

INSTRUCTIONS TO THE LEGAL ADVISER'S OFFICE

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Amending the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (as amended); implementing Directive 121/2006; and enacting the necessary legal adjustments needed following the adoption of the European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures

Introduction

1. On 27 June 2007, the European Commission published its formal proposal for a Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (the CLP Regulation). The intention of the Regulation is to adopt the UN's Globally Harmonised System on the classification and labelling of chemicals (the 'GHS') in all European Union Member States. The CLP Regulation will replace, over a period of 7 ½ years, the existing European legislation that currently governs the classification and labelling of chemicals – the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (99/45/EEC). The CLP Regulation is expected to be adopted end 2008/early 2009, and enter into legal force 20 days later.
2. The Regulation will be directly acting on Member States without the need for transposition. However, HSE will need to prepare enforcing regulations to allow the provisions to be enforced in the UK. We will also need to amend and finally revoke the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 – as amended - (CHIP 3), to allow classification and labelling under the new system. These instructions are intended to achieve the necessary amendments to CHIP 3.
3. We are seeking to implement the new CHIP regulations on **6 April 2009**.

Overall objective of the amended CHIP 3 Regulations

4. There are seven reasons why the CHIP 3 Regulations need to be amended. Firstly, the need to complete the implementation of Directive 2006/121/EC. This is the main driver to progressing these regulations quickly as we need to implement the remaining elements of Directive 2006/121/EC, the so-called REACH 'daughter' directive, as soon as possible. The UK's failure to meet the implementation date of 31 May 2008 is the subject of a recent Art 226 letter.

The Directive sets out the necessary amendments that need to be made to the Dangerous Substances Directive, the Dangerous Preparations Directive and the Safety Data Sheets Directive as a result of the REACH Regulation. Most of these amendments will be implemented through Defra's REACH Enforcing Regulations. However, a few provisions remain relating to classification and labelling which could not be dealt with until the CLP Regulation was concluded. These amendments are limited and relate mainly to test methods (Annex V of Dangerous Substances Directive) now under REACH Article 13, and a few bits and pieces relating to the GB Approved Classification and Labelling Guide (Annex VI of DSD).

5. Secondly, a new provision that will allow duty holders to voluntarily apply the CLP Regulation in addition to CHIP from the moment the Regulation is adopted and throughout the transitional period if they choose to do so, prior to the mandatory compliance dates of 1 December 2010 for substances and 1 June 2015 for mixtures. The regulations will also need to include a provision to 'switch-off' CHIP entirely (with the exception of the enforcing provisions) at the end of the transitional period in 2015.
6. Thirdly, the need to prepare enforcing provisions to allow the provisions of the CLP Regulation to be enforced. It is expected that all the existing enforcement powers and sanctions set out in Section 14 of CHIP 3 will be carried over but there may be new offences too, such as a failure to notify European Chemicals Agency (ECHA).
7. Fourthly, the inclusion of an ambulatory reference. The CLP Regulation includes provisions that allow certain Articles and the technical Annexes of the Regulation to be amended through Adaptations to Technical Progress or ATPs. This is usual for European law, especially those laws that are highly technical in nature. When such amendments are made, there needs to be a corresponding provision in national legislation to be sure that the changes will also apply in the UK. This can be achieved through an 'ambulatory reference' that will allow national law to stay current where the European law "is amended from time to time".
8. Fifthly, the term "preparations" currently required by the Dangerous Preparations Directive, needs to be replaced with the term "mixtures" as required by the CLP Regulation.
9. Sixthly, the disposal of the GB Approved Supply List. Currently, the HSE publishes Annex 1 of the Dangerous Substances Directive, and subsequent ATPs, through the Approved Supply List or ASL. Annex 1 and the ASL list all the harmonised classifications and labelling requirements agreed by Member States. The ASL is currently only available in paper form and requires a legal provision in CHIP to allow its publication. With advances in technology, access to the internet and availability of online chemical databases (including the forthcoming ECHA databases under the CLP Regulation) it is now appropriate to end the publication of the ASL.

10. Finally, two minor editorial changes to Rection 3(3)(a) and (b) to ensure that they refer to the correct current legislation. These changes do not affect the legal duties imposed by the regulations.

Background

11. Chemicals often have harmful or hazardous properties. People and/or the environment may suffer adverse effects from exposure to these properties. As a result, many countries have developed laws that require certain controls to be in place when supplying and using chemicals that could cause harm, to ensure the protection of people and the environment. Existing laws and regulations around the world, established to identify and communicate the hazardous properties of chemicals, are similar in many respects. However, their differences are significant enough to result in different classifications, labels or safety data sheets, for the same product in different countries. This affects both the level of protection and the extensive global trade in chemicals.
12. At the Earth Summit held in Rio de Janeiro in 1992, world leaders generated an international mandate, set out in Agenda 21 of the United Nations Conference on Environment and Development, to make available “a globally harmonised hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols”. This was endorsed at the World Summit in Johannesburg in 2002, with a commitment for countries to adopt the GHS in national legislation by 2008.
13. The CLP Regulation represents Europe’s response to that commitment. The Regulation will replace the existing European classification and labelling system (the Dangerous Substances Directive – 67/548/EEC; and the Dangerous Preparations Directive - 99/45/EC).

Dangerous Substances Directive (67/548/EEC)

14. The Council Directive on Dangerous Substances specifies the hazard classification, packaging and labelling requirements for dangerous substances supplied in the European Union. The technical content of the Directive is contained in a number of Annexes which are revised from time to time by means of European Commission Directives known as Adaptations to Technical Progress (ATPs). Directive 67/548/EEC has been amended many times (9 amendments and 29 ATPs).

Dangerous Preparations Directive (88/379/EEC & 99/45/EC)

15. The Council Directive on Dangerous Preparations specifies the hazard classification, packaging and labelling requirements for chemical preparations (mixtures or solutions composed of two or more substances). Directive 88/379/EEC was replaced by a new Dangerous Preparations Directive (1999/45/EC) in which the technical content was moved to a number of Annexes, which can be revised by Adaptations to Technical Progress. Directive 99/45/EC has been amended twice (ATPs).

Adaptations to Technical Progress (ATP)

16. An adaptation to Technical Progress (ATP) has the effect of changing the technical and / or scientific details of a European Directive. ATPs are European Commission Directives and are not subject to consideration by the Council of Ministers or approval by the European Parliament. This is because an ATP does not reflect policy. It is a technical document.

UK Legislation which implements the above Directives

17. Specifically, the CHIP 3 regulations are concerned with dangerous substances (chemical elements or compounds, such as mercury, sulphur, sulphuric acid, etc.); and dangerous preparations (mixtures of solutions of substances, such as cleaning fluids, inks and paints etc).

18. The term 'chemical' is used here to cover both substances and preparations.

18. CHIP requires suppliers of dangerous chemicals to decide what types of danger their products present (known as 'classification'); package them suitably; and provide information to their customers in the form of warning labels and safety data sheets¹. CHIP also provides the relevant statutory authority to enforce the provisions of the above Directives in Great Britain.

19. CHIP is the foundation of Great Britain's chemical control regime and the regulations affect a number of other pieces of UK legislation. Many regulations use the CHIP classification of chemicals to define the scope of specific actions: for example, changes to the classification of a chemical can make a worksite subject to the COMAH Major Hazard regime, or can trigger specific workplace controls for a carcinogen under COSHH etc.

20. Finally, CHIP also implements some consumer protection labelling requirements from the Marketing and Use Directive (76/769/EEC).

GB IMPLEMENTATION OF THE NECESSARY LEGAL AMENDMENTS AS A RESULT OF THE ADOPTION OF THE EUROPEAN REGULATION ON THE CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES (CLP REGULATION) DETAILED INSTRUCTIONS FOR HSE'S LEGAL ADVISERS

ISSUES

Scope

21. The new CHIP regulations should implement the outstanding provisions of Directive 2006/121/EC, ensure the additional legal amendments align national

¹ The duty to provide a Safety Data Sheet appears in Directive 91/155/EEC and is implemented through Regulation 5 of CHIP 3. However, the REACH Regulation (EC) No 1907/2006 repealed this Directive and incorporated the safety data sheet duties. DEFRA's REACH Enforcing Regulations subsequently repealed Regulation 5 of CHIP.

legislation with the CLP Regulation and should apply across Great Britain. There are no devolution issues in implementing Directive 2006/121/EC or as a result of the additional amendments. Whilst the Environment is a devolved policy area, other government departments, agencies that have a direct interest in environmental matters and the devolved administrations are fully aware of the contents of the CLP Regulation and that changes to any environmental classification and labelling requirements will be made in the UK through the CHIP regulations. This is the same situation as for the Directives that CHIP currently implements and is covered by the designation of the Secretary of State mentioned in the pre-amble to CHIP and by Regulations 14(1) and (2) which make CHIP enforceable as health and safety regulations under the Health and Safety at Work (etc) Act, and by Regulation 14(3) which establishes the Health and Safety Executive as the enforcing authority, (subject to the exemptions in 14(4) & (5)).

Timing and Transition Periods

22. Directive 2006/121/EC required Member States to bring into force “the laws, regulations and administrative provisions necessary to comply with this Directive with effect from 1 June 2008”. The UK has not met this implementation date. Its failure to do so is the subject of an Art 226 Letter.
23. The UK intended to implement Directive 2006/121/EC through Defra’s Enforcing Regulations for the REACH Regulations ((EC) No 1907/2006) and an amendment to the CHIP regulations. The delay in transposing Directive 2006/121/EC has resulted from our need to enact the broad suite of amendments and revocations associated with the REACH Regulation itself, with the expected CLP Regulation, and with the 2nd Adaptation to Technical Progress (ATP) of Directive 1999/45/EC (the ‘Dangerous Preparations Directive’).
24. It is important to avoid any reduction in the level of protection afforded to members of the public, workers and the environment. Implementing Directive 2006/121/EC by 1st June 2008 would have required revocation of part of the domestic legal requirement to supply safety data sheets, leaving these provisions unenforceable until entry into force of the UK REACH Enforcement Regulations.
25. The European Commission does not consider implementation dates as open to negotiation or movement, and therefore HSE currently faces the risk of Infraction Proceedings should it not implement the Directive as soon as possible. As a result, the outstanding provisions which relate to classification and labelling and fall within the scope of the CLP Regulation rather than REACH, need to be implemented in as timely and efficient a manner as possible, while avoiding potential gaps in our enforcing authorities’ ability to ensure compliance with existing and new law.
26. Additionally, the CLP Regulation provides duty holders with the option of labelling chemicals according to the new regime once it enters into force as an alternative to the current requirements. Therefore, prompt legal amendment is

needed to ensure that UK regulators can enforce the new provisions where necessary.

27. The CLP confers duties on chemical suppliers (manufacturers, importers, downstream users and, in part to a lesser extent distributors), to classify chemicals and communicate the hazards identified through labels and safety data sheets. These duties become obligatory on 1 December 2010 for substances and 1 June 2015 for mixtures. It is necessary to ensure that the relevant enforcing provisions align with these mandatory implementation dates.
28. The ambulatory reference referred to in paragraph 7 above, must take legal effect on the date the amending CHIP regulations enter into force. Such a provision will allow subsequent ATPs to the Regulation to be given legal effect in the UK without the need for further amendment to CHIP.
29. HSE is mindful of the Government's policy to align legislative implementation dates as far as possible to the biannual domestic common commencement dates (CCDs): 6 April and 1 October. In this case, the 6 April 2009 is the nearest practical CCD. Therefore amending Regulations must come into legal effect on 6 April 2008 and final draft regulations will be required as soon as possible, but not later than 3 November 2008. It is vital that the UK meets the 6th April 2009 date.

Type of Regulations

30. CHIP3 takes the form of consolidating regulations. However, the amendments outlined in these instructions although routine, implement (in part) approximately one third of Directive (2006/121/EC); re-enact HSWA enforcement provisions; and allow duty holders to apply a new regime for classification and labelling. There have also been two subsequent sets of amendments to CHIP 3, in 2005 (SI No 2571), and more recently (2008 SI No. 2008/2337). Therefore, we believe a set of consolidating regulations are required on this occasion.
31. Disease Reduction Division's International Chemicals Unit propose the new regulations to be known as the Chemicals Hazard Information and Packaging for Supply) Regulations 2009 – simplified to CHIP 4, subject to confirmation from HSE's Legal Adviser's Office.

UK Health and Safety Legislation

32. The new CHIP regulations should not go beyond the specified provisions of Directive 2006/121/EC or the scope of the instructed amendments. However, both the previous and existing CHIP regulations go beyond health and safety legislation because the regulations cover the classification, labelling and packaging for supply for both environmental and consumer protection in addition to worker protection. This is covered by the designation of the Secretary of State mentioned in the pre-amble to CHIP and by Regulations 14(1) and (2) which make CHIP enforceable as health and safety

regulations under the Health and Safety at Work (etc) Act, and by Regulation 14(3) which establishes the Health and Safety Executive as the enforcing authority, (subject to the exemptions in 14(4) & (5)). This has not been a problem in the past. Other government departments and agencies that have a direct interest in the environmental matters are fully aware of the contents of the CLP Regulation and the requirement to make the instructed amendments to align GB law with the enforcement and transitional provisions resulting from the adoption of the CLP Regulation. They are fully content with the amendments being enacted through the CHIP regulations.

Repeals, revocations and modifications

33. See detailed comments below.

Sanctions

34. The new regulations should not change the existing sanctions under CHIP 3 or other GB health and safety legislation.

Enforcement

35. The new regulations should not change existing UK or HSE enforcement practices or policies.

Transitional provisions

36. The CLP Regulation provides for transitional measures which must be enacted in the new regulations. The option for duty holders to comply with the CLP Regulation relating to substances must end on 1 December 2010, when the duty becomes mandatory under the provisions of the CLP Regulation. The option for duty holders to comply with the CLP Regulation relating to mixtures must end on 1 June 2015, when the duty becomes mandatory under the provisions of the CLP Regulation.

Appeal mechanisms

37. Not applicable for these regulations.

Defences

38. A 'due diligence' defence is provided in the principal regulations. No amendments to this defence are believed to be necessary.

Duties and duty holders

39. The new regulations should not add to the duties under CHIP 3. The new regulations should have the effect of bringing into the scope of the CHIP regime the necessary legal amendments needed as a result of the adoption of the CLP Regulation in respect of the available transitional periods, enforcement provisions, terminology and administrative adjustments.
40. The CLP Regulation imposes the required duties.

Human Rights issues

41. The legal amendments needed following the adoption of the CLP Regulation and Directive 2006/121/EC do not raise any Human Rights issues.

UK and HSE policy implications

42. The changes do not represent any shift in either UK or HSE policy.

DETAILED INSTRUCTIONS

Directive 2006/121/EC

43. Article 1 (3) of 2006/121/EC amends Article 3 of 67/548/EEC (Dangerous Substances Directive). The amendment refers to testing methods set out in the Regulation (EC) No 1907/2006 (REACH). However, these provisions have now been incorporated in the *Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*.

Comment/question: in order to fully implement the 2006/121/EC, do we need to make amendment to paragraph 10 of the Approved Classification and Labelling Guide?

44. [Related matter] – Article 1 of Regulation (EC) No 440/2008 states that all references to Annex V of 67/548/EEC should now refer to the Regulation.

Comment/question: this needs to be incorporated into CHIP, but it is not clear where. Can the LAO advise?

45. Article 1(4)(a) of 2006/121/EC amends Article 5 paragraph 1, first subparagraph of 67/548/EEC. However, the amendments appear only to include a new reference to Regulation (EC) No 1907/2006. The remaining text does not change.

Comment: we do not think any amendment is necessary to CHIP. The reference to Regulation (EC) No 1907/2006 is dealt with by the forthcoming REACH Enforcing Regulations. The remainder of the text remains unchanged for CHIP.

46. Article 1(4)(b) of 2006/121/EC amends Article 5 paragraph 2 of 67/548/EEC. The amendment proposes deleting the words “second indent” and replacing them with “first paragraph”.

Comment: we do not think any amendment is necessary to CHIP. This relates to an administrative reference and does not affect the duties in CHIP.

47. Article 1(11)(a) of 2006/121/EC amends Annex VI of 67/548/EEC. In the specified sections of the Annex, the words “Annex V” and/or “Annex V to this Directive”, shall be replaced with a reference to Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Comment/question: Annex V of 67/548/EEC has not been implemented in GB. However, the Approved Classification and Labelling Guide - ACLG - (which reflects the GB version of Annex VI of 67/548/EEC) refers to Annex V in a number of places. In order to fully implement 2006/121/EC, is it necessary to amend CHIP and the ACLG to reflect this requirement?

48. Article 1(11)(c) of 2006/121/EC amends Section 5.1, second paragraph of Annex VI of 67/548/EEC. The amendment from “The” to “.....classification.” are enacted through the forthcoming REACH Enforcing Regulations. The final sentence needs to be implemented through CHIP.

Comment/question: the CLP Regulation does not place a duty to generate new data or information, but it does say that a duty holder must take all relevant information into account when determining a classification. We conclude that this must include relevant information generated through Annexes IX and X of Regulation (EC) No 1907/2006. Is it therefore necessary to amend CHIP Regulation 4(5) and the ACLG to fully implement this provision?

49. Article 1(11)(d) amends Section 5.2.1.2, second paragraph, second sentence of Annex VI of 67/548/EEC.

Comment: in order to fully implement 2006/121/EC do we need to amend CHIP Regulation 4(5) and the ACLG?

General points/questions:

- The CHIP regulations must make reference to the implementation of 2006/121/EC or shall be accompanied by such a reference on their publication.
- If we have to make so many amendments to the ACLG, would it be more prudent to withdraw the Guide and replace its references in CHIP to refer to Annex VI directly until the mandatory transitional dates in 2010 and 2015?

Amendments to CHIP

Regulations

50. While the instructions below set out the existing CHIP regulations and the corresponding provisions in the CLP Regulation, this has been done to ease understanding of how the current legislation will appear in the new GHS based regime. International Chemicals Unit would wish to explore with LAO, if the majority of proposed amendments below can be incorporated more simply into the proposed CHIP 4.

General provision – early compliance with CLP Regulation

51. Currently in the GB, chemical classification, labelling and packaging legislation applies the requirements of 67/548/EEC and 1999/45/EC (Dangerous Preparations Directive), through the CHIP Regulations. The CLP Regulation will introduce requirements for chemical classification, labelling and packaging different from those in CHIP. These new requirements will enter into force over a transitional period, and will ultimately replace the CHIP requirements altogether.

52. The specific transitional arrangements which will have to be taken into account in the new CHIP regulations are as follows:

Substances

Entry into force (late 2008/early 2009) – 1 st December 2010	Suppliers must classify substances according to CHIP, and may continue to label them according to CHIP. However they <u>may</u> label according to CLP, in which case they must classify according to CLP <u>in addition</u> to CHIP.
1 st December 2010 – 1 st June 2015	Suppliers must classify substances according to both CHIP and CLP. They must label according to CLP.
1 st June 2015 onwards	Suppliers must classify and label according to CLP

Mixtures

Entry into force (late 2008/early 2009) – 1 st June 2015	Suppliers must classify mixtures according to CHIP, and may continue to label them according to CHIP. However they may label according to CLP, in which case they must classify according to CLP in addition to CHIP.
1 st June 2015 onwards	Suppliers must classify and label according to CLP.

Comment: Amendments to CHIP are required to ensure that it remains consistent with the above transitional arrangements. First, CHIP needs to be amended so that it also allows substances and mixtures to be classified, labelled and packaged in

accordance with CLP during the transitional periods, as an alternative to the classification arrangements it specifies itself. This will be accomplished by including in CHIP a derogation allowing compliance with CLP from its date of entry into force until the end of the transitional periods. Second, a provision needs be included in CHIP to disapply it completely once CLP is mandatory from 1st June 2015 (except for the provisions for enforcing CLP).

Regulation 3(3)(a) and (b) – to be updated to allow for changes in referenced legislation.

Comment: There have been some recent changes to the legislation to separate out Human Medicines, clinical trials and veterinary medicines and the CHIP Regulation 2002 reference to Section 130 of the Medicines Act is now out of date. For example, the Veterinary Medicines Regulations 2006 (as amended in 2007) changes the Medicines Act 1968 so that it no longer includes veterinary medicines. This leaves us with the difficulty that CHIP now appears to only apply to veterinary medicines. We also have similar difficulties with applicability to clinical trials (investigational medicinal products). The CHIP Regulations will update references to other legislation to ensure it is up to date

Regulation 4 – sets out the main duty to classify. CLP Regulation Article 4 and Title II refer.

Comment: Regulation 4 needs to allow duty holders to classify under the provisions of the CLP Regulation (in addition doing so under CHIP) should they choose to do so, according to the arrangements described above. However, Article 4 presents a number of issues that we may need to accommodate:

- a) Article 4.3 refers to “producers of articles”. This is new to CHIP, as the current regimes exempts articles from its scope. Therefore, do we need to include a definition of “supplier” in Regulation 2(1) to include this term?
- b) If we extend the definition in Regulation 2(1), will we need an additional enforcing provision to ensure we can enforce the duties assigned to this group?
- c) Article 4.3 places a duty on “manufacturers, producers of articles and importers” to classify those substances not placed on the market in accordance with Title II where (a) they are registered under Regulation 1907/2006; or (b) they are notified under Regulation 1907/2006. Is there a current duty to classify a substance that is not placed on the market? If not, do we need an additional provision in Regulation 4 to allow this?
- d) Article 4.5 (b) places a new duty on suppliers to co-operate to meet the requirements for classification, labelling and packaging under the CLP Regulation. We assume that as duty holders have no obligation to apply Article 4 until the mandatory compliance dates, it would not be appropriate to include this duty or the provision to enforce it in any amendments to Regulation 4. Is this correct?

Regulation 4(3)(b) – delete the reference made to “regulation 4 or 6(1) or (2) of the NONS Regulation”.

Comment: NONS Regulation provisions have been subsumed by Regulation 1907/2006.

Regulation 4(5), 4(7), Schedule 3, Approved Classification and Labelling Guide (paragraphs 9 and 10) – amend to allow the application of provisions in Articles 5 and 6 of the CLP Regulation.

Comment: The existing duty requires duty holders to be “aware of all relevant and accessible data that may exist in relation to the dangerous substance in question”. However, Article 5 of the CLP Regulation requires duty holders to “identify” and “examine” the “relevant available information”.

Regulation 4(4), 4(7), Schedule 3 Parts II (health) and III (environment) – amend to allow the application of the provisions in Article 10 of the CLP Regulation.

Comment: Articles 10.1(a), 10.2, 10.3(a) 2nd paragraph, 10.4 and 10.5 all confer new duties on manufacturers, importers and downstream users in respect of concentration limits and M-factors. (Article 10.1(b) does not confer a duty but allows a manufacturer, importer or downstream user to act in exceptional circumstances relating to health hazards).

Regulation 4(4), 4(5), 4(7) - amend to allow the application of provisions in Article 8.2 of the CLP Regulation.

Comment: there is no current duty to generate new information for the purposes of classifying substances or mixtures. Article 8.1 states that a manufacturer, importer or downstream user may generate new data relating to health and environmental hazards provided he has exhausted all other means. But there is no explicit additional duty.

However, Article 8.2 places a new duty on manufacturers, importers and downstream users to perform the tests in Annex I Part 2 for physical hazards unless adequate and reliable information is already available.

Where these tests are carried out for physical hazards, duty holders have until 1 January 2004 to comply with the specified (if rather vague) arrangement referred to in Article 8.3(b). As the CLP Regulation does not enter into force completely until 1 June 2015, is it necessary to incorporate this deadline and provision in the new CHIP regulations?

Regulation 4(4), 4(7), Schedule 3 paragraph 6 – amend to allow the application of provisions in Article 11, Annex I section 1.1.2.2 of the CLP Regulation.

Regulation 4(4), 4(5), 4(7), Schedule 3 paragraph 4(4) - amend to allow the application of provisions in Article 12 of the CLP Regulation.

Comment: Article 12 confers a new duty, to act on the evaluation undertaken in Article 9. It provides for an extension of the duty to identify information, data etc.

Regulation 4(4), 4(5), 4(7), Schedule 3 paragraph 4(4) - amend to allow the application of provisions in Article 13 of the CLP Regulation.

Comment: Article 13 confers a duty to classify where the evaluation in Articles 9 and 12 identifies one or more hazard categories.

Regulation 4(5) - amend to allow the application of provisions in Article 15 of the CLP Regulation.

Regulation 4(6) – amend to allow the application of provisions in Article 39(5a)* of the CLP Regulation.

Comments: do we need to incorporate Article 39(2) into Regulation 4? The Article provides a provision that suppliers may wish to follow but they are not legally obliged to do so. That said, if the CLP Regulation is in force and suppliers chose to follow a provision we assume we would therefore need the necessary authority to regulate?

Regulation 4(7), Schedule 3 paragraph 3 (3a – c) - amend to allow the application of provisions in Article 14.2 of the CLP Regulation.

Regulation 6 – amend to allow the application of provisions in Article 48 of the CLP Regulation.

Comments: relates to the advertising of dangerous substances and mixtures available for sale.

Regulation 7, Regulation 11(6)(a) and (b) – amend to allow the application of the provisions in Article 37* of the CLP Regulation.

Comments:

- a) Paragraph 1(a) relates to Regulation 7(1)(a) and Regulation 7(2)
- b) Paragraph 1(b) relates to Regulation 7(1)(b)
- c) Paragraph 1(c) relates to Regulation 7(1)(c)
- d) Paragraph 1(d) relates to Regulation 7(1)(d)
- e) Paragraph 2 relates to Regulation 11(6)(a) and (b)

Regulation 8(2), 8(3) - amend to allow the application of provisions in Article 17 of the CLP Regulation.

Comment: Article 17 sets out the general rules on labelling and includes new terminology and new duties, eg the introduction of the designated “signal words”.

Regulation 8(2)(b), 8(3)(b), 8(2)(c)(iv), Schedule 5 Part 1(2)(6) - amend to allow the application of provisions in Article 18 of the CLP Regulation.

Comment: do we need to make any reference to Regulation 5? Article 18 refers to the Safety Data Sheet provisions now incorporated into Article 31 of Regulation 1907/2006.

Regulation 8(2)(c)(i), 8(3)(c)(ii), Schedule 2 - amend to allow the application of provisions in Article 19 of the CLP Regulation.

Comment: Article 19 introduces the hazard pictograms. There are two new hazard pictograms to supplement the existing symbols.

Regulation 8(2), 8(3) - amend to allow the application of provisions in Article 20 of the CLP Regulation.

Comment: Article 20 introduces the ‘signal words’, “warning” or “danger” (Annex I Parts 2 to 5 refer). These are new (if we discount the specific warnings for labels set out in Schedule 5 Part II B. Should we amend Schedule 1?

Regulation 8(2)(c)(ii), 8(3)(c)(iii), 8(11)(a) and (b), 8(12)(a)(i)-(iv) - amend to allow the application of provisions in Article 21 of the CLP Regulation.

Comment: the “hazard statement” replaces the existing “risk phrase”.

NB: risk and safety phrases are listed, in full, in the Approved Supply List, which we are planning to dispose of.

Regulation 8(2)(c)(iii), 8(3)(c)(iv), 8(11)(a) and (b), 8(12)(b)(i) and (iii) - amend to allow the application of provisions in Article 22 of the CLP Regulation.

Comment: the “precautionary statement” replaces the existing “safety phrase”.

NB: risk and safety phrases are listed, in full, in the Approved Supply List, which we are planning to dispose of.

Do we need to make any amendment to Schedule 5?

Regulation 8(7) - amend to allow the application of provisions in Article 27(3a)* of the CLP Regulation.

Comment: is this amendment necessary? The wording is only slightly different.

Regulation 8 – amend to allow the application of provisions in Article 31* of the CLP Regulation.

Comment: it is not clear where the corresponding provision in the CHIP regulations can be found. The provision in the CLP Regulation places a specific duty on ensuring labels are updated when required.

Regulation 8 – amend to allow the provisions of Article 35* of the CLP Regulation.

Comment: we are not sure that CHIP is so explicit about the layout of the label. This provision relates to those which set the precedence of hazard and precautionary statements.

Regulation 9(1) and (2) - amend to allow the provisions of Article 36* of the CLP Regulation.

Comment: We are not sure whether this amendment is necessary. Is Regulation 9 still extant, or has it been completely overtaken by the Carriage of Dangerous Goods Regulations (the responsibility of the Department for Transport)? As a related question, will it be necessary to amend the CDG Regulations to refer to the CLP Regulation? Perhaps this is a question for DfT.

Does Article 37(2a) cross reference with Regulation 9?

Regulation 10 (7) – amend to allow the application of provisions in Article 31* of the CLP Regulation.

Comment: the provision deals with small or awkwardly shaped packaging and how you should read the label. Annex II Parts 2 and 5 may also be a relevance: Part 2 deals with Special rules for supplemental label elements for certain mixtures; part 5 lists the hazardous substances and mixtures to which Article 31(3) applies.

Regulation 10 and Regulation 8(1)(b) – amend to allow application of provisions in Article 34* of the CLP Regulation.

Comment: label application –

- a) Article 34 Paragraph 1 relates to Regulation 10(4)
- b) Article 34 Paragraph 2 relates to Regulation 10(3)
- c) Article 34 Paragraph 3 relates to Regulation 10(1) and 10 (3)

- d) Article 34 Paragraph 4 relates to Regulation 10(5) and 10(6)
- e) Article 34 Paragraph 5 relates to Regulation 8(1)(b)

Regulation 11 – amend to allow application of provisions in Article 37(2)* of the CLP Regulation.

Comments: do we need to make this amendment? The provisions in Annex 2, part 3 of the CLP Regulation maintain the existing requirements?

Regulation 12 – amend to allow the application of the provisions in Article 49 of the CLP Regulation.

Comments: Regulation 12 appears to apply only to mixtures (preparations). Article 49 applies to both substances and mixtures.

Regulation 14 - it is necessary to amend CHIP Regulation 14 to ensure that the relevant enforcing authorities can enforce the all the relevant statutory provisions set down in the CLP Regulation. Enforcement must also be possible in relation to the relevant statutory provisions where duty holders apply those provisions of the CLP Regulation prior to the mandatory compliance dates.

Schedules

Schedule 5 Part I paragraph 3 - amend to allow the application of provisions in Article 26* of the CLP Regulation.

Comment/question: this is not a new duty. Duty holders may apply the provision. Do we need to make reference in Regulation 1907/2006, as reference is made to Safety Data Sheets?

Note: Article 26* introduces a fee. And the decision to grant the duty holder's request is made by the European Chemicals Agency and not the relevant Competent Authority in the Member State, as is now the case.

Schedule 5 Part I paragraph 4 - amend to allow the application of provisions in Article 28* of the CLP Regulation.

Comment: presumably there is no need to relate this to Regulation 8? If you comply with Regulation 8, you comply with Schedule 5.

Schedule 5 Part I paragraph 4 and paragraph 2 – amend to allow the application of provisions in Articles 29* and 30* of the CLP Regulation.

Comment: this provision sets new rules on the precedence for using hazard statements and precautionary statements. Does Sch 5 Part I para 4 deal with this through “indication of danger” or does that just cover ‘corrosive’ and ‘explosive’ etc?

Articles in the CLP Regulation with no corresponding CHIP provision

53. There are a number of Articles in the CLP Regulation, the detail of which will need to be incorporated into the new CHIP regulations, but which do not have a corresponding CHIP provision. These are set out below.

Article 41 – this provision sets out a duty to notify the European Chemicals Agency of the details of any dangerous substance subject to registration under Regulation 1907/2006 or Article 1 of the CLP Regulation. This is a new duty, exclusive to the CLP Regulation.

Comments: can duty holders do this from the date on which the CLP Regulation comes into legal effect? Article 41(3) suggests that they can. If so, we will need to be able to ensure that the notification is taking place. Would specific reference need to be made in the amendments to Regulation 14 to ensure that we could do so?

Article 42 – This requires suppliers to make every effort to agree the entries that will populate the Industry section of the Classification and Labelling Inventory.

Comments: however, as the provision is not required under the CLP Regulation until December 2010, we are assuming that we should not be seeking to enforce compliance when not all suppliers will be notifying at this time? (see Article 41 above).

Article 57 – 67/548/EEC and 1999/45/EC are to be repealed with effect from 1 June 2015.

Article 58 – transitional provisions must be incorporated into CHIP. (see paragraphs 50 – 51 above).

Article 60 – entry into force dates.

Other proposed amendments

Ambulatory reference

54. Article 53* of the CLP Regulation gives the authority to the European Commission to “adjust and adapt Articles 6(5), 11(3), 12, 14, 18(3)(b), 25, 27 to 31(2) second and third sub-paragraphs, and Annexes I to VII to technical and scientific progress. The use of adaptations to technical progress (ATPs) is long established (detail appears in paragraph 16 above).
55. Under the current regime, where ATPs have been agreed and implemented in the past, it has been necessary to amend the CHIP regulations to give legal effect to the proposed changes. We understand that this is a necessary consequence of using the European Communities Act 1972 (section 2(2)) to implement those parts of CHIP that sit beyond the vires of HSWA 74, thereby preventing an ‘ambulatory reference’ from being incorporated into CHIP.
56. The recent Legislative and Regulatory Reform Act 2006, makes certain provisions relating to the European Communities. Section 28 of the Act inserts a new paragraph 1A in Schedule 2 of the European Communities Act 1972, allowing subordinate legislation to include ambulatory references to Community instruments. The reference to Community instruments includes directives or regulations.
57. It is necessary for the new CHIP regulations to include such an ambulatory reference to allow existing domestic to continuously refer to the CLP Regulation and/or its technical Annexes, including any subsequent amendments made through ATPs, without the need to make any amendments at domestic level. In 2015, when the existing domestic legislations is finally ‘switched off’, the remaining provisions relating to enforcement must refer to the CLP Regulation and its technical annexes. Directives 67/548/EEC and 1999/45/EC will no longer be in force.

Terminology amendments

58. The CLP Regulation deletes the term “preparation” and replaces it with “mixture”. This amendment needs to be incorporated.

Approved Classification and Labelling Guide

59. The Approved Classification and Labelling Guide (ACLG), is based on Commission Directive 2001/59/EC (28th Adaptation to Technical Progress of Directive 67/548/EEC) which sets out Annex VI to 67/548/EEC. The purpose of Annex VI is to provide a harmonised basis for the classification and labelling of dangerous substances and preparations (mixtures). The CHIP 3 regulations impose requirements by reference to the ACLG and, to that extent, it is legally binding.

60. There are certain references to provisions in the CLP Regulation which appear either in the CHIP regulations, in the ACLG, or in both – the detail is set out below. It is International Chemicals Unit's intention to amend and re-issue the ACLG. (Note: the ACLG must remain in place for the duration of the CLP Regulation's transitional arrangements. This reflects the continued need for the existing classification and labelling legislation to be applied throughout the transitional period).

61. The ACLG will also need to be amended to update references to Annex V of 67/548/EEC (on test methods), to Council Regulation No 440/2008 on test methods.

Paragraph 9

Paragraph 9 relates to the current regime's equivalent of the 'bridging principles' (Article 9.4 refers) described as "validated structure-activity relationships". Is any amendment needed or reference to be made to Article 9.4?

Paragraph 14

The provisions on animal and human testing for the purposes of the CLP Regulation (Article 7 refers) are less permissive than the current regime. For example, human 'patch testing' is currently permitted but would not be allowed under the CLP Regulation (Article 7.2 refers).

If a duty holder has tested according to the current regime, could they:

- a) use that data to classify under the CLP Regulation by applying Articles 5 (b) and 6(b), arguing that the results form part of the relevant and available data set; and if they did so
- b) could we enforce the provisions in Article 7 in the transitional period and beyond?

Paragraphs 156 -173 (classification and labelling in special cases)

Do we need to amend to allow application of Article 25* of the CLP Regulation? Article 25 (CLP Regulation Annex I Sections 1.3 and 2.1 refer):

- a) refers to paragraph 156 and CHIP Regulations 10(2), (4) and (5), and Regulations 8(2) and (3)
- b) refers to paragraphs 157 – 158 and CHIP Regulations 4 and 5(7)
- c) refers to paragraph 159
- d) refers to paragraph 160 and CHIP Regulations 4(4) and (5), and Regulation 8
- e) not clear on corresponding CHIP provision

[NB: not sure on corresponding CLP Regulation provision for "gaseous preparations (gas mixtures)" and "organic peroxides".]

[NB: Article 16 allows duty holders to classify differently from existing entries in the Classification and Labelling Inventory, provided they submit to the European Chemicals Agency reasons for the classification (Article 41 refers)].

Discontinuation of the GB Approved Supply List

62. Currently, the HSE publishes Annex 1 of the Dangerous Substances Directive and subsequent ATPs through the Approved Supply List or ASL. Annex 1 and the ASL list all the harmonised classifications and labelling requirements agreed by Member States. The ASL is currently only available in paper form and requires a legal provision in CHIP to allow its publication. With advances in technology, access to the internet and availability of online chemical databases (including the forthcoming ECHA databases under the CLP Regulation), we are considering whether it is appropriate to continue with the paper versions of the ASL. The amending CHIP regulations will need to include the necessary legal 'switch-off'.

Two minor editorial changes

63. There have been some recent changes to the legislation to separate out Human Medicines, clinical trials and veterinary medicines and the CHIP Regulation 2002 reference to Section 130 of the Medicines Act is now out of date. For example, the Veterinary Medicines Regulations 2006 (as amended in 2007) changes the Medicines Act 1968 so that it no longer includes veterinary medicines. This leaves us with the difficulty that CHIP now appears to only apply to veterinary medicines. We also have similar difficulties with applicability to clinical trials (investigational medicinal products). The CHIP Regulations will need to update references to other legislation to ensure it is up to date.

***Article numbers subject to change in final text of CLP Regulation.**

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