June 2015

Note to the file

ARTFood Draft Guidance – Pilot Project

Draft Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses

This Draft Guidance document is being made available as a "pilot project" in order to collect feedback and is open for commenting for a one year period. This will allow Applicants and Member States to gain experience with the approach proposed and to send their comments and feedback in light of their experience.

The interested parties are invited to use the form "ARTFood Draft Guidance – Pilot project feedback form" (download the file) and to submit comments until 30th June 2016 using ARTFood functional mailbox BPC-artfood@echa.europa.eu.

When sending the comments, indicate the chapter, the section and page of the document which your comment refers.

After 30th June 2016, the comments will be reviewed and a new draft of the guidance will go through the ECHA guidance consultation procedure (http://echa.europa.eu/documents/10162/13608/mb_63_2013_revision_consultation_procedure_guidance_en.pdf). Then, the Draft Guidance will be finalised and published on Biocides ECHA webpage.

ARTFood DRAFT Guidance on the Biocidal Products Regulation

DRAFT Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses (ARTFood Project 2)

DRAFT
June 2015

LEGAL NOTICE

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

This document forms the basis of a pilot project, where interested parties are invited to submit comments during a one year period. The document will then be finalised through the ECHA guidance consultation procedure. As such, the document does not constitute a precise assurance by the European Chemicals Agency as to the course of conduct that it follows. Users are reminded that the text of the BPR is the only authentic legal reference. Usage of the information in this document remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

ARTFood Draft Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses (ARTFood Project 2)

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If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document which your comment refers) using the Guidance feedback form. The feedback form can be accessed via the ECHA website or directly via the following link:
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PREFACE

This Draft Guidance is to be applied to applications for active substance approval and product authorisation submitted under the Biocidal Product Regulation (EU) No 528/2012 (the BPR). This document describes the BPR obligations and how to fulfil them

The ARTFood Project Plan was agreed at the Biocidal Products Committee meeting (BPC-4) in February 2014. The plan agreed that the three draft guidance documents that have been developed by DRAWG (Dietary Risk Assessment Working Group) will be finalised by ARTFood. These are:

1 Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products

2 Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses

3 Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses

This draft guidance is for the second project (referred to as Project 2),

Scope: The document will cover only representative non-professional biocidal use scenarios in a domestic environment (household), where biocides may come into contact with food and where this food is consumed within that particular household. For each scenario, assessment models are presented in this guidance. The document describes methods for estimating dietary exposure for the various use scenarios without a specific quantification of residues in food and details the reference values to which the exposure estimates are compared in order to determine risk.

The methods described in this guidance are to be seen as recommendations for performing assessment of biocide transfer into food. Applicants wishing to propose other methods for assessment may do so as long as these other methods are substantiated, well documented and in line with the general principles of this guidance document.

Status: A draft guidance was drafted by DRAWG and presented to the Technical Meeting (September and November 2013). ECHA and industry has submitted comments and the TM has agreed that ARTFood should finalise it. The document is proposed to be tested.

Procedure foreseen: Once finalised by the ARTFood after the March 2014 workshop on MRLs for Biocides, the draft document should be published on the ARTFood website as a "pilot project" open for commenting (e.g. for 18 months). This would allow Applicants and Member States to gain experience with the approach proposed; send their comments and in light of the experience the guidance could be finalised through the ECHA guidance consultation procedure (9-12 months).

Background to the document

The Dietary Risk Assessment Working Group (DRAWG) was formed in May of 2009 under the Biocidal Product Directive, upon request of the Biocides Technical Meeting, in order to develop guidance for dietary risk assessment (DRA) of biocidal active substances (a.s.). Under the new Biocidal Products Regulation, the Biocidal Product Committee (BPC) at its meeting in February 2014 (BPC-2) established and agreed upon the mandate of the Ad hoc Working Group on the Assessment of Residue Transfer to Food (ARTFood), to continue and finalise the guidance developed by DRAGW.

This draft document was originally part of the draft "Guidance on Estimating Transfer of Biocidal Active Substances into Foods" which was discussed at the Biocides Technical Meeting TMIII12. In that discussion, it was decided to divide the draft into two separate

documents, one on professional uses and one on non-professional uses. This draft guidance comprises the non-professional uses.

The aim of the draft guidance is to support Industry and Competent Authorities in the estimation of dietary risk to humans from biocidal products that are used in domestic environments (household) and could contaminate food.

Non-professional use scenarios cover only biocidal uses in a domestic environment, where biocides may come into contact with food and where this food is consumed within that particular household. To this end, relevant scenarios were identified based mainly on representative uses of biocidal active substances that have been notified under the EU active substances review programme. For each scenario, assessment models are presented in this guidance.

The methods described in this draft guidance are to be seen as recommendations for performing assessment of biocide transfer into food. Applicants wishing to propose other methods for assessment may do so as long as these other methods are substantiated, well documented and in line with the general principles of this draft guidance document.

NOTES to the reader:

This Draft Guidance document is being made available on the Biocides ECHA webpage as a "pilot project" in order to collect feedback and is open for commenting for a one year period. This will allow Applicants and Member States to gain experience with the approach proposed and to send their comments and feedback in light of their experience. The feedback and comments will be reviewed and the draft guidance revised accordingly through the ECHA guidance consultation procedure [http://echa.europa.eu/documents/10162/13608/mb_63_2013_revision_consultation_procedure_guidance_en.pdf].

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List of Abbreviations

Standard term / Abbreviation	Explanation
ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
a.s.	Active Substance
BPR	Biocidal Product Regulation (Regulation (EU) No. 528/2012 concerning the making available and use of biocidal products)
b.r.	Biocidal Residue
CLP	Classification, Labelling and Packaging Regulation (Regulation (EC) No 172/2008 on classification, labelling and packaging of substances and mixtures)
DBP	Disinfection By-Product
DRA	Dietary Risk Assessment
DRAWG	Dietary Risk Assessment Working Group
MRL	Maximum Residue Level
PT	Product Type

1. Introduction

The Biocidal Products Regulation (BPR) requires that a risk assessment is performed for biocidal products. Whenever food contamination results from the use of a biocidal product, a dietary risk assessment (DRA) should be performed.

The aim of this draft guidance is to estimate the dietary risk to humans from biocidal products that are used in domestic environments (household).

This document describes methods for estimating dietary exposure for the various non-professional use scenarios without a specific quantification of residues in food and details the reference values to which the exposure estimates are compared to in order to estimate dietary risk.

For the purpose of this draft guidance document, the term "biocide residue" is defined as "the residue in food resulting from the use of a biocidal product, which includes all toxicologically relevant compounds and may include the active substance and/or relevant degradation products and metabolites."

Biocidal products are divided into 22 product types (PTs) (Annex V of BPR), some of which are used on objects used to prepare food in domestic kitchens or in kitchens/on kitchen surfaces and other domestic areas where food is stored and/or prepared. In this way, biocidal active substances and/or their degradation products can be transferred into food. The non-professional use of biocides means that they may come into contact with food that is consumed within the household. For this reason, it is not relevant to propose a maximum residue limit and no need to estimate quantitatively biocide residues in food.

Based on representative uses submitted in the course of EU-wide biocidal active substance evaluations, a number of scenarios have been identified for how food can come in contact with biocidal products:

- Disinfectants and preserved cleaners in domestic kitchens (PT 4)
- Insecticides in domestic environments (PT 18)
- Drinking water disinfection (PT 5)
- In-can preservatives and disinfectants in dishwashing detergents (PTs 4, 6)

Other non-professional use scenarios are less likely to lead to dietary exposure, but this has to be considered on a case-by-case basis.

The direct treatment of food previously covered under PT20 (preservatives for food and feedstock) is not considered in this draft guidance since this PT is no longer within the scope of the BPR .

For each of the scenarios listed above, possible methods for estimation of dietary exposure will be discussed in this document. For these scenarios, the possibility of dietary exposure must be considered and addressed either by an assessment or a waiver in the form of a Justification for Non-Submission of Data detailing the reasons for the waiver.

The methods for assessment of dietary risk from biocides/biocide residue transfer into food described in this draft guidance are based on worst-case considerations assuming realistic maximum biocide residue intake. The biocide residue intake is calculated using the area of contact with food, making it unnecessary to include food consumption data in the assessment. The only exception is the scenario for drinking water disinfection, which includes water consumption rates in the calculation.

In addition, the methods differentiate between acute and chronic exposure scenarios.

Dietary risk assessment will only be conducted for two age groups, namely toddlers and adults. Toddlers were identified to be the worst case with regard to dietary assessment

and therefore cover the entire population of children (see Appendix 2 section 1). Only in cases where another age group represents the worst case should exposure also be calculated for this additional age group. Standard body weights and corresponding water intake figures are given in Appendix 1, section 2.

Biocidal products may contain formulants that are substances of concern. Substances of concern may be equally or more hazardous to human health than the active substance itself. A risk assessment for all substances of concern must therefore be performed according to the *Guidance on Biocidal Products Regulation: Volume III Human Health, Part B Assessment (Annex A)*.

Particular attention should also be paid to the formation of disinfection by-products (DBPs). Disinfectants (e.g. chlorine) are known to react with organic matter to produce an array of DBPs. Some DBPs such as nitrosamines and halofuranones are potent genotoxic carcinogens. A separate guidance document on how to evaluate DBPs and their formation is currently under development. Until this document is finalised, the issue must be addressed qualitatively in the product assessment report and recommendations to minimize the formation of DBPs should be provided, for example via label instructions. An approach for risk assessment of DBPs will be developed at Union level and will have to be followed for the DRA of active substances intended for drinking water disinfection once available.

Under Article 5(1) of the BPR, active substances that are classified as, or meet the criteria to be, classified as carcinogenic category 1A or 1B, mutagenic category 1A or 1B, reprotox category 1A or 1B (in accordance with the CLP Regulation), and/or meet the criteria for being PBT or vPvB according to Annex III to Regulation (EC) No 1907/2006 and/or have endocrine-disrupting properties should not normally be approved. Such active substances should not be allowed for use in biocidal products unless this would have a negative impact on society compared to the risk to humans and the environment of not using the biocidal product; or the risk is negligible; or the active substance is considered essential (Article 5(2) of the BPR). This draft guidance does not apply to active substances with such classification for health hazard.

2. Overview of Residue and Dietary Risk Assessment

Biocide residue and dietary risk assessment follow a stepwise procedure which is outlined in Figure 1. In the first step, the intended uses should be established and it should be assessed whether the use of the biocidal product leads to transfer of biocide residues to food. When transfer of biocide residues into food is foreseen, the dietary exposure is estimated based on modelling and it is compared with toxicological reference values (ADI and ARfD) in order to estimate the risk. If the exposure estimation is above 10% of the ADI or ARfD, a risk is identified and the nature of the residue needs to be defined. Finally, the exposure model should be refined through the use of additional data if a risk is identified.

Dietary risk is estimated by comparing the consumption of biocide residues via foods with toxicological reference values, provided that these values can address the toxicity of the residues. The applicable toxicological reference values for a DRA are usually the ADI (Acceptable Daily Intake) for chronic toxicity and the ARfD (Acute Reference Dose) for acute toxicity. ADI and ARfD are established as part of the hazard assessment of the active substance. If such reference values cannot be derived due to the lack of systemic adverse effects, no assessment is needed, unless local effects would be relevant to evaluate. If the toxicological information shows that an active substance and/or its toxicologically relevant degradation product(s) do not become systemically available and that primary irritation/corrosion at the site of first contact is the only relevant effect observed, a local risk assessment rather than a systemic DRA is required (see *Guidance on Biocidal Products Regulation: Volume III Human Health, Part B Assessment)*.

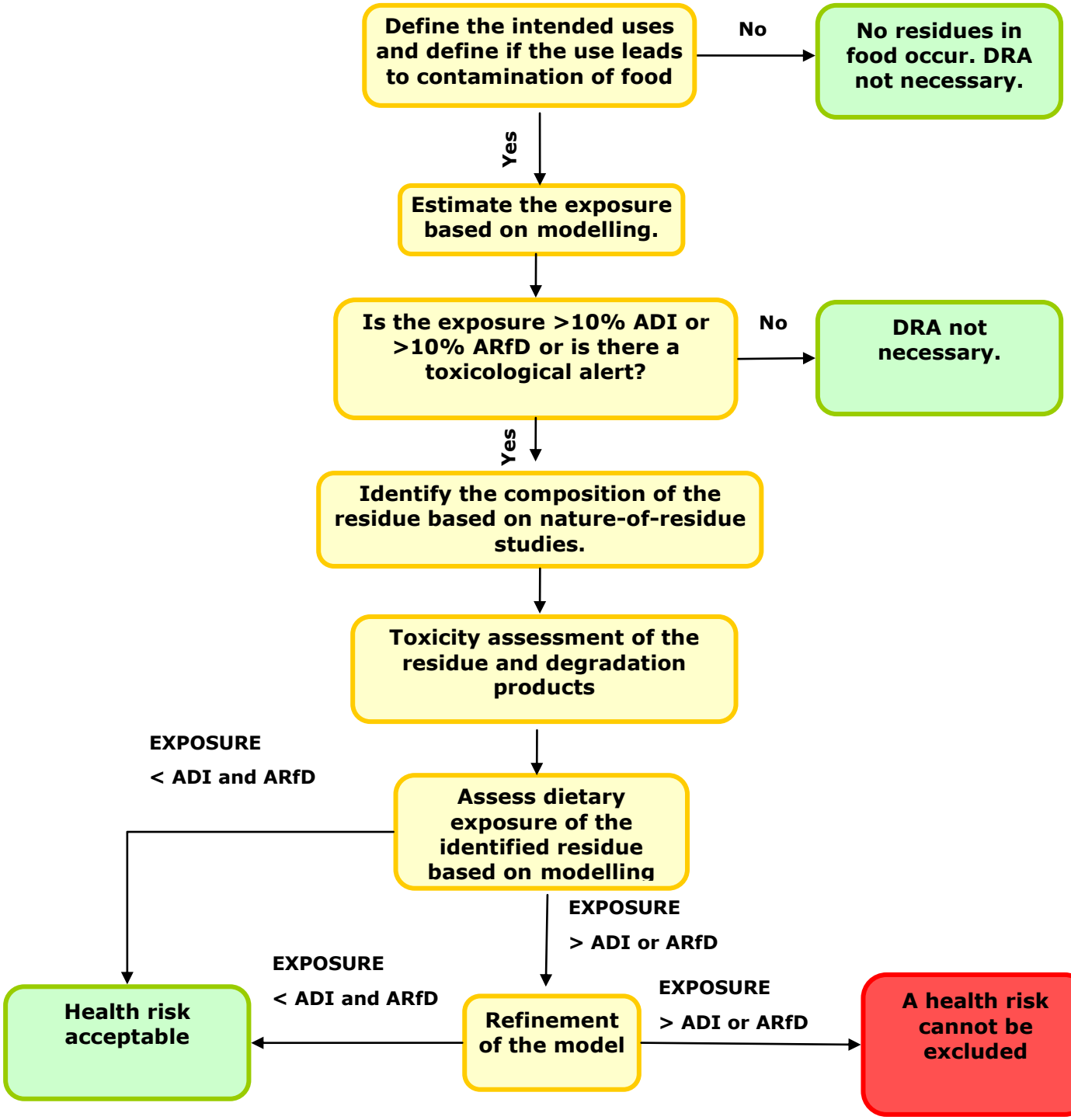

Figure 1: Steps in Dietary Risk Assessment

3. Assessing the possibility of food contamination

In the first step of a DRA, it is assessed whether the use of the biocidal product leads to contamination of food. Some biocidal products are designed to preclude food contamination. The product may carry on its label instructions to the user, an instruction to avoid food contact (e.g. "Keep away from foodstuff, eating utensils or food contact surfaces.") and/or may be formulated in a way that food contamination is unlikely (e.g. a gel spot application rather than an aqueous formulation, preventing splashes). If the Applicant concludes that food contamination can be excluded due to label instructions and/or special product formulations, the Applicant must submit a Justification for Non-Submission of Data listing the arguments that led to this conclusion. On the basis of the Justification, the Competent Authority evaluates whether the argumentation is valid. If this is the case, dietary risk does not have to be further evaluated.

Label restrictions can generally be accepted as risk mitigation measures, unless the restrictions appear impractical or not plausible. Restrictions which invite foreseeable non-proper use[1], i.e. use of biocidal products not in line with the instructions for use or without the consideration of some specific technical, operational and personal protective measures, should not be considered in the assessment. Label restrictions can be an appropriate risk mitigation measure for non-professional users, however, this has to be checked on a case-by-case basis. Particular attention should be paid in the evaluation because non-professional users are more likely to ignore or misinterpret unclear label restrictions than professional users.

A general statement regarding acceptable and non-acceptable label restrictions for the non-professional uses cannot be made. Instead it is the combination of label restrictions with specific product characteristics such as, intended use, formulation and product design, that will allow decisions on a case-by-case basis. Examples of label restrictions that an assessor may consider unclear or impractical are given in Table 1. The list is not exhaustive and does not constitute a set of rules, but provides examples of how a label restriction may be interpreted: other interpretations are possible depending on the specific product that is being evaluated.

In general, label restrictions on products for non-professional uses should be easy to understand and give clear instructions on what the non-professional user should do (and consider what the non-professional user can be expected to do correctly). They should not be ambiguous, too general or require unrealistic additional efforts by the non-professional user. They should furthermore be clearly visible and legible (i.e adequate font size, prominent location on the package).

Table 1: Examples of label restrictions that may be considered impractical

Biocidal product	Label restriction	Remarks
Electric vaporiser for insect control in residential homes	"Do not use in kitchens."	Non-professional user is likely to ignore or forget. If product works well in rooms it si intended for, non-professional user may also use it in kitchens.
	"Cover food before use."	For these product formulations

[1] Definition based on TNsG on Human Exposure, 2007: "Foreseeable non-proper (incorrect) use is the use of biocidal products not in line with the instructions for use or without the consideration of some or all common and specific technical, operational and personal protective measures (e.g. the over-application or inadequate dilution of a biocide, common spillage scenarios, use without or with non-proper RPE and PPE), which is expected to occur based on experience, monitoring data etc. and which is expected to be perpetrated by a large number of users of the biocidal product. Accidents, malfunctions or deliberate misuse are not addressed."

Biocidal product	Label restriction	Remarks
		(vaporiser), covering food does not prevent food contamination, because vapours diffuse under covers, into cupboards, and into food packaging etc.
Surface disinfectant for domestic kitchen counters	"Do not contaminate food." "Rinse surfaces after disinfection."	Too general. Does not give clear instructions. Non-professional users may e.g. not be aware that food can be contaminated through biocide residues that remain on surfaces. Unrealistic additional effort. Experience shows that non-professional users do not rinse after disinfection.
Biocidal products that require a preparation step	"Do not prepare product where food, feed or drinking water could be contaminated."	Ready-to-use products may be an alternative option to minimise exposure of non-professional users.

Table 2 lists a preliminary set of practical phrases that could be included in the label. This set is neither exhaustive nor finalised and may be changed or expanded in the future. Moreover, additional P statements might be assigned to dangerous substances and preparations in accordance with the CLP Regulation.

Table 2: Example set of practical phrases

Label restriction	Remarks
"Keep away from food, drink and animal feedingstuffs."	This sentence is recommended for acute toxic substances and preparations, which are likely to be used by the general public (non-professional user).
"Keep away from foodstuffs, eating utensils or food contact surfaces."	• May be acceptable for spray applications on surfaces • Not applicable for applications such as evaporation products
"Remove food before application" or "Store food away from the area to be treated"	• Generally acceptable for formulations that are sprayed or applied with a cloth or sponge • Not acceptable for vaporiser formulations
"Do not place product where food, feed or water could become contaminated."	For biocidal products with targeted spot applications (e.g. gel spots applied to cracks and crevices and other hard-to-reach spaces)
"Do not use in larders or food cupboards."	For applications such as evaporation products that may be placed in small closed compartments (e.g. strips/vaporiser)
"Apply biocidal product at least x metres away from places where food or feed are stored, prepared or consumed."	For rodenticides applied as foam or dust/tracking powder which are designed to adhere to the rodent's body.

4. Estimation of the exposure and comparison with reference values

A first estimation of the exposure should be carried out following the principles laid down in section 6 below, Estimating biocidal transfer into food, and according to the correct scenario.

The initial exposure estimation is based on the assumption that the parent substance is not degraded (i.e. the toxicity of the potential degradation product is covered by the toxicological reference value of the parent compound).

The estimated exposure should then be compared to the reference values, ADI for chronic exposure and ARfD for short term exposure to see if the exposure is below or equal to 10% of the ADI or ARfD, and) is the exposure in absence of particular concerns (i.e. a chemical structure without genotoxic alert or other any known toxic alert). If both of these are true then there is no need to investigate further the composition of the residue and there is no need to perform a dietary risk assessment.

However if the exposure is above the 10% of the ADI or ARfD, and/or if there is evidence of genotoxic alert or other any known toxic alert, then the composition of the residue should be analysed according to section 5 below, identifying the residue composition.

5. Identifying the residue composition

Before biocide residues in food or dietary exposure can be estimated, it must be determined which toxicologically relevant compounds the biocide residue consists of. This may include the active substance, one or more of its degradation products and metabolites or a combination of both. To identify the composition of the relevant biocide residue, nature-of-residue studies that simulate realistic use conditions of the biocidal product should be performed.

Generally, nature-of-residue studies should be performed, unless it can be shown that the use of an active substance leads to a consumer exposure (including the parent substance and all degradation products) below a threshold limit of 10% of the ADI (for chronic dietary exposure) or 10% of the ARfD (for acute dietary exposure). This is acceptable providing that the initial exposure estimate is based on the assumption that the parent substance is not degraded. In addition, a justification and/or evidence that structures with a genotoxic alert or any other known toxic alerts with a higher toxicity are not expected to be present, should be provided.

The decision on which degradation products are included in the residue definition for the risk assessment is made based on the toxicological properties of the substances.

Degradation products that have been found in sufficient quantities as metabolites in the toxicology studies submitted as part of the core data set, are already considered in setting the ADI/ARfD. It might be that other degradation products will be identified by nature of residue studies and for those products it should be assessed whether the parent reference values cover their toxicity profile. Read-across or QSAR, or other predictive models can be used to conclude on the adequacy of the parent ADI or ARfD with respect to the degradation products.

In some cases, waiving of the residue composition studies is possible on the basis of physical-chemical properties (solubility, log Pow, volatility, biodegradability, light sensibility, pH, pKa) if sufficiently justified or when the reaction products are already known.

In a first step, the residue composition at ambient conditions is assessed on the basis of the hydrolysis studies that are part of the core set of data submitted for biocidal active substances. If degradation is observed in these studies and, if it can be reasonably justified that no new degradation products are likely to be formed at higher

temperatures, studies at higher temperatures are not necessary. The relevant residue is then defined on the basis of the hydrolysis studies. Thermal stability data may also be considered.

If the formation of additional relevant degradation products in significant levels at higher temperatures cannot be ruled out, the assessment of the residue composition moves to the second step. In the second step, the residue composition is assessed on the basis of nature-of-residue studies with radiolabelled compounds designed to reflect the realistic use conditions of the biocidal product. The OECD guideline 507, Nature of the Pesticide Residues in Processed Commodities-High Temperature Hydrolysis, could be applied for performing studies with radiolabelled compounds. When defining the appropriate study conditions, the following must be kept in mind; degradation of the active substance can occur during (i)the application of the biocidal product, (ii) between application and biocide transfer to food (e.g. when biocide treated equipment is rinsed) and (iii) after biocide transfer to food (e.g. during food processing and/or preparation). To cover degradation that occurs after biocide transfer into food, nature-of-residue studies must be designed to cover common food processing conditions. The parameter which most likely affects the nature of the residue during most processing operations is hydrolysis and three different hydrolysis conditions have been defined to simulate most processing practices (see Table 3, from OECD guideline 507). In addition nature-of-residue studies must cover any other relevant degradation conditions that occur during or after application of the biocidal product. For example, biocides contained in machine dishwashing detergents are exposed to elevated temperatures (70°C) and changes in pH (7 and 11) throughout a machine wash cycle of approximately 215 minutes (see Appendix 3). These conditions are different from those seen during food processing and must therefore be built into the design of the nature-of-residue studies. On the other hand, single experiments can be waived if a condition does not apply to the use of the biocide under evaluation.

Table 3: Required conditions for nature-of-residue studies (OECD guideline 507)

Temperature (°C)	pH	Time (min)	Process represented
90	4	20	Pasteurisation
100	5	60	Baking, Brewing, Boiling
120	6	20	Sterilisation
Any other relevant conditions occurring during or after application of the biocidal product.			

The presence of the food commodity is not required for the nature-of-residue studies. Where appropriate, these studies should be conducted with exaggerated amounts of radiolabelled active substance. The values of the measured amounts of active substance and degradation products are then adjusted to the actual use conditions of the biocidal product. Regarding the characterisation and identification of degradation products, the principles reported in the OECD Guideline 507 apply.

Degradation products that make up less than 10% of the total residue do not need to be identified and require no additional toxicological information unless there is reason to believe that they are of toxicological concern, such as chemical structure. Based on the nature-of-residue studies and the toxicological data, a decision is made as to which degradation products are included in the biocide residue definition. The OECD (2009) guidance document on the Definition of Residues as well as the EFSA (2012) Scientific Opinion on Evaluation of the Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment may be useful in deciding how to proceed.

6. Estimating biocide transfer into food

The following sections describe methods for estimation of dietary risk from biocide transfer into food for the different use scenarios. It should be noted that potential transfer into food can be reduced by the introduction of risk mitigation measures and refinement options.

The methods described are to be seen as recommendations for performing assessment of biocide transfer into food. Applicants wishing to propose other methods and/or other refinement options for assessment may do so as long as these are substantiated and well documented.

6.1 Disinfectants and Preserved Cleaners in domestic kitchens

NOTE: This chapter is concerned with disinfectants (PT 4) as well as disinfectants/cleaners containing in-can preservatives (PT 6). For more guidance on the assessment of in-can preservatives, please see the "DRAWG Opinion on identifying worst-case exposure scenarios for PT6 biocidal products in order to minimise the number of scenarios to be assessed for dietary risk". Refer also to section 6.4 below for dishwashing.

A number of biocidal products marketed for domestic use (e.g. disinfectants and household cleaners containing in-can preservatives) have the potential to come in contact with food. Biocides applied to food contact surfaces such as kitchen counters or dining tables can be transferred to food during preparation and eating. Resulting biocide residues in foods may lead to significant dietary exposure, particularly for children, who consume food in a manner that makes it likely for food to come in contact with contaminated surfaces (Melnyk *et al*., 2000 and 2011). Estimating the amount of biocide residues in food for these uses would be laborious and not very precise since food preparation in the home is highly variable. Since a biocide-treated surface (e.g. a counter top) can be used to prepare any type of food, not one commodity but the whole diet of the consumer can potentially be exposed to the biocide when it comes into contact with the surface. Commodity-specific biocide residue estimates are therefore not practicable; instead, it is more useful to directly estimate dietary exposure.

6.1.1 Assessment approach

Assumptions

- 100% of surface biocide residues are transferred to food in contact with the surface. Product specific data on mass transfer efficiency may be considered if available.
- Additional deposition of biocide residues on top of food lying on counter tops is not considered.
- Exposure of adult and toddler age groups (toddlers represent the most sensitive consumer group (see Appendix 2)
- Default value for contaminated surface area in contact with food (that represents daily exposure of consumer)is 0.2 m^2 (acute and chronic exposure) (see Appendix 1 Table 4)
- Accumulation of active substance over time as a result of repeated applications is not considered. In domestic kitchens, daily cleaning of surfaces is assumed as dirty surfaces would not normally be used in the preparation of food.

Estimation of dietary exposure

$$Exp_{cons} = R_{surface} * A_{food\ contact} * TF \div bw$$

Where:

Exp_{cons}	dietary exposure (mg a.s./kg bw/d)
$R_{surface}$	biocide residues on surface (mg a.s./m^2)
$A_{food\ contact}$	area in contact with food (m^2)
TF	mass transfer efficiency factor (fraction of biocide residue transferred from surface to food)
bw	body weight (kg)

Refinement options

- Product specific data on amount of actual surface biocide residues (in particular for volatile substances that partially evaporate before food contact occurs or unstable substances that degrade rapidly following application)
- Product specific data on mass transfer efficiency (fraction of biocide residue transferred from surface to food). Since this parameter depends e.g. on the type of surface, the type of food item, the amount of contact time and the contact pressure (Akland *et al*. 2000), care must be taken when incorporating it in a refined assessment.
- Where fully justified, a dilution factor for PT6 can be used.

In support of the proposed exposure estimation, the reverse reference scenario might be used to estimate the maximum amount of the exposure that might be acceptable.

Example 1: Disinfectants and preserved cleaners in domestic kitchens

Biocidal product: Liquid disinfectant that is sprayed on counter tops in domestic kitchens

Calculation of surface residues

$R_{surface}$ = concentration of a.s. in biocidal product * application rate (both values are listed in the intended use table of the Applicant's dossier)

= 1 g a.s./L * 0.001 L/m²

= 1 mg a.s./m^2

Estimation of acute and chronic consumer exposure

$R_{surface}$	1 mg a.s./m^2	(see calculation above)
$A_{food\ contact}$	0.2 m^2	(default value for both acute and chronic exposure)
TF	100%	(default value in absence of product-specific data)
Bw	10 kg / 60 kg	(default value for toddler / adult)

6.2 Insecticides in residential homes

6.2.1 Airspace treatment

Several insecticide products available for non-professional use are applied into the airspace (i.e. spraying, vaporising, fogging of biocidal product with residues depositing from the air to surfaces). The following assessment model only applies to non-professional uses.

The exposure estimate is performed in two steps:

1. Calculation of biocide residues deposited from air to horizontal surfaces
2. Estimation of transfer from contaminated surfaces to food and calculation of dietary exposure

Assumptions

- a.s. is diffused into air and 100% of a.s. is deposited on horizontal surfaces only. Accumulation of biocide residues over several days is not considered. Biocide residues are assumed to be distributed evenly throughout the airspace. No room ventilation is considered.
- Biocidal product is used daily.
- 100% of surface biocide residues are transferred to food in contact with the surface. Product specific data on mass transfer efficiency may be considered if available.
- Exposure of adult and toddler age groups (toddlers represent the most sensitive consumer group, see Appendix 2)
- Default value for contaminated surface area in contact with food (that represents daily dietary exposure of consumer): 0.26 m^2 (chronic exposure) or 0.53 m^2 (acute exposure, see Appendix 1 Table 4)

Calculation of biocide residues deposited from air to horizontal surfaces

$$R_{surface} = m_{24h} * h_{room} / V_{room}$$

Where:

$R_{surface}$ biocide residues deposited from air to horizontal surfaces within 24 h (mg a.s./m^2)
m_{24h} mass of active substance released over 24h (should be determined from product information, default values e.g. for common application frequency etc) (mg)
V_{room} room volume treated (m^3)
h_{room} room height (m)

Estimation of dietary exposure

$$Exp_{cons} = R_{surface} * A_{food\ contact} * TF / bw$$

Where:

Exp_{cons} dietary exposure (mg a.s./kg bw/d)
$R_{surface}$ biocide residues on surface (mg a.s./m^2), (see calculation above)
$A_{food\ contact}$ area in contact with food (m^2)
TF mass transfer efficiency factor (fraction of biocide residue transferred from surface to food)
bw body weight (kg)

Refinement options

- Higher tier modelling using product specific data on mass transfer efficiency (fraction of biocide residue transferred from surface to food). Since this parameter depends for example on the type of surface, the type of food item, the amount of contact time and the contact pressure (Akland *et al*. 2000), care must be taken when incorporating it in a second tier assessment.
- Higher tier modelling that includes frequency of use, seasonal use, and removal by ventilation.
- Tests analysing amount of surface biocide residues for the application of the specific biocidal product

Example 2: Airspace treatment with domestic insecticide

Biocidal product: Liquid used in a heated vaporiser for space treatment against mosquitoes in residential properties by non-professional users

Mass of active substance released in 24h

Product information: 1 bottle containing 240 mg a.s. lasts for 720 h, max use 12 h/d

m_{24h} = (mass of a.s. per bottle/total duration of use per bottle) * duration of application per day

= (240 mg a.s./720 h) *12h = 4 mg

Calculation of residues deposited from air to horizontal surfaces

Mass of active substance released over 24h = 4 mg (calculation see above)

Room height for domestic homes = 2.5 m (default)

Room volume for domestic kitchen = 15 m^3 (default)

$R_{surface}$ = m_{24h} (mg) * h_{room} (m)/ V_{room} (m^3)

= 4 mg* 2.5 m /15 m^3 = 0.67 mg a.s./ m^2

Estimation of chronic consumer exposure

Residues deposited from air to surface = 0.67 mg/m^2 (calculation see above)

Area in contact with food = 0.26 m^2 (default)

Transfer factor (fraction of residue transferred from surface to food) = 100% (default)

Body weight = 10 kg / 60 kg (default value for toddler / adult)

Exp_{cons} = $R_{surface}$ (mg a.s./m^2) * $A_{food\ contact}$ (m^2) * TF/ bw (kg)

= 0.67 mg/m^2 * 0.26 m^2 * 100% ÷ 10 or 60 kg

$Exp_{cons,\ toddler}$: 0.0.017 mg/kg bw/d

6.2.2 Direct surface treatment

Insecticides may also be applied directly to surfaces. In this case it should be possible to know or calculate the amount of product used per square meter from the product information given by the Applicant. This value can then be used in the calculation to estimate dietary exposure for airspace applications. Alternatively, the direct surface treatment with insecticides could be compared with the use of disinfectants and cleaners

for surface cleaners (chapter 6.1), and the amount of product applied to the surface could be used in the calculation in this scenario.

6.2.3 Further considerations

Foreseeable mis-use may be incorporated into the estimation, for example the user forgets to switch off a vaporiser after maximal use duration of 12 hour, therefore consider 24 hour operation of the vaporiser

Other useful information or default values: (as given in OECD ESD for insecticides, acaricides and products to control other arthropods for household and professional uses):

- Private house: building 17.5 m long and 7.5 m wide, room height 2.5 m, living room 58 m3, default values for larger buildings available (Chapter 2.6 Building type of OECD ESD)
- More default values for application of insecticides available e.g. number of applications per day, size of treated area/volume (general, targeted spot application, larger building treatment), emission factors (floor, treated surface), spots of gel product per m^2 etc.

6.3 Drinking water disinfection

The Drinking Water Directive (Council Directive 98/83/EC on the quality of water intended for human consumption) must be followed for biocides used to disinfect drinking water at all stages before it is drawn from the tap. Drinking water disinfectants that are used at any point after that are within the scope of the BPR. Contamination of drinking water from application of biocidal products may occur for example in dispensers for water for human consumption, storage tanks for animal drinking water, preservation of water softening resins, direct addition to stored drinking water.

The disinfection of water with biocides (e.g. chlorinated and brominated disinfectants) leads to the inevitable formation of disinfection by-products (DBPs). The nature and amount of DBPs is related to the composition of the water, (i.e. the organic matter in the water), and it is not possible to predict beforehand which compounds will be formed and at which concentrations. This hampers a straightforward quantitative risk assessment based on comparisons with toxicological reference values. An approach for risk assessment of DBPs will be developed at Union level and will have to be followed for the DRA of active substances once available. Meanwhile, the formation of DBPs must be addressed qualitatively in the product assessment report and recommendations to minimize the formation of DBPs should be provided, for example via label instructions.

6.3.1 Assessment of disinfectants added to drinking water

Residues of disinfectants that are added directly to drinking water are estimated by assuming that they are present in the water in the amount of the application rate given on the label. The application rate is then multiplied by consumer intake rates for water and divided by body weight. Both water consumption data and default body weight should be derived from the EFSA database (see Appendix 2, section 2). Acute and chronic exposures have to be estimated separately using the following calculation:

$$Exp_{cons} = R_{application} * I_{water} * \frac{}{bw}$$

Where:

Exp_{cons}	dietary exposure (mg a.s./kg bw/d)
$R_{application}$	biocide application rate (mg a.s./L)
I_{water}	water consumption (L): average daily consumption for chronic exposure; 95^{th} percentile for acute exposure

bw body weight (kg)

6.3.2 Assessment of disinfectants used to treat water containers

Residues of disinfectants used to treat containers in which water is stored (e.g. water coolers) can be estimated with a generic approach assuming vessels of small volume with maximal surface area as a worst case (see Appendix 1 for default values). Acute and chronic exposures have to be estimated separately using the following calculation:

$$Exp_{cons} = R_{application} * A_{container} * \div V_{water} * TF * I_{water} \div bw$$

Where:

Exp_{cons}	dietary exposure (mg a.s./kg bw/d)
$R_{application}$	biocide application rate (mg a.s./m^2)
$A_{container}$	inner surface area of container (m^2)
V_{water}	volume of water in container (L)
TF	mass transfer efficiency factor (fraction of biocide residue transferred from inner container surface to water)
I_{water}	daily water consumption (L): average daily consumption for chronic exposure, high percentile for acute exposure
bw	body weight (kg)

Refinement options

- degradation of residues

6.4 In-can preservatives and disinfectants in dishwashing detergents

Biocidal active substances can be used as in-can preservatives (PT6) for a number of materials. Dishwashing detergents may contain in-can preservatives to stabilise or protect the product itself. They may also contain specific ingredients (e.g. silicone based defoamers) that are equipped with an in-can preservative. In addition to in-can preservatives, dishwashing detergents may also contain antibacterial agents (PT4) intended to kill bacteria on dishes and on hands. Sponges used for hand dishwashing can also be treated with disinfectants before use. Indirect oral consumer exposure can originate from biocide residues present on eating utensils and crockery cleaned with the dishwashing liquid or the disinfected sponge. The amounts of active substance carried over into foods in this way are generally expected to be minimal, nevertheless, a dietary exposure estimate should be carried out. Products are available for dishwashing by hand or with a dishwashing machine. The same default values apply to both cases, except for the concentration of detergent in the dish wash solution, where separate values are given for hand and machine dish washing.

6.4.1 Assessment approach

Dietary exposure can be estimated using the following calculation according to the HERA guidance document. The default values can be found in Appendix 1, Table 4. For long-term dietary exposure it can be assumed as a worst case that the scenario takes place daily.

Estimation of dietary exposure

$$Exp_{cons} = [F1 * C' * T_a' * S_a * F] \div BW$$

Where:

Exp_{cons}	dietary exposure (mg a.s./kg bw/d)
F_1 :	percentage of a.s. in dishwashing detergent
C´ :	concentration of detergent in dish wash solution (mg/L)
T_a´:	amount of water left on dishes after rinsing
S_a :	area of dishes in daily contact with food
F :	percentage of a.s. transferred from article and ingested
bw :	body weight

Example 3: In-can preservatives and disinfectants in dishwashing detergents

F_1 :	0.04 %	(value given by the Applicant)
C´ :	1400 mg/L	(value given by the Applicant)
T_a´:	5.5 x 10^{-8} L/cm^2	(default value)
S_a :	5400 cm^2	(default value)
F :	100%	(default value; refinement possible if based on real data)
BW :	10 kg / 60 kg	(default value for toddler / adult)

Exp_{cons} = [F_1 * C' * T_a' * S_a * F] ÷ bw

= [(0.0004) * (1400 mg/L) * (5.5x10^{-8} l/cm^2) * (5400 cm^2) * (1)] ÷ 10 or 60 kg

$Exp_{cons, adult}$: 2.77 x 10^{-6} mg/kg bw/d

$Exp_{cons, toddler}$: 1.66 x 10^{-5} mg/kg bw/d

7. Aggregate risk assessment

For a biocidal a.s. leading to exposure through more than one route (e.g. dietary and dermal), through more than one use (e.g. professional and non-professional), that is used in more than one PT and/or in more than one regulatory area (e.g. plant protection products, veterinary medicines, food contact materials or food additives), an aggregate risk assessment[2] should be conducted. No EU-wide harmonised guidance exists on how to perform aggregate risk assessments and therefore, in the absence of such a procedure, no aggregate dietary risk assessments will be proposed until respective guidance can be developed.

The concept of aggregate risk assessment is also relevant in the evaluation of a single biocidal use. In this case it refers to combining dietary and non-dietary exposures into a single exposure estimate. (see *Guidance on Biocidal Products Regulation: Volume III Human Health, Part B Assessment)*

[2] Aggregate risk assessment refers to the assessment of the total exposure to one substance resulting from more than one exposure path (oral, dermal, inhalation and dietary exposure) and/or from more than one use (uses in all relevant product types and uses in other regulatory frameworks).

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Appendix 1. Example

1 General default values for disinfectant and preserved cleaner, insecticides, drinking water disinfection and in-can preservatives in dishwashing detergents

Table 4: General default values

No.	Description	Default Values	Background Information: Remarks	References
5.1. Disinfectants and preserved cleaners in domestic kitchens				
7	**Area in contact with food (acute and chronic exposure)**	0.2 m^2		In the US EPA model for assessing disinfectant residues, a value of 0.2m^2 is used for surface area in contact with food. The value is based on a value of 0.4 m^2 which was used by FDA to evaluate food contact sanitizing solutions. The actual basis of this value cannot be documented from FDA sources, but its use is documented. The FDA value reflects surface area of all silverware, dishes and glasses that a person uses in an institutional setting for 3 meals a day. For the purpose of the US EPA model, the FDA value was cut in half, to reflect only counter top surfaces.
8	**Mass transfer efficiency factor**	100%	worst case; may be changed based on product specific data on mass transfer efficiency	-
5.2. Insecticides in residential homes				
9	**Room height**	2.5 m		OECD ESD for insecticides etc for household and professional uses
10	**Room volume (kitchen)**	15 m^3		General Fact Sheet, RIVM report 320104002/2006
11	**Area in contact with food (acute exposure)**	0.53 m^2	Combination of three surface components: a) area of food contact on kitchen counter b) area of exposed dishes with food contact c) area of exposed food	The derivation of the area in contact with food is explained in Appendix 1 , section.2.
12	**Area in contact with food (chronic exposure)**	0.26 m^2	Combination of three surface components: a) area of food contact on kitchen counter b) area of exposed dishes with food contact c) area of exposed food	The derivation of the area in contact with food is explained in Appendix 1, section.2.
13	**Mass transfer efficiency factor**	100%	worst case; may be changed based on product specific data on mass transfer efficiency	-

5.3. Drinking water disinfection				
14	volume of water container	5 L	A small volume container is considered the worst case.	-
15	Inner surface area of 5-L water cooler	0.18 m^2	Assuming a cylindrical 5-L water cooler with a base diameter of 14 cm, the height is: $V = \pi r^2 h \rightarrow h = V/\pi r^2 =$ 5000 cm^3/π 49cm^2 = 33 cm Then the inner surface area is: $A = 2\pi r^2 + 2\pi rh =$ 1760 cm^2 = 0.18 m^2	-
16	**Mass transfer efficiency factor**	100%	worst case; may be changed based on product specific data on mass transfer efficiency	-
17	**Daily water consumption**	see Appendix 2, section 2		
5.4. In-can preservatives in dishwashing detergents				
18	**Concentration of detergent in dish wash solution**	1400 mg/L		Weegels M.F. (1997), Exposure to chemicals in consumer product use. Faculty of Industrial Design Engineering, Delft University of Technology. The Netherlands.
19	**Amount of water left on dishes after rinsing**	5.5 x 10^{-5} mL/cm^2	This value was assigned a quality factor of 2, i.e. it is based on a single data source supplemented with personal judgment. The quality factors range from 1 to 4, where 1 means low quality and 4 means high quality. It is based on the value given in the HERA guidance 5.5 x 10^{-4} mL/cm^2 taking into account a dilution factor of 1/10 after one rinsing	HERA guidance document Methodology, February 2005
20	**Area of dishes in daily contact with food**	5400 cm^2		HERA guidance document Methodology, February 2005
21	**Mass transfer efficiency factor**	100%	worst case; may be changed based on product specific data on mass transfer efficiency	-
Miscellaneous				
22	**Body weight**	see HEEG		

		opinion 17		

2. Derivation of the area in contact with food used in the scenario for domestic insecticides (see default values 11 and 12 in Table 1)

The use of vaporised insecticides in homes can lead to residues on food that is stored uncovered on counters as well as on food contact surfaces such as kitchen counters and dishes stored in open cupboards and on racks. Dietary exposure to these residues is estimated using the size of the surface in contact with the food consumed daily. For the insecticide scenario, the following default values have been set for the size of these surfaces. Each default value represents a combination of three components:

Table 5: Total area of food contact

	acute exposure	chronic exposure
area of food contact on kitchen counter	0.2 m^2	0.1 m^2
area of exposed dishes with food contact	0.27 m^2	0.135 m^2
area of exposed food	0.06 m^2	0.02 m^2
Total area of food contact	**0.53m^2**	**0.26m^2**

The **area of food contact for residues on the kitchen counter** is based on the corresponding value from the scenario for disinfectants and preserved cleaners in domestic kitchens (0.2 m^2, see default value 7 in Table 4, Appendix 1). For the **acute** scenario, this value applies unchanged. For the **chronic** scenario, a factor of 50% is applied (i.e. 0.2 m^2 * 50% = 0.1 m^2) to reflect the fact that vaporisers are not used on a daily basis throughout the year (national specific conditions may apply for certain overseas locations of different climatic conditions).

The **area of exposed dishes with food contact** is based on the corresponding value from the scenario for dishwashing detergents (0.54 m^2, see default value 16 in Table 1, Appendix 1). For the **acute** scenario, this value is reduced by 50% to reflect the fact that not all dishes will be exposed to the biocidal product (i.e. 0.54 m^2 * 50% = 0.27 m^2). Table I.3 details why the factor of 50% is justified. For the **chronic** scenario, the value is reduced by an additional 50% to reflect that vaporisers are not used on a daily basis throughout the year (i.e. 0.54 m^2 * 50% * 50% = 0.135 m^2).

Table 6: Area of exposed dishes with food contact

	Average size (cm)	**Single object area (cm^2)**	**Objects used per day**	**Allocated total area (cm^2/day)**	**Scenario / Exposed food contact surface**	**Exposed food contact surface (cm^2)**
Plates						
Dinner plate	Ø 24	450	3 dinner plates	1350	3 plates piled up = 100% of upper plate	450
					3 plates stored vertically in a rack = max 33% of each object's food contact surface	450
Soup plate (deep part without rim); flat dessert or side plate	Ø 20	300	3 soup, side, dessert plates + 1 dinner plate		3 different piles: soup plates side plates dinner plates = 100% of upper plates	1050
					all stored vertically in a rack = max 33% of each object's food contact surface	450
Subtotal						**450 - 1050**
Cups/mugs & glasses	Ø 8 h 11	300	3 cups and/or glasses	900	all stored up side down = 0%	0
					3 coffee, tea, beer mugs hanging on a rack = 33% of each object's food contact surface	300
					3 glasses or mugs piled up to single pile =100% of upper object	300
					2 piles for glasses & cups/mugs resp. =100% of upper object	600
Subtotal						**0 - 600**

Cutlery (set of knife, fork, spoon)		40	3 sets	120	in drawer	0
Pots & pans						
1.5 L Saucepan or small frying pan	Ø 16 h 8	600	any combination of 3 small or 2 small + 1 big, or 2 big saucepans / pans	~2200	hanging on a wall or ceiling rack = 33% of each object's food contact surface	720
3-4 L saucepan, casserole or frying pan	e.g. Ø22, h 11 or Ø 26, h 7 or Ø28, h 5	1000-1100			piled up on shelf, smallest object on top = 100% of biggest objects surface (to consider uncovered parts of any object)	1000
Subtotal						**720 - 1000**
Cooking Utensils						
Cutting knifes				10	in knife block or drawer = 0%	0
Scoop, spatula, ladle, whisk , wooden spoon etc.				similar to 1 set of cutlery ~ 40	vertically in utensils holder or hanging on rack = max 100% of each object's food contact surface	40
Bowl	Ø 20 h 8		1 mixing bowl	750-800	on shelf, sorted and piled up = 100% of food contact surface of upper object	800
	Ø13 h 6		or 2 small bowls			375
Subtotal						**415 - 840**
TOTAL				~5400		**1585 – 3490** **30% - 65%**

If all of the 'highest exposure' scenarios are combined to a very worst case scenario, 65% of the total area in food contact of 5400 cm^2 will be exposed. Creating different scenarios (other than the worst case) out of the possibilities given in the table above, nearly all of the combinations will lead to an exposed area that is smaller than or approx. equal to 50% of the default value of 5400 cm^2.

It should be noted that for the scenarios of piled up objects also the vertical inner surfaces of bowls, saucepans, mugs etc. were considered as fully exposed areas (as if

horizontal) which may in reality not be the case - exposure of these areas may be dependent on the design of the object and could be much lower.

In conclusion, a value of 50% of default value of 5400 cm^2/day, i.e. **2700 cm^2/day** is considered a reasonable and conservative estimate for the exposed surface area of dishes stored openly in a domestic kitchen or dining area.

The **area of exposed food** was determined based on the fact that only certain foods are likely to be stored uncovered, e.g. fruits like apples or peaches, tomatoes, cucumbers or bread and other bakery products. Consumption and unit weight data were extracted from the EFSA PRIMo rev.2 and for comparison from the EFSA Comprehensive European Food Consumption Database (CEFCD) in order to determine consumption of fruits and vegetables and estimate the corresponding food surface area. Details are given in Table 7 (chronic consumption) and Table 8 (acute consumption).

Table 7: Area of exposed food (chronic consumption)

i) EFSA PRIMo rev.2 Mean consumption data

	Unit weight, edible portion [g]	Estimated unit surface [~ cm2]	exposed surface default [%]	Food consumption [g/day]			rate p&p [~ %]	Units of fruit/vegetable consumed per day (other than p&p)			Corresponding area 'consumed'					
											absolute [~ cm2 / day]			relative [~ cm2 /kg bw/ day]		
				PT	LT	IE		PT	LT	IE	PT	LT	IE	PT	LT	IE
Fruit																
Apples	131.8	200	75	63.0	130.7	59.7	50	0.239	0.496	0.226	36	74	34	0.60	1.06	0.45
Pears	158.4	230	75	20.3	11.1	17.6		0.128	0.070	0.111	22	12	19	0.37	0.17	0.26
Apricots	40.1	80	75	1.1	0	11.4	50	0.014	0.000	0.142	1	0	9	0.01	0.00	0.11
Cherries	7.0	20	75	2.2	1.9	1.6	30	0.220	0.185	0.160	3	3	2	0.06	0.04	0.03
Peaches	123.5	150	75	21.4	0	42.8	30	0.121	0.000	0.243	14	0	27	0.23	0.00	0.36
Plums	53.3	80	75	0.9	1.9	23.4		0.017	0.036	0.439	1	2	26	0.02	0.03	0.35
Table grapes	581.6	1000	55	16.7	0.9	19.5		0.029	0.002	0.034	16	1	18	0.26	0.01	0.25
Fruiting vegetables																
Tomatoes	102.6	100	75	53.7	43.4	30.2	30	0.366	0.296	0.206	27	22	15	0.46	0.32	0.21

Peppers	160.0	310	75	11.6	1.4	10.3		0.073	0.009	0.064	17	2	15	0.28	0.03	0.20
Cucumbers	411.4	500	75	1.6	27.4	8.0		0.004	0.067	0.019	1	25	7	0.02	0.36	0.10
Total fruit & vegetables				192.5	218.7	224.5					**138**	**142**	**174**	**2.3**	**2.0**	**2.3**

ii) EFSA Comprehensive European Food Consumption Database Which version was used? Needs to be updated when new release comes

Mean consumption data - chronic

	Unit weight, weighted mean [~ g]	Estimated unit surface, weighted mean [~ cm2]	Exposed surface default [%]	Food consumption of 70 kg adult [g/day]			Units of fruit/vegetable consumed per day			Corresponding area 'consumed'					
										absolute [~ cm2 / day]			relative [~ cm2 /kg bw/ day]		
				IT	ES	DK	IT	ES	DK	IT	ES	DK	IT	ES	DK
Pome fruits	140	210	75	72.6	79.1	70.4	0.52	0.57	0.50	82	89	79	1.2	1.3	1.1
Stone fruits	90	115	75	28.4	24.8	9.3	0.32	0.28	0.10	27	24	9	0.4	0.3	0.1
Fruiting vegetables	170	200	75	129.1	93.3	83.1	0.76	0.55	0.49	114	82	73	1.6	1.2	1.1
Total fruit & vegetable				230.1	197.2	162.8				**223**	**195**	**161**	**3.2**	**2.8**	**2.3**

Based on EFSA PRIMo rev.2 the top 3 highest chronic consumption of fruit& vegetables under consideration was obtained for Portugal (General population, bw 60 kg], Lithuania [Adult, bw 70kg] and Ireland [Adult, bw 75.2 kg]. EFSA CEFCD permitted only for extraction of aggregated data for the group of pome fruit, stone fruit and fruiting vegetable, respectively. Highest chronic consumption of adults was found for Italy, Spain and Denmark. A mean bw of 70 kg was applied to these data.

Surface area was roughly estimated based on the simplified assumption that all fruits were spheres and that cucumber were a cylinder of 30 cm length, using a rounded value for the diameter of the fruits. For the aggregated groups a mean unit weight and area was determined, weighted by the approximate ratio of consumption of individual crops in a group. With the exception of table grapes, where a greater part of the surface area is protected when considering the surface of the single berries, an exposed surface area of 75% is assumed for each fruit (given the bottom side is unlikely to be exposed). Where it is known that a considerable amount (> 25%) of the fruit or vegetable is usually consumed as processed and packaged (p&p) commodities (e.g. juice, jam, sauce, preserve), an additional factor was introduced for EFSA PRIMo data to account for the amount of food that will not be exposed in the considered scenario. EFSA CEFCD data permit the separate extraction of processed fruit and vegetable data, thus an additional factor was not used.

Result: Based on EFSA PRIMo rev.2, the estimated chronic exposure from openly stored fruits and vegetables will be around **2-2.3 cm^2/kg bw daily** (based on data for adults). This is confirmed by EFSA CEFCD data for Pome fruit and Stone fruit. The result is approximately twice as high for Fruiting vegetables due to the aggregation of data and the likely inclusion of additional crops (e.g. melons, aubergines, zucchini) in this group which are not relevant for the scenario considered here.

→ For the '60 kg adult' considered in this draft guidance document, the daily chronic exposure through fruits and vegetables would be around 140 cm^2. An overall value of 200 cm^2 provides a sufficiently big margin to also incorporate potentially contaminated bread, cake etc.

Table 8: Area of exposed food (acute consumption)

EFSA Comprehensive European Food Consumption Database 95th percentile acute consumption data															
	Unit weight, weighted mean [~ g]	Estimd. unit surface, weighted mean [~ cm^2]	Exposed surface, default [%]	Food consumption of 70 kg adult [g/day]			Units consumed per day			Corresponding area 'consumed'					
										absolute [~ cm^2 / day]			relative [~ cm^2 /kg bw/ day]		
				PL	LV	EE	PL	LV	EE						
Total fruit and fruit products				873.9	620.0	572.7									
Pome fruits	140	210	75	759.0	560.9	560.0	5.4	4.0	4.0	854	631	630	12	9.0	9.0

% of total				87	91	98									
				SL	ES	IT	SL	ES	IT						
Total fruit and fruit products				700.0	654.1	589.8									
Stone fruits	90	115	75	700.0	608.2	523.1	7.8	6.8	5.8	671	583	501	9.6	8.3	7.2
% of total				100	93	89									

A higher level of aggregation of consumption data can be useful when considering acute exposure to residues from more than one type of food. In contrary to the Pesticides assessment where it is assumed that different food items consumed within 24 h do not contain residues of the same substance, this must be considered for the food items exposed to residues from the insecticide vaporiser use. Values were calculated as for the chronic data. Fruiting vegetables were not considered for the reasons stated above. If compared to the Total fruit and fruit products consumption it can be deduced that the estimates for Stone fruits and Pome fruits will indeed be a good approximation of the 'total' acute intake of commodities of interest. Highest acute intake was ~**12 cm^2/kg bw/day** (pome fruits) and **~9.6 cm^2/kg bw/day** (stone fruits)

→ **For the 60 kg adult considered in this draft guidance document, the daily exposure would be 570 to 720 cm^2**, which corresponds well to a default figure of 600 cm^2.

Appendix 2. Default age groups, body weights and water consumption

1. Age groups for dietary risk assessment of biocidal products used by non-professionals.

Children in general can be considered more sensitive consumers than adults because they have a higher relative food intake (i.e. per kg bw) and are generally more sensitive to the toxic effects of chemicals. Due to the many developmental stages that influence behaviour, diet and sensitivity toward chemicals, children are further subdivided into "infants", "toddlers" and "older children".

According to the EFSA Scientific Opinion on Default Values, infants of age 3-6 months have the highest food intake on a body weight basis (132.4 g/kg bw/d). However, they consume mainly breast milk and formula milk. Since their diet differs considerably from that of the remaining population, they cannot be regarded as representative for the entire population and most dietary exposure scenarios do not apply to them. The age group with the next highest relative food intake are the 1-3 year old toddlers (114.4 g/kg bw/d). Their diet consists of many of the solid foods which adults eat as well. Toddlers should therefore be regarded the worst case with regard to dietary risk assessment.

Non-dietary risk assessment of non-professionals currently considers three age groups: infants, older children and adults. Of these age groups, it is the infant who reflects the worst case in most non-dietary exposure situations. Toddlers are not a defined age group in non-dietary risk assessment, but the infant scenarios were in fact built to include typical toddler behaviour (e.g. mouthing of objects). Considering this, toddlers may be regarded to represent the worst case in both dietary and non-dietary risk assessment and therefore cover the entire population of children.

With a view to avoid unnecessarily complex assessment scenarios, risk assessment for children should be limited to one age group, namely toddlers. In addition, exposure should routinely be calculated for the adult.

There may be special circumstances where another age group represents the worst case. In these cases, exposure should additionally be assessed for the most exposed age group.

2. Default body weight and water intake values

The HEEG Opinion 17, "Default human factor values for use in exposure assessments for biocidal products", provides the default body weight according to the age (infant, toddler, child, adult) to be used in the exposure assessment for biocidal product.

In the water drinking scenario, the water consumption values are required and the EFSA database should be used. The EFSA default body weights differ from the HEEG opinion, but since the water consumption is calculated based on the body weight, the EFSA default body weights should be used in the water drinking scenario instead of HEEG default values.

Appendix 3. Information provided by the applicant and from other regulatory areas

Table 9: Information to be provided by the Applicant

Information relating to the intended use
- target species/organisms - application method - frequency of treatments - application rate - concentration of active substance in product and in in-use product (e.g. in the spray formulation) - detailed description of areas to be treated (e.g. countertops, specified equipment, spot treatment) - product formulation It should be clearly specified in the intended use description provided by the Applicant whether every treatment is performed with the same application rate or if refresher treatments subsequent to the initial treatment are applied at a different rate.
Information relating to the active substance
- physic-chemical properties - degradation/volatilisation rate (environmental part of the dossier)

Table 10: Information on risk assessment from other regulatory areas

Plant Protection Products	
EU Pesticide database	http://ec.europa.eu/sanco_pesticides/public/index.cfm
Guidelines for pesticide residues	http://ec.europa.eu/food/plant/protection/pesticides/publications_en.htm
RMS Assessment Reports submitted for the EU peer review of active substances used in plant protection products	http://dar.efsa.europa.eu/dar-web/provision
JMPR Reports	http://www.who.int/foodsafety/publications/jmpr-reports/en/
Veterinary Medicinal Products	
EMA Summary Reports/ Summary Opinions	http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000433.jsp
JECFA Reports	http://www.codexalimentarius.net/web/jecfa.jsp
Food and Feed Additives	
EFSA: Evaluations of the Panel on food additives and nutrient sources added to food (ANS)	http://www.efsa.europa.eu/EFSA/ScientificPanels/ans/efsa_locale-1178620753812_1211902601909.htm
EFSA: Evaluations of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)	http://www.efsa.europa.eu/en/panels/fip.htm
EFSA: Evaluations of the FEEDAP Panel (Additives and products or substances used in animal feed)	http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_FEEDAP.htm
Food Contact Materials	
EFSA Note for Guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation	http://www.efsa.europa.eu/fr/efsajournal/doc/21r.pdf

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