EXPLANATORY MEMORANDUM TO

THE PLANT PROTECTION PRODUCTS REGULATIONS 2005

2005 No. 1435

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 This Statutory Instrument replaces the Plant Protection Products Regulations 2003 (S.I. 2003/3241) and the Plant Protection Products (Amendment) Regulations 2004 (S.I. 2004/1810).

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

3.1 None

4. Legislative Background

4.1 This Instrument continues to implement in England and Wales Council Directive 91/414/EEC. In addition it transposes five new EC Directives which amend Directive 91/414.

4.2 Three of the Directives (Commission Directives 2004/99/EC, 2005/2/EC and 2005/3/EC) amend Annex I to Council Directive 91/414/EEC which lists active substances that may be included in plant protection products (agricultural pesticides) authorised in the framework of the EC pesticides regime which is implemented in England and Wales by these Regulations.

4.3 One of the Directives (Council Directive 2005/25/EC) sets out the "Uniform Principles" (Annex VI of Directive 91/414) for plant protection products containing micro-organisms. This establishes common criteria to ensure that authorisations of plant protection products issued in Member States are assessed to the same standard.

4.4 Finally, Commission Directive 2004/66 amends Annex IV of Directive 91/414 which sets out safety phrases that must be placed on product labels. The Directive amends the Annex to include these safety phrases in the languages of the member States which acceded to the European Union in 2004.

4.5 These five Directives are transposed by being added to the list in Schedule 1 to the Regulations which sets out the instruments that amend Directive 91/414.

4.6 A transposition note is attached for each of the five Directives together with a transposition note that was prepared for the now revoked 2003 Regulations but which still explains how Directive 91/414 has been transposed by the Regulations.

4.7 This instrument transposes Commission Directives which are not subject to Parliamentary Scrutiny.

5. Extent

5.1 This Instrument applies to England and Wales only. Similar legislation is being prepared by the Scottish Executive, Environment and Rural Affairs Department and Department of Agriculture and Rural Development, Northern Ireland.

6. European Convention on Human Rights

6.1 Not applicable

7. Policy background

7.1 Active substances used in pesticides are evaluated at EU level and those that are found to be acceptable in terms of effects on people and the environment are authorised by means of inclusion in Annex 1 of Directive 91/414. These Regulations implement for the first time three Community Directives (Commission Directives 2004/99/EC, 2005/2/EC and 2005/3/EC) which add a further eight pesticide active substances to Annex 1. It is necessary to make amending legislation each time a substance is added to Annex 1. This is a frequent occurrence.

7.2 This Instrument is not politically or legally important. This is a long established and well understood piece of legislation which is being amended in an uncontroversial and relatively minor fashion.

8. Impact

8.1 A regulatory impact assessment has not been prepared in respect of these Regulations as they have no impact on the costs of business.

9. Contact:

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Transposition Note

The Plant Protection Products (Amendment) Regulations 2005

Commission Directive 2004/66/EC

Article	Purpose	Implementation	Comment
1	Amends Directive 91/414/EEC to include safety phrases for plant protection products for new Member States.	Regulation 2(1) and Schedule 1.	See regulation 19 and Schedule 3 paragraph 1(g) of the Plant Protection Products Regulations 2005.
2	Member States to adopt and publish laws regulations and administrative provisions to comply with the Directive by date of entry into force of the Treaty of Accession.		Regulations to come into force on 1 July 2005.
3	Date for Directive entering into force by the date of entry into force of the Treaty of Accession.		

Commission Directive 2004/99/EC

Article	Purpose	Implementation	Comment
1	Amends Annex I to Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances.	Regulation 2(1) and Schedule 1.	Regulation 2(1) and Schedule 1 to the Plant Protection Products Regulations 2005 show Directive 91/414 amended by Directive 2004/99/EC with effect from 1 July 2005.
2	Member States to adopt and publish laws regulations and administrative provisions to comply with the Directive by 30 June 2005 at the latest and to apply them from 1 July 2005.		Regulations to come into force on 1 July 2005.
3	Member States to review authorisations for all plant protection products containing acetamiprid and thiacloprid to ensure compliance with the conditions set out in Annex I by 30 June 2005; and to re-evaluate the product in accordance with the principles of Annex VI by 30 June 2006 at the latest.		Regulations 5 and 6 and to a limited extent 26 and Schedule 4.
4	Directive enters into force 1 January 2005.		

Commission Directive 2005/2/EC

Article	Purpose	Implementation	Comment
1	Amends Annex I to Directive 91/414/EEC to include *Ampelomyces quisqualis* and *Gliocladium catenulatum* as active substances.	Regulation 2(1) and Schedule 1.	Regulation 2(1) and Schedule 1 to the Plant Protection Products Regulations 2005 show Directive 91/414 amended by Directive 2005/2/EC with effect from 1 October 2005.
2	Member States to adopt and publish laws regulations and administrative provisions to comply with the Directive by 30 September 2005 at the latest and to apply them from 1 October 2005.		Regulations to come into force on 1 July 2005 and amendment of the definition of Directive 91/414 by Directive 2005/2 to be applied from 1 October 2005.
3	Member States to review authorisations for all plant protection products containing *Ampelomyces quisqualis* and *Gliocladium catenulatum* to ensure compliance with the conditions set out in Annex I by 30 September 2005; and to re-evaluate the product in accordance with the principles of Annex VI by 30 September 2006 at the latest.		Regulations 5 and 6 and to a limited extent 26 and Schedule 4.
4	Directive enters into force 1 April 2005.		

Commission Directive 2005/3/EC

Article	Purpose	Implementation	Comment
1	Amends Annex I to Directive 91/414/EEC to include imazosulfuron, laminarin, methoxyfenozide and s-metalochlor as active substances.	Regulation 2(1) and Schedule 1.	Regulation 2(1) and Schedule 1 to the Plant Protection Products Regulations 2005 show Directive 91/414 amended by Directive 2005/3/EC with effect from 1 October 2005.
2	Member States to adopt and publish laws regulations and administrative provisions to		Regulations to come into force on 1 July 2005 and

	comply with the Directive by 30 September 2005 at the latest and to apply them from 1 October 2005.		amendment of the definition of Directive 91/414 by Directive 2005/3 to be applied from 1 October 2005.
3	Member States to review authorisations for all plant protection products containing imazosulfuron, laminarin, methoxyfenozide and s-metalochlor to ensure compliance with the conditions set out in Annex I by 30 September 2005; and to re-evaluate the product in accordance with the principles of Annex VI by 30 September 2006 at the latest.		Regulations 5 and 6 and to a limited extent 26 and Schedule 4.
4	Directive enters into force 1 April 2005.		

Council Directive 2005/25/EC

Article	Purpose	Implementation	Comment
1	Amends Annex VI to Directive 91/414/EEC to include Uniform Principles for plant protection products containing micro-organisms.	Regulation 2(1) and Schedule 1.	Regulation 2(1) and Schedule 1 to the Plant Protection Products Regulations 2005 to show Directive 91/414 amended by Directive 2005/25/EC with effect from 1 July 2005.
2	Member States to adopt and publish laws regulations and administrative provisions to comply with the Directive by 28 May 2006.		Regulations to come into force on 1 July 2005.
4	Directive enters into force 28 April 2005.		

Transposition Note

Plant Protection Products Regulations 2003

Commission Directive 91/414/EEC

Article	Purpose	Implementation	Comment
1	Sets scope of Directive		Specific implementation not required
2	Definitions	Regulation 2	
3	General provisions 1 Member States ("MS") to prescribe that plant protection products may not be placed on the market and used in their territory unless authorised in accordance with the Directive 2 MS not to impede the production storage movement of PPPs which are not authorised in their territory if such products are intended for use in another MS 3 MS to prescribe that PPPs must be used properly 4 MS to prescribe Active substances shall not be placed on the market unless certain requirements are fulfilled.	Regulation 3(1) and (2) Regulation 3(5) Regulation 3(2)(b), (c) and (d) Regulation 3(3)	
4	1 MSs to ensure PPP is not authorised unless (a) its active substances are listed in Annex I and conditions set out therein are fulfilled (b) certain requirements are established in the light of current scientific and technical knowledge pursuant to uniform principles (c) the nature and quantity of active substances can	Regulation 6(1) and (2) Regulation 6(1) and (3)	

	be determined by appropriate methods (d) residues resulting from authorised uses can be determined by appropriate methods (e) its physical and chemical properties have been deemed acceptable (f) maximum residue levels have been provisionally established 2. Authorisation to stipulate the requirements relating to the placing on the market and use of the product 3. Compliance with requirements of paragraphs 1(b) – (f) to be established by official or officially recognised tests and analyses 4. Authorisations to be granted for fixed period of up to ten years. Authorisations may be renewed after verification. Authorisations may be renewed to allow verification to be carried out. 6. Authorisations to be cancelled or modified in certain circumstances	Regulation 6(1) and (4) Regulation 6(1) and (5) Regulation 6(1) and (6) Regulation 6(1) and (7) Regulation 5(6) Regulation 6(8) Regulation 5(1) Regulation 5(2) Regulation 5(3) Regulation 13 (3), (5), (6), (7) and (8)	
5	Provisions relating to the		These provisions are not

	inclusion of an Active substance in Annex I to the Directive		addressed to the Member States and no specific implementation is required.
6	Provisions relating to the procedure for inclusion of an Active substance in Annex I Requirement for a MS receiving an application for Annex I inclusion to ensure the applicant forwards it to the other MSs and Commission	Regulation 4(1)	
7	Ms to prescribe that holder of authorisation (or extension of use) must notify competent authority of all new information on potentially dangerous effects.	Regulation 14	
8	1. Ms may approve new active substances not listed in Annex I for a provisional period of up to 3 years 2. Until 31.12.2008 MS may continue to authorise the placing on the market of PPP containing active substances which are not listed in Annex I but which were on the market before 26th July 1993 3. MS to apply requirements of Article 4(1)(b)(i) to(v) and (c) to (f) to products referred to in paragraph 2 above 4. MS to have power to grant emergency approvals	Regulation 7 Regulation 8	Such approvals continue to be granted under the provisions of the Control of Pesticides Regulations 1986 Ditto
9	Procedures for application for authorisation of a PPP and extension of use	Regulations 13 and 10	
10	Mutual recognition of authorisations	Regulation 11	
11	Refusal of mutual	Regulation 12	

	recognition of authorisation		
12	Exchange of information		Specific implementation not required
13	1. MS to require applicants for authorisation of a PPP to submit a dossier satisfying the requirements of Annex III and for each active substance a dossier satisfying the requirements of Annex II 2. Applicants exempted from supplying certain information in certain circumstances 3. MSs not to use information referred to in Annex II for benefit of other applicants except in limited circumstances 4. MSs not to use information referred to in Annex III for benefit of other applicants except in limited circumstances 5. Ms to inform Commission of certain information 6. MSs to continue to apply existing national data rules for PPP on the market before 26th July 1993 which contain active substances not listed in Annex I 7. Requirement for applicants to notify MS of intention to carryout experiments on vertebrate animals	Regulation 5(4) Regulation 5(5) Regulation 15(1) and (2) Regulation 15(3) and (4) Regulation 15(5) Regulation 26, Schedule 4 paragraphs 1 and 12 Regulation 16	
14	MS to treat some information as confidential and other information as non-confidential	Regulation 17 and Schedule 2	
15	Article 5(1) of Directive	Regulation 18	

	78/631/EEC (now 1999/45/EC) to apply to all PPP		
16	PPP labelling requirements	Regulation 19 and Schedule 3	
17	MS to make necessary arrangements to check PPPs placed on the market.	Regulation 24	
18 19 20 21	Administrative provisions		These provisions are not addressed to the Member States and no specific implementation is required
22	Authorisations for trial purposes	Regulation 9	
23	Implementation requirements	Regulation 1	The Directive was originally implemented by The Plant protection products regulations 1995 (S.I. 1995/887) which are consolidated and modified, insofar as they extend to England and Wales by these Regulations