

To all interested parties

HSE proposals for simple amendments to the Biocidal Products Regulations 2001

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 at Annex 1 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. An advanced draft of the Amending Directive can be downloaded from the web page for this consultation.

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 detail, 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. We propose also to 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 Biocides Directive.

10 We propose 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 an 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, but 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 online questionnaire (<http://www.hse.gov.uk/consult/condocs/biocidesletter.htm>). If you prefer, you can save the questionnaire at Annex 3 to your computer and complete & send it later to the dedicated e-mail address created for this consultation at biocides.minireview@hse.gsi.gov.uk . If you decide to print out and complete a hard copy, please return it to:

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2009 No.

HEALTH AND SAFETY**The Biocidal Products (Amendment) Regulations 2010**

<i>Made</i>	- - - -	***
<i>Laid before Parliament</i>		***
<i>Coming into force</i>	- -	***

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 Commission Regulation (EC) No 1451/2007(4) to be construed as references to those instruments as amended from time to time.

(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.

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

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”—

(i) for paragraph (a) substitute—

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

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

(ii) for paragraph (b) and the words from “other than a supply” to the end, substitute—

“(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 “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(5); 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—

(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 14th 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 14th 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(6);
(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 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; 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 14th May 2010 to 14th 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 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 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 to be followed by Member States, the Commission and Industry following inclusion of an existing active substance into Annex I or IA(7).

(7) footnote to follow

Further details of HSE proposals for simple amendments to the Biocidal Products Regulations 2001

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 will be published in the Official Journal of the European Union. An advanced draft of the amending Directive is available to download from the consultation web page. 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 any 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 other 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. Regulation 3(1)(c) also amends the phrase “importation into Great Britain” to the more precise “importation of a biocidal product into Great Britain”. These changes bring the definition into line with that in the Biocides Directive.

8 The proposed Amending Regulations also make two 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(d) 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(e) 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) (hereinafter referred to as "the harmonised timelines document"). A copy of this document can be downloaded from the web page of this consultation. 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.

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

Q1: Please indicate which sector you are from:

A: Industry
Local government
National government
Charity
Trade association
Academic
Other (please specify)

Q2: In what capacity are you responding?

A: Employer
Employee
Trade union official
Safety representative
Training provider
Other (please specify)

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

A:

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?

A:

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? (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 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:

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

A:

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