Joint NGO recommendations for the forthcoming considerations of Council Working Group for Environment concerning the biocide regulation (COM (2009) 267)

Brussels, 12 October 2010

To Members of the Council Working Group for Environment

Joint NGO recommendations for WG ENVI considerations (Biocide Regulation (COM (2009) 0267))

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Dear Members of the Council Working Group for Environment,

You are currently discussing the Commission's proposal for a biocide regulation (COM (2009) 0267), which was recently voted on by the European Parliament in first reading. This act proposal will revise the current Biocidal Products Directive 98/8/EC and establish new provisions for the authorisation and use of, for example, disinfectants, preservatives, products for pest control and other biocidal products.

Pesticide Action Network (PAN) Germany, BUND/ Friends of the Earth Germany, Fédération Inter-Environnement Wallonie, Health and Environment Alliance (HEAL), Health Care Without Harm Europe (HCWH), National Movement Friends of the Earth Bulgaria, PAN Europe, PAN UK and Women in Europe for a Common Future (WECF) welcome the revision of the biocides legislation, but see an urgent need to improve the current European Commission draft, the European Parliament resolution as well as the relevant suggestions of the former Council Presidency in order to ensure the protection of the environment and human health against hazards and risks stemming from the use of biocidal products.

While taking into account our key NGO demands and recommendations on the biocide regulation, we suggest highlighting the following issues in view of the coming Council Environment Working Group considerations on this dossier:

- Ensure a consistent and enforceable cut-off regime without unnecessary loopholes on EU and on national level.
- Guarantee a sufficient substitution regime and consider non-chemical measures and preventive measures within the comparative assessment.
- Ensure the protection of vulnerable groups from hazardous biocides and the substitution of developmental neurotoxic and immunotoxic biocides.
- Confirm appropriate labelling provisions for all treated articles.
- Support consistent measures for the sustainable use of biocides.
- Demand for consistent data requirements for evaluation and authorization.
- Confirm a sufficient low-risk approach to promote less hazardous alternatives.
- Facilitate consistent measures concerning nano-biocides.

We provide more details in our comments and recommendations attached.

Please do not hesitate to contact us in case of any question.

We should be most grateful if you consider our recommendations.

Kind regards

See contacts

Annex

NGO recommendations for the forthcoming considerations of Council Working Group for Environment concerning the biocide regulation (COM (2009) 0267)

On 22 September 2010, the European Parliament agreed its first reading report (rapporteur: MEP Christa Klaß) regarding the Commission's proposal for a biocide regulation (COM (2009) 0267) [1]. This proposal will revise the current Biocidal Products Directive 98/8/EC and establish new provisions for the authorisation and use of, for example, disinfectants, preservatives, products for pest control and other biocidal products.

Pesticide Action Network (PAN) Germany, Fédération Inter-Environnement Wallonie, Health and Environment Alliance (HEAL), Health Care Without Harm Europe (HCWH), National Movement Friends of the Earth Bulgaria, Pesticide Action Network UK and Women in Europe for a Common Future (WECF) welcome some of the efforts for the benefit of the environment and health. For example, we appreciate European Parliament's clarification of the purpose of the regulation (Article 1): The provisions have to ensure a high protection level and that active substances or products placed on the market do not have harmful effects on humans, non-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick. This essential amendment still needs support from the Council.

When reflecting all amendments of the European Parliament as well as the proposals of the Commission[2] and the of former Spanish Council presidency (document which is dated from 30 June 2010)[3], many challenges remain. Several amendments are contradictory to each other and would weaken essential positive elements of the drafts that support sound alternatives for pest management and that improve transparency. A consistent protection of environment and health is necessary. While taking into account our key demands on the biocide regulation[4] and further related recommendations[5], we suggest highlighting the following issues in view of the coming Council Environment Working Group considerations on this dossier:

Ensure a consistent and enforceable cut-off regime on EU and on national level

We acknowledge that the Council and European Parliament also supports environmental-related criteria like PBT, vPvB and POPs for the exclusion of highly hazardous active substances from approval (cut-off). European Parliament also introduces measures for identifying endocrine disruptive properties (Art. 5 (1)). Besides, we acknowledge EP's efforts for further restricting the application of derogations to cases of serious danger or negligible exposure and for requiring substitution plans and risk-mitigation measures (Art. 5 (2)). On the other hand, the cut-off regime - as proposed

1 European Parliament (2010). Hyperlink: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0333+0+DOC+XML+V0//EN&language=EN

2 European Commission (2009): Proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products.Hyperlink: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0267:FIN:EN:PDF

3 Council of the European Union (2010). Document dated from 30 June 2010. Hyperlink: http://register.consilium.europa.eu/pdf/en/10/st06/st06564-re02.en10.pdf

4 PAN Germany, Birld Life, BUND et al. (2009). Hyperlink: http://www.pan-germany.org/download/biocides/NGO_Kernforderungen_Biozid-VO_091216.pdf

5 PAN Germany, PAN Europe, HEAL, WECF et al. (2010). Hyperlink: http://www.pan-germany.org/download/biocides/NGO_Position_EPEnvi_KLASSReport_220210.pdf, PAN Germany (2009). Hyperlink: http://www.pan-germany.org/download/biocides/PAN_Recommendation_Biocides_091126.pdf

by the majority of the Members of European Parliament - remains too weak because it still includes several vague derogations in Article 5 (2):

- Exemptions do not tackle the exposure of substances in realistic worst case situations during the whole life-cycle like non-proper use or non-proper disposal or accidents (Article 5.2.a).
- There is no clear definition of a “closed system”. The term is therefore problematic because it does not avoid potential environmental or human exposure (Article 5.2.a).
- In cases where the exposure of a cut off substance is „negligible“ under “normal” conditions of use , the application (of this derogation) is not restricted to those Member States which are essentially dependent on the use of this biocide due to a lack of safer alternatives (Article 5.2.a).
- The exemption case of “prevent” a serious danger or of a “public interest” is too vague (Article 5.2.b).
- The use of products with cut-off substances is not restricted to qualified, professional users.
- There are no obligations for post-authorization monitoring of highly hazardous biocides.
- There are inconsistencies with Regulation 1107/2009: Without further restrictions derogations can be even applied for carcinogenic substances of category 1A/B or reproductive toxic substances of category 1 A pursuant to Reg. (EC) 1272/2008.

We welcome the discussion in the Council on further tightening the conditions for applying derogations in case of negligible exposure (Article 5.2.a). We particularly support to consider realistic worst case situations as a condition. On the other hand we are concerned about initiatives in the Council to further maintain the vague derogation of Article 5.2.c (= inclusion of cut-off substances into Annex I possible in case of disproportionate negative impacts) and even to expand the application of this derogation to all biocidal product types (e.g. also on avicides, rodenticides). There is no need to maintain such an exemption. Possible cases (e.g. cable fire caused by rates) can be managed by safer alternatives (e.g. technical solutions) or by means of Article 5.2. a) or b) or pursuant to Article 45.

We are also concerned on a possible agreement in the Council that member states shall not have the full right to refuse or adapt a product in their territory which is authorised at EU level and may include an Article 5 or 9 active substance (Article 35, 4). It is suggested that member states can only request the Commission to decide on this issue but the Commission is not required to follow the request of the relevant member state. Besides, a request for refusal can only submitted on products that belong to PT 15, 17 or 23 *and* it can be only justified on grounds of animal welfare (Article 35, 4).

We recommend:

- It should be made clear that cut-off substances can only be used as a last resort in essential and clear defined cases, and not as the norm (Article 5, 2). The application of the derogations should be limited to cases where there is a serious danger to public health. Article 5.2.c should be deleted.
- The positive elements of the EP’s approach on Article 5 (2) shall be confirmed. Particularly the restrictions and conditions for applying the derogations shall be supported (above all, the binding evaluation of other means, demonstration by evidence that there is a gap of alternatives, the introduction of risk reduction measures and the establishment of substitution plans).
- Because cut-off biocides and candidates for substitution give reasons for serious concern and due to several identified loopholes in Article 5 and 9 and the centralised authorisation system, we consider it even more necessary to ensure that products with Article 5 or Article 9 substances do not get an EU-wide authorisation (tighten wording in Article 33 (1 a) new).

- At the very least, Member States should keep the flexibility to refuse an authorisation of such products or all product types on their territory (amend Article 35 (4) accordingly) if the application of such biocidal products may have adverse effects on human health and the environment.

Guarantee a sufficient substitution regime and consider non-chemical measures and preventive measures within the comparative assessment

The substitution of problematic chemicals with less hazardous alternatives is a cornerstone of the current biocide law as well as of REACH and pesticides regulation. We welcome that this approach is also central for the new biocides regulation. Additionally, the European Parliament introduces the idea of substitution plans (Art. 21, 6) in order to encourage the development of sound alternatives. These amendments need to be confirmed as they will be essential for the protection of vulnerable groups like children, pregnant women or elderly people.

At the same time, Council and European Parliament do not ensure a consistent substitution regime so far: There is still no initiative in the Council in order to support non-chemical alternatives at substance level (Article 9, 1). EP plenary rejected a relevant amendment of EP Environment Committee (amendment 67 concerning Article 9, 1).[6] The majority of the MEPs even voted against the suggestion of the Commission to consider non-chemical options in the framework of the comparative assessment of biocidal products (Article 21, 3a) although if these alternatives are demonstrated to be more effective. We propose coherency to the Pesticide Regulation 1107/2009/EC which considers non-chemical and preventive measures (cf. Art. 50) in order to support the phase-out of candidates for substitution and the application of integrative pest management measures. Furthermore, the comparative assessment is only applied on products which are at least 5 years on the market (Art. 21 (1)) and there are no restrictions for renewals (even) for highly hazardous substances (Art. 9 (4)). This would hold products on the market which can be a threat for vulnerable groups or the environment and this will also hinder, and not stimulate, innovation for sound products, non-chemical or preventive methods.

Hence, we recommend:

- Support non-chemical measures and preventive methods as alternatives for the substitution of active substances and for comparative assessment of biocidal products (Article 9, 1 and 21, 3).
- Support EP's initiative for establishing substitution plans (Article 21).
- Reject EP's attempt to introduce derogations from the comparative assessment. For instance, the comparative assessment should not be limited to biocidal products which are at least 5 years on the market (Article 21, 1).

Ensure the protection of vulnerable groups from hazardous biocides and the substitution of developmental neurotoxic and immunotoxic biocides

More and more scientific evidence is emerging showing that certain groups of the population such as pregnant women or children are especially vulnerable to harmful effects of chemical substances, including biocides. The recently adopted Regulation on Plant Protection Products recognises their vulnerability and ensures that their specific sensitivity is taken into account in risk as-

[6] European Parliament (2010). Hyperlink: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2010-0239+0+DOC+PDF+V0//EN&language=EN

sessment and authorisation. The European Parliament resolution also includes specific provisions for vulnerable groups. We believe that the EU Member States should not fall back behind these important health protection achievements.

With a view to protecting children's health, products with developmental neurotoxic and immunotoxic biocides are of specific concern, as these substances can severely harm the nervous system and brain development of children and cause irreversible, long term damages. The scientific community has recently urged decision-makers again to minimise and phase out the use of such biocides (see Collegium Ramazzini letter)[7].

The European Commission proposal encourages the substitution of these products when safer alternatives are available.

We call on you to reject attempts to delete this substitution requirement.

In view of the Conclusions of the Environment Ministers from December 2009 on chemicals mixtures, we also urge you to include requirements for mixtures testing in the biocides regulation.

We recommend:

- Introduce specific provisions for the protection of vulnerable groups (Article 1, Article 3).
- Confirm and strengthen Commission's and EP's support for the substitution of active substances with developmental neurotoxic and immunotoxic substances (Article 9, 1).
- Ensure sufficient data, risk-assessment and labelling requirements for the protection of vulnerable groups (Articles 16, 47, 58, Annexes II, III and VI).

Appropriate labelling provisions for all treated articles

The suggested new labelling provisions in the EP resolution for biocidal-treated textiles or furniture will introduce some positive aspects like indicating the product is "treated with biocides" or that it contains nano-biocides. On the other hand, EP seriously weakens the Commission's approach for the labelling of such articles:

For instance, the proposed provisions do not ensure that all treated articles or materials will get a sufficient labelling. Requirements for product information like providing the indication "treated with biocides" on the product and the name of ingredients would be restricted to cases where it is "relevant"(Article 47 (2a)). Or obligations for information on hazards or precautionary measures would be limited to relevant products where a biocide is intended to be released under normal or reasonably foreseeable conditions of use (Art. 47 (2d)). Relevant suggestions should be deleted as it contradicts the "right to know" of consumers. Furthermore it is impossible to exactly define such cases and an evaluation would be accompanied with costly administrative burden.

We welcome Council's efforts for some promising provisions concerning treated articles with a primary biocidal function (Art. 47, 1 in combination with the definition of biocidal product in Article 3). In this case the labeling provisions of Article 58 have to be applied which may allow more transparency for consumers if EP's suggestions concerning Article 58 get support. We also acknowledge Council's suggestion for establishing a binding statement on the label which indicates that the article is treated with biocides and that a web-address shall help to get further information (Article 47, 3). These requirements also consider articles which include biocides with an internal function (e.g. a carpet which is protected against moth damage). However we are concerned that neither the

[7] Collegium Ramazzini (2010). Hyperlink: http://collegiumramazzini.org/download/Biocide_Recommendations_CR.pdf

provisions for hazard or precautionary statement nor the information on active substances shall be applied in any case (Article 47, 3). Besides, it is not guaranteed that the label will be always established on the package of the product (Article 47, 3). As a consequence, consumers might not get all necessary information not until they buy the treated article. And it should be taken into consideration that not all consumers have access to or work with the internet (e.g. elder people).

Hence we recommend:

- Support the Commission's approach on Article 47 (2) which requires a labelling of all treated articles.
- The Commission's proposal should be strengthened by the positive amendments which were agreed by the EP: Treated articles shall be labelled with "treated with biocides" and there should be an additional special indication if nano-biocides were applied (Article 47, 2).
- A specific warning label should be required that better informs vulnerable groups like pregnant women, children or their parents or elderly people about risks and hazards of biocidal treated articles (Article 47, 2).
- At the very least, all treated articles shall be labelled with the statement "treated with biocides" (Article 47, 2) and with a precautionary phrase. The label shall be provided on the package and it should also include a web-address and an address for a hotline which is free of charge and where consumers can get all necessary information like the name of all ingredients.

Ensure consistent measures for the sustainable use of biocides

We welcome that the European Parliament is in favour of consistent and EU-wide measures for the sustainable use of biocides (i.e. to initiate a Directive for sustainable use and for guidelines concerning pest management in kindergarten and canals). This approach follows relevant efforts in the pesticide sector where an EU Directive requires a harmonised frame for the qualification and certification of professional users and salesmen and other risk reduction measures. Relevant measures would also contribute to tackle resistances and antimicrobial resistances which are a consequence of the wide and improper use of specific biocides (support relevant amendments in Article 15 and 66).

Hence we recommend:

- Support EP's initiative for establishing an EU-Directive for the sustainable use of biocides (Article 15) and facilitate the implementation of relevant measures by means of specific guidances on EU level (Article 66).

Consistent data requirements

Data requirements are essential in order to guarantee an effective authorisation system based on the current scientific knowledge to protect human health and the environment from the risks of biocides. If there are only insufficient data concerning a biocidal product it's potential hazardous effects might not be detected. We especially welcome the European Parliaments introduction of positive aspects like the reporting on risks posed by nano-biocides on the environment (Article 54) or the assessment of combination effects (Annex VI) and the risks for vulnerable groups (Article

16). EP also supports a general clause that requires sufficient data for Tier 1 in order to identify Article 5, 9 and 17 - biocides (Annex II, 1) and to ensure that reasons for data waiving are based on sufficient ground and get approval by competent authorities (Annex IV, introduction).

At the same time, several amendments further weaken the insufficient approach of the Commission for gathering relevant data on properties and risks of biocides, in particular:

- Information regarding an active substance can be provided by the assessment of one product of choice which includes this ingredient (Article 4). There is no criteria scheme how to choose this product, e.g. based on proposed market relevance or predicted environmental concentration.
- It is possible to waive data requirements for carrying out more-generation tests, eco-toxicity tests, neurotoxicity tests, mixture effects-test, multi exposure route tests, studies concerning the risks for water organisms (Annexes II and III). As a consequence, the risks and hazards of problematic active substances or biocidal products might be not identified and relevant biocides might be assessed as false or harmless.
- Besides, appropriate and applicable provisions for generating data on combination effects or antimicrobial resistances are not proposed (Annexes II and III) although such effects could be very problematic.

We therefore recommend:

- The requirements for Annexes II-IV shall be further improved. The data and information level for decision making shall not fall behind the current biocide or pesticide legislation.
- Due to the dependence of important toxicity tests (e.g. chronic exposure effects) on preliminary and/or shorter duration tests (including semi-chronic, acute, exposure and toxico-kinetic studies), no data requirement shall be waived unless there exists for the active substance or the product sufficient information to adequately (for safety) inform the subsequent tests.
- Data reviewed for the purposes of these Annexes shall include the independent academic literature, reachable entirely through searches of PubMed[8] alone. Good Laboratory Practices (GLP) shall not be the main determinant of data quality, as it is mostly the manufacturer of biocides and their financially-conflicted safety studies that use GLP.[9] Published papers from academics, because they do not follow GLP, shall not be excluded from determining TDIs/ADIs, etc. Financial conflict of interests shall be one criteria used by the agency in judging the quality of data.
- The provisions for dossiers shall be made coherent with relevant standards of the environmental legislation like the Water Framework Directive. For instance, data requirements shall be established in order to adequately assess risks and hazards of relevant water contaminating substances which are listed pursuant to Annexes VIII and X of Directive 2000/60/EC. (Annex II, 8).
- The positive elements of the EP vote should be considered and supported. For instance, data requirements shall enable the identification of cut-off-, substitution- and low-risk candidates on tier 1 level (Annex I, title 1).
- The positive elements of EP's approach for Annex VI should be considered for Annexes II-III: Enable an adequate assessment of combination effects, immunotoxic effects, effects on vulnerable groups and of nano-biocides.
- Add one test under ´realistic conditions´ (Annexes II& III, concerning water as well as soil), meaning the presence of other biocides, pesticides and chemicals normally present in soil

[8] Access to PubMed: http://www.ncbi.nlm.nih.gov/pubmed/

[9] With regard to general concerns please also see PAN Europe (2010: PAN-Europe commenting data requirements. Comments on SANCO draft documents (SANCO 11802 and 11803) on data requirements.

or water, to use ´normal´ stress-factors like low-oxygen or high level of nutrients, low soil biodiversity, polluted sediments and absence of water plants.
- Require applicants to do tests (after 1 year application) in house dust to see if the exposure calculations fit with reality (Annexes II, III).
- In addition, ECHA and national authorities should have enough time and resources to evaluate relevant data and dossiers. Hence, it is essential that the regulation provides at least 9 months time for ECHA for assessing relevant dossiers (Art. 35 (3)). And the Commission's concept of annual fees should be confirmed (Article 70(2d)).

Ensure a sufficient low-risk approach

There are suggestions in Council which support the weak Commission's draft on the low-risk regime. For instance, active substances which are used for low-risk products don't need an approval for inclusion into Annex I (Art. 16, 1, a). We believe that this proposal is acccompanied with many risks and hazards for consumers and the environment as relevant active ingredients might be insufficiently assessed. At the same time we acknowledge that the European Parliament has significantly improved the criteria for identifying products with potential of low-risk (Article 17). This initiative would confirm the current approach of the Biocidal Products Directive (98/8/EC).

We therefore recommend:

- Support the consistent EP approach for the low-risk regime (Article 17). In particular, require the inclusion of active substances in Annex I which are used in low-risk products and that the products do not contain any substance of concern.
- It should be confirmed that low-risk products are of low hazard and low exposure.

Facilitate consistent measures concerning nano-biocides

We welcome the initiative of the EP to introduce specific measures on nano-biocides, such as specific evaluation methods (Annex II), impact assessment reports (Article 54), measures for risk reduction and labelling (Article 58). Because there are many open questions on nano-biocides as regards to their risks it is still necessary to further tighten the current efforts.

We recommend:

- Support the initiatives of the EP for specific measures on nano-biocides (e.g. in Articles 47, 54 and 58 and Annexes II-III).
- Complete relevant amendments by introducing a procedure and timeline for establishing relevant specific evaluation methods in the EU (e.g. in Article 77).
- Initiate a (transitional) moratorium regarding the authorisation of nano-biocides as long as adequate evaluation methods are not established.

NGO recommendations on Bioicide Regulation (WG ENVI)

Contacts

Pesticide Action Network Germany Christian Schweer (Biocide Coordinator EU) Nernstweg 32 22765 Hamburg, Germany Tel. + 49 40-399 19 10-27 Fax + 49 40 -399 19 10 -30 christian.schweer@pan-germany.org www.pan-germany.org	Fédération Inter-Environnement Wallonie Valérie Xhonneux 150 associations au service de l'environnement 6 Bld du Nord 5000 Namur, Belgium Tel. +32 81/25 52 92 v.xhonneux@iewonline.be www.iewonline.be
Health and Environment Alliance Anne Stauffer 28 Boulevard Charlemagne 1000 Brussels Tel +32 2 234 3643 anne@env-health.org www.env-health.org	Health Care Without Harm Europe Anja Leetz Rue de la Pépinière 1, 1000 Brussels, Belgium Tel switchboard: +32 2503 3137 Tel direct: +49 6224 994871 Mobile: +49 175 732 0657 Fax: + 32 2402 3042 Email: anja.leetz@hcwh.org http://www.noharm.org/europe
Women in Europe for a Common Future Elisabeth Ruffinengo (Advocacy Officer) 1 Place de l'Eglise St André 74100 Annemasse, France Tel/fax: + 33 (0)4 50 49 97 38 elisabeth.ruffinengo@wecf.eu www.wecf.eu	Bund für Umwelt und Naturschutz Deutschland e.V. (BUND) Friends of the Earth Germany Jurek Vengels Am Köllnischen Park 1 10179 Berlin, Germany Fon +49/30/27586-422 Fax +49/30/27586-440 www.bund.net
National Movement Friends of the Earth Bulgaria Valentina Lukova Sofia 1113, Bulgaria PO box 39 tel/fax +359 2 9456938 mobile +359 899333276 skype: valentina_lukova	Pesticide Action Network UK Nick Mole (Policy Officer) Development House 56-64 Leonard Street London EC 2 A 4L T United Kingdom Tel. + 44 20 7065 0905 nickmole@pan-uk.org www.pan-uk.org
Tony Tweedale, M.S. PB 617 1000-Bruxelles 1 Belgique tel: +32-(0)2-611-1325 mobile(GSM): +32(0)487-438-888	Uppsala University hospital Clinical Microbiology, Eva Haxton Dag Hammarskjölds väg 17, SE-751 85 Uppsala Tel.: + 46 18 611 90 97 Fax.: + 46 18 55 73 01 E-mail: Eva.Haxton@medsci.uu.se Home page: www.medsci.uu.se
PAN Europe Gergely Simon (board member) Rue de la Pépinière 1 B-1000, Brussels Tel. +36 14110509 gergely@pan-europe.info www.pan-europe.info	