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Main Issues on the Further Development of the EC Biocidal Products Directive

from the Point of View of German Environmental, Consumer and Animal Welfare Organisations

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Main Issues

The undersigning non-governmental organisations (NGOs) call upon the ministries, authorities, members of parliament and economic organisations involved in the further development of the Council Directive 98/8/EC concerning the placing of biocidal products on the market to commit themselves to prioritised, preventative health and environmental protection. The NGOs call for compliance with the legal framework on biodiversity and animal welfare, for more transparency, and for an EU-wide binding strategy for a step-by-step termination or, as the case may be, reduction of the use of hazardous biocides and biocidal products.

From the point of view of the NGOs, special attention must be paid to the following five essential points in the further development of the Biocidal Products Directive:

1 Objective:
To strengthen the precautionary and substitution principles, to extend protection targets and ensure coherency

2 Scope of the Biocidal Products Directive:
Regulations on products treated with biocides must be included in the Directive

3 Procedures:
Maintaining national rooms for manoeuvre

4 Reporting:
Improving transparency and the participation of the expert community

5 Use of biocidal products:
Towards a binding reduction of biocides in the European Union
– Promotion of alternatives

Explanation of the main issues

1. Objective:
To strengthen the precautionary and substitution principles, to extend protection targets and ensure coherency

In the Biocidal Products Directive 98/8/EC (subsequently BPD) it is pointed out that due to the characteristics of biocidal products and the way they are used, they can present a risk to humans, animals and the environment. Preventative protection of the environment and human health should be given priority over the dismantling of trade barriers in the marketing of biocides and biocidal products in the European Union. This priority and the precautionary principle should be reflected in the preamble and the concrete regulations of the BPD. The evaluation of active substances and product authorisation must be further developed with preventative environmental, health, consumer, and animal protection in mind.

The BPD points out the need for close coordination with other legal provisions and international agreements. The BPD must be scrutinized with this in mind and existing specifications must be integrated explicitly. We would like to draw particular attention to the fact that biocides and pesticides are closely related due to their identical functions in repelling, harming or killing organisms. There must be compliance with standards applying to the protection of water courses (in particular, the requirements regarding the quality and emissions in the Water Framework Directive and relevant daughter directives[1]) as well as the generation goal of ending the release of dangerous substances into the marine environment by 2020 at the latest. It must also be ensured that there is coherency with drinking water protection, nature protection (Network Natura 2000: Fauna, Flora and Habitats Directive, Bird Protection Directive as well as the Biodiversity Convention), the Action Programme Environment and Health as well as with the protection and welfare of animals[2].

Drinking and ground water, the conservation of biodiversity, the protection of soil ecosystems as well as the protection of vulnerable groups of the population (such as children, pregnant women, users and bystander) should be named explicitly as additional objects of protection in the BPD.

The implementation of the substitution principle and the comparative assessment in the 1998 Directive sent a positive signal to the further development of other substance laws (industrial chemicals (REACH) and pesticides). We expect these important risk management strategies to be maintained and extended in the further development of the BPD. A steady decrease in the risks to health and the environment can only be achieved by replacing biocides and biocidal products by less toxic alternatives. We are of the opinion that the BPD can be further strengthened, also with regard to the promotion of innovations, if effective non-chemical alternative processes are employed as substitutes for active substances.

We see a considerable need for revision of the evaluation and decision-making procedures of active substances and product authorisation, in order to improve preventative environmental and health protection. Only a few aspects are mentioned here:

[1] The Directive on environmental quality standards in the field of water policy as well as the EU Groundwater Directive, among others

[2] 86/609/EEC

Risk assessment and risk management must be based on the respective up-to-date scientific knowledge. This means, among others things, taking metabolites, adjuvants and co-formulants into consideration as well as the effects of combinations and the risks to vulnerable groups of the population. Clear exclusion criteria according to the intrinsic eco-/toxicological characteristics of substances must be laid down for inclusion of active substances in Annex I and in Annex IA for biocides with a low risk potential. In risk assessment tests should be preferred which do not use animals, and applicants must be obliged to jointly use existing data from animal experiments.

In the evaluation of active substances, the type of use involving the greatest risk and "worst case" scenarios should be examined. The authorisation requirements should include exhaustive substance and product dossiers, practicable, sensitive residue analytics, as well as the execution of post-authorisation monitoring.

Temporary authorisation should only be issued for a short period in strictly regulated, exceptional cases of "State of Emergency". Concerning mutual recognition of authorisations within the community, a comparable, high standard is a prerequisite in the authorisation procedure. Individual states must be permitted the freedom to make their own decisions on risk management (ranging from special application restrictions to rejection of the approval of an authorisation) to secure national environment and health protection standards (see 3).

2. Scope of the application of the Biocidal Products Directive: *Regulations on products treated with biocides must be included in the Directive*

In its present form, the BPD does not regulate the marketing of products treated with biocides or the import regulations and control of these products into the European Union. The BPD should therefore be extended by a harmonised framework of regulations on treated products and imports.

3. Procedures: *Maintaining national rooms for manoeuvre*

The objective of the BPD is to harmonise the authorisation and marketing of biocides and biocidal products in the European Union. We welcome this approach and at present do not see the need to make basic changes in the legal instrument or dismantle the individual member states responsibilities on product authorisation. As risk management needs to be based on specific regional situations, with the precautionary principle in mind, the subsidiary principle should be maintained at all costs.

Further harmonisation of evaluation and decision-making procedures seems necessary; however, this should not be done at the expense of protection standards. Any harmonisation should rather lead to an EU-wide increase in the level of protection for humans and the environment (Imperative on Strengthening Protection).

4. Reporting:
Improving transparency and the participation of the expert community

If the BPD is to be a success, the access to information, dialogue participation and active involvement of the expert community, including environmental associations, must be substantiated and improved. The development of assessment criteria and procedures, substance dossiers, material balances, consumption pathways, and decision-making processes, should be kept transparent. Corresponding reports and background information should be meaningful, comparable and made promptly available to the general public via the internet. Reports on the implementation of the BPD should be published annually.

5. Use of biocidal products:
Towards a binding reduction of biocides in the EU – Promotion of alternatives

In contrast to the authorisation and marketing of biocides in the EU, their use has, as yet, been insufficiently harmonised within the EU. Basically, the aim of reducing the use of biocides as much as possible for the preventative protection of humans and the environment should be anchored in the BPD. Non-chemical alternatives and preventative measures (e.g. integrated pest management) should be given priority. Article 22 of the German Biocide Act clearly calls for the promotion of alternatives and the minimisation of biocide use, in comparison with the BPD. The inclusion of a concrete corresponding passage in the BPD would be desirable.

We regard the use of biocidal products by non-professional users and the lack of knowledge of professional users to be especially problematic. Severe restrictions on and uniform regulations governing these subjects (e.g. governing training and best practice) should be specified in the BPD.

Another option which could be used to regulate and reduce the use of biocidal products would be a new action framework (to be developed) on the sustainable use of biocides, similar to the Framework Directive already proposed on the sustainable use of pesticides. Such a framework directive would make compulsory, EU-wide implementation of national reduction plans and the setting of reduction targets within certain time limits possible.

The close relationship between pesticide and biocide use has already been acknowledged by the European Commission and the European Parliament, which have already proposed the inclusion of biocides in the “Thematic Strategy on the Sustainable Use of Pesticides”. The further development of the BPD should make provisions for this; for example, data collection on biocide use and coordinated reporting of control and monitoring results.

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