

## Position

**Proposal of the European Commission for a  
regulation concerning the placing on the market and  
use of biocidal products – COM (2009) 267 final**

**PAN's priority position for the forthcoming meeting of the  
Council's Working Group for Environment,  
Brussels 26 October 2009**



**Protect humanity and the environment from pesticides. Promote alternatives.**

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To members of the Council Working Group for Environment

**PAN's priority position on the proposed biocide regulation  
(Council WG Envi Meeting, 26 October 2009)**

Brussels, 22 October 2009

Dear Madam or Sir,

at the forthcoming meeting in Brussels on 26 October 2009 you will be dealing with four key issues concerning the biocide regulation draft introduced by the Commission on 12 June this year:

- low-risk products: criteria and authorisation (Art.17)
- exclusion criteria (Art.5 and Annex I)
- criteria for candidates for substitution (Art. 9)
- comparative assessment (Art. 21)

PAN welcomes the work on the revision of the biocide legislation but asks you to further improve the Commission's proposed provisions which you will presently address. In short:

In view of the **low-risk products** we recommend establishing clear and consistent criteria as well as enabling room for manoeuvre for member states to protect citizens' health and the environment.

Concerning the **exclusion criteria** we stress the need to add environmental criteria as already introduced in other chemical laws like REACH & the pesticide package and to delete the exemptions.

In principle we welcome the **criteria for candidates for substitution** but we see a need for stricter standards.

We welcome the principle of **comparative assessment** and the inclusion of non-chemical alternatives. However, we urge you to apply the provisions for comparative assessment to all biocidal products and not only to products with candidates for substitution in order to establish a progressive risk minimisation.

We should be most grateful if you would consider the following comments and recommendations to these issues as outlined in detail in the annex below.



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Please do not hesitate to ask for further information.

Yours sincerely

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## Annex

### PAN's priority position on the proposed biocide regulation (Council WG Envi Meeting, 26 October 2009)

#### Low-Risk Products

##### **Authorisation of Ecologically Sound Low-Risk Products**

We understand this new, simplified authorisation procedure to be an initiative to promote low-risk biocidal products within the EU. However, the Commission's draft allows the inclusion of active substances in low-risk biocidal products which are not listed in Annex I. These substances are consequently not evaluated with respect to their properties (e.g. toxicity) as is required for active substances used for 'normal' biocidal products. Besides it is possible that a low-risk product can also include hazardous substances. As a result, the intended legislation will bring about a completely non-transparent and hazardous situation. The principle should therefore remain that for each biocidal product only active substances can be used which are listed in Annex I. Furthermore there should be strict criteria to prevent the EU-wide authorisation of products with substances of concern.

We believe it is only acceptable to establish a community approach if there are strict criteria to prevent the authorisation of products with hazardous substances or substances of concern (see also PAN-position from the 9th October 2009).

*We therefore recommend amending the Commission's draft biocide regulation:*

*Amend Articles 17 **and** 3 of the draft regulation to provide a clear and expanded definition of the term 'low-risk biocidal product': A low-risk product is characterised by low hazardous properties **and** low potential exposure for humans and the environment taking into account the whole life cycle, including disposal. A low-risk product does not contain any substance(s) of concern.*

*Add Article 17 (1): The use of a low-risk product is necessary throughout the European Union and climatic and other regional specific conditions do not have any influence on the evaluation as a low-risk product.*

*Add Article 17 (1) (a): A biocidal product should not be considered to be a low-risk product if it satisfies at least one of the following conditions: persistent **or** bioaccumulative **or** toxic.*

*Add Article 17 (1) (a): A substance shall also not be considered as being of low risk if it is persistent (half life in soil is more than 60 days), or if the bioconcentration factor is higher than 100.*



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*Add Article 17 (1) (c): A substance shall not be considered as low risk if it is vii) explosive, viii) corrosive, ix) very toxic or toxic.*

*Delete Article 17 (2) because the criteria or conditions are not realistic. There is a risk that low-risk products could contain highly hazardous substances which have not been approved and have not been included in Annex I according to the current draft text. Furthermore there are several uncertain terms which suggest an unrealistic situation (e.g. “product is handled under strictly controlled conditions during all other stages”).*

*Add (a) into Article 16 (3): Also low-risk substances must be listed under Annex I. In addition they should be specially marked in this annex .*

## **Exclusion Criteria**

### **Strict Requirements for the Protection of Human Health and the Environment**

The proposed Article 5 of the biocide regulation draft maintains provisions for the exclusion of certain substances from the authorisation. In principle we welcome such efforts to ban chemicals which harm health. However, the intended cut-off scheme is not strict enough as the requirements introduced with REACH and the new adopted Regulation on Plant Protection Products: The criteria do not address any necessary precaution to protect the environment. Furthermore the proposed provisions contain several exemptions in combination with unclear notions (e.g. “negligible” or “disproportionate”) so that it is likely to authorise highly hazardous substances. The exemption 5 (1) (c) foresees that highly hazardous substances may be included in Annex I if “disproportionate negative impacts” arose from their non-inclusion. Thus, we are concerned that the proposed text might even result in a roll-back of standards established by current biocide legislation.

*We therefore strongly recommend setting clear cut-off criteria to protect human health and the environment:*

*Delete Article 5 (1) a) to obviate an inadequately stringent approach which only focuses on human health but not the environment and which only takes into account “normal conditions of use” but not the whole life cycle and which does not provide a clear definition of “negligible exposure”. The littera b) and c) are unnecessary. If a member state needs flexibility to handle a serious danger to public health within its territory it can temporarily permit active substances pursuant to Article 45 (derogations from the requirements). If cut-off products are permitted according to Article 45 the member state must develop and implement a plan of substitution and shall grant authorisation to a corresponding product only within its own territory (no provisions of mutual recognition).*



*Amend Art. 5 (2) to prevent authorisation of persistent, bioaccumulative and toxic (PBT)-, very persistent and bioaccumulative (vPvB) – and/or persistent organic pollutants (POP)-substances to take account of environmental risk.*

*Amend Art. 5 (2) to include concrete criteria to address biocides with endocrine-disrupting effects (EDC). There are no international or European actionable test procedures and classification systems to characterise endocrine disruptors. This means that Art. 57 (f) of the Regulation 1907/2006 (REACH) has no substantial meaning.*

*We propose adding the provisions for EDCs from the newly adopted Regulation on Plant Protection Products (Annex II 3.6.5.). According to this Regulation the Commission shall present a draft for an appropriate approach concerning specific scientific criteria within 4 years. As long as these criteria are not adopted, substances are considered to have endocrine-disrupting properties if they are:*

- a) carcinogen category III and toxic for reproduction category III or*
- b) toxic for reproduction category III and have toxic effects on endocrine organs.*

*Amend Art 5 (2) to prevent authorisation of developmental neurotoxic and immunotoxic substances (insert provision of Art 9 (1) (c)). We recommend introducing a provision that the Commission shall present a draft for an appropriate approach concerning specific scientific criteria within 2 years.*

## **Criteria for Candidates for Substitution**

### **Ensure a Holistic Approach to Promote Alternatives**

Art. 9 of the biocide regulation draft establishes criteria for candidates for substitution to protect human health and the environment. However, we believe that this provision has several gaps. The criteria do not sufficiently ensure protection of the environment or welfare of wild animals. For example, in the proposed text endocrine effects are only taken into account to protect human health but not the environment.

*We therefore urge you to:*

*Amend Article 9 (1): ensure a general obligation for comparative assessment and substitution requirements which not only addresses substances with hazardous effects or those which are of concern. All substances should be evaluated and replaced if there are more healthy or ecologically sound substances available. At least maintain the provisions drafted under Art. 10 (5) (i) of the current Biocidal Product Directive 98/8/EC.*

*Amend Article 9 (1) (b) to ensure that the substitution principle is applied for each criterion, also in case of ecotoxic effects. Substances which are frequently detected in the environment and which do not comply with the achievement of environmental standards estab-*



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*lished in other EU-legislation (e.g. Water Framework Directive, Habitats Directive) shall be designated for substitution to protect ecosystems and biodiversity.*

*Amend Article 9(1)(f) to address all substances with endocrine effects and not only those which cause harm. The criteria should also consider substances with effects on wild animals.*

*Amend Article 9(1)(c),(e),(f): add the sentence: "...in case the substance has not been excluded in accordance with the criteria laid down in Art. 5 (2)."*

*Add Article 9(2) to ensure that besides the agency the evaluating competent authority or authorities of other member states can also submit proposals for candidates for substitution.*

*Amend Article 9 (4) to guarantee appropriate authorisation periods: No renewals for candidates for substitution. Maximum inclusion period in Annex I of 5 years.*

*Introduce a new provision for mandatory substitution plans including non-chemical methods to ensure the phase-out of hazardous substances within 5 years.*

*The authorisation of a corresponding product must be conducted at member state level (no mutual recognition or community authorisation comparable to the provisions in the adopted Regulation on Plant Protection Products in Art.41 (2)).*

## **Comparative Assessment**

### **Introduce an Effective Mechanism for Innovation**

We welcome the concept of comparative assessment. However, we believe that the proposed Art. 21 is insufficient to protect human health and the environment. It relocates the comparative assessment of the level of active substances to the level of biocidal products. This is a change but also a roll-back in comparison with the current Biocidal Product Directive. Besides, it only necessitates carrying out a comparative assessment of products with candidates for substitution. This is problematic due to the shortcomings identified in the intended provisions for the substitution of active substances (see also above). Art. 21 (4) allows the authorisation of relevant biocidal products without a comparative assessment. This is critical as the conditions for the exemption are described as being too vague: Besides it should also be borne in mind that such products can include hazardous substances. Furthermore there is no obligation for authorities to ensure consistent phasing-out of products with hazardous substances.

For this reason we recommend comparative assessment at both product and substance authorisation levels. We also recommend the establishment of a successive risk minimisation system that allows a comparative assessment for substances and products which do not full-fill the criteria for substitution.



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*We therefore request the following amendments:*

*Amend Article 21 (1), at least comparable to the provision in Art. 50(2) of the new adopted Regulation on Plant Protection Products. According this Article member states may in exceptional cases apply the comparative assessment on products which do not contain candidates of substitution.*

*This is an important step to consider all biocidal products for comparative assessment and not only those with candidates for substitution.*

*Delete Article 21 (4) to guarantee that no new products enter the market which contain candidates of substitution. It counteracts the main objective of eliminating such products from the market.*

*Amend. Art. 21 (6): Limited product authorisation for products including candidates of substitution for 3 years. Such authorisations should only be possible at member state's level because member states must prepare individual plans for substitution (see below) which take into consideration regional-specific conditions, techniques and alternatives.*

*Amend Art. 21 (6): Ensure that member states establish mandatory plans for substitution.*

