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**To: Deputy Permanent Representatives COREPER I**

**Recommendations on upcoming trilogue on 2<sup>nd</sup> reading on the proposal concerning the placing on the market and use of biocidal products (COM (2009) 0267))**

Hamburg/Brussels, 14<sup>th</sup> October 2011

Dear Deputy Permanent Representatives,

Next week Council will start the negotiations with the European Parliament regarding the proposal concerning the placing on the market and use of biocidal products (COM (2009) 0267).

The Pesticide Action Network Germany, PAN UK, PAN Europe, Health and Environment Alliance HEAL, and many other environment, health and citizens' organisations have been following the legislative process closely and have issued several position papers and recommendations for the new biocides law. Our key demands for the 2<sup>nd</sup> reading can be found in our joint recommendations from 6<sup>th</sup> September 2011 [1].

With the deliberations now having reached the decisive state, European citizens are looking on to you to ensure that this new law upholds the high level of human health and environment protection. The guiding approach for this new law has to be precaution and prevention in order to ensure that active substances and biocidal products do not have harmful effects on humans, non-target species and the environment.

Europe's citizens are very much concerned about the impact of environmental pollution on their health, and the impact of chemicals is the top environmental health worry.

With this in mind, we call on you to consider the following concerns in your negotiations:

### **1. A consistent and enforceable cut-off and substitution system**

We welcome that there is broad agreement in the Council and EP on the hazard-based approach of the new law, excluding biocides that are carcinogenic, mutagenic, toxic to reproduction and disruptive to the endocrine system from future approval. However, it is important that the foreseen provisions become consistent, comprehensive and therefore enforceable, in order to really lead to a reduction of exposure to hazardous biocides for human health and the environment.

As we have stressed repeatedly, with regard to **derogations**, it must be ensured that these are kept to an absolute minimum, otherwise the spirit of the regulation would be compromised.

We ask you to follow the EP approach for the derogations, especially to drop exemption art. 5 (2)(c) and ensure that substitution plans are established.

Just this week, Council held a discussion on **endocrine disrupting chemicals**, and many countries supported more urgent risk management measures for them. The revision of the biocides is a concrete opportunity to take this forward.

We welcome Council support to include EDCs on the list of cut-off substances in the draft biocides law. We call on you to support as well giving a clear deadline for the development of EDC criteria (2013) and including peer-reviewed scientific data and information in the determination of endocrine disrupting biocides. This is the approach that you supported in the regulation on plant protection products, so it should be ensured that there is legal coherence between these two regulations.

We also urge you to support clear limits for the approval of art. 5 substances (that is 5 years).

**Substitution** is a key principle of EU chemicals law, and an important means to facilitate the development of less harmful biocides and technologies. With a view to protecting especially the health of future generations, we urge you to **include developmental neurotoxic and immunotoxic biocides in the list of candidates for substitution**. This is also an important contribution to ensuring a healthy European workforce. Regarding comparative assessment, we welcome that Council highlighted that non-chemical control or prevention methods should be considered in comparative assessment.

## 2. Support measures for the sustainable use of biocidal products

As concluded in the PAN Germany background report “Sustainable use of biocides in Europe” [1], there are serious shortcomings with regard to effective measures on the use phase across the EU. It is essential to establish an **EU legal framework and direct measures** to ensure the sustainable use of biocidal products in a similar way as introduced for plant protection products (Art. 55 of Reg EC 1107/2009 and DR 2009/128/EC). This is especially important given the growing concern of antibiotic resistance due to biocides overuse, which is a serious public health and veterinary health challenge.

Please support the EP rapporteur in her call for a **directive on the sustainable use** and for providing guidance and tools for the use phase in the regulation.

## 3. Union authorisation and EU member states rights

We welcome the general approach of a step by step implementation of Union authorisation in order to enable ECHA as the responsible agency to build up adequate structures and capacities. It also has to be ensured that **products which contain article 5 substances do not fall under Union authorisation**.

The new law should not threaten the high standards of health and environment protection set up by EU Member States. Regarding **mutual recognition, we think it is crucial to uphold national rights** to refuse authorisation and to adjust terms and conditions of use

Of special concern is that Member States retain the right to refuse products with art. 5 and art. 10 active substances in order to fulfil the goal of the regulation to reduce exposure to harmful biocides.

#### **4. Guarantee transparency for the public, stakeholder and national administration**

Stakeholders and the general public have a key interest in assessing if the new biocides regulation works. Putting the right transparency and **monitoring requirements** in place is therefore an essential element of the new law. We hope that you support the monitoring obligations put forward by the European Parliament, including a report on the impact of biocides on the environment, nano biocides and impacts on vulnerable groups as well as transparency through website information.

Adequate **labelling provisions** will enable consumers to make informed choices about biocidal products they're buying, and are also necessary for the adequate handling by professional users. We welcome Council's position of comprehensive labelling of treated articles.

#### **5. Adequately address health & environment challenges from nano biocides**

With the new law you will set the requirements on biocides for the years to come.

We welcome that you have taken up concerns to properly assess and regulate the health and environment risks from the use of nanomaterials in biocides. However, the requirements need to be strengthened in order to ensure adequate protection. This includes having a legislative proposal for the inclusion of the forthcoming nano definition in the biocides regulation, stating that products with nanomaterials can't fall under simplified authorisation, and clarifying that there has to be a separate risk assessment for nano biocides. There should also be clear labelling provisions for nano in place.

In order to achieve the goal of a high level of health and environment protection, it is also important to have timely rules for the ongoing review process. We welcome the proposal put forward by the EP's ENVI committee and ask you to support it.

For any further concerns, please see the joint NGO recommendations for the biocides 2<sup>nd</sup> reading [1].

If you have any questions, please do not hesitate to contact us.

Best regards,

on behalf of  
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Health and Environment Alliance, HEAL  
Anne Stauffer

## References

[1] Joint NGO recommendations for EP ENVI Committee's 2nd reading on the biocide regulation

(COM (2009) 267), 06 September 2011:

[http://www.pan-germany.org/download/biocides/NGO\\_recom\\_biocide-regulation\\_110906.pdf](http://www.pan-germany.org/download/biocides/NGO_recom_biocide-regulation_110906.pdf)

[2] PAN Germany (2010): Sustainable use of biocides in Europe – urgent need for action: [http://www.pan-germany.org/download/biocides/briefing\\_sustainable\\_use\\_of\\_biocides.pdf](http://www.pan-germany.org/download/biocides/briefing_sustainable_use_of_biocides.pdf)

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