

BfR calculator for estimating consumer exposure to biocide residues in food

Updated BfR Communication No. 023/2018, 10 July 2018*

Regulation (EU) No. 528/2012 requires that a risk assessment is performed for products containing biocidal active substances. The assessment includes the evaluation of residues in food and feed. Through the use of biocides in domestic households by non-professional users food can be exposed. This may occur either via direct exposure of food or upon contact of food items with biocide residues deposited on surfaces.

With active participation of the German Federal Institute for Risk Assessment (BfR) the Working Group ARTFood (Biocidal Product Committee Ad hoc Working Group for the **A**ssessment of **R**esidue **T**ransfer into **F**oods) of the European Chemicals Agency (ECHA) has developed the “Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses” (Guidance Non-Prof Uses). The document has been published on the ECHA website as part of the Guidance on the Biocidal Products Regulation [1].

The Guidance Non-Prof Uses proposes several scenarios for estimating consumer exposure to biocidal active substances in their food. In order to facilitate harmonized exposure estimates the BfR has developed an Excel-based tool for calculating the exposure for various scenarios. Calculations are based on assumptions and default values as described in the Guidance Non-Prof Uses. Calculator and guidance are intended to support competent authorities and industry in the estimation of dietary risk to humans from biocidal products that are used in domestic environments (households) and could contaminate food.

1 Consumer Information on Biocidal Product Regulation (EU) No. 528/2012

Biocidal products are applied to control harmful organisms, while at the same time they could pose a potential risk to humans and the environment. Therefore the Biocidal Product Regulation (EU) No. 528/2012 stipulates that during biocidal product authorisation a risk assessment is performed. The Biocidal Product Regulation also applies to biocidal products used in private domestic settings [2, 3], e.g. disinfectants or insecticides. For further information please visit the BfR-Webpage

- http://www.bfr.bund.de/en/biocidal_products_and_treated_goods-568.html

In case the use of a biocidal product may lead to residues in food, the risk assessment in the framework of the product authorization includes an evaluation of the consumer safety following the intake of residues in food.

2 Information on the ARTFood Guidance Document provided by ECHA

With active participation of the BfR, the Working Group ARTFood (Biocidal Product Committee Ad hoc Working Group for the **A**ssessment of **R**esidue **T**ransfer into **F**oods) of the European Chemicals Agency (ECHA) has developed the “Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses” (Guidance Non-Prof Uses). The document is intended to support competent authorities and industry and describes harmonised approaches for estimating consumer exposure to biocide residues in

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food which may result from the use of biocide products in domestic environments (households).

Initially the ARTFood Guidance has been made available by the ECHA as a draft document in June 2015. Following a one-year commenting period and completion of the ECHA consultation procedure the finalized Guidance Non-Prof Uses has been published in November 2017 as part of the ECHA Guidance on Biocidal Products Regulation (see Volume III Parts B+C, Section 5 for Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods - Non-professional Uses [1]). Changes compared to the draft guidance document were mainly clarifications in the text and the calculations as well as addition of further details, e.g. water consumption figures and reference to the Disinfection By-Product Guidance [4].

For estimating consumer exposure via the transfer of biocidal active substances used in domestic households (non-professional uses) into food, the Guidance Non-Prof Uses describes a tiered approach. An important step within this procedure is the estimation of the consumer exposure based on modelling.

The calculation of the intake of biocide residues by consumers is based on the contaminated surface area which could get in contact with food rather than on food consumption estimates since there is no quantitative data available on the migration of biocidal active substances from contaminated surfaces into food. The only exceptions are the scenarios involving exposure of drinking water. They include water consumption rates in the calculation. According to the ARTFood Guidance Document consumer exposure is calculated for adults (60 kg bodyweight) and toddlers (10 kg body weight), but further consumer groups (child with 24 kg bodyweight and infant with 8 kg bodyweight) were implemented in the calculation tool.

The calculation is based on essential information on the intended use of the biocidal product as well as on assumptions and default values as explained in the Guidance Non-Prof Uses, such as volume and size of a domestic kitchen or volume and inner surface area of a water container. If justified, e.g. if measured values are available for certain parameters, default values may be replaced accordingly.

3 Content and purpose of the BfR Calculator

In order to support and advance the use of the Guidance Document, BfR has developed an Excel-based tool for calculating the consumer exposure. The BfR calculator for estimating consumer exposure to biocide residues in food as a consequence to the use of biocidal products in domestic households is intended to facilitate the exposure estimation in accordance with the ARTFood Guidance Document.

The exposure scenarios currently considered are not a comprehensive collection. During the evaluation of further uses of biocidal products an adjustment of existing or addition of new scenarios may be required on a case-by-case basis. For evaluation it should be ensured that the chosen scenario is applicable to the intended use to be evaluated.

The BfR calculator also provides an overview of parameters applied in the models. Moreover, it contains example calculations that illustrate the calculations presented in the Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses” (Guidance Non-Prof Uses). Examples include surface disinfection, spraying of insecticides, disinfection of drinking water and its containers as well as dishwashing.

For product types and intended uses of biocidal products not covered so far, it may become necessary to develop new scenarios that could be included in a future updated version of the calculator.

The calculator can be downloaded from the BfR website:

- <https://www.bfr.bund.de/cm/349/bfr-calculator-for-estimating-transfer-of-biocide-residues-into-foods-non-professional-uses.xlsx>

4 References

[1] Guidance on Biocidal Products Regulation (BPR): Volume III Parts B+C, Section 5: Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods - Non-professional Uses

<https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>

[2] C. Pieper et al. HygMed 2014; 39 (3): 68-76. Antimikrobielle Produkte im Haushalt – eine Betrachtung zu Auswirkungen auf Gesundheit und Umwelt sowie zum Nutzen für den Anwender

<http://www.bfr.bund.de/cm/343/antimikrobielle-produkte-im-haushalt.pdf>

[3] BfR (2014). Fragen und Antworten zu Nutzen und Risiken von Desinfektionsmitteln im Privathaushalt. FAQ des BfR vom 22.Mai 2014

<http://www.bfr.bund.de/cm/343/fragen-und-antworten-zu-nutzen-und-risiken-von-desinfektionsmitteln-im-privathaushalt.pdf>

[4] Guidance on Biocidal Products Regulation (BPR): Volume V: Guidance on Disinfection By-Products

https://echa.europa.eu/documents/10162/23036412/bpr_guidance_vol_v_dbp_new_en.pdf/c7d11d09-8ae5-317f-0eeb-ec8b2aa938b3

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The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.