



## Sustainable use of biocides in Europe – urgent need for action



**A healthy world for all.**

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

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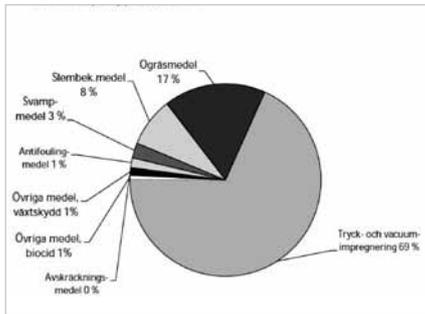
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► Sweden

Only the Swedish chemical agency KEMI provides public information on sales volumes of certain biocides in its annual pesticide statistics.

The figure above shows the share of different types of agents (for which the active substances are used) on the total sales volume of pesticides in 2009 (= 9243 tons). From right to left: 69% for wood preservatives for pressure and vacuum impregnation (biocides), 17% for herbicides, 8% for sludicides (biocides), 3% for fungicides, 1% for anti-fouling agents (biocides), 1% for other plant protection products, 1% for other biocidal products, 0% for repellents.

Source: KEMI (2010): Försälda kvantiteter av bekämpningsmedel 2009. Sunbyberg.

## Abstract

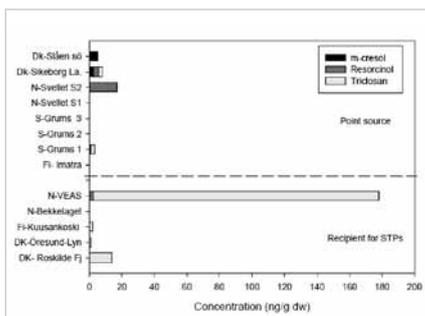
**Biocides are widely used to control harmful organisms outside the scope of plant protection. They are produced for disinfection, material preservation, pest control and other applications such as antifouling. Many active substances pose risks to human health and the environment once they are released.** As PAN Germany demonstrated in the briefing „Biocides – risks and alternatives” we are also confronted with many unanswered questions and data gaps on the use of biocides. There is not even a common legislative definition of the term „use”. In our understanding the term „use of biocides” comprises the phase between considering choosing a biocidal product, and the disposal of a biocide. We have prepared this briefing in order to give more insight into current heterogeneous approaches and shortcomings concerning the use phase of biocides in Europe. In doing so, we make clear that a harmonised policy across the Union is essential to minimise the risks of, and dependency on, using biocidal products. Such a policy must not only prescribe measures for risk reduction if biocides are applied; it must prioritise an Integrated Pest Management (IPM) approach, and promote alternatives.<sup>1</sup> Finally, we present six key policy demands to support the sustainable use of biocides in the EU. A harmonised legislative framework for the sustainable use of biocides is essential. It needs to be initiated in the context of the current review of the EU biocide law.

## Why is it necessary to deal with the use phase of biocides?

Although biocidal products often contain substances which are hazardous for human health and the environment they can be widely applied in the Union. Current provisions in Europe are insufficiently harmonised, transparent and comprehensive to deal with the current gaps and to be in line with the overall EU objective for sustainability.

### Hazards and risks of biocidal products

**Biocides are used to kill, deter or control harmful or unwanted pests such as bacteria, insects or rats. They are not harmless chemicals. Once they are applied or released they can adversely affect the environment and human health.** PAN Germany has demonstrated that at least 30% of the registered active substances on the Community market are harmful to aquatic life, corrosive, carcinogenic, reproductive toxic, endocrine disruptive or developmental immuno-toxic.<sup>2</sup> Many biocides can change our behaviour, cause allergies or contribute to cross-resistances of harmful organisms against both biocides and antibiotics.<sup>3</sup> There are particular risks for vulnerable groups such as children and pregnant women. For example, a study indicated that exposure to organophosphorus insecticides, which are common in household insect sprays, may contribute to childhood brain tumour.<sup>4</sup> Protected non-target species like young red kites are very sensitive to the second generation anticoagulants used in rodenticides.<sup>5</sup> The anti-bacterial and persistent triclosan affects the photosynthesis of diatoms (algae which play an important role in oxygen production).<sup>6</sup> The synergistic effects of certain insecticide and fungicide



► Sweden: Concentrations of triclosan and other chemicals in sediment

Environmental monitoring on biocides is rare. Swedish authorities sometimes conduct screenings (e.g. triclosan was monitored jointly by Denmark, Finland, Iceland and Norway).

The figure above shows that triclosan was detected in sediment samples nearby sewage treatment plants or other point sources in Denmark, Finland, Norway and Sweden. Source: Nordic Council of Ministers (2007): Bronopol, Resorcinol, m-Cresol and Triclosan in the Nordic Environment. Copenhagen.

mixtures are up to 12 times more potent to non-target aquatic crustaceans than the single or additive impact of such chemicals.<sup>7</sup> The risks of the majority of biocides on the EU market are still not fully known because they have not yet been officially assessed.<sup>8</sup> And sufficient risk assessment methods have still to be established to identify risks of nano-biocides.<sup>9</sup>

### Sustainability requirements

**According to Article 3 (3) of the Treaty on European Union (TEU) the internal market shall work for the sustainable development and, amongst other things, aim for a high level of protection and improvement of the quality of the environment.**<sup>10</sup> The current Sixth Community Environment Action Programme (EAP) is the key instrument for achieving the environmental objectives of the Union and has set priorities for the EU sustainable development strategy (Article 2).<sup>11</sup> Relevant objectives comprise the protection of habitats, halting the loss of biodiversity and ensuring a high level of quality of life and social well-being of citizens. By 2020 chemicals must be produced and used in such a way that there is no significant negative impact for health or the environment. Knowledge gaps concerning properties or use of chemicals must be overcome (Article 7). Dangerous chemicals should be substituted and emissions of priority hazardous substances phased out. Thematic strategies were explicitly initiated concerning indoor air quality and pesticides. The latter initiative was followed by the introduction of a Framework Directive for the sustainable use of pesticides. This law accentuates risk reduction measures, the promotion of preventative approaches (in the context of IPM) and alternatives to pesticides<sup>12</sup>. When establishing this strategy the Commission<sup>13</sup> and the European Parliament<sup>14</sup> also linked sustainability to the use of biocides.

### Widespread use of biocides

**According to Annex V of the Biocidal Products Directive 98/8/EC (BPD) there are 23 different types of application.** The purpose of their use ranges from hygiene and disinfection through material preservation to pest management and antifouling. Certain products can be explicitly used for human hygiene and the disinfection of private areas.<sup>15</sup> Furthermore, the law only excludes the wholesale of biocidal products which are classified as toxic, very toxic, carcinogenic, mutagenic or toxic for reproduction of (toxicity) category 1 and 2 according to Directive 88/379/EEC (Article 5 (2) BPD). Initial reports estimate that there are up to 60,000<sup>16</sup> products on the market and that almost 400,000 tons<sup>17</sup> of active substances are annually produced in and imported into the Union. 50.5% of this volume is used for type 2 products (disinfectants for private and public areas).<sup>18</sup> PAN Germany documented that up to 20 different and problematic pest control products can be bought in a supermarket, chemist's shop or do-it-yourself shop in Germany.<sup>19</sup> In up to 80% of the markets checked one or more biocidal products contained highly hazardous substances such as dichlorvos or brodifacoum.

### Limitations of the authorisation system

**Currently, the Community focuses on implementing an authorisation system in order to address the risks of biocides.** It could be argued that this approach is sufficient to address the use phase of biocides. The applicant of a product has to provide use-related data for the risk assessment (e.g. chapter V & VIII of Annex II b BPD). Besides, the competent authority can establish conditions for the market placement of a product (Article 5 (3) BPD). However, the authorisation system can only focus on the specific biocidal product for which an authorisation is required.

#### ► Germany

Improper use of antifouling paint in Germany.



It cannot go beyond this and address the question of how a serious infestation by any harmful organism can be effectively prevented or controlled (for example, by considering non-chemical preventive measures). It even cannot consider whether the market placement and use of a biocidal product is necessary. Another problem is that the authorisation body does not necessarily know the specific environmental and demographic circumstances in different regions, and the related risks of improper use. Local administrative bodies do not always have enough capacity to assess risks in the case of emissions and exposure.<sup>20</sup> Besides, the authority is not responsible for establishing concrete training requirements for different categories of users. Once a product is authorised and unforeseen problems arise it has restricted possibilities for a withdrawal.

**Legislative loopholes and shortcomings in implementation Article 3 (7) of BPD obliges the Member states to prescribe the proper use of biocidal products. Biocide use should be in line with the conditions of (product) authorisation and instructions on the product label.**

And the use should be limited to the minimum necessary, using a combination of chemical and non-chemical measures. But this provision is not harmonised across the Union and not clear enough for prioritising preventive measures. Relevant aspects such as training, sales statistics or efficient techniques for proper use are not mentioned in the biocide law. The implementation of the Directive is delayed and member states follow different approaches to risk mitigation.<sup>22</sup> An EU-funded study published in 2009 recommends more legal clarity at EU level and demonstrates that measures for training and certification differ from country to country and are partly non-existent, voluntary or only relevant for certain product types.<sup>23</sup> Prior to presenting concrete proposals on a new biocide law the EU member states and the Commission promised Community measures on the use phase.<sup>24</sup> However, adequate measures are still outstanding. Guidance has only been established for certain rodenticides.<sup>25</sup> The suggestions of the EU-funded study have not yet been considered.

► Article 3 (7)

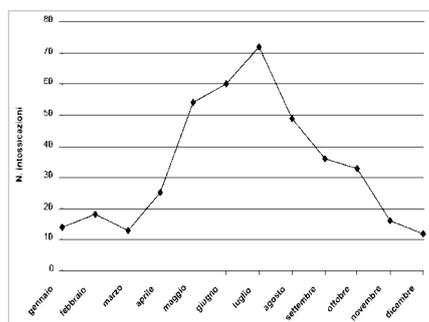
Member states shall prescribe the proper use of biocidal products. Proper use shall comprise:

- compliance with conditions of authorisation
- compliance with instructions on product label
- combination of chemical, biological, physical and other measures
- limit use to the minimum necessary
- compliance with Directive for occupational safety

Key provision of the Biocidal Products Directive 98/8/EC on the use phase (text abbreviated by the author)

**Preliminary results of an ongoing survey on biocide use PAN Germany initiated an investigation by NGOs in Europe in December 2010 in order to identify current administrative measures on the use phase.**

Results are: National statistics on sales are available in only 5 of the 20 EU member states which responded. Statistics are comprehensively established in Slovenia and made public in Sweden. Environmental monitoring specifically on biocides is carried out in only 4 of the responding countries and is limited (e.g. biocide screening in Sweden,<sup>26</sup> irgarol-monitoring in Germany<sup>27</sup>). In the majority of cases it is difficult or impossible to get updated information about all biocide-related poisoning incidents. According to available data from 5 EU member states,<sup>28</sup> more than 5000 accidents or exposures have been reported since 2007. In only 7 responding countries (e.g. Italy, Belgium or Poland) is it possible to identify whether children were affected (in these countries children were affected in up to 50% of the incidents)<sup>29</sup>. Concerning incidents related to pest control products it is rarely possible to distinguish between incidents related to plant protection and biocide use. This problem is often due to inadequate labelling. Only 4 of the responding countries provide public information on alternatives to some biocides (e.g. in Germany an official website informs about preventive measures and alternatives for nine application types)<sup>30</sup>. In Finland and UK authorities provide guidelines concerning the use of certain biocides.<sup>31</sup> There are hardly any coordinated (national) approaches for establishing integrated pest and biocides management in sensitive areas like nurseries or nature protection



► Biocide poisonings in Italy per month

The graph shows that most of the incidents in Italy happened in July (2005).

Source: Istituto Superiore di Sanita (2007): Sistema nazionale di sorveglianza delle intossicazioni acute da antiparassitari: osservazioni effettuate nel 2005. Rapporti ISTISAN 07/51. Roma, Milano.

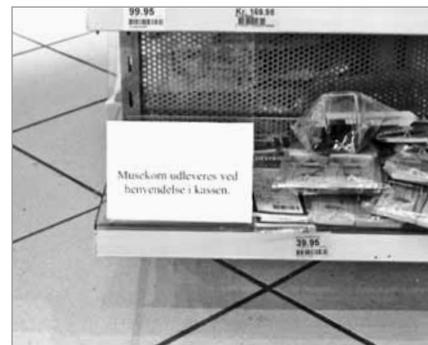
sites (e.g. some use restrictions in Sweden).<sup>32</sup> In 7 of the responding countries there are national requirements for the qualification and training of pest controllers. The training period ranges from 4 days to 3 years and in the majority of the cases it is not longer than 1 – 2 weeks. In Estonia and the Netherlands pest controllers have to undergo a training course every 5 years.

### Gaps in the Framework Directive for the sustainable use of pesticides

**Directive 2009/128/EC provides a harmonised framework for achieving the sustainable use of pesticides across the Union.** As clarified in its definitions this law does also cover biocides: according to Article 3 (10) of the Directive the term „pesticides” comprises plant protection products as defined in Regulation (EC) No. 1107/2009 and biocidal products as defined in Directive 98/8/EC. However, the Directive only regulates plant protection products at present (Article 2 (1)). Although the Directive includes a clause that promises to introduce provisions for biocidal products at a later stage (recital 2), it is neither binding, nor does it establish a concrete time line for establishing related measures. A concrete deadline for a revision of the Directive is only established for the year 2018 and it is not addressed to biocides, but to targets for National Action Plans (Article 4 (3)). Moreover, the Directive doesn't cover important application areas like disinfection, nor the handling of treated articles or nano-biocides.

### Shortcomings of the proposed biocide regulation

**The revision of the Biocidal Products Directive was initiated by the Commission in June 2009.**<sup>33</sup> Although the Commission's draft biocide regulation addresses biocide use in its title and scope – and also introduces a definition for „use” – it merely repeats the vague provisions of the biocidal products directive (Article 15 (5) of the draft regulation). The focus of the legislative initiative is to simplify the authorisation system. Biocidal products will be eligible for an EU-wide authorisation in future (Article 33) while provisions for the protection of environment and health are weakened. The European Parliament addressed this loophole when adopting its first reading resolution on the Commission's proposal.<sup>34</sup> The majority of MEPs call for a framework directive for Union action on the use phase which should include provisions for National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives (Article 15). The Commission is to submit a proposal two years after adopting the regulation. The Environment Council intends to stipulate appropriate precautionary steps and public information for minimising the use of biocidal products (Article 15).<sup>35</sup> With respect to the the Union authorisation of biocidal products the environment ministers require similar conditions of use for the product types concerned to be applied EU-wide (Article 33). But the Council's provisions are too vague to ensure the sustainable use of biocides. Hence it remains unclear whether consistent measures will be adopted in the end.



#### ► Denmark

Only in Denmark rat poison is not sold to the general public. Agents against mice are not stored on open shelves. Consumers have to ask the salesmen when they want to buy such a product. Photo: Hans Nielsen

# A comprehensive approach to the sustainable use of biocides

The identified shortcomings in biocides use policy can only be tackled with both an improved approach for the authorisation system and a legislative EU framework for the use phase which includes provisions for a set of relevant elements.

**Definitions:** A common understanding of key terms like „sustainable use” is needed. Article 1 of Directive 2009/128/EC suggests three dimensions: promotion of IPM (particularly preven-tive measures according to Annex III of this Directive), use of non-chemical alternatives and risk reduction in the case of application of a pesticide. There should be a hierarchy of actions, i.e. preventive measures should be prioritised whereas the use of biocides should be regarded as a last resort and non-use should be an option (depending on „threshold values”). It is also necessary to clarify other relevant terms such as „integrated pest management”, „best practice in biocide use” and „minimum necessary”. This needs to be done on a scientific basis.

**Inventory of the state of play and regular reporting:** A sufficient overview of and regular reporting on the state of play of biocides use, releases and impacts is essential to develop effective policies for the use phase. Studies, surveys and statistics are required for a preliminary assessment. Annual and public reports should in addition, measure progress towards objectives and clarify the need for adaptations. The EU has already established provisions for statistics. This law needs to be made applicable to biocides.

**Objectives and timeline:** A distinction needs to be made between quality-related targets (e.g. achievement of a high quality of health and biodiversity, reduction of impacts) and operative issues (e.g. reduction of biocide use). It is obvious that such targets need timelines and measurable indicators which assess the relevant objective. When introducing targets current EU objectives and hierarchies must be considered (e.g. quality standards according to Art. 4 of Directives 2000/60/EC).<sup>37</sup>

**National and EU Action Plans:** Action plans can be defined as an integrated and coordinated strategy for pest management which minimises the use of biocides and the risks of adverse effects resulting from biocide use. The Dutch biocide policy plan<sup>38</sup> established in 1996 and the ongoing Belgian programme for the reduction of pesticides and biocides represent important precursors for such a strategy.<sup>39</sup> Different administrative levels and sectors need to be involved. At the least an action plan should comprise of objectives, indicators, measures and instruments. Public participation must be guaranteed. A frequent review is also necessary.

**Training and Certification:** Skilled users are the backbone for achieving the sustainable use of biocides. Professional users in different working areas frequently have to make decisions about choosing biocidal products or alternatives and they need specific training for this. But training is also essential for retailers, salesmen and advisers. We need provisions which guarantee a high quality of qualification of each

## ► Germany

In Germany the Federal Environmental Agency has published a website to provide information on biocide related issues including alternatives.

Source: Umweltbundesamt (2011); [www.biozid.info/](http://www.biozid.info/)



## ► Spain

The Spanish code UNE 171210, on Good Practices in Disinfection, Extermination of Insects or Rodent Management, recommends the development of a case assessment and the implementation of structural corrective measures and of physical, physicochemical and biological methods prior to the use of chemical methods to control pests.

## ► Armenia – a model for the EU

In Armenia the use of insecticides containing highly hazardous substances is banned in nurseries. We have not yet identified such a requirement in any EU-country.

of these groups across the Union. It requires a minimum set of standards for the curriculum and for examinations. A certification regime can help to demonstrate the specific skills of the users. Because pest management techniques will be further developed over time, ongoing training should be prescribed.

**Pest and biocides management – principles, areas and protection of sensitive sites:** Following the approach of the Pesticides Directive, harmonised principles for IPM for the main application areas of biocides (hygiene, pest control, material preservation, anti-fouling) should be established. These approaches should be coordinated with relevant current sector standards and could be gradually implemented. IPM should also distinguish between different areas of use such as households, public places, offices and industrial plants. Special attention must be given to pest management in sensitive areas such as nurseries, schools, nursing homes for the elderly, hospitals, nature conservation sites and buffer zones around water bodies. The use of sound non-chemical alternatives has to be ensured.

**Specific issues and instruments:** Harmonised requirements are also necessary to handle the following issues:

- ▶ awareness amongst the general public (e.g. information, infrastructure for advice)
- ▶ conditions for sale (e.g. requirements for salesmen, retailers, access and storage)
- ▶ management of certain products (e.g. treated articles and nano-biocides)
- ▶ Use, cleaning and control of application equipment
- ▶ restriction of specific methods (e.g. ban on aerial spraying)
- ▶ promotion of preventive measures and alternatives
- ▶ establishment of environmental-economic instruments and further incentives
- ▶ public participation (e.g. establish procedures and fora like Belgium and France do)

## Key policy demands concerning the sustainable use of biocides in Europe

Currently, there are several opportunities at national and European level in order to establish relevant initiatives and measures for this purpose. Our six key demands are the following:

**Use essential opportunities for action:** There are two important political opportunities. The first occasion is the second reading of the biocide regulation which will probably start in the second half of 2011. We expect an agreement on effective provisions for the use phase. Secondly, member states are free to use the transposition of the Directive for the sustainable use of Pesticides (Directive 2009/128/EC) for establishing measures for biocides.

**Improve definitions and objectives:** A definition for „sustainable use” must establish priorities and prioritise non-chemical preventive measures for pest management. The use of biocides should be regarded as a last resort. Other important terms such as „integrated pest management” also need to be defined. Furthermore, we need transparent objectives for the use phase which are in line with overall EU goals to protect environment and human health. Hence, we suggest a principle objective of phasing in the use of alternatives and preventive measures by 2020 while simultaneously phasing out the use of hazardous biocides.

### ► Belgium

Only in Flanders the use of rodenticides or insecticides in certain public areas, such as buffer zones 6 m adjacent to surface waters, has to be basically phased out by 2014 at the latest in order to be in line with the objectives of the Water Framework Directive. The city of Gent achieved this objective in 2009. Source: VMM (2011): [www.zonderisgezonder.be/openbare-besturen](http://www.zonderisgezonder.be/openbare-besturen), Stad Gent (2003); Photo: Vlaamse Milieumaatschappij



**Introduce mandatory measures for key areas.** It is essential to establish mandatory EU measures for training, action plans, pest management in sensitive areas, IPM, public awareness and reporting, alternatives and financing. It is crucial to specify these requirements in the new biocide regulation and/or in the Directive 2009/128/EC or in a new Directive for the sustainable use of biocides so that they shall be applied not later than 2013. Relevant initiatives might prioritise measures for product types 2 (disinfectants) and 14-19 (pest control) due to their risks and widespread use.

**Establish action plans at EU and national level.** Besides addressing all relevant issues mentioned, it is necessary to coordinate them between different administrative levels and sectors, and together with all relevant stakeholders. For this purpose action plans must be established at national and EU level. Plans must include concrete objectives and indicators and must be frequently reviewed. Pesticide Action Plans can be a framework for this.

**Improve data availability and research.** The huge data gap on the use phase of biocides must be rectified. The EU Pesticide Statistic Regulation (EC) No 1185/2009 must be revised soon in order to stipulate data gathering on, for example, sales and use volumes. National and EU research programmes must support the development of preventive measures and alternatives. Reporting according to Article 24 of Directive 98/8/EC must better inform about poisonings, other adverse effects and measures for minimising risks. Monitoring must be improved in the framework of implementing Directive 2000/60/EC.

**Ensure transparency and public participation in policies.** Information on biocides use and on alternatives should be presented on a public web platform to be frequently updated by all relevant competent authorities and coordinated by ECHA. This information pool should be pro-actively advertised (e.g. via mass media). The organisation of public internet consultations or hearings are needed to facilitate public acceptance of use-related policies. Active involvement of the expert community should be promoted when establishing administrative measures.

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

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