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Kennisnotitie

Screening of underlying measurement data in human exposure assessments of biocides

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Introduction

The human exposure assessment to biocides in the EU follows the models and methodology documented by ECHA in their biocides methodology document (ECHA, 2024). This document is supplemented by Human Exposure Expert Group (HEEG)[1] opinions and recommendations of the Biocidal Product Committee Ad hoc Working group on Human Exposure (HEAdhoc) (Ad hoc Working Group - Human Exposure - ECHA (europa.eu), accessed June 6th 2024). Looking closely at the methodology document and supplementing documents, one can see that the underlying information describing exposure situations is based on either scenario building (modelling approach) or monitoring reports with measurement data. The modelling approach is typically used in the consumer exposure assessment, and measurement data mainly to assess exposure for the professional user. In this screening the focus is on the professional user of biocides, and as such on the monitoring reports and measurement data used for exposure assessment of working with biocides.

The monitoring reports include measurement data from studies concerning the use of biocides by professionals in occupational settings, which were mostly performed in the 1990s. These studies served as a basis for the 'old' Technical Notes for Guidance (TNsG) from 2002 and 2007 (TNsG 2002; 2007), and factually still serve as the basis for many default settings that are being used to date. This information is often considered in development of recommendations by the HEAdhoc and is mentioned in the methodology document, where the previous work from TNsG, HEEG and HEAdhoc are taken up. It does occassionally occur that new measurement data (typically from scientific publications) are incorporated into default settings.

The monitoring studies were performed by institutes such as TNO (The Netherlands) and HSL (UK), and are considered to be of high quality. However, the studies are often over 25 years old and the underlying raw data is difficult to retrieve or no longer available. The summary information, as described in the methodology document and supplementing documents, is often the only source of information. Therefore, by order of the Ministry of Social Affairs and Employment, RIVM has screened the underlying measurement data that is used to assess the professional exposure to biocides.

In the first place, it is a concern that evaluators are no longer able to trace back information to its original source. This is especially needed when an evaluator wants to check the appropriateness of current default settings. It also prevents derivation of potential new defaults that require extrapolation of the raw data to a new situation. Secondly, the measurement data may describe exposure situations from the past that are not always applicable

[1] The Human Exposure Expert Group (HEEG) preceded the Ad hoc working group on human exposure (HEAdhoc).

anymore due to changes of biocidal products. These changing conditions can be technical, operational and personal operation changes, next to differences in type of biocidal products or compositions of the products. For example, powder applications are more often changed to granular products, spraying techniques have changed to adjust to spray mists, and more often foams are being used. The underlying information from a situation years ago no longer describes the present biocidal product that is being assessed to date. Nevertheless the same underlying measurement data are still being used, though under high scrutiny and with care, to assess the exposure as accurately as possible, since often it is the only available information. The subsequent concern is that our knowledge on exposure, based on measurments, is lacking behind the biocidal product development as described above. This may lead to (intentional or unknown) overestimations or (unknown) underestimations of the true exposure and risk. Underestimations may lead to approval of unsafe products, whereas overestimations of the risk may lead to either rejection of approval, or otherwise product approval under perhaps too strict conditions and unneccesary use of personal protection equipment (PPE).

Aim of the screening

The aim of the current screening is to get an overview of the use of measurement studies across the product type (PT) codes (the use descriptor system for biocidal products) and corresponding subscenario's, as described in HEAdhoc Recommendation 6 (BPC Ad hoc Working Group on Human Exposure, 2020). Subsequently, to evaluate whether or not the measurement data are (still) considered fit for purpose to assess the exposure of professonials working with biocides, or that there is a need for new information (update) on that particular use or exposure scenario. It should be emphasized that a conclusion on a need for new information does not strictly mean that the currently available information cannot be used at all within the biocides framework. Nor is it possible to extrapolate our screening conclusions to EU or national biocides/biocidal product assessments. It does however mean that there is a growing possibility that the data is no longer suitable (at all or under circumstances) and should be further analysed and evaluated for the reasons already given in the introduction.

Hence, in this screening, possible weak spots in the exposure assessment of professionals to biocides can be identified. It can serve as a starting point for further research to assess where improvements are especially needed. In the section 'conclusions and discussion', possible steps for follow-up are discussed.

Method

HEAdhoc Recommendation 6 (BPC Ad hoc Working Group on Human Exposure, 2020) collates the preferred models on exposure assessment to biocides for both consumers and professional users with PT code as a basis for tabulation. HEAdhoc Recommendation 6 includes exposure models or default settings from previous TNsG versions, HEEG opinions, and HEAdhoc recommendations including those recommendations that were developed later on. Therefore, Recommendation 6 is considered as a solid base for the current screening. Our focus in this screening is on primary (direct application) exposure to biocides for professional users. For each PT code and specific exposure scenario mentioned in table 1[2] of Recommendation 6 the underlying information has been checked. Six scenarios from table 2 of Recommendation 6 were included as well, as they

[2] Table 1 in Recommendation 6 describes the methods and models for primary exposure, while Table 2 includes secondary exposure to biocides.

also included measurement data for the professional use for default development. Note that this recommendation is being updated on a regular basis, and therefore, also contains information from recent HEAdhoc consultations and recommendations. The first version was made available in January 2015, while in the current screening version 4 from May 2020 is used. In case a proposed model is based on measurement data, this is reported. Based on Recommendation 6 a list is obtained containing the PT code, the reference including year of publication, and the objective of the publication (e.g. publication describes dilution and mixing and loading of surface disinfection; is used in TNsG 2002 surface disinfection model 1). This is shown in the worksheet 'Recommendation 6 worker models'. Since Recommendation 6 refers to primary sources (e.g. study reports and papers) and to secondary sources, such as the TNsG and HEEG opinions utilizing primary sources, both have been included in the inventory.

For each 'PT code – measurement study'- combination an assessment based on expert judgment was made pointing out whether the data is fit for purpose. Reasons for indicating that a default value from a source is in need of an update are:
1) the biocidal products have changed (e.g. powder, granules, liquid),
2) the way the biocide is applied has changed (e.g. increase use of foams),
3) newer data or versions of publications are known to be available, or
4) the underlying data or the way of setting the default value are no longer considered appropriate to derive a default due to changing insights.

Our approach was that every entry of 'PT code – measurement study'- combination is regarded in view of products considered and activities included within the study. As a general rule for this exercise, data from before and including the year 2000 was considered in need of an update, as typically one or more of the reasons stated above apply. Bear in mind that the date of the year 2000 is arbitrarily set, but these data are over 20 years old and raw data is proven difficult to obtain at present. In case of data after 2000, it was considered that the data, generally, are still fit for purpose. No further explanation is given in those cases. Exceptions are 1) cases where data from before the year 2000 are still considered fit for purpose, or 2) when data from after 2000 are considered to be in need of an update. An asterisk may be added to this latter category when it is unknown if updates or newer versions exist for certain sources that are typically periodically updated.

In summary, expert judgment is given as follows:

- Before and including 2000 AND in need of an update
- Before and including 2000 AND fit for purpose→[explanation]
- After 2000 AND in need of an update→[explanation]
- After 2000 AND fit for purpose*

* information is fit for purpose, but may have been updated or newer versions of the documents are available. The authors of the current work did not check for updates. Recommendation 6 does contain a number of secondary sources. In case the primary source is considered to be old and it is a major element for the secondary source, the conclusion on whether the source is fit for purpose is inherited based on the conclusion for the primary source.

Results

The attached excel-file has three sheets (see Appendix A). Two sheets describe the same results though presented in a different way. The PT code vs Reference sheet gives the results ordered by PT code first, whereas the Reference vs. PT code sheet orders the list

starting with the reference. The latter sheet is provided to show that one reference may have been used in several areas of exposure assessment. A third sheet is given to aid the reader to cross-reference the entries to the entries in Recommendation 6 together with some additional information on the entry.

In general, based on the inventory it can be observed that most entries concerning measurement data are based on relatively old data. The majority of the data is mostly over 20 years old. Therefore, the majority of the data before and including 2000 may be considered in need of an update based on reasons stated above. Data from before 2000 that was judged 'fit for purpose' is predominantly for those activities that include manual labor and activities of manual handling of liquids. The mixing and loading steps, for example, are activities that have not changed much over time, and therefore, are still considered applicable, thus fit for purpose. It is not anticipated that new information would or could lead to new insights.

Old information concerning spraying techniques is mostly considered in need of an update. Spraying techniques have changed much over time often to increase the effectiveness of the delivery of the biocide, which has a side-effect of reducing exposure to the professional user. Especially when it concerns foggers and trigger spray applications and foams, we have observed differences in spray equipment from measurement studies compared to those described in recent dossiers. Spray applications resulting in foam are not covered in the measurement studies at all. Furthermore, some techniques are no longer in use, e.g. when it concerns the way rodenticides are used in bait stations. Although such uses may look similar, the potential for exposure is different due to the way bait stations are made and filled. An additional issue arises in view of how exposure defaults are derived. For example, some spraying models as described in TNsG 2002 cover multiple directions of spray (overhead, straight forward and downward) that could underestimate exposure if the spray application under review is predominantly overhead in reality. Thus, besides the fact that the studies are relatively old, the way the data has been processed for setting defaults could be no longer up to date, and therefore no longer fit for purpose, unless the monitored situation matches the assessed situation (see the example of combining spray directions).

Further it is noted that some measurement studies, or secondary sources referring to those studies, have been replaced by newer measurements or newer versions of those secondary sources have been published. In addition, though beyond the scope of this exercise as it does not concern measurement studies, it may be that reference is given to EN guidances (European norms) or opinions from the Scientific Committee on Consumer Safety (SCCS). They have been declared fit for purpose in our inventory, but with a caution (shown by an asterisk), which in those cases means that there may be newer versions available.

Due to a lack of robust exposure measurement data, comparisons between professional biocide use with and without risk mitigation measures (RMMs), remain for a large part unknown, and as such the effectivity of these measures, including the use of PPE. Some studies in the past did measure the effectivity of gloves, but other PPEs are rarely assessed. There is more information available in the literature from other domains (industrial chemicals, plant protection products) that could be considered in such assessments. Furthermore, developments in PPE also take place, which are not considered at the moment. Overall, the measurement data often do not consider (the effectivity of) RMM or PPE in relation to exposure to biocides.

A final observation on measurement studies that may be in need of an update concerns the use of hand disinfection, which is an example of a life changing event that has changed how professionals work. The recent COVID pandemic has resulted in a strong increase in the use of hand disinfection and stricter compliance with hygiene standards in the health care sector, especially in health care situations that require clean environments. Recent studies showed much higher frequencies of hand disinfection use during (Lopez et al. 2023; observed in general public) and after the pandemic (Huiberts and Wezenbeek, 2022; observed in health care), than studies before the pandemic as cited in HEAdhoc Recommendation 9. This indicates that current defaults and previous studies could underestimate exposure. Therefore, despite being very recent and good quality studies, the measurement studies on hand disinfection in Recommendation 6 (also referring to Recommendation 9) should be re-evaluated to assess if the information still represents the current use practices post-COVID. It may be that a distinction is needed between 'normal' day use of consumers and in general health care sectors and medium and intensive care sectors where due to the pandemic disinfection compliance has increased.

Conclusions and discussion

We have observed that exposure evaluations of biocidal products within the context of the authorization process on European level sometimes involve changes or innovations of biocidal product use on the one hand and exposure assessments based on 'old' information on the other hand. This seemingly mismatch in products and their uses versus old exposure information has led to this exercise. Based on our inventory it is concluded that human exposure assessments rely, for a large part, on measurement data that are eligible for an update. Moreover, it is noted that based on those old measurements, HEAdhoc recommendations are still being drafted, or approaches are taken in assessment reports, that seem to stretch the limits of the underlying data. This is likely the result of the incentive to work with the available information, and that the derived approach is perceived conservative enough for risk assessment. It should also be noted that during HEAdhoc recommendation development, new studies, when available, are always considered. Our screening does not criticize the way the biocidal product approval or HEAdhoc recommendation development operates, but does raise concern about the current state of underlying information for exposure assessment of professionals.

As mentioned before, this screening did not assess the possible (size of the) impact of the use of old data, and whether it would result in overestimations or underestimations of exposure. Based on the little information available from more recent exposure studies, and the overall trend to lower occupational and consumer exposure, and better protect the user of biocidal products, it is anticipated that exposure estimates are rather overestimates than underestimates. Overestimating is considered to have less health consequences than underestimating the exposure. However, it should be born in mind that overestimates of exposure can lead to unnecessary RMM, which can be burdensome to professional users as well. It may also mean that a biocidal product is not authorized onto the European market.

Within the framework of biocides, the incentive is to work with the information submitted to the assessor, and to apply conservative approaches using information on surrogates or extrapolations if the data do not completely match the exposure scenario. Measurement data are typically not provided by industry nor asked for by authorities during the authorization process as there is no obligation to provide such information. The authorities can only request measurement data if there is a clear risk identified when

using the currently available information, or if none of the data matches the intended use. The issue with this starting point of asking for additional data is that there is no clear reference point for when risk assessment uncertainties do indicate a clear risk. Moreover, exposure and risk assessors have the habit of applying more conservatism in the evaluation to cover for those uncertainties, thereby accepting the uncertainty about what we do not know. Since authorization and approval is regulated within the biocidal framework, the Occupational Safety and Health (OSH) regulation and authorities are not likely to request measurement information on the intended use, as it has already been assessed by authorities in the biocide framework. The OSH regulation does check if the conditions set out in the intended use are met. Overall, considering how both frameworks operate, a 'natural' growth of measurement studies is not foreseen.

Looking back to the mid 90s up to around 2002, when the TNsG 2002 was released, this was a time period where HSL and TNO performed a relatively large series of exposure measurement studies that are still the backbone of human exposure assessment to biocides to date. There is only a minimal contribution of newer studies to complete the set of information. It could be concluded that many of those studies by HSL and TNO have reached the end of their shelve-life and are in need of an update. The issue of 'old' measurement data will only grow if no actions are undertaken. There should be an incentive to deliver appropriate information to the authorities, or at least confirm with new information that the old information is still applicable to date. A strategy should be developed to ensure that old information is being updated over time and importantly, in time.

This screening is one of the first steps in the process. A second step is to further analyse how the measurement data are being used, what level of conservativeness or assumptions to cover for uncertainty are applied, and where data gaps exist. This will inform on the impact those studies may have in exposure assessments. If authorities can establish in what areas current information is no longer fit for purpose, they have a legal basis to request new information in the authorization process. This option could be pursued more often in those cases where it is believed that current information does not give sufficient confidence in the resulting exposure assessment. Besides that, it is also recommended to initiate a broad scale exposure measurement program that focuses firstly on potentially high exposure activities amongst professional users, bearing in mind the identified weak spots from this screening. There is a need to look at various (innovative) spraying activities and techniques, such as foams, and to investigate those activities that have underwent innovations, such as new formulation forms of powders and the use of combustion/formation techniques to spread the active substances. Hence, not only approaching the issue from an exposure perspective, but also from the application technique perspective. In addition, the focus should be on the inhalation and dermal route of exposure, taking into consideration the current practice and effectivity of using RMMs including PPEs.

Finally, following the conduction of new measurement studies, updates of guidance documents and recommendations are needed to ensure that the new information is utilized in the authorization process. Since the authorization process of active substances is at the European level, it is deemed necessary to approach the issue at the European level. It concerns the backbone of the exposure assessment of biocides and biocidal products, and consequently the risk assessment and evaluation of safe use. The HEAdhoc working group could play a vital role in further analysing the measurement studies, their impact, data gaps (analysis and elaboration) and work out a strategy to address the needs for assessing human exposure to biocides based on up to date information.

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Appendix A

https://www.rivm.nl/bibliotheek/rapporten/KN-2024-0036.xlsx