EXPLANATORY MEMORANDUM TO

The Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009

S.R. 2009 No. 238

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Enterprise, Trade and Investment to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under section 2(2) of the European Communities Act 1972 and Articles 17(1), (2), (3), (4) and (6) and 55(2) of, and paragraphs 1(1), (4) and (5), 2(2), 14(1) and 15 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978 and is subject to the negative resolution procedure.

1.3 The Rule is due to come into operation on 27 July 2009.

2. Purpose

2.1 This Statutory Rule concerns the identification of harmful properties of chemicals (hazards) and the communication of this information to users by means of labels. The Rule covers hazards to health, safety and the environment, and use of chemicals both in the home and at work.

2.2 The Rule, to be known as the CHIP 4 Regulations:

a. consolidates all amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations since 2002;

b. dovetails the requirements of CHIP with EC Regulation No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (the CLP Regulation) which adopts in Europe the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS);

c. provides for enforcement of the CLP Regulation in Northern Ireland; and

d. repeals the requirements of CHIP at the end of the transitional measures provided for in the CLP Regulation (1 June 2015), except for (c) above.

2.3 The Rule does not introduce any new duties.

3. Legislative Background

3.1 There are two European Directives that set out how to classify, label and package a hazardous chemical – the Dangerous Substances Directive

(No. 67/548/EEC) and the Dangerous Preparations Directive (No. 1999/45/EC). These Directives establish a single market for the supply of chemicals in the European Union. This means chemical suppliers across the European Union have to follow the same rules when classifying and labelling hazardous chemicals.

3.2 European Directives have to be implemented into national law. The Dangerous Substances Directive and the Dangerous Preparations Directive are implemented in Northern Ireland by the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2002 – commonly known as the 'CHIP' Regulations.

3.3 On 1 June 2015, the European Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of Substance and Mixtures (CLP Regulation) will replace and fully repeal the Dangerous Substances Directive and the Dangerous Preparations Directive. The CLP Regulation is directly acting in all EU Member States and does not require separate implementation into national law. The CHIP 4 Regulations will remain in force throughout the transitional period of the CLP Regulation but, with the exception of regulation 14 (enforcement), will also be repealed on 1 June 2015.

3.4 The CHIP 4 Regulations discharge the UK's obligation to appoint enforcing authorities to enforce the duties in the European Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (the CLP Regulation). The enforcing authorities (Health and Safety Executive for Northern Ireland and district councils including input from the Department for the Environment), penalties and sanctions remain the same as under the existing CHIP Regulations.

3.5 The CHIP 4 Regulations also implement the outstanding parts of European Directive No. 2006/121/EC[1]. This 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 European Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals – commonly known as the REACH Regulation.

4. Policy Background

4.1 In Europe there is already a well-established system for the classification (identification of hazards) and labelling of chemicals. However, in recent years, countries across the world have been working towards an international classification and labelling system, finally agreeing the

[1] Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency

Globally Harmonized System on the Classification and Labelling of chemicals (GHS).

4.2 European Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of Substance and Mixtures (CLP Regulation) adopts the GHS in EU Member States. Because the CLP Regulation will exist alongside the existing European classification and labelling system through the transition period until 1 June 2015, it is necessary to make changes to legislation in Northern Ireland (CHIP) to allow compliance with the CLP Regulation in line with the transitional arrangements.

4.3 The CHIP 4 Regulations will also make a few minor editorial amendments, including arrangements to ensure that the legislation keeps track of future changes to the CLP Regulation without the need to make new Regulations.

4.4 The implementation of Directive 2006/121/EC was included in this set of changes to ease the transition for duty-holders to the new arrangements by dealing with all the necessary amendments together.

4.5 **Consolidation** - the new CHIP 4 Regulations will consolidate all amendments to CHIP since 2002.

5. Matters of Special Interest to the Enterprise, Trade and Investment Committee

5.1 None

6. Consultation

6.1 The CHIP 4 Regulations have been subject to formal Health and Safety Executive for Northern Ireland (HSENI) consultation procedures. The draft CHIP 4 Regulations, together with a full explanation of the proposed amendments, an equality screening document and an assessment of costs and benefits were published in HSENI's consultative document (CD). The CD appeared on HSENI's web site and letters were issued to approximately 600 consultees inviting comments on the proposals.

6.2 The consultation ran from 20 February 2009 to 17 April 2009. The shorter eight week consultation was approved by the Minister for Enterprise, Trade and Investment to accommodate the urgency in implementing the remaining parts of Council Directive 2006/121/EC, and the wholly administrative nature of the proposed amendments.

6.3 During the eight week consultation period there were approximately 103 unique visitors to the HSENI website where the downloadable CD was hosted. There were no requests for a hard copy of the CD.

6.4 A total of 4 responses were received. No issues were raised.

7. Position in Great Britain

7.1 In Great Britain the corresponding Regulations are the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (S.I. 2009/716), which were made on 16 March 2009 and came into force on 6 April 2009.

7.2 As the Great Britain and Northern Ireland proposals, taken together, are intended to ensure that the UK meets the necessary requirements introduced by the CLP Regulation and implement the outstanding provisions of Directive 2006/121/EC, it is essential that the same legal requirements apply throughout the United Kingdom.

8. Equality Impact

8.1 The Statutory Rule has been screened for any possible impact on equality of opportunity affecting the groups listed in section 75 of the Northern Ireland Act 1998 and no adverse or differential aspects were identified.

9. Regulatory Impact

9.1 A short Impact Assessment (Summary: Interventions and Options) was conducted in respect of the corresponding Great Britain Regulations and is attached to this memorandum at Annex A. The overall assessment was that the Great Britain Regulations would be cost neutral.

9.2 The Department of Enterprise, Trade and Investment is of the opinion that the analysis and considerations set out in the Great Britain Impact Assessment can be applied directly to Northern Ireland. Consequently the overall assessment of the impact of the Northern Ireland Regulations is that they will be cost neutral.

10. Financial Implications

10.1 The CHIP 4 Regulations are unlikely to have any cost implications for business, charities and voluntary bodies. The changes will facilitate duty-holders in their transitional arrangements to move from the existing classification, labelling and packaging regime to the new one.

10.2 The impact on the public sector is minimal. HSENI will incur minor implementation and familiarisation costs in communicating the changes (externally and internally).

11. Section 24 of the Northern Ireland Act 1998

11.1 The Department has considered the matter of Convention rights and is satisfied that there are no matters of concern.

12. EU Implications

12.1 The CHIP 4 Regulations implement the remaining parts of Council Directive 2006/121/EC and Article 43 of Regulation (EC) No. 1272/2008.

12.2 A Transposition Note appears at Annex B to this memorandum

13. Additional Information

13.1 Not applicable.

Department of Enterprise, Trade and Investment
June 2009

GREAT BRITAIN SHORT IMPACT ASSESSMENT (SUMMARY: INTERVENTIONS AND OPTIONS)

FOR

CHEMICALS (HAZARD INFORMATION AND PACKAGING FOR SUPPLY) REGULATIONS 2009 – CHIP 4

1. The following pages contain a copy of the short Impact Assessment (Summary: Interventions and Options) that was conducted in respect of the corresponding Great Britain Regulations. The overall assessment shows that the Great Britain Regulations will be cost neutral.

2. The Department of Enterprise, Trade and Investment is of the opinion that the analysis and considerations set out in the Great Britain Impact Assessment can be applied directly to Northern Ireland. Consequently the overall assessment of the impact of the Northern Ireland Regulations is that they will be cost neutral.

Department of Enterprise, Trade and Investment
June 2009

Summary: Intervention & Options

Department /Agency:	Title:	
Health and Safety Executive	**Impact Assessment of proposals to amend the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002**	
Stage: Consultation	**Version:** 1	**Date:** 7th November 2008
Related Publications:		

Available to view or download at:

http://www..hse.gov.uk/consult/

Contact for enquiries: Jan Harris or Pierre Cruse **Telephone:** 0207717 6251/ 6122

What is the problem under consideration? Why is government intervention necessary?

The new European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures - CLP Regulation - is directly acting on all EU Member States. However, Member States, including the UK must implement the necessary enforcement provisions. It is proposed to achieve this through an amendment to the CHIP regulations. The regulations will also align domestic legislation with the CLP Regulation during the transitional period, until such time as the CLP Regulation replaces it in 2015.

What are the policy objectives and the intended effects?

To assist duty holders in preparing for the new European Regulation by amending domestic legislation: to reflect the transitional period; to implement the necessary enforcement provisions; and to allow duty holders to comply with the CLP Regulation before the mandatory compliance dates should they choose to for business reasons.

What policy options have been considered? Please justify any preferred option.

The UK is obliged to implement the changes described above under CLP Regulation, and failure to do so would create incoherent and inconsistent legal requirements and leave the UK open to infraction. Amending the existing CHIP regulations, which currently implement existing European legislation on classification and labelling of chemicals, provides an established and well understood legal framework in which to fulfil these obligations. Options to the CLP Regulation itself were fully considered in the RIA to that Regulation.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The costs and benefits of the policy will be reviewed in considering the outcomes of formal public consultation on the proposed amendments to CHIP.

Ministerial Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

.....Date:

Summary: Analysis & Evidence

Policy Option:	Description:

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	
£ 0	
Average Annual Cost (excluding one-off)	
£ 0	**Total Cost** (PV) **£ 0**

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups' 0
One-off **Yrs**	
£ 0 0	
Average Annual Benefit (excluding one-off)	
£ 0	**Total Benefit** (PV) **£ 0**

Other **key non-monetised benefits** by 'main affected groups' Ensures that CHIP is consistent with the CLP Regulation, and therefore provides clarity to all affected groups that CLP's transitional arrangements can be properly implemented and that it can be enforced.

Key Assumptions/Sensitivities/Risks Assumed that CHIP 4 will enable compliance with and enforcement of CLP Regulation. Assumed that editorial changes to CHIP 4 (e.g. updating references to other legislation) will not affect scope. Assumed that cost of enforcement and transitional arrangements fully considered in IA to CLP Regulation.

Price Base Year 0	Time Period Years 0	**Net Benefit Range** (NPV) **£ 0**	**NET BENEFIT** (NPV Best estimate) **£ 0**

What is the geographic coverage of the policy/option?				Great Britain	
On what date will the policy be implemented?				6 April 2009	
Which organisation(s) will enforce the policy?				HSE, LAs, EA, SEPA,	
What is the total annual cost of enforcement for these organisations?				£ N/A	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ 0	
What is the value of changes in greenhouse gas emissions?				£ 0	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro **0**	Small **0**	Medium **0**	Large **0**	
Are any of these organisations exempt?	No	No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease of £ 0 **Net Impact** £ 0

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

1. The European Regulation on the Classification, Labelling and Packaging of Substance and Mixtures (CLP Regulation) adopts in EU Member States the criteria set out in the UN agreement on the Globally Harmonized System on the Classification and Labelling of chemicals. The CLP Regulation is expected to be adopted in late 2008/ early 2009, though it will only become fully mandatory for substances after 1st December 2010 and mixtures after 1st June 2015.

2. The CLP Regulation will act directly in all Member States. However it is necessary to produce national enforcing regulations and to make various further amendments to national legislation (CHIP regulations) to align with the changes at European level.

3. The required amendments to the CHIP regulations are:

- Amendments to CHIP to enable compliance with the CLP Regulation in line with the EU Regulation's transitional arrangements
- Enforcement provisions
- Implementation of the outstanding provisions of Directive 121/2006/EC
- Discontinuation of the GB Approved Supply list
- Two minor editorial changes

The amended version of CHIP will be known as CHIP 4.

4. The sectors affected by this regulation are the same as those which are affected by the CLP Regulation itself. The Impact Assessment for the CLP Regulation identified six main affected groups: chemical manufacturers; downstream businesses; wholesalers; retailers; the public authorities; and retail consumers of chemical products.

5. The new regulation will make technical amendments to existing legislation to enable national law to align with European CLP Regulation. It introduces no significant new duties beyond those introduced by the CLP Regulation itself.

6. A full Regulatory Impact Assessment (RIA) was conducted for the CLP Regulation, in which the costs and benefits of the Regulation were considered. Although the proposed amendments to CHIP will contribute to the realisation of the CLP Regulation's costs and benefits, e.g. through national enforcing provisions, those costs and benefits are properly attributable to the CLP Regulation and it is not appropriate to further assess them in relation to this regulation.

Costs and benefits - costs

7. Costs associated with each element of the CLP Regulation are considered separately.

<u>Amendments to CHIP to enable compliance with the CLP Regulation</u>

8. Currently in the UK chemical classification, labelling and packaging legislation applies the requirements of the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC), through the Chemical Hazard Information, Packaging and Supply (CHIP) Regulations. The CLP Regulation will introduce requirements for chemical

classification, labelling and packaging broadly similar to those of CHIP, though there are some differences of detail. These new requirements will enter into force over a transitional period, and will ultimately replace the CHIP requirements altogether.

9. The specific transitional arrangements which will have to be taken into account are as follows:

Substances

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

Mixtures

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

10. 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).

11. It is not expected that the required amendments to CHIP have any cost implications. Amendments to CHIP are being introduced only to ensure legal consistency when the CLP Regulation is introduced. They are not in themselves the source of the transitional arrangements or of any other duties on suppliers. All costs of reclassifying and relabelling have already been taken into account in the RIA to the CLP Regulation itself, as well as costs due to the transitional arrangements[2], so it would be double counting to attribute any such costs to the amendments to CHIP. No further costs in addition to these are envisaged.

<u>Enforcement provisions</u>

12. Amendments to CHIP will include provisions to enforce all relevant requirements under the CLP Regulation. It is expected that existing enforcement provisions will be carried over from CHIP, together with provisions to enforce any new offences under CLP. As the scope of the

[2] See UK final Regulatory Impact Assessment (after consultation) on the proposed European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (based on the UN Globally Harmonised System – GHS), sections 5.11-5.16.

existing EU system and the CLP Regulation are very similar, no significant additional costs are expected for dutyholders.

13. Some modest training and other costs will be associated with introducing enforcement arrangements for CLP. However these were considered fully in the RIA to the CLP Regulation, so it would be inappropriate to cost them again in relation to this regulation.[3]

Implementation of Directive 121/2006/EC

14. This Directive sets out amendments that need to be made to the Dangerous Substances Directive (67/548/EEC), the Dangerous Preparations Directive (1999/45/EC) and the Safety Data Sheets Directive (91/155/EEC) as a result of the REACH Regulation. To transpose this Directive, corresponding amendments need to be made to the national legislation which implements it. Most of these amendments are being dealt with through Defra's REACH Enforcing Regulation. However a few elements relate to classification and labelling, and will be made through CHIP 4.

15. The relevant amendments to CHIP relate to updating of cross-references to legislation and have no substantive effects and introduce no new duties. For example, references to test methods previously specified in the Annex V DSD will have to be updated to refer to the relevant provisions of REACH. The amendments are expected to be cost neutral.

Discontinuation of the GB Approved supply list

16. HSE currently publishes Annex 1 of the Dangerous Substances directive and subsequent ATPs through the Approved Supply List or ASL. Annex 1 and the ASL contain all the harmonised classifications and labelling requirements agreed by Member States. The ASL is currently only available in paper form and requires the legal reference to it in CHIP to be amended with each re-issue. Once the CLP regulation comes into force, the provision in CHIP referring to the ASL will be 'switched off', and reference will be made instead to Annex VI of the CLP Regulation which will contain the harmonized list. The European Chemicals Agency will make this Annex available in the form of a searchable online database available free of charge over the internet.

17. There may be some small cost implications for businesses as a result of moving from a paper-based system to an internet-based system. Currently the ASL is only available in paper format and costs £34.95. To remain up-to-date a new version needs to be purchased each time Annex 1 to the DSD is updated (once every 1-2 years on average). If the ASL is replaced by an internet-based database, this charge will no longer have to be incurred. However companies without internet access will now have to seek this information from elsewhere.

18. Sales of the previous two editions of the ASL were 3690 and 2078 copies respectively. It would be reasonable to assume that the average of these two figures (2884) represents roughly the number of individual customers who would need to purchase a given edition of the ASL. If we assume that these customers will now save the cost of the ASL by moving to internet access, this would result in a saving of £100,796 to business as a whole.

19. Previous consultation with relevant stakeholders[4] has indicated that not all suppliers of chemicals can be assumed to have internet access (although the small firms contacted for this Impact Assessment were unable to identify any firms without such access). If a supplier does not have such access, removal of the ASL would require that they spend some additional time

[3] See UK final Regulatory Impact Assessment (after consultation) on the proposed European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (based on the UN Globally Harmonised System – GHS), section 5.15.
[4] Responses received to **CD217 - A consultative document on proposals for new amending Regulations about the Classification, Packaging and Labelling of Chemicals: CHIP 3.2**, http://www.hse.gov.uk/consult/condocs/cd217.htm

finding the classifications of the substances they supply. It is assumed that larger companies which supply a significant number of different chemicals are likely to have internet access. If only a small number of substances are supplied, information about harmonized classifications could be obtained in a number of ways, for example by seeking public internet access facilities or by phoning HSE or the Competent Authority.

20. It seems reasonable to assume that the costs of such additional time will be relatively small in relation to the total cost savings to business detailed above. To give an indicative figure, if 25% of current customers for the ASL are required to spend an additional 2 hours seeking substance classifications compared with using the ASL this would give a cost of £74,696, assuming the average cost for an employee's time is £20.72.[5]

21. In summary, the cost implications of discontinuing the ASL are expected to be minor, and any costs are likely to be compensated by corresponding benefits from not having to purchase the ASL. Moreover, the uncertainties of estimating the net cost are large. Therefore, the best overall estimate is that the removal of the ASL will be on balance cost neutral.

Updating references to British and International standards for child resistant fastenings

22. Regulation 11 and Schedule 6 of CHIP refer to several British and International Standards relating to child resistant closures and packaging, and tactile warnings of danger. These standards have either been updated or renamed since the latest version of CHIP was introduced, and stakeholders have requested that HSE update CHIP accordingly. Previously it has not been possible to make these amendments since the origin of these measures (Article 22 and Annex IX of the Dangerous Substances Directive) does not make available to Member States the facility to update to the latest standards. However, since the CLP Regulation includes reference to the new standards, it is proposed at this stage to update the references in CHIP to the new standards.

23. It is not expected that updating the reference to child resistant fastenings will have significant cost implications. The change will not introduce new standards, but will merely ensure that references are up to date, and in any case manufacturers are already to a large extent complying with the most recent standards. Moreover, once CLP is introduced, the new standards will become mandatory by 1st December 2010 for substances and 1st June 2015 for mixtures. There may be costs in applying the updated standards in advance of these dates for those companies not already doing so, but this is not expected to be large. In summary, this amendment is primarily administrative and we have no evidence that it will have significant costs for business.

Updating reference to Medicines Act 1968

24. CHIP currently contains certain exemptions for substances and preparations which are defined within other legislation. One such exemption is for medicinal products within the meaning of section 130 of the Medicines Act 1968.

25. However there have been some recent changes to the legislation to separate out Human Medicines, clinical trials and veterinary medicines. As a result of these changes, the Medicines Act 1968 has been replaced by several pieces of other legislation. The CHIP Regulations will update references to the legislation replacing the Medicines Act 1968 to ensure it is up to date.

26. The purpose of these amendments is to ensure that references to other legislation in defining the scope of CHIP is up-to-date, and are not expected to modify the scope of CHIP in any way. Therefore, the amendments are expected to be cost-neutral.

[5] This is based on the mean average wage for all employees in SIC 24 of £15.94 from the Annual Survey of Hours and Earnings (ASHE) 2006 (Office of National Statistics). Costs are multiplied by 1.3 to include non-wage employment costs.

Further general cost considerations

27. ***Familiarisation costs***. It is not expected that there will be any significant familiarisation costs for industry associated with this regulation. The legislation concerns legal amendments to ensure that the CLP Regulation can be enforced and implemented. It does not impose any new duties or significantly alter existing duties and the enforcing authorities remain the same. Therefore it should not be necessary for dutyholders to familiarize themselves with the detail of the regulation. It may be necessary for some suppliers to familiarise themselves with specific details within the regulation, such as the updated standards for child resistant closures, but this is not likely to impose significant costs. To be able to fully comply with the CLP regulation, including its transitional provisions, it is primarily necessary that duty holders familiarise themselves with the CLP Regulation itself, but this has been fully costed in the RIA to that Regulation.

Benefits

28. The chief benefit of this regulation is that it will provide legal certainty and administrative clarity that the CLP Regulation can be enforced and implemented, and its benefits realised. As such it can be seen as contributing to the overall benefits of the CLP Regulation. However the benefits of the CLP Regulation itself have been fully considered in the RIA to that Regulation, therefore to avoid double counting it is not appropriate to provide additional cost estimates for these benefits in relation to this regulation.

29. In addition to the above there may be a small benefits to businesses as a result of the information on harmonized classification becoming available over the internet rather than through purchasing the Approved Supply List, and as a result of clarifying and making fully consistent the requirements on child resistant closures. However, such benefits are likely to be of very minor significance.

Summary of costs and benefits

30. The only elements of this regulation for which potential costs or benefits have been identified are the removal of the Approved Supply List and updating the references to standards for child resistant fastenings. However the costs or benefits involved are likely to be extremely small, and the uncertainties involved in estimating them large. Moreover it is estimated that the potential small costs are likely on balance to be compensated by corresponding benefits. Therefore, the overall assessment of the impact of CHIP 4 is that it will be cost-neutral.

Small firms impact test

31. Four relevant trade associations who cover both chemical-related businesses and small businesses in general, were asked to provide the names of small firms who would be willing to participate in an initial impact study for CHIP 4. The names of 8 businesses were obtained who were willing to participate.

32. Each participating firm was asked the following questions relating to the impact of the regulation.

- Q1: Do you agree that the above amendments to CHIP, to be made in CHIP 4, have no cost implications? (Question refers to implementation of Directive 121/2006, amendments to CHIP to enable early compliance with CLP Regulation, and Enforcement provisions).
- Q2: Previous consultation has indicated that we should not assume that all businesses who will need to classify chemicals will have internet access. Are you aware of any

relevant businesses which do not have internet access? If you are, how do such businesses access information on the internet?
- Q3: Do you agree that the cost implications for businesses of replacing the ASL with an internet database are likely to be negligible?
- Q4: are we right to assume that manufacturers are currently complying with the latest standards for child resistant fastenings (etc.)? If not, what would be the cost implication to a business of complying with the latest standards?
- Q5: Are you aware of any other potential cost implications for businesses associated with the changes involved in CHIP 4 which have not been mentioned above?

33. Of the 8 businesses contacted, responses were received from 5. Respondents generally agreed that the amendments referred to in Question 1 would have no cost implications. One of the five respondents suggested that they would require a small amount of time to review the new provisions to ensure compliance. However, given that the provisions in question impose no new duties on suppliers beyond those of the CLP Regulation, this has not been included as a cost attributable to CHIP 4, since businesses do not need to do this to comply with CHIP 4 (see para. 24).

34. In relation to questions 2 and 3, respondents indicated that they were unaware of any businesses without internet access, and thought it unlikely that there were many such businesses. All respondents agreed that the replacement of the Approved Supply List would not impose any significant costs, and one welcomed it as a potentially time saving improvement. One respondent stated that they used software containing a database of harmonised classifications rather than the Approved Supply List. This software incurs an annual maintenance charge of £2698, however no reason was given why this should change if the ASL is replaced by an internet database, so this has not been included here as a cost.

35. Respondents were generally unaware of whether businesses were generally complying with the latest standards for child-resistant fastenings. Only one used such fastenings themselves, and stated that they would need to confirm compliance with the latest standards with the manufacturer. If changes were required, they would also have to carry out quality testing and change to specifications, process records and instructions. However they thought the cost in doing this would be 'probably minimal'.

36. No further costs were identified. One respondent was concerned that there may be a cost for re-issuing on site COSHH data, and of having to reclassify chemicals and revising their Health and Safety policies as a result of the new regulation. However, such costs if incurred would be attributable to the CLP Regulation rather than CHIP 4, so these have not been included here.

Competition assessment

37. The proposed regulation is not expected to have a significant impact on competition. The reasons for this are summarised briefly in relation to each element of the regulation below.

<u>Amendments to CHIP to enable compliance with the CLP Regulation</u>

38. The amendments are being made to render CHIP consistent with the transitional arrangements in the CLP Regulation. The RIA for the CLP Regulation itself identified that transition to GHS would lead to greater costs for some businesses than some others, and could in the worst case cause some suppliers to exit their respective market as a result of these transitional costs, although no specific evidence was obtained that this would take place.

39. However, any effects of the transitional arrangements on competition would be attributable to the CLP Regulation and not the amendments to CHIP. Furthermore, no additional effects

have been identified on competition beyond those of the transitional arrangements. Therefore, the amendments to CHIP are not expected to have any impact on competition.

Enforcement provisions

40. Effects of the enforcement provisions have been fully considered in the RIA for the CLP Regulation, so are not further considered in relation to this regulation. In any case, no impacts on competition have been identified.

Implementation of Directive 121/2006

41. The amendments are routine and editorial and are expected to have no effect on competition.

Discontinuation of the GB Approved supply list

42. The removal of the ASL may impose very slightly greater costs on suppliers who do not have internet access in relation to those that do, in relation to looking up harmonised substance classifications. However, these costs are not expected to be significant, for reasons explained above (see paras. 16-21). As a result, no significant impact on competition is expected as a result of these changes.

Updating references to standards for child resistant fastenings

43. There may be a small, short term impact on competition if some manufacturers incur extra one-off costs as a result of having to conform to updated standards on child-resistant fastenings (though most manufacturers are already applying the up-to-date standards). However, updating the standard will ultimately assist competition, by ensuring legal clarity about the standards to be applied and setting a level playing field for manufacturers. Therefore, the net impact of these amendments on competition is expected to be positive rather than negative.

44. In general is also worth noting that one of the aims of the GHS system is to remove trade barriers which arise from having several systems worldwide for classifying and labelling chemicals. By introducing the GHS system in the EU the CLP Regulation may therefore assist global competition, though the extent of this is uncertain and depends on the extent to which other countries and jurisdictions also introduce GHS. To the extent that CLP does enhance competition in this way, this can in part be attributable to the amendments to CHIP, however as with other benefits this is impossible to quantify meaningfully.

Updating reference to Medicines Act 1968

45. The amendments to the Medicines Act are purely editorial and designed to ensure that references to the relevant legislation are up-to-date. They are not expected to have an impact on competition.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	No
Disability Equality	No	No
Gender Equality	No	No
Human Rights	No	No
Rural Proofing	No	No

TRANSPOSITION NOTE: THE CHEMICALS (HAZARD INFORMATION AND PACKAGING FOR SUPPLY) REGULATIONS (NORTHERN IRELAND) 2009 ("CHIP 4")

DIRECTIVE: DIRECTIVE 2006/121/EC of the EUROPEAN PARLIAMENT and of the COUNCIL of 18 DECEMBER 2006 AMENDING COUNCIL DIRECTIVE 67/548/EEC ON THE APPROXIMATION OF LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS RELATING TO THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS SUBSTANCES IN ORDER TO ADAPT IT TO REGULATION (EC) No. 1907/2006 CONCERNING THE REGISTARTION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH) AND ESTABLISHING A EUROPEAN CHEMICALS AGENCY

REGULATION: REGULATION (EC) No. 1272/2008 of the EUROPEAN PARLIAMENT and of the COUNCIL of 16 DECEMBER 2008 ON CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES, AMENDING AND REPEALING DIRECTIVES 67/548/EEC and 1999/45/EC, and AMENDING REGULATION (EC) No. 1907/2006

Introduction

The Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 implement the remaining parts of Council Directive 2006/121/EC and Article 43 of Regulation (EC) No. 1272/2008.

Council Directive 2006/121/EC was published on 30 December 2006. Member States had to implement its provisions by 1 June 2008. The Directive sets out the necessary amendments needed to the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (99/45/EC), as a result of the entry into force of the European REACH Regulation (EC) No. 1907/2006.

The changes required by the Directive cover two areas:

a. Aspects concerning the revocation of the 'notification of new substances' (NONS) scheme and the provision of safety data sheets. These have been given effect as part of the UK arrangements for enforcing REACH, through the REACH Enforcement Regulations 2008 (SI 2008 No. 2852), which entered into force on 1st December 2008.

b. Aspects concerning the classification and labelling of substances – they adjust the references to the test methods following repeal of Annex V of Directive 1967/548/EEC (the 'Dangerous Substances Directive'), and their reinstatement through a new Commission Regulation. These amendments will be made as part of the changes in the UK through the enforcing Regulations for the European Classification, Labelling and Packaging Regulation (the 'CLP Regulation'), which will be implemented through a package of amendments in the CHIP 4 Regulations coming into operation on 27 July 2009.

The remaining parts of Directive 2006/121 are editorial in nature and alter references to the library of test methods following their transfer from Annex V of the Dangerous Substances Directive (now deleted) to a new European Commission Regulation (No. 440/2008) made under Article 13(3) of the REACH Regulation. The test methods themselves are unchanged. In the CHIP Regulations, the test methods are referenced in the Great Britain Health and Safety Executive's Approved Classification and Labelling Guide (ACLG), which implements Annex VI of the Dangerous Substances Directive. The Great Britain ACLG has been approved, by the Health and Safety Executive for Northern Ireland, for use with the CHIP Regulations. The appropriate changes will appear in the new issue of the ACLG to which CHIP 4 will give legal effect.

COUNCIL DIRECTIVE 67/548/EEC as last amended by Directive 2004/73/EC, Directive 2006/121/EC and Commission Regulation (EC) No. 440/2008		
Main elements of the Directive:		**Transposed by:**
Article 2.2	Defines what substances and preparations are 'dangerous' within the meaning of the Directive	Reg 2, by reference to Schedule 1
4	Identifies the basis for general principles of classification	Reg 4(2) – (4)
6	Places an obligation on suppliers of dangerous substances to carry out investigations	Reg 4(5)
22	Sets out packaging requirements	Reg 6 and 11
23	Sets out labelling requirements	Regs 7 and 8, Schedule 4, Table 3.2 of Part 3 of Annex VI to the CLP Regulation (EC Regulation No. 1272/2008), Approved Classification and Labelling Guide
24	Specifies details of the means of implementing the labelling requirements	Regs 7, 8 and 10
25	Provides exemptions from labelling and packaging requirements for: munitions and explosives	Reg 3(5)

COUNCIL DIRECTIVE 1999/45/EC as last amended by Directive 2006/8/EC		
Main elements of the Directive:		**Transposed by:**
Article 2.2	Defines what substances and preparations are 'dangerous' within the meaning of this Directive	Reg 2, by reference to Schedule 1
4	Identifies the basis for the general principles of classification and labelling	Reg 4(7)
5	Specifies the method of evaluating	Reg 4(7), by reference to

COUNCIL DIRECTIVE 1999/45/EC as last amended by Directive 2006/8/EC		
Main elements of the Directive:		**Transposed by:**
	hazards deriving from physico-chemical properties	Schedule 3 and the Approved Classification and Labelling Guide
6	Specifies the method for evaluating health hazards	Reg4(7), by reference to Schedule 3
7	Specifies the method for evaluating environmental hazards	Reg 4(7), by reference to Schedule 3
8	Places obligations on Member States to ensure compliance	Regs 12 and 14
9	Sets out packaging requirements	Regs 6 and 11
10	Sets out labelling requirements for preparations	Regs 7, 8 and 9, Schedule 4 and the Approved Classification and Labelling Guide
11	Specifies details of the means of implementing the labelling requirements	Regs 7 and 10 and the Approved Classification and Labelling Guide
12	Provides exemptions from the labelling and packaging requirements for: • munitions and explosives	Reg 3(5)
	• Preparations in a form not presenting risks (reference to Annex VII)	Approved Classification and Labelling Guide
	• Labelling of small/unsuitable packages	Reg 7(8) – (9) and 10(7)
15	Provides for safeguarding of the confidentiality of certain chemical names	Reg 7, by reference to Schedule 4 Part 1

COUNCIL DIRECTIVE 2006/121/EC			
Article:	**Objective:**	**Implementation:**	**Responsibility:**
Art 1 (3); Art 1 (11)	Member States to delete existing references to test methods in Annex V of Directive 67/548/EEC, and replace with references to the new European Commission Regulation No. 440/2008	In paragraph 2(b) of the Explanatory Note to the Regulations. The Great Britain Health and Safety Executive Approved Classification and Labelling Guide (approved for use in Northern Ireland by the Health and Safety Executive for Northern Ireland)	The Department of Enterprise, Trade and Investment, through amendments to consolidating Regulations.
	Member States to bring into force the laws, regulations and administrative provisions necessary to comply with the amending Directive by 1 June 2008.	In paragraph 2(b) of the Explanatory Note to the Regulations.	
	Member States to communicate to the European Commission the text of the main provisions of national law which they adopt		The Health and Safety Executive for Northern Ireland via the Great Britain Health and Safety Executive and UKREP
	Date of entry into force of the amending Directive	No action required.	