

New Amendments to EU Rules on “dangerous substances”

Directive 67/548/EC, which establishes the rules for placing chemical substances on the EU market, has been adapted for the twenty-ninth time. The Directive governs the notification of substances, exchange of information on them, assessment of potential risks to humans and the environment and their classification, packaging and labeling.

The latest adaptation amends:

Annex I - a list of (several thousand) substances for which harmonized classification and labeling has been agreed.

Annex V - testing methods for chemicals within the scope of the Directive.

The main changes are as follows:

- In Annex I, a substance need no longer be classified as a “carcinogen” or “mutagen” if it can be shown that it contains less than 0.1% w/w 1,3 butadiene (Einecs No 203-450-8).
- In Annex I, a number of entries have either been deleted or replaced.
- In Annex V, testing methods have been revised in order to obtain a reduction in the number of animals used for experimental purposes. In particular, the methods of assessing sub-chronic oral toxicity have been revised. There are also new methods for assessing physico-chemical properties and environmental toxicity.

EU Member States will have until October 31 2005 to put in place laws imposing these new requirements. Companies will now want to commence the process of ensuring that that their compliance programmes reflect these new requirements.