PAN Germany
Pestizid Aktions-Netzwerk e.V.

Pesticide Action Network Europe

PESTICIDE ACTION NETWORK *UK*

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 15 October 2009

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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, 15 October 2009)

Brussels, 9th October 2009

Dear Madam or Sir,

at the forthcoming meeting in Brussels on 15 October you will be dealing with two key issues concerning the biocide regulation draft introduced by the Commission on 12 of June this year:

- Final discussion on simplified procedures (EU-authorisation, role of ECHA, fees) - Art. 16 (3), Art.18, Chapter VII (Art. 32-37), Chapter XIII (Art. 64-69), Art. 70, Art.79
- Initial discussion on treated articles - Art. 47 & 81

PAN welcomes the work on revision of the biocide legislation but stresses the specific nature of each amendment proposed by the Commission. This is particularly the case for the provisions you will presently address.

In view of the simplification of the authorisation procedure we ask you to ensure significant improvements which will prevent any roll-back of existing and necessary standards for the protection of the environment and human health in the EU.

Regarding treated products, we strongly recommend that you support and further strengthen the intended provisions of the Commission's draft.

We should be most grateful if you would consider the following comments and recommendations:

Simplified Procedure

Ensure Appropriate Room for Manoeuvre by Member States

In the draft regulation there is a significant modification of requirements and responsibilities, for example: The new implementation of product authorisation at Community level by ECHA (e.g. Art. 35) or the new system of parallel mutual recognition. All modifications will reduce national room for manoeuvre in authorising biocidal products. This will consequently also af-

fect the enforcement of (necessary) stricter national standards for the protection of health and the environment.

There are several reasons why you should maintain freedom of manoeuvre by Member States with respect to the authorisation of biocidal products:

- Natural conditions and other circumstances (eg demographic aspects, vulnerable persons, type and frequency of uses, technical standards, availability of alternative measures) differ between regions. That is why it is difficult to establish EU-level standards without effective derogations for national or regional competent bodies to protect human health and the environment.
- Art. 176 of the EC-Treaty allows Member States to set stricter standards for protection of the environment. Secondary legislation like the proposed biocide regulation must comply with this principle.
- Other relevant legislation regarding the authorisation of products with active ingredients includes provisions to enable flexibility of national or regional competent bodies (see Art. 36(3) of the new adopted Regulation on Plant Protection Products).
- According to Art. 4 (2) of the Biocide Directive Member States may effectively request derogations for the protection of health and the environment.

We ask you to amend Art. 35 (1) to provide the opportunity for each Member State to give a statement with respect to the assessment report and conclusions of the evaluating competent authority (compare procedure in Art. 37 (3) of the regulation draft). This is also necessary as there is no (sufficiently) harmonised procedure for product evaluation. Early involvement of other Member States would reduce the risk of disputes at a later stage.

We urge you to include the provision comparable of Art. 36 (3) of the new adopted Regulation on Plant Protection Products[1]. Stipulating the need for a final decision by the Commission in many areas of product authorisation or in each disputed case is unacceptable and not in line with other laws. Amend Art. 35 (4) and 27, 29 and 76 accordingly to remain appropriate competencies for the national authorities so they may protect consumer welfare and the environment at regional level.

Ensure that Member States can take appropriate action, not just in a few very restricted cases. It should be clear that national authorities may intervene on behalf of citizens' welfare as well as to protect the environment and halt the loss of biodiversity. We therefore ask you to amend Art. 35 (4) and allow national authorities to refuse or restrict the authorisation

[1] REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, adopted text 3608/09: http://register.consilium.europa.eu/pdf/en/09/st03/st03608.en09.pdf

of all kinds of biocidal products inside their territories (in the Commission's draft this is limited to three product types as for biocides to control birds and fish).

There needs to be clarify on how the agency must consider the conclusions and assessment report of the evaluating competent authority for its opinion (clarify Art. 35 (2)).

Taking these amendments into account it would be useful to have a modified authorisation procedure and to involve ECHA in it. Regarding the agency's functionality, we welcome the relevant provisions for transparency (Art. 66).

Sustainable Community Product Authorisation

The draft regulation enables community authorisation to be granted to biocidal products containing one or more new active substances and low-risk products (Art. 32ff).

In view of the authorisation of low-risk products we believe it is only acceptable to establish a community approach if both the following criteria are met:

- *A clear and expanded definition of the term 'low-risk biocidal product' should be included in Article 17* ***and*** *Article 3 of the draft regulation: 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. A biocidal product should not be considered as a low-risk product if it satisfies at least one of the following conditions: persistent or bioaccumulative or toxic, very persistent or very bioaccumulative.*
- *The use of a 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.*

With new products it is incomprehensible why the draft proposes a community product authorisation. For example: according to the proposal, relevant new products may still include substances of concern which could entail more or less risk or harm when applying them under the various circumstances encountered around Europe's regions. We therefore recommend restricting EU product authorisation to low-risk biocidal products under well-defined conditions (see above).

With respect to the authorisation procedure for substances or biocidal products (assessment phase) we recommend that ECHA or the Commission chooses the competent authority to ensure a fair allocation of workload and impartial evaluation. Member States may apply their interests for the assessment of a specific active substance or biocidal product owing to earlier experiences (e.g. evaluation in the context of authorisation renewal). Amend Art. 7 (1) and Art. 35 (1) to ensure this procedure.

We ask you to amend Art. 33 (3) explicitly to exclude products from the community authorisation which contain substances for substitution. The responsible authorities for compara-

tive assessment on product level are the responsible national authorities. The procedures for Community authorisation or mutual recognition should therefore not be applied to products which contain candidates for substitution. The same limitation applies for product authorisation according to Art. 45 (e.g. temporary permission for products with substances not included in Annex I because of dangers to public health and the environment). Such decision-making needs to be done at national or local level (compare Art. 50 of the new adopted Regulation on Plant Protection Products).

There is also a need to define both, a comprehensive and simplified assessment (clarify Art. 37(2)).

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 (eg toxicity) as is required for active substances used for 'normal' biocidal products. As a result, the intended legislation will bring about a completely non-transparent and confusing situation. The principle should therefore remain that for each biocidal product only active substances listed in Annex I may be used .

Low-risk substances must be listed and specially marked under Annex I (add a) into Art. 16 (3)).

Fees for Innovation and Elucidation

In general we also see a need for common provisions for fees or charges as intended in Art. 70 of the Commission's draft.

We also recommend making it explicit that the budget should also be spent on services like conducting research on ecologically sound alternatives or supporting public information campaigns (amend Art. 70 (4)).

Treated Articles

We welcome the new regulation on articles treated with biocides as well as the framework for labelling.

These new provisions are necessary for at least the following reasons:

- The protection of consumers and transparency need to be improved.

- Provisions now address all biocides on the market, plus treated articles from third countries.
- Regulations can aid better monitoring, overview and effective control of all existing biocides on the market and their import to the EU via treated articles.
- They offer a better approach to ensure fair competition in the EU market.
- They improve occupational safety within the EU and in third countries.

However, the introduction of these regulations should begin before 2017.

We therefore recommend the full introduction of all relevant provisions for treated products in 2013 (amend Art. 81). We also recommend an additional text at the top of the label which reads 'treated with biocides' (amend Art. 47 (2)). The labelling ensures better checks on imports to the EU and the improvement of consumers' rights to information.

Please do not hesitate to ask for further information.

Yours sincerely

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