Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and the Council on reciprocal recognition of navigability licences for inland waterway vessels (Codified version)

COM(2008) 37 final — 2008/0021 (COD)

(2008/C 204/12)

On 13 February 2008, the Council decided to consult the European Economic and Social Committee, under Article 80(2) of the Treaty establishing the European Community, on the

Proposal for a Directive of the European Parliament and the Council on reciprocal recognition of navigability licences for inland waterway vessels (Codified version)

Since the Committee unreservedly endorses the proposal and feels that it requires no comment on its part, it decided, at its 443rd plenary session of 12 and 13 March 2008 (meeting of 12 March) by 121 votes in favour and 6 abstentions, to issue an opinion endorsing the proposed text.

Brussels, 12 March 2008.

The President
of the European Economic and Social Committee
Dimitris DIMITRIADIS

Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006

COM(2007) 355 final — 2007/0121 COD

(2008/C 204/13)

On 13 July 2007 the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the

Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 26 February 2008. The rapporteur was **Mr David Sears.**

At its 443rd plenary session, held on 12 and 13 March 2008 (meeting of 12 March), the European Economic and Social Committee adopted the following opinion by 124 votes in favour with 2 abstentions.

1. **Summary and recommendations**

1.1 The UN, acting on behalf of its member countries, has proposed a model for a 'globally harmonised system' (GHS) for the criteria and processes used in the 'classification, packaging and labelling of chemicals'. This is intended to support world trade and to assist less developed economies in their efforts to protect the safety and health of workers and consumers.

1.2 The EESC strongly supports this aim of global harmonisation, the form and legal basis of the implementing legislation

hereby proposed by the Commission, and the timetable proposed for implementation by manufacturers and suppliers to coincide with the first major deadline for the registration of 'substances' under Regulation (EC) 1907/2006 (REACH).

1.3 The EESC also agrees with the Commission's assessment that, although the changes to the system developed in the EU over the last 40 years are both inevitable and widely supported, the short term benefits within the EU are likely to be negligible and the costs potentially high. The EESC therefore believes that greater attention should have been paid to these, quite unusual, circumstances in the original impact assessment. In the absence of any significant overall benefit, any addition or modification to existing legislation that is not absolutely essential to implementing the UN proposal should be accompanied by a separate health, safety or economic justification. Above all, every effort must be made to ensure that existing standards are not compromised during the inevitably long transition period between these two largely equivalent systems. Education at the point of purchase will be a key requirement.

1.4 The EESC also believes that, given the very tight timetable, and the need to contain start-up costs, there is scope for flexibility in the proposal and in its immediate application. It has taken many years to develop the current system to a point where it properly protects the health and safety of workers and consumers across the EU and it is likely to be the same for the new globally harmonised system. What is key, however, is to commit sufficient long term resources at both the UN and in the Commission to ensure that the process of harmonisation continues — and that this eventually extends to the actual classification and labelling of widely traded goods as opposed to merely the criteria upon which these classifications are based.

1.5 The EESC notes, with concern, the length of this proposal, by itself and in conjunction with recent proposals such as REACH, the many other pieces of EU legislation with which these both interact, and the ever growing volume of guidance notes now deemed necessary. A new approach is essential if European industry (let alone the processes of monitoring or amending legislation) is not to be irretrievably damaged. It is simply not reasonable to assume that everyone, from the owner of the smallest SME to the typically larger groups of responsible officials in a national competent authority should have to routinely refer to more than 20 000 pages of interlinked documentation on these topics alone. A better way has to be found.

1.6 Under this same heading the EESC regrets the absence of key definitions and, in particular, the shift from the use of the word 'preparations', which has specific toxicological significance, to 'mixtures', which does not. The continuing absence of any EU definition of 'chemical' as either a noun or adjective continues to give rise to confusion for workers, consumers, managers and legislators alike. This proposal is intended to be neutral and uncontentious in content. It provides a great opportunity to correct mistakes at the detail level. This is already happening in the technical appendices. The provision of a standard set of definitions, applicable across all the related legislation should be tackled forthwith, leading eventually to a glossary of the key words in all languages, identifying those that mean the same (presumably 'chemical', 'chemical substance' and 'substance') and those that either have different meanings or are unrelated ('article' and 'product', for instance.). Cultural confusions or associations, in some languages, with the words 'substances' (taken to mean drugs, alcohol or tobacco) and 'chemicals' (as indications of terrorist or other illegal activities) should also be identified and avoided.

1.7 The EESC also notes the twin dangers of over-classification and over-labelling which eventually diminish the impact of warnings that are absolutely essential, and of relying on labels as the only sources of information for workers and consumers alike. Certainly the key information must be included. Links to other readily available sources are also important. The growing use of internet purchasing and online research on both benefits and risks of specific products suggests that further work on this is necessary. The needs of emergency responders and poison centres are not best served by long lists of standardised and unfamiliar names for components of complex mixtures. Indications of overall hazard and safety treatment, combined with contact data for round-the-clock follow-up offer the best protection for anyone affected. In specific circumstances where proprietary formulation technology is involved, the manufacturer is also protected, as in existing legislation, by this approach.

1.8 The EESC notes that there is no label proposed for the often very small quantities transferred between laboratories for the purposes of academic study or business R&D. This could be added to the array of labels proposed by the UN without difficulty and is to be preferred to the extremely restrictive, disproportionate and costly exemption currently proposed.

1.9 Finally the EESC notes that there will be a growing need to review the quality of the data used and the decisions made under the different jurisdictions world wide. The pressure to agree the outcomes of classification, not just the criteria and processes leading to them, will surely continue. The global needs and benefits of this are rather easier to understand.

2. **Introduction**

2.1 This proposal is designed to align existing EU legislation with a recently agreed UN model for a 'globally harmonised system' for the classification, labelling and packaging of raw materials, intermediate and finished products defined to be 'dangerous' or 'hazardous' and variously described as 'chemicals', 'substances', 'mixtures' or 'preparations'. European legislation

dating back to 1967 will be replaced. Many other directives and regulations, including Regulation (EC) 1907/2006 (REACH), currently being implemented, will require amendment. The longer term effects within the EU are intended to be positive, provided that costs can be contained and some rather minor benefits realised. Overall the proposal should facilitate world trade whilst maintaining high standards of protection for human health and the environment.

2.2 The 40-year old directive to be replaced is the Dangerous Substances Directive 67/548/EEC. This is generally regarded as the first piece of pan-European 'chemicals' legislation aimed, in particular, at protecting worker safety. It, and its many amending directives and adaptations to technical progress, now provide manufacturers and marketers, workers, distributors and consumers, in and outside the EU, with a harmonised system for the *classification* of '*dangerous substances*', using specified tests against agreed end points and hazard criteria; for their proper *labelling*, via a limited set of pictograms and standardised phrases to identify possible risks and to recommend procedures for safe handling; and for their *packaging*, to protect regular users and vulnerable groups, in particular, young children.

2.3 Twenty-one years after the adoption of Directive 67/548/EEC, the Dangerous Preparations Directive 88/379/EEC, extended the process from '*substances*' (a relatively finite list of 'elements and their compounds') to the theoretically infinite list of '*preparations*' ('mixtures of two or more substances'). Recognising that animal testing was undesirable or impossible on such a scale, the directive introduced into European law for the first time a theoretical relationship between the known or determinable hazards of the component substances and the most probable hazard of the eventual mixture. This could then be used to classify, label and package the preparation without the need for further testing.

2.4 Given that the vast majority of products sold to consumers are indeed '*preparations*' (or even '*articles*'); this was an important step towards ensuring consumer safety for products not already covered by specific and more restrictive directives, for instance those applying to the sale of pesticides, detergents or cosmetics. The 1988 directive was significantly amended in 1999 by Directive 1999/45/EC.

2.5 The above directives, together with the supporting Safety Data Sheet Directive 91/155/EEC, also subsequently modified, have, for many years, provided the cornerstones of worker and consumer protection across the EU. They interact with, and provide input to, virtually all other EU legislation aimed at protecting human health, safety and the environment. Constant updating is required to reflect changes in scope, manufacturing technology and test methods, product availability and possible usage, and to reflect the latest scientific understanding of the consequences of all of these and of ways to mitigate any undesired effects.

2.6 Equally important, these directives 'pursue internal market objectives' in that they seek to establish a Single Market in the EU for the various products affected. Products, whether they be raw materials, natural or synthetic products, intermediates or waste streams, finished products or articles, can be safely imported to or traded within and between Member States provided that they conform to these and other relevant pieces of EU legislation.

2.7 In 2001 the European Commission launched a White Paper entitled 'A Strategy for a Future Chemicals Policy'. This culminated last year in the adoption of Regulation (EC) 1907/2006, otherwise known as REACH, for the 'registration, evaluation, authorisation and restriction of chemicals'. An accompanying Directive 2006/121/EC, published and agreed at the same time, provided further amendments to Directive 67/548/EEC to bring the two into line. This process will presumably continue as more data become available or as legislative needs change.

2.8 All of the above refer to and affect the manufacture, distribution and marketing of specified products within the EU and trade between the EU and its importing and exporting partners. Similar but not identical systems have, inevitably, been developed over the same time-frame in a number of other economies worldwide with whom the EU regularly trades, via the multiplicity of large, medium and small enterprises established in and outside its borders.

2.9 A number of other countries, generally less well-developed in terms of their economies and/or legislative structures, have recognised the need for such a system for classification, labelling and packaging of 'dangerous substances' but await agreement on a globally recognised model to implement at local level.

2.10 Recognising, in the early 1990s, that these locally developed national or regional systems, whilst essential to the protection of human health, safety and the environment, could also form barriers to world-wide trade, the United Nations sought authority to develop a proposal for a Globally Harmonised System (GHS) for the 'classification, packaging and labelling of chemicals and for the provision of safety data sheets'. Models for this harmonisation already existed in the transport sector, in particular for physical hazards and acute toxicity.

2.11 Approval to develop this wider approach was given in Chapter 19 of Agenda 21 adopted at the United Nations Conference on Environment and Development (UNCED) in 1992. Technical input would be gathered from the Organisation for Economic Cooperation and Development (OECD), the International Labour Organisation (ILO) and the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG).

2.12 After nearly a decade of work, representatives of the 160 or so contributing UN member states reached agreement on the technical content of the new GHS in December 2002. The World Summit on Sustainable Development (WSSD) in Johannesburg in September of the same year encouraged its signatory countries 'to implement the GHS as soon as possible with a view to having the system fully operational by 2008'. The UN GHS, which now included the 2008 target date for implementation, was adopted by the UN Economic and Social Council in July 2003. These agreements were signed by representatives of all 27 member states of the, by now, enlarged EU.

2.13 A number of amendments to the original UN proposal were adopted in 2004 and included in the recommendations for 'a globally harmonised system of classification and labelling of chemicals (GHS)' published by the UN in 2005. This 540 page document, and its subsequent revisions, has become generally known as the 'Purple Book', following the colour adopted for its printed cover. Details of progress towards the 2008 target date, for 65 countries, including 27 from the EU, are available on the relevant UN website.

2.14 Further technical amendments were agreed by the UN in 2006 and included in a revised edition of the Purple Book published in 2007. The proposals include, inevitably for such an extended and complex process of global harmonisation of existing systems, a mixture of old and new test criteria and end points, pictograms, approved phrases and label designs. A 'building block' approach was introduced to allow different views to co-exist and to make it possible for an agreement to be reached between the participating countries (although excessive use of this would of course remove many of the intended benefits.)

2.15 The UN proposed model does not however have the necessary force of law and implementing legislation is required for those countries wishing to follow its recommendations. For the member states of the EU, this requires a proposal from the Commission.

2.16 The Commission started work in 2004 on an implementing proposal, publishing a first draft for an EU system in line with the GHS in 2006. Impact assessments were undertaken and published during this same period. A stakeholder consultation on the internet in the 3rd Quarter of 2006, together with a series of concerns expressed by the Commission's Legal Services, led to a major re-drafting of the original proposal. This was finally agreed and published by the Commission in June 2007. Technical reviews have already started in the appropriate working group of the Council. Opinions are now expected as ever from the European Parliament, the European Economic and Social Committee (EESC), and the Committee of the Regions.

2.17 There is a widespread desire that the current reviews neither delay nor significantly amend the harmonising proposals. The benefits are generally accepted as being diffuse, are related primarily to world trade, and will diminish if harmonisation is not achieved. Costs within the EU (or for those trading with the EU) will increase sharply if the implementation timetable differs from that already agreed for REACH. Any benefits for health, safety or the environment will be felt largely outside the EU, in countries not at present having effective systems of their own.

2.18 Implementation of the GHS will have consequential effects for EU transport legislation and for a raft of associated 'downstream' EU legislation affecting consumer products, the handling of chemicals for particular uses, the control of dangerous or hazardous chemicals, occupational health and safety, waste and end-of-life products. Further proposals will be introduced to cover these where necessary over the coming years. A full list of legislation likely to be affected was published by Commission Services in August 2006. Amendments to Regulation (EC) 1907/2006 (REACH) are included in the current proposal.

3. **Summary of the Commission's Proposal**

3.1 The proposal is set out in 3 'Volumes' and 7 'Annexes'. In the English language version, these total just over 2 100 pages. Although the main elements of the proposal are confined to the relatively short, 64 page, Volume I, new material, or new or revised interpretations of old material, are present throughout the document. The proposal must therefore be considered in its entirety as an essential piece of primary EU and national legislation affecting regulators, manufacturers, suppliers, distributors, traders, workers and consumers, in and outside the EU.

3.2 Volume II, comprising Annex I, sets out the detailed classification and labelling requirements for hazardous substances and mixtures (154 pages).

3.3 Volume III, comprising Annexes II to VII, provides a series of special rules for certain substances and mixtures; lists of new hazard and precautionary statements; new hazard pictograms; detailed harmonised classification and labelling for certain hazardous substances; and a translation table intended to assist users to show the changes from the classification and labelling requirements under Directive 67/548/EEC to the new requirements and hazard statements of the proposed Regulation (430 pages). A 'Legislative Financial Statement' for the proposal as a whole, which is required for the proper evaluation of the proposal but has little enduring value or interest as primary legislation, is included, or perhaps buried, at the end of this Volume.

3.4 Volumes IIIa and IIIb comprise Tables 3.1 and 3.2 as components of Annex VI, as set out in Volume III above. These together comprise a translation into the new regulatory framework of Annex 1 of the existing Directive 67/548/EEC — close to 1 500 pages recording decisions on the classification and labelling of specific hazardous substances accumulated over 40 years of product assessment in the EU.

3.5 The Commission's impact assessment, which must be read in conjunction with the above, is based on reports prepared by consultants RPA and London Economics and is relatively brief (34 pages).

3.6 The proposal is presented as a Regulation under Article 95 of the EC Treaty 'to ensure a level playing field for all suppliers of substances and mixtures in the internal market, as well as a high level of protection of health, safety, environment and consumers'.

3.7 The proposal recognises that the scope of existing EU legislation and the scope of the UN GHS proposal are not identical. Both differ in detail from the already largely harmonised transport regulations on classification and labelling. Changes under this proposal have, as far as possible, been kept to a minimum. In some cases further proposals will be required, in particular during the implementation phases of REACH.

3.8 The proposal adopts some new terms and definitions from the UN GHS, most noticeably the use of 'mixture' in place of 'preparation'.

3.9 The proposal recognises that any new system of classification could lead to the extensive use of laboratory animals. Alternative methods should be used wherever possible. Experiments on humans and other primates for the purposes of this classification appear to be expressly forbidden (depending on the unresolved legal and linguistic distinction, in the various official languages of the EU, between 'should not' and 'shall not') in the Commission's proposal (although such testing is permitted in the UN GHS model).

3.10 The problems associated with classifying 'mixtures' are recognised. 'Bridging principles' are provided which aim to facilitate read-across from products likely to have similar effects.

3.11 The proposal provides for the possibility of providing shorter common names for substances alone or as components of mixtures where the formal names as defined by the International Union of Pure and Applied Chemistry (IUPAC) exceed 100 characters in length. The use of product identifiers (numbers and names) supplied by the Chemical Abstracts Service of the American Chemical Society (CAS) will also continue. The controlled use of generic names which correctly identify the likely hazard without putting at risk any associated intellectual property associated with the precise composition of a mixture is maintained from existing legislation.

3.12 The necessary period of transition between the two systems is discussed in detail. It is clearly recognised that the new criteria must be applied first to 'substances' and later to 'mixtures'. To avoid unnecessary burdens on enterprises, there will be no obligation for an enterprise to reclaim or re-label products (either 'substances' or 'mixtures') already in the supply chain at the time that the relevant legislation comes into force.

3.13 Member States will be required to appoint authorities for the application and enforcement of the Regulation — and to establish 'appropriate sanctions for non-compliance'. It is noted that 'good cooperation between all competent authorities is essential'.

3.14 The Regulation will in principle apply to all substances and mixtures, except where other Community legislation lays down more specific rules. Cosmetics, flavourings, food additives, animal food and veterinary products, certain medical devices; products governed by rules relating to civil aviation, road or rail transport, and ammunitions (but not 'explosive products marketed for decorative effects', i.e. fireworks) are all excluded from the effects of this Regulation.

3.15 Waste as defined by Directive 2006/12/EC cannot, according to this proposal, be classified as either a 'substance' or a 'mixture' or an 'article' as defined by this Regulation and is therefore excluded from its effects.

3.16 Alloys are however defined to be 'mixtures' in line with point 41 of Article 3 in Regulation (EC) 1907/2006 (REACH) and are therefore included in this regulation, as presumably are true 'mixtures' (but not, in any useful sense, 'preparations') of naturally occurring substances such as metal ores, minerals and plant extracts.

3.17 Labelling requirements are changed in both layout and content from the existing EU system. Some existing pictograms are replaced; others are added for the first time. Existing permitted standardised 'risk' and 'safety' phrases are replaced with new 'signal words', 'hazard statements' and 'precautionary statements'.

3.18 All of the above approved words and statements are defined in all of the official languages of the EU and must be used as necessary on each label, depending upon the country in which the product is eventually sold. Multiple languages may be used, although the space available is becoming increasingly limited. (In some special cases additional translation of labels and supporting documentation may of course be required into legally necessary but not 'official' languages such as Welsh, or into other languages required, for instance Russian, Turkish, Arabic and Hindi, to meet the needs of specific indigenous or immigrant groups).

3.19 The proposal recognises that the process of classification, and therefore of labelling and packaging, is one of continuous update within the EU as new information or understanding becomes available or as test methods or legislative requirements change. Changes requiring action and the procedures then to be followed are set out in the text.

3.20 It is intended that the Regulation will come into force 20 days following its eventual publication in the Official Journal. Substances should be classified, labelled and packaged under existing legislation until no later than 1 December 2010 (to coincide with registration deadlines for REACH). Mixtures should be classified, labelled and packaged under existing legislation until no later than 1 June 2015. From then onwards, only the new legislation will apply.

4. **General comments**

4.1 The UN, acting on behalf of all its member countries, has proposed a model for a 'globally harmonised system' for the criteria and processes of classification, packaging and labelling of 'chemicals'. The member states of the EU have agreed that the model should be implemented, ideally by 2008. The Commission has proposed implementing legislation in the form of the Regulation now under discussion.

4.2 The EESC strongly supports the aim of global harmonisation, the form and legal basis of the legislation proposed, and the timetable proposed for implementation to coincide with the first major deadline for the registration of substances under Regulation (EC) 1907/2006 (REACH).

4.3 The EESC also notes that there must be flexibility to run the two systems in parallel, in particular for 'mixtures' which in many cases are themselves 'mixtures' of 'mixtures', each with a definable and sometimes long shelf life, measured in months or even years. The transition is unlikely to be fully within the timeframe proposed — but fortunately that does not mean that the process will be ineffective. In the absence of such flexibility, the start-up costs will increase and the intended long term benefits may not be realised.

4.4 The EESC also notes and agrees with the introductory comments of the Commission's impact assessment that 'in the long term, the GHS implementation seems worthwhile ... as cost savings will ultimately overcome the one-off costs of implementation' … although … 'implementation costs need to be kept in check so as to arrive at net benefits … in the foreseeable future and to avoid unnecessary costs and administrative burdens for SMEs'.

4.5 The EESC also notes the views expressed by the Commission in its Legislative Financial Statement that 'the legislative proposal relates to the implementation of an international agreement. Even a negative ex-ante evaluation would not result in the Commission not putting forward a legislative proposal since other policy options do not exist. A negative ex-post evaluation would not induce the Commission to withdraw from its commitment to implement the internationally agreed system of Classification and Labelling.'

4.6 Simply put, the Commission believes it had no choice but to put forward the proposal, whatever the calculated or actual balance of costs and eventual benefits. The EESC agrees that this is realistic under the circumstances but regrets that the impact assessment, even if not key to the decision making, did not explore further the likely costs of implementation, with a view to mitigating these effects during drafting. The fact that the same consultants (RPA) have prepared a detailed (and conflicting) analysis for just one affected sector (certain consumer products) suggests that this could have been done more widely and certainly more effectively if the money, time and will had been made available. As with all processes of harmonisation, the dangers of escalating costs and vanishing benefits are all too obvious.

4.7 It is, for instance, difficult to see why there should be any benefits at all for health, safety and the environment inside the EU as a direct consequence of this swap from one long-established and fully functioning system to another equally valid but unfamiliar system. In the short-term, consumer protection could even suffer as the two systems, with differing words, phrases and pictograms, run in parallel. A coordinated programme of education and training, focused on the retail sector, would go some way to reduce this risk.

4.8 There are also conceptual difficulties in understanding how the benefits to world trade will be fully realised with countries implementing the UN proposal on different time frames and with differing interpretations of the basic requirements. Early implementation by Japan and New Zealand has already given rise to concerns in Europe. Implementation in the US, with 4 or 5 systems currently running in parallel, is far from completion. Different language versions will of course continue to be required for globally traded goods, however the required labels and safety data sheets are harmonised.

4.9 The best that can be said therefore is that this is the start of a process of global harmonisation which mirrors what has already occurred across the member states of the EU and which will now require the same level of resources, supporting systems and processes to maintain on a global basis. This will be an unfamiliar role for the Commission and it will be important that it dedicates sufficient resources to allow the inevitable changes, updates and adaptations to technical progress to the current proposal to be made in a timely and effective manner. It is unclear that either the financial statement or the proposals for comitology and subsequent scrutiny are adequate in this respect.

4.10 Similar comments should be directed to the UN, to ensure that full harmonisation of not only the criteria for classification, but of the actual classifications determined and used as a basis for subsequent labelling and packaging, for globally traded high volume 'basic chemicals' (and eventually for the majority of globally traded high volume consumer products is achieved as quickly as possible. In both cases, close and continuing cooperation between the manufacturers of the products and the relevant regulators will be essential.

4.11 In the EU the Commission still needs to address the twin problems of dealing with the many only partially defined interactions with its own 'downstream' legislation — and of recognising and accommodating the needs of specific sectors, in particular for consumer products. Given that both systems are supposed to be equally effective, some flexibility should be possible to ensure that the broad framework of the proposal can be agreed as soon as possible.

4.12 On a similar theme, 'workers' (in the workplace) and 'consumers' (in a retail store, when shopping on line or subsequently at home) should of course all continue to be given the highest possible protection with respect to their health and safety. However the two environments and the information needs and support services available to those concerned are quite different. This is only partially recognised in this proposal. There is no need for a one-size fits all approach. Recent developments in consumer shopping patterns, in particular via the internet, should be recognised. The professional needs of emergency responders, first line health services and poison centres should also be taken into account with regard to the content of the labels and the relevance of the information specified.

4.13 The availability and value of other information sources apart from the label should also be recognised, in particular for consumers, where informed choices can be made using advice from consumer organisations or on-line from most manufacturers or suppliers. The bald statement by the Commission that 'the label is the only tool for communication to consumers' is therefore an over-simplification. For those reliant on the label alone, perhaps long after initial purchase, the need for clearly focused, understandable and relevant information is paramount. For others, additional information is readily obtainable under existing EU law or good commercial practice for anyone wishing to delve deeper. The many individual purchasing choices made solely on the basis of brand loyalty work both ways — a product may be assumed to be safe simply because it is made by Company X — and the value of that customer loyalty to Company X ensures that its products are indeed kept safe, reformulated, re-made or withdrawn if this is not the case. (Some recent and undoubtedly expensive voluntary global recalls of toys and other consumer goods due to the failure of internal quality controls illustrate this point quite clearly.)

4.14 For workers, and for everyone entering a workplace, where exposures are generally greater and/or more prolonged and where the need to maintain the highest standards of health and safety is a daily priority for all concerned, the packages and quantities contained therein are generally larger and the labels can be more detailed. Once again, there is no shortage of additional information, much of which must be made available under EU or other law at or before delivery of a raw material or intermediate product for further processing. A US website which, in an earlier (February 2005) EESC Information Report on REACH, was quoted as having 1.4 million Material Safety Data Sheets available, now has in excess of 3.5 million — and claims to be adding around 10 000 per day. Safety data sheets formatted for the EU and in the appropriate national languages for both substances and preparations are available from most manufacturers and suppliers and from some centralised sources — and must of course be provided to customers in Europe before any delivery of a product can be made. As these must be provided in all relevant languages and by all manufacturers and suppliers for all their products, a very large number of individual data sheets are required — and must be updated on a regular basis or as new legislation, such as this, demands.

4.15 Complementing the above, a newly launched (June 2007) OECD *eChemPortal* gives easy access to a range of databases maintained by its member governments and agencies, including for the EU, the European Chemicals Bureau. These databases provide data on many tens of thousands of individual substances manufactured and marketed in the EU and rejoice in a range of acronyms including ESIS (EU), CHRIP (Japan), OECD HPV (OECD), SIDS HVPC (UNEP), HPVIS (US EPA), INCHEM (IPCS), as well as better known and regularly used EU resources such as IUCLID, ORATS, HPVCS, LPVCS, ELINCS and EINECS, together with sector specific sites such as SEED, EUROPHYT, PHYSAN and CAT. Globally coordinated supporting programmes such as *pharmacovigilence* and *cosmetovigilance* ensure that any adverse effects of specific products are centrally and speedily recorded. The extension of these joint industry and regulator early warning programmes to other products in wide consumer use should be encouraged.

4.16 It is clearly good news that these data sources exist and are readily available — and even better if all of the above can indeed be updated, safety sheet by safety sheet, product record by product record, to reflect detailed changes required under the different national and regional implementations of the GHS without incurring unacceptable costs to all concerned — although it is again unclear whether this has been fully considered in the impact assessment.

4.17 This wealth of on-line information, combined with the length of the implementing legislation, is however becoming burdensome, as well as legally and intellectually challenging, to regulators and users alike. Regulation (EC) 1907/2006 (REACH) was, in its final published form in English, 850 pages long. REACH Implementation Projects (RIPs) and guidance notes, not yet finalised, are said to exceed 10 000 pages. Their final forms and eventual legal status are not yet known. The GHS proposal now under discussion exceeds 2 000 pages. Guidance notes will again be required — to this Regulation and to assist implementation in the 20 or so major pieces of downstream legislation,

including Directive 1996/82/EC (Seveso II), that it will affect. Thus the responsible institutions and bodies of the EU will shortly have produced or reviewed close to 20 000 pages of legislation or supporting material in this one area alone. It is difficult to see this as a model for better regulation — or as the ideal way to support the Lisbon objectives — or to endear the idea of a listening and supportive centrally administered EU to the citizens of Europe.

4.18 However, if these essential communication problems can in due time be surmounted (probably by breaking down the legislation into the essential components of definitions, clearly set out and agreed; test methods; end points; outcomes; required processes and procedures and so on; all separately published and updated on appropriate but different timetables, and not all requiring simultaneous publication as primary legislation) then great benefits will indeed be achieved. The data-based and generally applicable GHS should eventually affect and guide all those commenting on the best ways to protect human health, safety and the environment — and the benefits of this may be far greater than the rather small associated increases in world trade or in local employment currently used as the economic justification for the proposal.

5. **Specific comments**

5.1 The EESC notes the tight timetable for the adoption of this proposed Regulation, so that implementation can follow the same deadlines as defined by REACH in order to contain the once-off start-up costs. The EESC also notes that this is just the beginning of a global process which will require continuing change by all the participating regulatory bodies and by the businesses and others directly affected. There is therefore an obvious need to understand and rectify as many of the perceived problems as possible — and to implement the core of the proposal as flexibly as possible. Given that one good and well-tried system is being replaced by another, hopefully equally good, system, the risks attached to any specific derogations to allow time for problems to be solved, are slight.

5.2 As an example of this, the preparation and inclusion of a 'translation table', by Commission staff and national experts, of Appendix 1 of the existing Directive into Annex VI of the new Regulation whilst useful as a guide to the transposition from the old to the new requirements, has bypassed all the due processes of review and consent on which the more than 1 000 pages of decisions were originally built. If this is to become law with immediate effect, then resources must be devoted to checking this in detail, at a time when the majority of enterprises are fully stretched fulfilling the registration requirements of REACH. As it is often the case that EU legislation is adopted with some or all the Annexes still empty, a similar course could be followed here, so that the overall timetable is maintained. This also removes the problems of liability for incorrect 'translation' or 'transposition' of the requirements which at the moment would lie, unsatisfactorily, with the responsible Commission services. The fact that this process is reported to be highlighting many errors in the current legislation, in particular with the introduction of many new languages where 'translation', in its normal linguistic sense, is all important, brings only a small degree of comfort. Given the volume of data, it has to be assumed that new errors are being introduced at the same time which only the manufacturer or supplier of that product will discover in due course.

5.3 Similar comments apply to all instances where the new GHS will, without due consideration, increase the severity of current classifications, and hence labelling, packaging and possibly other impacts under any associated transport or downstream legislation. This could be the case, for instance, for some widely used consumer products such as, household detergents, where the new GHS appears to require quite nonsensical over-labelling. An example frequently quoted that, 'on spilling a commonly used detergent, the user should then remove all their clothes — and wash them in the same detergent' would merely bring the system, and those applying it, into disrepute. It certainly would not lead to the highest standards of protection for human health, safety and the environment. Careful use of the derogation under Article 30(1) where 'clearly unnecessary statements … may be omitted from the label' seems essential.

5.4 Also of concern are requirements to over-classify — a practice in some jurisdictions designed to limit the liability of manufacturers but again not really conducive to the proper protection of workers or consumers. Specifically the current proposal fails to distinguish adequately between products that are potentially 'irritants' (i.e., they can in certain cases cause temporary and reversible redness or swelling to the skin) and those that are 'corrosive' (i.e., they are likely to cause a permanent and possibly irreversible eating away of the skin, for instance by a strong acid or alkali or by the effects of oxygen). The potential for 'eye damage' alone is of course rather more frequent and in some cases is potentially more severe, with the risk of causing blindness, and should be identified whenever present by an appropriate and easily recognised symbol. All of this is aggravated by imposed or voluntary limitations on the use of animals for testing of products which now find themselves close to a revised end point and where both the labelling and packaging for consumer sales depend on the classification adopted. As the products affected in this way are likely to be exceptions rather than the rule, short term derogations would allow the proposal as a whole to be introduced without delay.

5.5 Over-labelling also has an undesired knock-on effect with regard to packaging, with child-resistant closures proving equally resistant to opening by older or infirm users. Advice on careful handling and storage of products in daily life is generally more valuable than devices that make them inaccessible to users

or lead to containers being left open or the contents being transferred to less safe alternatives. Consumers, with the support of helpful labelling and normal common sense and daily observation, do understand that products such as oven and drain cleaners must be treated with great respect; they are also, in most cases, quite capable of handling washing powder or solid dishwasher pellets without injury. Labelling them all as 'corrosive' with the key word 'DANGER' serves no good purpose and again puts the entire process at risk.

5.6 The above examples also put in question to what extent the various new (and old) pictograms, key words and phrases have been tested against the perceptions of different publics around the world. Although it is too late to change the existing UN GHS proposals, some additional words might be helpful, or amendments proposed, to improve clarity. The loss of the widely recognised 'St Andrews cross' symbol, rendered in black on orange, is particularly regretted. It will take a considerable time for replacement symbols to be properly recognised and there will be increased risks to consumers in particular until the new symbols are fully established. In store communication programmes to help all those making routine retail purchases should therefore be implemented (and centrally funded) as soon as possible. The needs of all those purchasing consumer products on-line, where a label is rarely visible at the time of purchase, require further study.

5.7 With regard to identifying the components of a preparation or mixture, the proposal reasonably requires the use of CAS numbers (which currently embrace more than 32 million organic and inorganic substances with partially or wholly defined structures, of which some 13 million are classified as being commercially available, often in very small quantities) and the use of IUPAC, CAS or other names to complete the identification. It is right to note however that these names are designed to define structures, not to identify hazards or risks. They are rarely of use to emergency responders or poison centres in that specific antidotes generally do not exist. The choice between inducing vomiting or neutralising in the stomach may however be critical to the first-aid treatment of an affected user. Subsequent contact with the manufacturer, at any time of day or night, seven days a week, for more specific advice is also likely to prove critical. It is this information, rather than the formal chemical name and molecular structure of one or more components of a complex mixture, which should be included on the label for use in the case of an emergency.

5.8 It follows that where the naming of a specific component, to the extent of defining its absolute chemical structure, has value only to a competitor, with the consequential loss of intellectual property rights for the original manufacturer, that the safeguards contained in the existing General Preparations Directive should be maintained. In general this is a problem only for 'performance fluids' such a lubricating oils and other high-technology preparations where consumer exposure is generally limited and the general hazards obvious irrespective of the specific components present.

5.9 The above also raises the problem of the proposed use of the word 'mixture', which should refer only to a system of substances that can be separated by physical means, to distinguish it from being a 'compound' or 'substance' (which cannot be so separated). The definition here seems to lump together a series of quite different material systems (naturally occurring ores, minerals, concentrates and plant extracts) with 'preparations' which contains the essential idea of a deliberately constructed mixture of known components from which the hazard of the final product can be reasonably determined. Alloys (and glasses) of course are neither of these and should be separately and more appropriately regulated, both here and in REACH. It is equally unclear why waste streams are excluded as a category, despite being included in some cases in the EINECS inventory as 'substances' under 'slimes' and 'sludges'. This would seem to imply that a mixed ore in its natural state must be classified (to no obvious purpose, as there is no likelihood of contact with consumers and no possibility of finding any replacement) whereas scrap iron or mixed paper waste, which must all be treated 'as is' in continuous processing and recycling operations, are excluded. All of the above must be handled safely in the workplace, but this is not the prime thrust of classification, and, indeed, these products are rarely either labelled or packaged. Sector or workplace specific legislation normally provides better protection.

5.10 Whatever the definitions are, they should be included in full in this proposal, not merely taken from the GHS or requiring reference to other documents. This would be a useful opportunity to define 'chemical' for the first time — both as a noun and as an adjective. If it is equivalent to 'substance', which presumably is the case, this should be made clear. This would also make more clear the scope of this and other directives and regulations which apply far more widely than to the products of the, more precisely defined 'chemical' industry. It would also make clear that the translation of the word 'chemical' as a noun into 'chemical substance' in languages lacking a single equivalent word does not imply the existence of alternative (and presumably non-toxic?) 'non-chemical substances'. This might also hopefully diminish the use of well meaning but meaningless statements such as 'most articles include chemicals' ([1]) (what do the rest contain?) or 'chemicals are used in almost every work place' ([2]) (whatever do they use in the other work places?). The EESC of course understands that any definitions used must be consistent across all legislation. However the EESC does not accept that any one piece of legislation is any more 'fundamental' than any other (or if it is, then this proposal clearly

([1]) From Commission 'frequently asked questions' on REACH.
([2]) From UK DEFRA guidance notes to MEPs on this proposal.

qualifies) and certainly does not accept that all the related legislation should be read in its entirety by all those involved, merely to determine what a word does or does not mean. This becomes important as translation into different languages creates differences that did not exist in the original — or obliterates distinctions which were vital. For example, the word 'product' is used here in a neutral sense for any goods likely to be purchased or used in the workplace or by a consumer. It absolutely is not intended to be synonymous with the word 'article' which has a special meaning under EU and other legislation. This is clear enough in English but may be less clear in other languages. Whatever the situation, the distinction must be maintained. Other linguistic and cultural confusions should also be identified and avoided. For instance, a 'substance-free environment' in Europe would be taken to refer, perhaps, to outer space. In the US it means a school where drinking and smoking are not permitted. In the popular press in many cultures, anyone found with traces of 'chemicals' on their hands or clothing is assumed to be a terrorist.

5.11 In every case it must be made clear to everyone, including the general public, what particular significance the various words used are intended to convey. The prohibition on the use of the word 'danger' in association with the word 'warning' may be of interest to experts in labelling although the two words are frequently used together in other communications aimed at reducing risk. If the word 'dangerous' means anything different to the word 'hazardous', in all the languages of the EU (and its trading partners) this should be made clear. Certainly it is difficult to distinguish between them in English. The use of abbreviations such as 'm-factor' which are meaningful only where local language translations of 'multiplying' indeed begin with the letter 'm' should be avoided. (The fact that under existing legislation there is constant reference to 'R' and 'S' phrases, for risk and safety respectively, merely shows that the legislation has been drafted in English, with little regard for the needs of other language users.)

5.12 With regard to the overall scope of this proposal, and to avoid drowning the process in data on the many millions of substances transferred in small or even minute quantities, a cut off point, based on sales per year, package size or weight, or known toxicity, would be helpful. Equally a label appropriate to the transfer, generally between laboratories, of very small quantities as samples for R&D to indicate that the 'product has not been tested or classified' and 'is for professional use only' would be a useful addition to the range of labels currently available. (The alternative new proposal to exclude 'substances and mixtures for scientific research and development' but only if used under conditions which assume that they are 'carcinogenic, germ cell mutagenic or toxic to reproduction' is inappropriate and should be deleted. There is no evidence brought forward to suggest that laboratory hazards require priority treatment or, contrary to normal expectation, that anyone working in a laboratory is at risk from lack of knowledge. If this is however shown to be the case, amendments to EU legislation on good laboratory practice would be a better route.)

5.13 Care should also be taken to ensure that the proposed classification and labelling process fully reflects, as now, the inherent hazardous properties of the individual substances and preparations or mixtures as placed on the market. Any extension to informal or unregulated mini-risk assessments by manufacturers or suppliers to cover possible or expected future use should be deleted as being inconsistent with both existing EU law and the UN GHS proposal.

5.14 With regard to enforcement, reporting and penalties for non-compliance, the proposal passes responsibility, quite reasonably, to the Member States, with the requirement that the provisions for this must be 'effective, proportionate and dissuasive' and that they shall be notified to the Commission within 18 months of entry into force of the Regulation. The EESC notes however that this proposal is designed, as in the existing legislation, to harmonise the criteria and processes used in any classification but not to harmonise the outcomes of this classification. Thus the penalties are likely to be minor in their size, effect and enforceability compared to the desire of manufacturers to fully and properly protect the workers and consumers upon whom their businesses depend. This being so, the workability of the overall proposal, in conjunction with other legislation such as REACH, remains critical.

5.15 Finally there will be a need to evaluate the quality of data received under different jurisdictions, to ensure that these are comparable and relevant to determining intrinsic hazards of novel and complex substances, including those of 'unknown or variable composition'. Ranking systems for this do exist, for instance from the Society of Chemical Hazard Communications. Peer reviewed data are also available in the Register of Toxic Effects of Chemical Substances. The proper process for this, presumably at the UN, does not seem to be fully defined or the resources and budgets put in place.

Brussels, 12 March 2008.

The President

of the European Economic and Social Committee

Dimitris DIMITRIADIS