Joint NGO recommendations

for EP ENVI Committee's 2nd reading on the biocide regulation (COM (2009) 267)

06 September 2011

To: Members of the EP Environment Committee

Recommendations for EP ENVI considerations for 2nd reading on the proposal of the placing of biocidal products on the market

(COM (2009) 0267))

Hamburg/Brussels, 06th September 2011

Dear Member of the EP ENVI Committee,

This Thursday, 8 September, you will discuss the draft recommendation of rapporteur MEP Christa Klaß for the EP's position on the 2nd reading on biocides.

Taking into account the rapporteur's proposal [1], the Council's common position (adopted on 21 June 2011) [2] and EP's first reading position on the biocide regulation (adopted on 22 September 2010) [3], Pesticide Action Network PAN Germany, PAN UK, and PAN Europe, BUND (Friends of the Earth Germany), European Environmental Bureau, Grüne Liga e.V., Health and Environment Alliance, Health Care Without Harm Europe, Women in Europe for a Common Future, and the Department of Clinical Microbiology Uppsala University Hospital call on you to ensure that the new biocides law guarantees the high level of protection of human health and the environment.

We particularly recommend to consider the following points:

1. A consistent and enforceable cut-off and substitution regime (esp. Art. 5, 10, 22)
2. A sufficient approval system and (simplified) authorisation (esp. Art. 18, 24)
3. Support measures for the sustainable use of biocidal products across the Union (esp. Art. 17, 75)
4. Guarantee transparency for the public, stakeholders and administration (esp. Art. 57, 64, 68, 70)

With this in mind, we would like to highlight the following detailed comments and suggestions for your consideration:

1. A consistent and enforceable cut-off and substitution regime (esp. Article 5, 10, 22)

- *Ensure that cut-off criteria are consistent and enforceable and in line with those of the Regulation on the Placing of Plant Protection Products on the Market (EC 1107/2009)*

Substances that are considered to be carcinogenic, mutagenic, toxic to reproduction and endocrine disrupting should be excluded ("cut-off") as soon as possible from use within the European Union due to their recognised adverse effects on human health and the environment. While there is broad agreement on this hazard-based approach, currently neither the Council

position nor the draft rapporteur's recommendation include a consistent cut-off regime in line with the Regulation on Plant Protection Products (Reg. EC 1107/2009).

We are especially concerned about the foreseen derogation system which appears to be at best confusing and at worst to undermine the spirit of the proposed Regulation. The Council's proposal for derogations from the exclusion criteria undermines the aim of phasing out highly hazardous biocides (especially derogation 2(c), that is approval for the benefit of indistinct social interests while leaving out a clear obligation for criteria and demonstrating the necessity for this). Accepting the Council's approach would be a further weakening of the EP's position in first reading, which we already considered to be leaving too many loopholes for hazardous biocides to stay on the market. In the interest of environment and health protection, exemptions to the exclusion criteria should be strictly limited.

Regarding the biocides which fall under the exclusion criteria, endocrine disruptors and their classification are of particular concern. As it currently stands there is no provision in the draft Regulation for a deadline for the determination of a suitable classification of an endocrine disrupting substance (EDC). Moreoever, peer reviewed scientific data and information should also be allowed to determine what constitutes an EDC.

Our recommendations:

- For classifying endocrine disruptive biocides, confirm the scheme according to Point 3.6.5. of Annex II of Reg. EC 1107/2009 (**amend Art. 5 Council position, reinstate EP's position in Art. 5(1) and 5(3));**
- Reject vague derogations **(delete Art. 5 (2)(c) Council position, reinstate EP's position on Art. 5(2));**
- Guarantee at the very least that member states have the competence to restrict biocides which fall under the cut-off and substitution criteria (Art. 5 and 10 substances) on their territory to prevent adverse effects on their citizens and on the environment **(reinstate EP's 1st reading position in Art. 36, reinstate in Art. 87)**.Member states should also have the competence to establish specific risk-mitigation measures (**reinstate EP's first reading in art. 36));**
- Require that the approval of article 5 cut-off substances is limited to 5 years **(reinstate EP's position on Art. 4).**

- *Institute a robust substitution regime including a sufficient comparative assessment*

Substitution is a critical mechanism for ensuring a high level of protection for human health and the environment, particularly for vulnerable groups, but also for stimulating innovation for less harmful products.

The proposals of the Council and the EP rapporteur include several serious shortcomings which would make the substitution regime ineffective. We are especially concerned about the gap in tackling biocides with developmental neurotoxic or immunotoxic properties. Council rejected considering developmental neurotoxic or immunotoxic biocides as candidates for substitution despite increasing scientific concern about their adverse effects during prenatal development and on infants or children. The EP rapporteur even suggests rejecting relevant testing obligations (am. 93 & 94). This would be a step back from the EP's 1st reading position, and also in contrast to requirements laid out in Reg. EC 1107/2009 (RPPP).

Another essential deficit is that the current proposal does not require substitution plans. It is not even guaranteed that highly hazardous biocides will be replaced by sound chemical or non-chemical alternatives within 10 years. It proposes a regular review of relevant biocides every 7 years and a comparative assessment of related products every 5 years, which are not sufficient to ensure that sound alternatives will be developed and phased-in effectively enough to reduce any hazard.

We are not convinced by the Council's argument that implementing substitution plans will result in too great of an administrative burden, there is no evidence as yet to back this assertion. Continued use of substances that could be candidates for substitution would also pose disproportionate risks and costs (e.g. costs for control or after-care like in the case of certain wood preservatives) while the effective promotion of alternatives would facilitate innovation. REACH (cf. Art. 62) and the Regulation of Plant Protection Products (cf. Art. 4) have already established requirements for substitution or phasing out plans.

Finally, Council's suggestions for allowing wide-scaled experiments through authorising biocidal products containing candidates for substitution before carrying out a comparative assessment is of potentially high risk for human health and the environment are to be rejected.

Our recommendations:

- Include developmental neurotoxic and immunotoxic substances in the list of criteria for candidate for substitution to facilitate their replacement with less harmful alternatives **(reinstate EP's 1st reading position/Commission proposal in Art. 10);**
- Insist on establishing substitution plans for guaranteeing the replacement of candidates for substitution **(reinstate EP's 1st reading on Art. 22);.**
- Reject any vague derogation which hinder the timely substitution of (highly) hazardous substances **(reinstate EP's 1st reading position , Art. 22(4) Council position);**
- **Support Article 6 and Annex II of the Council position** to establish sufficient testing standards for identifying Article 5 and 10 substances **(support).**

2. A sufficient approval system and (simplified) authorisation (esp. Article 18, 24)

- *Establish a simplified authorisation regime in line with the precautionary principle (Art. 24, 27)*

It is essential for any approval and authorisation regime for biocidal products that humans and the environment are consistently protected from risks and hazards. This principle should also be guaranteed when introducing and applying the simplified authorisation procedure. We are concerned that Council's proposal for this system is not balanced enough. For instance, environmental or human health criteria are not comprehensively considered for the assessment phase. In the Council's approach, there would be no obligation to assess combination effects. Moreover, active substances which could damage water ecosystems in the long term, biocides in nanoform or that have (developmental) immuno- and neurotoxic effects would not be excluded from the simplified authorisation procedure. The proposed procedure is not transparent and member states do not get enough competences in order to restrict the authorisation on their territory.

In order to establish a balanced and simplified authorisation regime we recommend to:

- Support EP rapporteur's proposal to ensure that environmental criteria will be appropriately considered in the risk assessment phase **(support am. 37 of draft EP recommendation)**;
- Ensure that active substances for which a hazard labelling is required do not fall under simplified authorisation; at the very least, require that combination effects will be assessed and that biocides are excluded which pose long term damage on water ecosystems or have (developmental) immuno- or neurotoxic effects or include nano materials **(amend Art. 24, 27 council position).**

- *Ensure sufficient assessment and evaluation of biocides in general (esp. Art 18)*

We are concerned that Council's proposal for the "regular" authorisation regime for biocidal products is not consistent enough to protect humans and the environment. A vague derogation in Article 18 makes it possible to sidestep dealing with biocides related threats on for example vulnerable groups, water resources or the endangered non-target wildlife if this can be justified on the basis of "disproportionate negative impact to the society". Technical requirements for evaluating product assessments (Annex VI) are not coherent with essential provisions of environmental Community laws (e.g. Water Framework Directive, Marine Strategy Directive).

Another problem is that biocidal products that are also used as pesticides do so far not meet the criteria of the stricter EC Regulation on Plant Protection (Art. 2). With regard to the approval of active substances, it is a significant step back when a biocide will only (in principle) be reviewed every 15 years or after a possibly longer period (Art. 12) if they are not listed in the Annex of the Regulation.

Our recommendations for your consideration are:

- reject vague derogations in the authorisation regime in order to effectively protect human health and the environment **(delete Article 18 (5) Council position);**
- ensure coherence with environmental Community laws (amend Annex VI Council position) and with the Regulation EC No 1107/2009 **(amend Art. 2(2) Council position); delete derogation for Art 2(2)(i)**support a frequent review of biocidal products (amend Art. 12 Council position) and call for the inclusion of active substances in the Annex of the regulation **(support EP rapporteur's amendment, but amend rapporteur's proposal for art. 17(3)(1a).**

- *Ensure a sufficient assessment and labelling of Nano biocides*

Because of their novel properties, nano biocides may pose new risks. The new biocides law should ensure that nano biocides are properly assessed and establish provisions to enable consumers to make informed choices. We think that the current proposals are a step in the right direction, but do not go far enough.

Our recommendations for nano biocides include:

- Insist on a separate and timely functioning assessment of biocides in nano form **(reinstate EP 1st reading position on Art. 18 Council);**

- Ensure an understandable and sufficient labelling of *all* biocidal nanomaterials, reject any derogation to these essential obligations **(amend Art. 57 and 68 Council position);**
- Ensure that there will be a report on the assessment of risks to human health and the environment by the use of nanomaterials at the latest 2 years after entry into force of the regulation **(reinstate EP's first reading position in art. 64).**

3. Support measures for the sustainable use of biocidal products across the Union (esp. Article 17, 75)

As concluded in the PAN Germany background report "Sustainable Use of Biocides in Europe" [4] there are serious shortcomings with regard to effective measures on the use phase across the EU. We have noticed a gap of data obligations, of adequate standards for integrated pest management and precautionary measures and of the protection of sensitive areas. Whereas the proposed new concept of product authorisation will facilitate the market placement of biocides in the EU, the Council position generally maintains the vague and ineffective provisions of the current Directive (Directive 98/8/EC) for the use phase.

It is essential to establish a framework Directive and direct measures to ensure the sustainable use of biocidal products across the Union in a similar way as has been introduced for plant protection products according to Article 55 of Regulation (EC) 1107/2009 and Directive 2009/128/EC. This is especially necessary given the risk of antibiotic resistance due to biocides overuse, which is a serious public health and veterinary health challenge.

We welcome EP rapporteur's suggestions to reinstate EP's first reading position on the sustainable use (am. 30 & 68 of the draft recommendation):

- Establish a framework Directive for facilitating the sustainable use of biocidal products across the Union **(amend Art. 17 Council position);**
- Introduce direct measures on EU level for assisting all efforts for the promotion of the sustainable use of biocidal products (**amend Art. 75 Council position)**.

4. Guarantee transparency for the public, stakeholders and administration (esp. Article 57, 64, 68, 70)

Neither the Council position, nor the rapporteur's draft recommendation guarantees that the effectiveness of the biocide regulation for the protection of human health and the environment will be visible to key stakeholders, or provide an opportunity for greater public scrutiny and participation.

For example, there is no obligation to monitor and to report the impact on vulnerable groups or the environment from the use of authorised biocidal products (Art. 64). Consumers are not able to find out in each case if and how the relevant biocidal product is authorised and whether it contains problematic substances. Until now, none of the draft positions include a suggestion to publicly list all biocidal products which are legally authorised in the Union (e.g. not in Art. 66 or 70), yet this seems paramount for better use and protection from consumers.

In terms of treated articles we welcome the Council's proposal to require a binding labelling system for all related products indicating that they contain or are treated with biocides (Art. 57). We also support binding information about the name of active substances used. However label-

ling would only be required when humans have direct contact with the active substance during a "foreseeable" use phase of the relevant treated article. This pre-condition is problematic since this would not consider malpractices (e.g. use of a treated rubbish bag for storing or packaging food).

Our recommendation is to draw together the positive elements of all the drafts to date with some adaptations as follows:

- call for frequent and public reporting regarding the impact of authorised biocidal products on human health and the environment **(reinstate EP's 1st reading position on Art. 64);**
- ensure an understandable and comprehensive labelling of *all* biocidal products and treated articles which, at the very least, clearly indicates a) the treatment or content ("include biocides" or "treated with biocides"), and b) the name of active substances used **(amend Art. 57 and 68 Council position), reject any derogation to these essential obligations;**
- establish a comprehensive and frequently updated public database concerning authorised biocidal products – including a specific list/ indication of products which are authorised according to the simplified authorisation procedure - on EU and national level **(amend Art. 70 Council position).**

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

We should be most grateful if you consider our recommendations.

Kind regards

see contacts

Contacts

Pesticide Action Network Germany Susanne Smolka Nernstweg 32 22765 Hamburg, Germany Tel. + 49 40-399 19 10-24 Fax + 49 40 -399 19 10-30 E-mail: susanne.smolka@pan-germany.org http://www.pan-germany.org	Pesticide Action Network Europe Gergely Simon (Board member) Tel. +36 203344336 E-mail: gergely@pan-europe.info http://www.pan-europe.info
Pesticide Action Network UK Nick Mole Development House 56-64 Leonard Street London EC 2 A 4L T Tel. +44 20 7065 0905 E-mail : nickmole@pan-uk.org http://www.pan-uk.org	BUND (Friends of the Earth Germany) Jurek Vengels Am Köllnischen Park 1 10179 Berlin, Germany Tel. +49 30 2758 6465 E-mail : Jurek.vengels@bund.net http://www.bund.net
European Environmental Bureau (EEB) Christian Schaible Boulevard Waterloo 34 1000 Brussels, Belgium Tel. +32 (0) 2289 1094 Fax +32 (0) 289 1099 E-mail : christian.schaible@eeb.org http:// www.eeb.org/	Grüne Liga e.V., Bundeskontaktstelle Wasser Michael Bender Prenzlauer Allee 230 10405 Berlin Tel. +49 30 – 443391-44 E-mail : wasser@grueneliga.de http://www.wrrl-info.de
Health and Environment Alliance HEAL Anne Stauffer 28 Boulevard Charlemagne 1000 Brussels Tel. +32 2 234 3643 E-mail : anne@env-health.org http://www.env-health.org	Health Care Without Harm Europe (HCWH Europe) Anja Leetz Rue de la Pépinière 1 1000 Brussels, Belgium Tel. +49 6222 76 93 202 Fax +32 2402 3042 E-mail : anja.leetz@hcwh.org http://www.noharm.org/europe
Women in Europe for a Common Future Elisabeth Ruffinengo 1 Place de l'Eglise St André, 74100 Annemasse, France Tel. + 33 (0)4 50 49 97 38 E-mail : elisabeth.ruffinengo@wecf.eu http://www.wecf.eu	Department of Clinical Microbiology Uppsala University Hospital 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 http://www.medsci.uu.se

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