

Health and Safety Executive Senior Management Team Paper			SMT/08/83
Meeting Date:	4 November 2008	FOI Status:	Board paper HSE/08/78 partially closed
Type of Paper:	For clearance	Trim Ref:	2008/567663
Exemptions:	Sections 22 and 35 of FOIA		

HEALTH AND SAFETY EXECUTIVE
Senior Management Team
**CONSULTATION DOCUMENT ON THE PROPOSED CHEMICALS (HAZARD
INFORMATION AND PACKAGING FOR SUPPLY) REGULATIONS 2009**

A Paper by **JAN HARRIS**

Advisor: **ROBIN FOSTER**

Cleared by Giles Denham on 29 October 2008

Issue

1. Clearance of the attached paper seeking the Board's agreement to the draft Consultative Document on the proposed new CHIP Regulations.

Timing

2. Urgent. See attached paper.

Recommendation

3. The SMT is invited to:
 - a) note the need for amendments to the CHIP regulations;
 - b) note the recommendation that HSE should carry out the function of the CLP Competent Authority and the proposed approach to establish the Competent Authority for the CLP Regulation; and
 - c) clear the attached paper at Annex A for submission to the Board.

Background

4. See the attached paper.

Health and Safety Executive Board		Paper No: HSE/08/78	
Meeting Date:	26 November 2008	FOI Status:	Partially closed
Type of paper:	Above-the-line	Exemptions:	Section 22 – Annex A Section 35 – Paragraphs 14, 23-25, 26(b) and Annexes B and C
Trim reference:			
CONSULTATION DOCUMENT ON THE PROPOSED CHEMICALS (HAZARD INFORMATION AND PACKAGING FOR SUPPLY) REGULATIONS 2009 AND CONSIDERATION OF THE COMPETENT AUTHORITY FOR THE EUROPEAN CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES REGULATION			

Purpose of this paper

1. To seek Board agreement to the publication of the Consultative Document on amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP), and to initiate the process to establish the Competent Authority under the European Classification, Labelling and Packaging of Substances and Mixtures Regulation (CLP Regulation).

Timing

2. Urgent. Clearance required on 26 November. The CLP Regulation is expected to be published in the Official Journal in November or December 2008, entering into legal effect 20 days later. We need to avoid conflict in regulations at both EU and national level. In order to accommodate these legal changes at the next appropriate common commencement date – 6 April 2009 – we need to consult reasonably quickly.
3. On 12 August, on behalf of the Board the Chair approved a compressed consultation period of 8 weeks to speed implementation of these changes.

Recommendation

4. That the Board:
 - a) approves the publication of the Consultative Document on the proposed CHIP Regulations at Annex A. (Annex C provides the detailed Instructions to the Legal Adviser's Office on drafting CHIP 4);
 - b) agrees with Option 1.1 in Annex B, that HSE should carry out the functions of the Competent Authority under the CLP Regulation;
 - c) agrees with Option 2.1 in Annex B, that the Competent Authority should be established by following the precedent set by the REACH CA model, which designates ministers as the CAs through domestic Regulations, who then delegate the function to the HSE;

Background

5. CHIP is a key part of Great Britain's chemical regime. It requires suppliers of chemicals to give health, safety and environmental information on dangerous chemicals by means of labels on packaging and safety data sheets. This enables users to take appropriate precautions.
6. CHIP implements several Single Market Directives; the Dangerous Substances Directive (DSD); the Dangerous Preparations Directive (DPD); and the Safety Data Sheets Directive (SDSD) the latter now repealed by

REACH. HSE leads on negotiations related to these Directives and any proposed Adaptations to Technical Progress (ATPs).

7. These Directives will be replaced by the forthcoming European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation), through which the European Union will adopt the UN's Globally harmonised System (GHS). Papers MISC/08/11, HSC/MISC/07/10, HSC/07/58 and HSC/07/08 have set out the detail of GHS, the European Commission's proposed regulation, the UK's negotiating strategy and, most recently the outcome of Member State negotiations and UK consultation.
8. On 3 September, the European Parliament voted to secure a First Reading Deal with the Council on the CLP Regulation to adopt the GHS in EU Member States. We anticipate that CLP Regulation will be published in the Official Journal in November or December, and will come into force 20 days after publication.
9. Directive 121/2006 is essentially 'tidying up' legislation consequent to REACH. The substantial provisions will be implemented by Defra, which has the policy lead, in its SI providing national enforcement measures for REACH. However, other aspects relating to classification and labelling are sensibly taken as amendments to the administrative provisions that sit alongside CHIP (ie the Approved Classification and Labelling Guide). Although these are no more than changes of references, the automatic early stage infraction process within the European Commission has resulted in reference to 121/2006 in a recent Article 226 letter. The Directive should have been implemented by 31 May 2008.

Argument

CHIP amendments driven by the CLP Regulation

10. Most of the proposed amendments to CHIP reflect the advent of the CLP Regulation at EU level. There are three main changes.
11. Firstly, the proposed CHIP amendments allow duty holders to meet the requirements of the CLP Regulation instead of CHIP, in line with the transition arrangements in the EC Regulation. These arrangements comprise a two-stage process whereby substances have to be reclassified and relabelled by 1 December 2010, and mixtures (previously called preparations) by 1 June 2015. As the CLP Regulation will be adapted to technical progress by means of Commission regulations – the first adaptation is already planned for June 2009 – the references in CHIP to the CLP Regulation have been 'future proofed' by using an ambulatory reference, ie by referring to the CLP Regulation "as amended from time to time". The substantive requirements of CHIP are switched-off from 1 June 2015.
12. Secondly, the proposed CHIP amendments provide for enforcement of the CLP Regulation. This is straightforward as the scope of the CLP Regulation is essentially the same as CHIP and the same enforcing authorities (mainly HSE and LAs) continue to do the same as they do now under CHIP. No changes to inspectors' warrants will be needed.
13. Thirdly, the CLP Regulation requires each Member State to appoint a competent authority (CA). The main functions of the CA are to:
 - a) Provide a national helpdesk to provide advice to duty holders and other interested parties on the requirements of the Regulation; and

- b) Propose, where appropriate, harmonised substance classifications which are taken forward through the process established in REACH.
14. Annex B presents an analysis of options on who might take on the role of the CA under the CLP Regulation, how it might be established, and how the CA should relate to the CA under REACH. In essence the analysis concludes that:
- a) HSE should be the CA under the CLP Regulations because:
 - i. We already undertake this role under the existing EU system, with assistance from the Environment Agency on environmental aspects and the Department of Health on aspects of public health;
 - ii. There appears to be no other candidates for the role;
 - iii. The role in paragraph 13(b) above is already delegated to HSE as the REACH CA;
 - iv. Interested parties inside and outside Government would expect a unified REACH and CLP CA, with one point of access for enquiries.
 - b) It seems sensible that the mechanism of establishing the CA for the CLP Regulation should mirror that followed for REACH, ie designation of Ministers through domestic Regulations, and delegation to HSE by Agency Agreements. In practice, the latter would be effected by amendment of the existing agreements for the REACH CA.
15. Finally, changes to the classification system inevitably trigger changes to downstream legislation on the control of chemicals. Some of these changes are being made at EU level, as alongside the CLP Regulation are amendments to the Detergents Regulation and to certain Directives on cosmetics, toys, volatile organic compounds, end-of-life vehicles, waste electrical and electronic equipment, and paints and varnishes. The changes are minor ones of terminology and reference. We have agreed with OGDs that these should be taken forward by the departments concerned, mainly BERR and Defra. However, we can expect the Commission to bring forward other changes, including changes to HSE-led legislation such as the Chemicals Agent Directive and the Seveso II Directive (COSHH and COMAH in our national legislation). These aspects are being monitored and, in the case of Seveso II, the relevant HSE staff are already actively engaged in discussions at EU level.

Other CHIP Amendments

- 16. Two other changes to CHIP are proposed in addition to those required by the advent of the CLP Regulation.
- 17. The first is to complete the 'tidying up' required by Directive 121/2006. This mainly involves altering references to the library of test methods following their transfer from Annex V of the Dangerous Substances Directive (now deleted) to a new Commission Regulation (No. 440/2008) made under Article 13(3) of REACH. The test methods themselves are unchanged. In CHIP, the test methods are referenced in the Approved Classification and Labelling Guide (ACLG). The appropriate changes will be made and the ACLG will be re-

issued. Although these changes are essentially editorial, it is important that they are made promptly as the Commission's automatic process that initiates possible infraction has started.

18. The second proposed change is to discontinue the Approved Supply List (ASL), which lists in CHIP the harmonised classifications and labels for around 7000 substances. The list is updated at intervals of approximately 18 months to 2 years, typically by the addition of several hundred new entries and the revision of a similar number. The list, in both the existing EU classification system and in the new GHS-based system, will be incorporated in the CLP Regulation. It is also available in on-line, searchable databases which in future will be maintained by the European Chemicals Agency (ECHA). We propose, therefore, to take this opportunity to discontinue publication and periodic reissue of the ASL. We consulted publicly on this proposals in a CD issued earlier this year on the previous amendments of CHIP to implement the 2nd ATP of the Dangerous Preparations Directive. The response was broadly favourable.

Consultation

19. [We have consulted with colleagues in the Corporate Specialist Divisions (Science and Technology Group); Legal Adviser's Office; Communications Directorate; Planning, Efficiency and Finance Division; International Unit; and in Hazardous Installations Directorate on the development of this paper. DN Relevant for SMT clearance – remove in Board version]
20. Through the CLP Regulation consultation process, we have established an industry wide network of contacts, in addition to the specialists on the ACTS Standing Committee on Hazard Information and Packaging (SCHIP), OGDs and agencies and the Devolved Administrations. We will consult these contacts again in addition to the 1500 subscribers to HSE's chemicals web pages.

Presentation

21. The HSE web site will carry an announcement about the proposed CHIP regulations and the launch of the consultation process once publication of the CD has been approved. We will also alert our industry and OGD networks. The CD will be free of charge and available for download and response on the HSE web site. Printed copies will be available on request.

Costs and Benefits

22. A draft Summary: Intervention and Options form has been completed for the proposed CHIP regulations. As the regulations do not introduce any additional duties or burdens on either duty-holders or regulators, the impact costs are deemed negligible. The costs and benefits of the CLP Regulation were fully evaluated and can be found at:
<http://www.hse.gov.uk/ria/chemical/eugh.pdf>

Financial/Resource Implications for HSE

23. As the Board is already aware, Defra presently funds the work of HSE as the REACH CA (around £1.2m pa). Defra will not fund HSE as the CLP CA, but we are confident that we can account separately for the work of the two CAs. In the future we anticipate that a PES transfer will be made so HSE's role as the REACH CA is funded directly.
24. REACH imposed new duties, whereas the CLP Regulation adjusts existing duties, keeping broadly the same scope. In terms of enforcement, therefore,

no additional resource is expected, other than training for inspectors on the new requirements (already covered as part of the IA for the CLP Regulation itself).

25. In terms of the CLP CA, the main additional workload is the Helpdesk, which Member States are obliged to provide under the CLP Regulation. Presently, HSE staff (policy and scientific), together with Infoline, already answer queries on the existing EU classification and labelling system. On average we estimate that these amount to an average of 10 enquiries per week, with an additional 25 enquiries per week fielded by Infoline. We can expect these to increase, with the advent of the CLP Regulation, with peaks as the deadlines for reclassification and labelling in the CLP Regulation approach (1 December 2010 and 1 June 2015). However, we expect the level of queries to the Helpdesk on the CLP Regulation to be significantly lower than that for REACH. We would also expect that those for REACH reduce somewhat from the present high levels as the deadline for REACH pre-registration passes, and as the REACH responsibilities settle and become more familiar. Determining the detailed role of the Helpdesks for the REACH, CLP, Pesticides and Biocides CAs and ensuring the necessary resource, will be an issue for any new Chemicals Directorate to address.

Action

26. That the Board:

- a) agrees publication of the Consultative Document at Annex A and notes the Chair's agreement to a compressed consultation period; and
- b) agrees that HSE should act as the Competent Authority for the CLP Regulation, in line with our role as the UK REACH CA, and that officials should initiate discussions with OGDs, agencies and the Devolved Administrations to this end.

Paper Clearance

19. This paper was produced by Jan Harris and Robin Foster, and was cleared by the SMT.
-

Partially Closed [TBC]

Options for Competent Authority for EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation)

Issue

1. To consider options for establishing a Competent Authority for the EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation).

Background

Competent Authority and Helpdesk

2. The CLP Regulation requires that each Member State set up a Competent Authority (CA) to perform certain administrative functions. The main role of the CA is that it can propose harmonised classifications for substances on behalf a Member State. The Competent Authority also has the right to request the information that a supplier has used to classify and label substances or mixtures that they have put on the market, and plays some minor administrative roles such as receiving information on whether requests for use of alternative chemical names have been granted.
3. CLP also instructs Member States to establish a 'Helpdesk' to give advice to dutyholders and others on their obligations under the Regulation. The CA and Helpdesk do not have to be run by the same organisation, but given that they will require very similar expertise, it is assumed in this paper that they will be run together.
4. Annex 1 lists the provisions in the CLP Regulation relating to the Competent Authority and the Helpdesk.

REACH Competent Authority

5. Board members will be familiar with the European REACH Regulation. The CLP Regulation will sit alongside REACH and the two regulations will act together to form the main legislation on chemicals within the EU.
6. HSE currently performs the functions of the Competent Authority for the REACH Regulation on behalf of the whole of the UK. The REACH CA has a range of functions which include:
 - Provision of a 'helpdesk' to provide advice to suppliers and other interested parties on their responsibilities and obligations under REACH.
 - Conduct of substance evaluation of prioritised substances and preparations of draft decisions.
 - Identification of substances of very high concern for authorisation.

- Making proposals for restrictions relating to the manufacture, marketing and use of certain dangerous substances, preparations and articles.
7. The REACH CA has been appointed via a structure in which ministers are formally responsible for the CA functions, but delegate these to HSC, now the Board (the appointment predates the HSC/E merger). This is achieved through a number of steps:
- A Designation Order in Council designates the Secretary of State for the Environment as able to appoint REACH CAs
 - The SoSs appoint relevant parties as CA in Wales and Northern Ireland.
 - These parties delegate their functions to HSC through 'agency agreements', which in turn directs HSE to perform these functions on their behalf.
8. Separate but similar arrangements are in place in Scotland, where separate legislation appoints the Scottish Parliament as formal CA for matters within its competence. This gives Scottish Ministers the authority to enter into an agency agreement with HSC, delegating to it the functions of the Competent Authority.

Options to be considered

9. There are two fundamental issues to be addressed in relation to the CLP CA:

Issue	Options
1. Who will perform the functions of the CA?	1.1 HSE
	1.2 HSE jointly with some other body (e.g. EA)
	1.3 Another body hosts the CA
2. What should be the relationship between the CLP CA and the REACH CA?	2.1 The CLP CA is incorporated into the REACH UK CA using the same legal mechanism.
	2.2 The CLP CA is set up separately from the REACH CA through CHIP 4

Issue 1: Who will perform the functions of the CA?

Option 1.1: HSE performs CA functions

10. There are a number of reasons why it would be natural for HSE to perform the functions of the CLP Competent Authority:
- HSE leads for HMG on classification and labelling policy for chemicals.
 - HSE has for a number of years led for HMG on proposing new harmonised hazard classifications for substances on behalf of GB, with assistance from EA on environmental classifications. In doing this HSE acts as de facto 'Competent Authority' for classification and labelling.
 - HSE deals with the majority of enquiries from dutyholders, stakeholders and members of the public regarding the current chemical

classification and labelling regime (again, with assistance from EA). In this sense it already performs the role expected of a 'helpdesk'.

- HSE volunteered to lead for HMG on negotiation of the CLP Regulation on the basis of its expertise, and after consultation with OGDs no objections were raised. HSE also takes the lead on classification and labelling issues on the REACH Competent Authority Steering Group, where Defra have the overall policy lead.
- HSE currently performs the functions of REACH CA, and there are significant overlaps between the role of REACH and CLP CAs.

11. HSE acting as CA for CLP would largely preserve the status quo, and there are no obvious disadvantages associated with this option.

Option 1.2: HSE acts as joint CA with another body

12. Currently HSE works with EA and SEPA in its work on harmonised classifications for CHIP, though in practice SEPA allows EA to lead. If a joint CA were to be set up, the obvious option would be to share the role between HSE and EA/SEPA.

13. Sharing the CA role in this way would not in practice alter the current working arrangements. However it would introduce administrative complications since the formal division of responsibilities between HSE, EA and SEPA would need to be negotiated and would not be straightforward (especially since this raised sensitivities in the context of REACH). Furthermore, the experience of a joint HSE and EA/SEPA CA in the context of COMAH is that such an arrangement has some awkward aspects.

14. In view of this, the option is not recommended since little would be gained in return for the additional problems created by requiring a formal agreement between HSE, EA and SEPA.

Option 1.3: Some other body (to be specified) acts as CA

15. In GB Government, only HSE has the expertise to carry out the functions of the CA, so in practice HSE would retain a major role even if another body were nominated as the designated CA. Moreover, no other body has expressed an interest in taking on HSE's current role in leading for HMG on classification and labelling issues. We are therefore not aware of any persuasive or significant reasons to pursue this option.

Summary recommendation: HSE currently performs the majority of roles of the CA, and we suggest that it should continue to do so (Option 1.1).

Issue 2: what should the relationship be between the CLP CA and the REACH CA?

Option 2.1. The CLP CA is incorporated into the REACH CA through the same legal mechanism (domestic Regulations – agency agreements)

16. The major role assigned to the CA for CLP is in proposing harmonised classifications for hazardous substances. In practice this is done via REACH processes, as classification and labelling is discussed in the REACH Risk Assessment Committee. This is reflected in the agency agreements that delegate the REACH CA functions to HSE, as proposing harmonised classification and labelling is also one of the roles of the REACH CA. Therefore, there is a significant overlap in the duties required of the two CAs.
17. This suggests that the most economical approach would be to incorporate the CLP CA into the REACH CA. Formally, this option would involve domestic Regulations giving the relevant Secretary of State the authority to designate ministers in Westminster, Wales and Northern Ireland as formal Competent Authorities for CLP (though separate legislation may be required for Scotland, as with REACH). These parties would then delegate the responsibilities of the CA to a relevant body (e.g. HSE).

Advantages

18. The main advantages of this approach are simplicity and alignment, in that merging the two CAs would be consistent with the Hampton principle that a new regulatory body should not be created when an existing one can do the work. Incorporating the role of the CLP helpdesk into the REACH helpdesk would also create a single point of contact for enquiries, which would be more convenient and simpler for dutyholders wanting to contact HSE about chemical related matters.
19. A further advantage is that the overall legal structure created by this approach would parallel that of REACH. It is therefore simpler and is likely to be easier to manage than introducing different legal bases for the REACH and CLP CAs. However a potential risk would be that because REACH and CLP functions would be tied together in single agency agreements, any future change to the REACH CA arrangements would carry over to the CLP CA, unless the CLP CA is separated from REACH.

Potential disadvantages and risks

20. An issue with this approach is that there may be some 'excess' duties which fall under CLP but not the REACH CA. For example, REACH duties are triggered by tonnage thresholds, whereas CLP classification duties are not. Therefore, proposing a harmonised classification for a substance that falls under these thresholds will fall within the remit of CLP, but not the REACH CA. In addition, Title XI of REACH – in which harmonised classification and labelling is given as one of the roles of the REACH CA – is transferred into CLP as soon as CLP comes into force. This may be regarded as removing some harmonised classification and labelling responsibilities from the role of the REACH CA, although such responsibilities will still be involved in proposals for registering or authorising a substance.
21. This is significant because Defra currently pay HSE £1.2m p.a. to deliver the CA function for REACH. Therefore, if there are tasks in scope of the CLP CA

but not the REACH CA, it would have to be ensured that this excess work was not charged to the Defra budget.

22. However, it is likely that this could be managed by a suitable system of work recording, and the same issue is likely to arise even if the two CAs are not merged. The issue will also resolve if, as currently planned, funding for REACH CA is provided by permanent PES transfer from Defra to HSE.

Relationship with the Devolved Administrations

23. Currently the REACH CA covers the whole of the UK. Therefore, if the CLP CA function is incorporated into the REACH CA, the natural option would be that the body acts as CA for CLP on behalf of the whole UK. It may be possible to draft agency agreements in such a way that the CLP CA function is separated from that of REACH and applies only to GB (say), but this would create a very awkward legal structure, so would be undesirable if it can be avoided.
24. There may be some political sensitivity in proposing that HSE act as UK-wide CA for classification and labelling (at present it effectively performs this role for GB, but not for Northern Ireland). However, it seems likely that a single UK CA would be acceptable to the Devolved Administrations, since this structure is already in place in respect of REACH, and Devolved Administrations are in any case unlikely to have the resources to take on this function independently of HSE. Moreover, the activities of the CA will be managed by a steering group in which the Devolved Administrations will have full involvement, in a similar way to the REACH CA.

Option 2.2: The CLP CA is established separately from the REACH CA function through CHIP 4.

25. The main alternative to incorporating the CLP CA into the REACH CA function would be to establish it directly by adding a provision to CHIP through the amendments being made in CHIP 4.

Advantages

26. The chief advantage of this option would be that it could be accomplished more simply from a legal point of view. CHIP 4 is already being introduced for other reasons, and a provision establishing a CA could be included very straightforwardly. The arrangement would also give legal clarity, since it would only require a single legal instrument to accomplish (for GB), and would therefore avoid some of the complexities of the REACH-type structure.
27. It could also be argued that a CA established through CHIP 4 would be a more permanent arrangement, since it would in future be more difficult to change secondary legislation than to modify agency agreements. This would have the advantage that HSE's role as the CLP CA (assuming it takes this role) would not necessarily be affected if at some future time there is a change, for example, in the REACH CA arrangements.

Potential disadvantages and risks

28. The major problem with establishing two separate CAs is that the links and overlap between the REACH and CLP CAs make this option very difficult to justify in terms of Hampton principles.
29. One reason is that it would be difficult to clearly distinguish the roles of the two authorities from a legal and administrative point of view. For example, this approach would also create problems in managing the Defra funding for the REACH CA, since it would not be clear who pays for work in the 'overlap' between the two CAs. Another problem would be that the combination of two separate CAs established through different types of legal instrument would create a complex legal structure that may be more difficult to manage in future than if the two authorities are linked.
30. For similar reasons, it would also be problematic to have two separate 'helpdesks' for REACH and CLP, since a system with two points of contact would be both confusing for dutyholders and interested parties within government, and more difficult for HSE to manage.

Relationship to the Devolved Administrations

31. Currently the CHIP regulations are made under HSWA, while Northern Ireland has separate but parallel legislation introducing essentially identical provisions. Therefore, if CHIP 4 were used as the mechanism to establish a CA for CLP, the most straightforward option would be for this CA to cover GB only, with Northern Ireland making separate arrangements. This would mirror the current arrangements whereby HSE acts as de facto Competent Authority for classification and labelling on behalf of GB only. However, it would also be possible for Northern Ireland to amend their own legislation so as to nominate HSE as CA, so this option could in theory be compatible with a UK-wide CA.

Summary recommendation: Option 2.1 (CLP CA should be incorporated into REACH CA) is recommended given the overlap in the roles of the two CAs.

Summary and overall recommendation

32. The following combination of options is tentatively recommended:

Option 1.1:	HSE performs the functions of the CLP CA
Option 2.1:	The CLP CA function is incorporated into the existing REACH UK CA, through an Order in Council and agency agreements.

33. The main advantages of this proposal are that it:

- Preserves and formalises HSE's known and accepted role of de facto CA in relation to classification and labelling for CHIP.

- Manages the overlapping roles of the CLP and REACH CAs by creating a single joint CA.
- Is compatible with the Hampton principle that two bodies should not be created when one can do the job.
- Is more user-friendly for dutyholders, since it creates a single point of contact for REACH and CLP enquiries
- Creates the simplest overall legal structure, since the arrangements for CLP will parallel the existing REACH arrangements
- Allows flexibility to modify the agency agreements in future if some change in the CA arrangements is required.

34. Potential disadvantages and risks of this approach are that it:

- Requires in principle re-opening the Agency Agreements which delegate the REACH CA responsibilities to HSE, which took significant effort to negotiate.
- Ties the CLP CA to the REACH CA, therefore any changes to the REACH arrangements would apply to the CLP CA unless the two functions are separated.

Financial/Resource Implications

35. Nominating HSE as the CA for CLP is not expected to have significant cost implications. HSE already carries out the functions required of the CA, i.e. proposing harmonised classification and labelling and dealing with enquiries, and designating HSE as CA would not materially affect this. There may be some resource implications as a result of HSE assuming the official helpdesk function for CLP, however this is covered in the main Board paper.

36. If the CLP CA is merged with the REACH CA and is seen to create additional duties, Defra's £1.2m funding for the REACH CA will need to be managed to ensure that spend is correctly attributed. However this should not affect the overall funding which HSE receives from Defra.

Consultation

37. Key HSE officials have been consulted in the drafting of this paper. Consultation with the Devolved Administrations is planned subject to Board agreement.

Annex 1 – Provisions in the CLP Regulation regarding the establishment and role of a Competent Authority:

Article 24 (Request for use of an alternative chemical name):

(5) The Agency shall inform competent authorities of the outcome of the request according to paragraph 3 or 4 and provide them with the information submitted by the manufacturer, importer or downstream user.

Article 34 (Report on communication on safe use of chemicals):

(1) By [the date of entry into force of the Regulation] the Agency shall carry out a study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels. This study shall be carried out in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice.

Article 37 Procedure for harmonisation of classification and labelling of substances:

(1) A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or M-factors, or a proposal for a revision thereof. The proposal shall follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.

...

(6) Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in Part 3 of Annex VI shall submit a proposal in accordance with the second subparagraph of paragraph 2 to the competent authority in one of the Member States in which the substance is placed on the market.

Article 43 (Appointment of competent authorities and enforcement authorities and cooperation between authorities):

Member States shall appoint the competent authority or competent authorities responsible for proposals for harmonised classification and labelling and the authorities responsible for the enforcement of the obligations set out in this Regulation.

The competent authorities and the authorities responsible for enforcement shall cooperate with each other in the performance of their tasks under this Regulation and shall give the corresponding authorities of other Member States all necessary and useful support to this end.

Article 44 (Helpdesk):

Member States shall establish national helpdesks to provide advice to manufacturers, importers, distributors, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation.

Article 49 (Obligation to maintain information and requests for information):

(1) The supplier shall assemble and keep available all the information used by that supplier for the purposes of classification and labelling under this Regulation for a period of at least 10 years after the substance or the mixture was last supplied by that supplier.

The supplier shall keep this information together with the information required in Article 36 of Regulation (EC) No 1907/2006.

(3) The competent authority or the enforcement authorities of a Member State in which a supplier is established or the Agency may require the supplier to submit to it any information referred to in the first subparagraph of paragraph 1.

However, where that information is available to the Agency as part of a registration pursuant to under Regulation (EC) No 1907/2006 or a notification pursuant to Article 40 of this Regulation, the Agency shall use that information and the authority shall address itself to the Agency.

Article 50 (Tasks of the Agency):

(1) The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.

(2) The Secretariat of the Agency shall:

(a) provide industry with technical and scientific guidance and tools where appropriate on how to comply with the obligations of this Regulation;

(b) provide Member State competent authorities with technical and scientific guidance on the operation of this Regulation and provide support to the helpdesks established by Member States under Article 44.

Article 52 (Safeguard Clause):

(1) Where a Member State has justifiable grounds for believing that a substance or a mixture, although satisfying the requirements of this Regulation, constitutes a serious risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision.

(2) Within 60 days of receipt of the information from the Member State, the Commission shall in accordance with the regulatory procedure referred to in Article 54(2) either authorise the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.

(3) In the case of an authorisation of a safeguard measure related to classification or labelling of a substance as referred to in paragraph 2, the competent authority of the Member State concerned shall in accordance with the procedure laid down in Article 37 submit a proposal to the Agency for harmonised classification and labelling, within three months of the date of the Commission decision.