EXPLANATORY MEMORANDUM TO

THE BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2007

2007 No. 293

1. This explanatory memorandum has been prepared by the Health and Safety Executive and is laid before Parliament by Command of Her Majesty.

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

2. Description

2.1 This instrument addresses the issues raised by the European Commission (EC) in infractions proceedings against the UK on what it considers is defective implementation of the Biocidal Products Directive 98/8/EC (BPD). Other amendments are necessary in order to deal with the effects of three EC Regulations on the transitional provisions for biocidal products already on the market in the UK before the European regime came into being; and to update and correct other references in the existing Regulations.

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

3.1 This instrument uses the new enabling power in paragraph 1A to Schedule 2 to the European Communities Act 1972 (as inserted by section 28 of the Legislative and Regulatory Reform Act 2006) to insert three ambulatory references into the Biocidal Products Regulations 2001 (BPR). These will allow references to the BPD and to the above mentioned EC Regulations within the BPR to be construed as being references to those instruments as amended from time to time. A paragraph in the preamble contains a declaration by the Secretary of State that he considers these ambulatory references to be expedient.

4. Legislative Background

4.1 The Biocidal Products Regulations 2001 and the Biocidal Products (Northern Ireland) Regulations 2001, as amended by the Biocidal Products (Amendment) Regulations 2003 and the Biocidal Products (Amendment) Regulations 2005, transpose the BPD. They set up a product approval system for non-agricultural pesticides, disinfectants and preservatives. It will be illegal to market these products unless they have been authorised under the BPR.

4.2 In its 3rd (2001-02) report the Joint Committee on Statutory Instruments (JCSI) cited two regulations in the BPR for defective drafting, on the grounds that they were too imprecisely worded to support the criminal sanction associated with them. The JCSI has since accepted the arguments put forward in support of the first of these (regulation 8(5), which requires the 'rational application' of a combination of pest control measures) and has assured the HSE that no further action will be taken. A solution to the second issue has been proposed to the JCSI for specific guidance to be issued on the requirements in regulation 25(6) relating to data sharing. These matters have no bearing on the amendment Regulations described in this Memorandum.

4.3 There is a two-stage system for authorisation under the BPR. First, active substances are assessed and included on a central list at Community level. Then, products containing listed active substances are authorised by Member States.

4.4 There are transitional provisions in the Directive, transposed in the BPR, under which existing products are gradually assimilated into the new regime. The active substances used in existing products will be reviewed in a programme lasting until 2010: a series of EC Regulations (referred to as Review Regulations) will govern the review. To deal with this, the BPR are disapplied in respect of biocidal products containing only existing active substance(s) so to allow these products to continue on the UK market under existing national legislation. The BPR are 'switched on' for such products when that active substance(s) within the product has been reviewed and accepted by the Community.

4.5 The EC wrote to the UK on 18 October 2005 setting out the areas where it considers we have not fully implemented the BPD. The letter contained a Reasoned Opinion, part of the legal process followed when the EC considers a Member State has not adequately transposed a Directive into national law. The UK has responded agreeing to amend our legislation. A Transposition Note is attached at **Annex A**.

4.6 The changes being made to address the Reasoned Opinion are:

a) Deleting regulation 3(2) and inserting regulation 3A to:

i) reflect the condition imposed by Article 16(1) of the BPD that, to qualify for the transitional derogation that 'switches off' the BPR until existing active substances have been reviewed, a product must contain *only* existing active substances;

ii) insert the 10-year time limit for the derogation so that it ceases to apply on 14th May 2010.

iii) require that advertising for all biocidal products placed on the market meets the requirements of regulation 33. (Currently, those products enjoying the transitional derogation do not have to comply with this requirement;)

b) Amending the "new active substance" references to "active substance" in regulations 4-6 of the BPR dealing with applications for inclusion of active substances on Annex I of the BPD so that these regulations apply to <u>all</u> active substances and not only new ones. An application for Annex I listing can be made whether the active substance is new or existing, subject only to the time restriction imposed by Article 5(3) of the Second Review Regulation.

c) Inserting a new paragraph 6A into regulation 9 to allow the applicant to omit certain information from their dossier if they consider that the information is unnecessary. What constitutes 'unnecessary information' is set out in Article 8(5). The applicant must be able to justify the omission.

d) Amending regulations 13 and 14 to allow the ministers (subject to certain conditions) to give a provisional authorisation or provisional registration for a new biocidal product where an application has been made to another Member State's competent authority for the active substance(s) to be evaluated for inclusion in Annex I or IA of the BPD;

e) Inserting into regulation 20 new paragraphs 2A and 2B to ensure that, when biocidal product authorisations are modified, those authorisations are

still in compliance with the requirements of Article 5 (which is already a requirement for the original authorisation);

f) Inserting into regulation 37 a new paragraph (1) to bring in the requirement that applicants must first evaluate existing test data before deciding whether further tests are necessary (with a view to minimising animal testing).

4.7 Other changes to the BPR are needed to take into account the effects of the Review Regulations in switching on the provisions in the BPD for certain classes of products. They are:

(a) Modifying the definition in regulation 2(1) of 'existing active substance' to reflect the definition in the First Review Regulation (although not raised in infractions correspondence, this emerged belatedly as an issue that would have risked further infractions proceedings if left uncorrected); and inserting a footnote to alert the reader to the provisions of the Second Review Regulation that biocidal products containing non-identified active substances are excluded from that definition and thus from the transitional derogation;

b) Inserting a paragraph 2A into Schedule 13 of the BPR, which 'switches on' the BPR on 1 September 2006 for products containing active substances identified but not notified by that date.

4.8 The amendments introduce a new provision in regulation 15A to allow us to approve "essential use" products, This 'essential use' approval has been brought about by recent amendments to the Second Review Regulation and allows the Community to approve the continued use of an existing active substance for an essential use. Certain of the UK's existing active substances have not been subject to any national approval; therefore it has been necessary to make provision to grant such approvals through the BPR.

4.9 The amendments also include updates for references to other regulations and changes reflecting the reorganisation of the NHS. They also provide clarification for certain paragraphs and correct some typographical errors. They also, as mentioned above, insert ambulatory references into the definitions of the BPD and the EC Review Regulations

5. Extent

5.1 This instrument applies to Great Britain. Northern Ireland will introduce its own Regulations, which will mirror closely the GB Regulations.

6. European Convention on Human Rights

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

7. Policy background

Policy

7.1 The BPD's main objective is the harmonisation of the Member States' legislation and regimes concerning biocidal products. Approximately 800 active

substances for use in biocidal products have been identified to the European Commission (EC) as being on the market when the Directive came into force on 14 May 2000. Manufacturers and suppliers of around 350 of these substances have notified to the EC their intention to support their substances through the 10-year review programme. The UK will be Rapporteur Member State (and so responsible for reviewing) some 30 of these substances in the first two of four phases of the review, with further substances yet to be allocated in the final phases. Applications can then be made under the BPR for authorisations to market biocidal products containing those active substances reviewed and accepted onto Annex I of the BPD.

7.2 Public interest is limited largely to manufacturers, suppliers and users of active substances and biocidal products.

7.3 The legislation is essential to fulfil the UK's commitment to the EC to address the issues highlighted in the Reasoned Opinion described in paragraph 4.5. Failure to address the issues ran the risk of proceedings in the European Courts and potentially heavy fines for the UK.

Consultation

7.4 A wide public consultation on proposals for the Amendment Regulations ran for 12 weeks ending on 9 June 2006. Those consulted included individuals and companies holding approvals for pesticides from the Health and Safety Executive (HSE), everyone registered with HSE as having an interest in biocides including those already liable for the General Industry Charge payments, and the members of the tripartite biocides consultation groups (i.e. industry associations and appointed representatives, environmental groups, TUs, Other Government Departments and Agencies, and members of the expert Biocides Consultative Committee). Twenty-nine responses were received, of which 13 (44.8%) were NIL responses. The substantive responses raised two issues:

- the proposal to align the data protection provisions with the EC guidance was considered premature as the guidance had no legal standing and had not been agreed by the European industry group. After further correspondence with the EC, these proposed amendments were removed; and
- the financial burden on industry of bringing in the advertising requirements with immediate effect. Several responses sought a deferral of this requirement to allow producers and distributors to exhaust current stocks of products, labels and other printed material before complying with the changes. These responses highlighted a misconception about the scope of the advertising requirement. In response, HSE wrote to all responders confirming that the provisions do not extend to product labelling or packaging, which are dealt with separately under regulations 30 and 31. Although the requirement will still take immediate effect, the implementation date has been delayed from that consulted on, i.e. from 1 October 2006 to 6 April 2007.

Guidance

7.5 The Amendment Regulations do not introduce any fundamental changes that require specific guidance to be issued.

Consolidation

7.6 Further amendments will be needed in late 2007 or in 2008, when consolidation of the BPR and its amending regulations will be considered.

Amendments may also be needed in order to keep the BPR in line with future review regulations.

8. Impact

8.1 A Regulatory Impact Assessment has not been prepared for this instrument as no impact is foreseen on business, charities or voluntary bodies.

8.2 The impact on the public sector is nil.

9. Contact

Garry Wiles at the Health and Safety Executive (Tel: 020 7717 6267 or e-mail: garry.wiles@hse.gsi.gov.uk) can answer any queries regarding the instrument.

TRANSPOSITION NOTE FOR PARTS OF THE BIOCIDAL PRODUCTS DIRECTIVE, IMPLEMENTED BY THE BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2007

DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 1998 concerning the placing of biocidal products on the market		
Article		**Transposed by**
7(6)	Where a proposed modification of an authorisation for a biocidal product concerns an extension of uses to which the biocidal product can be put, Member States shall modify the authorisation, subject to the particular conditions placed on the product's active substance(s) listed in Annex I or IA to the Directive	Reg.16
7(8)	Requires that Member States grant modifications only if the authorisation conditions imposed by Art.5 of the Directive remain satisfied	Reg.16
8(5)	Allows applicants to omit information from their application for biocidal product authorisation where they consider the information is not necessary or technically possible to supply. Applicants must justify this omission.	Reg. 8
8(9)	Requires that account is taken of previous test data when deciding on what new test data needs to be generated in order to minimise testing on vertebrate animals	Reg. 21
9	Requires that active substances for use in biocidal products can only be placed on the market when they have been included in Annex I or IA of the Directive	Reg. 7
11	Sets out the requirements for inclusion of active substances in Annex I or IA of the Directive	Reg. 7
15(2)	Allows Member States to issue provisional authorisations and registrations for biocidal products where they contain new active substances for which a dossier has been received but that have not yet been listed on Annex I/IA of the Directive, provided they have evaluated the dossiers and believe such substances meet the requirements for listing on Annex I/IA and the products they will be used in satisfy the authorisation conditions	Regs. 10, 11
16(1)	Allows biocidal products already on the market when the Directive came into force to remain on the market under national authorisations provided their active substance(s) have been duly notified to the European Commission as existing active substances. This derogation shall cease to apply on 14th May 2010.	Reg. 5
22	Requires that, with immediate effect, advertisements for biocidal products contain certain phrases as prescribed by the Directive, even if the biocidal product in question is remaining for the time being on the market under its national authorisation.	Reg. 5