EXPLANATORY MEMORANDUM TO

The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013
S.R. 2013 No. 206
and
The Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2013
S.R. 2013 No. 207

1. Introduction

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

1.2. The Statutory Rules are made under powers conferred by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972 and Articles 17(1) to (6), 40(2) and (4) and 55(2) of, and paragraphs 1(1) and (4), 3(1), 5, 12(1) and 14(1) of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978 ("the 1978 Order"). The Statutory Rules are subject to the negative resolution procedure.

2. Purpose

2.1 The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013 (the 'BPC Regulations (NI)') formally appoint national authorities and provide for enforcement, including penalties for infringement, in respect of two direct-acting European Union (EU) Regulations:

- 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) – "the Biocides Regulation"; see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF; and
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures – "the CLP Regulation" see: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF.

2.2 These two EU Regulations do not require transposition. No transposition note is therefore attached. However, EU member states are required to make arrangements in order to give full effect to aspects of these Regulations. The BPC Regulations (NI) make these arrangements and also make minor amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 (S.R. 2009 No. 238, "the CHIP Regulations"), see: http://www.legislation.gov.uk/nisr/2009/238/pdfs/nisr_20090238_en.pdf which continue to have effect until the CLP Regulation fully replaces the Dangerous Substances and Dangerous Preparations Directives.[1], implemented by the CHIP Regulations.

2.3 The BPC Regulations (NI) use the enabling power in paragraph 1A of Schedule 2 to the European Communities Act 1972 to insert ambulatory references. These ambulatory references are limited and relate to specific articles and annexes in the EU Regulations where technical updates are frequently made to reflect technical progress. This reflects the previous position in the domestic regulations, which implemented the CLP Regulation.

[1] Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, labelling and packaging of dangerous substances and Directive 1999/45/EC of the European Parliament and of Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, labelling and packaging of dangerous preparations.

2.4 The separate Biocidal (Fees and Charges) Regulations (Northern Ireland) 2013 ("the Biocidal Fees Regulations (NI)") make provisions for fees payable by dutyholders under the Biocides Regulation.

2.5 The BPC Regulations (NI) revoke the Biocidal Products Regulations (Northern Ireland) 2001 (S.R. 2001 No 422) ("the 2001 Regulations") and subsequent amendments to those Regulations (see paragraph 3.12). However, the BPC Regulations (NI) specifically do not revoke the provisions relating to fees and charges in the 2001 Regulations, and subsequent amendments. These are instead revoked in the Biocidal Fees Regulations (NI) 2013, in order to provide clarity over associated revocations and savings provisions and to avoid complicated cross-references.

3. Background

3.1. In the last few years significant changes have occurred or will shortly occur in the regulation of chemicals at EU level, as directly acting EU Regulations replace Directives that required transposition by Member States. In this case:

- On 1 September 2013 the Biocides Regulation will replace an existing Directive (98/8/EC). The existing domestic legislation which transposes 98/8/EC will then become obsolete and need to be revoked.
- In 2009, the EU Regulation on classification, labelling and packaging of substances and mixtures (the CLP Regulation) came into force. After a transitional period, it will entirely replace two Directives – the Dangerous Substances and Dangerous Preparations Directives. The existing domestic CHIP Regulations which transpose these Directives, can then be revoked, but the provisions they make for enforcement of the CLP Regulation will need to be replaced.

3.2. Each of the above EU Regulations require Member States to formally appoint national authorities and provide for enforcement, including penalties for infringement. For the Biocides Regulation, it is also necessary to prescribe a fees and charges structure covering all aspects of the product authorisation process.

3.3. To ensure the UK meets the obligations in these EU Regulations and to implement Government policy to recover certain costs from industry, the BPC Regulations (NI) and the Biocidal Fees Regulations (NI) revoke and where necessary replace the above domestic legislation. The Regulations are intended to provide transparency and consistency of approach and help to ensure the EU requirements are implemented in the least burdensome way that is possible.

3.4. To reduce the number of legislative instruments and simplify domestic regulation in this area, and in view of the similarities between the two regimes, the BPC Regulations (NI) replace the existing domestic provisions that support the CLP Regulation and combine these with provisions for the new Biocides Regulation. The biocides provisions also revoke and replace existing biocides legislation as recommended in Professor Löfstedt's independent review of health and safety legislation.[2]

3.5. The outcome is the replacement of four existing sets of regulations (three on biocides; and the CHIP Regulations) by two Statutory Rules (the BPC Regulations (NI) and the Biocidal Fees Regulations (NI)). The Health and Safety Executive will complete a review of the General Industry Charge, one aspect of the biocides fees structure, by 1 April 2014 to determine whether it continues to achieve the intended objective of full cost recovery and to ensure the fees structure remains in line with Government policy. The Health and Safety Executive for Northern Ireland (HSENI) will consult on proposals for any changes that are found to be necessary. Following this review, consideration will be given to incorporating the Biocidal Fees Regulations (NI) into the Health and Safety (Fees) Regulations (Northern Ireland) in 2014.

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[2] *Reclaiming health and safety for all*, Professor Ragnar Löfstedt, November 2011. http://www.dwp.gov.uk/docs/lofstedt-report.pdf

3.6. The provisions of the BPC Regulations (NI) come into operation on the date required by the EU Regulation to which they relate.

3.7. **The new directly acting Biocides Regulation** lays down revised rules for the authorisation of biocidal products relating to the making available on the market, use and control of such products within the EU. Biocidal products are products used to control organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. Examples are rodent poisons, insect repellents and wood preservatives. The placing on the market and use of such products is regulated because they can pose significant risks to humans, animals and the environment.

3.8. The Biocides Regulation requires Member States to appoint a competent authority or competent authorities and make arrangements for enforcement, including establishing a system of effective, proportionate and dissuasive penalties for non-compliance.

3.9. The BPC Regulations (NI) designate the Health and Safety Executive for Northern Ireland as the competent authority to carry out the obligations laid down in the Biocides Regulation.

3.10. The provisions in the BPC Regulations (NI) in respect of biocidal products are similar to corresponding provisions in the Biocidal Products Regulations (Northern Ireland) 2001, which they revoke, see: [http://www.legislation.gov.uk/nisr/2001/422/contents/made].

3.11. The Biocidal Fees Regulations (NI) update and replace the existing Regulations that set out the fees payable as part of the product authorisation process, including for the assessment of the data needed to demonstrate that a particular use of a biocidal product and its active substances (the chemicals that give products their biocidal properties) are effective against the target organisms and safe in use for humans and the environment.

3.12. Together, the BPC Regulations (NI) and the Biocidal Fees Regulations (NI) revoke the Biocidal Products Regulations (Northern Ireland) 2001 and all its amendments, subject to certain transitional and savings provisions (BPC Regulations (NI), regulation 15 and Schedule 1; Biocidal Fees Regulations (NI), regulation 9).

3.13. Provisions in the BPC Regulations (NI) relevant to the EU Biocides Regulation take effect in Member States on 1 September 2013 when domestic provisions are required to be in place.

3.14. The **CLP Regulation** adopts an international chemicals hazard classification and labelling system for the supply of substances and mixtures in the EU. The CLP Regulation came into force in 2009. It replaces the existing European system and after a transitional period takes full effect from 1 June 2015.

3.15. The CLP Regulation requires Member States to appoint a competent authority or competent authorities and to make arrangements for enforcement, including establishing a system of penalties for non-compliance.

3.16. The BPC Regulations (NI) designate the Department of Enterprise, Trade and Investment to carry out the obligations laid down in the CLP Regulation .

3.17. Provisions in the BPC Regulations (NI) in relation to enforcement of the CLP Regulation are based on existing provisions in the CHIP Regulations.

3.18. In addition, the BPC Regulations (NI) provide an opportunity to address some minor legal and administrative issues in the CHIP Regulations. Regulation 23 and Schedule 3 of the BPC Regulations (NI) update and correct the CHIP Regulations for the remainder of their tenure. Specifically, they provide for references to the EU Regulation on the export and import of hazardous chemicals (Regulation (EU) No.649/2012) (known as the Prior Informed Consent Regulation – “the PIC Regulation”) to replace the references to the 2008 PIC Regulation (Regulation (EC) 689/2008); bring the penalties in line with the provisions of the European Communities Act 1972; and, reinstate a requirement that suppliers who advertise chemicals alert potential buyers to any hazardous properties, which was incorrectly omitted from the CHIP Regulations.

4. Consultation

4.1. A consultation exercise on the BPC Regulations (NI) ran from 4 March 2013 to 13 May 2013. There were approximately 600 consultees, including interested stakeholders in the chemicals' sector, individuals and bodies representative of section 75 of the Northern Ireland Act 1998 and other organisations with an interest in equality and related issues (including each member of the Northern Ireland Assembly). The CD was also posted on HSENI's website. In total there were four replies, one of which broadly welcomed the proposals and the remaining responses not offering any substantial comment. This is attributed to the generally uncontroversial nature of the proposals.

4.2. A separate four week consultation ran from 3 May 2013 to 31 May 2013 on the Biocidal Products Fees Regulations (NI). This was specifically targeted at the biocidal products industry. A copy of the consultation document was sent to 10 companies. The CD was also posted on HSENI's website.

4.3. Three small companies engaged in the manufacture of disinfectants responded with concern that the fees proposed could adversely affect their business. In fact, the proposed regulations simply maintain the status quo on biocides fees and charges while providing greater transparency of the fees structure with the inclusion of a table of fees in the Biocidal Fees Regulations (NI). The proposed daily rates and the fee ranges estimated in the consultation document reflect current averages so do not represent an increase in current costs. This has been clarified with the respondents concerned.

4.4. A summary of the consultation responses and HSENIs response can be found on the HSENI website - http://www.hseni.gov.uk/biocides_authorities_cd_responses.pdf; and http://www.hseni.gov.uk/biocides_fees_cd_responses.pdf.

5. Equality Impact

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

6. Regulatory Impact

6.1. The impact on business, charities or voluntary bodies arising from the BPC Regulations (NI) and Biocidal Fees Regulations (NI) are expected to be negligible.

6.2. The impact on the public sector is also expected to be negligible.

6.3. An Impact Assessment was conducted in respect of the corresponding Great Britain Statutory Instruments and is attached to this memorandum (see Annex). The Impact Assessment includes changes in legislation concerning "Prior Informed Consent" which the corresponding Great Britain Regulations deal with on a UK wide basis. This issue is not, therefore, included in the Northern Ireland Regulations. The Department of Enterprise, Trade and Investment is of the opinion that the analysis and considerations in respect of the costs arising from the proposals in relation to biocides and CLP, as set out in the Great Britain Impact Assessment, can be applied proportionately to Northern Ireland.

7. Financial Implications

7.1. As detailed at paragraph 6 above.

8. Section 24 of the Northern Ireland Act 1998

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

9. EU Implications

9.1. The Statutory Rule is essential to support the EU Regulations referred to above.

10. Parity or Replicatory Measure

10.1. In Great Britain the corresponding Statutory Instruments are the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (S.I. 2013/1506) and the Biocidal Products (Fees and Charges) Regulations 2013 (S.I. 2013/1507). The Statutory Instruments were made on 15th June 2013 and will come into force on 1st September 2013

11. Additional Information

11.1. Not applicable

PART I

GREAT BRITAIN IMPACT ASSESSMENT

FOR

THE BIOCIDAL PRODUCTS AND CHEMICALS (APPOINTMENT OF AUTHORITIES AND ENFORCEMENT) REGULATIONS 2013 (S.I. 2013 NO. 1506); AND

THE BIOCIDAL PRODUCTS (FEES AND CHARGES) REGULATIONS 2013 (S.I. 2013 NO. 1507) ("THE GB REGULATIONS")

1. The following pages contain a copy of the Impact Assessment, prepared by the Great Britain Health and Safety Executive, in respect of the GB Regulations.

2. The Impact Assessment concluded that no additional costs would be imposed on dutyholders by the Regulations. Familiarisation costs will be negligible.

3. In relation to biocides fees there is expected to be a benefit from increased transparency and accountability of the fees system given that daily rates will now be published and set in legislation.

Title: Proposed Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations **IA No:** **Lead department or agency:** HSE **Other departments or agencies:** HSE NI	**Impact Assessment (IA)** **Date:** 01/06/2013 **Stage:** Final **Source of intervention:** **Type of measure:** **Contact for enquiries:** Deborah.Traynor@hse.gsi.gov.uk Tara.McNally@hse.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion:

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
0	0	0		

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

Direct-acting EU regulations apply to certain biocidal products and chemicals, ensuring common standards apply across the Union. A new EU Regulation on biocides (EU) 528/2012 (the Biocides Regulation) applies from 1 September 2013 and a new EU Regulation on the export and import of hazardous chemicals (EU) 649/2012 from 1 March 2014 (the 'PIC' Regulation). Intervention is necessary in order to ensure the UK continues to meet EU requirements of these, to simplify and streamline existing domestic requirements for them and to meet a Lofstedt recommendation to consolidate biocides sectoral legislation.

What are the policy objectives and the intended effects?

A Statutory Instrument would provide supporting domestic legislation for the Biocides Regulation and the PIC Regulation covering enforcement arrangements and appointing competent authorities. These would be combined with similar existing provisions for the EU Regulation on the classification, labelling and packaging of chemicals ((EU) 1272/2008). It would also provide more proportionate PIC enforcement powers, resolve some legal & administrative issues in the Chemical (Hazard Information & Packaging for Supply) Regulations 2009 and enable HSE to continue to recover its costs by charging fees for some biocides activity, the aim being to incorporate provisions for these into existing Health and Safety (Fees) Regs.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: do nothing: This is the baseline option.

Option 2: create the above SI and revoke seven existing SIs that implement aspects of EU chemicals legislation relating to biocides, PIC and CLP, consolidating the new provisions into one new SI. A non- or co-regulatory approach to enforcement was considered but would not be viable as it would not meet the requirements in the EU Biocides, PIC and CLP Regulations. These require Member States to put in place systems of official controls to enforce compliance and penalties that are effective, proportionate and dissuasive.

Will the policy be reviewed? It be reviewed. **If applicable, set review date:** /					
Does implementation go beyond minimum EU requirements?					
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro**	**< 20**	**Small**	**Medium**	**Large**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible : ---------- Date: ----------

Summary: Analysis & Evidence Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year na	PV Base Year na	Time Period Years na	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

This is the baseline option, therefore there are no costs.

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

This is the baseline option, therefore there are no costs.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

This is the baseline option, therefore there are no benefits.

Other key non-monetised benefits by 'main affected groups'

This is the baseline option, therefore there are no benefits.

Key assumptions/sensitivities/risks	**Discount rate (%)**	na

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0		

Summary: Analysis & Evidence Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years na	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

Data was available to monetise the impact of introducing improvement / enforcement notices notices for PIC enforncement. It is expected that this could cost a maximum of £480 in any one year; if there is a sucessful dispute of either an informcement or improvement notice, however the actual annual cost on the basis of an expected cost is well under £100 per year.

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

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

Other key non-monetised benefits by 'main affected groups'

The proposal will streamline current legislation which will reduce the impression that health and safely legislation is over burdensome and complex. It will also introduce enforcement mechanisms that are consistent with other enforcement processes in HSE improving the fairness and proportionality of HSE enforcement action.

Key assumptions/sensitivities/risks	**Discount rate (%)**	na

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0		

Evidence Base (for summary sheets)

1. Background

1.1. The chemical industry is very important to the UK with a reported turnover exceeding £57bn pa (source: the Chemical Industries Association) [3].

1.2. Direct-acting EU Regulations apply to certain biocidal products and other chemicals, ensuring common standards apply across the Union. A new EU Regulation on biocides (EU/528/2012, the Biocides Regulation) applies from 1 September 2013. A recast EU Regulation on the export and import of hazardous chemicals (EU/649/2012, the 'Prior Informed Consent' (PIC) Regulation) applies from 1 March 2014.

1.3. EU Regulation EC/1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) is entering into force progressively between 2010 and 2015. Every manufacturer, importer and supplier of chemical products in the UK may be affected by the CLP Regulation – it requires those who supply chemicals to understand if they can cause harm and if so to communicate this to users down the supply chain. The proposed measure considered in this impact assessment (IA) does not establish duties for these companies – the duty to classify chemical substances and mixtures and to label and package these accordingly is established in the EU Regulation itself.

1.4. Exports are a key part of the chemical industry. Whilst the number of businesses in the UK affected by the export notification provisions of 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 PIC. Furthermore, the provisions on packaging and labelling of exported chemicals apply to exporters of all hazardous chemicals, not just those listed in the PIC Regulation.

1.5. The exact number of producers of biocidal active substances in the UK is unknown but, under the current regime for control of pesticides, the Control of Pesticides Regulations 2008 (CoPR - under which certain biocides have been regulated), it is known that there are 28 sources of biocidal active substances (companies) with manufacturing sites in the UK, as extracted from HSE records of manufacturers and suppliers of active substances and approved products under CoPR.

1.6. Overall, there is relatively little information available at either an EU or a UK level on the numbers and sizes of companies and quantities of biocidal products and associated treated materials. This is largely due to the fact that biocides have only recently been regulated as such, and cut across other pre-existing categories of chemicals (for example, pesticides and general industrial chemicals) on which there are better-established sources of data. Information on biocides could only be extracted by conducting a high-cost survey of companies manufacturing chemicals, which would not be a proportionate solution simply to fill the gap in our knowledge of the biocides market.

[3] source: Chemical Industries Association industry overview, 23 June 2011

1.7. The main affected types of businesses are formulators of biocidal products, manufacturers of active substances, re-sellers of biocidal products and users of biocidal products, and manufacturers and importers of treated articles.

1.8. As the Regulation will tend to reduce the amount of testing needed (for instance through increased data sharing or waiving of certain test data), the proposed Regulation will also have an impact on the activity of testing laboratories.

1.9. The Regulation will affect the wide variety of end users of biocidal products and treated articles, both businesses and consumers. The impact will therefore be very diverse, ranging from impacts on users of specialist products such as rodenticides, to ordinary consumers who use household disinfectants or the wide variety of articles containing treated wood, fabrics, plastics and other materials. For example, differences in costs of the regime for biocides will affect the prices paid by users for biocidal products and treated articles. Similarly, changes to the number of products that may or may not be withdrawn from the market will affect the choice of products available to users.

1.10. The Regulatory Policy Committee (RPC) have provided 'green' opinions on the consultation stage impact assessments already prepared for these aspects of the proposal (RPC opinions RPC12-HSE-1428 and RPC12-HSE-1428(2) (for biocides fees); and RPC12-HSE-1430 (for PIC enforcement)). The RPC also provided a Regulatory Triage Confirmation (RPC12-FT-HSE-1557) based on the low cost of the proposed regulatory measures to support the EU biocides, CLP and PIC Regulations.

2. Problem under consideration

2.1. All three EU Regulations (Biocides, PIC and CLP) replace older EU law. Although these Regulations act directly in all Member States, some supporting domestic legislation is required to make enforcement arrangements, appoint competent authorities and, specifically for biocides, to enable the Health and Safety Executive (HSE) to continue to recover its costs in operating the regime.

2.2. The changes in legislation need to be in place by 1 September 2013, when the new EU Biocides Regulation comes into effect, to enable the relevant authorities to continue to enforce biocides and for HSE to continue to recover the costs for work it performs as the UK biocides competent authority in accordance with the EU Regulation.

2.3. PIC and CLP enforcement must also be enabled to continue, and the PIC enforcement regime would benefit from the provision of more proportionate tools to deal with non-compliance.

3. Rationale for intervention

3.1. HSE leads in these policy areas and aims to take advantage of the similarities between the regulatory measures required for these regimes to combine seven existing sets of domestic regulations into one statutory

instrument (SI). The effect will be to consolidate implementing provisions for the Biocides, PIC and CLP Regulations (including appointment of competent authorities, enforcement and biocides fees). Biocides fees will be dealt with in a separate SI, but the aim is to incorporate the provisions into the Health and Safety (Fees) Regulations at the first available opportunity. However, the impact of the biocides fees proposals are included within this IA.

3.2. The seven sets of domestic regulations to be combined into the new SI are:

- The Biocidal Products Regulations 2001 (SI 2001 no 880) and amending regulations in 2003 (SI 2003 No 429), 2005 (SI 2005 No 2451), 2007 (SI 2007 No 293) and 2010 (SI 2010 No 745)
- The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (SI 2009 No 716), also known as CHIP
- The Export and Import of Dangerous Chemicals Regulations 2008 (SI 2008 No. 2108)

3.3. Intervention is necessary to:

- Meet, or continue to meet, the requirements of the EU Regulations for enforcement mechanisms, penalties, appointment of Competent Authorities and Designated National Authorities and introduction of cost recovery mechanisms for biocides;
- Simplify and streamline existing domestic requirements for them; and
- Meet a recommendation to consolidate biocides sectoral legislation made in Professor Ragnar Löfstedt's report, *Reclaiming health and safety for all: An independent review of health and safety regulation*.

3.4. Both the existing and new EU PIC Regulations require Member States to enforce their provisions with effective, proportionate and dissuasive powers. This will also ensure all exporters operate on a level playing field, and do not see competitors gain advantage by failing to comply with PIC. However, in the UK, apart from formal advisory letters, the existing SI (2008/2108) only gives inspectors the power to enforce the PIC Regulation by prosecution; there is nothing in-between. The proposal would give inspectors the additional power to issue an Improvement Notice (IN) or an Enforcement Notice (EN).

3.5. 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 more proportionate enforcement tools. Prosecution can then be properly reserved for persistent offenders or blatant non-compliance. This approach would be in line with other health and safety enforcement arrangements. Creating this wider range of enforcement tools should mean an increased likelihood that they will be used, thus strengthening the incentive for dutyholders to be compliant. Fifteen out of 16 respondents to consultation (see below) supported the introduction of INs and ENs; their comments included 'the proposal provides flexibility to allow enforcement action that is proportionate to the infringement' and 'the use of Enforcement Notices will result in a more and fair enforcement in future'.

3.6. On biocides fees, new legal provisions are required to enable HSE to

continue to recover its full costs for the services it provides under the new EU Biocides Regulation, as required by the EU Regulation and in line with Government policy. The new regulations also provide the opportunity to make some improvements to the system under existing legislation, in order to improve the transparency and predictability of costs of the system for businesses.

3.7. Regulation 14 of CHIP already provides for the enforcement of CLP. The rest of CHIP principally relates to transposition of Directive requirements which will become obsolete as the Directives in question are progressively replaced by the new CLP classification regime over the coming years. CHIP is already drafted such that its provisions will expire in line with the necessary transitional arrangements. The result of this in 2015 would be a vestigial set of Regulations establishing a few data retention requirements which would expire in 2018 and also for the enforcement of CLP – the latter provisions would need to remain in force going forward.

3.8. The UK also has a duty under CLP to appoint a competent authority, mirroring similar duties in other EU law, and notably in both the Biocides and PIC Regulations. A law is necessary for these domestic administrative arrangements to be made.

3.9. In order that the necessary competent authority can be formally appointed and to improve regulatory efficiency once the CLP transitional period has passed, HSE propose to move the remaining parts of CHP into the consolidating SI and repeal CHIP.

3.10. At the same time, a number of issues have been identified in the drafting of CHIP. HSE propose to take the opportunity of the ‘Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013’ (BPC) to make some minor changes to address these for the remaining years of the CHIP Regulations having effect.

4. Consultation

4.1. A public consultation on the proposed BPC Regulations ran for 6 weeks from 20 December 2012 to 31 January 2013. The consultation was publicised on HSE’s website, through HSE’s PIC and Biocides e-bulletins, through HSE’s stakeholder groups and forums on biocides and on industrial chemicals, and by email to all those companies known to export chemicals listed in Annex I of the Prior Informed Consent Regulation. In total, 20 responses were received from a cross-section of stakeholders.

4.2. The consultative document asked 12 questions about the proposals: 4 general questions and 4 questions each specifically about the proposals for both CLP and for PIC. Key outcomes of the consultation are:

- 11 out of the 16 respondents answering the relevant question agreed with the proposal to consolidate the seven SIs into one SI;
- 15 out of the 16 respondents answering the relevant question considered that the proposed enforcement provisions are ‘about right’;

- 11 out of the 16 respondents answering the relevant question agreed that there were no other impacts on industry that needed to be considered regarding the proposed consolidation
- 15 out of the 16 respondents answering the relevant question considered that inspectors should be able to issue 'notices' for infringements of the EU PIC Regulation;
- There was overall support for the proposed amendments to address legal issues in CHIP 4.

4.3. The PIC-specific questions asked about the need for INs and ENs and assumptions made in the preliminary economic analysis for the proposed enforcement changes. There were between 13 and 16 responses to each of the PIC questions.

4.4. A separate consultation took place between 25 February 2013 and 22 March 2013 on the proposals for biocides fees. A consultation letter was used, with communications targeted at all companies known to be currently liable for biocides fees, as well as through HSE's biocides e-bulletin, biocides webcommunity and stakeholder group. HSE received 10 responses, including three from trade associations representing a combined membership of over 250 companies. No significant issues were raised on the proposals which maintain the status quo on biocides fees and charges, while providing greater transparency of the fees structure with the inclusion of a table of fees in the proposed biocides fees SI. Only two general questions were asked, requesting that respondents provide any comments on the proposed fee structure and on any other issues raised in the consultation. One of the main themes emerging from the consultation was concern about the level of the fees and the impact on SMEs, with some responses indicating there may have been a belief that fees would go up. However, the proposed daily rates and the fee ranges estimated in the consultation document reflect current averages so do not represent an increase in current costs. Costs will continue to be calculated based on the actual amount of time taken to process each application, so as to implement full cost recovery in line with HM Treasury's document, Managing Public Money.

5. Microbusinesses exemption

5.1. As the need for these measures arises from EU requirements, they are outside the scope of the microbusiness moratorium.

6. Policy objective

6.2 The objectives of these proposals are to:

- To meet requirements in three EU Regulations for enforcement provisions, penalties and competent authorities / Designated National Authorities and, for biocides, cost recovery mechanisms;
- To consolidate the above requirements
- To ensure that suitably more proportionate enforcement mechanisms are in place for the PIC Regulation;

- To make biocides fees provisions as transparent and predictable as possible for businesses and to ensure these provisions meet the principles for cost recovery set out in HM Treasury's document, Managing Public Money.

7. Description of options considered (including do nothing)

Option 1: Do nothing

7.1. The 'do nothing' option is the baseline (status quo) where no changes are made to current enforcement mechanisms. This is the baseline against which other options will be compared.

7.2. Option 1 would mean that the relevant authorities could not enforce provisions of the Biocides Regulation, and that HSE could not continue to recover its costs under the new EU Biocides Regulation. This is because current provisions only apply enforcement and cost recovery mechanisms to duties and work carried out under the Biocidal Products Regulations 2001, not to the EU Regulation. Failure to revoke and replace current provisions could result in under-implementation, with associated possibility of EU infraction proceedings. There would be similar consequences if PIC enforcement were not enabled. CLP enforcement is however presently enabled under CHIP Regulation 14, and so the 'do nothing' option would not result in under-implementation of CLP in this regard.

7.3. Member States have a duty under all three EU regulations to appoint authorities to act as 'competent authorities' (CLP and Biocides) or 'Designated National Authorities' (PIC). In the case of Biocides and PIC the authorities effectively need to be re-appointed. For CLP, HSE operates as the *de facto* authority, having fulfilled this role in the legacy system; the necessary formal appointment of authorities has not yet been undertaken. The 'do nothing' option would result in failure to make the necessary administrative arrangements.

Note on 'do nothing' option for biocides fees

7.4. For biocides fees, the appropriate 'do nothing' counterfactual that has been assumed in this Impact Assessment is a situation where current cost recovery mechanisms are carried over without change to support the new EU Biocides Regulation. This is effectively a 'do minimum' option representing maintenance of the status quo, and is similar to a situation that would be maintained if the EU Directive were to continue and the direct-acting Regulation were not introduced. The work required under the new EU Regulation is equivalent to what is required now and the amounts recovered by HSE will not change.

7.5. An alternative do nothing option was also considered, where the UK did not revoke current legislation and replace it in line with the new EU Regulation. This would mean that when the EU Directive is revoked, the current domestic Biocidal Products Regulations would be retained, resulting in a direct legal conflict with the new EU Regulation. The UK would no longer have a legally appointed Competent Authority to regulate the industry and process authorisations, and cost recovery would no longer be able to take

place. In consequence it is likely that no new authorisations for biocidal products could be granted (thus these products would not be allowed to be placed on the UK market) and when current authorisations ran out, products would need to be removed from the market. Given that biocidal products are very widely used this is likely to be a very large impact reaching every industry in some form. Therefore if this alternative do nothing option were used, it would result in each option being considered appearing to have an extremely large benefit of allowing the biocides industry (and indirectly every other industry) to continue to operate in the UK. This would be unrealistic and misleading in assessing what are in effect small modifications to an existing cost recovery system.

7.6. For these reasons it has been considered that the most appropriate baseline option is for assessing impacts of the biocides new fees regulations is the "do minimum" scenario whereby HSE continues to act as competent authority and to recover its costs in full from the biocides industry. This means that the current domestic biocides legislation is revoked and replaced with equivalent legislation complying with the new EU Regulation so as to effectively maintain the status quo.

7.7. The same approach was used in the initial consultation stage Impact Assessment for biocides fees which received a Green opinion by the Regulatory Policy Committee (RPC12-HSE-1428 and RPC12-HSE-1428(2)).

Details of 'do nothing' counterfactual for biocides fees

7.8. Currently cost recovery for biocides operates according to two mechanisms: fees for specific applications and a General Industry Charge.

7.9. Fees for specific applications apply when a company or person applies for a particular service from HSE under the Biocidal Products Regulations 2001, such as authorisation of a biocidal product or approval of an active substance; or amendments thereto. Fees are calculated with reference to a time-recording system that records the time taken by each member of staff on the application. The full cost of that time is calculated on a case-by-case basis and charged to the applicant.

7.10. Businesses who market biocides are also currently liable for an annual General Industry Charge. This charge is a flat fee charged annually to liable businesses. The charge is intended to cover costs incurred by the competent authority that are not attributable to specific applicants. Such costs include maintenance of a website, provision of advice, environmental monitoring and other costs. The charge is also calculated annually and retrospectively with reference to HSE's work-recording system.

7.11. Under the current Regulations, the General Industry Charge is also charged to a small number of businesses who support active substances under the EU active substance review programme but do not market biocidal products (estimated at 5% of the approximately 560 companies currently eligible). However the new EU Regulation only allows Member States to levy annual fees in relation to biocidal products made available on their markets. This means there will be a small (~5%) reduction in scope of the GIC from 1 September 2013 since companies only supporting active substances will no

longer be liable. It should be noted that this reduction in scope applies under the status quo, since the change is necessitated by the EU Regulation which is already place.

7.12. Under the do nothing option the cost recovery mechanisms for biocides would remain as at present.

Option 2: revoke seven existing SIs and consolidate new provisions relating to biocides, PIC and CLP into one new SI, and specifically:

- Introduce new provisions to allow inspectors to issue notices for breaches of PIC
- Appoint Competent Authorities for CLP, biocides and Designated National Authorities for PIC
- Introduce a new fee structure for biocides based on daily rates published in the SI.
- Minor amendments to the CHIP Regulations to resolve some legal and administrative issues

7.13. We propose to revoke seven existing SIs that implement aspects of EU chemicals legislation relating to biocides, PIC and CHIP, consolidating the new provisions for biocides and PIC with existing provisions related to CLP into one new SI. It is proposed that biocides fees are incorporated into the existing Health and Safety (Fees) Regulations at the first available opportunity.

7.14. For CLP, PIC and biocides, the enforcement and biocides fees provisions to be carried forward into the new consolidated SI and biocides fees regulations will be substantively the same as those in existing legislation. Changes in the new consolidated SI and the new biocides fees regulations will be:

- New provisions to enable inspectors to issue Improvement Notices and Enforcement Notices in relation to PIC;
- Formal appointment of Competent Authorities for Biocides and CLP and Designated National Authorities for PIC (the Biocides Competent Authority and PIC DNAs are effectively being re-appointed);
- Minor amendments to the CHIP Regulations prior to their ultimate replacement, to resolve some temporary legal and administrative issues;
- Introduction of daily charging rates in a Schedule of the biocides fees SI to make biocides fees more transparent and predictable.

PIC enforcement

7.15. Presently, beyond sending an advisory letter to an exporter who has not complied with PIC, the only available PIC enforcement option is prosecution. This is inconsistent with other health and safety enforcement arrangements. HSE wishes to correct this and thereby permit more proportionate enforcement.

7.16. The proposal would maintain the existing enforcement arrangements for PIC and, additionally, provide inspectors with powers to serve an ‘Improvement Notice’ or an ‘Enforcement Notice’. The notices would 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.

7.17. Notices have proved to be an effective and proportionate approach under health and safety legislation and under the EU REACH Regulation (EC/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.

Appointment of competent authorities/Designated National Authorities

7.18. Competent Authorities and, in the case of PIC, Designated National Authorities (DNAs) will also be appointed. These arrangements will not substantively change the status quo because HSE de facto carries out Competent Authority functions for Biocides and CLP at present, however they are necessary to give Ministers formal authority to undertake the Competent Authority role (which will then be delegated to HSE through Agency Agreements). In the case of PIC, the existing SI 2008/2108 makes HSE and HSE NI Designated National Authorities, as will the proposed SI.

CHIP amendments

7.19. Under Option 2 some legal and administrative issues identified in Chemical (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP) will also be resolved.

7.20. CHIP implements two directives – the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD). Both are due to be repealed from 1 June 2015 by the European CLP Regulation. Consequently, CHIP is also due to be revoked from 1 June 2015 (those regulations/provisions that need to remain will be accommodated by the new BPC Regulations).

7.21. The CHIP Regulations 2009 (aka CHIP 4) were a result of an amendment to take account of the advent of REACH and the EU CLP Regulation. A number of issues have been identified in the drafting of CHIP 4, and HSE propose to take the opportunity of the BPC Regulations to make some minor changes to address these for the remaining years of the CHIP Regulations having effect.

7.22. The proposed changes are:

7.22.1. *Alignment of the penalties/sanctions to those available in schedule 2 of the ECA*

7.22.1.1. One of the key issues is an example of a more broad problem created by the Health and Safety Offences) Act 2008 (HSAO). HSAO resulted in inconsistent penalties for summary offences between SIs enabled under the Health and Safety at Work etc. Act 1974 (HSWA) and the European Communities Act 1972 (ECA).

7.22.1.2. The proposed BPC Regulations will resolve this inconsistency by

bringing all penalties into line with ECA Schedule 2 penalties. HSE are not aware of instances where this inconsistency has caused enforcement difficulties, and do not expect the proposed resolution to impact on business.

7.22.2. *Re-implementing advertising provisions for dangerous preparations*

7.22.2.1. The DPD stipulates that Member States should require 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.

7.22.2.2. The CLP Regulation is subject to lengthy transitional arrangements which ran up to 1 December 2010 for substances and will continue until 1 June 2015 for mixtures. Suppliers can, if they choose, apply the CLP Regulation ahead of these mandatory dates.

7.22.2.3. When the CLP Regulation entered into force, HSE believed that the advertising provision in CLP (Article 48) would follow these same transitional arrangements and apply immediately, and so deleted the relevant CHIP provision.

7.22.2.4. We now know this is not the case. Subsequent legal advice indicates that Article 48 is not subject to the transitional provisions and cannot be applied to mixtures (preparations) unless CLP itself is being applied ahead of the mandatory compliance date of 1 June 2015.

7.22.2.5. As a result HSE propose to re-establish the duty on GB chemicals suppliers selling DPD-classified mixtures to provide the relevant information.

7.22.2.6. Substances are already subject to CLP so, in practice, the provision would only relate to those dangerous preparations not already voluntarily classified according to the CLP system. Businesses who are selling chemicals which have been classified but who are not informing customers of this during remote-selling will be expected to bring themselves into compliance sooner than the full entry into force of CLP in June 2015. Businesses who have maintained their legal compliance with the provisions from earlier versions of CHIP, and who in any case are responsibly communicating hazard information to customers, will not be required to do anything.

7.22.2.7. HSE are not aware of suppliers activity taking advantage of the lacuna and expect that there will be no significant cost associated with making this correction.

Biocides fees

7.23. Under option 2 new biocides fees regulations will be introduced that incorporate some small changes in relation to the status quo. In relation to application related fees, costs will continue to be calculated on a case-by-case basis with reference to time taken by staff on each application, using HSE's work-recording system. However the costs will be calculated using daily rates for each relevant type of work, to be published in a Schedule of

the SI. There will be two daily rates (£447 for active substance related work, £393 for other work include biocidal product authorisation). The daily rates have been calculated using average rates for the relevant type of work based on the data from the most recent year to date (April 2012-January 2013). The different rates for active substance and biocidal product work reflects the fact that the former requires a greater proportion of scientific specialist time, which is chargeable at a higher rate. These rates differ from those used in HSE's Fees For Intervention (FFI) calculations because the mix of grades and specialisms are different between the two regimes. FFI is HSE's cost recovery scheme where those who break health and safety laws are liable for HSE's related costs for the required intervention.

7.24. The rationale for the change is to give added transparency and predictability to the fee structure for affected businesses by including a more detailed fee structure and specific charging levels in the Statutory Instrument.

7.25. Under option 2 the General Industry Charge will be maintained for an interim period, and so we are not reviewing it as part of these changes.

7.26. A number of further options were examined in the consultation stage impact assessment including a move to a 'modular' system for application fees (whereby a suite of fixed fees would be charged for individual packages of work required within an overall evaluation) and charging the General Industry Charge on a per-turnover basis rather than a flat fee. However following further consultation within Government it has been determined that these options are not viable at the present time and are therefore not considered further in this assessment. The fee system will be kept under review and further proposals to increase its transparency and efficiency, together with an appropriate supporting impact assessment, may be brought forward in due course.

8. Alternatives to regulation

8.1. An entirely non- or co-regulatory approach to enforcement would not be viable as it would not meet the requirements on Member States in the three EU Regulations in question.

8.2. Specifically:

8.2.1. The EU Biocides, PIC, and CLP Regulations place a duty on the UK to appoint authorities (variously 'Competent Authorities' or 'Designated National Authorities') to perform certain functions under these Regulations; and

8.2.2. The EU Biocides and PIC Regulations place a duty on the UK to put in place a system of official controls to enforce compliance and penalties that are effective, proportionate and dissuasive. The EU CLP Regulation establishes a similar duty which is already fulfilled in the UK by Regulation 14 of CHIP - the present proposal is to consolidate this provision into the new BPC Regulations in due course.

8.3. However, alternatives to regulation are taken into account in this policy approach. Behavioural theory which tells us that people are 'influenced by the way choices are presented to them', and that they care about fairness

and reciprocity.[4]

8.4. The policy decision to provide PIC enforcing officers with more proportionate enforcement tools (i.e. the option of issuing a legally forceful notice rather than an advisory letter or pursuing prosecution) benefits from both insights. The legally forceful nature of a notice can be expected to result in the desired behaviour change more readily than a less formal enforcement action. At the same time, this proposal seeks to provide proportionate means to secure compliance in addition to advice/encouragement and prosecution. The use of enforcement notices should be more fair and could also result in more effective enforcement of PIC breaches, with correlated reciprocity gains against non-compliant dutyholders. In practice, as indicated in para 10.2.1.2.4, we doubt more than two notices for PIC would be issued each year, each should nonetheless serve to reinforce their value as a deterrent.

8.5. In order to have these effects, the power to issue enforcement notices will need to be given effect in law. The proposal draws on established powers used successfully in similar circumstances for the regulation of chemicals.

8.6. In relation to biocides fees, it is both a requirement of the EU Biocides Regulation and Government policy that services provided to biocides applicants should operate on the basis of full cost recovery. Fees regulations are required to give HSE the legal power to charge in order to implement full cost recovery. A non-regulatory approach would not be feasible.

9. One In, Two Out (OITO)

9.1. In the pre-consultation IA, it was thought there would be very small 'in' under OIOO for PIC. However, new guidelines for OITO have made clear that as these proposals are to meet EU requirements, they are therefore outside the scope of OITO. It should also be borne in mind that these proposals will give rise to no additional costs for compliant exporters

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

10.1. *General Assumptions*

10.1.1. The year of analysis is 2013.

10.1.2. 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)[5] and uprating by 30% to allow for non-wage costs (in accordance with the Green Book).

10.1.3. Figures presented in this IA 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.

[4] 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-be-interested

[5] See http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-200444

10.2. *Costs*

Option 1: do nothing

10.2.1. Under option 1 no changes are made to the status quo so no costs arise.

Option 2: revoke seven existing SIs and consolidate new provisions relating to biocides, PIC and CLP into one new SI, specifically:

- Introduce new provisions to allow inspectors to issue notices for breaches of PIC
- Appoint competent authorities/DNAs for CLP, biocides and PIC
- Introduce a new fee structure for biocides based on daily rates published in the SI
- Minor amendments to the CHIP Regulations to resolve some legal and administrative issues

10.2.1.1. **Costs to dutyholders**

10.2.1.1.1. **PIC background and labelling requirements**

10.2.1.1.2. Changes to PIC enforcement 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 a PIC Designated National Authority (DNA) of an export and, 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 export notification responsibilities under PIC and over the last three last years, approximately 400 notifications were made per annum. Additionally, the PIC Regulation requires exports of all hazardous substances to non-EU countries to be packaged and labelled in accordance with internal EU requirements unless these would conflict with any specific requirements of the importing country. Whilst the latter requirement potentially affects a larger number of exporters, ie not only those specifically listed in the annexes to the PIC Regulation, the duty is the same as under the existing PIC Regulation, so no additional costs arise.

10.2.1.1.3. Any additional costs for business would be faced by non-compliant exporter making their administrative response to an IN / EN, not what they must do to comply with the PIC Regulation.

10.2.1.2. **Administrative response to proposed PIC Improvement and Enforcement Notices**

10.2.1.2.1. When a non-compliant dutyholder receives an IN or EN, they will need to carry out the improvements suggested. These form part of the normal costs for compliance with the PIC Regulation and such associated costs are therefore beyond the scope of this impact

assessment.

10.2.1.2.2. However, additional activities like reading the IN/EN and communicating to HSE that the changes have been made, will give rise to a small cost. The consultation asked respondents about the additional time this would involve; six agreed with HSE's original estimate of 30 minutes, but eight did not. Although most of those who disagreed did not suggest an alternative time, a few indicated that it could take between 45 to 90 minutes. After careful consideration of the responses provided, we have concluded that approx 60 minutes is needed to deal with the IN/EN, which would include advising HSE that the conditions of a notice have been met, and for any internal discussions e.g. possibly obtaining approval before notifying HSE. Assuming an average opportunity cost per hour of £30, based on the average salary for the UK[6], this would represent costs of £30 for a dutyholder.

10.2.1.2.3. This is an upper estimate of opportunity cost as it is expected that there would already be some level of communication between the dutyholder and the competent authority at present. However, this will be informal compared to the formal communication with respect to an IN/EN.

10.2.1.2.4. Over the last five years, there have been fewer than half a dozen formal advisory 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 two IN/EN cases per annum. With 2 cases per year, this amounts to an annual cost of £60 for administrative responses to INs / ENs by non-compliant dutyholders.

10.2.1.2.5. 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 disputes and in any case no formal dispute process exists. We have looked at what percentage of the approx 5000 INs 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 that 1%. The dispute process takes on average 14 hours of a dutyholders time (including time for attending an Employment Tribunal). Using the average opportunity cost per hour of £30, disputes will cost approximately £420 for dutyholders. If we assume that 1% of IN/ENs are disputed (i.e. the expected annual cost), there would be a cost to dutyholders in the region of £8 per annum.

10.2.1.2.6. Combining the two costs above amounts to an annual cost of less than £500 to dutyholders. Given the cautious approach taken, this is deemed an upper limit of cost. This is therefore deemed to be a negligible cost to industry.

10.2.1.3. **Additional costs as a result of use of proposed PIC Enforcement**

[6] Source: Annual Survey of Hours and Earnings, ONS, 2011. Includes an additional 30% to account for non-wage costs.

Notices

10.2.1.3.1. 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), there is a possibility that a non-compliant dutyholder may incur additional transport and storage costs.

10.2.1.3.2. 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. 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 an exact estimate for this cost.

10.2.1.3.3. The consultation asked whether the introduction of notices would lead to any additional costs or savings for businesses, for example, transport or storage costs. Seven respondents answered that it would lead to additional costs and seven answered that it would not. However, none of them suggested what these costs might be. We have therefore been unable to quantify this and it remains an uncertainty of our calculation.

10.2.1.3.4. **Biocides fees**

10.2.1.3.5. The major change under Option 2 will be a move to calculating application-specific fees using daily rates for the specific type of application covered, rather than with reference to individual rates for each member of staff who works on the application (as is the case under the status quo).

10.2.1.3.6. On average the change should not affect costs to applicants because the daily rates were calculated on the basis of average costs for the type of application involved over the most recent year to date. Separate rates have been calculated for work on evaluating active substance applications and related tasks and for work on authorising biocidal products since these categories differ in the amount of specialist scientific resource involved and therefore in respect of the cost per day. Within the two categories there is little variance in costs so it has been decided not to break these rates down further.

10.2.1.3.7. There is the possibility that in individual cases the cost calculated under the status quo could vary slightly from the cost calculated according to the new daily rates. The maximum variance between Option 1 costs and Option 2 costs is around 6% and could vary in either direction.

10.2.1.3.8. Due to the way the daily rates have been calculated (as average costs for each type of application for April 2012 – January 2013), any deviations will in any case average out across the range of applicants as a whole.

10.2.1.3.9. Several responses to consultation indicated or suggested a belief that

application fees would go up under the new regulations. However this seems to have been based on a misunderstanding since under Option 2 costs will continue to be calculated based on the actual amount of time taken to process applications, based on daily rates based on current average costs for the type of application in question. No substantive evidence was provided to indicate that costs would rise.

10.2.1.3.10. Overall, it is therefore estimated that Option 2 will not to lead to additional costs to businesses compared with the status quo.

10.2.1.4. **Familiarisation**

10.2.1.4.1. Familiarisation costs for business are expected to be negligible. No new duties are proposed for businesses, and there should be no need for Biocides, PIC or CLP Regulations dutyholders to familiarise themselves with the proposed administrative arrangements in relation to enforcement, penalties and appointment of Competent Authorities/DNAs.

10.2.1.4.2. Earlier impact assessments considered the possibility of the need for dutyholders to familiarise themselves with the procedure to follow in the event of being issued with an IN or EN. However, further consideration has shown this to be unnecessary, as a compliant business will have no need to be familiar with these procedures, and a non-compliant business will be made familiar with the necessary information as part of the IN/EN serving procedure.

10.2.1.4.3. In relation to biocides fees, companies wishing to apply to authorise a biocidal product or approve an active substance will need to consult the fees to determine the likely cost of their application, but they would need to do this in any case under the status quo. Biocides companies also operate more generally in a complex regulatory environment and have to spend time keeping abreast of frequent regulatory updates (for example decisions on approvals/withdrawals of active substances).

10.2.1.4.4. The changes being proposed to biocides fees also do not in any case substantially affect the amount of money companies are going to be charged as compared with the status quo (see 10.2.1.3.3.) and other changes to the fee structure are relatively minor.

10.2.1.4.5. No response to the consultation gave any evidence that there would be any familiarisation costs for the new fee structure or raised concerns on this point.

10.2.1.4.6. It is therefore estimated that any familiarisation required can incorporated by affected companies as part of their usual work in keeping abreast of biocides regulatory developments and that costs compared with the status quo are zero.

10.2.1.5. **Impact on number of PIC prosecutions**

10.2.1.5.1. No new duties or offences are created by these proposals and 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 IN/ENs for PIC is, therefore, not

expected to change significantly the number of prosecutions and its impact on the justice system will be marginal.

10.2.1.6. **Costs to HSE**

10.2.1.6.1. For PIC there would be costs to HSE in terms of implementing the new arrangements and the resources to process notices and disputes. 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 the EN process created under the domestic REACH Enforcement Regulations 2008 (SI 2008/2852) to support the European Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006. So inspectors are unlikely to require much additional information.] The introduction of INs / ENs in this area will create an opportunity cost of HSE staff time, but this is expected to be small.

10.2.1.6.2. For biocides fees the revised fee arrangements will use the same time recording system and other administrative mechanisms as under the status quo and changes required to administrative processes will be minimal. Therefore both up-front and ongoing implementation costs to HSE are expected to be negligible.

10.3. **Benefits**

10.3.1.1.1. HSE Research[7] 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.

10.3.1.1.2. We expect that the possibility of an IN/EN being issued would provide an incentive to dutyholders who might otherwise not comply with PIC requirements to do so, reducing overall exposure to environmental and health and safety risk, but it is not possible to quantify this. A respondent to the consultation said: 'the ability to issue notices should also ensure that no commercial advantage is taken by less responsible suppliers'.

10.3.1.1.3. In relation to biocides fees, we expect there to be a benefit from increased transparency and accountability of the fees system under Option 2 compared with Option 1, given that daily rates will now be published and set in legislation. One consultation respondent welcomed the increased transparency in the Option 2 proposal and it was clear from questions raised by other respondents that being able to predict fee levels for different types of application was a major concern for biocides companies. However it is not proportionate to quantify this

[7] Research report: "Linking HSE Activities to Health and Safety Outcomes: A Feasibility Study". http://www.hse.gov.uk/research/rrhtm/rr913.htm

benefit.

11. Rationale and evidence that justify the level of analysis used in the IA (proportionality of approach)

11.1. The analysis presented identifies the impacts of the proposals for biocides, CLP and PIC, including introducing the power of INs and ENs for PIC. It quantifies and monetises these impacts, where possible, based on current available research and data. HSE has not deemed it proportionate or accurate to refine estimates beyond what is presented in this IA.

12. Risks and assumptions

12.1. Formal and informal consultation was used to make the improvements for the final stage IA. Assumptions on familiarisation were tested through consultation. They were also triangulated with internal research on the length of time to read guidance and assumptions tested in other impact assessments. There was also an intention to develop case studies on the costs of transport and storage. However, replies to the consultation provided no clearer understanding of costs or any examples. Therefore, this remains an uncertainty in our calculations.

12.2. In addition to the assumptions, there are some risks and uncertainties around the assumptions that we have made. There are also elements of the proposal that will remain untested until the changes are actually in place – specifically in terms of behaviour and, for example, the number of INs and ENs served under PIC and appeals against them, or whether there are any additional costs or savings to business from the introduction of notices (see 10.2.1.3.3 above). Although we have tried to reduce these uncertainties, it has not been possible to eliminate these completely in our calculations. However, these uncertainties are likely to be small.

12.3. In relation to PIC, 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 is likely to be far higher than the costs of dealing with an IN/EN.

12.4. In relation to Biocides, the analysis assumes that there are no external reasons to believe that the import/export of chemicals or biocides volumes will change significantly, as the regime introduced by the Biocidal Products Directive is substantively maintained under the EU Biocides Regulation.

13. Summary and preferred option with description of implementation plan

13.1. The preferred option is Option 2.

13.2. The Biocides part of the proposed measures will apply from 1 September 2013. We have already begun to make dutyholders aware of them through the biocides e-bulletins and the biocides web pages on the HSE website, and will continue to do this as well as developing the biocides web community pages to include relevant information on the changes. We are

also considering holding a stakeholder event later in 2013 to describe the main changes brought about by the EU Biocides Regulation.

13.3. The PIC part of the proposed measures, including the additional enforcement measures in this IA, will apply from 1 March 2014. Although the measures do not change the duties of dutyholders, we shall make them aware of the new enforcement tools. This will be done 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.

13.4. For CLP, the part of the proposed measures appointing competent authorities will come into effect from 1 September 2013. It will be necessary for HSE to sign 'agency agreements' with the bodies formally appointed as competent authorities in order to formalise the present *de facto* operation of these responsibilities by HSE as required by the EU CLP Regulation. This will have no bearing on UK businesses. The part of the proposed measure relating to CLP enforcement will come into effect in June 2015 to match the planned demise of CHIP. HSE are revising the classification website to improve accessibility and reflect the transition from CHIP to CLP, and also engage with trade associations and other stakeholders by direct meetings and support, telephone helplines and specialist consultation groups.

Annex 1 – Regulatory Policy Committee Assessment

Regulatory Policy Committee	**Validation of the One-in, Two-out Status and the Net Direct Impact on Business**
Validation Impact Assessment (IA)	UK Implementation of aspects of EU chemicals legislation – biocides; export and import of hazardous chemicals (PIC); and classification, labelling and packaging of chemicals (CLP)
Lead Department/Agency	Health and Safety Executive
IA Number	
Origin	European
Expected date of implementation (and SNR number)	1 October 2013
Date of Regulatory Triage Confirmation	16/10/2012
Date submitted to RPC	03/05/2013
Date of RPC Validation	03/06/2013
RPC reference	RPC13-HSE-1787
Departmental Assessment	
One-in, Two-out status	OUT of SCOPE (EU)
Estimate of the Equivalent Annual Net Cost to Business (EANCB)	Not applicable
RPC assessment	**VALIDATED**

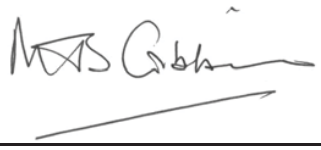
Background (extracts from IA)

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

Direct-acting EU regulations apply to certain biocidal products and chemicals, ensuring common standards apply across the Union. A new EU Regulation on biocides (EU) 528/2012 (the Biocides Regulation) applies from 1 September 2013 and a new EU Regulation on the export and import of hazardous chemicals (EU) 649/2012 from 1 March 2014 (the 'PIC' Regulation). Intervention is necessary in order to ensure the UK continues to meet EU requirements of these, to simplify and streamline existing domestic requirements for them and to meet a Lofstedt recommendation to consolidate biocides sectoral legislation.

What are the policy objectives and the intended effects?

A Statutory Instrument would provide supporting domestic legislation for the Biocides Regulation and the PIC Regulation covering enforcement arrangements and appointing competent authorities. These would be combined with similar existing provisions for the EU Regulation on the classification, labelling and packaging of chemicals ((EU) 1272/2008). It would also provide more proportionate PIC enforcement powers, resolve some legal & administrative issues in the Chemical (Hazard Information & Packaging for Supply) Regulations 2009 and enable HSE to continue to recover its costs by charging fees for some biocides activity, the aim being to incorporate provisions for these into existing Health and Safety (Fees) Regs.

RPC comments As this is an EU measure with no evidence of gold-plating, it is out of scope of One-in, Two-out (Better Regulation Framework Manual 2.9.8 ii). As this EU measure has been cleared for the fast track, validated as a low cost measure, no EANCB figure is required.		
Signed		**Michael Gibbons,** Chairman

PART II

NORTHERN IRELAND COSTS AND BENEFITS

THE BIOCIDAL PRODUCTS AND CHEMICALS (APPOINTMENT OF AUTHORITIES AND ENFORCEMENT) REGULATIONS (NORTHERN IRELAND) 2013

AND

THE BIOCIDAL PRODUCTS (FEES AND CHARGES) REGULATIONS (NORTHERN IRELAND) 2013

General

1. The Department of Enterprise, Trade and Investment is of the opinion that the analysis and considerations set out in the Great Britain Impact Assessment can be applied to Northern Ireland.

Costs

2. Based on the Great Britain impact assessment, it is anticipated that the Regulations will impose no additional costs on dutyholders.

Benefits

3. The introduction of the new Regulations will simplify and streamline current legislation. A benefit is also anticipated in relation to biocides fees in terms of increased transparency and accountability of the fees system given that daily rates will now be published and set in legislation.

Conclusion

4. There is no alternative to the introduction of revised Regulations in order to meet, or continue to meet, the requirements of the EU Regulations for enforcement mechanisms, penalties, appointment of Competent Authorities and cost recovery mechanisms for biocides. Failure to revoke and replace current provisions could result in under –implementation of the EU Regulations with associated possibility of EU infraction proceedings.