

Short impact assessment

First and Second Adaptations to technical progress (ATPs) of classification, labelling and packaging (CLP) regulation - 2008/411944

<p>Description of the intervention:</p>	<p>The CLP (classification, labelling and packaging of substances and mixtures) Regulation, introducing the UN-agreed Globally Harmonized System for classification and labelling of chemicals in the EU, will enter into force in late 2008/early 2009. The technical annexes of this Regulation, as well as certain articles, will be updated from time to time to ensure they are kept as comprehensive and accurate as possible – this is done through the EU comitology process. The amendments are known as adaptations to technical progress (ATPs) to the Regulation.</p> <p>The first ATP to CLP will also incorporate the 30th and 31st ATPs to the Dangerous Substances Directive (67/548/EEC), part of the previous set of legislation on classification and labelling of chemicals that the CLP Regulation will eventually replace. The 30th ATP was agreed in 2006 and the 31st ATP will be voted on later this year. However it has been agreed that both will enter into force as part of the 1st ATP to CLP in June 2009. Both ATPs propose new entries to Annex 1 of Directive 67/548/EEC which lists the harmonised classification and labelling requirements for approximately 7000 substances.</p> <p>The harmonized list of classifications is an agreed list of classifications of the hazardous properties of substances which it is obligatory for all suppliers to use. Therefore the main impact will be to change the classifications of the specified substances, necessitating different labels. It is possible that further amendments to the harmonized list or other technical annexes to the CLP Regulation will be made in the 1st ATP, but this is not presently known.</p> <p>Because the CLP Regulation will be directly acting in all EU Member States, the ATP will also act directly and will not need to be transposed into national legislation.</p>
<p>Objectives:</p>	<p>The objective of the 1st ATP to CLP is to ensure that the system for classifying, labelling and packaging chemicals is kept up to date to reflect the latest scientific knowledge. A secondary objective is to ensure that the latest agreed ATPs to the Dangerous Substances Directive – which have been postponed until the entry into force of the CLP regulation – are incorporated into EU law.</p>

Calculation of costs:	Familiarisation costs		£0
	The details of the 30 th and 31 st ATP have already been available for over a year. Additional familiarisation costs once 1 st ATP introduced likely to be insignificant.		
	Updating labels for affected substances		£450,700
	Estimated on the basis of 600 changes to existing classifications for substances. Relabelling costs £150 (min) to £500 (max) per substance (2005 prices). Est 10 suppliers per substance. Lower estimate assumes 50% of label changes can be made in normal process of renewing stock and are therefore cost neutral.	Lower Estimate	£3,000,000
		Upper Estimate	
	Updating labels for preparations containing affected substances		£1,125,000
	Estimated 25% of substances used in preparations. For each substance, 100 preparations require relabelling. Relabelling costs £150 (min) - £500 (max). Lower estimate assumes 50% of label changes can be made in normal process of renewing stock and are therefore cost neutral.	Lower Estimate	£7,500,000
	Upper Estimate		
Relabelling costs for pesticide labels		£150,000	
Estimated that 10% of substances in ATP are active pesticide substances, and that these are used in 10X number of products, of which 10% have a booklet style label. Cost of updating booklet-style label is estimated at £5000 per substance. Lower estimate assumes 50% of label changes can be made in normal process of renewing stock and are therefore cost neutral.	Lower Estimate	£300,000	
	Upper Estimate		
Updating Safety Data Sheets for substances		£420,000	
Estimated 10 suppliers per substance. Cost estimates £140 (min) to £320 (max) to update SDS per substance per supplier. Lower estimate assumes that 50% of changes done in normal process of renewing stock, and are therefore cost neutral.	Lower Estimate	£1,920,000	
	Upper Estimate		
Updating Safety Data Sheets for preparations		£1,050,000	
Estimated 25% of 600 substances used in preparations, and 100 preparations per substance. Cost estimates £140 (min) to £320 (max) to update SDS per substance per supplier. Lower estimate assumes that 50% of changes done in normal process of renewing stock, and are therefore cost neutral.	Lower Estimate	£4,800,000	
	Upper Estimate		
Sites becoming COMAH lower tier		£0	
Lower estimate based on fact we have no specific evidence that any particular change will lead to an increase in number of COMAH sites. Upper estimate based on estimates	Lower Estimate	£5,508,000	
	Upper Estimate		

	<p>may cause environmental damage. It may also cause consumers to move towards use of products less likely to damage the environment, or cause industry to formulate products which are less hazardous to the environment. Again, the magnitude of these potential benefits is impossible to quantify meaningfully.</p> <p>New harmonised classifications of substances also benefit both industry and regulators by providing a single source of mandatory classifications. This removes the need for suppliers of chemicals to carry out the classification process themselves, the cost of which has been estimated as around £2000 per substance on average. Harmonized classifications also contribute to the Single Market by requiring all suppliers of harmonized substances to use the same classification and provide consistent hazard information to users and consumers. This improvements will be beneficial to UK industry both domestically and in trade with other Member States.</p>
Consultation:	The approach to this impact assessment has been discussed with EAU. <i>[DN: The cost estimates for updating labels and reclassifying substances etc. are being checked with industry stakeholders and should be updated in light of their responses.]</i>
Chief Economist's comments:	
Recommendation:	N/A

Signed:

Date:

HSE's Chief Economist

Explanatory notes

1. The cost estimates in this impact assessment were produced for the Regulatory Budgets pilot exercise. They are indicative only and should not be used or quoted more widely.
2. Cost estimates are based chiefly on estimates of average costs for relabelling etc. made in the final RIA for the 29th ATP to the Dangerous Substances Directive. *[DN: These are being checked at the time of writing with industry stakeholders and will be updated in light of this if necessary].*
3. The number of substances to be reclassified is based on a known figure of 580 modified entries into the 30th and 31st ATPs to the DSD. New entries are assumed to be largely cost-neutral since most classifications will confirm the classification already notified under the Notification of New Substances Regulation (NONS). However it is also assumed that a small number (20) of new classifications may be for existing substances not notified under NONS which have been assigned a new classification as hazardous.
4. It should be noted that industry strongly opposed some of the reclassifications which will be included in the 30th and 31st ATPs to the Dangerous Substances Directive, specifically, reclassification of borates and boric acid as category 2 toxic to reproduction, and reclassification of nickel salts as possessing CMR properties. These reclassifications may have some significant indirect financial implications for industry (e.g. supermarkets may as a result be unwilling to market products containing borates, even though borates are present at concentrations so low that the products themselves would not themselves be classified as toxic to reproduction). However these cost impacts would be as a result of actions that would not be mandatory given the reclassifications and have therefore been considered not properly attributable to the reclassifications themselves. The cost estimates will be revised as appropriate in light of any further information received.