the Directives relating to fertilizers and mandates have been given to the CEN by DG Enterprise in order to prepare reports and standards:

– one on organo-mineral fertilizers
– and another one on chelating agents.

The future work of DG Enterprise could lead CEN/TC 260 to work on new standards concerning analytical methods for several products in order to apply the directives.

Direct links to the process of elaboration of EC "Fertilizer" directives and an input channel of technical know-how to DG Enterprise.

Furthermore, CEN/TC 260 can help DG Enterprise in future product definition harmonisation.

1.4 Annex IV

Examples of standardisation in EU legislation

Council Directive 67/548/EEC: the many different sources of Standards in chemicals legislation

Council Directive 67/548/EEC was adopted in 1967 and forms the basis of a substantial part of the EU legislation on hazardous chemicals.

The Directive comprises a Directive text, including 32 articles, and includes nine Annexes. The Directive itself is based on Article 95 (100 A), and, as such, can be modified only by the Council and the Parliament. The Annexes may all be modified by a Committee procedure. Changes to these Annexes are made in the form of Commission Directives adapting the Directive to Technical Progress. These Commission Directives are adopted, following a proposal by the Commission to a Technical Progress Committee made up of representatives of the Member States and chaired by a representative of the Commission. Voting on the draft Directive proposal takes place on the basis of the votes allocated to each Member State by Article … of the Treaty. If the proposal receives a favourable opinion from the Committee (i.e. the proposal is adopted by a qualified majority of the Member States), the Commission shall then adopt the draft Directive. Should the proposal not receive a favourable opinion (i.e. a qualified majority is not obtained), the proposal is then submitted to the Council and the Parliament, that then have certain fixed deadlines to respond to the proposal.

The contents of the Annexes, whatever their origin, are thus subject to formal adoption procedures

The Annexes varying in length and scope, some being very extensive. The Annexes relate to the two areas covered by the Directive:

- Classification and Labelling of dangerous Substances and Preparations and

Annexes I, II, III, IV and VI deal with Classification and Labelling. Annex VI gives detailed criteria for assessing whether substances and preparations should be considered as dangerous, and gives guidance on how these criteria should be applied. In many cases, the test data on which the assessment is based is obtained using the methods described in Annex V.

Annex I lists hazardous substances for which harmonised classification and labelling provisions have been agreed by the EU based on the criteria given in Annex VI.

Annexes II to IV provide information about labelling dangerous substances and preparations. Annex II shows the symbols and indications of danger to be used on the label. Annex III lists the standard phrases indicating the nature of the hazards (the so-called R-phrases), and Annex IV lists the standard phrases (S-phrases) giving advice on safe handling of the dangerous substances and preparations.

Annex IX provides information about packaging of dangerous substances, and includes guidance on child-proof closures and tactile warning devices.

➤ Notification of New substances

Annex V, VII and VIII deal primarily with Notification, although Annex V includes information that is also required for Classification and Labelling.

Annexes VII and VIII provide details of the information required for notification of chemicals being put on the European market for the first time. The tests required (normally those listed in Annex V) are in general related to the quantities of chemical placed on the European market.

Annex V includes a large number of test methods for assessing physical chemical, health and environmental hazards of dangerous chemicals. These tests are used when collecting data for the notification of new substances, testing existing substances under Regulation

(EEC) 793/93. The results of these tests form to a large extent the basis for the criteria given in Annex VI for classifying substances and preparations as dangerous.

Examples of standards in the Directive

Four of these Annexes make varying and at times extensive use of standards to define the technical requirements of the Directive. More detailed reference to these Annexes are shown at the end of this background document.

The standards used derive from four sources: the UN, the OECD, CEN and ISO.

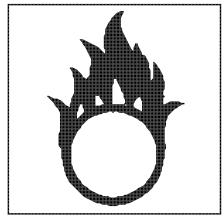
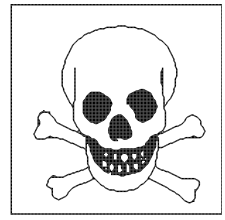
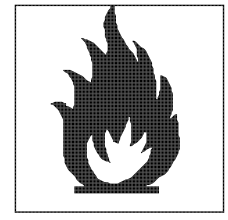
Symbols have been included in the Directive that have been developed by a UN Committee.

Test methods for establishing the potential hazards of chemicals have been included. These test methods for the most part constitute a transposition into Community legislation of methodology developed by the OECD Test Guidelines programme. Methods to ensure that these tests are carried out appropriately are required by the Directive, which mandates the use of Good laboratory practice, a form of management standard, also developed by the OECD.

Finally, the Directive makes references to a number of EN and ISO standards. Some of these (notably those related to packaging requirements) have been developed under mandate from the Commission. All references to these standards include specific reference both to the standard and to its publication date, so that subsequent revision of the standards by the standards organisation requires explicit confirmation in the legislation.

Annex II

Annex II includes the symbols and indications of danger used on the labels required for dangerous substances and preparations. The symbols are formally part of this Directive. Examples of these symbols are shown below.

These symbols were originally developed in a quite separate organisation which regulates the transport of Dangerous Goods. In 1956, the United Nations Economic and Social Council published the first edition of the UN Recommendations concerning the Transport of Dangerous Goods. The symbols agreed in this context were later adopted for use in the EC legislation on the supply and use of these chemicals. The working of UN CETDG which is responsible for regulating transport of dangerous goods including the preparation of technical standards for testing, packaging and labelling is described elsewhere5.

Annex V

Annex V contains a number of test methods to determine the hazardous properties of substances and preparations. The large majority of these test methods are based on test methods developed by the OECD Test Guidelines programme.

The OECD Guidelines for the Testing of Chemicals are a collection of the most widely used internationally agreed testing methods used by government, industry and independent laboratories to identify and characterise potential hazards of new and existing chemical substances (including biocides and agricultural pesticides) and chemical preparations/mixtures. They cover tests for physical-chemical properties of chemicals, human health effects, environmental effects, as well as degradation and accumulation in the environment.

The Test Guidelines are incorporated into EU legislation by including them in Annex V to Directive 67/548/EEC. As a consequence, the Guidelines have a mandatory position in the requirements for testing of chemicals.

Annex VI

Annex VI gives the general classification and labelling requirements for dangerous substances and preparations. Much of the guidance criteria set out in the Annex are related to the test methods described in Annex V. However there are also references to ISO and CEN standards.

References to standards are included in the criteria as a supplement to the test methods given in Annex V.

Test methods for viscosity as included in the criteria for R65, which relates to mainly organic solvents that can give rise to lung damage if the chemical is aspirated into the lungs.

R65 Harmful: may cause lung damage if swallowed
Liquid substances and preparations presenting an aspiration hazard in humans because of their low viscosity:

(a) For substances and preparations containing aliphatic, alicyclic and aromatic hydrocarbons in a total concentration equal to or greater than 10 % and having either

– a flow time of less than 30 sec. in a 3 mm ISO cup according to ISO 2431 (April 1996 / July 1999 edition) relating to 'Paints and varnishes - Determination of flow time by use of flow cups',

– a kinematic viscosity measured by a calibrated glass capillary viscometer in accordance with ISO 3104/3105 of less than 7 x 10^{-6} m^2/sec at 40° C (ISO 3104, 1994 edition, relating to 'Petroleum products - Transparent and opaque liquids - Determination of kinematic viscosity and calculation of dynamic viscosity'; ISO 3105, 1994 edition, relating to 'Glass capillary kinematic viscometers - Specifications and operating instructions'), or

– a kinematic viscosity derived from measurements of rotational viscometry in accordance with ISO 3219 of less than 7 x 10^{-6}

m^2/sec at 40° C (ISO 3219, 1993 edition, relating to 'Plastics – Polymers/resins in the liquid state or as emulsions or dispersions – Determination of viscosity using a rotational viscometer with defined shear rate').

Note that substances and preparations meeting these criteria need not be classified if they have a mean surface tension greater than 33mN/m at 25° C as measured by the du Nouy tensiometer or by the test methods shown in Annex V Part A.5.

(b) For substances and preparations, based on practical experience in humans.

Reference to standards is also used in the criteria for calculating the flammability and oxidising properties of certain gas mixtures.

9. SPECIAL CASES: PREPARATIONS

9.1.1. Evaluation of physicochemical properties

9.1.1.1. Flammability

Coefficients of equivalency (Ki)

The values of the coefficients of equivalency Ki, between the inert gases and nitrogen and the values of the maximum contents of flammable gas (Tci) may be found in tables 1 and 2 of the ISO Standard ISO 10156 edition 15. 12. 1990 (new: 1996 edition) relating to 'Gases and gas mixtures - Determination of fire potential and oxidising ability for the selection of cylinder valve outlets'.

Maximum content of flammable gas (Tci)

The value of the maximum content of flammable gas (Tci) may be found in table 2 of the ISO Standard ISO 10156 edition 15. 12. 1990 (new: 1996 edition) relating to 'Gases and gas mixtures - Determination of fire potential and oxidising ability for the selection of cylinder valve outlets'.

When a Tci value for a flammable gas does not appear in the above standard, the corresponding lower explosivity limit (LEL) will be used. If no LEL value exists, the value of Tci will be set at 1 % by volume.

9.1.1.2. Oxidising properties

Coefficients of equivalency between oxidising gases and oxygen

The coefficients used in the calculation to determine the oxidising capacity of certain gases in a mixture with respect to the oxidising capacity of oxygen in air, listed under 5.2. in the ISO Standard ISO 10156 edition 15. 12. 1990 (new: 1996 edition) relating to 'Gases and gas mixtures - Determination of fire potential and oxidising ability for the selection of cylinder valve outlets', are the following.

O_2	1
N_2O	0,6

When no value for the Ci coefficient exists for a gas in the cited standard a value of 40 is attributed to this coefficient.

There are also reference to standards is setting certain labelling requirements. The requirements for substances are shown below; similar provisions not shown here are also given for labelling mixtures of gases (preparations).

8. SPECIAL CASES: SUBSTANCES

8.1. Mobile gas cylinders

For mobile gas cylinders the requirements concerning labelling are considered to be satisfied when they are in agreement with Article 23 or Article 24 (6) b.

However, by way of derogation from Article 24 (1) and (2), one of the following alternatives can be used for gas cylinders with a water capacity of less than or equal to 150 litres:

– the format and dimensions of the label can follow the prescriptions of the ISO Standard ISO/DP 7225 (1994 edition) relating to 'Gas cylinders - Precautionary labels',

– the information specified in Article 23 (2) may be provided on a durable information disc or label held captive on the cylinder.

8.2. Gas containers intended for propane, butane or liquefied petroleum gas (LPG)

These substances are classified in Annex I. Although classified in accordance with Article 2, they do not present a danger to human health when they are placed on the market in closed refillable cylinders or in non-refillable cartridges within the scope of EN 417 as fuel gases which are only released for combustion (EN 417, September 1992 edition, relating to 'Non-refillable metallic gas cartridges for liquefied petroleum gases, with or without a valve, for use with portable appliances; construction, inspection, testing and marking').

Annex IX

This annex[6] describes in detail the provisions related to child-proof fastenings and to tactile warning devices used for packaging dangerous substances and preparations.

part A

Provisions related to child-proof fastenings

1. Reclosable packages
Child-proof fastenings used on reclosable packages shall comply with ISO standard 8317 (1 July 1989 edition) relating to "Child-resistant packages – Requirements and methods of testing for reclosable packages" adopted by the International Standards Organisation (ISO).

[6] OJ L 136, 8.6.2000, p. 89.

2. *Non-reclosable packages*

Child-proof fastenings used on non-reclosable packages shall comply with CEN standard EN 862 (March 1997 edition) relating to "Packaging - Child-resistant packages – Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products" adopted by the European Committee for Standardisation (CEN).

3. *Notes*

1. Evidence of conformity with the above standards may be certified only by laboratories which conform with European Standards series EN 45 000.

2. Specific cases

If it seems obvious that packaging is sufficiently safe for children because they cannot get access to the contents without help of a tool, the test does not need to be performed.

In all other cases and where there are sufficient grounds for doubting the security of the closure for a child, the national authority may ask the person responsible for putting the product on the market to give it a certificate from a laboratory, described in 3.1,m stating that either:

– the type of closure is such that it is not necessary to test to the ISO or CEN standards referred to above or
– the closure has been tested and has been found to conform with the standards referred to above.

PART B

Provisions related to tactile warning devices

The technical specifications for tactile warning devices shall conform with EN ISO standard 11683 (1997 edition) relating to "Packaging – tactile warnings of danger – Requirements".

1.5 Annex V

Examples of essential requirements from three selected Directives

– Directive 94/27/EC Packaging and packaging waste

– Directive 88/378/EEC Safety of Toys

– Directive 43/23/EEC Low voltage equipment

Note: Essential requirements from a fourth Directive, Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery (as amended by Directive 93/44/EEC) are too extensive for this Annex, but can be found online at http://europa.eu.int/eur-lex/en/

Packaging and Packaging Waste Directive: 94/27/EC

ANNEX II: ESSENTIAL REQUIREMENTS ON THE COMPOSITION AND THE REUSABLE AND RECOVERABLE, INCLUDING RECYCLABLE, NATURE OF PACKAGING

1. Requirements specific to the manufacturing and composition of packaging

– Packaging shall be so manufactured that the packaging volume and weight be limited to the minimum adequate amount to maintain the necessary level of safety, hygiene and acceptance for the packed product and for the consumer.
– Packaging shall be designed, produced and 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.

2. Requirements specific to the reusable nature of packaging

The following requirements must be simultaneously satisfied:
– the physical properties and characteristics of the packaging shall enable a number of trips or rotations in normally predictable conditions of use,
– possiblity 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.

3. Requirements specific to the recoverable nature of packaging

(a) 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.

(b) 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.

(c) 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.

(d) 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.

1.5.1 Safety of Toys Directive 88/378/EEC

ANNEX II: ESSENTIAL SAFETY REQUIREMENTS FOR TOYS

1. General principles

1.1. In compliance with the requirements of Article 2 of the Directive, the users of toys as well as third parties must be protected against health hazards and risk of physical injury when toys are used as intended or in a forseeable way, bearing in mind the normal behaviour of children. Such risks are those:

(a) which are connected with the design, construction or composition of the toy;

(b) which are inherent in the use of the toy and cannot be completely eliminated by modifying the toy 's construction and composition without altering its function or depriving it of its essential properties.

1.2. (a) The degree of risk present in the use of a toy must be commensurate with the ability of the users, and where appropriate their supervisors, to cope with it. This applies in particular to toys which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.

(b) To observe this principle, a minimum age for users of toys and/or the need to ensure that they are used only under adult supervision must be specified where appropriate.

1.3. Labels on toys and/or their packaging and the instructions for use which accompany them must draw the attention of users or their supervisors fully and effectively to the risks involved in using them and to the ways of avoiding such risks.

2. Particular risks

2.1. Physical and mechanical properties

(a) Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.

(b) Accessible edges, protrusions, cords, cables and fastenings on toys must be so designed and constructed that the risks of physical injury from contact with them are reduced as far as possible.

(c) Toys must be so designed and constructed as to minimize the risk of physical injury which could be caused by the movement of their parts.

(d) Toys, and their component parts, and any detachable parts of toys which are clearly intended for use by children under 36 months must be of such dimensions as to prevent their being swallowed and/or inhaled.

(e) Toys, and their parts and the packaging in which they are contained for retail sale must not present risk of strangulation or suffocation.

(f) Toys intended for use in shallow water which are capable of carrying or supporting a child on the water must be designed and constructed so as to reduce as far as possible, taking into account the recommended

use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.

(g) Toys which it is possible to get inside and which thereby constitute an enclosed space for occupants must have a means of exit which the latter can open easily from the inside.

(h) Toys conferring mobility on their users must, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy developed by it. Such a system must be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.

(i) The form and composition of projectiles and the kinetic energy they may develop when fired from a toy designed for that purpose must be such that, taking into account the nature of the toy, there is no unreasonable risk of physical injury to the user or to third parties.

(j) Toys containing heating elements must be so constructed as to ensure that:
— the maximum temperature of any accessible surfaces does not cause burns when touched,
— liquids and gases contained within toys do not reach temperatures or pressures which are such that their escape from a toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.

2.2. Flammability

(a) Toys must not constitute a dangerous flammable element in the child 's environment. They must therefore be composed of materials which:
1. do not burn if directly exposed to a flame or spark or other potential seat of fire; or

2. are not readily flammable (the flame goes out as soon as the fire cause disappears);or
3. if they do ignite, burn slowly and present a low rate of spread of the flame; or
4. irrespective of the toy 's chemical composition, are treated so as to delay the combustion process. Such combustible materials must not constitute a risk of ignition for other materials used in the toy.

(b) Toys which, for reasons essential to their functioning, contain dangerous substances or preparations as defined in Council Directive 67/548/EEC[7], in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or preparations which may become flammable due to the loss of non-flammable volatile components.

(c) Toys must not be explosive or contain elements or substances likely to explode when used as specified in Article 2 (1)of the Directive. This provision does not apply to toy percussion caps, for which reference should be made to point 10 of Annex I and the related footnote.

(d) Toys and, in particular, chemical games and toys, must not contain as such substances or preparations:
— which, when mixed, may explode:
— through chemical reaction, or through heating,
— when mixed with oxidizing substances,
— which contain volatile components which are flammable in air and liable to form flammable or explosive vapour/air mixture.

[7] OJ No 196 16.8.1997, pp. 1-67.

2.3. Chemical properties

1. Toys must be so designed and constructed that, when used as specified in Article 2 (1)of the Directive, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes.

   They must in all cases comply with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations.

2. In particular, for the protection of children's health, bioavailability resulting from the use of toys must not, as an objective, exceed the following levels per day:
   0,2 μg for antimony,
   0,1 μg for arsenic,
   25,0 μg for barium,
   0,6 μg for cadmium,
   0,3 μg for chromium,
   0,7 μg for lead,
   0,5 μg for mercury,
   5,0 μg for selenium,
   or such other values as may be laid down for these or other substances in Community legislation based on scientific evidence. The bioavailability of these substances means the soluble extract having toxicological significance.

3. Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC[8] in amounts which may harm the health of children using them. At all events it is strictly forbidden to include, in a toy, dangerous substances or preparations if they are intended to be used as such while the toy is being used.

[8] OJ No 187, 16.7.1988, p. 14.

However, where a limited number of substances or preparations are essential to the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardization (CEN)according to the procedure of the committee set up by Directive 83/189/EEC,provided the permitted substances and preparations comply with the Community classification rules in respect of labelling, without prejudice to point 4 of Annex IV.

2.4. Electrical properties

(a) Electric toys must not be powered by electricity of a nominal voltage exceeding 24 volts and no part of the toy may exceed 24 volts.

(b) Parts of toys which are connected to, or liable to come into contact with a source of electricity capable of causing electric shock, together with the cables or other conductors through which electricity is conveyed to such parts ,must be properly insulated and mechanically protected so as to prevent the risk of such shock.

(c) Electric toys must be so designed and constructed as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.

2.5. Hygiene

Toys must be so designed and manufactured as to meet the requirements of hygiene and cleanliness in order to avoid any risk of infection, sickness and contamination.

2.6. Radioactivity

Toys must not contain radioactive elements or substances in forms or proportions likely to be detrimental to a child's health. Council Directive 80/836/ Euratom shall apply[9].

1.5.2 Low Voltage equipment Directive 73/23/EEC

ANNEX I: PRINCIPAL ELEMENTS OF THE SAFETY OBJECTIVES FOR ELECTRICAL EQUIPMENT DESIGNED FOR USE WITHIN CERTAIN VOLTAGE LIMITS

1. General conditions

a) The essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the equipment, or, if this is not possible, on an accompanying notice.

b) The manufacturers or brand name or trade mark should be clearly printed on the electrical equipment or, where that is not possible, on the packaging.

c) The electrical equipment, together with its component parts should be made in such a way as to ensure that it can be safely and properly assembled and connected.

d) The electrical equipment should be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 of this Annex is assured providing that the equipment is used in applications for which it was made and is adequately maintained.

[9] OJ No L 246, 17.9.1980, p. 1.

2. Protection against hazards arising from the electrical equipment

Measures of a technical nature should be prescribed in accordance with point 1,in order to ensure:

a) that persons and domestic animals are adequately protected against danger of physical injury or other harm which might be caused by electrical contact direct or indirect;

b) that temperatures, arcs or radiation which would cause a danger, are not produced;

c) that persons, domestic animals and property are adequately protected against non-electrical dangers caused by the electrical equipment which are revealed by experience;

d) that the insulation must be suitable for foreseeable conditions.

3. Protection against hazards which may be caused by external influences on the electrical equipment

Technical measures are to be laid down in accordance with point 1, in order to ensure:

a) that the electrical equipment meets the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered;

b) that the electrical equipment shall be resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered;

c) that the electrical equipment shall not endanger persons, domestic animals and property in foreseeable conditions of overload.

Technical Specifications in Legislation: New Approach and other methods

Legislation is normally considered as an activity that primarily involves legislators, governments and civil servants. However, in certain forms of legislation there are areas of a highly technical nature where a wider form of expertise is required.

In 1985, the Council adopted a Resolution introducing a new approach to the problem of how to access this wider form of expertise. The "New Approach" uses Standards developed under mandate to CEN[1] as a means of developing necessary technical guidance to supplement Community legislation. This involves the delegation of forming what is intended to form part of legally binding legislation to a private organisation. However, the problem of the inclusion of highly technical requirements in legislation is not new, and other methods of addressing the problem, which do not involve delegation to private organisations, are also used. This paper describes some of these other approaches.

1. Transport of Dangerous Goods

The regulation of the transport of dangerous goods is an area where much of the regulation is of a highly technical nature. The regulations governing this transport are elaborated in the context of a United Nations Committee, in which UN Member States take part. In 1956, the United Nations Economic and Social Council (ECOSOC) published the first edition of the UN Recommendations concerning the Transport of Dangerous Goods. The UN CETDG updates these Recommendations[2], and the Eleventh Revised Edition was adopted in 1999. These Recommendations include a series of detailed test methods and specifications that are in effect very

[1] Centre Européen de Normalisation.
[2] United Nations Committee of Experts on the Transport of Dangerous Goods.

similar to standards[3]. These specifications include test methods to determine the effects of dangerous goods, including a series of tests for explosive properties. The Recommendations also contain rules for the classification and labelling of dangerous goods, as well as detailed specifications for containers for these goods.

The UN CETDG is a working group where the United Nations Economic Commission for Europe (UN ECE) provides the Meeting Secretariat. The relevant national authority represents member countries. Other countries, not taking an active role in the elaboration of the Recommendations have Observer status. Industry and other organisations can take part in these meetings with the status of observers. Agreement on UN Transport Recommendations follows a formal vote. The UN recommendations ("Red book") are adopted on the basis of a majority vote from countries that are formally considered as active members of the Committee[4]. Countries with observer status only do not have voting rights for adoption of these Recommendations. Adoption of the regional ADR[5] and RID Recommendations (where again the UN ECE provides the Meeting Secretariat) is again obtained by the result of a majority vote, where all signatory countries[6] are eligible to vote.

The UN regulations for transport of dangerous goods by road and rail have subsequently been adopted as the basis for European legislation[7].

[3] Standards are documents for common and repeated use, which give rules, guidance or characteristics of activities or with the results of activities. These documents are agreed by Consensus, and adopted by a relevant body. The intention is to obtain optimal order in a particular context. Definition from EN 45020.

[4] Denmark has Observer status in this Committee, and is therefore not eligible to vote.

[5] An Agreement drawn up by the UN ECE in Geneva, whereby most States in Europe have agreed common rules for the movement of Dangerous goods by road across their frontiers and through their territories. The abbreviation "ADR" comes from key words in the French Title. The RID regulations cover transport of dangerous goods by rail.

[6] Members comprise 14 of the 15 EU Member States (not the Irish Republic), two of the three EEA Member States (Liechtenstein, Norway, but not Iceland), Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Republic of Moldova, Romania, Russian Federation, Slovakia, Slovenia, Switzerland, the Former Republic of Macedonia, Yugoslavia.

[7] Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws

2. Codex Alimentarius

The regulation of food safety is similarly an area where much of the regulation is of a highly technical nature. The food standards programme is elaborated in the context of a United Nations Committee, in which UN Member States take part. There are two UN organisations concerned with nutrition, the Food and Agriculture Organisation (FAO) and the World Health Organisation. (WHO), and, as a result, many initiatives in this area are taken by Joint Committees of the two organisations. A Joint FAO/WHO Food Standards Programme was established in 1962. This programme, also known as the Codex Alimentarius Commission, met for its first session in 1963. This intergovernmental body is comprised of representatives of more than 120 member nations[8].

The Codex Alimentarius develops food safety standards that serve as a reference for international food trade. Its primary mission is to protect the health of consumers and to ensure fair practices in international food trade. To this end the Codex Alimentarius Commission adopts standards for commodities, codes of practice and maximum limits for additives, contaminants, pesticides residues and veterinary drugs, which are prepared by specialised committees and task forces.

The General Subject Committees are the Codex Committee on Food Additives and Contaminants (CCFAC), the Codex Committee on Pesticide Residues (CCPR) and the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). These Codex Alimentarius Committees are assisted by a number of working groups such as the Joint FAO/WHO Expert Committee on Food

of the Member States with regard to the transport of dangerous goods by road, OJ L 319, 12.12.1994, p.7, as amended by the European Parliament and Council Directive 2000/61/EC, OJ L279, 1.11.2000, p.40. Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail, OJ L 235, 17.9.1996, p.25, as amended by the European Parliament and Council Directive 2000/62/EC, OJ L279, 1.11.2000, p.44.

[8] European members comprise: all 15 EU Member States, two of the three EEA Member States (Norway, Iceland but not Liechtenstein), Albania, Armenia, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Georgia, Hungary, Israel, Latvia, Lithuania, Malta, Republic of Moldova, Poland, Romania, Russian Federation, Slovakia, Slovenia, Switzerland, the Former Republic of Macedonia, Turkey, Yugoslavia.

Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).

Since the conclusion of the Uruguay Round in 1994, the role of Codex Alimentarius Standards has been strengthened. The World Trade Organisation Agreement on Sanitary and Phytosanitary Measures considers that WTO members applying the Codex Alimentarius standards meet their obligations under this Agreement.

The Member States of the EU are all members of the Codex Alimentarius. The European Commission is an observer. The European Commission and the Member States attempt to present joint comments on issues discussed in Codex Committees which are within the competence of Community legislation. These comments are presented in EU position papers co-ordinated by the Directorate General for Consumer and Health Protection acts as the contact point and work.

3. OECD Test Guidelines Programme

In the area of chemicals control, the first initiatives towards the systematic collection of data on chemicals were taken in the OECD[9]. In 1974, a Ministerial Meeting adopted a number of Recommendations, including one on the pre-marketing assessment of the potential effects of chemicals on man and the environment[10]. A natural consequence of this Recommendation was that agreed testing methods would be need to be developed to achieve this goal, and the OECD Test Guidelines Programme was started in 1977. There was also concern that this aim should be achieved "without unnecessary impediments to trade and industrial development in the countries directly involved", and this resulted in the adoption of a Decision on Mutual Acceptance of Data (MAD) in 1981. The basis for the MAD agreement is that tests carried out according to OECD Test Guidelines[11] and according to Good Laboratory Practice (GLP) are

[9] Organisation for Economic Co-operation and Development.

[10] OECD Council Recommendation on the Assessment of the Potential Environmental Effects of Chemicals, adopted on 14th. November, 1974. C(74) 215.

[11] The first set of OECD test guidelines was published in 1981. In some cases (e.g. OECD TG 301) these were based on methods already published; others were a synthesis of the normally accepted national test guidelines.

regarded as acceptable data by OECD Member States irrespective of where the tests were originally carried out.

The OECD Guidelines for the Testing of Chemicals are a collection of the most widely used internationally agreed testing methods used by government, industry and independent laboratories to identify and characterise potential hazards of new and existing chemical substances (including biocides and agricultural pesticides) and chemical preparations/mixtures. They cover tests for physical-chemical properties of chemicals, human health effects, environmental effects, as well as degradation and accumulation in the environment.

Since they were first adopted in 1981, the OECD Guidelines for the testing of chemicals represent a basic set of tools that are primarily for use in regulatory safety testing and subsequent chemical and chemical product notification and chemical registration. The Test Guidelines are updated as required in order to keep pace with progress in science. In addition, new Test Guidelines are developed and agreed upon, based on specific needs identified by OECD Member countries. OECD-wide networks of governmental National Co-ordinators and national experts provide the opportunity for input from scientists in government, academia and industry. Broad acceptance and recognition of the Test Guidelines as the international standard has been achieved through these networks. Since their inception, 11 addenda have been published. Today, the OECD Guidelines comprise 90 adopted guidelines, 16 de-restricted Guidance Documents and more than 30 draft guidelines and Guidance Documents. A list of these documents is available[12]. In addition to the adopted and draft Test Guidelines as well as Guidance Documents, the Test Guidelines Programme produces documents and reports that are useful as background information (e.g. Detailed Review Papers and Workshop Reports).

[12] http://www.oecd.org/ehs/test/

The OECD comprises 30 Member States[13]. Agreement on the OECD Test Guidelines follows submission to the OECD Council. Here agreement is based on Consensus. Most but not all OECD Member States[14] take part in the Test Guidelines programme. The Test Guidelines are incorporated into EU legislation by including them in Annex V to Directive 67/548/EEC[15]. As a consequence, the Guidelines have a mandatory position in the requirements for testing of chemicals.

[13] In addition to the 15 EU Member States and two of the three EEA Member States (Iceland, Norway, but not Liechtenstein), , the OECD includes: Australia, Canada, Czech Republic, Hungary, , Japan, Korea, Mexico, New Zealand, Poland, Slovak Republic, Switzerland, Turkey and the United States.

[14] 14 of the 15 EU Member States (not Luxembourg), one of the three EEA Member States (Norway, not Iceland or Liechtenstein), Australia, Canada, Czech Republic, Hungary, , Japan, Korea, Mexico, New Zealand, Poland, Switzerland, Turkey and the United States. The European Commission, the Business and Industry Advisory Committee to the OECD (BIAC) and the Trade Union Advisory Committee (TUAC) also take part. Israel, Slovak Republic, Slovenia and South Africa may participate and contribute to the work of the programme in the future.

[15] Annex V is found in the following Directives: Commission Directive 88/302/EEC of 18 November 1987 adapting to technical progress for the ninth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. O.J. L133, 30.5.1988, p. 1 (corrigendum: O.J. N° L136, 2.6.1988, p. 20); Commission Directive 92/69/EEC of 31 July 1992 adapting to technical progress for the seventeenth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. O.J. L383, 29.12.1992, p. 113; O.J. L383A, 29.12.1992, p. 1; Commission Directive 93/21/EEC of 27 April 1993 adapting to technical progress for the eighteenth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. O.J. L110, 4.5.1993, p. 20; O.J. L110A, 4.5.1993, p. 1; Commission Directive 96/54/EC of 30 July 1996 adapting to technical progress for the twenty-second time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. O.J. L248, 30.9.1996, p. 1; Commission Directive 98/73/EC of 18 September 1998 adapting to technical progress for the 24th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. O.J. L305, 16.11.1998, p. 1. Corrigendum: O.J. L285, 8.11.1999, p.1; Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the -classification, packaging and labelling of dangerous substances O.J. L 136, 8.6. 2000, p.1; Commission Directive 2000/33/EC of 25 April 2000 adapting to technical progress for the 27th time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances O.J. L 136, 8.6. 2000, p. 90. Commission Direc-

It should be noted that there is an overlap in the scope of these test methods and a number of ISO and CEN standards. The latter have been developed in support of environmental legislation, rather as part of chemicals control legislation. There is a considerable overlap both in the scope and detailed content of many of these test methods. Since the purpose of the standards is mainly in support of environmental legislation, this overlap is most apparent in tests for environmental effects. However, a range of ISO[16] test methods, particularly those applied to medical appliances, also have a considerable overlap with the OECD test methodology. A report listing the relevant OECD test guidelines and the corresponding ISO standards has been prepared by the OECD[17].

4. Conclusion

The procedures in the three examples described above are in principle very similar to those resulting from the use of the New Approach. In all cases, detailed technical guidance in the form of standards, guidelines, or other relevant documents are elaborated by other organisations than working groups functioning directly under the European Commission. In all three cases, the recommendations or guidelines that have been developed as instruments that are not necessarily legally binding, are subsequently incorporated into legally binding EU legislation.

These working groups normally include representatives from all EU Member States. Ireland is not represented in the UN CETDG Transport Working Group; Luxembourg is not represented in the OECD Test Guidelines programme. The results of both programmes are subsequently incorporated into EU legislation, in practice with few if any amendments. However, as both countries are Member States, they are present when these guidelines are incorporated

tive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. O.J. L225. 21.8.2001, p.1 – 333.

[16] International Standards Organisation.

[17] OECD Test Guidelines Programme: Revised Comparison between OECD Test Guidelines and ISO standards in the areas of ecotoxicology and health effects. OECD 16th. April, 1999: ENV/JM/TG/RD(99)3.

into EU legislation. A similar situation applies to the EEA Countries: Iceland does not take part in the UN CETDG Working Groups or the OECD Test Guidelines programme; Liechtenstein does not take part in the OECD Test Guidelines programme or the UN Codex Alimentarius Commission work. Since EEA Members are consulted on EU legislation (although they do not have voting rights in the adoption), these countries are consulted when these guidelines are adopted as EU legislation.

In all the three fora concerned, other interest groups including Industry, trade unions and other NGOs have the right to participate as Observers. In addition, adoption of these recommendations at a national level also includes consultation with a large range of government bodies and national organisations. The workings of these organisations have as a result not in general been criticised for a lack of broad consultation. In the case of the development of standards, concern has been expressed that consultation is insufficiently broadly based. The Council Resolution of 28th. October, 1999 on the role of standardisation in Europe[18] point 39 stresses that "*interested parties such as workers', consumers' and environmental interest groups should be fully involved in the standardisation process at all relevant stages when standards are drawn up at the international level*". Both European consumer and environmental interest groups have expressed dissatisfaction with the process.

In all the three fora concerned, the votes are cast to reflect a national position, and not that of a private organisation. Hence, setting standards that have a direct consequence for human health, safety or the environment remain formally the responsibility of the government bodies concerned, and are not delegated to outside parties. The situation concerning standards is somewhat different. The actual standards are adopted in the context of the procedures of the relevant Standards Organisation. When approving standards mandated in the context of the New Approach, the Commission in the Official Journal publishes reference to them. A formal objection (safeguard clause) procedure can be introduced against a standard if a Member

[18] OJ C141, 19.5.2000 p.1

State or the Commission notes that a harmonised standard does not satisfy the requirements of the Directive. The Commission then decides after consultation with the Member States whether these objections are justified, and, if they are, reference to the standard is withdrawn in the Official Journal. However, the formal objection has no effect on the standard, but only on the presumption of conformity.

Finally, all three fora involve international partners outside the EU/EEA area. In the case of the UN CETDG and Codex Alimentarius, membership is in principle open to all UN Member States, although in practice, not all take an active part. The membership of the OECD is more limited. However, in many areas, the OECD co-operates closely with the United Nations Organisations with similar interests. In the area of chemicals' control, the OECD co-operates closely with a number of different UN organisations in the process of the harmonisation of classification criteria. The OECD has taken the lead in discussions of classification of criteria for human health and the environment, whilst the UN CETDG has taken the lead in discussions of classification for physical-chemical effects. Since in any case, the fora concerned provide non-binding recommendations, the final inclusion of these as EU legislation continues to be a matter for the European Community, irrespective of the wider scope of the organisations in which the recommendations are developed. In all three cases, development of standards in these fora has the character of international rather than regional co-operation, and, as such, is closer to the level of discussion at ISO than in CEN.

Experience in these fora shows that a number of different organisations are currently used to develop technical guidance similar to that developed in Standardisation organisations such as CEN and ISO. It should be noted however, that all three examples relate to developments of standards for specific areas, rather than the more general scope of the wider range of CEN / ISO product related standards. The Governmental basis of these organisations makes it possible to avoid some of the difficulties.

Steering Committee

The Steering Committee has assisted in a broad advisory capacity to define general guidelines and contents of the programme. It is composed of different stakeholders to ensure openness and transparency of the programme. Members include:

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Abbreviations

AENOR	Asociación Espa_ola de Normalización y Certificación
BAT	Best Available Techniques
BATREF/BREF	BAT Reference document
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
CMC	CEN Management Center
CO2	Carbon Dioxide
DG	Directorate General
DG SANCO	DG Health and Consumer Protection
EC	European Communities
EEA	European Economic Area
EEB	European Environmental Bureau
EEC	European Economic Community
EEE	Electrical and Electronic Equipment
EIA	Environmental Impact Assessment
EMAS	Environmental Management Standards
EPD	Environmental Product Declaration
ETSI	European Telecommunications Standards Institute
EU	European Union
EUEB	European Union Eco-labelling Board
GDP	Gross Domestic Product
IMPEC	Committee on Impact on the Environment of Electric and Electronic Equipment
IPP	Integrated Product Policy
IPPC	Integrated Pollution Prevention and Control
ISO	International Standards Organisation
LCA	Life Cycle Assessment
NGOs	Non Governmental Organisations
ODS	Ozone Depleting Substances
OECD	Organisation for Economic Cooperation and Development
PBB	Polybrominated Biphenyl

PBDE	Polybrominated Diphenyl Ether
POEM	Product Oriented Environmental Management
PSR	Product Specific Requirements
REACH	Registration, Evaluation and Authorisation of Chemicals
RoHS	Restriction of Hazardous Substances
SABE	CEN Strategy Advisory Board on the Environment
SOGS	Senior Official Groups on Standardisation and Conformity Assessment Policy
OECD	Organisation for Economic Cooperation and Development
TC	Technical Committee
UN CETDG	United Nations Committee of Experts on Transport of Dangerous Goods
UNCED	Conference on Environment and Development
VAT	Value Added Tax
WEE	Waste Electrical and Electronic Equipment
WTO	World Trade Organisation

Data Sheet

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Abstract:
In recent years, the debate among stakeholders concerning the role of the New Approach to develop health or environment-related standards has become highly polarised. It is in this context that the Workshop on the New Approach in Setting Product Standards for Safety, Environmental Protection and Human Health (Copenhagen, 29-30 November 2001) was convened. From the discussions that took place at the Copenhagen Workshop, it can be concluded that neither concept is »the best«. Traditional methods and the »New Approach« can perhaps be better seen as developments, towards more refined instruments, with their own particular strengths and weaknesses. Seen From this perspective, the art in developing new legislation is to ensure that the most relevant form of instrument is chosen.

Terms:
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