

ANNEX “BIOCIDES”

(Public Consultation on Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation)

A) PAN Germany list of potentially endocrine-disrupting biocides (“potential ED-biocides”)

The list takes into account active substances already approved or notified (pending) for authorisation within the review programme and one new substance* which are listed in at least one of the references 1 – 7.

Active Substance	CAS Number	CLP*	References (ED properties)	Product Type (PT) (Annex V, 528/2012/EC)	
				Approved (Date of approval)	Pending
Abamectin⁺	71751-41-2	R 2	UK (HSE/CRD)	18 (01/07/13)	
Bendiocarb	22781-23-3		McKinlay	18 (01/02/14)	
Bifenthrin⁺	82657-04-3	C 2	EU-list Cat. 1 McKinlay	8 (01/02/13)	
Boric acid	10043-35-3	M 1b	EU-list Cat. 1	8 (01/09/11)	
Carbendazim	10605-21-7	C 1b M 1b	EU-list Cat. 2 McKinlay		7, 9, 10
Chlorocresol	59-50-7		EU-list Cat 2		1, 2, 3, 6, 9, 13
Cypermethrin⁺	52315-07-8		EU-list Cat. 2 McKinlay	8 (01/06/15)	18
Cyproconazole⁺	94361-06-5	R 2	McKinlay	8 (01/11/15)	
Deltamethrin⁺	52918-63-5		EU-list Cat. 1 McKinlay	18 (01/10/13)	
Diazinon	333-41-5		EU-list Cat. 2 McKinlay		18
Diuron⁺	330-54-1	C 2	EU-list Cat. 2 McKinlay		7, 10
Fenoxycarb⁺	72490-01-8	C 2 tbc R 2	EU-list Cat. 2 McKinlay	8 (01/02/13)	
Fipronil⁺	120068-37-3		McKinlay	18 (01/10/13)	
lambda-Cyhalothrin⁺	91465-08-6		EU-list Cat. 1 McKinlay	18 (01/10/13)	
Metam-Sodium	137-42-8		EU-list Cat. 1		9, 11
Permethrin	52645-53-1		EU-list Cat. 2 McKinlay	8 (01/05/16) 18 (01/05/16)	9
2-Phenylphenol	51-03-6		EU-list Cat. 2		1, 2, 3, 4, 6, 7,

			McKinlay		9, 10, 13
Piperonyl butoxide	51-03-6		EU-list Cat. 2 McKinlay		18
Propiconazole⁺	60207-90-1		McKinlay	8 (01/04/10) 9 (01/06/15)	7
Pyriproxyfen⁺	95737-68-1		McKinlay	18 (01/02/15)	
Tebuconazole⁺	107534-96-3	R 2	McKinlay KEMI DK Cat. 1	7 (01/07/15) 8 (01/04/10) 10 (01/07/15)	9
Terbutryn	886-50-0		EU-list Cat. 1		7, 9, 10
Tetramethrin	7696-12-0		McKinlay		18
Thiacloprid⁺	111988-49-9	C 2 tbc R 2	McKinlay KEMI	8 (01/01/10)	
Thiram	137-26-8		EU-list Cat. 1 McKinlay		9
Triclosan	3380-34-5		Kortenkamp WHO/UNEP DK Cat. 1		1
Zineb	12122-67-7		EU-list Cat. 1 McKinlay	21 (01/01/16)	

*CLP-classification: C= carcinogenic; R= toxic to reproduction; M= mutagenic; 1 or 2 = Category 1 or 2 (1272/2008/EC), tbc = to be considered, ⁺used as pesticides (see PAN Europe's impact assessment annex 1b)

References:

- 1) EU-List: European Commission: Priority List according to database EDS_2003_DHI2006.mdb; ZIP-download under:
http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm#priority_list
- 2) McKinlay, R., J.A. Plant, J.N.B. Bell, N. Voulvoulis (2008): Endocrine disrupting pesticides: Implications for risk assessment. *Environment International* 34 (2008) 168 – 183
- 3) KEMI: Swedish Chemicals Agency (2008): Interpretation in Sweden of the impact of the “cut-off” criteria adopted in the common position of the Council concerning the Regulation of placing plant protection products on the market (document 11119/08)
- 4) Kortenkamp, A. et al. (2011): State of the art of the assessment of endocrine disruptors. Final report. http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf
- 5) DK: Danish Centre on endocrine disruptors (2012):
<http://mst.dk/media/mst/9106715/chemicalsreportandannex.pdf>
- 6) UK (HSE, CRD): WRC PLC (2013): (2013): Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD. WRc Ref: Defra9088.01 January 2013.
http://randd.defra.gov.uk/Document.aspx?Document=11345_PS2812finalreportfull.pdf
- 7) WHO/UNEP (2013): State of the science of endocrine disrupting chemicals – Summary for decision makers: <http://www.who.int/ceh/publications/endocrine/en/>

B) Information on alternatives

Note: PAN Germany provides a preliminary list of possible alternatives including non-chemical alternatives and prevention measures for relevant biocidal product types. The list should not be equated with a quantitative comparative assessment.

It must be considered that experience and knowledge of comparative assessments is still weak for biocides. The review program for biocides is still running (until 2014). Data and knowledge on the biocidal market and use is insufficient (PAN Germany, 2014). As a result, the state of knowledge about amount, relevance, effectiveness and risks of both specific potential ED-Biocides and it's alternatives is limited and differs considerably for various active substances and types of uses. It is important to improve data in quality, quantity and availability to compile systematic and up-to-date information on the market, the use (directly or in treated articles) and on the environmental and health impacts of biocides.

According to the BPR the comparative assessment of biocides has also to consider non-chemical alternatives for the substitution of biocides of high concern such as endocrine disruptors and in a broader sense prevention measures. There is an urgent need to establish general and product-type specific guidelines of IPM (Integrated Pest Management) and harmonized best practices guidance for biocidal use. We recommend therefore the implementation of a Directive on sustainable use of biocidal products in the EU.

Product type	Potential ED-biocides	Potential alternatives: biocides*, non-chemical (biocide-free) alternatives & prevention measures
1) Human hygiene	2-Phenylphenol, Chlorocresol, Triclosan	<p><u>Biocides</u>: 28 other active substances are used and notified in PT 1 (1 approved, 27 pending). Some of these biocides should be adequate substitutes for the 3 potential ED-biocides and provides an adequate compensation, e.g. to ensure hand disinfection in professional medical sectors and other sensitive professional areas.</p> <p>Risk-Benefit: There is a broad agreement of experts that antimicrobial everyday products and antimicrobial treated articles is not necessary (but might be risky) for the general public: http://www.umweltbundesamt.de/sites/default/files/medien/publikation/long/3629.pdf (see Annex I, 1.4)</p> <p><u>German Federal Agency of Environment</u>: http://www.biozid.info/deutsch/desinfektion-hygiene/desinfektion-hygiene-detailansicht/?tx_ubabiozid_pi3[id]=6&tx_ubabiozid_pi3[cat]=27&tx_ubabiozid_pi3[action]=show&tx_ubabiozid_pi3[controller]=Hygiene&cHash=df24427e9c34fdc77d2a30fb812087cd;</p> <p><u>PAN Germany (2013)</u>: http://www.pan-</p>

		<p>germany.org/download/biocides/biocide-treated_consumer_products.pdf;</p> <p>The FDA highlights 2013 that there is currently no evidence that over-the-counter (OTC) antibacterial soap products (contain triclosan and other sanitized substances) are any more effective at preventing illness than washing with plain soap and water (http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378393.htm)</p> <p><u>Prevention and non-chemical (biocide-free) measures:</u> General protective and hygienic measures, e.g. soap</p>
<p>2) Disinfectants and algacides not intended for direct application to humans or animals</p>	<p>2-Phenylphenol, Chlorocresol</p>	<p><u>Biocides:</u> 79 other active substances are used and notified in PT 2 (3 approved, 76 pending). Some of these biocides should be adequate substitutes for the 2 potential ED-biocides.</p> <p><u>Risk-Benefit:</u> There is a broad agreement of experts that antimicrobial everyday products and antimicrobial treated articles are not necessary (but might be risky) for the general public (see PT 1)</p> <p><u>Prevention and non-chemical (biocide-free) measures:</u></p> <p>See EU Ecolabel 2011/383/EU: http://ec.europa.eu/environment/ecolabel/</p> <p>Chemical alternatives (e.g. chlorine-, ozone treatment) Thermal disinfection, UV-, filter-, ultrasonic technologies http://www.umweltbundesamt.de/sites/default/files/medien/publikation/long/3629.pdf (Annex I chapter 2);</p> <p>http://www.biozid.info/deutsch/desinfektion-hygiene/desinfektion-hygiene-detailansicht/?tx_ubabiozid_pi3[id]=4&tx_ubabiozid_pi3[cat]=27&tx_ubabiozid_pi3[action]=show&tx_ubabiozid_pi3[controller]=Hygiene&cHash=698f26c54f3a31cf2bd0565084891df3</p>
<p>3) Veterinary hygiene</p>	<p>2-Phenylphenol, Chlorocresol</p>	<p><u>Biocides:</u> 45 other active substances are used and notified in PT 3 (2 approved, 43 pending). Some of these biocides should be adequate substitutes for the 2 potential ED-biocides.</p> <p><u>Prevention and non-chemical (biocide-free) measures:</u> Thermal disinfection, UV-technology http://www.umweltbundesamt.de/sites/default/files/medien/publikation/long/3629.pdf (Annex I chapter 3);</p> <p>http://www.biozid.info/deutsch/desinfektion-hygiene/desinfektion-hygiene-</p>

		detailansicht/?tx_ubabiozid_pi3[id]=11&tx_ubabiozid_pi3[cat]=27&tx_ubabiozid_pi3[action]=show&tx_ubabiozid_pi3[controller]=Hygiene&cHash=8cf1113445ea1eb97aaf962a3f539a2e
4) Food and feed area	2-Phenylphenol,	<p>Biocides: 55 other active substances are used and notified in PT 4 (5 approved, 50 pending). Some of these biocides should be adequate substitutes for the 1 potential ED-biocide.</p> <p>Geueke B. (2014): Dossier – Biocides and food contact materials. Food Packaging Forum, http://www.foodpackagingforum.org/food-packaging-health/biocides-and-food-contact-materials</p> <p><u>Prevention and non-chemical (biocide-free) measures:</u> Thermal disinfection, steam-, pressure cleaner technologies, UV-technology http://www.umweltbundesamt.de/sites/default/files/medien/publikation/long/3629.pdf (Annex I chapter 3);</p>
6) Preservatives for products during storage	2-Phenylphenol, Chlorocresol	<p>Biocides: 43 other active substances are used and notified in PT 6 (1 approved, 42 pending). Some of these biocides should be adequate substitutes for the 2 potential ED-biocides.</p> <p>List of in-can preservation, Appendix 1, Basic Criteria RAL-UZ 102 “Blue Angel - Low-Emission Wall paints”: https://www.blauer-engel.de/sites/default/files/raluz-downloads/vergabegrundlagen_en/102-1004-Appendix-1.pdf,</p> <p>Other “Blue Angel” label providing lists of preservatives: e.g. RAL UZ 12a, RAL UZ 113, RAL UZ 84b.</p>
7) Film preservatives	2-Phenylphenol, Carbendazim, Diuron, Propiconazole, Tebuconazole, Terbutryn,	<p>Biocides: 20 other active substances are used and notified in PT 7. Some of these biocides should be adequate substitutes the 6 potential ED-biocides.</p> <p>Risk-benefit: the growth of microorganisms and algae’s is mainly an esthetical problem.</p> <p><u>Prevention and non-chemical (biocide-free) measures:</u></p> <p>PT7-free products: “Blue Angel” label RAL UZ 102, RAL UZ 113</p> <p>External thermal insulation composite systems without biocide coatings (paints or plaster), to prevent the growth of algae and fungi (PT 7): Blue Angel, RAL-UZ-140: https://www.blauer-engel.de/en/products/construction/external-thermal-insulation-composite-systems-etics</p> <p>Integrative prevention measures (location, constructive measures and alternative façade materials, see: UBA (2014):</p>

		<p>Entscheidungshilfen zur Verringerung des Biozideinsatzes an Fassaden, Part 1-5.</p> <p>Part 1: http://www.biozid.info/fileadmin/Assets/Startseite/Biozid-Merkblatt_1.pdf</p> <p>Part 2: http://www.biozid.info/fileadmin/Assets/Startseite/Biozid-Merkblatt_2.pdf</p> <p>Part 3: http://www.biozid.info/fileadmin/Assets/Startseite/Biozid-Merkblatt_3.pdf</p> <p>Part 4: http://www.biozid.info/fileadmin/Assets/Startseite/Biozid-Merkblatt_4.pdf</p> <p>Part 5: http://www.biozid.info/fileadmin/Assets/Startseite/Biozid-Merkblatt_5.pdf</p>
<p>8) Wood preservatives</p>	<p>Bifenthrin, Boric acid, Cypermethrin, Cyproconazole (candidate subst.), Fenoxycarb, Permethrin, Propiconazole Tebuconazole</p>	<p><u>Biocides</u>: 32 other active substances are used and notified in PT 8 (27 approved (+candidates of substitution: Creosote and Flufenoxuron), 5 pending). Some of these biocides should be adequate substitutes for the 8 potential ED-biocides.</p> <p><u>Prevention and non-chemical (biocide-free) measures</u>:</p> <p>Acetylation of dry wood, Wood treated with furfuryl alcohol - The treated wood has improved moisture-dimensional stability, hardness, and decay and insect resistance; rubinia or oak heardwood, heat / technical drying wood, application of constructive preventative measures [see technical guidance DIN 68800, revised 2012]</p> <p>“Blue Angel” label: RAL-UZ 38, RAL-UZ 76, RAL UZ 38</p> <p>Alternatives to PT 8 railroad ties: composite ties, ties are made from recycled materials, including rubber, plastics, and fiberglass Alternatives to PT 8 poles: steel pools, concrete poles</p> <p>Control measures:</p> <p>a) Thermal Processes (Hot-Air Technique) to Control Ligniperdous Insects (Blue Angel, RAL-UZ 57: https://www.blauer-engel.de/en/products/home-living/thermal-processes-hot-air-technique-to-control-ligniperdous-insects</p> <p>b) High frequency technology (only possible within certain limits)</p> <p>c) Microwave technology</p> <p>http://www.umweltbundesamt.de/sites/default/files/medien/publikation/long/3629.pdf (Annex I chapter 8);</p> <p>http://www.biozid.info/deutsch/materialschutz/materialschut</p>

		<p>Z- detailseite/?tx_ubabiozid_pi2[id]=15&tx_ubabiozid_pi2[cat]=34&tx_ubabiozid_pi2[action]=show&tx_ubabiozid_pi2[controller]=Material&cHash=fa45e092a8cde9b793c71af05337793b</p>
9) Fibre, leather, rubber and polymerised materials preservatives	2-Phenylphenol Carbendazim, Chlorocresol, Metam-Sodium Permethrin, Propyconazole, Tebuconazole, Terbutryn, Thiram	<p>Biocides: 26 other active substances are used and notified in PT 9 (26 pending). Some of these biocides should be adequate substitutes for the 8 potential ED-biocides.</p> <p>See label criteria for textiles and other products containing PT 9, e.g.: EU Ecolabel: http://ec.europa.eu/environment/ecolabel/; “Blue Angel “: www.blauer-engel.de; Other: www.label-online.de</p>
10) Construction material preservatives (e.g. masonry, composite materials)	2-Phenylphenol, Carbendazim, Diuron, Tebuconazole, Terbutryn	<p>Biocides: 20 other active substances are used and notified in PT 10 (20 pending). Some of these biocides should be adequate substitutes for the 5 potential ED-biocides.</p> <p>Risk-benefit: the growth of microorganisms and algae’s is mainly an esthetical problem.</p> <p><u>Prevention and non-chemical (biocide-free) measures:</u></p> <p>Comparable to PT 10: http://www.umweltbundesamt.de/sites/default/files/medien/publikation/long/3629.pdf (Annex I chapter 10);</p> <p>http://www.biozid.info/deutsch/materialschutz/materialschutz Z- detailseite/?tx_ubabiozid_pi2[id]=10&tx_ubabiozid_pi2[cat]=35&tx_ubabiozid_pi2[action]=show&tx_ubabiozid_pi2[controller]=Material&cHash=b0515eab178a9b956743d0e94bd1476a</p>
11) Preservatives for liquid-cooling and processing systems	Metam-Sodium	<p>Biocides: 44 other active substances are used and notified in PT 11 (44 pending). Some of these biocides should be adequate substitutes for the one potential ED-biocide.</p>
13) Working or cutting fluid preservatives	2-Phenylphenol Chlorocresol	<p>Biocides: 24 other active substances are used and notified in PT 13 (24 pending, one new substance is approved). Some of these biocides should be adequate substitutes for the 2 potential ED-biocides.</p>
18) Insecticides, acaricides and products to control other arthropods	Abamectin, Bendiocarb, Diazinon, Fipronil, Piperonyl butoxide,	<p>Biocides: 48 other active substances are used and notified in PT 18 (27 pending, 21 approved). Some of these biocides should be adequate substitutes for the 11 potential ED-biocides.</p>

	<p>Pyriproxifen,</p> <p><i>Pyrethroids:</i> Cypermethrin, Deltamethrin, Lambda-Cyhalothrin, Permethrin Tetramethrin</p>	<p>Risk – benefit: EU-wide harmonized Integrated pest management (IPM), best practice guidance, professional training guidance are missing; high risk because of incorrect, overdosed or unnecessary use of PT 18 products particularly in private households.</p> <p><u>Prevention and non-chemical (biocide-free) measures:</u></p> <p>Many biocide-free, non-chemical and prevention measures are available, see information at: http://www.pan-germany.org/deu/projekte/biozidrisiken_mindern/schaedlings_bekaempfung.html,</p> <p>Species-specific prevention measures: http://www.biozid.info/deutsch/schaedlingsratgeber/schaedlingsratgeber_listenansicht/?tx_ubabiozid_pi5[cat]=3&cHash=5882eb34c59f018b21467f5f61d98c19</p> <p>http://www.umweltbundesamt.de/sites/default/files/medien/publikation/long/3629.pdf (Annex I chapter 18);</p> <p>“Blue Angel” products RAL UZ 34: https://www.blauer-engel.de/produktwelt/haushalt-wohnen/abwehr-und-bekampfung-von-sch-dlingen-in-innen-umen-ohne-giftige-wirkstoffe</p>
<p>21) Antifouling products</p>	<p>Zineb</p>	<p><u>Biocides:</u> 10 other active substances (incl. 2 new AS) are used and notified in PT 21 (10 pending, 2 approved). Some of these biocides should be adequate substitutes for the 1 potential ED-biocide.</p> <p>Risk-benefit: Sustainable use of antifouling surface-treatment products is not feasible, because the active substances they include are washed out. http://www.biozid.info/uploads/media/HGP_Antifouling_06.1.2014_final.pdf</p> <p><u>Prevention and non-chemical (biocide-free) measures:</u></p> <p>Various biocide-free and non-chemical alternatives are available. E.g. Mechanical cleaning methods are especially effect as alternative in fresh water environments. Daehne D. et al. (2012): Reinigung als Alternative zu biozidhaltigen Antifouling-Beschichtungen: http://cms.springerprofessional.de/journals/JOU=35152/VOL=2012.14/ISU=3/ART=157/BodyRef/PDF/35152_2012_Article_157.pdf</p>

		<p>A number of European countries have already enacted a general ban on use of antifouling products that contain biocides in inland bodies of water, among them Denmark, Sweden, and Great Britain (Umweltbundesamt, press release No. 47/2014).</p> <p>Scientific projects on alternatives: FOULPROTECT : http://www.ifam.fraunhofer.de/de/Presse/Biozidfreie_Beschichtungen.html; CHANGE: http://changeantifouling.com/</p> <p>DBU: https://www.dbu.de/phpTemplates/publikationen/pdf/100114115432l2be.pdf</p> <p>EPA: http://www.epa.gov/region09/waste/features/safe-paint/index.html</p> <p>UBA: http://www.biozid.info/deutsch/biozidprodukte/biozidprodukte-detailansicht/?tx_ubabiozid_pi1[id]=62&cHash=55852aaf013336cbf4ffbdabcc63db3f</p>
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*Pending / notified AS: European Commission (2014): REGULATIONS COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council; Approved AS: biocide-helpdesk-database on approved active substances: <http://www.reach-clp-biozid-helpdesk.de/de/Biozide/Wirkstoffe/Genehmigte-Wirkstoffe/Genehmigte-Wirkstoffe.html>;

PAN Germany (2014): Endocrine disrupting biocides - Why highly hazardous biocides must be phased out: http://www.pan-germany.org/download/biocides/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf

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