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Towards a Sustainable Use of Biocides

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TOWARDS A SUSTAINABLE USE OF BIOCIDES

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

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Foreword

During the discussion of its future work programme in May 2018, the OECD Working Group on Biocides (WGB) emphasised the importance of the sustainable use of biocides. It was decided to develop a document that would describe the common understanding of the WGB on what sustainable use of biocides could entail and that could be used as a guiding principle for the WGB when dealing with this topic.

This Document was approved by the Working Group on Biocides on 18 December 2020. The Chemicals and Biotechnology Committee agreed to its declassification on 25 January, 2021.

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Preface

The OECD Working Group on Biocides (WGB) deals with products that have “an effect on an unwanted organism, but [are] not a medicine, a veterinary medicine, a medical device, a food additive, an agricultural pesticide or a cosmetic”¹. Products controlling unwanted organisms by mere physical or mechanical action are generally not considered as biocidal products. biocidal products can be disinfectants, material preservatives, pest control products or other products protecting humans, animals or materials against unwanted organisms. The exact definitions of the term “biocide” are slightly different in the OECD countries and depend on national or regional legislation.

Past discussions within the OECD Working Group on Biocides showed that member countries increasingly see the need to engage in the field of sustainable use. This document describes the common understanding of the WGB on what sustainable use of biocides could entail. It serves as a guiding principle for the OECD Working Group on Biocides when projects are planned that are supposed to support sustainable use of biocides.

After a short description of the background of the discussion and a brief introduction to the sustainable use of biocides, the document describes different possible aspects of sustainable use: an optimised use of biocides and substitution options of biocidal active substances or the products containing them.

The goal of this document is to provide ideas for OECD members about what could be done within the countries to strive towards a sustainable use. Possible actions for the OECD Working Group on Biocides could include joint projects of WGB members or exchange of ideas and/or existing approaches for some of the described building blocks in chapter 3 and 4.

¹ <http://www.oecd.org/env/ehs/pesticides-biocides/biocidesprogramme.htm> [accessed on 04/09/2020]

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1. Background

1. In the context of the widely recognised general definition of sustainable development², sustainable use of biocides can help protecting the health and property of the current generation. Nevertheless, at the same time possible risks for current and future generations should be considered and evaluated carefully during pre-market approval of biocides. As it may not be possible to determine today which impacts might prevent future generations from being able to meet their needs, close attention has to be paid to mitigate or avoid especially long-term negative effects.

2. The 2030 Agenda for Sustainable Government by the United Nations defines 17 Sustainable Development Goals (SDG) that define the actions countries should take to work towards sustainability. While biocides can make important contributions to reaching the SDG, they can also pose risks preventing some goals from being reached.

3. Biocides are important to protect humans, animals or materials against harmful organisms. Amongst other uses, they contribute to the protection of humans and animals against infectious diseases e.g. by controlling rodents or harmful bacteria. For this reason, biocides can contribute to reaching SDG 3 (Good health and well-being) or SDG 6 (Clean water and sanitation). They also contribute to reaching SDG 12 (Responsible consumption and production) by extending the service life of materials and thus protecting resources. For these reasons, they play an important role for society. But biocidal active substances are substances designed to affect living organisms and these effects are not necessarily limited to the targeted harmful organisms. Humans can be affected during the use of the products or using treated materials during their service life, especially if they are not stored, applied or discarded properly. Non-target organisms in the environment can also be affected when the substances enter the environment. For these reasons, biocides can also compromise reaching the SDG 3, SDG 6, SDG 14 (Life below water) and SDG 15 (Life on land). Accounting for specific risks posed by chemicals, SDG 12 contains the target 12.4³ to minimise negative effects of chemicals.

4. Regulatory risk assessments in OECD countries are conducted to take into account these potential risks. They are set up to evaluate the risks posed by single biocides to humans and the environment and play an important role to achieve sustainable use. A large quantity of data is generated and used for the risk assessment. Unacceptable risks envisaged during assessment can be managed and minimised and, if not, approval can be refused.

5. However, biocides are designed to affect living organisms negatively. Even if pre-market approval already can deliver a high level of protection, knowledge gaps can still remain (European Commission 2019). Additionally, humans and organisms in the environment are in reality not only exposed to a single substance or product but to a mixture of chemical and non-chemical stressors. This mixture toxicity is only considered to some

² A sustainable development is considered to be able to meet “the needs of the present without compromising the ability of future generations to meet their own needs” World Commission on Environment and Development 1987.

³ By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment

extent in some OECD countries during risk assessments. For these reasons, the most sustainable way of using biocides is to adapt their use to the minimum necessary and efficacious. Measures going beyond pre-market approval are needed to accomplish this sustainable use of biocides. These could be integrated in post market mechanisms.

6. Sustainable use of biocides is closely linked to the concept of sustainable chemistry. This concept combines preventive protection of environment and health with an innovative economic strategy as innovation is stipulated. The OECD states that “within the broad framework of sustainable development, we should strive to maximise resource efficiency through activities such as [...] risk minimisation, pollution prevention, [...] and the development of products that are durable and can be reused and recycled” (OECD 1999).

2. Sustainable use of biocides

7. Sustainable use of biocides means that the benefits of a biocidal application are maintained while the possibility of negative impacts the application may have on humans and the environment including the development of resistances is reduced as far as possible. A prerequisite for this consideration is knowledge about possible negative impacts and about the efficacious use of a biocide, as it is generated during pre-market approval. This requires the continuous further development of assessment methodologies.

8. Before the decision to use a biocide is taken, all possibilities to control the unwanted situation should be evaluated. Only when this is taken into account, can the use be minimised to the lowest efficacious amount necessary.

9. To ensure that biocides are efficacious, a thorough assessment of efficacy under normal condition of use should be undertaken during pre-market approval. Efficaciousness could even be monitored regularly for the different fields of use. Biocides which are not efficacious are not sustainable.

10. Early measures to prevent infestation or alternative biocide-free control measures can reduce the use of biocides. If the use of a biocidal product cannot be prevented or cannot be substituted by biocide-free measures completely, careful consideration should be given to the choice of biocide. This concept is related to the concept of Integrated Pest Management (IPM) that “is an ecosystem approach to crop production and protection that combines different management strategies and practices to grow healthy crops and minimize the use of pesticides” (FAO 2020). Applying IPM to biocidal uses has already been explored by the WGB for biocides used as private area and public health area disinfectants (OECD 2016) and could be considered during approval of biocidal products.

11. Substitution of biocides can take place on several levels. The Global Chemicals Outlook II (UN Environment Programme 2019) states that substitution of chemicals “aims to provide a safer functional match”. With this shifted focus from chemicals as substitutes to more holistic solutions considering the function of the chemical, more alternatives can be taken into account compared to a mere replacement of one biocidal active substance with another. A description of the substitution options of biocidal active substances can be found in chapter 3.

12. The main features of the use of a biocidal product are specified during product approval, if biocides are approved in a country. However, its use can further be optimized. Details on possibilities to optimise the use of biocidal products can be found in chapter 4.

13. While a lot of uses of biocides are important to protect humans, animals and materials against unwanted organisms, there are biocides on the market whose usefulness for specific applications could be questioned. These products are designed to tackle issues that do not represent a factual threat to humans, animals or materials. To avoid them, their approval could be refused. This would relieve the burden from users' shoulders to decide whether a product is necessary. However, current legislation in most OECD countries does not include the possibility to do so, unless it can be shown that products are not efficacious. This lack enhances the necessity to communicate about the sustainable use of the products to potential users.

14. Materials treated with biocides, for example to extend their use phase, become waste at some point of time. As circular economy is deemed to be an important approach

to use resources more efficiently, recyclability of materials is of growing interest. This topic has not been discussed in detail for materials treated with biocides so far but could be regarded as an important field of research in the future to ensure sustainable use. The research has to consider this trade-off between a longer lifespan of materials versus potentially hazardous substances introduced into the material cycle.

3. Preventive measures and substitution

15. Sustainable use of biocides is a use that is adapted to the necessary and efficacious amount (see chapter 2). This can be done using measures preventing the need of an application of a biocide. Another way to reduce their use and associated risks is replacing them by biocide-free alternatives. If their use cannot be prevented or substituted by biocide-free measures, careful consideration should be given to the choice of the active substance.

16. All these measures can be summarised under the concept of “functional substitution” (Tickner et al. 2015) being featured in the Global Chemicals Outlook II (UN Environment Programme 2019) or the “Strategy to promote substitution to safer chemicals through innovation” by the European Chemicals Agency (ECHA 2018). The fundamental idea of this concept is a result-oriented substitution focussing on the function of the chemical, not on the chemical itself. With this shifted focus from chemicals to holistic solutions, much more alternatives can be taken into account compared to a mere replacement of a biocidal active substance with another. For this reason, the concept is promoting innovative solutions in line with sustainable chemistry.

17. According to OECD, the substitution of chemicals is a topic of growing interest in industry, NGO and the public sector (OECD 2019b). The OECD Substitution and Alternatives Assessment Toolbox provides guidance (<http://www.oecdsaatoolbox.org/>). The OECD Ad Hoc Group on the Substitution of Harmful Chemicals initiated a cross country analysis on the assessment of alternatives and substitution of chemicals (OECD 2019a). This analysis gathered successes and challenges of existing programs.

18. Depending on the substitution level, different stakeholders are involved in the substitution process, for example chemists, product designers, manufacturers, vendors or users. To illustrate what kinds of substitution measures could be supported to encourage the sustainable use of biocides, examples were collected and are presented in this chapter.⁴

a. Preventing the need of biocides

19. An important question to be asked is the question of the need of a specific biocidal function. In case of disinfection measures in the health sector, control measures are generally not to be questioned, as they are crucial for infection control. However, there are household uses of disinfectants, where a need can indeed be questioned in general if no infectious disease is present in the household concerned. Tickner et al. already mentioned the example of triclosan in hand soap for consumers (Tickner et al. 2015). Its health benefit

⁴ More examples and activities in EU member states can be found in the report “Survey and strategy for sustainable use of biocides” (Danish Environmental Protection Agency 2015) and the document “Towards the substitution of active substances of high concern in biocidal products and innovation in areas where a need for alternatives is identified” (Competent Authority Meeting 2018).

could not be demonstrated for consumers in comparison with handwashing using plain soap (Kim et al. 2015). Washing the hands with plain soap would thus be an appropriate substitute for triclosan containing soap as it fulfils the same function: reduction of bacterial counts on the hands of the users. The US Food and Drug Administration acknowledged this fact in its rule 81 FR 61106 on consumer antiseptics prohibiting certain disinfecting hand soaps (US FDA 2016).

20. Another aspect of preventing the use of biocides is the acceptance of certain levels of pests under consideration of the specific circumstances (e.g. household vs. canteen kitchen). Not every insect is harmful and not all levels of bacteria are dangerous for human health. However, this aspect of the usefulness of a specific application is difficult to judge by consumers (see section 13 for further discussion). This is particularly true in countries with large numbers of poisonous or other harmful insects.

21. Sometimes, guidelines or laws might lead to requirements requesting a higher use of biocides than necessary. Tickner et al. mention a non-biocidal example of chemical flame retardants requested by flame retardant standards that do not consider other measures to enhance fire safety (Tickner et al. 2015). Screening documents for such requirements for biocides and taking the findings into account could help reducing unnecessary applications or to support appropriate application rates. In these cases, the respective documents could be revised from time to time regarding these findings.

22. A common option to reduce the need for biocidal products are preventive measures against infestations, the first step of IPM. Possible measures can be constructional, such as sufficient roof overhang to prevent facades from getting wet avoiding construction material preservatives or hygienic design in the food sector to avoid disinfectants. Other measures can be organisational, such as keeping food and feed in closed containers away from insects and rodents. Implementing these measures can be challenging and may not always lead to complete eradication. However, these measures can make an important contribution to reduce the use of biocides in combination with other measures.

b. Substitution on product level

23. For a substitution on product level, the purpose of the biocide has to be considered. Generally speaking, for biocidal active substances, this would be the control of the target organism in a specific setting (for example by killing or by repelling). A substitution on product level could be, but does not need to be, by another biocidal product with a more favourable risk profile. However, to enable users and regulators to identify products with a more favourable risk profile, criteria for these products would have to be defined. Databases could help users to identify alternative products. One example of such database is the Viennese Database of disinfectants supporting public procurement of Vienna in choosing disinfectants for the health sector considering efficacy, occupational safety and environmental protection (WIDES database: <https://www.wien.gv.at/umweltschutz/oekokauf/desinfektionsmittel/>). Similar projects could be established for other biocidal product types and countries.

24. Biocide-free alternatives also play an important role for substitution to reduce the use of biocidal products to the minimum necessary. The suitability of a substitute has always to be assessed specifically for every application. This includes considerations on efficacy and risk and factors such as technical aspects of the application. While biocides are subject to risks assessments in a lot of countries, biocide-free alternatives are usually not. For this reason, less data on their efficacy, target animals' suffering during control measures or their risks for humans and the environment is available. At this moment, this might prevent users from substituting biocides by biocide-free alternatives. To support biocide-free alternatives, appropriate test guidelines and certificates or even legal requirements for the testing of alternatives might help. Also, the inclusion of acknowledged biocide-free alternatives in Best Practice Codes and training measures could be useful. While approved biocides can be found in national or regional databases, there is no

comparable overview for biocide-free alternatives. Such registers might help users to identify suitable alternatives.

25. An example of an existing biocide-free alternative for a specific application can be mechanical hull cleaning of pleasure crafts, preferably carried out when the boat is painted with biocide-free hard surface paints. Mechanical hull cleaning could be an efficacious and competitive method when the regional fouling pressure is low and the boating season is short as it is the case, for example, in the Baltic Sea.

26. Another example could replace pest control products in specific settings. Pest control products, such as insecticides or rodenticides, are used to prevent spreading of infectious diseases or to protect materials. Possible alternatives could be traps for different situations, for example mechanical traps, glue traps, electrocution traps or drowning traps. However, humaneness of the control measure for the target organisms should be considered. The measures should be as specific as possible to the target organisms to avoid harm to non-target animals.

c. Substitution on substance level

27. On this level, the biocidal active substance would be substituted by another chemical leading to the same biological effect on the pest. The substituting chemical should have favourable properties compared to the active substance to be substituted regarding its specific risks to humans and the environment while still being efficacious. This substitution is conducted rather during product development than by the user of the final product.

28. This type of substitution requires the availability of efficacious active substances posing less risks. An adequate variety of active substances or substance classes with different modes of action in biocidal products has to be ensured to prevent development of resistance. Since decades, the design of chemicals helping in preventing risks has been demanded by science, being one of the twelve principles of green chemistry (Anastas and Farris 1994, Anastas and Warner 2000). However, only little progress has been made so far in putting this concept into practice. First examples for pharmaceuticals demonstrate that the concept could work (Rastogi et al. 2015). Targeted research programmes or policy measures on 'safe-by-design' or 'benign-by-design' could help in applying the concept to biocidal active substances.

29. Also existing active substances might offer opportunities to reduce risks. For anticoagulants for example, the use of specific diastereomers of existing anticoagulant rodenticides could be a way forward (Damin-Pernik et al. 2017). Studies have shown that the diastereomers, which are less prone to bioaccumulate, show a comparable potential of toxicity to rodents.

4. Use optimisation of biocides

30. In many OECD countries, biocidal products are approved after extensive efficacy testing and risk assessment for humans and the environment. Based on these assessments, decisions are taken whether or not to approve a product for specific uses or to establish risk mitigation measures to minimize unacceptable risks. If biocides are approved in an OECD country, the specific provisions laid down in the product approval define how a product can be used efficaciously without posing an unacceptable risk.

31. Product approval is key for sustainable use of biocides. However, the use of biocides can be optimised further with measures going beyond product approval.⁵ For this optimisation, several measures can be taken:

a Best Practice Codes

32. Best Practice Codes for the use of biocidal products can be developed and implemented. Best Practice Codes could e.g. provide advice to users, enabling them to perform the minimal necessary and most efficacious application of a biocide considering all necessary risk mitigation measures. They can also offer guidance to users which non-biocidal substitutes could be used for specific applications. Furthermore, information on other measures could be provided to avoid infestation or to minimise the use of biocides in an efficacious way. Thus, such codes should not be product-centred but focus on all reasonable control measures against specific harmful organisms. The main target group are professional users. To ensure high compliance, adherence to available Best Practice Codes could be made mandatory for this group of users.

33. At present, national Best Practice Codes only exist for a limited number of uses. Not all cover all aspects like efficaciousness, human health and environmental effects. Priority lists could be established which Best Practice Codes should be developed for which user groups. Stakeholder cooperation to create new Best Practice Codes could be supported. To assist the preparation of new codes and to enhance exchange of existing Best Practice Codes between OECD countries, general standard criteria could be established on necessary information to be included in the Codes. A first compilation of Best Practice Codes by the members of the OECD Working Group on Biocides can be found here: <https://www.oecd.org/chemicalsafety/pesticides-biocides/biocides.htm>.

b Training and education

34. Some pests, for example bed bugs, are too difficult to be controlled by consumers. Professional users should be aware of the risks of using biocides in general. They should know how to use a biocide efficaciously and how to exercise optimised control e.g. by Best Practice Codes. Obligatory training and further education of professional users can help to

⁵ The European Commission has compiled its views on sustainable use of biocides in the “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”, including the discussion of best practices, monitoring, IPM, equipment or labelling schemes (European Commission 2016).

disseminate and promote this kind of information. As such trainings do not exist for all product types in all OECD countries, each country would have to prioritise which training would be most important to establish first. Non-professionals cannot be reached by this measure. For them, information has to be provided in different ways (see points c and d).

c Information and awareness raising

35. Information and awareness raising are important to communicate risks and the correct use of biocides. Furthermore, preventive and alternative measures can be communicated to potential users of biocidal products.⁶ The main target group for this are non-professional users. This group cannot be reached by training and further education measures. Possible communication tools are for example websites or smartphone apps. However, these tools only reach a limited group of users that is already actively looking for information. Thus, additional communication pathways should be considered.

36. Science-based advice could be given by independent consultants to professional users on how to follow instructions and how to fight harmful organisms in the most sustainable way. This is not an established concept at present in OECD countries. Nationally, countries could define their priorities on where advisory services are deemed to be needed the most.

d Regulation of sales

37. Free availability and extensive advertisements for biocidal products might lead to unnecessary use of products resulting in exposure of humans or emissions to the environment without having a significant benefit for hygiene or material protection (see example of triclosan in paragraph 19). It could be made mandatory to only permit scientifically proven claims as advertisements, similarly to health claims on foods in the EU, where only scientifically proven health claims approved by the European Commission are permitted⁷. Some countries, for example Australia or Canada, already have such legislation in place for pest control products.⁸ By implementing this in other countries as well, unnecessary use might be minimized.

38. Free sales of user-restricted products could be prohibited to ensure that only authorised user groups can buy such products. Appropriate regulation may ensure that the product is only delivered to the right user group (e.g. no self-service and no sale via internet without presentation of training certificate). Such measures could also ensure that for example disinfectants can be provided in sufficient quantity to medically necessary applications.

39. For biocidal products with high risk potential that are nevertheless approved for non-professional users in some OECD countries, it might be reasonable to sell them only over the counter after general information on their use is provided. This restriction of self-service provides an opportunity to raise awareness for possible risks and the safe use of the product and to not only communicate use instructions, but also additional information e.g. on preventive measures or biocide-free substitutes.

⁶ Example for anti-fouling: <https://www.umweltbundesamt.de/en/publikationen/antifouling-in-recreational-boating-guidelines-for>

⁷ Example of Regulation 1924/2006 (EU) on nutrition and health claims made on foods: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32006R1924&from=DE>

⁸ Example from Canada: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2016/guidelines-advertising-pest-control-products-dir2016-01.html>

e Equipment for the application of biocides

40. The design, construction and maintenance of machinery for biocide application can play a significant role in minimizing the risks of biocides. Inappropriate or badly maintained equipment for biocides may cause undesired losses (e.g. through spray drift) or overuse (e.g. malfunction of automatic dosing equipment) leading to unnecessarily high exposure. The equipment that is put on the market for the application of biocides should be state of the art technology to reduce risks. To ensure this state of the art, provisions could be implemented to ensure the quality of equipment used combined with regular inspections of equipment that is already in use.

f Reduction of biocides use in sensitive areas

41. Sensitive areas like nature and water protection sites exist worldwide. Some biocidal products can be used directly in these areas, or in their neighbourhood, possibly leading to indirect emissions to these areas. The vulnerability of sensitive areas should be considered. For example, leisure boats painted with biocidal antifouling paints may be prohibited in certain protected lakes. Preventative measures or biocide-free substitutes could be used preferably. To reduce emissions, state-of-the-art technology could be used to prevent a negative impact of the application on the environment.

g Monitoring

42. To develop targeted measures to reduce the exposure of humans and the environment, systematic human and environmental monitoring is needed. The results may be used to reveal risks that have not been detected during risk assessment and show opportunities to manage these risks. The results may also be used for performance review of existing risk management.

43. An efficacious use of biocides is key to protect humans, animals and materials from harm and to fulfil the purpose of the products' use. The development of resistance can interfere with this goal. A reduced variety of active substances could promote resistance and has to be taken into account in resistance management strategies. For the continued sustainable use of many biocides (e.g. anticoagulant rodenticides) one important step is monitoring resistance in target species. For substances with known modes of resistance or suspected to lead to resistance, monitoring campaigns could be established to ensure an efficacious use.

44. Some regulatory regimes already contain post-market monitoring and assessment mechanisms (e.g. re-evaluation, special review, incident reporting). Such regimes could be established in other OECD member states as well. To monitor the impact of policy measures, post market monitoring, including data on the amounts of biocidal products placed on the market, sold or used, would be beneficial.

h Enforcement

45. Adhering to mandatory risk mitigation measures, Best Practice Codes or other measures mentioned above supporting an optimised use of biocides is critical for the success of these measures. Controls to protect consumers or users of products from false or misleading information could be implemented. To enforce the proposed measures, the competent authorities would need adequate personnel to monitor the market and use.

46. Voluntary certifications of sustainable use of biocides and associated auditing schemes could also promote compliance to Best Practice Codes. This could even be a selling point towards customers.

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