**Post Implementation Review report**

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

## Post Implementation Review Report

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| **Title:** Review of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regs | Post Implementation Review |
| | **Date:** 21/08/2018 |
| **Lead department or agency:** HSE | **Type of regulation:** EU |
| | **Type of review:** Statutory |
| **Other departments or agencies:** HSE NI | **Date measure came into force:** 01/09/2013 |
| | **Recommendation:** Not relevant |
| **Contact for enquiries:** Andrew Maxey | **RPC Opinion:** Not relevant |

**Contents**



**URN: BIS/16/258**

# Executive summary of the Post Implementation Review of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (S.I. 2013/1506)

## Introduction

1. This document provides an overview of the Post Implementation Review (PIR) of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (BPC).

2. Attached to this covering paper are the associated PIR, along with evidence sources (Appendix 1) and evidence summary (Appendix 2). This provides the Government's views on the effectiveness of the Regulations and whether they achieved their policy aim.

## Background

3. The BPC Regulations support the directly-acting EU Biocidal Products Regulation EU No 528/2012 (BPR), Classification, Labelling and Packaging for substances and mixtures Regulation EU No 1272/2008 (CLP), and the Export and Import of Hazardous Chemicals Regulation EU No 649/2012 (commonly known as PIC), in that they cover domestic enforcement arrangements, penalties and the appointment of competent authorities (for BPR and CLP) and designated national authorities (for PIC).

4. HSE reviewed the biocides aspects of BPC in 2016 and the CLP and PIC aspects of BPC in 2017.

## Findings

5. The PIR falls under the *de minimis* threshold of £5m and therefore does not require verification by the Regulatory Policy Committee.

The main points that came out of the BPC PIR are:

- the original impact assessment (IA) identified that the BPC Regulations impose minimal costs on businesses;
- there is no evidence that the original IA assumptions are not still relevant and no intelligence of costs that the IA did not consider;
- while we adopted a proportionate approach to the review, the evidence base is considered sufficiently robust;
- there were no significant lessons or changes or areas for simplification identified by the review;
- no changes are needed to BPC as a result of this review.

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**Post Implementation Review**

1. **What were the policy objectives and the intended effects? (If policy objectives have changed, please explain how).**

The aims of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (BPC) were for the UK to meet the EU requirements set out in the Biocidal Products Regulation (EU) 528/2012 (BPR), simplify and streamline domestic arrangements and meet a Löfstedt recommendation to consolidate biocides sectoral legislation.

The original policy objectives, set out in the final impact assessment for BPC, were:

- **Objective One**: meet requirements in three EU Regulations for enforcement provisions, penalties and competent authorities/Designated National Authorities and, for biocides, cost recovery mechanisms;
- **Objective Two:** consolidate the above requirements;
- **Objective Three:** ensure that, by introducing the option of serving notices, in addition to instigating prosecutions, suitably more proportionate enforcement mechanisms were in place for the Export and Import of Hazardous Chemicals Regulation (known as Prior Informed Consent or PIC); and
- **Objective Four:** make biocides fees provisions as transparent and predictable as possible for businesses and to ensure these provisions met the principles for cost recovery set out in HM Treasury's document *Managing Public Money*.

This is a statutory review of a Statutory Instrument providing supporting domestic legislation for the Biocidal Products Regulation (BPR), Classification, Labelling and Packaging for substances and mixtures Regulation (CLP) and Prior Informed Consent (PIC) Regulation covering enforcement arrangements and the appointment of competent authorities (for BPR and CLP) and designated national authorities (for PIC).

While it was originally intended that biocides fee provisions would form part of BPC, they were detached and dealt with in a separate SI. They have since been incorporated into the Health and Safety and Nuclear (Fees) Regulations 2015.

2. **Describe the rationale for the evidence sought and the level of resources used to collect it, i.e. the assessment of proportionality.**

The expectations in the impact assessment (IA) were that the costs to business would be negligible, in terms of familiarisation and changes in fees. The full IA subsequently estimated that there would be no net cost to business. This was signed off on 18 June 2013 and published at: http://www.legislation.gov.uk/ukia/2013/45/pdfs/ukia_20130045_en.pdf. We have found no compelling evidence in this review to contradict the IA and the PIR therefore falls under the *de minimis* threshold of £5m and therefore does not require verification by the Regulatory Policy Committee.

Part of the cost of the Regulations would be any costs arising for HSE and for dutyholders of the issuing, responding to and disputing of improvement notices. The IA estimated that there would be no more than two improvement notices issued per annum, and there was a less than one per cent chance of dispute'. No such notices have been issued, therefore the costs of issuance and dispute are nil.

The PIR guidance suggests a light touch PIR is proportionate for such regulations. Therefore, the primary evidence sought was aimed at determining whether the Regulations had met their objectives, identifying any unintended consequences and understanding how the implementation of the Regulations could be improved.

**3. Describe the principal data collection approaches that have been used to gather evidence for this PIR.**

There was sufficient documentary evidence available to demonstrate that the Regulations achieved the aims of meeting the requirements in BPR on enforcement, penalties, CAs/ DNAs and biocides cost-recovery mechanisms; meeting the Löfstedt recommendation to consolidate biocides legislation, simplifying and streamlining domestic legislation; making PIC enforcement more proportionate; making biocides fees transparent and predictable and to making biocides fees compliant with Managing Public Money (see Appendix 1).

To identify any unintended consequences and understand how the implementation of the Regulations could be improved, HSE also sought qualitative evidence from businesses affected by the Regulations, reviewed available existing relevant data sources and consulted with enforcing authorities. For biocides elements of the PIR, this consisted of:

- A consultation with HSE inspectors and legal advisors;
- E-mail correspondence with 40 competent authorities, which attracted 5 responses, 3 of which were nil responses;
- Evidence gathered via crowdsourcing: a link to a survey containing questions was sent out to 27,000 subscribers to HSE biocides e-bulletins, which attracted 36 responses: 22 were manufacturers or suppliers; 6 were manufacturer/supplier and users and 8 were users only.

For the CLP and PIC elements of the PIR, research consisted of:

- An interview and written submission with HSE's Chemicals Regulation Division (CRD) Enforcement Team;
- A letter sent to HSE's internal stakeholders and enforcement partners;
- A survey on the CLP aspects sent directly to stakeholders identified by the CRD policy team, which attracted 30 responses: 15 manufacturers, importers or downstream users responsible for classifying substances and mixtures placed on the market; 2 suppliers responsible for labelling and packaging substances and mixtures placed on the market; 3 combination of supplier/manufacturer/user roles and 7 other - 4 consultants; one who responded out of 'academic interest'; one trade association; and one REACH consortium manager;
- A survey on the PIC aspects of BPC was sent to around 30 PIC stakeholders, which attracted six responses: one from an importer of hazardous chemicals covered by the BPC Regulations; one from a respondent who was both an importer and exporter of hazardous chemicals covered by the BPC Regulations; others were NEBOSH, a health and safety engineer, a chemical cleaning station; and health and safety in commercial port.

The combined evidence has been used to answer the various research questions. More detail can be found in the evidence summary at Appendix 2.

**4. To what extent have the regulations achieved their policy objectives? Have there been any unintended effects?**

- **Objective One: Achieved.** The BPC proposals for meeting requirements in three EU Regulations for enforcement provisions, penalties and competent authorities/Designated National Authorities and, for biocides, cost recovery mechanisms were shared with the EU Commission and received no negative feedback. N.B. The definition of 'serious harm' within CLP does not cover environmental damage. However, other legal means exist to enforce on environmental damage, and no negative feedback on the CLP enforcement provisions has been given by HSE's legal advisers and enforcement partners during consultation nor by the EU Commission.
- **Objective Two: Achieved:** The final published progress report on implementing the recommendations for improving health and safety law in Professor Löfstedt's report *Reclaiming health and safety for all* included an evaluation of the BPC consolidation which concluded that the provisions in seven Statutory Instruments for enforcement and appointment of national authorities for various European laws on biocides and hazardous chemicals had been consolidated. (https://www.gov.uk/government/collections/improving-health-and-safety-progress-reports);
- **Objective Three: Achieved**: Had BPC not come into force the relevant authorities would not have been able to enforce provisions of the EU PIC (including Article 18, which required Member States to make necessary arrangements for official controls to enforce compliance and for monitoring exporters' compliance). A Memorandum of Understanding (MoU) is in place between HSE, HSENI, HMRC (Customs Directorate) and Border Force - to provide a framework for enforcement at the border, with a Single Point of Contact, and for liaison, collaborative working and sharing of information, The introduction of notices to secure compliance under PIC has benefited industry by providing more proportionate enforcement tools, so that prosecution can then be properly reserved for persistent offenders or blatant non-compliance. This approach is in line with other health and safety enforcement arrangements
- **Objective Four: Achieved.** Correspondence with the Treasury on 11 June 2013 confirmed that the biocides fees provisions met principles for cost recovery set out in HM Treasury's document *Managing Public Money.*

A small number of respondents to the crowdsourcing claimed there had been unintended effects of the biocides and CLP elements of the Regulations. However, the examples were almost exclusively related to the BPR, CLP and PIC regimes themselves rather than being related to the BPC Regulations. The results of the survey on CLP aspects of BPC came too late for an EU REFIT fitness check of chemicals regulation (excluding REACH). Reports on the implementation of direct-acting regulations tends to be five-yearly but the UK will have left the EU by the time of the next such reports: the Biocides report is due in 2020 and one on CLP enforcement is due in 2022.

**5a. Please provide a brief recap of the original assumptions about the costs and benefits of the regulation and its effects on business (e.g. as set out in the IA).**

The IA estimated that there would be zero financial costs and benefits on industry. No new duties were proposed for businesses, so there were no resulting compliance costs and hence minimal need for BPR, PIC or CLP legislation dutyholders to familiarise themselves with the proposed administrative arrangements in relation to enforcement, penalties and appointment of Competent Authorities/DNAs.

The key predicted non-monetised benefits of BPC are that by streamlining legislation it would reduce the perception of health and safety legislation as over-burdensome and complex, and that bringing enforcement in line with other enforcement mechanisms in HSE would increase the fairness and proportionality of enforcement.

**5b. What have been the actual costs and benefits of the regulation and its effects on business?**

The actual costs to business are minimal. There is no evidence that the assumptions made in the original IA are not still relevant, and HSE has received no intelligence of additional costs that the IA did not consider. Familiarisation costs were broadly agreed to be negligible, although one survey respondent felt that this would vary with 'Company size, training budget and expertise available. [Costs were] Negligible to large companies but potentially significant to SMEs' and Chemicals Regulation Division (CRD) Enforcement Team raised the costs of familiarisation of companies weighing up the options of whether to continue their operations. There is some evidence that a minority of producers and users of chemicals have taken a commercial decision to cease producing certain biocidal products or changed their formulation, or that they have been unable to purchase these. Analysis reveals that this is for reasons such as the costs or time taken to get approval for specific substances, and is therefore the result of the wider BPR, CLP and PIC legislation.

**6. Assessment of risks or uncertainties in evidence base / Other issues to note**

**We are satisfied that the evidence base is proportionate, yet sufficiently robust. However, there were some issues to note:**

- CRD Enforcement Team has requested Enforcement Notice (EN) powers for the CLP and Biocides elements of BPC, as already exists for PIC. However, the EN provision has not been in fact used for the other aspects of the Regulations.

- Within CLP the definition of 'serious harm' does not include environmental damage. Although it is sometimes possible to enforce using other regulations, or use incomplete Safety Data Sheets under REACH (Annex II, Article 31) to enforce. While this is a sub-optimal workaround and not ideal from an enforcement perspective, it is still in line with our legal duties and delivers on the stated objective.

- The CRD Enforcement Team observed that enforcement in territorial waters is handled differently between Biocides, PIC and CLP, arguing that consistency between the Regulations would be beneficial from an enforcement perspective as this would reduce time spent by the team having to review each regulation separately.

However, these are unlikely to warrant high priority in the near future, as there would typically need to be a risk of actual serious harm: the low level of actual enforcement suggests this is not the case. Moreover, as the purpose of the Regulations is to enable the enforcement of direct-acting EU legislation, the BPC will need to be adapted as part of the UK's preparations to leave the EU. As such the provisions of the BPC Regulations are unlikely to attract any priority consideration at the current time, beyond ensuring that the ability to ensure retained EU chemicals legislation remains in place alongside the cited penalties.

**7. Lessons for future Impact Assessments**

The PIC IA gave a monetary value for the cost of implementing the relevant enforcement tools, whereas CLP IA did not. It would have been helpful to have a consistent approach

CRD Enforcement Team also argued that future IAs would be more rigorous if they reflected the likely potential variation in the monetisation estimates for regulators, depending on the breach identified.

**8. What next steps are proposed for the regulation (e.g. remain/renewal, amendment, removal or replacement)?**

Despite the request for the introduction of an EN and the two issues identified by the CRD Enforcement Team, the small number of breaches identified are predominantly technical. Based on the risk gap and relative priority therefore, HSE does not propose changes in the BPC legislation beyond those essential to EU exit.

**9. For EU measures, how does the UK's implementation compare with that in other EU member states in terms of costs to business? (Maximum 5 lines)**

ECHA data on authorised biocidal products and product-type combinations comparing the UK to other Member States (MS) shows a higher number of licences granted in the UK: 624, compared to the next highest number of authorisations, 534) than in any other MS (as of 14/05/2018). Additionally, the UK plans to keep rodenticides on the market because of the existence of a specific voluntary stewardship scheme, although other MSs have chosen to allow only professional uses of these.

**Appendix 1**

## Evidence sources

### E-mail consultation with BPC Competent Authorities

On 7 March 2016 HSE emailed some 40 contacts representing UK competent authorities or bodies with an interest in enforcing BPC. Main recipients included CRD's Enforcement Team, LGA, ORR, Scottish Government and Welsh Government. Copy recipients included EA, FSA, MHRA, Natural England and Natural Resources Wales.
Five responses were received by 4 April 2016, three of which (LGA, MHRA and ONR) were nil returns. The substantive replies were from ORR and Scottish Government. After the close of the survey, a late response was received from Natural England.

### Survey of Environmental Health Officers (EHO) and Trading Standards Officers (TSO).

On allocation of enforcement responsibility, BPC specifically mentions two other bodies: the local authority and the local weights and measures authority. In view of the nil return from LGA it was decided to undertake one more survey aimed at filling this gap in HSE's knowledge, to seek any views from the next section details the results of this additional work.
HSE conducted a separate short survey of EHOs and TSOs involved with biocidal products enforcement. This was done through HSE's HELA Extranet (around 6,000 contacts). The survey opened on 8 April and closed on 22 April 2016. It attracted no responses and so there are no supplementary findings to those indicated by the survey of CAs and enforcement bodies reported on above. As a final attempt to get views from a TSO, HSE emailed a personal operational contact that should be aware of possible enforcement of BPC by TSOs. This resulted in one late reply to the effect that they had searched their files and found only one case involving an LA prosecution over biocides. But this prosecution related to a shopkeeper who covered up the sale of a biocidal product after a suicide, the perversion of justice issue being dealt with by the police.

### Consultation with PIC enforcement Agencies

A letter about PIC aspects of BPC was sent to 4 partner enforcement authorities and received 3 responses - from CRD Enforcement Team, Border Force Operational Policy (Home Office) and HSE Northern Ireland (HSENI).

### Consultation with CLP enforcement partners

A letter was sent to 30 respondents. 3 nil returns were received from the Maritime and Coastguard Agency (MCA), Medicines and Healthcare products Regulatory Agency (MHRA) and HSENI, with substantive responses received from the CRD Enforcement Team, Welsh Government and The Chartered Trading Standards Institute (CTSI).

### Crowdsourcing views of BPC stakeholders

Evidence gathered via crowdsourcing: a link to a survey containing questions was sent out to 27,000 subscribers to HSE biocides e-bulletins, which attracted 36 responses: 22 were manufacturers or suppliers; 6 were manufacturer/supplier and users and 8 were users only.

### Survey of CLP stakeholders

A survey on the CLP aspects sent directly to stakeholders identified by the CRD policy team, which attracted 30 responses: 15 manufacturers, importers or downstream users responsible for classifying substances and mixtures placed on the market; 2 suppliers responsible for labelling and packaging substances and mixtures placed on the market; 3 combination of supplier/manufacturer/user roles and 7 other - 4 consultants; one who responded out of 'academic interest'; one trade association; and one REACH consortium manager.

**Survey of PIC stakeholders**

A survey on the PIC aspects of BPC was sent to around 30 PIC stakeholders, which attracted six responses: one from an importer of hazardous chemicals covered by the BPC Regulations; one from a respondent who was both an importer and exporter of hazardous chemicals covered by the BPC Regulations; others were NEBOSH, a health and safety engineer, a chemical cleaning station; and health and safety in commercial port.

**Interviews with HSE Inspectors**

Group interviews were carried out with relevant teams of HSE inspectors to discuss biocides elements (meeting on 18/11/15) and CLP and PIC elements (10/05/2017).

**HSE administrative data**

Data requested on numbers of prosecutions, INs and ENs issued.

**Documentary Review**

Review of original IA, Legislative text and correspondence received about the BP and ECHA data on product authorisations.

## Mapping of Evidence Sources against Research Questions:

| Question | Evidence Source: Interview with Inspection team | Consultation with Competent authorities / Enforcement partners | Biocides stakeholders survey | CLP stakeholders survey | PIC stakeholders survey | HSE administrative data | E-mail consultation with Regulatory Training Programme providers | Desktop review |
|---|---|---|---|---|---|---|---|---|
| Do HSE inspectors have sufficient legal powers to enforce? | X | X | | | | X | | |
| Did the policy meet the requirements in the EU BPR in relation to enforcement? | X | X | | | | | | |
| Did the policy meet the requirements in the EU BPR in relation to penalties? | X | X | | | | | | |
| Did the policy meet the requirements in the EU BPR for competent authorities? | | | | | | | | |
| Were there any unforeseen consequences? | X | X | X | X | X | | | |
| Did any companies redirect their work outside of GB as a result of the Regs? | | | X | | | | | |
| How many suppliers and manufacturers are there and what size are they? | | | | | | X | | |
| How many INs have been issued per annum? | X | | | | | X | | |
| What proportion of INs were disputed? | X | | | | | X | | |
| Did the number of prosecutions go up? | X | | | | | X | | |
| Did HSE incur no costs from training inspectors for the new ENs/ INs? | | | | | | | X | |
| How much of dutyholders' time does it take to engage with (a) the issuance of an IN and (b) the disputation thereof? | | | | | | X | | |
| Did the prospect on INs serves as an incentive to dutyholders to comply where they otherwise would not have? | X | | | | | | | X |
| What are the areas that currently lack clarity in the eyes of CAs/enforcement partners? | X | X | | | | | | |
| What opportunities might stakeholders (business + CAs/DNAs) think there are for simplifying operational procedures.? | | X | X | X | X | | | |
| Did it ensure that suitably more proportionate enforcement mechanisms are in place for the PIC Regulation? | X | | | | X | | | |
| Was it cost neutral? | | | | | | | | X |
| What did businesses need to do to become familiar with the changes, what process did they take and what costs did they incur? | X | | X | X | X | | | |

## Appendix 2

# Evidence Summary for Post-Implementation Review of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations

**1. Do HSE inspectors have sufficient legal powers to enforce?**

**Biocides elements**

Interviews with the HSE inspection team on 18/11/15 indicated that inspectors are content with the full set of Health and Safety at Work Act (HSWA) powers open to them. Respondents did note that there was not an option of using an Enforcement Notice (EN) (although this option does exist for PIC and REACH).

**CLP**

The following regs introduce legal powers for HSE inspectors with regard to CLP:

• BPC R17 – allows for enforcement using powers in HSWA including appropriate Articles in HSWA to serve both improvement and prohibition Notices

• BPC R18 - covers allocation of enforcement responsibility

• BPC R3(4) extends application of BPC to areas outside Great Britain including territorial waters by virtue of HSWA (Application Outside Great Britain) Order 2013.

**PIC**

• BPC R7(b) states HSE and HSENI as Designated National Authorities (DNA) have 'responsibility for controlling the export and import of chemicals listed in Annex I of the PIC regulation…'

One point to note is that, as for CLP, the EU regulation itself allows for a different authority(ies) from the DNA to be designated to meet the requirements of Article 18(1). A MoU is in place between HSE, HSE NI, HMRC (Customs Directorate) and Border Force - to provide a framework for enforcement at the border and for liaison, collaborative working and sharing of information. However, no transfer of powers is included within the MoU. The Enforcement team argued that for efficiency, it would be better if enforcing authorities at the points of exit had powers themselves to deal with issues of PIC non-compliance rather than to detain shipments for HSE to then go and take action. (N.B. The previous enforcing regulations for PIC, were not carried over to BPC).

**Conclusion**

HSE inspectors have sufficient legal powers to enforce the three aspects of the Regs. Inspectors also raised the issues of enforcement on environmental issues, under CLP, and the question of whether HSE is the right body to enforce on PIC. However, based on the risk gap and relative priority, HSE does not propose changes in the BPC legislation beyond those essential to EU exit.

**2. Did the policy meet the requirements in the EU BPR in relation to enforcement? (pg. 8 in IA)**

**Biocides elements**

The BPC proposals for meeting requirements in three EU Regulations for enforcement provisions, penalties and, for biocides, cost recovery mechanisms were shared with the EU Commission and received no negative feedback**.**

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Responses from the Scottish Government and ORR enforcement provisions agreed that enforcement provisions were sufficient.

**CLP**

Respondents to the enforcement partners survey were asked whether BPC met the requirements of CLP in relation to enforcement. One said yes, one raised points for consideration (i.e. power to prohibit where risk of serious harm to the environment and enforcement against natural persons) and the other did not answer this question.

Anecdotal reports from the inspection team suggested that HSE cannot enforce on the totality of the BPC Regulations as HSE can only prohibit supply where there is a risk of serious personal injury, not, for example, risks to the environment or animals. They therefore argued in favour of the introduction of a **s**imilar statement to BPC R8(6) and R8(7) within R17 to allow for prohibition of CLP contraventions which, in the opinion of an inspector, involve or will involve a risk of serious harm to the environment. However, they did note that it is sometimes possible to enforce on environmental issues using other regulations, or use incomplete Safety Data Sheets under REACH (Annex II, Article 31) to enforce and "plug the gap". (Local Authorities can also enforce under the Consumer Protection Act (under 18(5)). However, the team feel that this is a sub-optimal workaround and not ideal from an enforcement perspective.

Responses from the Office of Road and Rail (ORR, formerly the Office of the Rail Regulator) and Scottish Government (collected 4 April 2016) to the enforcement partners consultation agreed that the BPC enforcement provisions were sufficient. After the close of the survey, a late response from Natural England advised that they knew they could enforce for serious breaches (e.g. use of biocidal products at an SSI) but that the organisation had not employed a member of staff with appropriate skills to cover eco-toxicity issues until relatively recently.

Inspectors argued for the introduction of:

An Enforcement Notice (EN) to deal with cases where classification of product is insufficient for an inspector to be either:

- of the opinion that 'serious personal injury' or serious harm to the environment' would result in order to serve a prohibition Notice
- or that a prosecution is a proportionate response to non-compliance with an improvement Notice where that Notice requires e.g. inclusion of a classification, the absence of which isn't considered to result in 'serious personal injury' nor serious harm to the environment
- Restructured presentation of application of Consumer Protection Act - propose movement of R18(5) out of R18 and under an independent regulation e.g. under a title 'Application of the 1987 Act'.

However, administrative evidence provided in March 2016 showed only 6 cases a year of non-compliance around biocides. These mainly involved technical/ administrative failings e.g. the supply of unauthorised but unclassified biocidal products and advertising breaches. None of these actually presented serious or significant health effects, so the actual risk gap is low. CRD enforcement of technical/ administrative failings is not a current priority (although enforcement is under review) and to warrant high priority in future there would typically need to be a risk of actual serious harm. Thus, based on risk gap and relative priority, HSE does not intend to proceed with the request for an EN in relation to the biocides provisions of BPC.

CLP places duties on the following dutyholders: manufacturers, importers, distributors, downstream users and producers of articles. With the exception of producers of articles, definitions of these dutyholders refer to both natural and legal persons. Inspectors also raised the following issues for consideration about whether BPC in

conjunction with HSWA allows for enforcement against natural persons (e.g. members of the public) where required:

- Does section 33(1)(c) of HSWA allow for enforcement via BPC of CLP 'supply' provisions where suppliers are not supplying as 'an activity involving work'? The BPR section of BPC that Regulation 9(6)(a) implies that enforcement of a 'non-work' use of a biocidal product is anticipated to be feasible – is this via HSWA 33(1)(c), or other legislation for Local Authorities to enforce under?
- Would the relevant enforcing authority want to enforce/ have appropriate powers if a member of the public supplied a chemical product to another member of public without appropriate information provision/ packaging as required by CLP via whatever platform, e.g. non-business sellers of internet auction sites e.g. eBay/ Amazon/ Gumtree/ car-boot sellers etc.
- In terms of consistency, there is no CLP section on 'Limitation on entry to domestic premises in certain circumstances' similar to R10 for biocidal products. What if a car-boot seller is storing stock of inadequately labelled chemical products in a domestic premise? In addition, is this approach consistent with HSE's strong, broader defence of an unfettered entry?
- Making clear the demarcation between HSE and HSE NI taking up territorial sea cases?

**PIC**

Although an Enforcement Notice was already extant for PIC and REACH, had BPC not come into force the relevant authorities would not have been able to enforce provisions of the EU PIC (including Article 18). (Article 18 required Member States to make necessary arrangements for official controls to enforce compliance and for monitoring exporters' compliance). The following Regs facilitate the enforcement of PIC:

- BPC R19 and R20 allow for enforcement using the 1974 Act and 1978 Order, respectively.

BPC brought in new Enforcement Notice powers for PIC. Inspectors observed that it was difficult to say if these met the requirements of EU BPR as there haven't been any enforcement cases. However, they did observe that they now have a Single Point of Contact (SPOC) at Border Force etc. so may have greater contacts and information about breaches of PIC.

A letter about PIC aspects of BPC was sent to 4 partner enforcement authorities and received 3 responses - from CRD Enforcement Team, Border Force Operational Policy (Home Office) and HSENI. In response to the question "Did BPC meet the requirements of PIC in relation to enforcement?", two answered yes and one raised an issue on efficiency in relation to only HSE or HSENI being able to address PIC non-compliance at points of export: the EU regulation itself allows for a different authority(ies) from the DNA to be designated to meet the requirements of Article 18(1) (as discussed in (1).

**Conclusion**

The evidence supports the case that the BPC met the requirements of the EU BPR with regard to enforcement for BPC where there is a risk of serious personal injury caused by a company. However, questions were raised the process for enforcing CLP against natural persons carrying out 'non-work' activities; or where there was a threat of environmental harm; and about the demarcation between HSE and HSENI taking up territorial sea cases. In the case of PIC, there may be efficiency gains of allowing bodies other than HSE to enforce. However, based on the risk gap (no enforcement cases), the possibility of 'work arounds' in the case theoretical environmental breaches, and relative priority, HSE does not propose changes in the BPC legislation beyond those essential to EU exit.

**3. Did the policy meet the requirements of the EU BPR with regard to penalties?**

**Biocides elements**

The BPC proposals for meeting requirements in three EU Regulations for enforcement provisions, penalties and competent authorities/Designated National Authorities and, for biocides, cost recovery mechanisms were shared with the EU Commission and received no negative feedback.

**CLP**

The current penalties available to HSE are:

- Serve Improvement and Prohibition Notices to 'Name and Shame'
- Prosecute to hold duty holder to account and potentially result in serving of a fine or prison term.

Inspectors considered the financial penalties applicable to successful prosecution of a CLP contravention to be more dissuasive following an update to the Sentencing Guidelines last year.

Inspectors urged consideration of the potential need for mechanism to allow on the spot fines to be served in order to support penalties being sufficiently dissuasive, with the rationale being that as with all chemicals supply and use regulations, in the absence of prosecution, and where a company can be brought into compliance, there is currently no additional cost in requiring them to come into compliance over and above what existing compliant companies have had to outlay to be compliant themselves.

**PIC**

BPC R32 states the applicable penalties.

Inspectors, as for CLP, raised the issue of whether without prosecution the penalties are considered to be dissuasive enough

**Conclusion**

There are penalties in place for each of the three aspects of the Regulations. Although this may be partly attributable to a number of factors (litigation, insurance etc.) in addition to the Regulations, the low level of identified breaches identified seems to indicate that there is a very high level of compliance.

**4. Did the policy meet the requirements in the EU BPR for competent authorities (CAs)/Designated National Authorities (DNAs)? (pg. 8 in IA)**

**BPC**

The BPC proposals for meeting requirements in three EU Regulations for competent authorities/Designated National Authorities were shared with the EU Commission and received no negative feedback.

**CLP**

Article 43 says Member States shall designate a competent authority or authorities responsible for application of CLP and authorities responsible for enforcement; and Article 44 says that they shall provide advice to interested

parties. Inspectors agreed that in practice HSE carries out the day to day competent authority function and thus provides the advice that may be sought.

**PIC**

- BPC R7(a) states HSE and HSE NI to be the designated national authorities in accordance with Article 4 of Regulation (EU) no 649/2012.
- BPC R7(b) extends the role of the DNA further than that specified in Article 4.

**Conclusion**

The policy meets the requirements in the EU BPR for CAs/DNAs.

**5. Were there any unforeseen consequences?**

**Biocides elements**

A small number of respondents to the crowdsourcing claimed there had been unintended effects of the biocides legislation. They argued that, as the legislation limits the range of products available which were previously deemed perfectly safe, a smaller number of products are necessarily left on the market: this may result in development of resistance to the dominant products on the market, leaving many nuisance weeds and other pest species uncontrollable; disproportionate costs of registering new products for SMEs. However, the examples appeared to be related to the BPR rather than BPC: this did generate an Issues log with around 30 points to consider if and when BPR is revised. (One response did appear to be related to BPC, but was a complaint about a web-based, rather than personalized way service, rather than an unintended consequence).

**CLP**

The Enforcement team claimed that giving Trading Standards Officers (TSOs) the opportunity to use Consumer Protection Act, with which they are more familiar, to address CLP contraventions provides them with a slight disincentive to become familiar with enforcement via HSWA which is required to enforce BPC.

While 10 respondents to the survey did cite unintended consequences, if was clear from their answers that these were not in fact consequences of the Appointment of Authorities and Enforcement Regulations, but of the wider BPR and/or CLP legislation and were therefore out of scope.

**PIC**

Five of the six survey respondents could not identify any unintended consequences. One said: "The market is becoming far less competitive, with major manufacturers swapping BPC products, therefore not wishing to upset other suppliers. Obtaining suitable information, is difficult, especially as suppliers are holding on to this. It will mean even less competition in the long term." However, this response has no logical link with the BPC; and is likely to refer to the direct-acting PIC Regulation as that deals with the import and export of hazardous chemicals for which an inability to obtain the necessary safety information from suppliers would be an important issue.

**Conclusion**

No significant unintended consequences were identified from the BPC.

**6. Did any companies redirect their work outside of GB as a result of the Regs? (pg. 18 in the IA)**

**Biocides elements**

There would be limited opportunity for firms to market outside GB as must have GB authorisation. (NB: BPC only deals with authorisation of products in GB, so applications in other MS would be done through that country's national legislation.) While it was considered disproportionate to conduct a bespoke data gathering exercise, ECHA data in 2016 on authorised suppliers comparing UK to other MS shows a higher number of licences granted in the UK (615, compared to the next highest number of authorisations, 317) than in any other member states.

**CLP**

No reason why this should be the case. This is because the chemicals being stored and used by businesses and their intrinsic hazards will not change so the precautions that need to be taken to protect workers will remain the same.

**PIC**

This is not applicable to PIC as the relevant legislation was designed to facilitate exports.

**Conclusion**

There is no evidence of businesses relocating to outside GB. GB grants higher level of authorisations than other MS. Although we do not know what the level of authorisations would have been without BPC, this does indicate that costs are not prohibitive.

**7. How many suppliers and manufacturers are there and what size are they?**

Biocides elements

As of 31 May 2018, there were 100 suppliers and manufacturers registered as UK substance and/or product supplier on the ECHA Article 95 List. The IA estimates 28 SMEs.

https://echa.europa.eu/documents/10162/23907025/art_95_list_en.pdf/5b06dde8-ab28-46f3-9170-0c04b271ffc1

**CLP**

The survey was sent to 30 stakeholders, from trade associations who may represent say 50% of (an estimated 3000) manufacturers

**PIC**

**Conclusion** – see above

**8. How many INs/ ENs have been issued per annum? (pg. 15 in the IA)**

**Biocides elements**

None

**CLP**

One IN issued for CLP to date

**PIC**

No ENs issued for PIC

**Conclusion**

Only one IN has been issued (for CLP). ENs cannot be issued for CLP or BPC - ENs can be issued for PIC, but none have been to date.

**9. What proportion of INs were disputed? (pg. 15 in the IA)**

**Biocides elements**

Not applicable

**CLP**

Not applicable

**PIC**

Not applicable

**Conclusion**

Not applicable

**10. Did the number of prosecutions go up? (pg. 17 in the IA)**

**BPC**

No

**CLP**

No

**PIC**

No

**Conclusion**

The number of prosecutions did not go up.

**11. Did HSE incur nil costs from training inspectors for the new ENs/ INs? (pg. 17 in the IA)**

E-mail correspondence with the Regulatory Training Programme owners indicated that no additional training costs were incurred as a result of any of the aspects of the BP.

**12. How much of dutyholders' time does it take to engage with (a) the issuance of an IN and (b) the disputation thereof?**

This could not be calculated as there were no disputations.

**13. Did the prospect of INs serves as an incentive to dutyholders to comply where they otherwise wouldn't have? (pg. 17 in the IA)**

The value and effectiveness of notices in securing compliance is well established. In 2010/11 HSE inspectors issued 11,020 notices under the Health and Safety at Work etc. Act 1974, compared to instituting 551 prosecutions.

**PIC**

In the opinion of inspectors, the introduction of notices to secure compliance under PIC has benefited industry by providing more proportionate enforcement tools, so that prosecution can then be properly reserved for persistent offenders or blatant non-compliance. This approach is in line with other health and safety enforcement arrangements. Creating this wider range of enforcement tools should in theory increase the likelihood that they will be used, thus strengthening the incentive for dutyholders to be compliant. Fifteen out of 16 respondents to PIC consultation 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'.

**14. What are the areas that currently lack clarity in the eyes of CAs/enforcement partners?**

**Biocides elements**

None identified

**CLP**
None identified

**PIC**
None identified

**Conclusion**
No areas of the legislation are seen by competent authorities/ enforcement partners as lacking in charity.

**15. What opportunities might stakeholders (business + CAs/ DNAs) think there are for simplifying operational procedures?**

**BPC**

None identified

**CLP**

CRD Enforcement team noted that enforcement in territorial waters is handled differently between Biocides and CLP and argued that consistency between the Regulations would be beneficial from an enforcement perspective as this would reduce time spent by Compliance Team having to go back and review each Regulation separately.

**PIC**

Follow up correspondence with the Enforcement Team revealed difference in enforcement with BPC NI.

**Conclusion**

Where it is possible to have consistency between the enforcement application, powers and allocation across the three different regimes covered by BPC then this would simplify enforcers' work.

**16. Did BPC ensure that suitably more proportionate enforcement mechanisms are in place for the PIC Regulation? (pg. 8 in IA)**

**BPC**

Not applicable

**CLP**

Not applicable

**PIC**

Prior to the introduction of BPC, beyond sending an advisory letter to an exporter who has not complied with PIC, the only available PIC enforcement option was prosecution. This is inconsistent with other health and safety enforcement arrangements. HSE wished to correct this and thereby permit more proportionate enforcement. Under BPC, inspectors were provided with powers to serve an IN or EN, when the inspector is of the opinion that a person has contravened or is likely to contravene a PIC requirement, e.g. an EN could prohibit the export of a PIC-listed chemical until the steps set out in the notes had been taken.

While the new provision for improvement and enforcement notices ensure does make available more proportionate enforcement tools than would previously been the case, these enforcement tools have not, in fact been used. An inspector commented:

“I appreciate that we don’t have examples to demonstrate this but powers for customs' officers to detain shipments are seen to be crucial to stopping shipments at the point of export. The PIC enforcement Notice is also a versatile tool which can be used to prohibit the further movement of goods and used to

effect recalls. Our view remains as previously, that the improvement and enforcement notices will allow proportionate enforcement action to be taken where it may not otherwise be appropriate to take forward a prosecution."

**Conclusion**

Although no notices have been served under the PIC, 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.

**17. What did businesses need to do to become familiar with the changes, what process did they take and what costs did they incur? (pg. 16 in the IA)**

**BPC**

The actual costs to business are minimal, there is no evidence that the assumptions made in the original IA are not still relevant, and HSE has received no intelligence of additional costs that the IA did not consider.

**CLP**

The HSE Impact Assessment concluded that the costs associated with the CLP aspects of BPC, including the time spent by businesses familiarising themselves with the changes, were negligible.

However, the CRD team commented "The rationale that 'already compliant' companies won't have to familiarise themselves with the consequences of not complying makes sense, but what about companies weighing up the options of whether to comply? [N.B. Further clarification was sought from the team on the meaning of this, and it was explained that they were referring to companies deciding whether or not to continue their operations, under the new Regs.)

Seven survey respondents concurred that the costs were negligible. However, of the 9 who disagreed, the majority were referring to direct-acting legislation. Two gave answers which did refer to BPC valid answers: one argued that although the time to familiarize was low, the cost of compliance, especially in time was large; while another said that costs depended on the "company size, training budget and expertise available. [Costs were] Negligible to large companies but potentially significant to SMEs". The former respondent was a manufacturer, importer or downstream user responsible for classifying substances and mixtures placed on the market' working for a company with over 250 employees. The latter was a consultant from a company employing >250.

**PIC**

All but one of the survey respondents felt the cost of familiarisation with the Regs was negligible

The CRD enforcement team response referred to an understanding of a notice rather than the actual Regulation and therefore estimated that cost of time spent reading the EN and notifying HSE once they had put in place appropriate measures (£60 estimate from IA) did not reflect the time spent by dutyholders undertaking the necessary activities to achieve compliance, rather it tried to capture the cost of time spent 'reading the EN as it came through the door, and notifying HSE once they had put in place appropriate measures'.. However, one claimed that "The costs, of obtaining information, is very, very significant. How customers use the product isn't always clear, so major work to get this information is necessary."

**Conclusion**

The weight of informed opinion points to familiarisation costs being negligible for most compliant firms, although one respondent did make the point that this was to some extent dependent on size and expertise.

**18. Was BPC cost-neutral?**

The IA estimated that there would be zero financial costs and benefits on industry. No new duties were proposed for businesses, so there were no resulting compliance costs and hence minimal need for BPR, PIC or CLP legislation dutyholders to familiarise themselves with the proposed administrative arrangements in relation to enforcement, penalties and appointment of Competent Authorities/DNAs.

The actual costs to business are minimal. There is no evidence that the assumptions made in the original IA are not still relevant, and HSE has received no intelligence of additional costs that the IA did not consider.

The inspection team observed "CLP and PIC are slightly different to other chemicals regulations in that, in many circumstances, there may have been very limited financial investment by companies to comply with the requirements other than the employment of appropriate regulatory staff e.g. where a company supplies a substance with a harmonised classification for which classification and labelling are straightforward, or for PIC given there is no charge for the notification process.

Other chemical regulations involve significant upfront financial investment to get substances registered or products authorised. CLP may also require this level of financial investment where the company has to conduct testing itself in order to establish the appropriate classification for a substance or mixture."

Familiarisation costs were broadly agreed to be negligible, although one survey respondent felt that this would vary with 'Company size, training budget and expertise available. [Costs were] Negligible to large companies but potentially significant to SMEs' and Chemicals Regulation Division (CRD) Enforcement Team raised the costs of familiarisation of companies weighing up the options of whether to continue their operations. There are also costs arriving from the disputation of notices, as only one (non-contested) notice has been issued.

There is some evidence that a minority of producers and users of chemicals have taken a commercial decision to cease producing certain biocidal products or changed their formulation, or that they have been unable to purchase these. Analysis reveals that this is for reasons such as the costs or time taken to get approval for specific substances, and is therefore the result of the wider BPR, CLP and PIC legislation, rather than BPC.

No additional training costs have been borne by HSE.

**19. Lessons for future IAs**

An inspector commented "…I am uncertain why PIC had the impact of changing its enforcement tools monetised whereas CLP did not have the impact of implementing enforcement tools assessed. Certainly for CLP there will be more than 2 advisory letters anticipated in a typical year, please also see comments to Q8 in PIC documentation. Overall, the impact assessment would be more rigorous if it reflected the likely potential variation in the monetisation estimates. The values given are considered to be representative for a competent person dealing with a straightforward, easy to understand breach. However, they are likely to underestimate the time required by someone unfamiliar with the legislation and / or trying to understand a more complicated breach."