Health and Safety Executive Board			Paper No: HSE/09/80
Meeting date:	26 August 2009	**FoI status:**	Fully open
Type of paper:	Below the line	**Exemptions:**	
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Consultation on changes to the Biocidal Products Regulations 2001			

Purpose of the paper

1. To ask the Board to approve for publication a Consultation Letter (CL) on minor, non-controversial revisions to the Biocidal Products Regulations 2001 (BPR). The draft CL at **Annex 1** sets out our plans to implement the *'Directive of the European Parliament and of the Council 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"), and to make some other minor changes.

Background

2. There are two recent developments with the European biocides regime established by the Biocidal Products Directive 98/8/EC (the BPD):

- The first concerns the European Commission's proposal for an EC Regulation to replace the BPD, with far-reaching changes to the biocides regime. The Board considered this at its 22 July meeting (Paper HSE/09/67 refers) and consultation on this is already underway, so consultees can help inform the UK negotiating position for negotiations that started in July and will resume in September;
- The second is the subject of this paper, and concerns consultation on straightforward changes to the domestic Regulations amending BPR, which is not subject to such urgency and does not have to be launched over the summer holiday period

3. A paper was submitted in November 2008 for urgent clearance, by the Chair and Chief Executive, of the UK negotiating position on proposals by the European Commission for the amending Directive. The paper explained that the European Commission's review of active substances in biocidal products already on the European market before the BPD came into force (known as "existing" active substances) had fallen behind schedule (to date, only 30 active substances have completed the review process), and the amendment was needed to allow completion of the review of the remaining 400+ existing active substances being supported by industry.

4. The amending Directive does this by extending the transitional period by four years from 14 May 2010 to 14 May 2014, with similarly extended data protection periods for information submitted for this purpose. Member States are required to transpose the Directive by 14 May 2010, which is the end date of the current transitional period. This could not be achieved through the new EC Regulation described in paragraph 2, which will enter into force in January 2013 at the earliest.

5. The BPD is implemented in the UK by the Biocidal Products Regulations 2001, as amended, (BPR) and the Biocidal Products (Northern Ireland) Regulations 2001, as amended BPRNI). The CL at Annex 1 includes draft Regulations that will amend the current GB legislation to implement the amending Directive.

Argument

6. The Biocidal Products (Amendment) Regulations 2010 ("the amendment Regulations") deal with three main issues, full details of which are in the CL at Annex 1:

a) Keeping biocides on the market after 14 May 2010:
If the transitional period is not extended beyond 2010 the consequences of removing hundreds of 'unreviewed' active substances and all biocidal products containing them from the market would be substantial adverse economic effects on the biocides industry (including many SMEs), as well as a detrimental effect on human and animal health because many products used to combat harmful organisms would no longer be available.

. b) Updating certain references in the BPR:
These changes will take account of changes to other legislation referred to in the BPR and reflect changes in the machinery of Government since the BPR were made.

c) Adjusting the BPR in the light of operational experience:
The amendment Regulations would introduce changes to certain definitions in BPR, and minor amendments to certain deadlines in Schedule 13 for applications for product authorisation and mutual recognition of authorisations in other Member States, that would align the GB Regulations fully with the BPD and with processes in other MS.

7. All of these changes are minor and do not impose any additional costs or savings on business, and so a full impact assessment is not required. A Short Impact Assessment is attached (**Annex 2**).

8. The Biocidal Products (Amendment) Regulations 2010 will extend only to GB and are expected to come into force on the Common Commencement date of 6 April 2010. NI will make its own arrangements in parallel with those in GB.

Consultation:

9. A consultation plan is being agreed with Communications Directorate (**Annex 3**). HSE Northern Ireland, who will need to introduce equivalent NI legislation to complete full UK implementation, have been fully informed of our developing plans. We have consulted OGDs with an interest and they are content with the general approach to the public consultation, which we propose to do (subject to the HSE Board's agreement) via a consultation letter between 1 September-23 November 2009. The proposals will affect almost exclusively only those already within the biocides and pesticides system operated by HSE. We can and will alert them directly to the CL because their contact details are available to HSE's Chemicals Regulation Directorate (CRD) as those liable to pay the Pesticides Levy and the Biocides General Industry Charge. They include many SMEs.

Guidance:

10. No dedicated guidance is necessary since the changes are administrative and do not change the way the biocides regime operates.

Advice:

11. Information for industry on the consequences of the changes will be placed on the HSE biocides micro-site, and will be automatically notified by an e-mail alert to all those registered to receive it.

12. The HSE Challenge Panel examined the proposal at a meeting on 22 July 2009 and agreed the general approach. They emphasised the need for effective communications with the target audience, and with this in mind we have produced a simple Consultation Letter with further details in Annexes for those interested.

Presentation

13. We anticipate that industry will welcome the extended transitional deadline, which will allow them to keep their products on the market.

Financial/Resource Implications for HSE

14. The only cost to HSE will be in amending the GB implementing legislation, which is part of the work programme of LLHRD.

Paper clearance

15. This paper was cleared by the Senior Management Team on 5 August 2009.

Contact

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Annex 1

Draft Consultation Letter

To all interested parties

HSE proposals for simple amendments to the Biocidal Products Regulations 2001 (as amended)

Introduction

1 This letter sets out the Health and Safety Executive's (HSE's) proposal for a simple set of Regulations making minor amendments to the Biocidal Products Regulations 2001(the 2001 Regulations) and seeks your views. The proposed new Regulations are contained in Annex 1 and would be known as the Biocidal Products (Amendment) Regulations 2010 (hereinafter called "the Amendment Regulations").

2 The Amendment Regulations deal with three main issues:

a) Keeping biocides on the market after 14 May 2010;

b) Updating certain references in the 2001 Regulations; and

c) Adjusting the 2001 Regulations in the light of operational experience

3 We need to consult formally on these proposals and that is the purpose of this letter.

4 **We believe the changes will affect almost exclusively only those already affected by 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.**

Background

5 The 2001 Regulations implement in Great Britain (GB) the Biocidal Products Directive 98/8EC (the Biocides Directive) concerning the harmonisation of the European market for biocidal products. The Biocides Directive established a 10-year review of active substances of biocidal products that were on the European Market when the Biocides Directive came into force on 14 May 2000 (known as 'existing' substances), during which time biocidal products containing such existing active substances could remain on the market subject to current national legislation.

Keeping biocides on the market after 14 May 2010

6 The European Commission has confirmed what is already well known - the review of existing active substances has progressed more slowly than anticipated and will not be completed within the 10-year deadline, which is due to end on 14 May 2010. To address this, a Directive has been agreed amending the Biocides Directive to extend by four years the transitional period during which existing active substances will be reviewed and considered for inclusion in Annex I of the Biocides

Directive, and to extend data protection periods by the same period for information submitted under the Biocides Directive. The "Amending Directive" also provides for the possibility of a further extension (limited to two years) of the transitional period & review programme should it be needed.

7 The proposals set out in this Consultation Letter concern the implementation of the Amending Directive so that biocidal products containing existing active substances in the review programme can remain on the market in GB beyond 2010. 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. For further details please refer to Annex 2.

Updating certain references in the 2001 Regulations

8 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 we propose to update the references accordingly to reflect those changes. We also propose to amend the definition of "the Ministers" to reflect subsequent changes in the machinery of Government. Details of the references affected are set out in Annex 2.

Adjusting the 2001 Regulations in the light of experience

9 Following questions from industry about the way that "placing on the market" is defined in regulation 2(1) of the 2001 Regulations, it has become clear that this definition is ambiguous and creates an unintended discrepancy with the Biocides Directive. We propose to address this discrepancy to provide clarity for industry about the position when storing and supplying unauthorised products for export outside the European Customs territory. The proposed amendment to the definition of "placing on the market" in regulation 3(c) of the Amending Regulations makes 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. This is explained further in Annex 2.

10 We propose also to take 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 of the 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

11 Further details are contained in Annex 2.

12 Finally, we propose to make a small adjustment to 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. This affects only products not sold or intended for use as biocidal products, which are subsequently bought and used for biocidal purposes that require a COPR approval. Because such products

are not covered by the 2001 Regulations, the ‘switch-off’ mechanism would not apply in these particular circumstances, and so the products would be subject to COPR indefinitely to no purpose. The proposed solution is to amend the definition of “COPR biocidal product” in paragraph 1 of Schedule 13 to the 2001 Regulations. Further detail is in Annex 2.

Consultation

13 If you wish to comment on the draft Regulations, please complete the questionnaire attached at Annex 3. If you complete it electronically, please send it to the dedicated e-mail address created for this consultation at [dn: insert address]. If you complete a hard copy, please return it to:

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London
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E-mail: garry.wiles@hse.gsi.gov.uk

NB: This is a first draft of the Regulations and is subject to legal checks and further amendment before it is finalised for consultation

(**Annex 1)**

D R A F T S T A T U T O R Y I N S T R U M E N T S

2009 No.

HEALTH AND SAFETY

The Biocidal Products (Amendment) Regulations 2010

Made - - - -	***
Laid before Parliament	***
Coming into force - -	***

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972([1]) ("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([2]), ("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([3]) to

([1]) 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.

([2]) 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).

([3]) S.I. 2001/880, amended by S.I. 2003/429, 2005/2451 and 2007/293.

Commission Regulation (EC) No 1451/2007([4]) 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 6th 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) in the definition of "placing on the market", omit "a supply for"; and

(d) omit the definition of "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; and

(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; 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 and in paragraph 12 of Schedule 4 to the 2005 (Scotland) Regulations.".

5. In regulation 3A—

(a) after paragraph (1), insert—

"(1A) Schedule 13 shall not apply to a biocidal product which contains any active substances other than existing active substances.";

(b) (2), for the "14th May 2010" substitute the "14th May 2014"; and

(c) after paragraph (3) insert—

"(4) Notwithstanding paragraph (2) above, if a decision to include an existing active substance in Annex I or IA sets a later date for compliance with Article 16(3) than 14 May 2014 Schedule 13 shall continue to apply 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".

([4]) OJ No. L325/3, 11.12.2007, p.1.

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

8. In Schedule 2—

(a) in paragraph (g), for "the Medical Devices Regulations 1994" substitute "the Medical Devices Regulations 2002";

(b) omit paragraph (j); and

(c) after paragraph (u), insert—

"(v) the Plant Protection Products Regulations 2005; and

(w) the Plant Protection Products (Scotland) Regulations 2005.".

9. In Schedule 13—

(a) in the definition of "COPR biocidal product", for "a biocidal product to which COPR 1986 applies;" substitute "any substance, preparation or organism prepared or used for any of the purposes listed in regulation (3(1)(b)) of COPR 1986;";

(b) omit paragraph (2A);

(c) 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

(d) 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 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/…/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;

(d) the definition of "second review regulation" has been omitted; and

(e) the definition of "the Ministers" has been amended to reflect the fact that responsibility for biocides has moved from MAFF to Defra which is headed by the Secretary of State rather than the Minister.

5. Regulation 4 updates the 2001 Regulations so that it refers to the correct paragraph of Schedule 4 of both the Plant Protection Products Regulations 2005 and the Plant Protection Products (Scotland) Regulations 2005.

6. Regulation 5—

(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) extends the time period during which biocidal products can remain under existing national authorisation from 14th May 2010 to 14th May 2014 in accordance with the requirements of the Amending Directive ; and

(c) 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 14th May 2010 to 14th May 2014 in accordance with the requirements of the Amending Directive.

8. Regulation 7 extends the data protection periods for biocidal products from 14th May 2010 to 14th 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 2005.

10. Regulation 9—

(a) changes the definition of a "COPR biocidal product" so that all relevant products under COPR are included in the definition;

(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 to be followed by Member States, the Commission and Industry following inclusion of an existing active substance into Annex I or IA([5]).

([5]) footnote to follow

(**Annex 2)**

Further details of HSE proposals for simple amendments to the Biocidal Products Regulations 2001 (as amended)

Background

1 The European Commission published a report in October 2008 on the first eight years of the operation of the Biocides Directive. The report included information on the 10-year review of existing active substances. The report confirmed that the review has progressed more slowly than anticipated and so would not be completed within the 10-year deadline. It recommended that measures should be introduced to extend the review period to allow the process to be completed for all existing active substances in the review programme.

2 Subsequently a '*Directive of the European Parliament and of the Council amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods*' (hereinafter called "the amending Directive") has been agreed and published. [*dn: provide OJ reference and a link here when published*]. This Directive:

- Extends the 10-year transitional period by a further four years, to allow existing active substances, and the biocidal products they are used in, to remain on the market pending the outcome of the review;
- Extends data protection by the same period for data submitted under the Biocides Directive;
- Provides for a further extension (limited to two years), by Comitology decision, of the transitional period and review programme, if needed.

Keeping biocides on the market after 14 May 2010

3 **Regulation 3A** and Schedule 13 of the 2001 Regulations implement Article 16 of the Biocides Directive, which allows continued application of the current national legislation until the end of the transitional period. Article 1(2) of the amending Directive amends Article 16 by extending the transitional end date from 14 May 2010 to 14 May 2014. We propose to amend paragraph (2) of regulation 3A accordingly to reflect the new transitional end date. This is done via regulation 5(b) of the draft Regulations.

4 We propose also to amend **Regulation 3A** to make use of the provision in Article 1(2) of the amending Directive. This allows Member States (MS) to continue applying national legislation beyond the extended transitional period, where the deadline specified for them to grant product authorisations under Article 16(3) of the Biocides Directive goes beyond 14 May 2014. This amendment would be done via regulation 5(c) of the draft Regulations, and averts the situation where there would otherwise be a gap between such products ceasing to be controlled under existing national legislation before being fully controlled under the 2001 Regulations.

5 **Regulations 23 and 24 of the 2001 Regulations set out the data protection provisions for active substances (23) and biocidal products (24).** As

required by Article 1(1) of the amending Directive, the draft Regulations amend all the references in these particular regulations so that 14 May 2014 becomes the new cut-off date for data protection in line with the extended transitional period. This is done through regulations 6 and 7 of the draft Regulations, which will ensure that the information submitted continues to be protected during the extended transitional period while the review of 'existing' active substances is still underway.

Updating certain references in the 2001 Regulations

6 The references that we propose to update in the 2001 Regulations are set out in regulations 3 and 8 of the Amending Regulations, as follows:

a) Replacing references to "the second review regulation" by "the fifth review regulation", which is now the main European Commission Regulation dealing with the review of existing active substances. It replaced the second review regulation and its amendments.
b) Amending the definition of "the Ministers" to reflect the fact that the responsibilities of the Minister of Agriculture lie now with the Secretary of State for Environment, Food and Rural Affairs. In practice, the functions of the Ministers under the 2001 Regulations are delegated to HSE as the designated UK Competent Authority for biocides, via an agency agreement signed in 2003.
c) Updating the reference to "the Medical Devices Regulations 1994", which were replaced in 2002.
d) Updating the references to the Plant Protection Products legislation in regulation 3 and Schedule 2. The 1995 Regulations, which applied to GB) were replaced by new Regulations in 2005, and at the same time Scotland introduced its own Regulations. The amendments reflect those changes.

Adjusting the 2001 Regulations in the light of operational experience

7 **Regulation 2(1)** sets out the definitions of certain words and phrases used in the 2001 Regulations. The definitions should be consistent with those used in the Biocides Directive.

Article 2(1)(h) of the Biocides Directive defines "placing on the market" as:

"Any supply, whether in return for payment or free of charge, or subsequent storage other than storage followed by consignment from the customs territory of the Community or disposal. Importation of a biocidal product into the customs territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive."

So, the Directive stipulates that <u>any</u> supply constitutes placing on the market as does any "subsequent storage", with the only exception being "storage followed by consignment from the customs territory of the Community or disposal". Thus, once there has been a supply of an unauthorised biocidal product, the Directive forbids any subsequent storage of it <u>other</u> than storage followed by consignment out of the customs territory of the Community or by disposal.

Currently, Regulation 2(1) of the 2001 Regulations defines 'placing on the market' as:

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

(b) any subsequent storage,

other than a supply for storage followed by consignment from the customs territory of the European Community or followed by disposal, and 'place on the market', 'placed on the market' and 'on the market' shall be construed accordingly;"

This definition inadvertently introduced the concept of "a supply for storage" which is not in the Directive, creating an ambiguity for some in industry. Regulation 3(1)(c) of the draft Regulations addresses this ambiguity by removing the phrase "a supply for" from the definition, thereby reverting to the exact wording in the Biocides Directive.

8 The proposed amending regulations also make two other minor adjustments to Schedule 13.

i. The first concerns **the adjustment of two of the timelines for authorisation of products to bring the GB authorisation procedures closer into line with those of the other MS**. We propose to address the following issues in these amending Regulations:
    a. Schedule 13(5) of the 2001 Regulations states that applications for product authorisation have to be made within three months of the date that an active substance is included on Annex I. This requirement is not in the Biocides Directive, and so we propose to bring the 2001 Regulations into line by specifying that the application has to be received on or before the date the decision to include the active substance on Annex I takes effect rather than 3 months later, as currently specified. This is done through an amendment to Schedule 13(5) by regulation 9(c) in the draft Regulations. In practice this means that the maximum time available for industry to submit applications for product authorisation is 24 months following inclusion of an active substance on Annex I, instead of 27 months;
    b. Schedule 13(8) of the 2001 Regulations states that, when a company has applied for their authorisation/registration in one of the other Member States, they should send their application to the UK for mutual recognition of that authorisation/registration within 3 months of the authorisation being granted by the other Member State. Again, this is not in the Biocides Directive, and so we propose to bring the 2001 Regulations into line with the other MS by changing the deadline in Schedule 13(8) to 2 months, via regulation 9(d) in the draft Regulations.

As well as aligning GB law more precisely with the Biocides Directive, this aligns product authorisation processes in GB with the recently published EU guidance 'Harmonised timelines and procedures to be followed by Member States, the Commission and industry following inclusion of an existing active substance into

Annex I or IA' (CA-March07-Doc.9.2.1) [*dn; Creative Services - please provide a link to TRIM document 2009/291478*] (hereinafter referred to as "the harmonised timelines document"). The outcome is greater clarity for industry and Member States on the actions they need to take and on the timetables to be met following decisions on the inclusion of active substances in Annex I of the Biocides Directive.

ii. The second concerns the interface between the current UK regulatory regime governing non-agricultural pesticides (the Control of Pesticides Regulations 1986 – COPR) and the new regime established by the 2001 Regulations. We have identified a potential problem with the mechanism contained in Schedule 13(13) of the 2001 Regulations for 'switching off' COPR once the 2001 Regulations take effect for that product. The problem arises only where someone buys a chemical that is not marketed as a biocide, and then decides to use it as a biocide. In this case, the supplier of the chemical does not intend it to be used as a biocide, and so the 2001 Regulations do not apply to that use.

Schedule 13 switches the 2001 Regulations on when the active substance used in the product is included (or not included) into Annex I of the Biocides Directive and at the same time switches off COPR for that biocidal product. Schedule 13(13) states:

> *Where-*
> *(a) there is made a decision referred to in paragraph 2; and*
> *(b) by virtue of that paragraph these regulations apply to a COPR biocidal product containing the unlisted active substance in question, COPR 1986 shall cease to apply to that COPR biocidal product when that decision takes effect.*

A 'COPR biocidal product' is defined as "a biocidal product to which COPR 1986 applies". The use of a chemical as a biocide in the circumstances described above does not of itself make it a biocidal product. Therefore it is not a 'COPR biocidal product', and so COPR would not be 'switched off' by Schedule 13(13) in these specific circumstances. In effect, COPR continues to apply to no useful purpose.

The proposed amendment to the definition of "COPR biocidal product" in Schedule 13(1) fixes this legal conundrum via regulation 9(a) in the draft Regulations such that COPR is fully switched off under these circumstances.

(Annex 3)

Public consultation on HSE proposals for simple amendments to the Biocidal Products Regulations 2001

Q1: 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? (Paragraphs 6 & 7 in the letter, and the more detailed information in paragraphs 3-5 of Annex 2 refer)

A:

Q2: 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?

A:

Q3: 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? (Paragraph 9 in the letter, and the more detailed explanation in paragraph 7 of Annex 2, refer)

A:

(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? (Paragraph 10 of the letter and paragraph 8i a) and b) of Annex 2 refer)

A:

(iii) Do you have any comments on the proposed solution to the problem 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?

A:

Q4: Do you have any comments on the changes proposed in this document that are not covered by questions 1-5 above?

A:

Annex 2

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 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:…….. **Date:** …21 July 2009…
HSE’s Chief Economist

Annex 3

Communications Plan

HSE proposals for simple amendments to the Biocidal Products Regulations 2001 (as amended)

AIMS & OBJECTIVES

Aim

Through a communication strategy, to support amendment of the Biocidal Products Regulations (BPR) by 6 April 2010, by informing external/internal stakeholders about the BPR Consultative Letter (CL), and providing them with the opportunity to respond to the CL.

Objectives

1. Using appropriate media, to inform internal/external stakeholders (including devolved administrations, Gibraltar, HSE, OGDs) about the CL, of how to respond and when by. **By 01.09.09**
2. Using appropriate media, feedback the outcome of the CL to in/external stakeholders, and tell them what happens next and when. **By 24.12.09**
3. Inform in/external stakeholders of laying the Regs. **By 20.03.10**
4. Devise a cost-effective method to validate 1-3 above. **By 16.02.10**
5. Devise a cost-effective method to evaluate 1–3 above. **By 16.02.10**
6. Complete validation **by 30.04.10**
7. Complete evaluation **by 31.05.10**

Validate

- The *number* of emails informing consultees about the CL that are returned as undeliverable.

Evaluate

- In line with GAP9 "Evaluating Consultation Effectiveness", incorporate questions which measure whether (and by how much) the Communications Strategy has met its objective.

Overall aim

- All key stakeholders are aware of the consultation and have the opportunity to comment.

Customers

HSE, OGDs, Devolved Administrations

Stakeholders

External (priority list: individuals, trades unions, workers reps., employers representatives, business (large & SMEs); HSE NI & OGDs.

Internal – Legal Advisers Office, Economic Advisers Unit, Chemicals Regulatory Directorate, Local Authority Unit, International Unit, Agriculture & Food Sector – Agriculture Policy, Communications Directorate, Creative Services, Business Strategy Directorate, HSE Board.

RISKS to successfully implementing this project plan

European Commission delays adoption of the proposal beyond March 2009

- Beyond our control, but we may then have to make a case for bringing the regulations into force outside the common implementation dates

Consultation Letter isn't ready

- Clear and achievable deadlines (agreed with all relevant partners, inc. LAO, Creative Services) when drafting & clearing, including slippage time.

e-CL version on web is delayed

- Closing date for responses cannot be moved substantially.
- Ask web team to foresee risks, and how to mitigate.

Number of responses is lower than expected/desired

- Reminders throughout via letter/email/web/press etc

Reactive work competes for priority with *Comms* Work

- Project Manager to negotiate with DR HoSs for help.

Significant, unforeseen and unexpected policy issues compromise BPR work

- Promptly communicate with HSE Board.

Staff resources are temporarily/permanently unavailable

- Project Manager to consider/negotiate staff on temp loan from other DDs.

Senior Management withdraw support

- Beyond this section's control.

Communications Strategy project team members are unclear of their roles and responsibilities (as per GAP 9)

- **All team members are *a)* identified *b)* consulted during draft strategy/project planning stages;**
- Team members proactively raise concerns with Project Team Leader, on a 1:1 basis or at relevant project team meetings.

Project team members are insufficiently competent to carry out their responsibilities (as per GAP 9)

- At the outset, individuals discuss concerns and remedial action with their Line Manager.
- Line Manager(s) discuss remedial action with Project Team Leader.

SCOPE

Background

The Biocidal Products Directive 98/8/EC was adopted on 16 February 1998 and came into effect on 14 May 2000. The Directive establishes a single market in biocidal products and is implemented in GB by the Biocidal Products Regulations 2002 (SI 2001/880); and in Northern Ireland by the Biocidal Products Regulations 2001 (SR 2001/422), as amended by The Biocidal Products (Amendment) Regulations 2003 SI 2003/429); The Biocidal Products (Amendment) Regulations 2005 (SI 2005/2451); and the Biocidal Products (Amendment) Regulations 2007 (SI 2007/293). The Regulations will ultimately require all biocidal products to be authorised before they can be placed on the markets. The European Commission has published a proposal to make some simple amendments to Directive 98/8/EC that would extend the transitional period for a further four years to 2014, and to provide continued data protection for the extended period. An amendment to the Regulations is required in order to implement these changes.

HSE cannot assume that all stakeholders will understand the detail of the regulations and how it might affect them. The CL will explain the above in plain language to all stakeholders; the intention is to help stakeholders understand how these changes might affect them and their business, and to give them the opportunity and facility to tell us what they think of it, without giving the impression that there is a choice as to *whether* we implement the changes.

EXCLUSIONS

- This project plan does not manage the process (of implementing the amendments to BPR) e.g. oversee the production of the CL within HSE.
- The project plan does not set out to maximise or minimise the number of respondents.

KEY PRODUCTS

1. Communications Strategy phase 1: launch CL
2. Communications Strategy phase 2: laying Regulations
3. Communications Strategy project team meetings
4. Key messages for before, during and after release of the CL
5. Press Releases/Briefings (if required)
6. “Off the shelf” article for journals/magazines etc
7. Web article/summary
8. Web link
9. e-CL
10. HSE Infoline briefing
11. Validation and evaluation methodology (in line with GAP9 and Cabinet Office Good Practice)

KEY DATES
(10.07.09) Draft Comms Strategy cleared within Long Latency Health Risks Division (LLHRD) (26.08.09) Draft Comms Strategy cleared via HSE Board paper
MAJOR INTERFACES with other projects or areas of work
NONE

QUALITY / ACCEPTANCE CRITERIA

Communications Project Plan

- Key messages for before, during and after release of the CL, are cleared within LLHRD and Creative Services as being consistent with internal and external communication strategies.

- Cleared by HSE Board (as subsumed within relevant Board paper).

Press Releases

- Cleared within LLHRD/Creative Services as appropriate for relevant Press Offices to circulate

e-Consultative Letter (e-CL)

- An effective and efficient web link of the CL, and covering narrative, are "live" on day of CL publication.

"Off the shelf" article for journals/magazines etc

- Priority is given to fit for purpose articles for primary target audience

Web notices/links etc

- Pages/articles/links are easy to read and understand and take the user direct to CL within 3 clicks.
- Link is live and effective on day of CL publication
- Internal/external IT contact identified to deal with web problems.

Consultation Letter

- That the CL contains enough information to enable any stakeholder to understand the reason for publishing the CL – and to respond to it if they wish – through various means within the deadline.
- All CL material is written in plain language
- CL is available in other languages if appropriate
- There is an efficient and effective collection system for relevant material from respondents, in place BEFORE the CL is published.
- An effective and efficient query/information system is established for external enquirers to obtain copies, broadly understand its contents, and know CL end date.
- Relevant ICU/HSE/Infoline staff are identified and have accurate and relevant information to answer general respondents' enquiries.

Validation

- A minimum percentage/number of (to be agreed within project team) e-mail alerts to stakeholders is returned to HSE because contact details are incorrect.

Evaluation

- Answers within GAP9 "Individual Consultation Exercise Checklist" of a selected representative group, confirm that good practice was followed.
- Lessons learned from evaluation are shared with LLHRD and HSE colleagues.

CONSTRAINTS

- ICU staff resources – insufficient to cover this work *and* section's other responsibilities.
- Conflicting priorities, e.g. *unexpected reactive*/illness/annual leave/reduction in staff time allocated to carry the project forward
- Other HSE colleague resources are insufficiently resourced for this unplanned work.
- Time: the Regs. must be *made* by 14.05.10 at the latest i.e. date the current transitional period ends

AUTHORISATION TO PROCEED

PROJECT MANAGER	DATE	AUTHORISING AGENT	DATE
……	……	……	……