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PAN-list of potential cut-off biocides

Background paper

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Background

According to the draft regulation on marketing and use of biocide products, cut-off criteria are to be defined in the approval process for biocidal active substances (Article 5). With the cut-off process, especially dangerous substandes will be listed, to protect people and the environment from the negative impacts of their usage. While the terms of inclusion into Annex 1 are formulated rather generally and are therefore open to interpretation, at least for these especially dangerous substances a clear regulative framework is proposed, to simplify and shorten the decision and to reduce bureaucracy. PAN Germany supports this approach, particularly because it is in accordance with the two other EU-legislations on chemicals, REACH and the pesticide regulation 1107/2009. Especially controversial discussion takes place about exceptions that define, under which preconditions cut-off candidates can be used in the future. For this reason it makes sense to have a look at which biocidal active substances would be regulated by article 5. A data bank-query by PAN-Germany identified possible cut-off candidates.

Evaluation procedure

- **Cut-off criteria**

As cut-off criteria especially dangerous substance-inherent properties are being used. For evaluation, two proposals are taken as a basis: the draft of the Commission (COM (2009) 267 final, from 12th of June 2009) and the proposed ammendments of the rapporteur of the EU parliament, Mrs. Christa Klaß (2009/0076(COD) from 1st of February 2010). While the draft of the Commission is limited to the human-toxicological criteria cancerogenity, mutagenicity, reproductive toxicity as well as endocrine disruptive properties, the Klaß draft adds to the list criteria of unacceptable environmental impacts. These are PBT-substances (persistent, bioaccumulative and toxic), vBvP-substances (very persistent and very bioaccumulative), as well as substances with POPs-properties according to the Stockholm Convention on persistent organic pollutants (short POPs). Even though not specified in the Klaß-draft, PAN Germany assumes that for the criteria of PBT and vPvB the definitions from REACH (1907/2006); Annex III) are taken as a basis.

- **Selection of the biocidal active substances**

In this evaluation only notified biocidal active substances will be considered1 that in the review-programme were either already included in Annex I of the regulation 98/8/EC for one or more product types or those that have a pending status in the evaluation process.
Excluded from the analysis are microorganisms. Organisms represent a totally different category of active substances from chemical substances. For example, organisms can spread by themselves and reproduce. Some inherent properties of active substances like for example persistence and bioaccumulation are not applicable to organisms. In context with the approval of pesticides, many microorganisms are classified as “unharmful”, e.g. compare EC

[1] COMMISSION REGULATION (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

2008[2]. Nine other biocides are further excluded from analysis, because they are not clearly identifiable mixtures of substances or reaction products. For these substances neither CAS nor EC numbers were appointed.

From the approximately 350 notified biocidal active substances under Regulation 1451/2007 315 remain, for which a data bank query was conducted on 1st June 2010.

- **Constraints of the data bank query**

In a relational data bank all biocides are linked via the CAS number with the lists of the EU, the U.S. EPA etc. All used lists normally contain the CAS number for each substance, unless they are mixtures of substances or microorganisms. Even though the CAS number should be unique for each substance, the descriptions do not always match. E.g. for "Melaleuca alternifolia, extract australian tea-tree oil" different CAS numbers are used in the notification list (85085-48-9) and in the pesticide authorisation (CAS 68647-73-4)[3] Even though known differences were corrected, it can happen that information is lacking due to differing CAS numbers.

The evaluation is based on "binding" lists, like Annex I of EU-Regulation 67/548 or the GHS Regulation 1272/2008[4]. Indeed this Annex is legally binding, but not always on the newest level of knowledge in science and of the authorities. As an example, the rodenticide brodifacoum is classified as a reproductive toxic substance (R 1A) in the dossier of the review-programme, but a formal classification according to the above mentioned binding lists is not existent.

Furthermore Annex I of the EU-Regulation 67/548 or the GHS regulation 1272/2008 only lists substances that are classified as "dangerous" in accordance with these Regulations. That means that substances that are not listed in this annex are either classified as "nonhazardous" or that a decision for their classification was not yet reached. Because it is not displayed for which substances an evaluation is still pending, it has to be assumed that the number of possible cut-off substances is underestimated.

[2] EC (2008): Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances. Official Journal of the European Union L 330/6.0 9.12.2008

[3] COMMISSION DIRECTIVE 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances. Official Journal of the European Union L 344/89

[4] EC (2008): REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THECOUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Results

- **CMR-Biocides**

Substance	CAS - number	Classification	Product-types		
			Pending	Non-inclusion Annex I	Inclusion Annex I
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008[5] as **carcinogenic** category 1A or 1B					
Creosote	8001-58-9	C 1B	8		
Ethylene oxide	75-21-8	C 1B	2	20	
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as **mutagenic** category 1A or 1B					
Carbendazim	10605-21-7	M 1B	7; 9; 10	6; 11; 12; 13	
Ethylene oxide	75-21-8	M 1B	2	20	
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as **toxic for reproduction** category 1A or 1B					
Carbendazim	10605-21-7	R 1B	7; 9; 10;	6; 11; 12; 13	
Warfarin[6]	81-81-2	R 1A			14
Boric acid	10043-35-3	R 1B	18; 22	1; 2; 3, 6, 7, 9; 10; 11; 12; 13	8
Disodiumtetraborate, anhydrous	1330-43-4	R 1B	1, 2, 7, 9, 10; 11; 13		8
Diborontrioxide	1303-86-2	R 1B			8
Active substances which meet the criteria to be classified in accordance with Regulation (EC) No 1272/2008 as **CMR-substance** category 1A or 1B					
Brodifacoum[7]	56073-10-0	R 1A			14

The list of notified CMR-substances could be amplified by a few more substances that, like brodifacoum, according to experts match with the cut-off criteria, but have not yet been formally classified according to 1272/2008/EC.

[5] EC (2009): Commission Regulation 790/2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Official Journal of the European Union, L 235/1

[6] The salt warfarin sodium (CAS 129-06-6) has no classification according to 1272/2008/EC.

[7] No official classification according to 1272/2008/EC, but evaluated as R 1A in: Draft evaluation report by the rapporteur Member State Italy (July 2008) on Brodifacoum

The following table lists further notified active substances that are classified as carcinogenic by the US-american Environmental Protection Agency (EPA). Some of these substances are classified as C2-substances according to 1272/2008/EC: chlorotalonil, folpet and diuron. Other active substances did not get EU classification as cancerogenic: formaldehyde, metam-sodium, imazalil (35554-44-0), fenoxycarb, permethrin and tolylfluanid.

Active substance	CAS number	Classification	Product types		
			Pending	Non-inclusion Annex I	Inclusion Annex I
Other notified active substances classified as carcinogenic according to US-EPA criteria[8]					
Sodiumdimethyldithiocarbamate	128-04-1	Likely to be carcinogenic	9;11; 12	2; 3; 4; 5; 6; 10; 13	
Folpet	133-07-3	Group B2-Probable human carcinogen	6; 7; 9; 10		
Metam-sodium	137-42-8	Likely to be carcinogenic	9; 11	2; 4; 6; 12; 13; 20	
Chlorothalonil	1897-45-6	Likely to be carcinogenic	6; 7; 9; 10		
Diuron	330-54-1	Known/Likely to be carcinogenic	6; 7; 10		
Imazalil	35554-44-0	Likely to be carcinogenic	3	2; 4; 13; 20	
Imazalil (technical grade)	73790-28-0	(Likely to be carcinogenic)[9]	3	2; 4; 13	
Formaldehyde	50-00-0	Group B1-Probable human carcinogen	1; 2; 3; 4; 5; 6; 9; 20; 22; 23	11; 12; 13	
Permethrin	52645-53-1	Likely to be carcinogenic	2; 3; 5; 8; 9; 18; 22		
Methylenedithiocyanate	6317-18-6	Group B2-Probable human carcinogen	12	6; 7; 9; 10; 11; 13; 22	
Tolylfluanid	731-27-1	Likely to be carcinogenic	7; 21	10	8
Fenoxycarb	72490-01-8	Likely to be carcinogenic	8		

[8] US EPA (2006–2009): Chemicals Evaluated for Carcinogenic Potential. Science Information Management Branch, Health Effects Division Office of Pesticide Programs, U.S. Environmental Protection Agency (US EPA). April 26 2006; September 12 2007, September 24 2008; September 03 2009

[9] The US EPA has only one entry for imazalil (CAS-number 35554-44-0). It is necessary to clarify, whether the carcinogenic properties apply to both formulations.

- **Endocrine disrupting biocides**

So far there are no fixed classification criteria for hormonally active substances (EDCs). To close this gap, the Klaß proposal takes on the specifications of the new pesticide regulation 1107/2009/EC for the classification of endocrine disrupting pesticides. According to the Klaß proposal, the Commission should take provisions by means of delegated acts until 30 July 2015 to define the endocrine disrupting properties in accordance with precise scientific criteria.

In the meantime, interim arrangements are to apply. According to these arrangements, substances that are or have to be classified as carcinogenic (category 2) and toxic for reproduction (category 2) in the Regulation 1272/2008/EC are to be classified as endocrine disrupting, until the new criteria are adopted. Furthermore, substances that are or have to be classified as toxic for reproduction (category 2) according to Regulation 1272/2008/EC and that have toxic effects on the endocrine organs, can be regarded as substances with endocrine disrupting properties (R2+ tox. end. organs).

In the data bank query no notified biocide that is still in the review-process is classified as C2+R2 according to 1272/2008/EC. Chlorotoluron would be such a substance, but all notified usages have already been excluded. Furthermore, there is no substance classified as R2 among the notified active substances that is also in the EU-lists of the priority endocrine chemicals in categories 1 or 2[10, 11, 12].
Candidates for which the cut-off provision could possibly apply according to experts are active substances that are assigned to the EU-category EDC 1. For these substances an endocrine effect was already proven in intact organisms. The table shows the notified biocidal active substances that are listed as EDC 1 substances, but which do not (yet) have an R2 classification.

Biocidal active substances of the category EDC 2 for which evidence for endocrine disruptive potential exists, for example through in-vitro testing, could be included in the list of cut-off substances, if they would be classified as R2 by experts: piperonyl butoxide, d-phenothrine, cypermethrin, biphenyl-2-ol, carbendazim, chlorocresol, diuron, fenoxycarb, permethrin, and prometryn.

[10] EC (2000): Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting, European Commission, Delft

[11] EC (2004): Commission Staff Working Document SEC (2004) 1372 on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706), Europäische Kommission, Brüssel

[12] EC (2007): Commission staff working document on the implementation of the "Community Strategy for Endocrine Disrupters" - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706), (COM (2001) 262) and (SEC (2004) 1372), SEC(2007)

Active substance	CAS number	Classification	Product types		
			Pending	Non-Inclusion Annex I	Inclusion Annex I
Notified active substances which have been classified as **endocrine disrupting chemical**, EDC category 1 [10, 11, 12]					
Deltamethrin [11]	52918-63-5	EDC 1	18	8	
Boric acid[12]	10043-35-3	EDC 1	18; 22	1; 2; 3; 6; 7; 9; 10; 11; 12; 13	8
Bifenthrin [11]	82657-04-3	EDC 1	8; 18		
Metam-sodium[10]	137-42-8	EDC 1	9; 11	2; 4; 6; 12; 13; 20	
Lambda-Cyhalothrin[11]	91465-08-6	EDC 1	18		
Terbutryn[11]	886-50-0	EDC 1	7; 9; 10		
Thiram[10]	137-26-8	EDC 1	9	2; 6; 7; 10; 11; 12	
Zineb[10]	12122-67-7	EDC 1	21		

- **PBT / vPvB Biozide**

The following criteria define PBT and vPvB substances[13]:

P: Persistent: Half-life > 60 Tage in marine water or > 40 days in freshwater or half-life > 180 days in marine sediment or > 120 days in freshwater sediment

vP: Very persistent: Half-life > 60 days in marine or freshwater > 180 days in marine or freshwater sediment

B: Accumulative: Bioconcentrationfactor (BCF) > 2.000

vB: Very bioaccumulative: Bioconcentrationfactor (BCF) > 5.000

T: Toxic: Chronic NOEC < 0.01 mg/L or CMR or endocrine disrupting effects (NOEC= no observed effect concentration)

Lindan and Tributyltin oxide match all PBT-criteria, but all notified uses were excluded for these substances already.

The rodenticide floucomafen that was already included in Annex I and fulfills all PBT criteria according to the dossiers[14]. But because in the Footprint-Database[15] it has a lower BCF from

[13] Definition see: http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt

[14] Competent Authority Report (2007): Floucomafen (PT 14) evaluation report, rapporteur MS: The Netherlands

1972 it does not fit the criteria completely. Similarly the rodenticide difenacoum is viewed by experts as “potentially” PBT and even vPvB substance[16]. What is missing is the necessary accumulation-test in an aquatic organism, e.g. fish. Because at the moment only a calculated BCF is available, difenacoum does not meet all criteria.

There is not enough data available at the moment to identify further substances. Even without taking into account toxicity (T), no pesticide, which is also a biocide, matches the criteria > 40 days half-life period in water and > 2000 (BCF). Some rodenticides have very high BCF values and long half-life periods in soil, but either data for decomposition in water and sediments are not available in the used databases or the accumaltion test for aquatic organisms is missing.

For biocides, which are no pesticides, the data basis is equally insufficient. In the procedure to identify PBT substances in the EU, only chemicals with a high volume of production were evaluated[17]. The Footprint-database that contains half-life periods and data to BFC, is a database on pesticides only[18].

The definitive number of PBT substances depends on whether or not in the review process or evaluation of active substances the necessary test procedures according to the criteria will be conducted.

- **POPs-Biozide**

Persistent organic pollutants (POP) are identified through Regulation (EC) Nr. 850/2004 of the European Parliament and the Council from 29 April 2004 about persistent organic pollutants. Among the notified biocidal active substances none is classified as POP.

[15] FOOTPRINT (2010): The FOOTPRINT Pesticide Properties DataBase. Database collated by the University of Hertfordshire as part of the EU-funded FOOTPRINT project (FP6-SSP-022704) (www.eufootprint.org)

[16] Competent Authority Report (2007): Difenacoum (PT 14) evaluation report, rapporteur MS: Finland

[17] EC JRC (2010) PBT List at http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt by European Commission Joint Research Center (EC JRC)

[18] FOOTPRINT (2010): The FOOTPRINT Pesticide Properties DataBase. Database collated by the University of Hertfordshire as part of the EU-funded FOOTPRINT project (FP6-SSP-022704) (www.eufootprint.org)

Conclusion

At the moment, the following eight notified substances would fulfill the proposed cut-off criteria UNAMBIGUOUSLY.

Active substance	CAS Number	Classification	Product types		
			Pending	Non-inclusion Annex I	Inclusion Annex I
Creosote	8001-58-9	C1B	8		
Ethylene oxide	200-849-9	C1B M1B	2	20	
Carbendazim	10605-21-7	M1B R1B	7; 9; 10	6; 11; 12; 13	
Warfarin[19]	81-81-2	R1A			14
Boric acid	10043-35-3	R1B	18; 22	1; 2; 3, 6, 7, 9; 10; 11; 12; 13	8
Disodiumtetraborate, anhydrous	1330-43-4	R1B	1, 2, 7, 9, 10; 11; 13		8
Diborontrioxide	1303-86-2	R1B			8
Brodifacoum[20]	56073-10-0	R1A			14

This corresponds to **2.3 %** of the total of 315 active substances taken into account. Probably some of the EDC 1 substances fit into the cut-off criteria, if they, according to expert's opinion, also meet the R2 criteria. Adding the seven substances that fit into category EDC 1, the proportion of potential cut-off substances is raised to **4,8%.**

Whether or not the table will be expanded by some more substances, depends on which weight is given to the experts' opinion. Possibly, a limited number of further active substances could be added that, like brodifacoum, are evaluated as CMR substance, but were not classified as 1A or 1B CMR so far.

To what extent the numbers will increase by environmentally hazardous substances, will also depend on whether data according to PBT and vPvB-criteria will be collected. Up to now this is not always the case. These gaps in knowledge may further increase, if the Commission proposal of a two-tired procedure for data requirements is adopted. In this case, active substances could be included into Annex I in the first stage, without being assessed according to the cut-off criteria and without having the possibility to identify the substance as a substitution candidate (according to Article 9 of the COM-proposal).

[19] The salt warfarin sodium (CAS 129-06-6) has no classification according to 1272/2008/EC.

[20] No official classification according to 1272/2008/EC, but evaluated R1A in: Draft evaluation report by the rapporteur Member State Italy (July 2008) on brodifacoum

PAN Germany is therefore against strictly graded data requirements (Annex II) and the possibilities for waiving from data requirements (Annex IV). The data requirements should be fashioned in a way that all cut-off and substitution criteria are verifiable in the initial evaluation and authorisation process and that decisions for the classification can be made promptly.

Basically, the proportion of especially substances of high concern affected by the cut-off procedure is limited. One reason for this is that many problematic substances have not been notified for the review programme by producers. Directive 98/8/EC has set a clear and positive signal for environmental and consumer protection that has now, through the adoption of article 5 in the new regulation, gained a legislative basis. PAN Germany explicitly welcomes the addition of the environmental criteria. This is in accordance with other legislation on chemicals like REACH and the pesticide legislation and relates well to the objectives of the Water-framework-Directive 2000/60/EC.

Exceptions for the further use of identified cut-off substances should be clearly limited to imminent danger-clauses on national or regional level. Exceptions should be justified scientifically and transparently, should be limited temporally and be compulsorily accompanied by measures for the future substitution of the substance. PAN Germany considers the actual exception clauses under article 5.1 phrased too generally, too weak and too broad.

PAN Germany also considers further amendments for the exclusion of biocidal active substances necessary. A clear signal should be set to identify and exclude from the lists those substances that are especially hazardous for children's health in terms of developmental neurotoxicity and immunotoxicity. Furthermore, biocides based on nanotechnology should not be included in Annex I until specific test procedures have been implemented to conduct an adequate evaluation process.

PAN Germany phrased these and other recommendation to the draft regulation in several position papers. The positions are being supported by numerous German and European civil society organisations.

Background information and positions at:
http://www.pan-germany.org/deu/~stellungnahmen.html

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