



STATUTORY INSTRUMENTS.

**S.I. No. 158 of 2011**



EUROPEAN COMMUNITIES (AUTHORISATION, PLACING ON THE  
MARKET, USE AND CONTROL OF BIOCIDAL PRODUCTS)  
(AMENDMENT) REGULATIONS 2011

**(Prn. A11/0523)**

S.I. No. 158 of 2011

EUROPEAN COMMUNITIES (AUTHORISATION, PLACING ON THE  
MARKET, USE AND CONTROL OF BIOCIDAL PRODUCTS)  
(AMENDMENT) REGULATIONS 2011

I, SIMON COVENEY, Minister for Agriculture, Fisheries and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), for the purpose of giving further effect to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998<sup>1</sup>, hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) (Amendment) Regulations 2011.

2. The European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended by substituting for the matter in the Third Schedule the matter in the Schedule to these Regulations.

<sup>1</sup>O.J. No. L123 of 24.4.1998, p.1

*Notice of the making of this Statutory Instrument was published in  
"Iris Oifigiúil" of 8th April, 2011.*

## Schedule

“1. The European Communities (Flavourings for Use in Foodstuffs) Regulations, 1992 (S.I. No. 22 of 1992).

2. The European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations 1994, (S.I. No. 176 of 1994) as amended by the European Communities (Animal Remedies and Medicated Feedingstuffs) (Amendment) Regulations 2003 (S.I. No. 365 of 2003).

3. The European Communities (Medical Devices) Regulations, 1994 (S.I. No. 252 of 1994) as amended by the European Communities (Medical Devices) (Amendment) Regulations, 2001 (S.I. No. 444 of 2001), the European Communities (Medical Devices) (Amendment) Regulations, 2002 (S.I. No. 576 of 2002), the European Communities (Medical Devices) (Reclassification of Breast Implants) (Amendment) Regulations, 2003 (S.I. No. 358 of 2003), the European Communities (Medical Devices) (Tissues of Animal Origin) Regulations, 2003 (S.I. No. 554 of 2003), the European Communities (Medical Devices) (Reclassification of Hip, Knee & Shoulder Joint Replacements) (Amendment) Regulations 2007 (S.I. No. 92 of 2007), and the European Communities (Medical Devices) (Amendment) Regulations 2009 (S.I. No. 110 of 2009).

4. The European Communities (Active Implantable Medical Devices) Regulations, 1994 (S.I. No. 253 of 1994), as amended by the European Communities (Medical Devices) (Amendment) Regulations, 2001, (S.I. No. 444 of 2001), and the European Communities (Active Implantable Medical Devices) (Amendment) Regulations, 2009, (S.I. No.109 of 2009).

5. The European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations 2000 (S.I. No. 437 of 2000), as amended by the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations 2001 (S.I. No. 342 of 2001), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations 2002 (S.I. No. 344 of 2002), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment No. 3) Regulations 2002 (S.I. No. 380 of 2002), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations 2005 (S.I. No. 61 of 2005), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) (No. 2) Regulations 2005 (S.I. No. 192 of 2005), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) (No. 3) Regulations 2005 (S.I. No. 193 of 2005), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations 2007 (S.I. No. 171 of 2007), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations 2008 (S.I. No. 34 of 2008), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) (No. 2) Regulations 2008 (S.I. No. 59 of 2008), the European Communities (Additives, Colours and Sweeteners in

Foodstuffs) (Amendment) (No. 3) Regulations 2008 (S.I. No. 369 of 2008), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations 2009 (S.I. No. 126 of 2009), the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations 2010 (S.I. No. 522 of 2010), and the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) (No. 2) Regulations 2010 (S.I. No. 534 of 2010).

6. The European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulation 2003 (S.I. No. 83 of 2003), as amended by the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 2) Regulations 2005 (S.I. No. 224 of 2005), the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 4) Regulations 2006 (S.I. No. 381 of 2006), the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 4) Regulations 2009 (S.I. No. 329 of 2009), the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 4) Regulations 2010 (S.I. No. 541 of 2010), and the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations 2011 (S.I. No. 104 of 2011).

7. The European Communities (Food Additives other than Colours and Sweeteners) Regulations 2004 (S.I. No. 58 of 2004), as amended by the European Communities (Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2005 (S.I. No. 369 of 2005), and the European Communities (Food Additives other than Colours and Sweeteners) (Amendment) Regulations 2008 (S.I. No. 40 of 2008).

8. The European Communities (Cosmetic Products) Regulations 2004, (S.I. No. 870 of 2004), as amended by the European Communities (Cosmetic Products) (Amendment) Regulations 2005 (S.I. No. 711 of 2005), the European Communities (Cosmetic Products) (Amendment No. 2) Regulations 2006 (S.I. No. 64 of 2006), the European Communities (Cosmetic Products) (Amendment No. 3) Regulations 2006 (S.I. No. 373 of 2006), the European Communities (Cosmetic Products) (Amendment No. 4) Regulations 2006 (S.I. No. 506 of 2006), the European Communities (Cosmetic Products) (Amendment No. 5) Regulations 2007 (S.I. No. 235 of 2007), the European Communities (Cosmetic Products) (Amendment) Regulations 2008 (S.I. No. 6 of 2008), the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2008 (S.I. No. 370 of 2008), the European Communities (Cosmetic Products) (Amendment) Regulations 2009 (S.I. No. 191 of 2009), the European Communities (Cosmetic Products) (Amendment) (No. 2) Regulations 2009 (S.I. No. 552 of 2009), the European Communities (Cosmetic Products) (Amendment) Regulations 2010 (S.I. No. 194 of 2010), the European Communities (Cosmetics Products) Regulations 2010 (S.I. No. 417 of 2010), and the European Communities (Cosmetics Products) (Amendment) (No. 3) Regulations 2010 (S.I. No. 440 of 2010).

9. Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004<sup>2</sup>.

10. European Communities (Feed Additives) Regulations 2005 (S.I. No. 242 of 2005).

11. Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), as amended by the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2009 (S.I. No. 3 of 2009), the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) (No. 2) Regulations 2009 (S.I. No. 553 of 2009), and the Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2010 (S.I. No. 287 of 2010).

12. European Communities (Plastics and other materials) (Contact with food) Regulations 2007 (S.I. No. 587 of 2007), as amended by the European Communities (Plastics and other materials) (Contact with food) (Amendment) Regulations 2009 (S.I. No. 88 of 2009), the European Communities (Plastics and other materials) (Contact with food) (Amendment) (No. 2) Regulations 2009 (S.I. No. 463 of 2009), and the European Communities (Plastics and other materials) (Contact with food) (Amendment) (No. 2) Regulations 2009 (S.I. No. 301 of 2010).

13. European Communities (Animal Remedies) (No. 2) Regulations 2007, (S.I. No. 786 of 2007), as amended by the European Communities (Animal Remedies) (Amendment) Regulations 2009 (S.I. No.182 of 2009).

14. European Communities (Food and Feed Hygiene) Regulations 2009 (S.I. No. 432 of 2009), as amended by the European Communities (Food and Feed Hygiene) (Amendment) Regulations 2010 (S.I. No. 312 of 2010), the European Communities (Food and Feed Hygiene) (Amendment) (No. 2) Regulations 2010 (S.I. No. 488 of 2010), and the European Communities (Food and Feed Hygiene) (Amendment) (No. 3) Regulations 2010 (S.I. No. 587 of 2010).”.



GIVEN under my Official Seal,  
31 March 2011.

SIMON COVENEY,  
Minister for Agriculture, Fisheries and Food.

<sup>2</sup>O.J. No. L136 of 30.04.2004, p.1

EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation)*

These Regulations update legislation concerning the use of biocides in medical, foodstuffs, feedstuffs and cosmetic processes deemed to be outside the scope of Directive 98/8/EC as amended.

BAILE ÁTHA CLIATH  
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
Le ceannach díreach ón  
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,  
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,  
nó tríd an bpost ó  
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,  
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,  
CONTAE MHAIGH EO,  
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)  
nó trí aon díoltóir leabhar.

---

DUBLIN  
PUBLISHED BY THE STATIONERY OFFICE  
To be purchased directly from the  
GOVERNMENT PUBLICATIONS SALE OFFICE  
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,  
or by mail order from  
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,  
UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO,  
(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)  
or through any bookseller.

---

€2.54

