

In onderstaande tabel zijn de aan te wijzen richtsnoeren en nationale beoordelingsmethoden opgenomen.

Deel A bevat de **richtsnoeren** die de ministers van LNV en VROM op basis van de artikelen 2.4 en 3.4 van de Regeling gewasbeschermingsmiddelen en biociden voornemens zijn aan te wijzen.

Deel B bevat de **nationale beoordelingsmethoden** die de ministers van LNV en VROM op grond van de artikelen 8, derde lid, en artikel 12, derde lid, van het Besluit gewasbeschermingsmiddelen en biociden voornemens zijn aan te wijzen. Bijlage XV is gereserveerd voor deze methoden.

#### Deel A: Richtsnoeren

*Aan te wijzen richtsnoeren als bedoeld in artikelen 2.4 en 3.4 Rgb*

#### Gewasbeschermingsmiddelen

Richtsnoeren	Rgb artikelen
Algemeen	
Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. SANCO/221/2000 rev. 10. (25.02.2003)	
Guideline developed within the Standing Committee on the Food Chain and Animal Health on the taxonomic level of micro-organisms to be included in Annex I to Directive 91/414/EEC. Sanco/10754/2005, rev 5. (15.04.2005)	
Draft guidance document on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC. Rev 2. (12.11.2007)	
OECD Draft Document ENV/JM/PEST(2006)4, Status of work to develop a Guidance Document as well as a description of the topics that will be presented in the document, 12 January 2006, draft.	
Werkzaamheid	
Proposal for existing and harmonizing efficacy and crop safety extrapolation to reduce the need for efficacy trials on minor use. SANCO/D3/S12.395857, final (2005).	
Fysisch/chemische eigenschappen	

Richtsnoeren	Rgb artikelen
Guidance document on the assessment of the equivalence of technical materials of substances regulated under Council Directive 91/414/EEC. SANCO/10597/2003, rev.7 final 2 (2005)	
Analysemethoden	
Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414/EEC. SANCO/3029/1999, rev 4(2000).	
Guidance document on residue analytical methods. SANCO/825/2000, rev 7 (2004)	
Technical material and preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414/EEC. SANCO/3030/1999, rev 4 (2000)	
Humane toxicologie	
Guidance for the setting and application of Acceptable Operator Exposure Levels (AOEL's). SANCO/7531, rev 10. (2006)	
Guidance for the setting of an Acute Reference Dose (ArfD). 7199/VI/99, rev 5. (2001)	
Guidance document on dermal absorption. SANCO/222/2000, rev 7. (2004)	
Residuen	
Guidelines for the generation of data concerning residues as provided in Annex II part A, section6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, foreword and appendices A-I. Sanco, 1607/VI/97, rev 2.(1999) 7028/VI/p5, rev 3.(1997) 7029/VI/95, rev 6.(2000) 7524/VI/95, rev 2.(1997) 7525/VI/95, rev 8.(2008) 7035/VI/95, rev 5.(1997) 7030/VI/95, rev 3.(1997) 7031/VI/95, rev 4.(1996) 7032/VI/95, rev 5.(1997) 7039/VI/95.(1997)	

Richtsnoeren	Rg artikelen
Milieu	
Guidance document on persistence in soil. 9188/VI/97, rev. 8. (2008)	
Soil persistence models and EU registration. 7617/VI/96 (1997)	
FOCUS (2000) "FOCUS groundwater scenarios in the EU review process" – The report of the work of the Groundwater Scenarios Workgroup of FOCUS (FORum for the Co-ordination of pesticide fate models and their USE). Sanco/321/2000, Rev. 2. (2002)	
Generic guidance for FOCUS groundwater scenarios, version 1.1. (2002)	
FOCUS (2001) "FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios. SANCO/4802/2001, rev. 2. (2003)	
FOCUS (2007) "Landscape and mitigation factors in aquatic risk assessment. Volume 1. Extended summary and recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. SANCO/10422/2005, version 2.0. (2007)	
FOCUS (2005) "Landscape and mitigation factors in aquatic risk assessment. Volume 2. Detailed technical reviews". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. SANCO/10422/2005, version 1.0. (2005)	
FOCUS (2006) "Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration" Report of the FOCUS Work Group on Degradation Kinetics. SANCO/10058/2005, version 2.0. (2006)	
FOCUS (2006) "Pesticides in air: considerations for exposure assessment". Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference Sanco/10553/2006, Rev 2. (2008)	
Guidance document on aquatic ecotoxicology in the context of Directive 91/414/EEC. SANCO/3268/2001, rev 4 final. (2002)	
Guidance document on terrestrial ecotoxicology in the context of Directive 91/414/EEC. SANCO/10392/2002, rev 2 final. (2002)	
Guidance document on risk assessment for birds and mammals under Council Directive 91/414/EEC. SANCO/4145/2000, final (2002)	

Extra 1: analysemethode residuen in oppervlaktewater: bepalingsgrens 0,1µg/l of lager als dat voor een stof eco- of humaan toxicologisch nodig is.

Extra 2: niet-professionele toepasser met behulp van Europese beoordelingsmethodieken voor de professionele toepasser beoordelen

Extra 3: eerste tier norm RWZI wordt gelijkgesteld aan eerste tier norm waterorganismen

Extra 4: toetsing aan meetgegevens op basis van 90-percentiel waarde

Extra 5: nationale driftcijfers in risicobeoordeling waterorganismen, vogels, niet-doelwit planten en – arthropoden

## Biociden

Richtsnoeren	Rg artikelen
Algemeen	
<p>Technical Notes for Guidance in support of the directive 98/8/EC of the European Parliament and the council concerning the placing of biocidal products on the market. Principles and practical procedures for the inclusion of active substances in annexes I, IA and IB. (TNSG on Annex I inclusion) Final draft. (2002)</p>	
<p>Technical Guidance Document in support of the directive 98/8/EC concerning the placing of biocidal products on the markets. Guidance on data requirements for active substances and biocidal products. (TNSG on data requirements) Final draft version 4.3.2 (2000).</p>	
<p>Technical Notes for Guidance in support of the directive 98/8/EC of the European Parliament and the council concerning the placing of biocidal products on the market. Common principles and practical procedures for the authorisation and registration of products. (TNSG on product evaluation). Ver 10.0 Final draft (2002)</p>	
<p>Manual of decisions for implementation of directive 98/8/EC concerning the placing on the market of biocidal products.</p>	
<p>Technical Guidance Document on Risk Assessment in support of the Commission Directive 93/67/EEC on risk assessment for new notified substances, the Commission Regulation (EC) N0. 1488/94 on risk assessment for existing substances, published in 1996 and Directive 98/8/EC of the European Parliament and of the Council. European Communities (2003).</p>	
Werkzaamheid	
<p>Technical notes for guidance on product evaluation. Appendices to chapter 7 Product Type 14. Efficacy evaluation of rodenticidal biocidal products. (2009)</p>	
Fysisch/chemische eigenschappen	
<p>Draft -Technical Notes for Guidance on the assessment of technical equivalence of substances regulated under Directive</p>	

Richtsnoeren	Rgb artikelen
98/8/EC. Version 4.	
Analysemethoden	
Humane toxicologie	
User guidance. Human exposure to biocidal products. version 1 (2004).	
Additional Guidance for Exposure during manufacture (2006)	
Human exposure to biocidal products : Technical notes for guidance. (2008)	
Residuen	
Milieu	
EUSES 2.1. <a href="http://ecb.jrc.ec.europa.eu/euses/">http://ecb.jrc.ec.europa.eu/euses/</a>	

Extra 1: analysemethode residuen in oppervlaktewater: bepalingsgrens 0,1µg/l of lager als dat voor een stof eco- of humaan toxicologisch nodig is.

Extra 2: niet-professionele toepasser met behulp van Europese beoordelingsmethodieken voor de professionele toepasser beoordelen

Extra 3: eerste tier norm RWZI wordt gelijkgesteld aan eerste tier norm waterorganismen

Extra 4: methodiek afleiden DT50- en Kp-waarden

Extra 5: werkzaamheidsnorm desinfectantia

(onderdeel M van de voorliggende wijzigingsregeling)

Deel B: Nationale methodieken en modellen  
*Bijlage als bedoeld in de artikelen 2.4a en 3.4a*

Referentie	Gewasbeschermingsmiddelen	Biociden	Opmerkingen
Algemeen			
Ctgb (2009) Combinatietoxicologie	X	X	
Werkzaamheid			
Ctgb (2008) Nadere specificering beoordeling werkzaamheid van desinfectantia voor drinkwater.		X	
EPPO Standards. Guidelines for the efficacy evaluation of plant protection products. 2e ed. Vol 1-5. (2004).	X		
Fysisch/chemische eigenschappen			
Analysemethoden			
RIVM (2003) Classification of crops grown in or imported into the European Union for pesticide residue assessment. Report 613340006/2003.	X		
Humane toxicologie			
Paulussen, J.J.C., Mahieu, C.M., Bos, P.M.J. Default values in occupational risk assessment, TNO report V98.390 (1998).	X	X	
Assessment factors for human risk assessment, RIVM Factsheet FSV-004/00 (2001).	X	X	
Hakkert, B.C. (2001). - Occupational risk assessment of pesticides – Method used in the Netherlands for the setting of Acceptable Operator Exposure Levels. TNO-report V4245.	X	X	
Bremmer et al. Pest control products factsheet, to assess the risk for the consumer. RIVM 2002. Report 613340003/2002. (Nederlandse versie - Rapport 613340002/2002).		X	
OECD (1997) Guidance document for the conduct of studies of	X		

Referentie	Gewasbeschermingsmiddelen	Biociden	Opmerkingen
occupational exposure to pesticides during agricultural application. Series on testing and assessment No. 9. OECD/GD(97)148			
Hazard assessment for direct immunotoxicity, RIVM Factsheet FSV-009/00 In Report 601516010. (2002)	X		
RIVM-rapport 601516 007 m.b.t. factsheets over acetylcholine-esteraseremming en MetHB-vorming.	X		
JMPR (1998) General Considerations: Interpretation of choline-esterase inhibition	X		
WHO (1987) EHC 104, Principles for the Toxicological Assessment of Pesticide Residues in Food, WHO 1990; EHC 70, Principles for the Safety Assessment of Food Additives and Contaminants in Food.	X		
Calculating cancer risk, 1995/06WGD	X		
Drooge, H.L. van, Huijbers, R.F., Kerkman, M., Groeneveld, C.N., Schipper, H.J. Pesticide application patterns of contract workers in agriculture. TNO report V3680 (2001).	X		
OECD Series on testing and assessment No. 9. Guidance document for the conduct of studies of occupational exposure to pesticides during agricultural application. OECD/GD(97)148.	X		
EUROPOEM I. (1996). The development, maintenance and dissemination of a European Predictive Operator Exposure Model (EUROPOEM) database. Draft final report, Commissie-document 7857/VI/97.	X		
EUROPOEM Re-entry: Post application exposure to pesticides of workers in agriculture, Report of the re-entry workgroup, EUROPOEM II project, 2002; FAR3, CT96-1406, Draft Report.	X		
EUROPOEM Bystander: Bystander working group report. EUROPOEM II project, 2002, Draft report.	X		
Van Hemmen, JJ. (1992) Assessment of occupational exposure to pesticides in agriculture. Part I General aspects. Part II Mixing and loading. Part III Application. S-reeks S141 1/3, Ministerie SZW, Den Haag.	X		
Van Goldstein Brouwers, YGC, Marquart, J, Van Hemmen, JJ. (1996) Assessment of occupational exposure to pesticides in Agriculture. Part IV Protocol for the use of generic exposure data. TNO Voeding, Rijswijk, Nederland, TNO report V 96.120.	X		

Referentie	Gewasbeschermingsmiddelen	Biociden	Opmerkingen
Lundehn, J. R., Westphal, D., Kieczka, D., Krebs, B., Löcher-Bolz, S., & Maasfeld, W. (1992). Uniform principles for safeguarding the health of applicators of plant protection products (Uniform principles for operator protections); Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft Bundesrepublik Deutschland, Heft no. 277, Berlin, Germany.	X		
Snippe R.J., Drooge H.L. van, Schipper H.J., Pater A.J. de, Hemmen J.J. van, (2002). Pesticide exposure assessment for registration purposes.. TNO- report V3642. (2002)	X		
Golstein Brouwers Y.G.C. van, Marquart J., Hemmen J.J. van, (1996) Assessment of occupational exposure to pesticides in agriculture. Part IV: Protocol for the use of generic exposure data. TNO-rapport V 96.120.	X		
Schipper, H.J., Brouwer, D.H., Van Hemmen, J.J. (1996). Exposure to pesticides during planting and potting activities. Pilot in tomato and cyclamen crop. TNO-report V96.134.	X		
Schipper, H.J., Brouwer, D.H., Van Hemmen, J.J. (1996). Exposure to pesticides during application and harvest activities. Pilot in mushroomhouses. TNO-report V96.136.	X		
Beelen, M.S.C., Golstein-Brouwers Y.G.C. van Hemmen J.J. van, (1996). Exposure modelling for fruit growing in the Netherlands. Preliminary analysis of Dutch field studies. TNO-rapport V 96.050.	X		
Schipper, H.J., Brouwer, D.H., Van Golstein-Brouwers, Y.C.G., Van Hemmen, J.J. (1996). Boom en heesterteelt: werkzaamheden en gebruik. TNO-rapport V96.135.	X		
De Vreede, J.A.F., Van Amelsfoort, M. (1997). Exposure to pesticides in a tree nursery using the spray boom and spray lance. TNO-report V97.111.	X		
De Vreede, J.A.F., Van Amelsfoort, M. (1997). Exposure to pesticides during application in tree nurseries using an airblast technique. TNO-report V97.119.	X		
De Cock, J.S., Van Hemmen, J.J. (1997). Pesticides exposure modelling for fruit growing in the Netherlands. Usefulness of available exposure data for authorization procedures. TNO-file R96-559.v03.	X		
De Haan, M., Brouwer, D.H., Van Hemmen, J.J. (1998). Exposure during mechanical application of a granular pesticide. TNO-report V97.779.	X		



Referentie	Gewasbeschermingsmiddelen	Biociden	Opmerkingen
Brouwer, et al. (1997). Determination of efficiency for exposure reduction of protective clothing by biological monitoring in a field study. S131-6. ISBN 90-1208-455-5.	X		
RIVM (2004) CONSEXPO 4.0	X		
H.J. Bremmer et al. Pest control products factsheet. To assess the risks for the consumer (2006) Updated version for ConsExpo 4. RIVM report 320005002.		X	
Peppelman, G., van der Lans, A.M., Groot, M.J., Anbergen, R.H.N., van den Ende, J.E., Hendrix, A.T.M. (2002) De toediening van gewasbeschermingsmiddelen in relatie tot arbeid. Blootstellingsrisico's. Praktijkonderzoek Plant & Omgeving (PPO), sector fruit, bollen. Rapportnummer 2002-23..	X		
Van der Jagt, K. E. en S. Dekkers (2002) Advies met betrekking tot het gebruik op de werkplek van ABC #4 antifouling een middel op basis van koper(I)oxide. TNO-rapport 02-025-H-353.		X	
W. ter Burg et al. Oral exposure of children to chemicals via hand-to-mouth contact (2007). RIVM report 320005004.		X	
R. Gerritsen-Ebben et al. (2007) Effective personal protective equipment (PPE). TNO report V733.	X	X	
UK-POEM 07. <a href="http://www.pesticides.gov.uk">www.pesticides.gov.uk</a>	X		
L.C.H. Prud'homme de Lodder et al (2006). Assessment of secondary exposure to lawn pesticides. RIVM SIR report 09709A00.	X		
L.CH.Lodder et al. Disinfectants products factsheet. To assess the risks for the consumer( 2006). RIVM report 320005003.		X	
J.G.M. Engelen et al. (2007) Non-food products: how to assess children's exposure. RIVM report 320005005.		X	
Residuen			
RIVM (2003) Classification of crops grown in or imported into the European Union for pesticide residue assessment. Report 613340006/2003.	X		
RIVM (2004) Guidelines for selection and presentation of residue values of pesticides. Report 613340007/2004	X		

Referentie	Gewasbeschermingsmiddelen	Biociden	Opmerkingen
Milieu			
Van der Linden, A.M.A et al (2004). The new decision tree for the evaluation of pesticide leaching from soils., RIVM report 601450019/2004.	X		
RIVM, VROM, VWS (1998). USES 2.0, the Uniform System for the Evaluation of Substances." National Institute of Public Health and the Environment (RIVM), Ministry of Housing, Spatial Planning and the Environment (VROM), Ministry of Health, Welfare and Sport (VWS), The Netherlands. RIVM report 679102044	X	X	Voor gewasbeschermingsmiddelen alleen onderdelen emissieroute via RWZI en verhardingen
De Leeuw, J. et al (1995). Risk of granules and treated seeds to birds on arable fields. CML report 118	X		
De Snoo, G.R. en R. Luttkik (2004). Availability of pesticide-treated seed on arable fields. Pest Management Science 60:501-506.	X		
Van den Berg et al (2006). FOCUS PEARL 3.3.3 - Documentation update for PEARL 3.3.3 (addendum to model documentation)	X		
Tiktak, A. et al, 2003, The GeoPEARL model, Model description, applications and manual. RIVM report 716601007/2003	X		
Tiktak, A. et al, 2004, The GeoPEARL model, Part II. User guide and model description update. RIVM report 716601008/2004	X		
Van den Berg, F et al, 2008, Uncertainty and sensitivity of GeoPEARL. Alterra report 1330, PBL-rapport 500123001	X		
Van Vlaardingen P.L.A. and E.M.J. Verbruggen (2007), Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS).	X		
Adriaanse, P.I. et al, (1996). Fate of pesticides in field ditches: the TOXSWA simulation model. Alterra-rapport nr. 023	X		Blootstellingsroute via drift en niet drainage en afspoeling
Adriaanse, P.I. et al (2008). Development of an assessment methodology to evaluate agricultural use of plant protection products for drinking water production from surface waters - a proposal for the registration procedure in the Netherlands. Alterra-rapport nr. 1635, ISSN 1566-7197.	X		
Ctb (2005) Tijdelijke beoordelingsmethodiek drinkwatercriterium	X	X	Voor verhardingen
Ctgb (2009) Metabolieten		X	

Referentie	Gewasbeschermingsmiddelen	Biociden	Opmerkingen
MAMPEC 2.5 <a href="http://delftsoftware.wldelft.nl/">http://delftsoftware.wldelft.nl/</a>		X	