EXPLANATORY MEMORANDUM TO

The Biocidal Products (Amendment) Regulations (Northern Ireland) 2010

S.R. 2010 No. 163

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Enterprise, Trade and Investment to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Rule is made under section 2(2) of the European Communities Act 1972 and Articles 17(1), (2), (3) and (5), 40(2) and (4) and 55(2) of, and paragraphs 1(1), (4) and (5), 3(1), 12(1), 14(1) and 15 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978 and is subject to the negative resolution procedure.

2. Purpose

2.1 This Statutory Rule implements Directive 2009/107/EC by extending the end date of the transitional provisions in the Biocidal Products Regulations (Northern Ireland) 2001[1] ("the 2001 Regulations"), from 14 May 2010 to 14 May 2014. The transitional provisions allow existing biocidal products to remain on the market in Northern Ireland (subject to existing national legislation) while the active substances contained in them are reviewed at European Level for safety and efficacy. Data protection for information submitted on these products and substances is extended by the same period. The Rule also updates certain references in the 2001 Regulations and adjusts the 2001 Regulations in the light of operational experience.

3. Legislative Background

3.1 The Biocidal Products Regulations (Northern Ireland) 2001 and the Biocidal Products Regulations 2001 transpose the Biocides Directive in the United Kingdom.

3.2 There are transitional provisions in the Biocides Directive under which existing products are gradually assimilated into the new regime during a review period. The review was due to be completed by 14 May 2010, but has fallen behind schedule. *Directive 2009/107/EC 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* puts in place the necessary measures to extend the transitional measures in the Biocides Directive, and the corresponding data protection periods for data submitted for this purpose. The changes being made to domestic legislation will allow existing active substances in the review, and the biocidal products they are used in, to remain on the market in Northern

[1] S.R. 2001 No. 422

Ireland (NI) during the extended review period, and will extend the relevant data protection periods.

3.3 Other changes brought about by this Statutory Rule include:

a updating certain references in the Biocidal Products Regulations (Northern Ireland) 2001 ("the 2001 Regulations") to other legislation where that legislation has changed;

b amending the definition in the 2001 Regulations of "placing on the market" so that it is consistent with the definition in the Biocides Directive;

c making two minor adjustments to two of the timelines for the authorisation of products to bring the NI authorisation procedures closer into line with those of other Member States;

d amending the definition in the 2001 Regulations of "COPR biocidal product" to ensure that the particular products defined will not be caught by two pieces of legislation once they come to be regulated under the 2001 Regulations.

4. Policy Background

What is being done and why

4.1 The Biocides Directive'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 were identified to the European Commission (EC) as being on the market when the Biocides Directive came into force on 14 May 2000. Manufacturers and suppliers of around half of these substances have notified to the EC their intention to support their substances through the review programme. Applications can then be made under the Biocidal Products Regulations (Northern Ireland) 2001 ("the 2001 Regulations") for authorisations to market biocidal products containing those active substances reviewed and accepted onto Annex I of the Biocides Directive.

4.2 The amendments to the 2001 Regulations brought about by this Statutory Rule will ensure that the existing active substances in the review programme and products containing them can remain on the NI market pending the outcome of the review.

4.3 Public interest is limited largely to the manufacturers and suppliers of active substances and biocidal products already part of the review.

Consolidation

4.4 This Rule amends the parent Rule for the fourth time. It was not appropriate to consolidate the legislation on this occasion because of the very tight timescale within which the Directive had to be implemented (it was

published in September 2009 and must be implemented by May 2010), and the fact that much of the legislation will be revoked when a European Commission proposal for a directly-acting EC Regulation to replace the Biocides Directive takes effect in 2013.

5. Consultation

5.1 A consultation exercise ran from 26 October 2009 to 18 January 2010. There were approximately 600 consultees, including individuals and bodies representative of section 75 of the Northern Ireland Act 1998 and other organisations with an interest in equality and related issues (including each member of the Northern Ireland Assembly). No adverse comments were received in relation to the proposed Statutory Rule.

6. Equality Impact

6.1 The Statutory Rule has been screened for any possible impact on equality of opportunity affecting the groups listed in section 75 of the Northern Ireland Act 1998 and no adverse or differential aspects were identified.

7. Regulatory Impact

7.1 A regulatory impact assessment was not prepared on these changes as there will be no new impact on Northern Ireland business beyond that contained in the 2001 Regulations. There is no impact on charities, social enterprise or voluntary bodies.

7.2 The impact on the public sector is nil.

8. Financial Implications

8.1 The Statutory Rule will have no cost implications for business, charities or voluntary bodies.

9. Section 24 of the Northern Ireland Act 1998

9.1 The Department has considered the matter of Convention rights and is satisfied that there are no matters of concern.

10. EU Implications

10.1 The legislation is essential to implement the changes to the Biocides Directive brought about by Directive 2009/107/EC. Failure to do so would result in the risk of proceedings in the European Courts and potentially heavy fines for the UK.

10.2 A Transposition Note appears at Annex A to this memorandum

11. Parity of Replicatory Measure

11.1 In Great Britain the corresponding Statutory Instrument is the Biocidal Products (Amendment) Regulations 2010 (S.I. 2010/745), which were made on 10 March 2010 and came into force on 6 April 2010.

11.2 As the Great Britain and Northern Ireland proposals, taken together, are intended to ensure that the UK meets the necessary requirements and implement Directive 2009/107/EC, it is essential that the same legal requirements apply throughout the United Kingdom.

12. Additional Information

12.1 Not applicable.

Department of Enterprise, Trade and Investment
22nd April 2010

Transposition Note for DIRECTIVE 2009/107/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods Implemented by the Biocidal Products (Amendment) Regulations (Northern Ireland) 2010		
Article	**Description**	**Transposed by**
1(1)	Amends Article 12 of Directive 98/8/EC dealing with the data protection provisions for information submitted under the Directive for the inclusion of active substances on Annex I of the Directive and for the authorisation or registration of biocidal products containing active substances listed on Annex I. In particular it extends by up to four years the cut-off date for data protection in line with the extended derogations for active substances and biocidal products that are subject to the transitional measures in Article 16 of the Directive. Provision is also made for the further extension of this period by up to two years in line with any decision made under comitology procedures to extend the transitional deadline in Article 16	Regulation. 2(4)(c), (5) and (6)
1(2)	Amends Article 16 of Directive 98/8/EC that provides for a review programme to evaluate all active substances already on the market when the Directive came into force ('existing active substances') to determine whether they satisfy its requirements and can be included on its Annex I, and 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. The amendment extends the date the derogation shall cease to apply by four years to 14th May 2014 to allow the review programme to be completed. Provision is also made for the derogation to be further extended if required, by up to two years by comitology decision.	Regulation 2(4)(b) and (c)