Consultation on regulatory measures to support EU chemicals legislation and proposals on reducing seven existing sets of domestic regulations into one statutory instrument (7 into 1 package)

This consultative document is issued by the Health and Safety Executive in compliance with its duty to consult under section 50(3) of the Health and Safety at Work etc Act 1974.

Comments should be sent to:

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Health and Safety Executive
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Merton Road
Bootle
L20 7HS

Tel: 0151 951 3301

E-mail: ChemicalsConsultation@hse.gsi.gov.uk

to reach there no later than 31 January 2013

The Executive tries to make its consultation procedure as thorough and open as possible. Responses to this consultation document will be lodged in the Health and Safety Executive's Knowledge Centre after the close of the consultation period where they can be inspected by members of the public.

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004 (EIR)). Statutory Codes of Practice under the FOIA and EIR also deal with confidentiality obligations, among other things.

If you would like us to treat any of the information you provide, including personal information, as confidential, please explain your reasons for this in your response. If we receive a request under FOIA or EIR for the information you have provided, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will be disregarded for these purposes. Requests for confidentiality should be made explicit within the body of the response.

HSE will process all personal data in accordance with the DPA. This means that personal data will not normally be disclosed to third parties and any such disclosures will only be made in accordance with the Act.
CONSULTATION ON REGULATORY MEASURES TO SUPPORT EU CHEMICALS LEGISLATION AND PROPOSALS ON REDUCING SEVEN EXISTING SETS OF DOMESTIC REGULATIONS INTO ONE STATUTORY INSTRUMENT (7 INTO 1 PACKAGE)

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A CONSULTATION BY THE HEALTH AND SAFETY EXECUTIVE

1. The Health and Safety Executive (HSE) has a statutory duty to consult on its proposals under the Health and Safety at Work etc. Act 1974 (HSWA). It believes that public consultation provides an open and transparent approach to decision-making. Following consultation, the Health and Safety Executive will make a recommendation to the Secretary of State on the best way forward.

2. This consultation applies to proposed domestic legislation to support the EU regulations on:
   • Biocides
   • Classification, Labelling and Packaging of substances and mixtures (CLP)
   • Export and Import of Hazardous Chemicals (commonly known as the PIC Regulation).

3. The proposals that relate to the EU PIC Regulation would apply on a UK-wide basis, and for these PIC proposals this consultative document is provided on behalf of HSE and HSE Northern Ireland (NI). HSE will collate the responses and all those relating to PIC proposals will be considered by both parties.

4. The proposals that relate to the EU Biocides Regulation and the EU CLP Regulation would apply only in Great Britain. HSE NI will conduct a similar but separate consultation for equivalent proposals there.

A.1 HOW TO RESPOND

5. A summary of the proposal and the questionnaire can be found at http://www.hse.gov.uk/consult. You are welcome to comment on any issue raised by this document. You can:

   Complete the online questionnaire; or
   Respond by email – you should send this to: ChemicalsConsultation@hse.gsi.gov.uk

or

   Respond on paper – you can do this either by:
   Printing the online questionnaire; or
   Making a written response in whatever format you wish.

Send your completed response to:

   Deborah Traynor
   Health and Safety Executive
   Redgrave Court
   Bootle
   Merseyside
   L20 7HS
6. We would be grateful if you could include an email address when you provide your response, so that we can inform you of when the HSE intends to publish information concerning consultation responses on the HSE website.

7. Responses must be received by 31 January 2013.

8. If you require a more accessible format of this document please send details to creative@hse.gsi.gov.uk and your request will be considered.

A.2 WHAT HAPPENS NEXT?

9. We will acknowledge all responses and give full consideration to the substance of arguments on the proposals; we may contact you again if, for example we have a query concerning your response.

10. We will tell you when the HSE will publish information concerning the consultation responses. We will provide a summary of those who responded to this consultation and we will produce a summary of the views expressed on each question; this information will be placed on the HSE’s website.

A.3 CONSULTATION PRINCIPLES

11. HSE is committed to best practice in consultation and to the Government’s Consultation Principles. The Government is improving the way it consults by adopting a more proportionate and targeted approach, so that the type and scale of engagement is proportional to the potential impacts of the proposal. The emphasis is on understanding the effects of a proposal and focussing on real engagement with key groups rather than following a set process. The key Consultation Principles are:

- Departments will follow a range of timescales rather than defaulting to a 12-week period, particularly where extensive engagement has occurred before;
- Departments will need to give more thought to how they engage with and consult with those who are affected;
- Consultation should be ‘digital by default’, but other forms should be used where these are needed to reach the groups affected by a policy; and
- The principles of the Compact between government and the voluntary and community sector will continue to be respected.

A.4 HOW YOUR RESPONSES WILL BE HANDLED

12. We will acknowledge all responses and give full consideration to the substance of arguments in the development of proposals. The Health and Safety Executive will then decide on how best to take the regulations forward based on an interpretation and analysis of the consultation responses.
A.5 QUERIES AND COMPLAINTS

13. If you have any comments or complaints about the way this consultation has been conducted, please contact the HSE Consultation Coordinator by writing to:

Teresa Farnan  
Health and Safety Executive  
th  
7th Floor Caxton House  
6-12 Tothill Street  
London SW1H 9NA  

Or send an email to teresa.farnan@hse.gsi.gov.uk.

14. We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with HSE’s Chief Executive, Geoffrey Podger, at Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. You can also write and ask your MP to take up your case with us or with Ministers. Your MP may also ask the independent Parliamentary Commissioner for Administration (the Ombudsman) to review your complaint.
B  PURPOSE OF THIS CONSULTATION

15. The Health and Safety Executive (HSE) and for PIC, HSE Northern Ireland, are consulting on a proposed new Statutory Instrument (SI) to put in place domestic administrative arrangements on enforcement and the appointment of Competent Authorities (CAs)/Designated National Authorities (DNAs) to support the three directly applicable EU Regulations listed below:

   a) Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (to replace the Biocidal Products Directive 98/8/EC)
   b) Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals, commonly known as the PIC (Prior Informed Consent) Regulation (a recast of Regulation (EC) 689/2008); and
   c) Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

16. HSE also proposes to put in place new regulations to enable HSE to charge for the work it carries out under the new Biocides Regulation; however this will be covered in a separate consultation on the proposed fee regime, including the fee structure and fee levels. We also seek your views on the possibility of charging under CLP, and are further consulting on unrelated administrative amendments to other domestic chemicals regulations.

17. No changes are proposed to the main duties for Biocides, PIC and CLP, which are, or will be, established at EU level in directly applicable Regulations.

18. Further detail about the background and proposal is given below. You do not need to read this to respond, and may prefer to focus on the specific regulatory area that most affects you.

C  BACKGROUND

19. Significant changes have occurred or will shortly occur in the regulation of chemicals at EU level. These changes centralise legal requirements by introducing directly acting EU Regulations in place of Directives that have to be transposed by Member States. They also give specific roles to the European Chemicals Agency (ECHA) based in Helsinki, Finland (see paragraph 48).

20. Recent developments in the chemical legislation on which HSE has the UK Government policy lead include:

   a) Negotiations have recently concluded on a new directly acting EU Biocides Regulation, which will replace the existing Directive 98/8/EC when it takes effect in Member States on 1 September 2013. The existing national legislation that transposes 98/8/EC will become obsolete on the same date and will be revoked by the proposed statutory instrument.
   b) Negotiations have also recently concluded on a recast of the existing directly applicable EU PIC Regulation (EC) No 689/2008,
leading to a new Regulation which will replace EC 689/2008. The new Regulation will apply from 1 March 2014.

c) The directly applicable EU Regulation on Classification, labelling and packaging of substances and mixtures (CLP, EC 1272/2008) came into force in 2009 and continues to be adapted to reflect the Globally Harmonised System (GHS). Three adaptations have already been agreed and two more are presently in preparation.

21. Although these EU Regulations are directly applicable, some changes in domestic legislation are needed. All three EU Regulations require the UK to formally appoint competent authorities (in the case of PIC called Designated National Authorities) to undertake specified tasks. All three also require the UK to establish arrangements for the enforcement of these Regulations. These obligations are placed on EU Member State governments and no additional duties are expected to be placed on industry as a consequence of this proposal. It is anticipated that, subject to a proportionate validation stage impact assessment (IA) being undertaken post-consultation for this proposed consolidation, this proposal will be largely cost neutral, with any cost for business likely to be limited to minimal familiarisation and administration costs.

22. As the necessary legal and administrative arrangements to appoint competent authorities and to provide for enforcement are similar (though not identical) in all three cases, HSE is seeking views on whether it is appropriate to bring them together in one new statutory instrument.

23. The proposed new domestic arrangements for biocides would revoke all existing national legislation for biocides made under HSWA and so would consolidate existing biocides legislation as recommended in Professor Löfstedt’s independent review of health and safety legislation ‘Reclaiming health and safety for all’ which was published in November 2011 (http://www.dwp.gov.uk/docs/lofstedt-report.pdf).

24. We are also consulting on the principle of introducing charging for taking forward harmonised classifications under CLP.

D OVERVIEW OF PROPOSED LEGISLATIVE CHANGES

25. A draft of the proposed legislation (Statutory Instrument (SI)) is at Annex A. As a consequence of changes in EU Biocides and PIC regulations, HSE has identified six existing national Regulations that would be revoked. A further national Regulation (Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (SI 2009/716; CHIP 4) which implements the European classification scheme for hazardous substances and preparations prior to the EU CLP Regulation coming into full force on 1 June 2015 was also identified for revocation within this proposal. It is proposed that these statutory instruments are revoked with effect from the dates specified within the proposed consolidated SI, which align with the timescales in the corresponding EU Regulations.

26. The legislation proposed for revocation is:

- Biocidal Products Regulations 2001 (SI 2001 No. 880)
• Biocidal Products (Amendment) Regulations 2003 (SI 2003 No. 429)
• Biocidal Products (Amendment) Regulations 2005 (SI 2005 No. 2451)
• Biocidal Products (Amendment) Regulations 2007 (SI 2007 No. 293)
• Biocidal Products (Amendment) Regulations 2010 (SI 2010 No. 745)
• The Export and Import of Dangerous Chemicals Regulations 2008 (SI 2008 No. 2108)
• Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (SI 2009 No. 716; CHIP 4) from 1 June 2015

27. The net effect of such consolidation would be to revoke seven existing SIs and replace them with one new SI.

28. A number of minor amendments to CHIP 4 would also be made, as set out in section E.3.6 of this consultation.

29. The new SI would not include the details of national fees chargeable under the EU Biocides Regulation – HSE is considering introducing these separately through future Health and Safety (Fees) Regulations.

30. Should a significant issue arise during or after consultation that prevents the establishment of the proposed consolidated SI then the detailed provisions set out in this Consultative Document to establish competent authorities and to provide for enforcement will be taken forward in separate SIs for Biocides, PIC and CLP, taking into account the comments received.

E THE PROPOSALS IN DETAIL

E.1 Biocidal Products

E.1.1 Legislative changes

31. Placing on the market and use of biocidal products is currently regulated at EU level through Directive 98/8/EC (the ‘Biocidal Products Directive’ or BPD). The Directive aims to harmonise the EU market in biocides and provide a high level of protection for human and animal health and the environment by introducing an EU-wide authorisation regime for biocidal products. The authorisation procedure it introduces has two steps: first, active substances are assessed at EU level for inclusion in a positive EU list. Once substances are included in this list, companies can apply to individual Member States for authorisation to place products containing these substances on the market in their territory. Inclusions for active substances and authorisations of products are in both cases granted only after an assessment of risks and efficacy based on a substantial data package provided by the applicant.

32. The BPD is implemented in Great Britain through the Biocidal Products Regulations 2001 (BPR 2001) and in Northern Ireland through the Biocidal Products Regulations (Northern Ireland) 2001 (BPRNI). Since these SIs entered into force, each has been amended four times.
33. A summary of each piece of legislation, including each amending SI, is given in Table I.

34. The BPD will be repealed on 1 September 2013 and replaced by a new directly applicable EU Regulation on placing on the market and use of biocidal products. The new Regulation retains the basic structure of the BPD – a two step procedure for approving active substances at EU level and authorising biocidal products in Member States. However it aims to improve and update the system by introducing changes in a number of areas. The main changes include:

- an extension in scope to cover articles treated with biocides
- new provisions on data sharing and data waiving
- a new centralised EU authorisation scheme for a range of biocidal products
- provisions to harmonise the fee structure (but not the levels of fees) across Member States.

35. Because the BPD will effectively be replaced by the new EU Regulation, we intend to revoke the GB legislation that implements the BPD on the same date. Northern Ireland will revoke their equivalent legislation on the same date. The GB legislation to be revoked includes BPR 2001 and its subsequent amendments (see Table I).

36. However new legislation will be required at the same time to support the new EU Regulation, specifically, to enable the EU Regulation to be enforced in the UK, to appoint a UK competent authority, and to set maximum penalties for non-compliance. Transitional arrangements are also required to enable parts of legacy systems (BPD and the Control of Pesticides Regulations 1986) to remain in place until affected products are brought under the new EU Regulation. We propose that these new provisions should be introduced through the new consolidated SI, to enter into force on 1 September 2013. Details of each of these provisions is given below.
Table I – list of current domestic biocides legislation to be consolidated/revoked

<table>
<thead>
<tr>
<th>Legislation</th>
<th>SI number</th>
<th>Web link</th>
<th>Brief description of contents</th>
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<tr>
<td>Biocidal Products Regulations 2001 (BPR)</td>
<td>SI 2001 No. 880</td>
<td>(<a href="http://www.legislation.gov.uk/uksi/2001/880/contents/made">http://www.legislation.gov.uk/uksi/2001/880/contents/made</a> )</td>
<td>Implement the BPD in Great Britain, and set out measures which allow fees to be charged by Competent Authorities for operating the regime in Great Britain – a role delegated by Ministers to HSE – and for the provisions of BPR to be enforced.</td>
</tr>
<tr>
<td>Biocidal Products (Amendment) Regulations 2003</td>
<td>SI 2003 No. 429</td>
<td>(<a href="http://www.legislation.gov.uk/uksi/2003/429/contents/made">http://www.legislation.gov.uk/uksi/2003/429/contents/made</a> )</td>
<td>The regulations amend the BPR to allow HSE to set a ‘General Industry Charge’. The General Industry Charge is a flat fee charged by HSE to companies placing biocidal products on the market or participating in the EU review programme of active substances that was set up under Directive 98/8/EC, to recover costs incurred by HSE that are not fairly attributable to specific applicants or companies, such as monitoring of biocides and providing information to applicants and companies with duties under the Regulations.</td>
</tr>
<tr>
<td>Biocidal Products (Amendment) Regulations 2005</td>
<td>SI 2005 No. 2451</td>
<td>(<a href="http://www.legislation.gov.uk/uksi/2005/2451/contents/made">http://www.legislation.gov.uk/uksi/2005/2451/contents/made</a> )</td>
<td>The regulations make a minor correction to the General Industry Charge provisions, to ensure that HSE can recover as far as possible from all UK suppliers of biocidal products the full costs of the work it undertakes under the Biocidal Products Regulations 2001.</td>
</tr>
<tr>
<td>Legislation</td>
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E.1.2 Enforcement and penalties

37. Under the new EU Regulation we propose to maintain similar enforcement arrangements to those in place under the Biocidal Products Regulations 2001. Under these arrangements, the EU Regulation will be enforced by applying the relevant provisions from the Health and Safety at Work etc. Act 1974. Specifically, this means that enforcement responsibility will continue to be divided between HSE and Local Authorities, whereby HSE enforces non-retail sale of biocides and use of biocides in workplaces, and Local Authorities enforce retail sale, labelling and packaging of biocides, and use of biocides in cases that do not involve work (other than by domestic servants in a private household).

38. Inspectors’ powers and enforcement tools will be the same as those allocated under other health and safety legislation, including powers of entry and the power to issue Improvement and Prohibition notices to dutyholders who do not comply with the law. We propose a similar limitation to that currently included in BPR 2001 on powers of entry to domestic premises, meaning that an inspector will only be able to access such premises if he or she has obtained a warrant from a magistrate permitting this (though he or she may enter without a warrant with the occupier’s permission). A minor amendment to the existing power in BPR will be made so that a warrant is required for any entry into domestic premises (not just in relation to an activity not involving work). This is to align with the policy principles in the current Home Office review of powers of entry. For more detail see http://www.homeoffice.gov.uk/crime/powers-entry/.

39. Maximum penalties available for breaches of the new EU Biocides Regulation will be those permitted under the European Communities Act 1972. They are imprisonment for a term not exceeding three months or a fine of up to £5,000 on conviction of a summary offence and up to two years’ imprisonment on conviction on indictment. A penalty of an unlimited fine might additionally or alternatively apply to a conviction on indictment.

E.1.3 Appointment of competent authorities

40. Currently “the Ministers” are appointed as competent authorities for biocides in BPR 2001, where “the Ministers” refers to the Secretary of State in England and Wales, and in relation to Scotland, the Secretary of State and the Scottish Ministers acting jointly. BPRNI appoints the Health and Safety Executive for Northern Ireland (HSENI) as competent authority in Northern Ireland. The responsibility for acting as competent authority is delegated to HSE by the Ministers and by HSENI through Agency Agreements, and in practice HSE acts as biocides competent authority for the whole of the UK. We propose to put in place similar arrangements for the new EU Regulation, so that HSE will continue to act as biocides competent authority for the whole of the UK.
E.1.4 Transitional arrangements

41. Although BPR 2001 will be revoked on 1st September 2013, certain parts of the existing legislation will need to be retained to ensure that products still authorised under previous legislation (BPR 2001 and the Control of Pesticides Regulations 1986 (COPR)) can continue to be regulated according to existing provisions until authorised under the new Regulation. Suitable transitional arrangements are largely set out in the EU Regulation itself, but additional domestic provisions are required to support these.

42. The required arrangements are somewhat complex, but include:

(a) Provisions to allow biocidal products to remain on the market, and to continue to be regulated under existing provisions, where the active substances in those products are still being assessed under the EU review programme of existing active substances, until two years after the approval of the last active substance in the product (or other timescales depending on the situation). We propose to temporarily retain relevant parts of BPR 2001 and COPR so that they continue to apply in such cases until the review programme is complete.

(b) Removal of the existing provisions for ‘certificates of exemption’, issued by the UK Competent Authority (CA) allowing the product to remain on the market until the authorisation process for the product under BPR 2001 is completed. Instead we propose to continue to apply the relevant provisions of COPR until the product is authorised under the new EU Regulation. This should provide better clarity for applicants on how their products are regulated.

(c) Provisions to temporarily retain those parts of the BPR 2001 that set out the provisions under which product applications under BPR 2001 are authorised, so products can continue to be assessed under the provisions of the existing Directive 98/8/EC where the EU Regulation so requires.

(d) Provision to allow biocidal products that have already been authorised or registered under BPD to continue to be marketed and used subject to the conditions of the authorisation/registration until it expires or is cancelled, in line with the EU Regulation. Therefore, we intend to retain parts of BPR 2001 that detail the conditions that apply to companies using and marketing such products.

43. In all these situations, the current provisions in BPR 2001 enabling fees to be charged by the competent authority will need to be retained to ensure that HSE can continue to recover its costs in operating the existing regime during the transitional period.
E.2  The Export and Import of Hazardous Chemicals Regulation (PIC)

The following proposals for PIC apply to the whole of the UK. Comments are therefore invited from respondents in both Great Britain and Northern Ireland

E.2.1 Legislative changes


45. This SI provides for the appointment of Designated National Authorities (DNAs) and for enforcement of the PIC Regulation for the whole of the UK (unlike Biocides and CLP, where separate arrangements currently apply for Northern Ireland).

46. In 2014, the PIC Regulation will be replaced by a new version. The requirements on those who export and import chemicals will remain substantively the same. The main changes are the transfer of responsibility for implementing certain technical aspects of the Regulation from the European Commission's Joint Research Centre to the European Chemicals Agency, and alignment of classification and labelling with the EU Classification, Labelling and Packaging Regulation (1272/2008).

47. The new PIC Regulation was published in the EU Official Journal in July 2012 and entered into force in August 2012. It will apply from 1 March 2014. As the domestic SI specifically refers to the existing EU PIC Regulation, it will need to be amended or revoked and replaced from the same date as that from which the new PIC Regulation starts to apply. The PIC component of this proposed consolidated SI will therefore take effect from 1 March 2014.

E.2.2 Enforcement and penalties

48. The proposed new consolidated SI maintains the current enforcement arrangements for PIC. Presently the only PIC enforcement option available is prosecution. However, in addition, we are proposing to give inspectors the power to issue an Improvement Notice (under section 21 of the HSWA and Article 23 of the Health and Safety at Work (Northern Ireland) Order 1978) and an Enforcement Notice, (likely to be similar to the Enforcement Notice created under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Enforcement Regulations (SI 2008/2852)) which can be served where an inspector is of the opinion that a person has contravened or is likely to contravene a PIC requirement. For example, an Enforcement Notice could prohibit the export of a PIC listed chemical until the steps set out in the notice have been taken.

49. HSE believes that the low level of enforcement action on PIC to date is in part due to the lack of proportionate enforcement mechanisms. Notices have proved to be an effective and proportionate approach under health and safety legislation and under REACH ((EC) No 1907/2006). Provision of enforcement by way of notices would enhance inspectors’ ability to take enforcement action proportionate to the facts and circumstances in any case, and help to ensure that those who comply are not disadvantaged.

50. A preliminary economic analysis for the proposed changes to PIC enforcement is included at Annex B. In this analysis we have assessed the total costs that would arise and details are provided about how the costs were calculated.
E.2.3 Appointment of Designated National Authorities

51. The arrangements for the appointment of DNAs in the proposed SI are the same as those under the existing SI 2008/2108. These would specifically appoint HSE and HSE NI as the DNAs for the UK. The export of chemicals is not a devolved matter, so this differs from the arrangements for Biocides and CLP.

52. HSE has explored the feasibility of charging for the work it does, as a UK DNA, in processing notifications of exports of hazardous chemicals under the PIC Regulation. Member States’ DNAs are permitted to charge under the PIC Regulation: about six Member States are known to currently do so. After consideration, HSE has decided not to introduce charging for PIC export notifications at this time.

E.3 Classification, Labelling and Packaging (CLP) Regulations

E.3.1 Legislative changes


54. CHIP 4 continues to implement in Great Britain the provisions of the Dangerous Preparations Directives (1999/45/EC as amended and adapted to technical progress) until such time as the requirements of the directly applicable CLP Regulation (1272/2008) are fully applicable. Northern Ireland has its own CHIP regulations (Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 (S.R. 2009 No. 238)) which also apply until the CLP Regulation comes fully into force on 1 June 2015. The CLP Regulation introduced a system for classification and labelling of the hazardous properties of chemicals based on the UN Globally Harmonised System (GHS).

55. Introduction of the proposed consolidated SI therefore provides the opportunity to revoke CHIP 4 in full from 1 June 2015, and include in the consolidated SI the matters in E.3.2, E.3.3, E.3.4 and E.3.6 below.

E.3.2. Enforcement and penalties

56. Under CLP we propose to maintain similar enforcement arrangements to those in place under CHIP 4. As with biocides, CLP will be enforced by applying the relevant provisions from the Health and Safety at Work Act etc. 1974. Specifically, this means that enforcement responsibility will continue to be divided between HSE and Local Authorities whereby HSE enforces non-retail supply, and Local Authorities enforce retail sale, labelling and packaging.

E.3.3 Appointment of competent authorities

57. HSE has long fulfilled the role of competent authority (CA) for Great Britain under CHIP 4 and, with the agreement of other Government Departments and the devolved administrations, fulfils the same role informally under the CLP Regulation. This position has however never been formalised as required under Article 43 of the CLP Regulation.
58. Under the proposed consolidated SI HSE's [and HSE NI's] de facto position as CAs for CLP would be formalised following the same approach as in REACH and Biocides i.e. relevant Ministers (relevant Departments in NI) would be formally given the roles, and their functions would then be delegated to HSE via Agency Agreements.

E.3.4 Transitional arrangements

59. It is proposed that from 1 June 2015 (when the transitional provisions in CLP end and the DPD no longer applies) most of CHIP 4 will be revoked by the proposed SI. However, a minor CHIP 4 provision relating to companies retaining data on preparations (currently CHIP 4, regulation 12) will need to remain in place until 1 June 2018.

60. HSE intend that the SI will include arrangements to accommodate the 2-year period of grace given in Article 61 of the CLP Regulation for re-labelling and re-packaging mixtures already ‘on the shelves’ on 1 June 2015.

E.3.5 Fees and charges

61. HSE is considering whether it would be appropriate in principle to recover costs for taking forward at EU level proposals to establish harmonised substance classifications.

62. In practice these costs arise in two ways. The majority are for active substances in plant protection products and biocides where HSE (on behalf of the UK) has led the evaluation under the reviews of these substances at EU level. An outcome of these reviews is often a proposal for a new or amended entry in Annex VI of the CLP Regulation for the active substance in question. Such proposals result from the evaluation of comprehensive data sets and cover all known hazards. The remainder arise where HSE takes forward proposals for harmonised classification of industrial chemicals when industry has robust data to show that an existing harmonised classification in Annex VI needs to be amended. These proposals normally relate to carcinogenicity, mutagenicity, reproductive toxicity; or respiratory sensitisation, though other hazards can be addressed if justified at EU level.

63. In future it is likely that the processes for approving active substances for plant protection products and biocides, and for agreeing harmonised classification for these substances will become more integrated, leading to efficiency gains. To this end, discussions have already started between the European Food Safety Agency (EFSA), the European Chemicals Agency (ECHA) and others in the context of plant protection products. Under the new EU Biocides Regulation ECHA will have a role in co-ordinating the programme for reviewing active substances used in biocides, as well as in processing harmonised classifications. As those seeking approval of all such active substances already pay fees where HSE undertakes the evaluation, and as in future harmonised classification will become an outcome of the same evaluation, it seems reasonable that HSE should recover the cost of taking forward harmonised classification as well as active substance approval.

64. Harmonised classification is important in establishing a single market in the supply and use of chemicals, and so benefits industry. Industrial chemicals are not, of course, subject to approval, and it is likely that the resource in HSE for taking forward amendments to harmonised classifications of industrial chemicals will continue to be limited. However, if charges are introduced for harmonised
classification of active substances in plant protection products and biocides, in principle, it seems reasonable to consider also charging for industrial chemicals.

65. You are invited to comment on whether in principle HSE should charge for its time in dealing with an application from, for example, a company or trade association to:

   a. Establish a new or amended harmonised classification for an active substance used in plant protection products and biocides, in a case where HSE has led the EU evaluation of these substances under the review programmes; or,

   b. Amend an existing harmonised classification for an industrial chemical, where there is a robust case for doing so and HSE has the resource to progress it.

E.3.6 Other CHIP 4 amendments

66. You are invited to comment on the following minor amendments to CHIP 4, which are driven by legal issues and which do not affect the duties on industry in relation to classification, labelling and packaging.

Advertising

67. The Dangerous Preparations Directive (DPD) (1999/45/EC) requires suppliers who advertise chemicals to alert potential buyers to any hazardous properties. This applies to all suppliers, including those advertising or trading via the internet, distance selling etc.

68. When the CLP Regulation entered into force the relevant Dangerous Substances Directive (DSD) (67/548/EEC) / DPD implementing regulation for advertisement was deleted from CHIP 4. This was incorrect and the deleted provision should be reinstated until 1 June 2015.

Alignment of penalties

69. CHIP 4 is made jointly under HSWA and section 2(2) of the European Communities Act (ECA). Such a joint legal base is necessary to cover consumer safety and environmental hazards which would not otherwise be within scope of the powers available in HSWA.

70. ECA specifies the penalties and sanctions available where a dutyholder is found to have committed an offence under the provisions of that Act. These were historically the same as in HSWA, but the arrival of the Health and Safety (Offences) Act 2008 created a disparity where cases are heard summarily. The penalties available on summary conviction under HSWA are now significantly (four times) higher than those in ECA. In short, the 2008 Act created a disparity in the available penalties for breaches of CHIP 4.

71. HSE believes the disparity is most easily resolved by aligning the penalties available on summary conviction for offences under CHIP 4 with those in ECA (maximum 3 months’ imprisonment or a fine of £5,000), while ensuring that offences are triable either way.

Defence exemption

72. CHIP 4 does not include a specific defence exemption. An older version of CHIP did have this, but it was removed because it was based on a statutory certification scheme that was not strictly foreseen in the Directive.
73. While CHIP has a finite period to run, including a defence exemption (omitting the certification scheme) would ensure legal certainty for MoD in some aspects of its work, and would be consistent with a similar exemption in the ‘7 into 1’ SI which would reflect Article 1.4 of the CLP Regulation.


74. The European Commission has proposed a recast of the DPD. CHIP 4 refers only once to the existing DPD by name and number - in the derogation allowing suppliers to apply to keep certain substance information confidential. To continue to implement this derogation, this reference in CHIP 4 would need to be amended to refer to the new recast directive, should the recast be adopted before 1 June 2015. HSE proposes to insert the new reference if available.

F IMPACT ON BUSINESS

75. It is Government policy to use an Impact Assessment (IA) to assess and understand the impact, both costs and benefits, of all new regulations. An important part of the IA is the cost-benefit analysis which identifies the costs and benefits of a proposal and quantifies, in monetary terms, as many of them as is proportionate.

76. In line with Government guidance, HSE has conducted a preliminary economic analysis of the proposals relating to PIC enforcement. This is attached in Annex B.

77. This analysis indicates that for the PIC enforcement proposals, there would be an estimated familiarisation cost of £1000 in the first year and an ongoing annual cost (administration processes) in the region of £500, spread across approximately 35 UK PIC businesses.

78. HSE will prepare a simplified, proportionate validation stage impact assessment on the proposals before final decisions are made. Therefore consultees are particularly requested to comment on the analysis in Annex B, and to identify other costs or benefits and provide full justification for the costs or benefits they identify. This information will be helpful to HSE in preparing a robust and proportionate IA. Some questions on the potential costs and benefits of this proposal are included in the consultation question set.
G CONSULTATION QUESTIONS

General Questions:

**Question 1** – Do you agree or disagree with the proposal to revoke the seven Statutory Instruments and consolidate the required provisions relating to enforcement and Competent Authorities of Biocides, PIC and CLP into one Statutory Instrument?

Please give reasons for your answer.

**Question 2** – Do you think that the provisions in the proposed legislation to ensure that the various enforcing authorities can act when someone with a duty under the EU Regulations does not carry out that duty are:

(a) More than is necessary
(b) About right
(c) Insufficient

Please give reasons for your answer.

**Question 3** – Do you agree or disagree with the statement made in paragraph 21 of the Background to this proposal ‘...subject to a proportionate validation stage impact assessment being undertaken post-consultation for this proposed consolidation, this proposal would be largely cost neutral, with any cost for business limited to minimal familiarisation and administration costs.’?

If you disagree, then please give your opinion on:

(a) How long will firms spend on familiarisation (reading about the changes)?
(b) What other additional duties do you consider will be placed on industry?

**Question 4** – To the best of your knowledge, are there any other impacts on industry of the proposed consolidation of these Regulations?

If ‘YES’ then:

(a) What other impacts do you consider it will impose?
(b) What costs or benefits do you believe the proposed consolidated SI would bring?

PIC specific questions:

**Question 5** – For the purposes of enforcement, should inspectors additionally be able to issue ‘notices’ for infringements of the EU PIC Regulation, thereby enabling them to take enforcement action proportionate to the facts and circumstances in any case (see paragraphs 48 to 50)?

Please provide your reasons for your answer.

**Question 6** – In the PIC Enforcement economic analysis on the provision of additional enforcement powers, it was necessary to make assumptions about timing.

Do you agree with our estimate of the additional time needed to advise HSE that the requirements in a ‘notice’ have been met? (We have estimated 30 minutes – but
note that this does not include the time taken to comply with PIC requirements specified in the notice, which would need to be taken in any case).

If ‘NO’ please provide an alternative estimate and explain your reasons.

**Question 7** – Will the introduction of notices lead to any additional costs or savings for you, e.g. around transport and storage? If ‘YES’, please explain.

**Question 8** – Are there any positive or negative impacts as a result of the proposals for PIC that we have not identified? Please provide reasons for your answer.

**CLP specific questions:**

**Question 9** – The ‘7 into 1’ proposals do not include any proposal for HSE to introduce a charge for its time and expertise in considering and taking forward proposals for harmonised classification, in line with similar regulatory regimes and current government policy on cost recovery. Do you think that at some stage in the future it would be appropriate for HSE to introduce a charge for:

(a) Active substances used in plant protection products and biocides where HSE has led the EU evaluation of these substances under the review programmes (see paragraphs 61 - 65);

(b) Industrial chemicals where there is a robust case for amending an existing harmonised classification and HSE has the resource to progress it (see paragraphs 61 - 65)?

Please provide your reasons for your answer.

**Question 10** – Do you have any comments on the amendments proposed to address certain legal issues in CHIP 4 concerning:

(a) Advertising (see paragraphs 67 - 68)?

(b) Alignment of penalties (see paragraphs 69 - 71)?

(c) Defence exemption (see paragraphs 72 - 73)?

(d) Recast of the Dangerous Preparations Directive (see paragraph 74)?

**Question 11** – Are there any further comments you would like to make on the issues raised in this consultation document?

**Question 12** – Is there anything you particularly liked or disliked about this consultation?
2013 No.

HEALTH AND SAFETY

The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013

Made ***

Laid before Parliament ***

Coming into force in accordance with regulation 1

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 ("the 1972 Act") in relation to—

(a) biocides2;

(b) the regulation and control of classification, packaging and labelling of hazardous substances and mixtures3;,

(c) measures relating to consumer protection4;

(d) the control of the import and export of goods5; and

(e) the notification and control of substances6.

The Secretary of State makes these Regulations—

(a) in exercise of the powers conferred on him by section 2(2) of and paragraph 1A of Schedule 2 to the 1972 Act; and sections 15(1), (2), (3)(c), (5)(b), (6), (8) and (9) and 82(3)(a) of, and paragraphs 1(1)(b) and (c) and (4), 2(1),4(1), 6, 13(1) and 15(1) of Schedule 3 to the Health and Safety at Work etc. Act 1974(c), ("the 1974 Act"), and

(b) for the purposes of giving effect without modifications to proposals submitted to him by the Health and Safety Executive under section 11(3) of the 1974 Act.

Before submitting proposals for these Regulations to the Secretary of State, the Health and Safety Executive has consulted the bodies that appeared to it to be appropriate, as required by section 50(3) of the 1974 Act.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for references in these Regulations to—

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1 1972 c.68. The power of Ministers to make regulations in relation to matters in or as regards Scotland is preserved by section 57(1) of the Scotland Act 1998(c.46).
2 S.I. 1999/2788
3 S.I. 1976/897.
4 S.I. 1993/2661.
5 S.I. 1983/1706.
6 S.I. 1981/1536.
(a) Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products to be construed as including references to Annexes I to VII of that Regulation as those Annexes are amended from time to time;


(c) Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals to be construed as including references to Annexes I, II, V and VI of that Regulation as those Annexes are amended from time to time.

PART 1
INTRODUCTION

Citation, commencement and extent

1. These Regulations may be cited as the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.

2.—(1) Except as provided by paragraphs 2 to 6 these Regulations come into force on 1st September 2013.

(2) Chapter 3 of Part 3 and regulation 36(b) comes into force on 1 June 2015.

(3) Regulation 36(c) comes into force on 1 June 2018.

(4) In so far as they apply to Chapter 3 of Part 3 of these Regulations and the CLP Regulation, regulations 4, 8, 9, 10 and 11 come into force on [1 June 2015].

(5) Regulation 34(f) and Chapter 4 of Part 3 of these Regulations come into force on 1 March 2014.

(6) In so far as they apply to Chapter 4 of Part 3 of these Regulations and the PIC Regulation, regulations 4, 7, 8, 9, 10 and 11 come into force on 1 March 2014.

3.—(1) These Regulations shall not extend to Northern Ireland except as provided by paragraphs (2) and (3).

(2) In so far as Regulations 4, 7, 8, 9, 10 and 11 apply to Chapter 4 of Part 3 of these Regulations or the PIC Regulation they shall extend to Northern Ireland.

(3) Regulations 1, 2(1), (5) and (6), [36(f)] and Chapter 4 of Part 3 of these Regulations shall extend to Northern Ireland.

(4) Except for the regulations listed in paragraph 5, these Regulations apply outside Great Britain as sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc Act 1974 (Application Outside Great Britain) Order 2013(7).

(5) The Regulations referred to in paragraph (4) are—

(a) regulation 7;

(b) Chapter 4 of Part 3; and

(c) regulations 4, 8, 9, 10 and 11 in so far as they apply to Chapter 4 of Part 3 and the PIC Regulation.

Interpretation

4.—(1) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc Act 19748;

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 19789;

(7) to be completed once 2013 Order is made

8 1974 c. 37
“the Great Britain Executive” means the Health and Safety Executive established under section 10 of the 1974 Act;
“the 1998 Regulations” means the Health and Safety (Enforcing Authority) Regulations 1998;
“the 2009 Regulations” means the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009;
“the Biocides Regulation” means Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products;
“competent authority” means the authority appointed in a member State for the purpose of carrying out the duties of a competent authority under the Biocides Regulation and the CLP Regulation;
“COPR 1986” means the Control of Pesticides Regulations 1986
“COPR biocidal product” means any substance, mixture or organism prepared or used for any of the purposes listed in regulation 3(1) of COPR 1986 which is not a plant protection product;
“devolved administration” means the Scottish Ministers, the Welsh Ministers or the Northern Ireland Assembly;
“the Northern Ireland Executive” means the Health and Safety Executive for Northern Ireland established under Article 12 of the 1978 Order;

(2) Where an expression is defined in the Biocides Regulation, the CLP Regulation or the PIC Regulation and is not defined in these Regulations, is has the same meaning as in the Biocides Regulation in relation to biocidal products, the CLP Regulation in relation to Classification, labelling and packaging of substances and mixtures and the PIC regulation in relation to the export and import of hazardous chemicals.

PART 2

APPOINTMENT OF COMPETENT AUTHORITIES AND DESIGNATED NATIONAL AUTHORITIES

5. For the purposes of Article 81(1) of the Biocides Regulation, the designated competent authority is—
   (a) in relation to England and Wales, the Secretary of State; and
   (b) in relation to Scotland, the Scottish Ministers and the Secretary of State acting jointly.

6. —(1) Subject to paragraph (2), for the purposes of Article 43 of the CLP Regulation the competent authority is—
   (a) in England, the Secretary of State;
   (b) in Scotland, the Scottish Ministers;
   (c) in Wales, the Welsh Ministers.

9 S.I. 1978/1039 (N.I. 9)
11 S.I. 2009/716
(2) In relation to matters outside the competence of a devolved administration, the competent authority is the Secretary of State.

7. The Great Britain Executive and the Northern Ireland Executive are the designated national authorities—
(a) to act for the performance of the administrative functions required by the PIC Regulation, in accordance with Article 4 of that Regulation; and
(b) to have the responsibility for controlling the import and export of chemicals listed in Annex I of the PIC Regulation, in accordance with Article 18 of that Regulation.

PART 3
ENFORCEMENT AND APPEALS
CHAPTER 1
EXEMPTIONS, PENALTIES, DUE DILIGENCE DEFENCE, FAILURE TO DISCHARGE A DUTY

Exemptions

8. (1) A person is exempt from compliance with a provision within the Biocides Regulation, CLP Regulation or PIC Regulation in specific cases, if that person has the benefit of a defence exemption made by the Secretary of State or delegated person in respect of that provision

(2) These Regulations shall not apply to a substance or preparation which is a sample taken by an authority responsible for the enforcement of any requirement imposed by or under any enactment.

Penalties

9. The maximum penalty for an offence under these Regulations is—
(a) on summary conviction, imprisonment for a term not exceeding three months or a fine not exceeding level 5 on the standard scale(12); and
(b) on conviction on indictment, imprisonment for a term not exceeding two years, or a fine or both.

Due diligence defence

10. (1) In any proceedings for an offence under these Regulations, [other than in relation to regulation 25] it is a defence for the person charged to prove that they took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(2) A person is to be taken to have established the defence provided by paragraph (1) if they prove—
(a) that they acted under instructions given to them by their employer; or
(b) that they acted in reliance on information supplied by another person without any reason to suppose that the information was false or misleading,

and in either case that they took all such steps as were reasonably open to them to ensure that no offence would be committed.

(3) If, in any case, the defence provided by subsection (1) involved an allegation that the commission of the offence was due to—

(a) an act or omission by another person, other than the giving of instructions to the person charged with the offence by their employer; or

(b) reliance on information supplied by another person,

the person charged shall not, without leave of the court, be entitled to rely on that defence unless within a period ending seven clear days before the hearing, they have served on the prosecutor a notice giving such information identifying or assisting in the identification of that other person as was in their possession.

**Failure to discharge a duty**

11.—(1) A failure to discharge a duty placed by these Regulations on the Great Britain Executive or the Northern Ireland Executive is not an offence under section 33(1)(c) of the 1974 Act or under Article 31(1)(c) of the 1978 Order.

(2) A failure to discharge a duty placed by these Regulations, the Biocides Regulation or the CLP Regulation on the Member State or Competent Authority is not an offence under section 33(1)(c) of the 1974 Act.

(3) A failure to discharge a duty placed by these Regulations or by the PIC Regulation on a designated national authority is not an offence under section 33(1)(c) of the 1974 Act or under Article 31(1) of the 1978 order.

**CHAPTER 2**

**BIOCIDAL PRODUCTS**

**Application of the 1974 Act**

12. (1) The following provisions of the 1974 Act apply to this Chapter and to the Biocides Regulation, subject to the following provisions of this Chapter and to the extent that they would not otherwise do so, as if they were health and safety regulations for the purposes of that Act-

(a) sections 18 to 27 and sections 28(7) to (10) (in relation to enforcement);

(b) subject to regulation 9 and paragraphs (2) and (3), sections 33 to 42 (in relation to offences)

(2) A breach of any duties referred to in paragraph (3) shall not constitute an offence under the 1974 Act.

(3) The duties referred to in sub-paragraph (1) are those contained in Articles 6(1), 7(1) and (3) to (5), 8(1) and (2), 13(1), (2), (3), 14(1) and (2), 17(2) and (4), 19(1) and (3), 20(2), 22(1) to (3), 25(1) to (4), 28(1) to (5), 29(1) and (2), 30(1) to (7), 31(1) and (2), 32(1), (2) and (4), 33(1) to (5) and (7), 34(1) and (3), 35(1) and (4), 36(2) and (3), 38(1) and (2), 42(1) and (3) to (5), 43(1), 44(1) to (3), 45(1) and (2), 46(3), 49(2), 52(1), (2), (4) and (9), 53(1) and (2), 58(2), 61(2), 63(2), 64(1) to (3), 70(3), 80(1) to (3), 86, 87, 88(3), 90(2), 92(1), 93(1) and 94(1) of the Biocides Regulation

(4) Any function of the Health and Safety Executive under any provision of the 1974 Act under or in respect of health and safety regulations (including their enforcement) shall be exercisable as if this Chapter and the Biocides Regulation were, to the extent that they would not otherwise be so, health and safety regulations for the purposes of that Act.

(5) The sections of the 1974 Act apply to this Chapter and the Biocides Regulation as if any reference to—

(a) danger, or danger to health and safety, were a reference to danger to the health or safety of humans or animals or to danger to the environment; and

(b) harm were a reference to harm to humans, animals or the environment.
(6) Sections 22 and 25 of the 1974 Act apply to this Chapter and the Biocides Regulation as if the reference to serious personal injury in those sections were a reference to—
(a) serious personal injury to humans;
(b) a breach of the Regulations and serious injury to animals; or
(c) a breach of the Regulations and serious harm to the environment.

**Allocation of enforcement responsibility**

13. (1) Notwithstanding the 1998 Regulations, and subject to paragraphs 2 to 5, the enforcing authority for this Chapter and the Biocides Regulation is the Health and Safety Executive.

(2) Where a biocidal product or treated article within the meaning of the Biocides Regulation is placed on the market or made available on the market within the meaning of the Biocides Regulation in or from any shop, mobile vehicle, market stall or other retail outlet; or otherwise to members of the public, including by way of free sample, prize or mail order, the enforcing authority for the Articles listed in paragraph (3) is the local weights and measures authority.

(3) The Articles referred to in paragraph (2) are—
(a) Article 17(1), in so far as it relates to making Biocidal products available on the market;
(b) Article 58(2) to (6);
(c) Article 69(1) and (2); and
(d) Article 95(3).

(3) The enforcing authority for Article 71 of the Biocides Regulation is the local weights and measures authority.

(4) The 1998 Regulations apply to the enforcement of Articles 56(1) and (2) of the Biocides Regulation.

(5) The enforcing authority for Article 17(1) (in so far as it relates to use of Biocidal products) and (5) of the Biocides Regulation—
(a) in respect of any use not related to an activity involving work; or
[b] in respect of any use by a domestic servant in a private household,]

is the local authority for the area in which the use occurs.

**Limitation on entry to domestic premises in certain circumstances**

14.—(1) An inspector may not enter domestic premises in the exercise of his powers under the 1974 Act, as applied to this Chapter by virtue of regulation 12, unless a justice has issued a warrant authorising him to enter and exercise his powers in those domestic premises.

(2) A justice may not issue such a warrant, unless on an application made by the inspector, he is satisfied—
(a) that the inspector has reasonable grounds for believing that there is present in the domestic premises anything to which those powers relate; and
(b) that—
(i) it is not practicable to communicate with any person entitled to grant entry to the domestic premises,
(ii) a person entitled to grant entry to the domestic premises has unreasonably refused an inspector entry,
(iii) entry to the domestic premises is unlikely to be granted unless a warrant is produced, or
(iv) the purpose of entry may be frustrated or seriously prejudiced unless an inspector arriving at the domestic premises can secure immediate entry to them.

Appeal

15. [Appeal provisions to be inserted similar to those in the Biocidal Products Regulations 2001]

Transitional and savings provisions

16.—(1) The Control of Pesticides Regulations 1986 are saved for the purposes of regulating COPR biocidal products.

(2) COPR applies to COPR biocidal products for which no Certificate of Exemption has been issued under the 2001 Regulations until the decision to authorise or not to authorise the COPR biocidal product under the Biocides Regulation is made.

(3) If the biocidal product is authorised under the Biocides Regulation, the Biocides Regulation applies.

(4) If the biocidal product is not authorised under the Biocides Regulation—

(a) the product may continue to be made available on the market for a period of 180 days from the date of the decision not to authorise the product; and

(b) the product may continue to be stored or used for a period of 365 days from the date of the decision not to authorise the product.

(5) COPR continues to apply to the product during the periods described in paragraph (4).

17.—(1) Regulations 8(2)-(4) and (6), 29, 33, 39A and 40 and Schedules 12 and 13 of the Biocidal Products Regulations 2001 are saved for the purposes of regulating biocidal products for which Certificates of Exemption issued under the 2001 Regulations are extant.

(2) The regulations in paragraph (1) apply to biocidal products for which a Certificate of Exemption under the 2001 Regulations has been issued until the decision to authorise or not to authorise the biocidal product under the Biocides Regulation is made.

(3) If the biocidal product is authorised under the Biocides Regulation, the Biocides Regulation applies.

(4) If the biocidal product is not authorised under the Biocides Regulation—

(a) the product may continue to be made available on the market for a period of 180 days from the date of the decision not to authorise the product; and

(b) the product may continue to be stored or used for a period of 365 days from the date of the decision not to authorise the product.

(5) COPR continues to apply to the product during the periods described in paragraph (4).

18.—(1) The Biocidal Products Regulations 2001 are saved for the purposes of evaluating applications for biocidal product authorisations which were submitted pursuant to Directive 98/8/EC and were not complete on 1st September 2013.

(2) Regulation 8 of the Biocidal Products Regulations 2001 is saved for the purposes of regulating the biocidal products that remain on the market [pursuant to Article 92].

19.—(1) COPR applies to COPR biocidal products which were available on the market on 1st September 2013 but which were not within scope of the Biocidal Products Regulations 2001 until 1st September 2017.

(2) COPR applies to the COPR biocidal products referred to in paragraph (1) for which an application for authorisation under the Biocides Regulation is made on or before 1st September 2017 until the date of the decision granting the authorisation.

(3) Where—

(a) the decision referred to in paragraph (2) is to authorise the biocidal product, COPR ceases to apply and the Biocides Regulation applies to the biocidal product;

(b) the decision referred to in subparagraph (2) is not to authorise the biocidal product, COPR continues to apply to the biocidal product—
(i) in relation to making available on the market for 180 days after the date of the decision; and
(ii) in relation to storage and use of the biocidal product until 365 days after the date of the decision;
(c) no application for authorisation of the biocidal product has been made by 1st September 2017
COPR continues to apply to the biocidal product—
(i) in relation to the making available on the market until 28th February 2018; and
(ii) in relation to the storage and use of the biocidal products until 1st September 2018.

CHAPTER 3
CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES
AND MIXTURES

Application of the 1974 Act

20.(1) The following provisions of the 1974 Act apply to this Chapter and to the CLP Regulation, to the
extent that they would not otherwise do so, as if they were health and safety regulations for the purpose of
that Act—
(a) sections 18 to 28 (in relation to enforcement)
(b) subject to regulation 9 sections 33 to 42 (in relation to offences)
(2) Any function of the Health and Safety Executive under any other provision of the 1974 Act under or
in respect of health and safety regulations (including their enforcement) shall be exercisable as if this
Chapter and the CLP Regulation, were, to the extent that they would not otherwise be so, health and
safety regulations for the purposes of that Act.

Allocation of enforcement responsibility

21.(1) Notwithstanding the 1998 Regulations and subject to sub-paragraphs 2 to 6, the enforcing authority
for this Chapter and the CLP Regulation is the Health and Safety Executive.
(2) Where a substance, mixture or article falling within the meaning of the CLP Regulation is placed on the
market within the meaning of the CLP Regulation in or from any shop, mobile vehicle, market stall or
other retail outlet; or otherwise to members of the public, including by way of free sample, prize or by mail
order, the enforcing authority for Articles [ ] is the local weights and measures authority.
(3) For Articles 35(2) and 48 of the CLP Regulation the enforcing authority is the weights and measure
authority.
(4) The 1998 Regulations apply to the enforcement of Articles [ ].
(5) Subject to paragraph 6 where a substance or mixture is supplied, or a substance, mixture or article
falling within the meaning of [ ], and the provisions of the CLP Regulation, is placed on the market within
the meaning of the CLP Regulation in or from premises which are registered under section 75 of the
Medicines Act 1968, the enforcing authority shall be the Royal Pharmaceutical Society.
(6) In every case where, by virtue of these Regulations and the CLP Regulation, these Regulations and the
CLP Regulation are enforced by the Royal Pharmaceutical Society or the local weights and measures
authority, they shall be enforced as if they were safety regulations made under section 11 of the Consumer
Protection Act 1987 and the provisions of section 12 of the Act shall apply to these Regulations and the
CLP Regulations as if they were health and safety regulations for the purposes of that Act and as if the
maximum period of imprisonment on summary conviction specified in subsection (5) thereof were 3
months instead of 6 months.
CHAPTER 4
EXPORT AND IMPORT OF HAZARDOUS CHEMICALS

Application of the 1974 Act and the 1978 Order to this Part of these Regulations and PIC Regulation

22. (1) The provisions of the 1974 Act specified in paragraph (2) shall apply for the purposes of the enforcement and provision of offences in Great Britain of this chapter and the PIC Regulation as if they were health and safety regulations for the purposes of that Act, and any function of the Health and Safety Executive under any other provision of the 1974 Act under or in respect of health and safety regulations (including their enforcement) shall be exercisable as if this chapter and the PIC Regulation were, to the extent that they would not otherwise be so, health and safety regulations for the purposes of that Act.

(2) The provisions referred to in paragraph (1) are-

(a) Sections 19 and 20 (appointment and powers of inspectors)
(b) Sections 21, 23 and 24 (improvement notices)
(c) Section 25A to 28 (Customs powers to detain imports, power to obtain information, information provided by Customs, and restrictions on disclosure of information); and
(d) Subject to regulation 9, sections 33 to 42 (provisions as to offences).

(3) For the purposes of paragraph (1)—

(a) Section 25A of the 1974 Act shall have effect as if in subsection (1) of that section, after the word “substance”, there were inserted the words “or any article bound for export or any substance bound for export”; and

(b) Section 27A of the 1974 Act shall have effect as if in subsection (1) of that section, after the word “imports”, there were inserted the words “or exports”.

23.—(1) Subject to Regulations 9, 11(3) and 24(2), the provisions of the 1978 Order specified in paragraph 2 shall apply for the purposes of the enforcement and the provision of offences in Northern Ireland of the PIC Regulation and this chapter as if the PIC Regulation and this chapter were health and safety regulations for the purposes of that Order, and any function of the Northern Ireland Executive under any provision of the 1978 Order shall be exercisable as if the PIC Regulation and these Regulations were health and safety regulations for the purposes of that Order.

(2) The provisions of the 1978 Order referred to in paragraph (1) are-

(a) Articles 21 and 22 (appointment and powers of inspectors);
(b) Articles 23, 25 and 26 (improvement notices);
(c) Articles 27A to 30 (customs officer’s power to detain imports, power to indemnify inspectors, power to obtain information, information provided by Commissioners for Revenue and Customs, and restrictions on disclosure of information); and
(d) Articles 31 to 39 (provisions as to offences).

(3) For the purposes of paragraph (1)—

(a) Article 27A of the 1978 Order shall have effect as if in paragraph (1) of that Article, after the word “substance”, there were inserted the words “or any article bound for export or any substance bound for export”; and

(b) Article 29A of the 1978 Order shall have effect as if in paragraph (1) of that Article, after the word “imports”, there were inserted the words “or exports”.

29
Allocation of enforcement responsibility

24. (1) Subject to paragraph (2), it shall be the duty of the Great Britain Executive and the Northern Ireland Executive to make adequate arrangements for the enforcement of this Chapter and the PIC Regulation and accordingly, references to the enforcing authority in the provisions applied for those purposes by regulations 22 and 23 shall be construed as references to the Great Britain Executive and the Northern Ireland Executive.

(2) Contravention of Article 15(2) of the PIC Regulation, which prohibits the export of chemicals and articles the use of which is prohibited in the Union for the protection of human health or the environment, as listed in Annex V of the PIC Regulation, shall be subject to enforcement under the Customs and Excise Management Act 1979.

False or misleading information

25. An exporter or importer shall not provide information pursuant to the requirement of any Article of the PIC Regulation knowing it to be false or misleading in a material particular, or being reckless as to whether it is false or misleading in a material particular.

Enforcement notice

26. If an authorised person is of the opinion that a person has contravened, is contravening or is likely to contravene a provision in the PIC Regulation, the authorised person may serve on that person an enforcement notice.

27. An enforcement notice must-
   (a) state that the authorised person is of the opinion referred to in the preceding paragraph;
   (b) specify the matters constituting the contravention or the matters making it likely that the contravention will arise, as the case may be;
   (c) specify the steps that must be taken to remedy the contravention or to remedy the matters making it likely that the contravention will arise, as the case may be; and
   (d) specify the period within which those steps must be taken.

28. An enforcement notice may contain provision prohibiting the export of chemicals or articles as defined in the PIC regulation until the steps specified under regulation 27(c) have been taken or the notice has been withdrawn.

29. Where an enforcement notice has been served but is not to take immediate effect-
   (a) the notice may be withdrawn by an authorised person at any time before the end of the period specified therein;
   (b) the period so specified may be extended or further extended by an authorised person at any time when an appeal against the notice is not pending.

30.—(1) A person on whom an enforcement notice is served may within such period from the date of its service as prescribed appeal to—
   (a) an employment tribunal in Great Britain;
   (b) an industrial tribunal established under Article 3 of the Industrial Tribunals (NI) Order 199613 in Northern Ireland,
   and on such an appeal the tribunal may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the tribunal in the circumstances thinks fit.
   (2) Subject to paragraph (3), the bringing of the appeal shall not affect the operation of the enforcement notice.

13 S.I. 1996/1921 (N.I. 18)
(3) Where an appeal under this regulation is brought against an enforcement notice within the period allowed under paragraph (1), the tribunal may, on the application of the appellant, direct that the bringing of the appeal shall have the effect of suspending the operation of the notice until the appeal is finally disposed of or, if the appeal is withdrawn, until the withdrawal of the appeal.

31. It is an offence for a person to contravene any requirement or prohibition imposed by an enforcement notice, including any such notice as modified on appeal.

32. For the purposes of regulations 26 to 31, an “authorised person” means [a person authorised in writing by the Great Britain Executive or the Northern Ireland Executive who appears suitable to act on its behalf subject to any limitations or conditions as the Great Britain Executive or Northern Ireland Executive sees fit].

PART 4
REVIEW, REVOCATIONS AND AMENDMENTS

Review

33.—(1) The Secretary of State must from time to time—
(a) carry out a review of regulations 5 to 32,
(b) set out the conclusions of the review in a report, and
(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to the measures taken to implement rules on enforcement and appointment of authorities in relation to the PIC, CLP and Biocides Regulations in other member States.

(3) The report must in particular—
(a) set out the objectives intended to be achieved by the measures taken to implement rules on enforcement and appointment of authorities in relation to the PIC, CLP and Biocides Regulations,
(b) assess the extent to which those objectives are achieved, and
(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which regulations 5 to 32 come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Revocation of regulations

34. The following regulations are revoked:
(a) the Biocidal Products Regulations 2001(14);
b) the Biocidal Products (Amendment) Regulations 2003(15);
(c) the Biocidal Products (Amendment) Regulations 2005(16)
(d) the Biocidal Products (Amendment) Regulations 2007(17)
(e) the Biocidal Products (Amendment) Regulations 2010(18);
(f) the Export and Import of Dangerous Chemicals Regulations 200819

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(14) S.I. 2001/880
(15) S.I. 2003/429
(16) S.I. 2005/2451
(17) S.I. 2007/293
(18) S.I. 2010/745
19 S.I. 2008/2108
Amendments to the 2009 Regulations

35. The 2009 Regulations are amended in accordance with the provisions of the Table in the Schedule.

36. The following provisions of the 2009 Regulations are revoked:
   (a) regulation 5;
   (b) regulations [4, 6 to 11 and 13]; and
   (c) regulations [1 to 3, 12, and 14 to 18].

Consequential amendments

37. [Provision to be made for consequential amendments]

SCHEDULE 1
AMENDMENTS TO THE 2009 REGULATIONS

<table>
<thead>
<tr>
<th>Regulations to be amended</th>
<th>Regulation and Schedule to be amended</th>
<th>Amendments to be made</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009</td>
<td>Paragraph (ii) of the preamble</td>
<td>Substitute: “Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals be construed as including references to [Annexes I and V] of that Regulation as those Annexes are amended from time to time”</td>
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<tr>
<td>Regulation 3(3)(c)</td>
<td>For the words “Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals, of which Annexes I and V are as amended from time to time” substitute: “Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals, of which [Annexes I and V] are as amended from time to time”</td>
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<td>After regulation 5 insert- “Advertisements for dangerous preparations 5A. (1) Subject to paragraph (2), a</td>
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<tr>
<td>Regulations to be amended</td>
<td>Regulation and Schedule to be amended</td>
<td>Amendments to be made</td>
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<td>person who supplies a dangerous preparation shall not advertise that dangerous preparation, or arrange for the production of any such advertisement, unless mention is made in the advertisement of the type of hazard indicated on the label. (2) Paragraph (1) shall apply only in respect of a dangerous preparation where the advertisement enables a person, otherwise than in the course of a business, to conclude a contract to purchase the dangerous preparation before that person has seen the label relating to the dangerous preparation. (3) In this regulation “supply” has the same meaning as it has in section 46 of the Consumer Protection Act 1987.”.</td>
<td>For the words “and the CLP Regulations as if these Regulations and the CLP Regulation were health and safety Regulations for the purposes of that Act except that those sections shall not apply to duties placed by the CLP Regulation on the competent authority or the Member State.” substitute “as if these Regulations were health and safety Regulations for the purposes of that Act.”.</td>
</tr>
<tr>
<td>Regulation 14(1)</td>
<td>After Regulation 14(1) insert-“(1A) The maximum penalty for an offence under this regulation is- (a) on summary conviction, imprisonment for a term not exceeding three months or a fine not exceeding £5,000; and (b) on conviction on indictment, imprisonment for a term not exceeding two years, or a fine, or both.”.</td>
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<tr>
<td>Regulation 14(2)</td>
<td>Omit “and the CLP Regulation”</td>
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<tr>
<td>Regulation 14(3)</td>
<td>Omit “and the CLP Regulation”</td>
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<td>Regulation 14(4)</td>
<td>Omit</td>
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<td>Regulation 14(5)</td>
<td>Omit “and the CLP Regulation”</td>
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<tr>
<td>Regulation 14(6)</td>
<td>Substitute- “In every case where, by virtue of this regulation, these Regulations are enforced by the local weights and measures authority, they shall be enforced as if they were safety regulations made under section 11 of the Consumer Protection Act 1987 and the provisions of section 12 of that Act shall apply to these Regulations as if they were safety regulations for the purposes of that Act and as if the maximum period of imprisonment on summary conviction specified in subsection (5) thereof were 3 months instead of 6 months.”</td>
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<tr>
<td>Regulation 15</td>
<td>Omit “and the CLP Regulation”</td>
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<td>Regulation 16</td>
<td>Omit “and the CLP Regulation”</td>
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SCHEDULE 2
APPEALS

[Provisions will be inserted that largely replicate Schedule 10 to the Biocidal Products Regulations 2001]
Consultative Document Annex B – Proposed PIC Enforcement Changes – Preliminary Economic Analysis

Purpose of Analysis

1. **Background**
   1.1. The EU Prior Informed Consent (PIC) Regulation on the export and import of dangerous chemicals (EC No 689/2008) implements within the EU the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade, and certain aspects of the Stockholm Convention on persistent organic pollutants. It applies to chemicals that are banned or severely restricted at EU level. Its effect is to require a notification to be sent to countries importing these chemicals and in certain circumstances requires explicit consent by the importing country before export from the EU can occur. It also includes provisions on packaging and labelling of exported chemicals in line with internal EU requirements, except where these conflict with the requirements of the importing country.

   1.2. Negotiations have recently concluded on a recast of the PIC Regulation. This will lead to its replacement with a new PIC Regulation, which is expected to apply from 1 March 2014. This is happening alongside several other significant changes that have occurred or will shortly occur in the regulation at EU level of biocides and the classification, labelling and packaging of chemicals. Although these EU Regulations are all directly applicable, some changes in domestic legislation are needed: all three EU Regulations require the UK to formally appoint competent authorities (in the case of PIC called Designated National Authorities) to undertake specified tasks; and all three require the UK to establish arrangements for the enforcement of these Regulations. In view of the close similarities, it has been decided to make these changes through a single set of consolidated regulations. The proposed additional enforcement measures in this preliminary economic analysis form part of these regulatory proposals.

2. **Problem under consideration**
   2.1. The chemical industry is very important to the UK (reported turnover of £57bn pa) and exports are a key part of this. Whilst the number of businesses in the UK affected by the PIC Regulation is small (around 35 exporters have been involved in recent years), the UK is nonetheless one of the top three Member States exporting chemicals listed in the PIC Regulation. It is important to ensure these UK exporters all operate on a level playing field, and do not see competitors gain advantage by failing to comply with PIC, for example by exporting a chemical without the importing country having been properly notified. The PIC Regulation requires Member States to enforce its provisions with effective, proportionate and dissuasive powers; similar provisions appear in the forthcoming recast PIC Regulation. Beyond formal advisory letters, the existing SI (2008/2108) provides for prosecution, but nothing in-between. We wish to correct this position by adding powers that will enable inspectors, where appropriate, to take more proportionate action.

3. **Rationale for intervention:**
   3.1. At present, inspectors do not have the power to issue an Improvement Notice (IN) or an Enforcement Notice (EN) (see paragraph 5.2 for definitions) when enforcing the PIC Regulation. The only enforcing power that they have is prosecution. Experience has shown that prosecution is not an effective or proportionate mechanism and that INs / ENs would be more appropriate to the type of non-compliance that officers deal with under PIC.

   3.2. By creating more proportionate mechanisms for enforcement, there is an increased likelihood that the mechanisms will be used, thus strengthening the incentive for dutyholders to be compliant and ensuring a level playing field for all exporters.
3.3. The proposal is for the existing enforcement arrangements to remain, but for inspectors to have additional powers to issue INs and ENs, thereby enhancing their ability to take action appropriate to the facts and circumstances of any case.

3.4. The value and effectiveness of notices in securing compliance is well established. In 2010/11 HSE inspectors issued 11020 notices under the Health and Safety at Work etc. Act 1974, compared to instituting 551 prosecutions. Provision of notices to secure compliance under PIC will benefit industry by providing better tools to maintain a level playing field. Prosecution is then properly reserved for persistent offenders or blatant non-compliance.

4. **Microbusinesses exemption**

4.1. The additional enforcement powers to issue INs and ENs are being given to inspectors, with no new duties impacting on duty holders (including microbusinesses). At this stage we expect microbusinesses to be in scope as they, like all duty holders, will need to be aware of the additional enforcement powers of inspectors.

4.2. Further details on the impact on microbusinesses will be given for the final stage impact assessment, when a final decision has been made on whether they are in scope.

5. **Policy objective:**

5.1. The objectives of this proposal are to implement Government policy to:

- Continue to provide protection for workers, the environment and society as a whole;
- Improve standards of health and safety and environmental protection, by increasing compliance;
- Provide a level playing field for duty holders that comply with the law.

6. **Description of options considered (including do nothing):**

**Option 1: Do Nothing**

6.1. The “Do Nothing” option is the baseline (status quo) where no changes are made to current enforcement mechanisms. This is the baseline which other options will be compared against.

**Option 2: Giving inspectors the power to issue Improvement Notices and Enforcement Notices under PIC regulatory enforcement**

6.2. Under option 2, inspectors would be given the following powers of enforcement in addition to prosecution:

6.2.1. Improvement Notice (Section 21 of the Health and Safety at Work Act 1974). Issued by an inspector, an IN requires a person to remedy a contravention of a statutory provision (in this case of the PIC Regulation) or the matters occasioning it within a specified time. Where an appeal is lodged against an IN, the operation of the IN is suspended until the appeal is heard;

For example, an IN might be appropriate where an exporter has failed to put in place the administrative arrangements needed to comply with the PIC Regulation; and,

6.2.2. Enforcement Notice created under the proposed regulations. Issued by an inspector, an EN would require a person to remedy a contravention of the PIC Regulation. It would mean the activity should not be carried on, by, or under the control of the person on whom the notice is served unless the
contravention has been remedied. An appeal would not suspend the operation of
the EN before it is heard.

For example, the EN could be used to prevent an export from taking place until the
requirements of the PIC Regulation are met, unlike the effect of an appeal against
an IN described above. An EN is therefore appropriate to more serious cases of
contravention than an IN.

A similar EN already exists under the Registration, Evaluation Authorisation and
This allows enforcers to stop the marketing of a substance until a contravention of
REACH is remedied.

6.3. Instead of an Enforcement Notice, consideration was given to enabling
inspectors to issue a Prohibition Notice (Section 22 of the Health and Safety at Work
Act 1974). An inspector may serve a PN if they are of the opinion that an activity
carried on (or likely to be carried on) involves (or will involve) a risk of serious personal
injury. It means the activity should not be carried on until the matters giving rise to the
inspector’s opinion have been remedied. An appeal against a PN only suspends it if
the tribunal so directs.

In the case of PIC, being able to demonstrate that there is a risk of serious personal
injury is highly improbable. This is because the danger from the hazardous chemical is
unlikely to arise until it comes to be used in the importing country, which would be
beyond EU and UK jurisdiction. Therefore, a PN would not be appropriate in this case.

6.4. Option 2 is the preferred option as doing nothing will continue to severely limit
inspectors’ ability to take proportionate action against non-compliers. Option 2 will enable
more effective and proportionate enforcement of PIC legislation.

7. Alternatives to regulation

7.1. In line with the Government’s principles of regulation we have considered
alternative, non-regulatory or self-regulatory means of achieving the same outcome
and Government guidance on alternatives to regulation 20

7.2. However, as this proposal seeks to provide proportionate means to secure
compliance in addition to advice/encouragement and prosecution, such provision
needs to have a legal base. The proposal draws on established powers used
successfully in similar circumstances for the regulation of chemicals.

7.3. This proposal takes into account insights from behavioural theory which tells
us that people are “influenced by the way choices are presented to them (i.e. a formal
communication with enforcement power will send a stronger message than a letter);
and care about fairness and reciprocity (i.e. enforcing officers are able to use
proportionate enforcement tools)”.21

8. One In One Out (OIOO)

8.1. The changes resulting from the introduction of the power to enforce through
INs and ENs are within scope of OIOO. The costs to dutyholders would be an “in”.
However, it is expected that the amount of this “in” would be very small as the number
of dutyholders is small (around 35). After considering the implications for business, the
“in” is estimated to be in the region of £620 per annum.

21 See: http://www.bis.gov.uk/policies/better-regulation/better-regulation-executive/reducing-regulation-made-simple/alternatives-to-
regulation/behavioural-economics-why-should-policy-makers-beinterested
8.2. The corresponding “Out” for this legislation will be taken from that calculated in the Impact Assessment for “Implementing the Common Sense, Common Safety Recommendation to Amend RIDDOR Regulation 3(2)”, the Impact Assessment for which was rated fit for purpose by the Regulatory Policy Committee on 1/11/2011.

9. Monetised and non-monetised costs and benefits of each option

General Assumptions

9.1. Costs and benefits are assessed over 10 years as there is no reason to depart from the general advice in the Department for Business Innovation & Skills IA toolkit to use this time frame.

9.2. The discount rate used is 3.5%, in line with the HM Treasury Green Book\(^2\) guidance.

9.3. The first year of analysis is 2013. The regulatory change comes into force in September of that year and therefore it is expected that any one-off costs (other than familiarisation for new start-ups which will happen each year) will take place in the first eight months of 2013.


9.5. HSE Staff costs are based on an internal finance model (Ready Reckoner) and are not inflated by 30% as they already include estimates for non-staff overheads.

9.6. Industry costs per hour are assumed to be approximately £30. This is based on costs presented in the Annual Survey of Hours and Earnings (2010) (Office for national statistics)\(^2\) and uprating by 30% to allow for non-wage costs (in accordance with the Green Book)

9.7. Cost calculations for OIOO will have a present value base year of 2010 and a price base year of 2009, in line with the published OIOO guidance.

9.8. Figures presented in this economic analysis are, in general, rounded to two significant figures; however, calculations are based on non-rounded numbers. Given this, some figures presented may not add up to the totals presented.

Costs

Option 1: Do Nothing

9.9. Under option 1, there are no changes made to the powers of inspectors and there are no costs or benefits associated.

Option 2: Giving inspectors the power to issue Improvement Notices and Enforcement Notices under PIC regulatory enforcement.

9.10. Under option 2, there will be costs to dutyholders (in terms of responding to INs / ENs) and costs to HSE of setting up and maintaining the system. These are detailed below.

\(^2\) [http://www.hm-treasury.gov.uk/data_greenbook_index.htm](http://www.hm-treasury.gov.uk/data_greenbook_index.htm)

10. Costs to dutyholders

10.1. Changes under option 2 would not affect the duties on business; they only affect the enforcement activity that supports the existing PIC Regulation. Enforcement is mainly about ensuring exporters have, when appropriate, notified their PIC Designated National Authority (DNA) of an export and additionally, for certain specified chemicals, obtained through their DNA explicit consent to its import from the importing country before the export proceeds. At present there are in the region of 35 known exporters with responsibilities under PIC and over the last three last years, approximately 400 notifications were made per annum. HSE and chemical trade associations periodically remind industry of the existence and requirements of PIC, and so it is expected that the majority of dutyholders know about PIC Regulation.

10.2. Costs to business will arise through their administrative response to INs / ENs, not what dutyholders must do to comply with the PIC Regulation.

11. Familiarisation

11.1. There will be a familiarisation cost to dutyholders in the industry. As HSE holds a database with the contact details of all known PIC dutyholders, changes will be communicated directly to all concerned. We assume that the known 35 exporting dutyholders will spend, on average, an hour reading and understanding the changes suggested. Assuming an average opportunity cost per hour of £30, based on the average salary for the UK24, this would represent costs of £30 for each dutyholder undertaking familiarisation. This amounts to a total one-off cost in the region of £1000.

11.2. In addition to existing dutyholders, there will be familiarisation costs for new dutyholders, e.g. new start-ups (although there are very few of these on an annual basis). The burden on new dutyholders is assumed to be negligible as it would fall within a wider familiarisation process of understanding the legislative framework within which they operate.

12. Administrative response to Improvement Notices and Enforcement Notices

12.1. When dutyholders receive an IN or EN, they will need to carry out the improvements suggested. The associated costs of complying with the PIC Regulation are not within scope of this preliminary economic analysis. However, activities like reading the IN/EN and communicating to HSE that the changes have been made will fall within scope.

12.2. It is expected that a dutyholder reporting that they have complied would spend half an hour communicating this to HSE (i.e. drafting and sending a letter or email). This assumption will be tested during consultation (see risks and assumptions, section 18 for full details of what will be tested and how).

12.3. Over the last five years, there have been fewer than half a dozen formal advice letters in this area. Allowing for behavioural changes (e.g. the increase in legal power may mean that inspectors increase formal communication), we cautiously estimate that there would be a maximum of 5 IN / EN cases per annum. This equates to an annual cost of £75 for dutyholders in their administrative responses to INs / ENs. The impact on inspector behaviour is considered in more detail in sections 16 and 17.

12.4. Dutyholders may choose to dispute an IN/EN. It is not practical to use the number of disputes against previous advisory letters to determine what proportion of INs / ENs will be disputed, because the number of such letters issued in the first place is so small, there is no record of any such disputes and in any case no formal dispute process exists. So instead, we have looked at what percentage of the approx 5000 INs

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24 Source: Annual Survey of Hours and Earnings, ONS, 2011. Includes an additional 30% to account for non-wage costs.
issued by HSE inspectors annually under the Health and Safety at Work Act are disputed. Records show that the number of such disputes is less than 1%. As the use of PIC INs and ENs will be new, we cautiously assume that one of 5 would be disputed per annum. We will check this assumption during consultation.

12.5. The dispute process will take on average 14 hours of dutyholders time (including time for attending an Employment Tribunal). Using the average opportunity cost per hour of £30, disputes will cost approximately £420 per annum for dutyholders.

12.6. We consider this to be a significant overestimate and will further consider our assumptions before drafting the final stage impact assessment to ensure our calculations are as best representative of the future dutyholder response.

13. **Additional costs for dutyholders as a result of Enforcement notices**

13.1. Although there will be no additional duties under the PIC Regulation, if an EN is issued, exporters will not be able to export the chemical concerned until the requirements of the EN are fulfilled. In this instance, depending upon the location of the chemical at the time an EN is issued (e.g. at a port, rather than their own premises), the dutyholder may incur additional transport and storage costs. Furthermore, there is no guarantee that they will, where necessary, get consent to export after fulfilling their duties.

13.2. The cost of any such additional transport and storage will, amongst other things, depend on the quantity and type of chemical, as well as the facilities available to the dutyholder in this position. During consultation, we will see if it is possible to develop any scenarios to create case study costs. However, given the number of variables (tonnage of chemical, storage facilities, length of time for dutyholder to become compliant etc) we doubt it would be proportionate or even possible to generate a robust estimate for this cost.

13.3. In total the costs to duty holders as a result of disputes and administration is therefore in the region of £500 per annum.

14. **Impact on number of prosecutions**

14.1. Since the current SI 2008/2108 came into force in September 2008 there have been no prosecutions for failure to comply with the PIC Regulation. The introduction of INs / ENs is therefore not expected to change significantly the number of prosecutions.

15. **Costs to HSE**

15.1. There would be costs to HSE in terms of implementing the new arrangements and the resources to process notices and disputes.

15.2. There will be negligible costs associated with training inspectors in terms of the IN / EN processes as these are pre-existing tools with which officers are already familiar. [We anticipate that the EN process will be similar to that for a REACH EN, so inspectors are unlikely to require much additional information.]

15.3. The introduction of INs / ENs in this area will create an opportunity cost of HSE staff time, but this is expected to be small. Estimates of this will be provided for the final stage Impact Assessment, when we will have a better idea of the resources allocated to this area.
16. Benefits

16.1. HSE Research\textsuperscript{25} into the occupational health and safety system, of which HSE is an important part, has found that the complexity of the system means that its behaviour is influenced by many interrelated causes in a highly non-linear way. It is therefore not possible with current data to categorically identify and quantify causal links between the resource devoted to HSE activities and health and safety outcomes.

16.2. We expect that the possibility of an IN / EN being issued would provide an incentive to dutyholders who might otherwise not comply with the law, reducing overall exposure to environmental and health and safety risk, but it is not possible to quantify this.

17. Rationale and evidence that justify the level of analysis used:

17.1. The analysis presented identifies the impacts of introducing the power of INs and ENs. It quantifies and monetises these impacts, where possible, based on current available research and data. At this point, it is not deemed proportionate or accurate to refine estimates beyond what is presented in this economic analysis. However, the following improvements, where possible, will be made for the final stage Impact Assessment:

- The assumptions in terms of familiarisation will be tested and if necessary refined via consultation. These will also be triangulated with internal research on the length of time to read guidance and assumptions tested in earlier impact assessments;
- Behavioural change of inspectors will be considered through discussions with the experts in this area. Specific consideration will be given to whether more INs / ENs compared to letters will be issued.
- Case studies on costs of storage will be developed.

17.2. Consultation will be used to test the assumptions we have made and identify any issues that we have not addressed.

18. Risks and assumptions:

18.1. In addition to the assumptions that we intend to refine prior to the final stage Impact Assessment, there are some risks and uncertainties around the assumptions that we have made.

18.2. There are elements of the proposal that will remain untested until the changes are actually in place – specifically in terms of behaviour and the number of INs and ENs served and appeals against them. Although we will aim to reduce these uncertainties before the final stage Impact Assessment, it will not be possible to eliminate these completely.

18.3. The analysis assumes a continued level of chemical export activity over the analysis period and that giving inspectors these additional powers does not create an incentive for business to relocate outside the UK, nor deter new entrants from starting-up in the UK. It is unlikely that exporters will redirect their business as a result of this change, as the likely costs of moving their business to another EU Member State would be far higher than the costs of dealing with an IN / EN.

\textsuperscript{25} Research report: “Linking HSE Activities to Health and Safety Outcomes: A Feasibility Study”.
http://www.hse.gov.uk/research/rhtm/rr913.htm
19. Direct costs and benefits to business calculations (following OIOO methodology):
   19.1. Costs to business will be in the form of familiarisation costs and ongoing administrative responses to an IN or EN. The one off cost to industry is estimated in the region of £1000, with the annual cost of less than £500 (for administration processes). Therefore the equivalent annual net cost to business for OIOO is estimated to be £620.

20. Wider impacts
   20.1. Although protecting the health and safety of people and the environment outside the UK are not in scope of this analysis, there will be a benefit for countries outside the EU who receive PIC listed chemicals from the UK.

21. Cost summary table (£k) for dutyholders

<table>
<thead>
<tr>
<th></th>
<th>One-off (Familiarisation)</th>
<th>ongoing costs (per annum)</th>
<th>HSE costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Option 2</td>
<td>1</td>
<td>&lt; 0.5</td>
<td>Not quantified yet</td>
</tr>
</tbody>
</table>

22. Summary and preferred option with description of implementation plan.
   22.1. We anticipate the PIC part of the proposed regulatory measures, including the additional enforcement measures in this preliminary economic analysis, will apply by 1 March 2014. Although the measures do not change the duties of dutyholders, they will need to be made aware of the new enforcement tools. We shall do this by means of our online PIC eBulletin system, the HSE website and through contact with the relevant trade associations. Inspectors will generally be made aware of these additional tools, and more specific training/guidance will be arranged for those likely to deal with PIC exporters. All of the above awareness raising will occur in late 2013 and early 2014.
Consultation on regulatory measures to support EU chemicals legislation and proposals on reducing seven existing sets of domestic regulations into one statutory instrument (7 into 1 package)

The full text of this and other Consultative Documents can be viewed and downloaded from the Health and Safety Executive web site on the internet: www.hse.gov.uk/consult/index.htm