



Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

The Manual was published by Earthscan/Routledge from 2010 to 2012. It was designed as an on-line interactive reference work and annual printed versions were also produced.

This section is the text of the Manual as published in 2012. It is therefore important to note the following:

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The Manual should be cited as follows:

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Maximum residue levels of pesticides

Formal references	
Regulation (EC) No 396/2005 (OJ L70 16.3.2005)	Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Proposed 14.3.2003 – COM(2003)117	
Regulation amended by	
Regulation (EC) No 299/2008 (OJ L97 9.4.2008)	Amends maximum residue levels of pesticides in or on food and feed of plant and animal origin, as regards the implementing powers conferred on the Commission
Annexes of Regulation amended by	
Regulation (EC) No 178/2006 (OJ L29 2.2.2006)	Regulation establishing Annex I listing the food and feed products to which maximum levels for pesticide residues apply
Regulation (EC) No 149/2008 (OJ L58 1.3.2008)	Regulation establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto
Regulation (EC) No 260/2008 (OJ L76 19.3.2008)	Regulation establishing Annex VII listing active substance/product combinations covered by a derogation as regards post-harvest treatments with a fumigant
Regulation (EC) No 839/2008 (OJ L234 30.8.2008)	Regulation amends Annexes II, III and IV on maximum residue levels of pesticides in or on certain products
Regulation (EC) No 256/2009 (OJ L81 27.3.2009)	Regulation amends Annexes II and III as regards maximum residue levels for azoxystrobin and fludioxonil in or on certain products
Regulation (EC) No 822/2009 (OJ L239 10.9.2009), Corrigendum (OJ L60, 10.3.2010)	Regulation amends Annexes II, III and IV as regards maximum residue levels for azoxystrobin, atrazine, chlormequat, cyprodinil, dithiocarbamates, fludioxonil, fluroxypyr, indoxacarb, mandipropamid, potassium tri-iodide, spirotetramat, tetraconazole and thiram in or on certain products
Regulation (EC) No 1050/2009 (OJ L290 6.11.2009), Corrigendum (OJ L338, 19.12.2009)	Regulation amends Annexes II and III as regards maximum residue levels for azoxystrobin, acetamiprid, clomazone, cyflufenamid, emamectin benzoate, famoxadone, fenbutatin oxide, flufenoxuron, fluopicolide, indoxacarb, ioxynil, mepanipyrim, prothioconazole, pyridalyl, thiacloprid and trifloxystrobin in or on certain products
Regulation (EC) No 1097/2009 (OJ L301 17.11.2009)	Regulation amends Annex II as regards maximum residue levels for dimethoate, ethephon, fenamiphos, fenarimol, methamidophos, methomyl, omethoate, oxydemeton-methyl, procymidone, thiodicarb and vinclozolin in or on certain products
Regulation (EU) No	Regulation amends Annex II as regards to maximum residue

304/2010 (OJ L94, 15.4.2010)	levels for 2-phenylphenol in or on certain products
Regulation (EU) No 459/2010 (OJ L129, 28.5.2010)	Regulation amends Annexes II, III and IV on maximum residue levels of pesticides in or on certain products
Regulation (EU) No 765/2010 (OJ L226, 28.8.2010)	Regulation amends Annexes II and III as regards maximum residue levels for chlorothalonil clothianidin, difenoconazole, fenhexamid, flubendiamide, nicotine, spirotetramat, thiacloprid and thiamethoxam in or on certain products
Regulation (EU) No 310/2011 (OJ L86, 1.4.2011)	Regulation amends Annexes II and III as regards maximum residue levels for aldicarb, bromopropylate, chlorfenvinphos, endosulfan, EPTC, ethion, fenthion, fomesafen, methabenzthiazuron, methidathion, simazine, tetradifon and triforine in or on certain products
Regulation (EU) No 460/2011 (OJ L136 24.5.2011)	Regulation amends Annex III as regards the maximum residue level for chlorantraniliprole (DPX E-2Y45) in or on carrots
Regulation (EU) No 508/2011 (OJ L137 25.5.2011)	Regulation amends Annexes II and III as regards maximum residue levels for abamectin, acetamiprid, cyprodinil, difenoconazole, dimethomorph, fenhexamid, proquinazid, prothioconazole, pyraclostrobin, spirotetramat, thiacloprid, thiamethoxam and trifloxystrobin in or on certain products
Regulation (EU) No 520/2011 (OJ L140 27.5.2011)	Regulation amends Annexes II and III as regards maximum residue levels for benalaxyl, boscalid, buprofezin, carbofuran, carbosulfan, cypermethrin, fluopicolide, hexythiazox, indoxacarb, metaflumizone, methoxy- fenozide, paraquat, prochloraz, spiroadiclofen, prothioconazole and zoxamide in or on certain products
Regulation (EU) No 524/2011 (OJ L142 28.5.2011)	Regulation amends Annexes II and III as regards maximum residue levels for biphenyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole in or on certain products
Legal base (original Regulation)	Articles 43 and 168 TFEU (originally Articles 37 and 152(4)(b) TEC)
Binding dates	
Notification date	23 February 2005
Formal compliance (apart from chapters II, III and IV)	4 April 2005
Formal compliance for chapters II, III and IV	1 September 2008

Purpose of the Regulation

The purpose of Regulation (EC) No 396/2005 is to protect consumers and animal health by setting limits and controls on the amounts of pesticides on food and animal feeding stuffs and to facilitate trade by setting common standards. The Regulation is not primarily intended to protect the environment.

Summary of the Regulation

The Regulation establishes the maximum levels of pesticide residues permitted on food and feed of plant or animal origin that are intended for human or animal consumption. The Regulation concerns all commodities covered by previous repealed Directives, including fruits, vegetables, dry pulses, oilseeds, cereals, spices, sugar plants and products of animal origins. This list of products is periodically revised.

Products are not subject to the limits if they are intended for manufacture of non-food products, for sowing or planting, for authorized testing of active substances and for export to EU third countries when the country of destination requires a particular treatment to prevent introduction of harmful organisms.

A new provision introduced by this Regulation is the introduction of a default limit for products for which no maximum residue levels (MRLs) have been specifically established. The default limit is set at 0.01 mg/kg. Specific MRLs are listed in Annex II containing limits already established by previous Directives. Annex III provides provisional MRLs which are allowed under specific circumstances.

Derogations from the limits may be authorized, even if they exceed MRLs, provided that the products are not intended for immediate consumption, if appropriate controls are in place to ensure that such products are not made available to the consumer and that the other Member States and the Commission have been informed. In exceptional cases, products not complying with limits may be authorized if they do not represent an unacceptable risk notified with an appropriate risk assessment. Certain active substances listed in Annex IV are not subject to any residue limit.

According to the Regulation a control programme is to be prepared and coordinated by the Commission identifying specific samples to be included in national control programmes ensuring compliance with the MRLs. This control programme is updated and adopted every year.

Development of the Regulation

Prior to Regulation (EC) No 396/2005 EU legislation on pesticides residues was based on four framework Council Directives, covering fruit and vegetables (Directive [76/895/EEC](#)) cereals and food of animal origin (Directives [86/362/EEC](#) and [86/363/EEC](#)), and animal feeding stuffs (Directive [90/642/EEC](#)), which established different MRLs for different sets of commodities.

The European Commission announced in May 2001 that its fifth round of Simplification of Legislation in the Internal Market (SLIM) would focus on reducing the regulatory burden and cost to users of legislation on pesticide residues in fruit and vegetables. The SLIM initiative, an early manifestation of the Better Regulation approach, was launched in 1996. The SLIM report published in November 2001 called for EU rules on MRLs to be ‘comprehensively overhauled and streamlined’. Its main recommendations were for the four main MRL Directives to be replaced by a single piece of legislation covering all food products and for a more direct procedure for setting MRLs. In addition, it recommended that the EU re-examine the rules requiring MRLs to be set at the limit of detection for any non-authorized pesticide–foodstuff combination, with a view to speeding up the consequent MRL-setting process by the Member States. In response to this report, in March 2003, the Commission proposed a Regulation that would harmonize EU MRLs of pesticides permitted in products of plant and animal origin.

Implementation of the Regulation

The delay in bringing the Regulation into effect completely was due to the fact that a number of Annexes establishing MRLs through separate amending Regulations required consideration by the European Food Standards Authority. Annex I, listing the food and feed products to which maximum levels for pesticide residues apply, was adopted in February 2006 (Regulation (EC) No 178/2006 of 1 February 2006 amends Regulation (EC) No 396/2005 to this effect), and Annexes II, III and IV, setting MRLs for products covered by Annex I, were adopted in January 2008 (Regulation (EC) No 149/2008 of 29 January 2008 amends Regulation (EC) No 396/2005 to this effect). This Regulation constituted the last of the Regulations establishing Annexes to Regulation (EC) No 396/2005, which meant that the Regulation could be applied as a whole from 1 September 2008.

A Commission Recommendation ([C/2008/369](#)) of 4 February 2008 proposes a coordinated Community monitoring programme for 2008 to ensure compliance with certain MRLs, and national monitoring programmes for 2009 and 2010.

In September 2008 the Commission published a report¹ on the Implementation of Regulation (EC) No 396/2005. In effect this is not an implementation report as such but a summary of the Regulation and how it harmonizes the earlier Regulations.

Enforcement and court cases

So far there have been no European Court of Justice cases linked to this Regulation.

Related legislation

The following pieces of legislation have a strong interaction with this Directive:

- Regulation (EC) No [1107/2009](#) concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
- Directive [8/98/EC](#) on placing of biocidal products on the market.
- Directive [2009/128/EC](#) establishing a framework for Community action to achieve the sustainable use of pesticides.

Reference

1 CEC (2008) Implementation of Regulation (EC) No 396/2005 on Maximum Residues Levels of pesticides, DG Health and Consumer Protection, September 2008, http://ec.europa.eu/food/plant/protection/pesticides/implementation_reg_396_2005.pdf, Accessed 29.01.10