

(2005/C 255/05)

On 28 October 2004, the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the abovementioned communication.

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee’s work on this subject, adopted its opinion on 16 March 2005. The rapporteur was Mr Sears.

At its 416th plenary session (meeting of 6 April 2005), the European Economic and Social Committee adopted the following opinion by 126 votes to 2, with 6 abstentions.

1. Introduction


1.2 Each of these has been maintained and extended over the intervening years by further EEC and EC Directives amending the legislative content of the instruments and by adapting to technical progress the various annexes which set out, amongst other technical points, the laboratory tests to be followed, the details of the risk and safety phrases to be used, and the chemical identities, CAS, EC and Index Numbers and applications, of the substances affected.

1.3 The directives, as amended, also seek to preserve the Internal Market for the substances and preparations affected and therefore must remain consistent with each other and with other legislative instruments affecting specific sectors (e.g. pesticides or cosmetics) or supporting particular action programmes (e.g. EU action plans to combat cancer).


1.5 The adaptations to technical progress set out in Commission Directive 2004/73/EC include updates to Annex I of Council Directive 67/548/EEC for specific substances relating to their classification, packaging and labelling to reflect the latest scientific data, and to Annex V of the same Directive, to amend the methods for the determination of physiochemical properties, toxicity and ecotoxicity of substances and preparations in order to reduce to a minimum the number of animals used for experimental purposes.

1.6 Commission Directive 2004/73/EC setting out these changes was published in April 2004 (OJ L152 1-311). A number of substances were classified or reclassified as being carcinogenic, mutagenic or teratogenic (CMRs or c/m/r substances). The measures provided for were stated to be in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives for the Elimination of Technical Barriers to Trade with Dangerous Substances and Preparations. In such cases, there is no requirement for an earlier Opinion on the proposal from the Commission from either the European Parliament or the European Economic and Social Committee.

1.7 Under another Council Directive 94/60/EC (an earlier, fourteenth, amendment to Council Directive 76/769/EEC), c/m/r substances may not be used in substances or preparations placed on the market for sale to the general public. It follows that an implementing measure is required, i.e. the current proposal, to add these substances to Annex I of Council Directive 76/769/EEC. In compliance with Article 95 of the Treaty, in this case the co-decision procedure has to be followed with the European Parliament and the Economic and Social Committee has to be consulted.
1.8 In the course of 2004, the Commission consulted a number of organisations representing the relevant stakeholders, including CEFIC, CONCAWE, Eurometaux and BLIC (representing the chemical, oil, metal and rubber industries in Europe) and BEUC (representing consumers in Europe), together with experts from the Member States.

2. Summary of the Commission’s proposal

2.1 The proposal will insert 346 entries containing substances newly classified or re-classified under Commission Directive 2004/73/EC in the Appendix of Annex I to Council Directive 76/769/EEC. However, of these, 304 are already subject to restrictions on sale to the general public due to their earlier classification as c/m/r substances of category 1 or 2. Thus only 42 substances will be restricted for sale to the general public for the first time.

2.2 Of the 42 substances restricted for the first time, a large number are used as raw materials or intermediates in organic synthesis or for specific professional applications. No evidence was produced during consultation to suggest that they are used in substances or preparations placed on the market for sale to the general public or that any derogations are required.

2.3 Of the 304 substances now reclassified, 145 will move from being classified as carcinogenic category 2 to category 1. This will require two corrections for each substance, adding the substance to its new category and deleting it from its existing category. A number of changes are also required to the ‘Notes’ accompanying each entry.

2.4 The proposal is intended to preserve the Internal Market and at the same time ensure a high level of protection for health of consumers and for the environment. The costs are estimated to be low, due to the limited use of these substances by the general public. However, as usage of c/m/r substances by the general public cannot be properly controlled by other measures, the proposed restriction on sale is the only available approach.

2.5 Member States will have twelve months from the date of entry into force of this Directive to adopt and publish the laws, regulations and administrative provisions necessary to comply with the Directive.

3. General comments

3.1 As with the previous amendments to Council Directive 76/769/EEC, this proposal deals with a number, in this case a very large number, of unrelated substances. These include petroleum hydrocarbon streams, pesticides and fungicides, general industrial chemicals and inorganic and organic raw materials and intermediates.

3.2 Unlike other recent amendments, however, this is not the primary legislation affecting these products. This proposal is merely a necessary consequence of changes to their classification and labelling as already proposed and implemented under Council Directive 2004/73/EC. Any concerns over the validity of the classification should therefore have been resolved earlier and cannot be re-opened at this stage.

3.3 The Commission has however verified as far as possible that consequent restrictions on sale to the general public as a result of their classification or re-classification as c/m/r substances will not add significantly to the costs of manufacturers. Direct enquiries to CONCAWE for the oil industry in respect of the petroleum hydrocarbon streams listed and to CEFIC for the chemicals industry in respect of the two phthalates listed (BBP and DIPP) support this conclusion.

3.4 Confirmation of this lack of impact is more difficult for the pesticides and fungicides shown here under their proprietary names (Benomyl, Azafenidin, Dinocap, Linuron) or as inorganic chemicals (cadmium chloride) due to the absence of information on current manufacturers, if any, in Europe. Internet searches suggest that in most cases the hazards are already well known and again it must be assumed that the products can be withdrawn from sale to the general public without negative impacts on users, i.e. suitable replacements are readily available.

3.5 The proposal also highlights some general difficulties in understanding and following existing EU law with respect to so-called ‘substances’. Many of the ‘substances’ listed here and contained within the original EINECS inventory of ‘existing substances’, are properly classified as ‘UVCB substances’ i.e. complex mixtures of known or unknown composition as defined in an academic paper published in 1999 and subsequently referred to in a footnote on page 18 of the ‘Manual of Decisions for Implementation of the Sixth and Seventh Amendments to Directive 67/548/EEC’ published by the European Chemicals Bureau in 2002. Certainly they are not simple substances as generally understood, and in addition, in this particular case, few are currently marketed. This supports the view of the Commission when the EINECS list was first published...
that ‘EINECS overstated the number of commercially significant substances by a factor of four’, i.e. there were then around 25 000 ‘substances’ actually on the market in significant quantities. Presumably some of these have now been replaced by the 5 000 or so ‘new substances’ listed in ELINCS — with similar problems of definition and identification — to give a round total of 30,000 substances actually on the market in 2005. This is more containable that the 100 000 number often quoted but still raises questions of public and professional access to the data already collected (but not regularly updated) on at least half of these and to the problems for the competent authorities in Member States in defining whether or not a substance is ‘existing’ or ‘new’ and if so which regulatory procedure should be followed.

3.6 Given that the proposal known as REACH incorporates, depends upon and interfaces with this existing legislation, these concerns should be addressed as soon as possible. It is likely that additional resources will be required and these should be put in place as soon as possible.

4. Specific comments

4.1 The EESC supports the limitations on marketing and use contained in this proposal. These are necessary and desirable consequences of decisions on classification, packaging and labelling already taken by the Commission services in conjunction with experts from the Member States and after discussion with suppliers and other stakeholders.

4.2 However, as with previous amendments to Council Directive 76/769/EEC, the EESC regrets the linking of unrelated products in a single text which might, in other circumstances, require specific and continuing amendments to match external realities. This does not support good, timely, effective and, above all, transparent, governance.

4.3 The complex and seemingly random nature of the lists of substances provided in the Annex to this proposal and to Council Directive 2004/73/EC suggest that attention should now be paid to improving the quality and availability of the data currently held, before adding massively to that currently stored. If an improved system can be demonstrated, using the best of modern technology and techniques for data dissemination, then the benefits of REACH in respect of accumulating and sharing data relevant to the protection of human health and the environment will be more evident.

4.4 REACH is also intended to simplify the existing system, and in so doing bring benefits to all the stakeholders involved. Certainly there seems to be some scope for this. Above all, REACH, however formulated, must not add to an already complex and, on this occasion at least, somewhat opaque process.

Brussels, 6 April 2005

The President
of the European Economic and Social Committee
Anne-Marie SIGMUND