

Health and Safety Executive Board		Paper No: HSE/10/16	
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Keywords:	Biocidal Products Amendment Regulations		
<b>PROPOSED BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2010: RECOMMENDATIONS FOLLOWING CONSULTATION</b>			

## Purpose of the paper

1. The Board is asked to note the outcome of the recent consultation on HSE proposals for the Biocidal Products (Amendment) Regulations 2010, approve the Regulations at **Annex 1** and agree that they be sent to Lord McKenzie to sign. The amendments are minor; none of the changes have any cost or benefit implications for industry. A draft covering letter and background note from the Chair on behalf of the Board to Lord McKenzie is at **Annex 2**.

## Background

2. The European Commission reported in October 2008 that its 10-year review of the efficacy and safety of active substances in biocidal products on the market when the Biocidal Products Directive 98/8EC (BPD) came into force on 14 May 2000 had fallen behind schedule and would not be completed on time. To address this, the Commission published a Directive<sup>1</sup> extending the transitional deadline in the BPD from 14 May 2010 to 14 May 2014 so that the review could be completed and those existing active substances under review, and the products they are used in, could remain on the market in the interim, subject to existing national legislation. The amending Directive also extended to the same date the data protection period for information submitted in support of the review.

3. Member States were required to implement the changes to the BPD brought about by the amending Directive. HSE, which is the designated UK competent authority for biocides and as such has the UK lead responsibility, published a consultation letter on 1 September 2009 seeking views on proposals for draft Regulations making simple amendments to the Biocidal Products Regulations 2001 (BPR), the implementing national legislation, in line with the changes to the dates in the BPD. We also took the opportunity to update certain references in the BPR and adjust the BPR in the light of operational experience.

4. The consultation ran for 12 weeks until 23 November 2009. As expected, it did not attract a high level of interest, with 8 full responses and 3 partial responses received. 7 of the full responses were from companies manufacturing and/or marketing biocidal products and industry associations. Nobody raised any issues of substance. A summary and analysis of the responses is at Annex 3.

5. The draft Regulations on which we consulted extend only to Great Britain (GB). HSE Northern Ireland (HSENI) has consulted separately and the NI Regulations will

<sup>1</sup> Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods

follow closely those for GB, both in content and timing. As the European Directive has a single market Treaty base it does not have to be implemented in Gibraltar.

6. This consultation is separate from that described in paper HSE/09/67, considered at the 22 July Board meeting, on a subsequent Commission proposal for an EC Regulation replacing the BPD, with more far reaching changes to the biocides regime. → . ←

### **Argument**

7. The proposed amendments are minor (albeit necessary) administrative measures that will allow the status quo to continue for a further four years. They do not impose any additional costs on or achieve any additional benefit to industry, hence the expected low response rate. As such, a full Impact Assessment (IA) was not required, but a Short IA has been signed off by the HSE Chief Economist, and is attached as Annex C to the Chair's letter to the Minister (Annex 2).

8. The consultation responses were almost entirely in favour of or unopposed to the proposals, and none of the comments raised any areas of contention.

### **Action**

9. Chair to write to Lord McKenzie along the lines of Annex 2 with the HSE Board's recommendation.

### **Paper clearance**

10. Cleared by the SMT at its 6 January 2010 meeting.

Draft of the Biocidal Products (Amendment) Regulations 2010

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DRAFT STATUTORY INSTRUMENTS

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2010 No.

HEALTH AND SAFETY

The Biocidal Products (Amendment) Regulations 2010

*Made* - - - - - \*\*\*  
*Laid before Parliament* - - - - - \*\*\*  
*Coming into force* - - - - - 6<sup>th</sup> April 2010

The Secretary of State is a Minister designated<sup>(1)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(2)</sup> (“the 1972 Act”) in relation to biocides.

The Secretary of State makes these Regulations—

(a) in exercise of the powers conferred on him by section 2(2) of, and paragraph 1A of Schedule 2 to, the 1972 Act; and sections 15(1), (2), and (8), and 82(3)(a) of, and paragraphs 1(1)(b) and (c) and (4), (4)(1), 13(1) and 15(1) of Schedule 3 to the Health and Safety at Work Act 1974<sup>(3)</sup>, (“the 1974 Act”), and

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

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

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for references in the Biocidal Products Regulations 2001<sup>(1)</sup> to

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<sup>(1)</sup> S.I. 1999/2788.

<sup>(2)</sup> [1972 c.68](#); Schedule 2 was amended by section 28 of the Legislative and Regulatory Reform Act [2006 \(c. 51\)](#). As regards Scotland, see also section 57(1) of the Scotland Act [1998 \(c.46\)](#) which provides that, despite the transfer to the Scottish Ministers by virtue of section 53 of that Act of functions in relation to observing and implementing Community law, any function of a Minister of the Crown in relation to any matter shall continue to be exercisable by him as regards Scotland for the purposes of section 2(2) of the European Communities Act 1972.

<sup>(3)</sup> 1974 c.37. Sections 15(1) and 50(3) are amended by the Employment Protection Act 1975 (c. 71), paragraphs 6 and 16 respectively. Section 15(1) is further amended by S.I. 2002/794, art 5(2), Schedule 2. Section 50(3) is further amended by the Health Protection Agency Act 2004, Schedule 3, paragraph 5(1) and (3) and S.I. 2008/960, which also inserts section 50(1AA).

Commission Regulation (EC) No 1451/2007<sup>(2)</sup> to be construed as references to those instruments as amended from time to time.

### **Citation and Commencement**

1. These Regulations may be cited as the Biocidal Products (Amendment) Regulations 2010 and shall come into force on 6<sup>th</sup> April 2010.

### **Amendment of the Biocidal Products Regulations 2001**

2. The Biocidal Products Regulations 2001 are amended as follows.

3.—(1) In regulation 2(1)—

(a) after the definition of “feedingstuff”, insert—

““the fifth review regulation” means Commission Regulation (EC) No 1451/2007 as from time to time amended;”

(b) in the definition of “new active substance”, substitute “fifth” for “second”;

(c) for the definition of “placing on the market” substitute—

“placing on the market” means—

(a) any supply, whether in return for payment or not, within Great Britain; or

(b) importation of a biocidal product into Great Britain; or

(c) any subsequent storage other than storage followed by—

(i) consignment from the customs territory of the European Community or

(ii) disposal,

and “place on the market”, “placed on the market” and “on the market” shall be construed accordingly;” and

(d) omit the definition of “the second review regulation”.

(2) In regulation 2(2)(a), omit “and the Minister of Agriculture, Fisheries and Food, acting jointly”.

4. In regulation 3—

(a) for paragraph (3) substitute—

“(3) These Regulations shall not apply to a biocidal product which is a relevant plant protection product where and to the extent that the biocidal product is placed on the market or used for a purpose over which—

(a) but for the provisions of Schedule 4 to the 2005 Regulations, control under the 2005 Regulations, would otherwise be exercisable; or

(b) but for the provisions of Schedule 4 to the 2005 (Scotland) Regulations, control under the 2005 (Scotland) Regulations would otherwise be exercisable.”;

(b) in paragraph (8)(a), omit the word “and”;

(c) after paragraph (8)(a), insert—

“(aa) “the 2005 (Scotland) Regulations means the Plant Protection Products (Scotland) Regulations 2005<sup>(3)</sup>; and”; and

(d) in paragraph (8)(b), for “in paragraph 8 of Schedule 4 to the 2005 Regulations” substitute “in paragraph 12 of Schedule 4 to the 2005 Regulations.”.

5. In regulation 3A—

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<sup>(1)</sup> S.I. 2001/880, amended by S.I. 2003/429, 2005/2451 and 2007/293.

<sup>(2)</sup> OJ No. L325/3, 11.12.2007, p.1.

<sup>(3)</sup> S.S.I. 2005/331

- (a) in paragraph (1), for “which contains no active substances other than existing active substances” substitute “where all the active substances in that product are existing active substances.”;
- (b) For paragraph (2) substitute—  
“(2) subject to paragraph (4), paragraph (1) shall cease to apply on 14<sup>th</sup> May 2014”; and
- (c) after paragraph (3) insert—  
“(4) Where a decision under Article 16(2) to include an existing active substance in Annex I or IA sets a date for compliance with Article 16(3) which is later than 14<sup>th</sup> May 2014, paragraph 1 shall continue to apply in relation to biocidal products that include that active substance until the date set in that decision.”.

6. In regulation 23, for each reference to “2010”, wherever it appears, substitute “2014”.

7. In regulation 24, for each reference to “2010”, wherever it appears, substitute “2014”.

8. In Schedule 2—

- (a) Omit paragraph (g) and (j); and
- (b) after paragraph (u), insert—  
“(v) the Medical Devices Regulations 2002<sup>(1)</sup>;  
(w) the Plant Protection Products Regulations 2005; and  
(x) the Plant Protection Products (Scotland) Regulations 2005.”.

9. In Schedule 13—

- (a) in paragraph (1), for the definition of “COPR biocidal product”, substitute—  
“COPR biocidal product means any substance, preparation or organism prepared or used for any of the purposes listed in regulation 3(1) of COPR 1986, which is not a plant protection product;  
“Plant protection product” has the same meaning as in Regulation 2(1) of the Plant Protection Products Regulations 2005; and”;
- (b) after paragraph (1), insert—  
“**1A.** This Schedule applies only in relation to a biocidal product where all the active substances in that product are existing active substances.”
- (c) in paragraph (2A), for “the first sub-paragraph of Article 4.2 of the second review regulation” substitute “Article 4 of the fifth review regulation”;
- (d) in paragraph (5), for “not later than 3 months after that decision takes effect” substitute “not later than the date that decision takes effect”; and
- (e) in paragraph (8), for “not later than 3 months” substitute “not later than 2 months”.

Signed by authority of the Secretary of State for Work and Pensions

*Bill McKenzie*  
Parliamentary Under Secretary of State  
Department for Work and Pensions

Date

### EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations amend the Biocidal Products Regulations 2001 (S.I. 2001/880) (“the 2001 Regulations”) to make further provision as regards Great Britain for the implementation of Directive

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<sup>(1)</sup> S.I. 2002/618

98/8/EC of the European Parliament and Council (OJ No. L123, 24.4.98, p.1.) concerning the placing of biocidal products on the market (“the Directive”).

**2. These Regulations—**

- (a) implement Directive 2009/107/EC of the European Parliament and of the Council of amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods (“the Amending Directive”);
- (b) update references and make minor corrections in the 2001 Regulations; and
- (c) take account of developments that require further amendment to the 2001 Regulations.

**3. The main changes made by these Regulations are as follows.**

**4. Regulation 3 amends the definitions of “new active substance”, “placing on the market” and “second review regulation”—**

- (a) the Fifth Review Regulation, which replaces the Second Review Regulation, has been defined;
- (b) the definition of “new active substance” has been amended so as to refer to the Fifth Review Regulation and not the Second Review Regulation which has been revoked;
- (c) the definition of “placing on the market” has been amended to remove an ambiguity and reflect the intention of the Directive more clearly; and
- (d) the definition of “second review regulation” has been omitted.

**5. Regulation 4 updates the 2001 Regulations so that it refers to the correct paragraph of Schedule 4 of the Plant Protection Products Regulations 2005.**

**6. Regulation 5—**

- (a) extends the time period during which biocidal products can remain under existing national authorisation from 14<sup>th</sup> May 2010 to 14<sup>th</sup> May 2014 in accordance with the requirements of the Amending Directive ; and
- (b) provides for a further period of time during which biocidal products can remain under existing national authorisation if a decision to include an existing active substance in Annex I or IA of the Directive sets a later date for compliance with Article 16(3) than 14 May 2014.

**7. Regulation 6 extends the data protection periods for active substances from 14<sup>th</sup> May 2010 to 14<sup>th</sup> May 2014 in accordance with the requirements of the Amending Directive.**

**8. Regulation 7 extends the data protection periods for biocidal products from 14<sup>th</sup> May 2010 to 14<sup>th</sup> May 2014 in accordance with the requirements of the Amending Directive.**

**9. Regulation 8 adds the Medical Devices Regulations 2002, the Plant Protection Products Regulations 2005 and the Plant Protection Products (Scotland) Regulations 2005 to Schedule 2 and removes the Medical Devices Regulations 1994 and the Plant Protection Products Regulations 1995.**

**10. Regulation 9—**

- (a) clarifies that a biocidal product can only remain on the UK market under its existing national authorisation if all the active substances within it are existing active substances;
- (b) removes the reference to the second review regulation which has been revoked; and
- (c) changes specific time periods so they are in line with the harmonised timelines and procedures Member States have voluntarily agreed should be followed by Member States, the Commission and industry following inclusion of an existing active substance into Annex I or IA.

**11. A full regulatory impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside L20 7HS. A copy of the transposition note in relation to the implementation of the Amending Directive can be obtained from the Health and Safety Executive, International Branch at the same address. Copies of these documents have been placed in the Library of each House of Parliament.**

**Draft covering letter and background note to Lord McKenzie**

**Proposals for the Biocidal Products (Amendment) Regulations 2010**

At its meeting on 28 January 2010, the Health and Safety Executive Board agreed to recommend to you proposals for the Biocidal Products (Amendment) Regulations 2010. I am now writing to ask you to make the Regulations so that they can come into force on 6 April 2010, the next common commencement date.

The main driver for the amending Regulations is the need to implement changes to the Biocidal Products Directive 98/8/EC (BPD) brought about by European Directive 2009/107/EC of 16 September 2009. This extends the transitional deadline in the BPD that allows active substances, and the biocidal products containing them that were on the European market when the BPD came into force in 2000, to remain on the market (subject to existing national legislation) pending a Europe-wide review of the active substances to determine whether they are sufficiently effective and do not pose unacceptable risks to humans, animals or the environment. The amending Directive also extends to the same date the data protection period for information submitted for the purposes of the BPD.

The amending Regulations deal with three main issues:

- Keeping biocides on the market after 14 May 2010
- Updating certain references in the Biocidal Products Regulations 2001
- Adjusting the 2001 Regulations in the light of operational experience

The BPD is transposed in Great Britain (GB) by the Biocidal Products Regulations 2001, and in Northern Ireland (NI) by the Biocidal Products Regulations (Northern Ireland) 2001. I attach a background note (Annex A) summarising the main changes introduced by the amending Regulations, all of which are minor (albeit necessary) administrative changes that will ensure the continued smooth running of the national biocides regime. A draft of the amending Regulations is attached at Annex B. They apply only to GB. NI carried out its own consultation based closely on the GB exercise and will be making separate amending Regulations. As the European Directive has a single market Treaty base it does not have to be implemented in Gibraltar.

JUDITH HACKITT  
Chair, Health & Safety Executive

## Background Note

### Introduction

1. The European Commission reported in October 2008 that its 10-year review of the efficacy and safety of active substances in biocidal products on the market when the Biocidal Products Directive 98/8EC (BPD) came into force on 14 May 2000 had fallen behind schedule and would not be completed on time. To address this, the Commission published a Directive<sup>1</sup> extending the transitional deadline in the BPD from 14 May 2010 to 14 May 2014 so that the review could be completed and those existing active substances under review, and the products they are used in, could remain on the market in the interim, subject to existing national legislation. The amending Directive also extended to the same date the data protection period for information submitted in support of the review.

2. Member States are required to implement the changes to the BPD brought about by the amending Directive. HSE, the designated UK competent authority for biocides and the UK policy lead, published a consultation letter on 1 September 2009 seeking views on proposals for draft Regulations making simple amendments to the Biocidal Products Regulations 2001 (BPR), the implementing national legislation, in line with the changes to the dates in the BPD. We also took the opportunity to update certain references in the BPR, and to adjust the BPR in the light of operational experience. None of the changes have any cost or benefit implications for industry.

3. The consultation ran for 12 weeks until 23 November 2009. As expected, it did not attract a high level of interest. 106 participants participated in the online consultation, with 8 full responses and 3 partial responses received. 7 of the full responses were from companies manufacturing and/or marketing biocidal products and industry associations. Nobody raised any issues of substance.

### Draft Regulations – main changes

4. The changes will affect, almost exclusively, only those already in scope of the existing biocides regime, and will not bring any additional costs or savings to industry, as they do not change any legal duties or procedures established by the 2001 Regulations. As such, a full Impact Assessment was not required, but HSE's Chief economist has signed off a Short Impact Assessment, attached at Annex C.

### Keeping biocides on the market after 14 May 2010

5. The main driver for the amending Regulations is the implementation of Directive 2009/107/EC so that biocidal products containing existing active substances in the review programme can remain on the market in GB beyond 2010.

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<sup>1</sup> Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods

This simply involves amending the end date of the transitional period from 14 May 2010 to 14 May 2014 wherever it appears in the 2001 Regulations.

#### Updating certain references in the 2001 Regulations

6. The 2001 Regulations refer to various other pieces of legislation where they are relevant to the scope or operation of the biocides regime. Since the 2001 Regulations were made, several of these have changed and the amending Regulations update the references accordingly to reflect those changes. They also amend the definition of “the Ministers” to reflect subsequent changes in the machinery of Government.

#### Adjusting the 2001 Regulations in the light of experience

7. The amending Regulations address an unintended discrepancy between the 2001 Regulations and the BPD in the definition of “placing on the market”, to provide clarity for industry about the position when storing and supplying unauthorised products for export outside the European Customs territory. The changes introduced by regulation 3(1)(c) of the amending Regulations make clear that any act of supply constitutes a placing on the market, as does any act of storage other than storage followed by consignment out of the customs territory of the Community or by disposal. They also amend the reference to importation into Great Britain, being an act of placing on the market, so that it refers more precisely to importation of a biocidal product, in line with the definition in the BPD.

8. We have taken the opportunity to amend Schedule 13 of the 2001 Regulations dealing with the transitional provisions for biocidal products containing existing active substances, by adjusting two of the timelines for authorisation of products, to bring the requirements in the 2001 Regulations closer into line with those in other Member States (MS). This involves shortening the deadlines:

- a) by three months, by which applications must be received for authorisation or registration of biocidal products; and
- b) by one month, by which an application must be received for mutual recognition in GB of an authorisation given by another Member State.

9. Finally, we have adjusted the mechanism contained in the 2001 Regulations for ‘switching off’ the Control of Pesticides Regulations 1986 (as amended) (COPR), the existing GB legislation under which certain products are currently regulated, once the 2001 Regulations take effect. As the definition of a COPR biocidal product is wider than that of the definition of a biocidal product in BPR, some COPR biocidal products are not covered by the 2001 Regulations. This means that the ‘switch-off’ mechanism does not apply to these products which, unless they are also switched off, would remain subject to COPR indefinitely, contrary to the intention of BPD. This is remedied in regulation 9 of the amending regulations, which amends the definition of a “COPR biocidal product” in paragraph 1 of Schedule 13 to the 2001 Regulations.

**Annex B to Chair's letter**

**[Copy of the Biocidal products (Amendment) Regulations to be placed here]**

## SHORT IMPACT ASSESSMENT

### Description of the intervention:

A Statutory Instrument amending the Biocidal Products Regulations 2001 (BPR), in order to implement a Directive amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods.

### Objectives:

The amending Directive has as its objectives:

- Extending from 14 May 2010 to 14 May 2014 the transitional period during which existing active substances will be reviewed and considered for inclusion in Annex I of the Biocidal Products Directive 98/8/EC (BPD), to allow existing active substances and the biocidal products they are used in to remain on the market pending the outcome of the review;
- Extending data protection by the same period for data submitted under the BPD;
- Providing for a further extension (limited to two years) by Comitology decision of the transitional period & review programme if needed

We will also take the opportunity to amend the BPR to:

- Amend the definition of "placing on the market", which unintentionally deviates from that used in the BPD and has created an ambiguity that industry has been seeking to exploit for the storage of unauthorised biocidal products for supply outside the European Customs territory;
- Correct an unintended effect of the 2007 amendments to the BPR that prevents a Provisional Authorisation/Registration being granted in the initial stages for products containing both new and existing active substances, contrary to the intentions of the BPD to encourage innovation;
- Fulfil our commitment to bring two of the deadlines by which industry must submit applications under the GB product authorisation procedures into line with other MS. This is set out in agreed guidance in a European Commission document on the harmonised timelines and procedures to be followed by MS, the Commission and industry following the inclusion of an existing active substance into Annex I of the BPD;
- Make a small adjustment to the mechanism for switching off the existing legislation (the Control of Pesticides Regulations 1986 - COPR) once the BPR take effect, for the specific circumstance where someone buys a chemical that is not marketed as a biocide and then uses it as a biocide in their own home

### Calculation of costs:

The proposed amendments will not bring any additional costs to industry, nor will they produce any savings, since these are simple amendments to allow the status quo to continue for a further 4 years. There will be an administrative cost to HSE of consulting on and bringing into force the Statutory Instrument amending the existing legislation, and this is estimated to be no more than £50K in 2009/10.

**Impact on industry (including any effect on the Admin Burdens Baseline):**

The changes will affect almost exclusively only those already in the biocides/pesticides systems, who have notified their intention to support active substances through the review or registered an interest in biocides with HSE, including the many SMEs within the biocides industry.

The potential loophole created by the anomalous definition of “placing on the market” is closed.

Applications for product authorisation and mutual recognition (which have not yet begun to be submitted) will have to be sent in between 1-3 months earlier than previously allowed.

**Benefits (quantified where possible):**

The scope of the BPD is very wide, covering 23 product types including disinfectants for home and industrial use; preservatives for manufactured and natural products; non-agricultural pesticides for use against insects, rodents and other vertebrates and specialised products such as embalming & taxidermist fluids and antifouling products. Extending the transitional deadlines will ensure the benefits described in the RIA for the 2001 Regulations that these Regulations are amending will be realised.

Industry wishing to place innovative new products on the market will be able to apply for a PA/PR without having to wait until all existing active substances have been listed on Annex I of the BPD.

The GB product authorisation procedures will be more closely harmonised with those of other MS.

Industry will have greater clarity on when storage for consignment out of the European Customs territory constitutes placing on the market.

**Consultation:**

This approach has been discussed with HSE’s Chief Economist and the Better Regulation Team.

**Chief Economist’s comments:**

I am satisfied that an appropriate level of analysis has been employed for this short IA: the amendment to the BPR will bring very limited costs, and benefits which are real but cannot be quantified.

**Recommendation:**

That based on proportionality, a full impact assessment is not produced.

**Signed:**.....  
**HSE’s Chief Economist**

**Date:** ...21 July 2009...

**ANALYSIS OF RESPONSES TO THE 1 SEPTEMBER – 23 NOVEMBER 2009  
CONSULTATION ON PROPOSALS FOR THE BIOCIDAL PRODUCTS  
(AMENDMENT) REGULATIONS 2010**

No paper documents were issued. An e-mail alert advising how to access the consultation was sent to the several thousand companies and individuals registered to receive information on developments with biocides and pesticides, including all those liable for the pesticides levy and the biocides General Industry Charge.

106 participants joined in the consultation.

8 participants provided full responses to the questionnaire. Of these 7 identified themselves as representing industry and 1 was from a non-affiliated individual. 3 participants completed the questionnaire partially but did not submit their response.

Analysis of responses for each question:

**Q3:** Do you have any comments on the way these Regulations implement the amendments to the Biocidal Products Directive 98/8/EC brought about by the Amending Directive, which aims to keep biocides on the market beyond 14 May 2010?

Number of responses = 8

Number agreed/no comment = 7

Number disagreed = 0

Other = 1 specific concern raised in the comments.

Remarks: the concern, about the change to the wording on storage in the definition of 'placing on the market', related to a specific scenario. The concern was unfounded and a personal response to this effect has been sent.

**Q4:** Do you have any comments on the proposals set out in paragraph 8 of the letter for updating certain references in the 2001 Regulations, also described in more detail in paragraph 6 of Annex 2?

Number of responses = 7

Number agreed/no comment = 7

Number disagreed = 0

Other = 0

**Q5:** Do you have any comments about the proposals for adjusting the 2001 Regulations in the light of operational experience. In particular:

**(i)** Do you agree that the proposed amendment to the definition of "placing on the market" in the Biocidal Products Regulations 2001 adequately removes ambiguity about when the act of storage constitutes a placing on the market, and aligns the definition with the Biocides Directive?

Number of responses = 8

Number agreed/no comment = 5

Number disagreed = 1

Other = 2

Remarks: The 'no' response was simply that with no comment. One of the 'other' responses stated that they required more information before they could comment. This was supplied promptly but no further response was received. The second 'other' response raised concerns that the definition of 'placing on the market' was still not clear in relation to what constitutes a supply for their own particular circumstances, and suggested the adoption of a definition in draft Commission proposals for future changes to the Directive. A response was sent that it would be inappropriate to deviate from the Directive at this stage, since the aim of the HSE proposals was to bring the UK legislation closer into line with it. Further clarification was provided that it would not be appropriate for Regulations to try to prescribe all the possible scenarios with regard to placing on the market/supply, but rather this would be dealt with by guidance and advice on individual circumstances where needed.

**(ii)** Do you have any comments on the way we propose to amend two of the timelines in Schedule 13 of the 2001 Regulations, concerning applications for product authorisation and mutual recognition?

Number of responses = 7

Number agreed/no comment = 7

Number disagreed = 0

Other = 0

**(iii)** Do you have any comments on the proposed solution to ensure the Control of Pesticides Regulations 1986 are fully 'switched off' in the specific circumstances described in paragraph 12 of the letter, and in paragraph 8ii of Annex 2?

Number of responses = 7

Number agreed/no comment = 7

Number disagreed = 0

Other = 0

**Q6:** Do you have any comments on the proposals in this document that are not covered by questions 1-5 above?

Number of responses = 7

Number agreed/no comment = 5

Number disagreed = 0

Other = 1 specific issue not related to the consultation.

Remarks: The 'other' response requested an exemption certificate under the Regulations for a particular special circumstance. The request was forwarded to the appropriate HSE team for a response.

**Q7:** Is there anything you particularly like or dislike about this consultation? Please provide comments

Number of responses = 6

Number no comment/thanks = 5

Other = more information requested by one respondent. Dealt with under response to Q5(i) above.