To: Deputy Permanent Representatives COREPER I

Biocides: putting human health and the environment first (COM (2009) 0267)

Hamburg/Brussels, 14th November 2011

Dear Deputy Permanent Representatives,

The Council and European Parliament are currently in the final negotiations on the proposal concerning the placing on the market and use of biocidal products (COM (2009) 0267).

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 2nd reading can be found in our joint recommendations from 6th September 2011 [1].

With the deliberations now having reached the decisive state, European citizens are looking 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. Derogations to cut-off system should be the exception rather the rule

We continue to be very concerned about the foreseen derogation under Art. 5 (2) c) which causes confusion (also for the industry concerned) and undermines the purpose of the Regulation. The exemption on "disproportionate negative effects for society" would open the door to many hazardous biocides continued to being used because of the absence of a clear legal language, definition or any other clarification, e.g. the difference to the exemption (b) "prevent or to control a serious danger to public".

We also expect an over-the-top capacity burden for long-term case-by case discussion about this unclear exemption c). It counteracts the aim of the revision to reduce the administrative burden and to support the biocide industry through simplification of the approval and authorisation procedure.

Exemptions a) and b) in article 5 are sufficient to cover all concerns in case of serious dangers. Thereby a biocidal product containing cut-off biocides should be used only under conditions excluding the contact with humans and the release to the environment according to exemption a). Moreover, there are further derogations possible under Art. 54 for exceptional circumstances.

In principle, derogations with regard to the cut-off system or to product authorisation (Art.18(5)) should be acceptable only if it is shown that there are no effective alternative substances or technologies available.

2. Evaluation and identification of endocrine disrupting biocides should reflect the current state of science

We welcome that there is broad agreement in the Council and EP on the need to act on endocrine disruptor biocides, on the interim criteria, and also about setting the deadline of 2013 for the development of EDC criteria.

However, another main issue is the need for 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, and which has been set a clear signal to learn the lesson from the past.

Recently, the the French Food and Environment Safety Agency ANSES published 2 reports on Bisphenol-A which highlight the importance of including all available studies when considering potential health and environment effects. Previous evaluations considered only studies which are performed according on good laboratory practice, and has left out hundreds of studies which showed effects of BPA at low-doses.

As the European Commission is currently working on criteria for determining endocrine disruptors, we believe the reference to draw on peer-reviewed scientific data and information is needed to provide clear guidance for this important work.

3. Avoid non-planned phasing-out of substances of highly concern

If an active substance is restricted as “cut-off” candidate but it is further used for a limited period by way of derogation, at the same time, Member States shall draw up a phasing out (*substitution*) plan concerning the control of the serious danger by other means, including non-chemical methods. This approach is already adopted in the new regulation on plant protection products (PPP-Reg 1107/2009, Art. 4(7)) because only such strategic approach can guarantee the stepwise elimination of highly hazardous substance.

A strategy is necessary to send clear signals to the industry and other stakeholder in order to support and to start innovations for alternatives. Therefore we call for the inclusion of such substitutions plans into the Biocide Regulation (Art. 5(2) and Art.18(5)).

4. Show commitment to protecting children’s health

The original Commission proposal foresaw the inclusion of developmental neurotoxic and immunotoxic biocides in the list of candidates for substitution, and this approach has been supported by the European Parliament. We are surprised to see that the EU member states apparently hinder making progress on this important point for reducing health risks for children. De-

velopmental neurotoxic and immunotoxic biocides need to be clearly listed in art. 10 as an expression of commitment to protecting children's health.

5. Support framework measures on sustainable use

The argument cited most often against the establishment of a Framework Directive on sustainable use of biocidal products is the lack of data linked to biocide use such as market data, usage data, environmental impact data, poisoning and human health data and others. There have been several stakeholder meetings and studies covered by the EU Commission pointing out this biocide specific deficit of information (compared to other chemicals such as pesticides, pharmaceuticals or relevant industrial chemicals). Each further report or study will finally provide the same and well-known deficits and won't help to solve the problem.

From our point of view the main reason of these data gaps results from the absence of any harmonized legal framework regarding the use phase. So the main question is how to go beyond the circle of no-knowledge – no-action and vice versa?

The lack of harmonised use regulation will also affect the union authorisation of biocidal products in the future. The union authorisation is restricted for biocidal products "which have similar conditions of use" (Art. 41(1)). Similar conditions of use is neither known nor reality for much biocide applications at present, e.g. technical standards of application and protection equipment or qualification standards of professional users which all influence the conditions of use as well as the intensity of exposure and risks.

6. Enable EU member states rights

The new law should not threaten high standards of occupational health, public health and environment protection set up by EU Member States. We think it is crucial to uphold national rights to refuse authorisation and to adjust terms and conditions of use. This principle has already been adopted in the Regulation on plant protection products.

For any further concerns, please see the joint NGO recommendations for the biocides 2nd reading [1]. If you have any questions, please do not hesitate to contact us.

Best regards,

on behalf of

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Reference

[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

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