EUROPEAN
COMMISSION

Brussels, 17.03.2016
COM(2016) 151

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the sustainable use of biocides pursuant to Article 18 of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

(Text with EEA relevance)

Contents

1. INTRODUCTION

1.1. The Biocidal Products Regulation (the BPR)

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012[1] (hereafter referred to as 'the BPR') regulates the making available on the market and use of biocidal products. The BPR repealed Directive 98/8/EC[2] (hereafter referred to as 'the BPD') and entered into application on 1 September 2013.

Biocidal products, such as disinfectants, wood preservatives, insecticides, insect repellents or rodenticides, are a family of products intended to destroy or control harmful or unwanted organisms (such as viruses, bacteria, fungi, insects or vertebrate animals) that have detrimental effects on the environment, on animals, on humans, their activities or the products they use or produce. Biocidal products are used in a wide variety of ways by both industrial and professional users as well as by the general public.

The objective of the BPR is to improve the functioning of the internal market whilst ensuring a high level of protection of human health, animal health and the environment.

The authorisation scheme of biocidal products is based on a two-step approach.

First, the active substance responsible for the biocidal effect has to be approved at EU level, after an assessment of its hazardous properties and possible risks.

Second, every biocidal product has to be authorised at EU or national level.

However, for active substances that were already on the market when the BPD entered into force, the approach is the reverse. The BPD has established a transitional period for the assessment of these active substances, during which the biocidal products containing these active substances can still be placed on the market in accordance with Member States national practices.

It is important to highlight that, despite the risks inherent to their use, biocidal products play an important role in EU citizens' daily life. For example, insecticides and disinfectants are essential for public health to help control vector-borne diseases (such as malaria, dengue fever, chikungunya, Zika), food-borne diseases (such as salmonellosis, listeriosis) or hospital-acquired infections (such as MRSA). Biocidal products are also widely used in materials such as plastics, paints, textiles, wood, etc. to protect these materials against microbial, fungi or insect decay.

Responding to this societal demand requires important investments from companies placing biocidal products on the market, in particular to provide the data required to demonstrate that their products are safe and effective.

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Text with EEA relevance - OJ L 167, 27.6.2012, p. 1–123.

[2] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market - OJ L 123, 24.4.1998, p. 1–63.

As stated above, biocidal products are used in many and very diverse sectors[3]. This brings many challenges, in particular for the communication with and awareness-raising of end-users and stakeholders.

1.2. Sustainable use

Sustainable use can be defined for biocidal products as the objective of reducing the risks and impacts of the use of biocidal products on human health, animal health and the environment and of promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to biocidal products.

It should however be noted that biocidal products are also important tools to protect human health, animal health and the environment and that non-chemical alternatives may not always be effective, practical or even available. Therefore, sustainable use strategies shall also ensure that sufficient biocidal products remain available to achieve these objectives.

1.3. Objective of the report

Article 18 of the BPR stipulates that the Commission shall, on the basis of experience gained with the application of the BPR, present to the Council and the European Parliament a report on how the BPR contributes to the sustainable use of biocidal products. This report shall also reflect on the need to introduce additional measures, in particular for professional users, in view of reducing the risks posed to human health, animal health and the environment by biocidal products.

The same article lays down elements that need to be examined and which relate to:

- the promotion of best practices as a means of reducing the use of biocidal products to a minimum;
- the most effective approaches for monitoring the use of biocidal products;
- the development and application of integrated pest management principles with regard to the use of biocidal products;
- the risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens etc., and whether additional measures are needed to address those risks;
- the role of improved performance of the equipment used for applying biocidal products.

The purpose of this report is therefore to examine the elements listed in Article 18 of the BPR (section 2) but also to reflect on additional ones (section 3).

This report is based on a preliminary study[4], which included a large survey of representatives from Member State Competent Authorities, industry and NGOs (hereafter referred to as 'the study').

[3] The BPR covers 4 main groups of biocidal products themselves divided into 22 product-types ranging from disinfectants for human hygiene to embalming and taxidermist fluids, through in-can preservatives, insecticides, rodenticides and antifoulings products.

[4] Analysis of measures geared to the sustainable use of biocidal products, by Milieu Ltd 2015.

2. HOW DOES THE BPR CONTRIBUTE TO THE SUSTAINABLE USE OF BIOCIDES

This section gives an overview of the findings of the study and shows how the BPR is contributing or can contribute to the sustainable use of biocides.

2.1. Promotion of best practices to reduce the use of biocidal products

A best practice is an exemplary approach or methodology, frequently presented in guidelines aimed at reducing risks and at promoting technical understanding when applying a product or technique. From the point of view of implementation and applicability (preferably EU wide), the involvement of stakeholders in developing best practice guidelines is essential. Best practice guidelines focus on the use phase of biocidal products and are a tool to be used beyond the authorisation process to promote the sustainable use of these products.

In order to ensure a harmonised approach to the sustainable use of biocidal products across the EU, one of the challenges is to ensure dissemination of best practice and adherence to the principles of sustainable use of biocidal products.

2.1.1. Introducing best practices through product authorisations or substance approval

Product authorisations shall stipulate the terms and conditions relating to the making available on the market and use of the products they are granted for. In particular, they shall contain instructions for the safe use and disposal of biocidal products.

One of the means to promote the dissemination of available guidance documents or best practice codes is to make a reference to these in the product authorisation, so that the instructions for use of the product explicitly refer to them. For example, in Germany, authorisations of anticoagulant rodenticides include a legally binding reference to a best practice code for the application of these products by specialised and licensed professionals, which is based on existing industry guidelines and EU legal provisions[5]. This option however expects the end-user to read and correctly follow the recommendations given.

If a certification or training scheme is available, reference to such scheme can be made in the authorisation. For example, this approach is being adopted in the UK in relation to the authorisation of rodenticides, where compliance with a proposed industry stewardship scheme will be required as a condition of authorisation of anticoagulant rodenticides[6].

With antifoulants, all active substances approved to date contain a provision that obliges persons making antifouling products available on the market for non-professional users to supply these products with appropriate gloves.

---

[5] http://www.baua.de/de/Chemikaliengesetz-Biozidverfahren/Biozide/pdf/Allgemeine-Kriterien-Version1-3-englisch.pdf?__blob=publicationFile&v=2

[6] Second Generation Anticoagulant Rodenticide (SGAR) Stewardship Regime

This is an example of obligations imposed on points of sale to ensure that not only the information but also personal protective equipment reaches the end-user. It shows how requirements can be imposed on the supply chain and in particular at the retail level to disseminate best practices and to foster the sustainable use of biocidal products.

Such obligations are made possible since the scope of the BPR covers the making available of biocidal products (i.e. from first supply up to the point of use) and since active substances are approved through implementing Regulations, measures of general scope, allowing the adoption of provisions aimed at the supply chain.

Through substance approval, prohibitions of over-the-counter or internet sales could, for instance, be applied to biocidal products containing active substances meeting the exclusion criteria but approved and authorised on the basis of the derogation provided under Article 5(2) of the BPR. Additionally, for such biocidal products, one could consider restricting distribution and sale by adequately qualified professionals.

2.2. Effective approaches for monitoring the use of biocidal products

The study revealed that today very little information is collected by the Member States on the use of biocidal products.

At EU-level, there is currently no specific monitoring system for annual sales data on biocidal products. In the future, the Register for Biocidal Products (R4BP) hosted by the European Chemicals Agency might offer a tool to collect such data[7].

However, it is important to clearly define what would be the required content and purpose of collecting this information and how it could support the objectives of the BPR, including sustainable use.

2.3. Integrated pest management principles (IPM) and use of biocidal products – best practices

The study revealed that a wide range of best practice documents relating to different product types have already been developed by industry associations or Member States.

2.3.1. Best practice codes

Guidelines or best practice codes can be developed by industry to promote the sustainable use of biocidal products on the basis of IPM principles.

In that respect, a noteworthy development is the 'Guideline on Best Practice in the Use of Rodenticide Baits as Biocides in the European Union'[8], produced by the European biocides industry. This guideline describes what to do before, during and after rodenticide applications, gives practical guidance that should be followed in the many varied situations of

[7] http://echa.europa.eu/support/dossier-submission-tools/r4bp

[8] http://www.rrac.info/content/uploads/CEFIC-EBPF-RWG-Guideline-Best-Practice-for-Rodenticide-Use-FINAL-S-.pdf

rodenticide use, describes how to monitor for the presence of rodent infestations without the permanent application of rodenticide baits and discusses alternatives to rodenticides. The guidance document also provides advice on where to obtain information about anticoagulant resistance and the best way to manage it.

2.3.2. HACCP

The application of the principles of Hazard Analysis and Critical Control Points (HACCP) is obligatory for food business operators[9]. Likewise, feed business operators who carry out specific operations must apply procedures based on the HACCP principles.[10]

Especially for disinfectants, HACCP is a preventative approach (including the monitoring of the potential risks) which, if applied correctly, provides for sound hygiene management, which may also help using disinfectants in accordance with the principles of sustainable use.

Furthermore, HACCP systems, together with the specific codes and guidelines developed in these sectors, commonly address disinfection, pest control and training of operators.

2.3.3. Standards and certification

The development of standards, combined with a certification process, can also be used to ensure proper and sustainable use of biocidal products.

The recently adopted European Standard (EN 16636)[11] provides a good example of what can be achieved.

Compliance with EN 16636 will enable pest management providers to demonstrate that they have the necessary competence and know-how to deliver pest management services, that they have a management system to ensure a consistent level of quality and that they systematically minimise risks for clients and the public, as well as the risk of potential negative impacts on the environment and animal welfare.

Such initiatives directly contribute to the sustainable use of biocidal products.

2.4. Risks in specific areas such as schools, workplaces, kindergartens etc.

2.4.1. State of play

Based on the analysis of the majority of active substances approved to date under the BPR (wood preservatives, insecticides, repellents and attractants and antifouling products), the study concluded that either no specific risk

[9] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs - OJ L 139, 30.4.2004, p. 1–54.

[10] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene - OJ L 35, 8.2.2005, p. 1.

[11] European Standard for pest management services (EN 16636) - CEN, European Committee for Standardisation

was reported, or that the risk mitigation measures laid down in the specific conditions of the product authorisation do sufficiently cover the risks at the use stage of those biocidal products.

For the other product types which are placed on the market in accordance with national rules, no specific risk was reported.

It should also be noted that Article 17(5) of the BPR requires Member States to take measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use. The study acknowledges the importance of this information, particularly for uses in areas where vulnerable people, such as children, can be exposed to products.

Regarding the risk to water or groundwater, the study encouraged Member States to utilise information available from other monitoring regimes, such as the monitoring of priority substances and river basin specific pollutants under the Water Framework Directive, which could usefully inform on the specific risks to the water environment from biocidal products. In this context, a watch-list mechanism[12] has been developed to ensure targeted EU-wide monitoring of substances of possible concern (including emerging pollutants) to support the prioritisation process in future reviews of the priority substances list.

In addition, the 'Information Platform for Chemical Monitoring' (IPCheM)[13] designed and implemented by the Commission, offers a single access point to chemical monitoring data collections managed by and available to European Commission bodies, Member States, international and national organisations and researchers.

2.4.2. Dissemination of information

As stated above, training and the sharing of information are fundamental to ensure that risk mitigation measures are appropriately applied in order to protect specific areas.

Therefore, should further measures be required to ensure the proper application of risk mitigation measures, these can largely be pinned down to measures to increase the dissemination of information to the end-user and to strengthen education and training.

Training and information should also address how to avoid unnecessary applications and use possible non-chemical alternatives.

In that respect, several Member States (such as Belgium[14] or Denmark[15]) have already made noticeable and even creative efforts to communicate the principles on the sustainable use of biocidal products to the general public.

---

12 Article 8b of Directive 2013/39/EU amending Directives 2000/60/EC and 2008/105/EC; Commission Decision (EU) 2015/495

13 https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

14 http://www.belgium.be/fr/publications/publ_ongewenste-gasten-in-huis-of-tuin.jsp

15 http://www.hverdagsgifte.dk/

2.5. The role of improved performance of equipment used to apply biocidal products

It should be noted that many biocidal products – in particular those intended for the general public - are applied without equipment or the equipment used mainly concerns items like gloves and other personnel protective equipment, already regulated by Directive 89/686/EEC[16].

Therefore, when specific equipment is used, it is mainly in industrial or service sectors where a lot of equipment is already designed to minimise exposure (e.g. automated systems for wood treatment) and avoid overdosing (e.g. calibrated dosing of in-can preservatives, calibration of sprayers for antifouling paints) and considered fit for purpose.

Furthermore, should specific restrictions or requirements be desired, they could be ensured, on a case-by-case basis, by including specific conditions in the substance approval or product authorisation.

Lastly, if the use of appropriate dosing equipment is an important factor in the application of some biocidal products, there are other factors that need also to be considered in order to minimise exposure, such as the selection of the appropriate product, determination of weather conditions, the level of infestation, etc. This again demonstrates the relevance of proper use instructions adapted to each product type being available to the users.

[16] Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment, OJ L 399 of 30 December 1989.

3. TOOLS TO STIMULATE INNOVATION AND PROMOTE SUSTAINABLE USE

Other tools or actions, which could be used to stimulate innovation and the development of new products with a better profile, have been considered.

3.1. Exclusion, substitution and comparative assessment

The BPR provides, with the exclusion and substitution criteria for active substances, and with the comparative assessment for biocidal products containing active substance candidates for substitution, very powerful mechanisms to phase out the use of substances of high and very high concern. In addition, this creates incentives to develop better alternatives.

These mechanisms have not yet reached their full potential, as many active substances are still under evaluation and many biocidal products are still to be authorised. But they are expected to make a significant contribution to the sustainable use of biocides.

3.2. Labelling schemes

The study explored means of easily and visibly identifying biocidal products that would have a lesser impact on human health, animal health and the environment, with the objective of helping end-users make informed choices, but also of giving those products an advantage towards their competitors, thereby creating a clear incentive for industry to develop better products.

The study in particular analysed whether existing eco-label schemes (such as the EU Ecolabel, the Blue-Angel or Nordic-swan eco-labels) could be used for that purpose and whether industry associations or individual companies had developed (voluntary) schemes, which could be a source of inspiration.

3.2.1. The EU Ecolabel Regulation

The purpose of Regulation (EC) No 66/2010[17] (hereafter referred to as 'the Ecolabel Regulation') is to provide a voluntary EU award scheme to help consumers identify products and services that have a reduced environmental impact throughout their life cycle, from the extraction of raw material through to production, use and disposal.

The study however showed that biocidal products are not perceived as suitable or eligible for the scheme, because of their inherent properties and of their very purpose of controlling unwanted organisms

The wide variety of biocidal products and multiple sectors of use was also pointed out as a difficulty since EU Ecolabel criteria are developed on a product specific basis.

Finally, the EU Ecolabel promotes available alternatives to biocidal products, such as biocide-free materials as an alternative to conventionally impregnated materials.

[17] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, OJ L 27/1, 30.1.2010.

3.2.2. Industry initiatives

A few initiatives have been taken by industry or industry associations to promote sustainable practices or to highlight the 'green' credentials of their products.

Even if limited to individual company initiatives, often as part of their product stewardship or of their marketing strategy, these initiatives demonstrate that measures can be taken by companies to reduce the impact of biocidal products on the environment.

In addition, they provide useful elements which could be used more widely to stimulate innovation or the development of new products with a better profile for human health, animal health and the environment and more generally contribute to the sustainable use of biocidal products.

3.3. Best available techniques under Directive 2010/75/EU on industrial emissions[18]

At the EU level, the development and review of the 'best available techniques reference documents' (BREFs)[19,20], under the framework of Directive 2010/75/EU on industrial emissions, can provide opportunities to identify and promote best practice on the sustainable use of biocides in the context of industrial manufacturing.

Through these BREFs, the use of less hazardous substances is encouraged and some of them, directly or indirectly, address the use of biocidal products in specific industrial sectors.

[18] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast), OJ L 334, 17.12.2010

[19] Article 13(1) of the Industrial Emissions Directive (IED, 2010/75/EU)

[20] http://eippcb.jrc.ec.europa.eu/reference/

4. CONCLUSIONS

As stated in the introduction, the BPR has been fully operational only since 1 September 2013. This means that limited experience has been gained to date with the current legislation.

Furthermore, substance approval, product authorisation, comparative assessment of biocidal products containing candidates for substitution with the aim of phasing-out their use, are already important contributions to the objective of fostering the sustainable use of biocidal products.

Therefore, the completion of the on-going assessment of all the active substances that were already on the market when the BPD entered into force and the authorisation of biocidal products containing these active substances, shall be the first and main priority with a view to promoting the sustainable use of biocidal products.

Member States as well as industry need thus to concentrate their efforts and resources on substance approval and product authorisation.

In addition, Member States will need to invest additional resources on enforcement activities to ensure that no product is illegally placed on their market and that biocidal products are properly labelled.

With regard to possible additional measures, to reduce the risks posed to human health, animal health and the environment by biocidal products, the study concluded that the risks are already appropriately addressed by measures imposed through the conditions of approval of active substances or the authorisation of biocidal products.

More particularly, for professional users, the study concluded that the control measures applied under EU worker health and safety legislation as well as chemicals legislation combined with the risk mitigation measures specified at the stage of the biocidal product authorisation were sufficient – if adhered to – to address risk from exposure.

Furthermore, due to the very diverse nature of biocidal products and the variety of applications, it does not seem appropriate to simply extend the scope of the Framework Directive on the Sustainable Use of Pesticides to biocidal products. Instead, the key objectives of that Directive in relation to biocidal products can be achieved through different means and more targeted actions. For the same reasons, extending the scope of the Machinery Directive to biocidal products does not seem appropriate either.

With regard to the means and targeted actions, the correct, safe and sustainable use of biocidal products requires the availability and effective dissemination of appropriate guidance or information, whether that use be in a professional context or not.

For industrial use, when BREFs are developed, best practice guidelines on the use of biocidal products should, where relevant, be incorporated.

For professional use, developing guidance documents, providing training and certification of the users on application of best practices, go hand in hand.

For non-professional use, emphasis should be put on the provisions in the authorisation and the labelling of the product. Technical solutions like smart tags or quick response codes (QR) providing a link to the authorisation holder's website can be helpful to allow users to refer to specific product properties and use instructions.

In conclusion, the Commission will pursue the following actions, and invite Member States to do the same:

- focus and strengthen efforts on the review programme of existing active substances to ensure it is completed at the latest by end 2024;
- ensure that once active substances are approved, product authorisations are granted, amended or cancelled within 3 years;
- invest additional resources on enforcement activities;
- benefit from the legislative tools available, in particular by closely following the developments of BREFs that can be relevant for biocidal products used in industrial processes;
- encourage communication and awareness raising campaigns to inform end-users, through websites, in-store leaflets or videos, quick response codes on biocidal products, etc.;
- encourage the development and implementation of standards (e.g. under CEN) that could contribute to the sustainable use of biocidal products;
- welcome research initiatives on the sustainable use of biocides and alternatives to biocidal products.