



## Joint NGO recommendations on

the European Parliament ENVI Committee's vote on  
amendments to the Commission's proposal for a biocide  
regulation (COM (2009) 0267), Brussels 22 June 2010

Brussels, 15 June 2010



A healthy world for all. Protect humanity and the environment from pesticides. Promote alternatives.

## To Members of the EP ENVI Committee

### NGO recommendations for the ENVI vote on Klaß report (Biocide Regulation (COM (2009) 0267)), Brussels 22 June 2010

Brussels, 15 June 2010

Dear Committee Member,

In view of your vote on the Klaß report on a regulation concerning the placing on the market and use of biocidal products (COM (2009) 0267) we provide you our assessment and recommendations to restate and improve human health and environmental protection.

As it stands the Commission's proposal weakens existing safety rules for biocides and is not coherent with the general rules of REACH or Regulation (EC) No. 1107/2009. It would allow the authorisation of highly hazardous biocides and establish an inadequate "simplified" authorisation system. The current substitution principle, which requires always replacing biocides if safer alternatives are available, would be full of loopholes.

The Klaß report has a couple of good intentions, especially by including the highly environmental toxic properties in the cut-off criteria, but it requires significant further improvements if it is to help ending human harm, particularly on vulnerable groups such as children, pregnant women or elderly people, and the dramatic loss of biodiversity.

Therefore, we call on you as a matter of priority to:

- Establish the precautionary principle as the guiding principle for authorising biocides – **support amendments 103, 128**
- Vote for including highly hazardous biocides such as PBT & developmental immuno- and neurotoxic substances under the foreseen cut-off criteria, as well as nano-biocides (due to significant knowledge gaps), and ensure coherence with the Water Framework Directive to phase out emissions of all hazardous substances – **support amendments 27, 178, 179 and 180 and reject amendment 168**
- Strengthen the substitution principle & non-chemical preventive measures – **support amendment 212 and reject amendments 200, 300, 311**
- Promote the sustainable use of biocides – **support amendments 94, 233, 234, 448**
- Ensure sufficient safety provisions for the authorisation of biocides that address risks of nano-biocides, combination effects and antimicrobial resistances – **support amendments 44, 143, 249, 258, 331, 357, 423, 577**
- Guarantee transparency for consumers and citizens – **support amendments 420, 422, 423, 438, 441**

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

Annex



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## NGO recommendations for the EP ENVI-Committee vote on amendments to the Commission's proposal for a biocide regulation (COM 0267), Brussels 22 June 2010

On 22 June 2010 the European Parliament's ENVI Committee will vote on amendments to the Commission's draft regulation concerning the placing on the market and use of biocidal products (COM (2009) 0267).<sup>1</sup>

PAN Germany and PAN Europe, Det Økologiske Råd, EEB, Fédération Inter-Environnement Wallonie, Health and Environment Alliance, Health Care Without Harm Europe, Levego Muncacsoport, MDRGF, National Movement Friends of the Earth Bulgaria, Stichting Natuur en Milieu and Women in Europe for a Common Future welcome the Committee's discussion of relevant issues at its previous meetings, such as the ban on highly hazardous biocides, provisions for low-risk products and the use phase of biocides.

However, we believe that not all biocides-related challenges were adequately considered as outlined in our positions and information (e.g. joint NGO position, PAN Germany Briefing)<sup>2</sup>:

- Many biocides such as insecticides, rodenticides or household disinfectants are widely sold to the public, although they can contain highly hazardous substances which can cause cancer or damage the DNA, the reproductive or immune system. They can also have endocrine disrupting effects, that is impairing our hormone system with long-lasting harmful consequences, immunotoxic and/ or endocrine disruptive effects.
- Biocides are of particular concern for vulnerable groups like pregnant women, elder people or children which are affected in up to 56% of all biocidal-related and documented incidents in the EU.<sup>3</sup>
- In the context of market checks in Europe, we identified several biocidal products for wholesale which contain the insecticide permethrin or the fungicide carbendazim. Both were already phased-out as pesticides and are featured on an EU priority list for pesticides with evidence for endocrine disruptive properties.<sup>4</sup> Permethrin is also known as

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<sup>1</sup> Cf. European Parliament (2010): Committee on the Environment, Public Health and Food Safety: Meetings Documents 26/4/2010. Agenda No. 20.

[http://www.europarl.europa.eu/meetdocs/2009\\_2014/organes/envi/envi\\_20100426\\_1500.htm](http://www.europarl.europa.eu/meetdocs/2009_2014/organes/envi/envi_20100426_1500.htm)

<sup>2</sup> Cf. [http://www.pan-](http://www.pan-germany.org/download/biocides/NGO_ENVI_recommendation_biocides_20100427.pdf)

[germany.org/download/biocides/NGO\\_ENVI\\_recommendation\\_biocides\\_20100427.pdf;](http://www.pan-germany.org/download/biocides/biocides_risks_and_alternatives.pdf)

[http://www.pan-germany.org/download/biocides/biocides\\_risks\\_and\\_alternatives.pdf](http://www.pan-germany.org/download/biocides/biocides_risks_and_alternatives.pdf)

<sup>3</sup> Cf. European Commission (2008): Composite report in accordance with Article 24 of Directive 98/8/EC.p. 79 (= figures for affected children in Belgium in the year 2005).

<sup>4</sup> Cf. European Commission (2007): Commission staff working document on the implementation of the "Community Strategy for endocrine Disrupters" - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706), (COM (2001) 262) and (SEC (2004) 1372). SEC(2007) 1635. European Commission (EC).Brussels, 30.11.2007

an acute neurotoxicant. An US study indicated on the base of urin samples that children have higher exposure to permethrin and other pyrethroids than adults.<sup>5</sup>

- The common sale and use of anticoagulant rodenticides such as brodifacoum or bromadiolone have been accompanied by several incidents of human poisoning (e.g. bromadiolone is one of the active substances which were frequently involved in more than 15.000 documented cases of poisonings in the EU)<sup>6</sup>. (Secondary) poisoning of endangered species is also regarded as a serious challenge (e.g. poisoning of red kites in France which are listed for special protection pursuant to Annex I of the Birds Directive 2009/147/EC).<sup>7</sup>
- Products containing nano-silver are widely present on the EU-market although their safety has not been comprehensively proven.<sup>8</sup>
- Problematic substances like propiconazole (wood preservative) have been already detected in groundwater while the concentration of methyl triclosan (a persistent metabolite of triclosan which is used for disinfection or treatment of cosmetics and textiles) has significantly increased in fish samples of several German rivers.<sup>9</sup>
- There is considerable confusion about market volumes, use and impacts of biocides in Europe. For example, combination effects of chemical's mixtures and antimicrobial resistance have been highlighted as relevant health issues at EU level (e.g. Environment Council conclusions on combination effects & SCENIHR-opinion on antimicrobial resistance)<sup>10</sup> since these effects can also result from the biocide use. Many questions remain. Without appropriate data the biocide policy will remain inefficient.

<sup>5</sup> Cf. Barr, DB et al. (2010): Urinary concentrations of metabolites of pyrethroid insecticides in the general u.s. Population: national health and nutrition examination survey 1999-2002. In: Environ Health Perspect. 2010 Jun;118(6):742-8.

<sup>6</sup> Cf. European Commission (2008): Composite report in accordance with Article 24 of Directive 98/8/EC. P. 64

<sup>7</sup> For example, a French investigation demonstrated lethal (secondary) acute poisoning on red kites in more than 80% of relevant suspected cases over 10 years. The death was particularly linked to the use of anticoagulants and insecticides. The researchers concluded: "*Acute poisoning remains a potential threat on a weakened population, especially when antivitamin K are used on large areas or as a result of illicit poisoning.*" Cf. Berny, Philippe & Gaillet, Jean-Roch (2008): Acute poisoning of red kites (milvus milvus) in France: Data from the SAGIR Network. See: <http://www.jwildlifedis.org/cgi/content/full/44/2/417>

<sup>8</sup> Because of several significant data gaps concerning the effects of nano materials the German Federal Environment Agency (UBA) recommended: „[...] any use of products that contain or might release nano-materials should be avoided if at all possible as long as their effect on mankind and the environment is largely unknown.“ Cf. Umweltbundesamt: Nanotechnology for mankind and environment – Seize upon opportunities, reduce risks. Press Release No. 75/2009. See: [https://www.umweltbundesamt.de/uba-info-presse-e/2009/pdf/pe09-075\\_nanotechnology\\_for\\_mankind\\_and\\_environment\\_seize\\_upon\\_opportunities\\_reduce\\_risks.pdf](https://www.umweltbundesamt.de/uba-info-presse-e/2009/pdf/pe09-075_nanotechnology_for_mankind_and_environment_seize_upon_opportunities_reduce_risks.pdf)

<sup>9</sup> Rüdell, H. et al. (2004): Triclosan and Methyl-Triclosan in Fish samples from the German Environmental Specimen Bank. [http://www.ime.fraunhofer.de/Images/2004\\_UPB\\_Triclosan\\_Fish\\_tcm279-63497.pdf](http://www.ime.fraunhofer.de/Images/2004_UPB_Triclosan_Fish_tcm279-63497.pdf)

<sup>10</sup> As regards combination effects the EU Environmental Council concluded in its meeting in Brussels on 22 December 2009, amongst others: “3. STRESSES that further action in the field of chemicals policy, research and assessment methods to address combination effects of chemicals is required, in particular taking into account the fact that existing EU legislation in most cases builds on a chemical-by-chemical assessment approach.”; cf.

[http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/envir/112043.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/112043.pdf); in view of the role of biocides for the development of antimicrobial resistance effects and of the EU-wide necessity to carry out more research on this issue cf. SCENIHR (2009): Assessment of the Antibiotic Resistance Effects of Biocides, January 19<sup>th</sup> 2009,

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/docs/scenihhr\\_o\\_021.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_021.pdf)

- The current biocide legislation (Directive 98/8/EC) has not been adequately implemented to date<sup>11</sup>. This is partly due to complex procedures, but also key gaps in resources, controls, risk-reduction measures and reporting.

The Commission’s proposal intends to tackle the authorisation system’s current shortcomings by lowering existing standards for protecting human and animal health and the environment. This would aggravate problems instead of solving them.

While the EP’s Committees for Industry and Consumer Protection support some improvements to transparency and protection, they seek to weaken provisions on banning highly hazardous biocides and substituting substances of concern (e.g. products with developmental immunotoxic substances or against birds can be widely applied).

We therefore recommend that you consider the following amendments in the ENVI vote:

**Ensure the precautionary principle**

The precautionary principle should be considered and included as the regulation’s primary purpose to ensure a high level of protection for human and animal health and the environment. This principle is particularly important in cases of scientific uncertainties and to adequately protect citizens from the adverse effects of biocides. A relevant amendment should bring the biocide legislation in line with current EU chemical laws such as REACH or the Regulation on Plant Protection Products,<sup>12</sup> as well as with the EU general aim to be based on a “high level of protection of human health and the environment”<sup>13</sup>. Furthermore, REACH and the Regulation on Plant Protection Products require special protection of vulnerable groups.<sup>14</sup>

*We recommend you **support** establishing the precautionary principle in Article 1 and ensuring a high level of environmental and health protection (**amendments 103 and 128**).*

**Phase out for highly hazardous biocides and nano-biocides**

Article 5 establishes a phase out (cut-off) on biocides which are very harmful to human health, such as substances which are carcinogenic, mutagenic, toxic to reproduction and have endocrine-disruptive effects. Although we welcome this concept in principle, the Commission’s approach must be improved in view of criteria and derogations.

*Ensure adequate, comprehensive criteria*

Particularly in view of the need to protect the health of vulnerable groups and the environment it is necessary to extend the criteria for the cut-off regime. This would also be in line with current chemical laws like the Regulation on Plant Protection Products (Reg. EC 1107/2009) which has established environmental-related standards and in line with the objective of the Water Framework Directive to phase out emissions of all hazardous substances

<sup>11</sup> e.g. French helpdesk on biocides “[www.helpdesk-biocides.fr](http://www.helpdesk-biocides.fr)” was put on-line on April 23<sup>rd</sup> 2010, and, hence, with a significant delay

<sup>12</sup> Cf. Art. 1 of Regulation (EC) No 1907/2006 & Regulation (EC) 1107/2009 that require to ensure a high level of protection for health and the environment and to apply the precautionary principle

<sup>13</sup> Article 3, Consolidated version of the Treaty on European Union,

<sup>14</sup> Cf. Recital 69 of Regulation (EC) No. 1907/2006 (REACH) and Recital 8 of Regulation (EC) No. 1107/2009



(Article 1 c) of Directive 2000/60/EC). We therefore welcome amendments that phase out substances including those with persistent, bio-accumulative and toxic properties (PBT), very persistent and very bio-accumulative properties (vPvB), persistent organic pollutants (POPs) and priority hazardous substances pursuant to Directive 2000/60/EC. The list of criteria should also be expanded to include biocides with developmental neurotoxic and immunotoxic effects, to guarantee adequate protection for those most vulnerable, the children. There should also be no approval of biocidal substances whose safety cannot be assessed due to significant knowledge gaps on the methodology for exposure estimates and hazard identification (e.g. nano-biocides).

*We recommend you **support** relevant amendments which add appropriate criteria for the cut-off regime (**amendments 27, 175, 178-180**).*

### *Restrict derogations*

In principle, it is essential to consistently phase out highly hazardous substances to protect human health, the environment and animal welfare. The Commission's approach is not appropriate and merely opens the door to the continued marketing of dangerous substances, which are proven to have serious adverse health and environment impacts. Under the Commission's approach, highly toxic biocides would also receive approval in cases where it is not essential to control serious threats to public health. The draft biocide regulation even allows unclear exemptions without tackling current gaps in the authorisation system (e.g. no provisions to overcome data gaps on market volumes, usage, existence and effectiveness of risk mitigation measures, combination effects, impacts or alternatives of highly hazardous biocides). As a result, problematic substances can be further sold, used and released into the environment without guaranteeing the effective monitoring or control throughout their life cycle (including disposal). This also contradicts the concept of REACH (Reg. 1907/2006) where monitoring and consistent substitution are prescribed for such substances. Regarding the planned biocide regulation, adverse effects on employees, children and vulnerable ecosystems remain likely. This system also fails regularly to stipulate the need to consider and prefer sound and effective alternatives at the outset rather than allowing highly hazardous substances to receive approval as a last resort (e.g. we should prefer non-chemical solutions like rodent-proof houses or cables to prevent damage or disease).<sup>15</sup>

*For this reason, we recommend you support initiatives that guarantee a consistent phase-out of highly hazardous substances. Exemptions should be limited to well-defined emergency cases at national level and should be linked to consistent standards and criteria (e.g. necessity to be documented by evidence, implement risk-reduction measures, substitution plans), taking into account that article 45 allows for further use of biocidal products which do not comply with the regulation in case of danger to public health or the environment. At the very least, requirements should be in line with relevant EU legislation like the Biocidal Prod-*

<sup>15</sup> Cf. Approach of the Canadian Authority: [http://www.hc-sc.gc.ca/cps-spc/alt\\_formats/pacrb-dgapcr/pdf/pubs/pest/pnotes/rats-eng.pdf](http://www.hc-sc.gc.ca/cps-spc/alt_formats/pacrb-dgapcr/pdf/pubs/pest/pnotes/rats-eng.pdf)



ucts Directive (98/8/EC), REACH and Regulation on Plant Protection Products to ensure legal consistency and the same level of protection.<sup>16</sup>

*At the same, we recommend you **reject** suggestions that further weaken the Commission's existing approach (**amendments 168-170**). It is unacceptable for any highly hazardous biocides to get approval for all types of application or for a non-transparent case. Given that additional legislative suggestions will also weaken data requirements and criteria for product authorisation it is likely that highly toxic substances can be widely used in drinking water plants, textiles or kindergartens.*

### **Confirm and strengthen the substitution principle - Support non-chemical preventive measures**

An innovative element of the current biocide legislation is addressing the risks of biocides and to substitute biocides of concern. To date, it is unclear what has been done in the EU since 1998 to promote appropriate alternatives to preventive measures. Such efforts are necessary to reduce dependency on hazardous substances. Besides, there are hardly any effective criteria or incentives to encourage industry or users consistently to select or develop products of less or no concern. It is not even certain if existing alternatives to all application types (e.g. non-chemical and effective techniques for rodent control in waste water pipes) are well-known throughout Europe. German and Austrian authorities already recommended avoiding household disinfectants and to use alternatives.<sup>17</sup> This is also relevant to addressing antimicrobial resistances. But we also believe it is essential to develop and promote non-chemical alternatives since we need a variety of healthy and intelligent strategies, innovative products – also for employment - and a sound approach to save limited resources (chemicals are largely based on fossil fuel). Although we partly welcome the draft biocide regulation of the Commission because it requires to considering non-chemical solutions for the comparative assessment, we criticize new significant loopholes for the substitution regime (e.g. no application of the substitution principle on substance level, exemption from the requirement of comparative assessment, renewal of an authorisation possible).

*We therefore recommend you **support** and strengthen the Commission's approach when promoting criteria, transparency and instruments in view of the substitution of problematic substances (**amendments 96, 199, 209-210, 212-213, 218-219, 295, 303, 308, 451**).*

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<sup>16</sup> Above all: only apply-able in case of serious danger and on national level, necessity demonstrated by documented evidence, mandatory phasing-out plans & risk reduction measures (cf. Art. 4 Reg. (EC) 1107/2009), guarantee monitoring and efforts in research and development of alternatives (cf. Art. 60/ 62 Reg. (EC) 1907/2006), approval limited to 120 days and other Member States have to be informed (cf. Art. 15 Dir. 98/8/EC)

<sup>17</sup> Cf. <http://www.bfr.bund.de/cd/2336>

*We recommend you **reject** initiatives that will weaken the substitution principle by hindering non-chemical approaches or restricting criteria and products foreseen as candidates for substitution such as developmental neurotoxic substances (**amendments 195-198, 200-201, 203, 215, 286-288, 290, 293-294, 296, 298, 300, 309, 311, 452, 454-455**).*

### **Promote the sustainable use of biocides**

There are no European harmonised standards for the proper and sustainable use of biocides.<sup>18</sup> For example, minimal requirements for training or certification of professional users are still outstanding, contrary to existing EU requirements for pesticides, which have just been updated in the recent EU Directive on the sustainable use. There are also no sufficient common guidances or Integrated Pest Management Plans to answer questions like what can be done before biocides are chosen and applied. It is also not documented how biocides are used in sensitive areas like kindergartens, schools or riverside sites and the nature of precautionary measures to prevent adverse effects of biocides. There are indications that children are particularly affected when using or storing biocides (e.g. in Sweden in more than 40% of relevant incidents)<sup>19</sup>. We do not even know what requirements have been introduced to reduce risks when using highly hazardous biocides. A promising approach for a strategy has only been established in Belgium.<sup>20</sup>

Furthermore, the European Parliament (6<sup>th</sup> parliamentary term) urged with its unanimously adopted resolution on a thematic strategy on the sustainable use of pesticides that “*the Commission should forthwith include pest control products (biocidal product types 14-19) as defined in Annex V to Directive 98/8/EC within the scope of the Thematic Strategy, as they pose similar risks to human health and the environment. The Commission was urged to extend the scope of the Thematic Strategy to include other biocides as soon as possible.*”<sup>21</sup>

*We therefore recommend you **support** amendments which endorse harmonised measures for the sustainable use of biocides in Europe (**amendments 94, 103, 233, 234, 323, 448**). This approach is also in line with the Regulation on Plant Protection Products that includes relevant efforts for the application of pesticides, in particular key provisions of the Directive for the sustainable use of pesticides (Directive 2009/128/EC).<sup>22</sup>*

<sup>18</sup> Cf. European Commission, DG Environment (2009): Assessment of different options to address risks from the use phase of biocides. [http://ec.europa.eu/environment/biocides/pdf/report\\_use.pdf](http://ec.europa.eu/environment/biocides/pdf/report_use.pdf)

<sup>19</sup> Cf. [http://ec.europa.eu/environment/biocides/pdf/composite\\_report\\_2006.pdf](http://ec.europa.eu/environment/biocides/pdf/composite_report_2006.pdf), p. 92

<sup>20</sup> Cf. Federale Overheidsdienst Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu (2010): PRPB. Federaal programma ter vermindering van de afhankelijkheid van en de risico's verbonden aan pesticiden en biociden: <http://www.health.belgium.be/eportal/Environment/Chemicalsubstances/PRPB/index.htm>

<sup>21</sup> Cf. EP non-legislative resolution based on the own-initiative report by Irena BELOHORSKA (NI, SK) in response to the Commission's communication on the “Thematic Strategy on the Sustainable Use of Pesticides”. A6-0291/2007 / P6-TA-PROV(2007)0467. Brussels 27.10.2007. See: <http://www.europarl.europa.eu/oeil/resume.jsp?id=5430492&eventId=1012935&backToCaller=NO&language=en>

<sup>22</sup> Cf. Article 55 of Regulation (EC) No 1107/2009

## Ensure sufficient requirements for the authorisation of biocidal products & substances

The previous discussions in the EP Environment Committee also dealt with the question of whether the central product authorisation system should be applied to some or all products. On this issue, it is necessary to consider the different environmental circumstances within European regions. The use of the same biocidal product can pose different impacts and risks to an ecosystem in southern Europe compared to another one in western or northern Europe. Besides, we must also consider specific demographic patterns in the different regions and needs, like protecting children, elderly people and other vulnerable groups. So it is essential to require sufficient data requirements and criteria for authorising a biocidal product, particularly for EU-wide authorisation. This is also necessary to address antimicrobial resistances, cumulative risks (see SCENIHR-opinion from 2009)<sup>23</sup> or combination effects (see Environment Council conclusions from end of 2009 and relevant conclusions of an international expert workshop in Denmark in the same year)<sup>24</sup>.

For example, biocides which have endocrine disruptive effects and which are used for different purposes can be exposed through contaminated food, treated plastics, textiles, paints and cosmetics, among others. Citizens and wildlife would be confronted with a “cocktail” of biocides with additive and synergistic effects. Many amendments do not address this challenge appropriately and further weaken the poor approach of the Commission’s draft which does not sufficiently consider combination effects and limits basic data requirements to only some (eco-) toxic or other relevant information (as consequence of the two-tier approach and data waiving). The suggested criteria for low-risk products will even result in authorisation of products with highly toxic substances. This is also a step back to the standards of the existing biocide legislation which defines low risk as low hazard (e.g. products must be free of substances of concern).

*We therefore recommend you **support** further improvements on the concept of the Commission for product authorisation (amendments 11, 44, 143, 152, 181-182, 184-186, 188, 190-193, 235-249, 251, 256, 258-266, 268-269, 273-274, 276-277, 321-322, 324, 327-331, 333, 347-349, 355-357, 376, 378, 465, 466, 531, 554, 561-562, 567, 574-580). Low-risk products should include substances of no concern and should be listed in Annex I. Combination effects of substances, impacts of nano-biocides and on vulnerable groups should also be sufficiently assessed. We also welcome initiatives for the support of data/expert ex-*

<sup>23</sup> The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) stated in its opinion from 19 January 2009: “One of the problems within Directive 98/8/EC and directives dealing with similar kinds of substances is that cumulative risks and impacts resulting from the use of the active substance outside the scope of the Directive (e.g. in plant protection products, cosmetics, medicines, food contact materials, food hygiene, industrial chemicals, textiles and clothes, wood and plastic objects) are not addressed in the evaluation process. This is especially problematic in view of such cross-cutting issues as antimicrobial resistance.” Cf. European Commission, DG Health and Consumer Protection: Assessment of the Antibiotic Resistance Effects of Biocides. [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_021.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf), p. 10

<sup>24</sup> Cf. Council of the European Union: Council conclusions on combination effects of chemicals. 2988<sup>th</sup> Environment Council meeting. Brussels, 22 December 2009. See: [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/envir/112043.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/112043.pdf); the members of the international workshop concluded, amongst others: “[...]The predominant chemical-by-chemical approach in risk assessment was regarded as insufficiently protective against the possibility of mixture effects/ effects of combined exposure.” Cf. Kortenkamp, Andreas (2009): Expert Workshop on combination effects of chemicals, 28-30 January 2009, Hornbaek, Denmark. See: [http://www.mim.dk/NR/rdonlyres/C59693B7-2421-4748-89F0-5937496E0A28/0/BILAG\\_2\\_Expertworkshop.pdf](http://www.mim.dk/NR/rdonlyres/C59693B7-2421-4748-89F0-5937496E0A28/0/BILAG_2_Expertworkshop.pdf), p. 2

*change to avoid or reduce animal testing (**amendment 483**).*

*At the same time we recommend you **reject** the “two –tier approach” (deletion of the relevant text on page 100 of the Commission’s draft) and amendments which weaken data and other requirements for the protection of human health and the environment (**amendments 12, 145, 147-149, 250, 252-253, 255, 281, 285, 353-354, 358-359, 362-363, 379, 381, 383-385, 387-388, 394-395**).*

*It is still necessary to establish sound approaches of data generating and testing to achieve both to overcome with animal tests and to ensure the protection of human health and environment. Relevant suggestions are still outstanding.*

### **Guarantee transparency for consumers and citizens**

Transparency is important for consumers, citizens and political institutions. Hence, we are concerned that the Commission’s draft requirements for the labelling of treated articles will be weakened by several initiatives (e.g. restricted to vague conditions, no registration number). This would not only water down the provisions for transparency but also the protection of consumers (e.g. a registration number also provides information on problematic non-active substances which might be relevant to vulnerable people in case of emergency). As regards ingredients present in their nano form, there are no provisions for consumer information so far. Hence, nano-materials must be clearly indicated in the labelling of the products, as requested by a large majority of the European Parliament in its resolution on regulatory aspects of nanomaterials.<sup>25</sup>

While a number of amendments suggest public access to some data, it remains uncertain whether implementation reports and figures on biocides-related poisonings will be further published. This would contradict achievements of the Biocidal Products Directive (e.g. binding publication of composite reports)<sup>26</sup> and of the UNECE - Aarhus Convention (e.g. publish information on environmental or environmental-related matters)<sup>27</sup>.

*We therefore recommend you **support** amendments which guarantee sufficient labelling requirements, particularly for vulnerable groups and concerning nano-biocides, and measures for transparency (**amendments 398, 410, 413, 427, 430-432, 434-435, 438-439, 441, 472**). We also urge you to confirm the publication of implementation reports and to strengthen the requirements for these reports (**amendments 419-424**).*

*We recommend you **reject** amendments which suggest weakening current standards for transparency (**amendments 397, 401-408, 412, 436**).*

<sup>25</sup> See European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials available at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0328&language=EN>

<sup>26</sup> Cf. Art. 24 of Directive 98/8/EC

<sup>27</sup> Cf. Art. 5 of the UNECE Convention on Access to Information Public, Participation in Decision Making and Access to Justice in Environmental Matters, done at Aarhus, Denmark. On 25 June 1998.