EXPLANATORY MEMORANDUM TO

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

2013 No. 1506

AND

THE BIOCIDAL PRODUCTS (FEES AND CHARGES) REGULATIONS 2013

2013 No. 1507

1. This explanatory memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instruments

2.1 The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (the 'BPC Regulations') formally appoint national authorities and provide for enforcement, including penalties for infringement, in respect of three 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;
- Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (a recast of Regulation (EC) 689/2008) - known as the Prior Informed Consent Regulation - "the PIC Regulation", see: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106: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 three 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 make these arrangements and also make minor amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (S.I. 2009/716) (the CHIP Regulations), see:

http://www.legislation.gov.uk/uksi/2009/716/contents/made which continue to have effect until the EU Regulation on classification, labelling and packaging of substances and mixtures (the CLP Regulation) fully replaces the Dangerous Substances and Dangerous Preparations Directives**1**, implemented by the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009.

2.3 The separate Biocidal Products (Fees and Charges) Regulations 2013 make provisions for fees payable by dutyholders under the Biocides Regulation.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (the BPC Regulations) 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 and the EU Regulation concerning the export and import of hazardous chemicals (the PIC Regulation).

3.2 The BPC Regulations revoke the Biocidal Products Regulations 2001 (S.I. 2001/880) and subsequent statutory instruments that amended those Regulations (see paragraph 7.9) (except for provisions in those instruments that amend Northern Ireland regulations). However, the BPC Regulations specifically do not revoke the provisions relating to fees and charges in the Biocidal Product Regulations 2001, and subsequent amendments. These are instead revoked in the Biocidal Products (Fees and Charges) Regulations, in order to provide clarity over associated revocations and savings provisions and to avoid complicated cross-references.

4. Legislative Context

4.1 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.
- On 1 March 2014, the recast PIC Regulation will replace the existing PIC Regulation (EC 689/2008). The Export and Import of Dangerous Chemicals Regulations 2008 (S.I. 2008/2108), see: http://www.legislation.gov.uk/uksi/2008/2108/contents/made which provide for enforcement of the existing PIC Regulation, then become obsolete and will need to be revoked and replaced.

1 Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling 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, packaging and labelling of dangerous preparations.

- 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 Chemicals (Hazard Information and Packaging for Supply) Regulations 2009, which transpose these Directives, can then be revoked, but the provisions they make for enforcement of the CLP Regulation will need to be replaced.

4.2 As indicated in paragraph 2.1, 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.

4.3 To ensure the UK meets the obligations in these EU Regulations and to implement Government policy to recover certain costs from industry, the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (the BPC Regulations) and the Biocidal Products (Fees and Charges) Regulations 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.

5 Territorial Extent and Application

5.1 The BPC Regulations extend to Great Britain in relation to the Biocides Regulation and the CLP Regulation, and to the whole of the United Kingdom in relation to the EU Regulation concerning the export and import of hazardous chemicals (the PIC Regulation).

5.2 Separate legislation is being made in Northern Ireland in relation to the Biocides Regulation and the CLP Regulation. As the PIC Regulation concerns external trade, which is a reserved matter, these BPC Regulations make provision for the implementation of the PIC Regulation in Northern Ireland.

5.3 The Biocidal Products (Fees and Charges) Regulations extend to Great Britain. Separate legislation is being made in Northern Ireland.

6 European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7 Policy background

7.1 The duties created under the three EU Regulations are evolutions of long-standing and well-understood duties under the previous legislation, and are important in the protection of human health and the environment from risks associated with supply, use and import/export of hazardous chemicals.

7.2 To reduce the number of legislative instruments, simplify domestic regulation in this area, and in view of the similarities between the three regimes, the BPC Regulations replace the existing domestic provisions that support the EU Regulation on classification, labelling and packaging of substances and

mixtures and the EU Regulation concerning the export and import of hazardous chemicals (the PIC Regulation) and combine them with provisions for the new Biocides Regulation. The biocides provisions revoke and replace existing biocides legislation as recommended in Professor Löfstedt's independent review of health and safety legislation.**2**

7.3 The outcome is the replacement of seven existing sets of regulations (five on biocides and one each on PIC and the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009) by two statutory instruments (the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (the BPC Regulations) and Biocidal Products (Fees and Charges) Regulations). In 2014, there will be further consolidation when the provisions in the Biocidal Products (Fees and Charges) Regulations are incorporated in revisions to the Health and Safety (Fees) Regulations, see paragraph 12.2.

7.4 The provisions of BPC Regulations come into force on the date required by the EU Regulation to which they relate.

7.5 **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.

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

7.7 The BPC Regulations designate the Secretary of State as the competent authority for England, the Welsh Ministers for Wales, and the Scottish Ministers for Scotland, to carry out the obligations laid down in the Biocides Regulation. For matters outside the competence of a devolved administration, the competent authority is the Secretary of State.

7.8 The provisions in the BPC Regulations in respect of biocidal products are similar to corresponding provisions in the Biocidal Products Regulations 2001, which they revoke, see: http://www.legislation.gov.uk/uksi/2001/880/contents/made .

7.9 Provisions are also made to enable the competent authorities for biocides to recover in full costs incurred in respect of work carried out under the new Biocides Regulation, as was the case under the Biocidal Products Regulations 2001. Previously, the Biocidal Products Regulations 2001**3**, which implemented

2 *Reclaiming health and safety for all*, Professor Ragnar Löfstedt, November 2011, see http://www.kcl.ac.uk/sspp/departments/geography/people/academic/lofstedt/review/lofstedt-reportfinal.pdf

3 As amended by the Biocidal Products (Amendment) Regulations 2003 (SI 2003/429); the Biocidal Products (Amendment) Regulations 2005 (SI 2005/2451); the Biocidal Products (Amendment) Regulations 2007 (SI 2007/293); and the Biocidal Products (Amendment) Regulations 2010 (SI 2010/745).

the Biocidal Products Directive, included the fees and charges provisions that applied under that Directive.

7.10 The Biocidal Products (Fees and Charges) Regulations 2013 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.

7.11 Together, the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (the BPC Regulations) and the Biocidal Products (Fees and Charges) Regulations revoke the Biocidal Products Regulations 2001 and all its amendments, subject to certain transitional and savings provisions (BPC Regulations, regulation 16 and Schedule 2; Biocidal Products (Fees and Charges) Regulations, regulation 8).

7.12 Provisions in the BPC Regulations relevant to the Biocides Regulation take effect in Member States on 1 September 2013, and domestic provisions are required to be in place by that date.

7.13 **The EU Regulation on the export and import of hazardous chemicals (the PIC Regulation)**, a recast of the existing PIC Regulation, continues to regulate the export and import of certain hazardous chemicals, giving countries the power to make informed decisions as to whether they wish to import any PIC-listed chemicals. In doing so, it gives effect to the UN Rotterdam Convention, see: http://www.pic.int/ which promotes shared responsibility and cooperation in the international trade of specified hazardous chemicals. The procedures outlined in the Rotterdam Convention are often called Prior Informed Consent.

7.14 The recast PIC Regulation updates the existing PIC Regulation, establishes the correct legal base, and consolidates a number of previous amendments. It applies from 1 March 2014.

7.15 The PIC Regulation requires Member States to designate national authorities and make arrangements for enforcement, including establishing a system of penalties for non-compliance.

7.16 Provisions in the BPC Regulations relating to enforcement of the PIC Regulation are based on existing provisions in the Export and Import of Dangerous Chemicals Regulations 2008, which they revoke. Similarly, as in the existing provisions, the BPC Regulations designate the Health and Safety Executive (HSE) and the Health and Safety Executive for Northern Ireland (HSENI) as the designated national authorities.

7.17 Provisions are also broadened to enable inspectors to issue enforcement notices in relation to any breach of a duty in the PIC Regulation, facilitating more proportionate enforcement than under previous arrangements and improving consistency with other health and safety law.

7.18 **The EU Regulation on classification, labelling and packaging of substances and mixtures (the CLP Regulation)** adopts an international chemicals hazard classification and labelling system for the supply of substances and mixtures in the EU. The EU Regulation on classification, labelling and

packaging of substances and mixtures (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.

7.19 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.

7.20 The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (the BPC Regulations) designate the Secretary of State as the competent authority for England, the Welsh Ministers for Wales, and the Scottish Ministers for Scotland, to carry out the obligations laid down in the EU Regulation on classification, labelling and packaging of substances and mixtures. For matters outside the competence of a devolved administration, the competent authority is the Secretary of State.

7.21 Provisions in the BPC Regulations in relation to enforcement of the CLP Regulation are based on existing provisions in the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (the CHIP Regulations).

7.22 In addition, the BPC Regulations provide an opportunity to address some minor legal and administrative issues in the CHIP Regulations. Regulation 35 and Schedule 4 of the BPC Regulations 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 (the PIC Regulation) to replace the references to the 2008 PIC Regulation; 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.

8 Consultation outcome

8.1 **For the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (the BPC Regulations)** a six-week public consultation was held. In addition to making the consultation document publicly available via the Health and Safety Executive (HSE) website, interested stakeholders were notified of the consultation directly. These included HSE's specific stakeholder groups and forums on biocides, industrial chemicals, and all those suppliers known to export chemicals subject to the PIC Regulation. Relevant e-bulletins were also used to promote widespread consultation.

8.2 The consultation period reflected the uncontroversial nature of the changes The Regulatory Policy Committee (RPC) confirmed that the BPC Regulations and Biocidal Products (Fees and Charges) Regulations could proceed through the 'fast-track' regulatory process on the grounds of it being a low cost measure.

8.3 The proposals were widely accessed (6110 consultative document page requests) and downloaded (2492 downloads), but the public consultation yielded only 20 responses. This is attributed to the generally uncontroversial nature of the proposals.

8.4 Setting aside those responses to the consultation that were unrelated to the proposed regulations or offered advice on detail for the Impact Assessment, the substantive responses were broadly supportive.

8.5 Key outcomes of the consultation were:

• 11 out of the 16 respondents who commented agreed with the proposal to consolidate the seven sets of regulations. The main concern was for the regulatory burden on business. However, these regulations essentially represent a continuation of existing arrangements, impose no additional duties on business and reduce the number of regulations in force;

• 15 out of the 16 respondents who commented considered that the proposed enforcement provisions were 'about right'. One respondent was concerned that the enforcement provisions might be seen as a means to raise funds for the Health and Safety Executive (HSE). However, no provisions are planned in respect of cost recovery for enforcement of the duties in these EU Regulations;

• 15 out of the 16 respondents who commented considered that inspectors should be able to issue 'notices' for infringements of the EU Regulation on the export and import of hazardous chemicals (the PIC Regulation). One respondent suggested that only prosecution was appropriate for breaches of the duties in the PIC Regulation. However, this would not be a proportionate level of response for most breaches that are likely to occur;

• There was overall support for the proposed amendments to address legal issues in Chemicals (Hazard Information and Packaging for Supply) Regulations 2009.

8.6 HSE has followed up specific points with individual respondents where appropriate.

8.7 **For the Biocidal Products (Fees and Charges) Regulations** a separate four-week consultation was held. This was conducted through a consultation letter posted on HSE's website and was specifically targeted at the biocidal products industry by emails to all companies currently liable for the General Industry Charge (around 560 companies); and by notifications via HSE's biocides e-bulletin, biocides web community, and biocides stakeholder group.

8.8 HSE received ten 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 Biocidal Products (Fees and Charges) Regulations. Although some responses indicated there may have been a belief that fees would go up, in fact 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 was clarified with the respondents concerned.

8.9 Taking into account the consultation responses and dialogue with devolved administrations, HSE maintained the general approach of the proposed Biocidal Products and Chemicals (Appointment of Authorities and Enforcement)

Regulations 2013 (BPC Regulations) and Biocidal Products (Fees and Charges) Regulations, with some minor technical amendments.

8.10 A more detailed report of the responses to both consultations may be found in the April 2013 Health and Safety Executive (HSE) Board paper HSE/13/39, see: http://www.hse.gov.uk/aboutus/meetings/hseboard/2013/240413/consultation-outome-7-in-1-package.pdf

9 Guidance

9.1 As the BPC Regulations do not alter the duties on business that are set out in the three EU Regulations, HSE does not plan further guidance for industry beyond updating that already available to aid compliance. These Regulations carry forward well-established and well-understood regimes regulating certain chemicals and biocidal products and, in respect of biocides, charging for the costs arising.

9.2 HSE uses its website to provide extensive guidance on biocides (see: http://www.hse.gov.uk/biocides/), the EU Regulation on the export and import of hazardous chemicals (the PIC Regulation) (see: http://www.hse.gov.uk/pic/), and the EU Regulation on classification, labelling and packaging of substances and mixtures (the CLP Regulation) (see: http://www.hse.gov.uk/ghs/eureg.htm). It also uses e-bulletins and web communities to provide regular updates to interested stakeholders (for example see: http://www.hse.gov.uk/press/subscribe.htm). The existing guidance will be updated to reflect the BPC Regulations, which consolidate, but broadly maintain the existing framework for appointment of national authorities and enforcement.

10 Impact

10.1 The impact on business, charities or voluntary bodies arising from the BPC Regulations and the Biocidal Products (Fees and Charges) Regulations is expected to be negligible. On 3 June 2013, the Regulatory Policy Committee (RPC) validated the One–in Two-out status of the measure as out of scope and the findings of the impact assessment that this is a low cost measure for which there will be no net cost to business from these Regulations.

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

10.3 An Impact Assessment is attached and will be published alongside this Explanatory Memorandum on www.legislation.gov.uk.

11 Regulating small business

11.1 The legislation applies to small business. During consultation, HSE engaged with small businesses through specific stakeholder groups and forums on biocides, industrial chemicals, and all those suppliers known to export chemicals that are subject to the PIC Regulation.

11.2 However, as the BPC Regulations and the Biocidal Products (Fees and Charges) Regulations do not introduce any new duties on business and there is no net cost to business, the impact on firms employing up to 20 people will be minimal.

11.3 As these measures arise from EU requirements, and do not contain ‘gold plating’ they are outside of the scope of the microbusiness moratorium.

12 Monitoring and review

12.1 The Secretary of State will review the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 after five years to determine whether they achieve their intended objective and, if those objectives remain appropriate, whether they could be achieved with less regulation.

12.2 The Health and Safety Executive (HSE) will complete a review of its General Industry Charge, one aspect of its biocides fees structure, by 1 April 2014 to determine whether it continues to achieve its intended objective of full cost recovery and to ensure the fees structure remains in line with Government policy contained in Managing Public Money. Due to complexities and time constraints, it was not possible to complete this review and implement the necessary changes before 1 September 2013, which is the deadline for meeting the obligations under the Biocides Regulation. HSE will consult on proposals for any changes that are found to be necessary. Following this review, HSE plans to incorporate the Biocidal Products (Fees and Charges) Regulations into the Health and Safety (Fees) Regulations in 2014.

13 Contact

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