NGO recommendations

in view of

the considerations in the ENVI-Committee on the amendments to the Commission's proposal for a bio-cide regulation (COM 267)

(28 April 2010)

Brussels, 27 April 2010

To Members of the EP Committee for Environment, Public Health and Food Safety

NGO recommendations in view of the considerations in the ENVI-Committee on the amendments to the Commission's proposal for a biocide regulation (COM 0267), Brussels 28 April 2010

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Dear members of the EP- Committee for Environment, Public Health and Food Safety,

On the 28th April 2010 you will consider the amendments to the Commission's draft for a regulation concerning the placing on the market and use of biocidal products (COM (2009) 0267). 580 amendments are suggested by the EP rapporteur Christa Klass and further members of the Committee which underline the demand from MEPs for further clarifications and completions of the initial proposal of the Commission.[1]

A stronger biocide legislation is necessary for health and environment

PAN Germany and EEB, Federation Inter-Environnement Wallonie, Grüne Liga, HEAL, HCWH, Levego Munkacsoport,PAN Europe and PAN UK welcome the review of the current biocide legislation (Directive 98/8/EC) as many shortcomings have occurred in the context of the registration, authorisation and marketing of biocidal products. Biocides such as insecticides, rodenticides or household disinfectants are widely sold to the public, although they can contain highly hazardous substances with carcinogenic, immunotoxic or endocrine disruptive effects. . Nano-biocides are commonly used in a wide range of consumer products, including textiles, despite scientific evidence of risks for human health[2] and the environment[3]. Nano-silver particles used in anti-odor socks tend to end up in waste water, hampering the growth of bacteria in waste water treatment plants. Biocidal silver may also

[1] Cf. http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/pr/805/805468/805468en.pdf; http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/am/812/812192/812192en.pdf; http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/am/812/812192/812192en.pdf; http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/am/810/810555/810555en.pdf; http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/am/811/811563/811563en.pdf

[2] There is evidence that nanosilver can be detrimental to human health when ingested or used in medical devices, see for instance: Carlson, C., et al., Unique Cellular Interaction of Silver Nanoparticles: Size Dependent Generation of Reactive Oxygen Species. The Journal of Physical Chemistry B, 2008. 112(43): p. 13608-13619.

[3] See for instance: Luoma, S., Silver nanotechonologies and the Environment: old problems or new challenges?. Project on Emerging nanotechnologies, 2008.

disrupt the functioning of key soil microbial communities and prevents use of sewage sludge for agricultural fields. In France only, it is estimated that 17 tonnes of nano silver are released every year in water due to the machine washing of anti-odorant socks containing nano silver.[4] Currently, we have to face serious intransparencies on the market which hinder product safety and the protection of human health and the environment. There are many data gaps (e.g. concerning market volumes, combination effects of biocides & its metabolites) which make it impossible at present to get a clear picture of the situation and to take sustainable decisions.

Official sources confirmed infringements against provisions on safety instructions and accurate advertisement in up to 50% of the controls. Sufficient standards for the use phase haven't been established yet, but they are necessary in order to ensure a responsible and efficient handling of biocides. As a consequence, authorities have already recorded more than 15.000 cases of poisoning yet the real extent of the impact of biocide use remains unclear due to data gaps in the majority of the member states. Particularly vulnerable groups like small children have been affected in up to 56% of biocides-related incidents which were documented at national level.[5] As well, impacts for both the wildlife (e.g. adverse effects of the rodenticide difenacoum for birds or of the antifouling agent Cybutryn for the aquatic ecosystem) and for house animals have already demonstrated. These figures underline that the rules governing the internal market are neither functioning concerning health and environmental protection, nor do they ensure an incentive framework for the promotion of sound products and other sustainable alternatives for pest management.

The Commission's approach must be improved

We believe that the Commission's proposal is not balanced enough in order to cope with the identified shortcomings. Several suggested modifications by the Commission would weaken current standards for the protection of human health and environment from the risks of biocides while the procedure for product authorisation is problematically simplified and accelerated. This approach does not only threaten to weaken the positive suggestions in the Commission's draft (e.g. labelling of treated articles and promotion of non-chemical alternatives) but it can also result in serious risks for European consumers as well as for responsible and innovative enterprises which invest in sustainable solutions.

The members of the EP Industry Committee already demonstrated with their vote on the biocide regulation on 7 April 2010 that they are concerned about provisions which allow the marketing of certain insecticides without a previous authorisation, and that they prefer to improve transparency standards like the labelling of products with nano-biocides.

[4] See recent recommendations from the French « Agence française de sécurité sanitaire de l'environnement et du travail » (Afsset), 24 March 2010, http://www.afsset.fr/index.php?pageid=452&newsid=546&MDLCODE=news#

[5] Cf. European Commission, Directorate-General Environment (no year): Composite Report in Accordance with Article 24 of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market. Covering the Period from December 2003 to November 2006. Brussels. PDF-Download: http://ec.europa.eu/environment/biocides/pdf/composite_report_2006.pdf

Your considerations can also contribute to set a clear signal for a better system for the handling of biocides and to prevent a weakening of current protection standards or relevant suggestions.

With regard to the joint NGO position on the draft Klaß report,[6] we welcome some amendments of the ENVI-Committee which can strengthen and complete the draft report of EP-rapporteur Mrs. Klaß. Relevant suggestions for the modification of the cut-off and low-risk approach would improve the Commission's proposal on environmental and health issues in order to ensure a sufficient protection level against the adverse effects of biocides. As well, there are amendments which can better protect vulnerable groups like little children, efficiently promote alternatives, address combination effects and encourage the sustainable use of biocides.

Address and cope with significant shortcomings and deteriorations

We urge you to have a critical discussion on the following amendments which are associated with serious challenges for human health and the environment:

- Introduction and extension of vague exemptions that allow a regular and EU-wide approval of highly hazardous substances (e.g. amendments 168-170). Such biocides are intended to be applied in drinking water plants and against birds and fishes. This approach does pose additional risks and impacts for human health and wildlife.

- Weakening of the suggested substitution regime (e.g. amendments 195-198, 200-201, 290, 300, 311). It is not justified by evidence why non-chemical alternatives should be excluded when carrying out a comparative assessment of a biocidal product and why exemptions for substitution should be granted without clear criteria for the protection of human health and environment. As well, we are concerned that PBT-substances would get permission for several authorisation periods and that developmental neurotoxic or immunotoxic substances would be excluded from the substitution as suggested by some amendments tabled.

- Destruction of transparency standards for treated articles and with regard to other implementation issues (e.g. amendments 397, 401-408, 436). Many amendments do not favour a labelling of all treated articles. The criteria for this delimitation remain unclear. It is obvious that this concept would result in a significant administrative burden and consumers would be confronted with many uncertainties. Furthermore 99 % of the amendments accept directly or indirectly that implementation reports should not be further published.

- Confirmation and extension of cases for data waiving (e.g. amendments 507, 553). It is not acceptable that current data standards like for water protection or the conservation of endangered species don't need to be taken into consideration when an applicant has to prepare a dossier on a biocidal product. An ex-

[6] Cf. http://www.pan-germany.org/download/biocides/NGO_Position_EPEnvi_KLASSReport_220210.pdf

emption might be only granted in order to prefer or promote sound methods that replace animal or human testings.

- One-zonal approach for the authorisation of any kind of biocidal product or by means of a reduced understanding of “low-risk” (e.g. amendments 63, 250, 253). Many suggestions would prefer a system that would allow the EU-wide permission of highly toxic substances and products which are not sufficiently proven. Furthermore, competent authorities do not have any possibilities in order to refuse the marketing of a product on their territory although it could be of concern for citizen’s health or for the local environment.

- Exemptions for the authorisation of altered biocidal products without applying clear criteria and standards for the protection of human health and environment (e.g. amendments 145, 147-149, 362-363).

We should be most grateful if you consider our concerns and recommendations.

Please do not hesitate to contact us for further information.

Yours sincerely

see contacts

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