
Dangerous Preparations Directive

Directive 1999/45/EC, the revised Dangerous Preparation Directive (DPD), has recently replaced the original Directive 88/379/EEC. The scope of the DPD has been expanded to include environmental classification and labelling criteria for preparations, revised disclosure requirements, Safety Data Sheets and implications for distance selling. The new Directive requires Member States to adopt and publish laws, regulations and administrative provisions necessary to comply with the Directive before 30 July 2002.

This article briefly highlights and explains the significance of the changes regarding the classification and labelling of preparations. More detailed information on the new Dangerous Preparations Directive may be found in CONCAWE report 00/56, *Revised Dangerous Preparations Directive (1999/45/EC)—implications for petroleum products*.

ENVIRONMENTAL CLASSIFICATION

The major change is the introduction, for the first time, of the requirement for suppliers of finished products to evaluate preparations for environmental hazards and to classify and label them if appropriate. This is also applicable to producers of additives and additive packages.

Recommendations for the environmental classifications of petroleum substances can be found in CONCAWE report number 98/54 titled *Classification and labelling of petroleum substances according to the EU Dangerous Substances Directive* and its subsequent updates.

GENERIC NAMES—DISCLOSURE REQUIREMENTS

The provision to use generic chemical names for confidentiality reasons when disclosing dangerous components on labels and data sheets is now restricted to substances with certain harmful and irritant classifications. It now applies only to components classified as Xn R20, R21, R22, Xn R65 and Xi R36, R37, R38. Further, generic chemical names may not be used for substances for which an EU occupational exposure limit (OEL) has been imposed.

Previously a supplier was permitted to use generic names, where applicable, the only requirement being to inform the competent authority in the Member State where the preparation was first put on the market. No provisions were made to define acceptable generic names.

According to the new Directive a supplier who wishes to use a generic name, must now request permission from the competent authority in the Member State where the preparation was first put on the market. The specific procedure includes a list of information that must be provided (Annex VI part A). The supplier must forward a copy of this permission to each of the Member States where the product is to be subsequently marketed.

SAFETY DATA SHEETS (SDSs)

Under Directive 88/379/EEC, Member States were required to ensure that a system be set up for the mandatory supply of SDSs to professional users for all preparations classified as dangerous.

This still applies, but Article 14 now extends the requirement to give professional users the right to be supplied, on request, with SDSs containing 'proportionate' information for certain non-dangerous preparations. This extension applies to those preparations, not classified as dangerous by the DPD, but containing at least one substance:

- that poses health or environmental hazards; or
- for which Community OELs are imposed,

and

where the concentration of any such individual component is 1% w/w or greater for non-gaseous preparations, or 0.2% v/v or greater for gaseous preparations.

As a consequence, CONCAWE member companies will need to have SDSs available for all products which meet the criteria specified above, so that sheets can be provided on request.

For the petroleum industry, the provision of safety data sheets for non-dangerous preparations has significant implications. For example, several different lubricant formulations may be sold under a single product name, all of which are non-hazardous according to the DPD, but each contains different hazardous components at the 1% w/w concentration level or above. Provision of separate SDSs for each formulation may not be practicable and could even be confusing. Generic SDSs may be more suitable particularly if coupled with formulation-specific information on the label such as the sensitizers present (if above 0.1% w/w), batch number, or date and place of manufacture.

The appropriate annex to Directive 91/155/EEC covering the format of SDSs is to be amended by 30 July 2002 to include the provision of SDSs for non-dangerous preparations. An ad-hoc Commission group is currently examining what proposal should be made.

DISTANCE SELLING

Any advertisement for a preparation within the scope of the DPD which enables a member of the general public to conclude a contract for purchase of such preparation without first having sight of the label for that preparation must make mention of the type(s) of hazard indicated on the label. The key words of the text are 'advertisement', 'preparation', 'enables', 'member of the general public' and 'conclude'.

On the basis of a legal opinion provided to CONCAWE, it would appear that, where an advertisement for a preparation enables a member of the general public to order that preparation by telephone, fax, e-commerce, mail, etc., the seller would be required to inform the buyer, in advance of concluding a contract for purchase, of the type(s) of hazard on the product label. An example of this would be a website (which, it is commonly held, is an advertisement) which allows for on-line purchasing of a preparation.

In contrast, where an advertisement for a preparation does not enable a member of the general public to conclude a purchase contract, product label disclosure is not necessary. Examples of this would include billboards, pole signs, as well as magazine and television advertisements, which do not include, for example, an order form or an order line telephone number.

This interpretation could vary from country to country based on Member State transposition of the distance selling provision into national regulation. CONCAWE member companies will therefore have to clarify the applicable interpretation in the countries where they conduct retail operations.