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Substitution of critical biocidal active substances under European law – Development of a comparative assessment concept for the environment

Final Report

For our Environment

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Substitution of critical biocidal active substances under European law – Development of a comparative assessment concept for the environment

Final Report

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Abstract

Authorisation of biocidal products in the European Union is a two-stage process, where the biocidal active substances are approved in a first step at the European level, and the biocidal products are authorised in a second step at member state level. If an active substance is designated as Candidate for Substitution (CFS) during this process, a comparative assessment must be carried out for each biocidal product containing this CFS by the competent authority. The aim of the current project was to evaluate the practicability of the existing technical guidance for this procedure by conducting a number of exemplary comparative assessments, and to develop recommendations for improvements. The analysis of the existing guidance revealed that essential concepts are only vaguely defined and would need considerable expert judgement and *ad hoc* decisions to be applied within a comparative assessment. The here developed recommendations relate to the definition of a product's intended uses, which are subject to a comparative assessment, and the requirement for chemical diversity of active substances in authorised products that currently often leads to a stop of the comparative assessment. Further recommendations relate to the use of risk mitigation measures and various hazard indices for a qualitative comparative assessment, and a standardised process of a quantitative, risk-based comparative assessment using recalculated risk quotients as decisive step. It is acknowledged that particularly the recommendations regarding the risk-based comparison may result in a considerable workload related to the comparative assessment of biocidal products. However, such efforts appear to be a precondition for a sound and defensible comparison of environmental risks. This could not be obtained by comparing risk quotients that were derived using different assumptions for the products within the assessment.

Kurzbeschreibung

Die Zulassung von Biozidprodukten in der Europäischen Union ist ein zweistufiger Prozess, in dem die bioziden Wirkstoffe zunächst auf europäischer Ebene genehmigt werden, und die Biozidprodukte in einem zweiten Schritt auf der Ebene der Mitgliedsstaaten zugelassen werden. Wenn ein Wirkstoff in diesem Prozess als Substitutionskandidat eingestuft wurde, muss im Rahmen des Zulassungsverfahrens von Biozidprodukten, die diesen Wirkstoff enthalten, eine vergleichende Bewertung durch die zuständige Behörde durchgeführt werden. Das Ziel dieses Projektes war es, anhand der beispielhaften Durchführung einiger vergleichender Bewertungen die Praktikabilität des dazu vorliegenden technischen Leitfadens zu prüfen und Vorschläge für Verbesserungen zu entwickeln. Die Analyse des vorliegenden Leitfadens zeigte, dass wesentliche Konzepte nur vage definiert sind, so dass eine vergleichende Bewertung in erheblichem Ausmaß von Experteneinschätzungen und *ad hoc*-Entscheidungen abhängt. Die im Projekt entwickelten Verbesserungsvorschläge betreffen insbesondere die Definition der Verwendungen des relevanten Produktes, welche konkret der vergleichenden Bewertung unterliegen, sowie die Anforderung an die Diversität der Wirkstoffe in zugelassenen Produkten, durch die eine vergleichende Bewertung derzeitig oft frühzeitig beendet wird. Weitere Empfehlungen betreffen die Nutzung von Risikominderungsmaßnahmen und Gefahrstoffeinstufungen als Kriterien für einen qualitativen Vergleich und ein standardisiertes Vorgehen bei einem quantitativen, risikobasierten Vergleich, der auf neu zu berechnenden Risikoquotienten beruhen sollte. Zugegebenermaßen werden die vorgeschlagenen Verbesserungen, insbesondere im Hinblick auf den risikobasierten Vergleich, voraussichtlich zu einer erheblichen Erhöhung des Arbeitsumfangs der für die vergleichende Bewertung von Biozidprodukten zuständigen Behörden führen. Allerdings wird dieser Aufwand als Voraussetzung angesehen für einen tragfähigen und vertretbaren Vergleich von Umweltrisiken. Dies könnte nicht erreicht werden basierend auf Risikoquotienten, die unter unterschiedlichen Annahmen für die zu vergleichenden Produkte hergeleitet wurden.

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List of Abbreviations

a.s.	Active substance
ACP	Ant Control Product
BP	Biocidal Product
BPR	Biocidal Product Regulation
CA	Competent Authority
CAR	Competent Authority Report
CFS	Candidate for Substitution
d.w.	Dry weight
$DegT_{50}$	Degradation half life
$DissT_{50}$	Dissipation half life
DMI	Demethylase Inhibitor
DT_{50}	Degradation/Dissipation half life
ECHA	European Chemicals Agency
EC_x	Concentration with x% effect
ERA	Environmental Risk Assessment
ESD	Emission Scenario Document
EU	European Union
FRAC	Fungicide Resistance Action Committee
H/P	Hazard and Precautionary (statement)
LCA	Life Cycle Assessment
MoA	Mode of Action
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PAR	Product Assessment Report
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PPP	Plant Protection Product
PPPR	Plant Protection Product Regulation
PT	Product Type
R4BP	Register for Biocidal Products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Mitigation Measures
RQ	Risk Quotient

SoC	Substance of Concern
SPC	Summary of Product Characteristics
STP	Sewage Treatment Plant
SVHC	Substance of Very High Concern
TER	Toxicity Exposure Ratio
TGN	Technical Guidance Note
UBA	Umweltbundesamt (German Environment Agency)
vB	Very Bioaccumulative
vP	Very Persistent
w.w.	Wet weight
WP	Work Package
ZB	Zulassungsbescheid (Authorisation letter)

Summary

Authorisation of biocidal products in the European Union (EU) is a two-stage process, where the biocidal active substances (a.s.) are approved in a first step at the European level, and the biocidal products are authorised in a second step, in general at member state level. Depending on certain criteria specified in Article 10 of the Biocidal Product Regulation (BPR), a.s. can be designated as Candidates for Substitution (CFS) during the (re-)approval process at European level. These criteria are based on properties like persistence, potential for bioaccumulation, ecotoxicity, potential for endocrine disruption, toxicity towards humans, potential to be transferred to groundwater, or purity of the technical active substance. If an a.s. is designated as a CFS, a comparative assessment must be carried out for biocidal products containing this a.s. by the competent authority during the authorisation process.

A Technical Guidance Note (TGN) was provided by the European Commission to facilitate the implementation of this procedure. The TGN foresees a tiered approach in which first eligible alternative products are identified for the relevant product, which contains the a.s. identified as CFS. In the subsequent screening step, the chemical diversity of active substances among the alternative products and the question whether the CFS fulfils one or more of the exclusion criteria listed in Article 5 of the BPR are addressed. If the comparative assessment is not already stopped in the screening step due to inadequate chemical diversity, the TGN provides several decision trees that guide the further assessment either to a comparison with non-chemical alternatives (Tier II), a comparison of the relevant with alternative products based on qualitative criteria (Tier I-A) such as Hazard and Precautionary statements (H/P statements) and Risk Mitigation Measures (RMMs), or a comparison based on quantitative criteria (Tier I-B) such as risk quotients.

The aim of the current project was to evaluate the practicability of this existing guidance by conducting a number of exemplary comparative assessments. Based on this experience an improved guidance should be developed with respect to environmental hazard and risks, so that the reliance on expert judgement is minimised. Given that the approach should be harmonised among member states and that the final agreement of the member states (MS) on the draft TGN was achieved just prior to project start, it was agreed that no fundamentally new guidance should be developed. Rather, recommendations and improvements to the existing TGN should be provided through the project.

An analysis of the existing TGN in a first step revealed that essential concepts were only vaguely defined, and would need considerable expert judgement and *ad hoc* decisions to be applied within a comparative assessment. These essential concepts include for example the characterisation of the relevant product (i.e. the product containing the CFS in question) as outlier with regard to the previously identified alternative products, the definition of a 'significant lower overall risk', and the comparison of risk quotients. From the first evaluation of the TGN, it was concluded that the procedure will have to be defined much clearer if comparative assessments are to provide a robust basis for the substitution of a biocidal product that would otherwise be suitable for authorisation.

In the next step, exemplary comparative assessments were conducted to identify limitations, problems and gaps of the current guidance. For this exercise, wood preservative products and ant control products were selected as representatives of two different product types (PTs). For each of the two PTs, three different uses were subjected to an exemplary comparative assessment. The relevant and eligible alternative products were selected among those authorised products for which authorisation dossiers or at least summary of product characteristics (SPC) were available to the German Environment Agency. Since this pool of products available for the present project did not represent all available alternative products on the market, the comparative assessments conducted here are clearly an exemplary exercise that does not imply any regulatory consequences for any of the individual products. It is important to note that a comparative assessment relates to the intended uses of a product, not to the product as such. The steps of assessing non-chemical alternatives, economic disadvantages, and the overall risk taking human and animal health into account were omitted from the case studies as this

was beyond the scope of the present project. In order to gain as much experience as possible, the comparative assessment continued in all cases until the final steps, i.e. Tier I-B, regardless of stop criteria such as inadequate chemical diversity.

For the wood preservative products, the following three intended uses, defined as suggested by the TGN, were selected for the comparative assessment: 1) targeting wood destroying fungi – use class 3 – non-professional user – brushing application; 2) targeting wood destroying fungi – use class 3 – professional user – brushing application; 3) targeting wood disfiguring fungi – use class 3 – industrial user– dipping application. The same relevant product was selected for the intended uses 1 and 2, but a different one for the intended use 3. All relevant products contained the active substance tebuconazole as CFS, which was also contained in some of the alternative products. The number of alternative products ranged from two to five. None of the three relevant products was identified as outlier in a Tier I-A assessment, i.e. they had in the meaning of the TGN no significantly worse profile than the majority of alternative products. A quantitative assessment according to Tier I-B could not be conducted for the wood preservative products, because for none of the three intended uses risk quotients for the relevant and the alternative products were available for the same compartments at the same level of refinement.

For the ant control products, three intended uses, all targeting the black garden ant *Lasius niger*, were selected for the comparative assessments: 1) Outdoor use by non-professionals via nest application; 2) Indoor use by non-professionals via bait box application; 3) Outdoor use by professionals via gel baits. The relevant product in the intended use 1 contained spinosad as CFS, while fipronil was contained in the relevant products of intended uses 2 and 3. Spinosad, but not fipronil was also contained in some of the respective alternative ant control products. The application method was not used as criterion in the mapping step, resulting in alternative products being identified that had a different application method than the relevant product. The number of alternative products ranged from four to eight. For none of the intended uses, an unequivocal decision was achievable regarding the identification of the relevant product as outlier in a Tier I-A assessment according to the TGN. In order to conduct a quantitative comparative assessment according to Tier I-B, an effort was made to re-calculate risk quotients for the soil compartment using the same scenarios and mostly identical assumptions and scenarios for the calculations for all products. The resulting risk quotients differed by more than factor 10 between the relevant and several alternative products for the intended use 1, but not for the intended uses 2 and 3. This finding indicated that substitution of the relevant ant control product in the intended use 1 could be justified. However, it remains open whether the comparison of products applied by very different methods based on highly unified assumptions can be seen as appropriate. Similar to the outcome of the Tier I-A, the result of the Tier I-B for the intended use 1 of the ant control products was not unequivocal, although it suggested that substitution of the relevant product could be justified under certain assumptions. Yet, in both cases this result was clearly dependent on the application method, i.e. nest application as open environmental application in contrast to the more contained application of the alternative products in bait boxes. Hence, the substitution decision of the comparative assessment was mainly related to the application method, but not to the properties leading to the CFS status.

Overall, it was found during compilation of the relevant data for the qualitative comparative assessment that RMMs are not yet well standardised in terms of wording across different products, product types, and competent authorities. This rendered the comparison of the strictness of the RMMs rather ambiguous. Hence, the current effort of competent authorities to establish harmonised terms for RMMs that are agreed among member states could also be helpful for future comparative assessments. Another finding from the exemplary assessment was that RMMs could not be identified from the SPC alone, and it was often not clear whether they were formally RMMs, i.e. established due to identified risks, or rather conditions of use prescribed by the applicant. The same requirement (e.g. application of a top coat after application of the wood preservative product) represented for one product a formal RMM resulting from identified risk and a condition of use for another product. However, it remained

open if a risk assessment without the consideration of this condition of use would have resulted in a RMM requiring a top coat. Therefore, the differentiation between conditions of use and RMM appeared arbitrary and rather questionable in the context of a comparative assessment.

Based on a detailed deficit analysis, a number of recommendations were developed within the project to improve transparency and decrease the need for expert judgement in future comparative assessments. The tiered approach of the TGN that aims at reducing the number of complex quantitative comparative assessments by setting filtering steps is fully supported. However, the complexity of the current framework could be reduced by establishing only three tiers (screening step, Tier I and Tier II) and by foreseeing fewer possible pathways through the decision trees of the individual tiers.

Substantial effort was invested within the project for the first step of the comparative assessments, the identification of eligible alternative products. As a consequence, it is recommended to increase the degree of harmonisation and standardisation of the terms relevant for the use description within the six categories defined by the TGN. Since the identification of eligible alternative products is a critical step that can considerably reduce the workload in later steps of the comparative assessment, it is further recommended to extend the type of information required for the definition of the intended use. Most importantly, the application aim, which is linked to efficacy claims for the product, and any restrictions regarding the field of use should be included. Both criteria can render a potential alternative product non-eligible. Excluding such products as alternatives in the procedure as early as possible will not only improve efficiency, but also help avoiding wrong decisions, e.g. with regard to the remaining chemical diversity. The most suitable tool for this improvement would be a database into which all intended uses of biocidal products are entered upon authorisation using standardised description terms. Intended uses should be entered as combination of (1) the product type, (2) the exact description of the intended use, (3) the function of the active substances and the taxa group, species and developmental stages of the targeted organisms, (4) the field of use including any restrictions, (5) the user category, and (6) the application aim and method. Having the proposed additional information available in an easily accessible digital database would considerably help in quickly narrowing down the number of potential alternative products and in obtaining the requirements for eligible non-chemical alternatives.

Chemical diversity is stated in the TGN as the criterion that can lead to the stop of the comparative assessment in the screening step. This criterion is solely based on the argument of preventing resistance development. The TGN suggests three active substance/mode of action combinations remaining after restriction of the relevant product as adequate chemical diversity. It is recommended to further specify this criterion by stating that restriction of the relevant product should not reduce the diversity in authorised products below the level that is deemed adequate. This formulation would prevent stopping the comparative assessment in cases were chemical diversity is low already, but a meaningful number of products qualify as alternatives within the mode of action (MoA) group represented by the relevant product. This would allow to implement restrictions for the CFS-containing product with the worst risk profile within this MoA group without further reducing chemical diversity. In addition, the criterion of chemical diversity should be extended to 'diversity' only, i.e. include also micro-organisms authorised as active substances under the BPR.

The aim of the Tier I-A according to TGN is to direct the comparative assessment either to Tier I-B or Tier II, while stopping the comparative assessment in Tier I-A is no option. In order to reduce the complexity and redundancy of the current flow charts, it is recommended to direct a continuing comparative assessment at the end of the screening phase either to Tier I or Tier II, and thereby omit Tier I-A. Tier I-A is based solely on RMMs and H/P statements. Particularly RMMs were found not suitable for a comparative assessment. First of all, RMMs are no indicators of remaining risk, which should be compared among the products according to the TGN. Secondly, RMMs are currently hardly standardised and harmonised, which makes their usage, and particularly decisions about their relative strictness, very cumbersome and ambiguous. Thirdly, RMMs can often not be distinguished from conditions

of use, and it is highly questionable that such a distinction would actually be meaningful with regard to a comparative assessment. Hence, using RMMs in a comparative assessment of biocidal products is not recommended.

Instead of Tier I-A, it is recommended to establish a hazard-based screening as first filtering step in Tier I. A scoring and ranking system was developed within the project and applied to the same intended uses for which the exemplary comparative assessment had been conducted. The hazard-based criteria included: PBT properties of all active substances in the product, (non)classification of all active substances as environmental endocrine disruptor, hazard statements for the product with regard to the environment, and the number of SoC with regard to the environment contained in the product. In addition, the degree of environmentally open application was considered as criterion if different application methods were represented by the products within one intended use. Scores for the individual criteria were set arbitrarily, aiming at a relative weighting of these properties. Similarly, the threshold for the rank obtained by the relevant product that guides the decision towards a further quantitative comparative assessment or to stop the assessment was set arbitrarily. The application of this tool to the case studies of the present study revealed that all assessments of wood preservative products would proceed to the quantitative comparison in contrast to the outcome from a Tier I-A assessment according to TGN. For the ant control products, only the intended use 1 would proceed to a risk-based comparative assessment, while the Tier I-A approach according to TGN could not reach at an unambiguous decision. Yet, this result was only due to including environmentally open application as additional criterion. Overall, the proposed hazard-based scoring and ranking system achieved very low discriminatory power for the selected case studies. This may indicate a generally limited usefulness of this system as filtering step in Tier I. Hence, both the absolute scores and their weighting and the applied threshold for the decision would need further discussion, fine tuning and evaluation with more case studies before the hazard-based scoring and ranking step can be seen as an efficient filtering tool preceding the quantitative comparative assessment.

For a quantitative risk-based comparative assessment of biocidal products, it was found that a recalculation of the relevant risk quotients is unavoidable. The following recommendations were derived for a risk-based comparative assessment approach:

- The recalculation of risk quotients should apply unified standard scenarios based on already established emission scenario documents and use identical standard assumptions and default parameters for all products.
- Recalculations should be restricted to the emission scenarios and compartments identified as relevant based on the existing product assessment reports.
- Differences among products regarding, for example, dosing, application rates, and risk mitigation measures should be taken into account for the recalculation.
- Degradability should be consistently considered for all relevant substances in all products, because persistence is one of the key criteria that result in the status of an CFS and thereby probably triggered the comparative assessment.
- Mixture toxicity should be taken into account according to the recently established guidance for biocidal products.
- The usage of the recalculated risk quotients is a key point that needs to be further evaluated in more in-depth case studies and discussions. One recommendation is to align the approach for biocidal products with that being established for plant protection products. This would mean, among others, to adopt the criterion of a difference of at least factor 10 between the recalculated risk quotients of products as significantly different risk.

It is acknowledged that the here proposed recommendations regarding the diversity criterion may lead to a greater number of products reaching the quantitative risk-based comparative assessment. The resulting increased workload may be counterbalanced to some degree by the proposed more de-

tailed definition of the intended use, which presumably results in a lower number of potential alternative products. In addition to the anticipated increased number of quantitative comparative assessments, the recommendation of using recalculated risk quotients for this decisive step would further increase the workload related to the requirement of a comparative assessment. The workload could in turn be alleviated by establishing a database-driven system for the parallel calculation of these RQs and their storage for future comparative assessments.

Zusammenfassung

Die Zulassung von Biozidprodukten in der Europäischen Union ist ein zweistufiger Prozess, in dem die bioziden Wirkstoffe zunächst auf europäischer Ebene genehmigt und die Biozidprodukte in einem zweiten Schritt zugelassen werden, in der Regel in den einzelnen Mitgliedsstaaten. Basierend auf bestimmten Kriterien, die in Artikel 10 der Biozid-Verordnung (Biocidal Product Regulation, BPR) genannt werden, können biozide Wirkstoffe im Verlauf der europäischen Wirkstoffprüfung als Substitutionskandidaten (engl. Candidates for Substitution, CFS) deklariert werden. Diese Kriterien basieren auf Eigenschaften wie Persistenz, Bioakkumulationspotenzial, Ökotoxizität, das Hormonsystem schädigende Eigenschaften, Humantoxizität, Potenzial zur Grundwasserkontamination oder Reinheit des verwendeten Wirkstoffes. Wenn ein Wirkstoff als CFS eingestuft wurde, muss im Rahmen des Zulassungsverfahrens von Biozidprodukten, die diesen Wirkstoff enthalten, eine vergleichende Bewertung durchgeführt werden.

Von der Europäischen Kommission wurde eine technische Anleitung (Technical Guidance Note, TGN) erstellt um die Einführung des Verfahrens der vergleichenden Bewertung zu unterstützen. Die TGN beschreibt ein mehrstufiges Verfahren, in dem für das relevante Produkt, welches einen als CFS eingestuften Stoff enthält, zunächst die in Frage kommenden Alternativprodukte identifiziert werden. Im nachfolgenden Screening-Schritt wird die chemische Diversität der Wirkstoffe der Alternativprodukte geprüft und es wird festgestellt, ob der CFS eines oder mehrere der in Artikel 5 der BPR aufgeführten Ausschlusskriterien erfüllt. Für den Fall, dass die vergleichende Bewertung nicht im Screening Schritt aufgrund zu geringer chemischer Diversität abgebrochen wird, enthält die TGN mehrere Fließschemata, die entweder zu einem Vergleich des relevanten Produkts mit nicht-chemischen Alternativen führt (Tier II), zu einem Vergleich mit alternativen Produkten auf der Basis qualitativer Kriterien (Tier I-A) wie H- und P-Sätzen sowie Risikominderungsmaßnahmen (Risk Mitigation Measures, RMMs), oder zu einem Vergleich aufgrund von quantitativen Kriterien (Tier I-B) wie Risikoquotienten.

Das Ziel dieses Projektes war es, die Praktikabilität des in der TGN beschriebenen Verfahrens zu prüfen, indem einige vergleichende Bewertungen beispielhaft durchgeführt wurden. Basierend auf den dabei gewonnenen Erfahrungen sollten im Hinblick auf Gefährdungen von und Risiken für die Umwelt Empfehlungen entwickelt werden, um die Abhängigkeit des Verfahrens von Experteneinschätzung zu verringern. Da die TGN kurz vor Beginn des Projektes zwischen den Mitgliedsstaaten abgestimmt und finalisiert wurde, sollte das Projekt keine von Grund auf neue Anleitung entwickeln, sondern auf Empfehlungen und Verbesserungen der vorliegenden TGN abzielen.

Die Analyse der TGN in einem ersten Schritt zeigte, dass wesentliche Begriffe und Vorgehensweisen nur vage definiert sind, so dass eine vergleichende Bewertung in erheblichem Ausmaß von Experteneinschätzungen und *ad hoc*-Entscheidungen abhängt. Dies betrifft beispielsweise die in der TGN vorgesehene Ausreißeranalyse für das relevante Produkt im Vergleich mit den Alternativprodukten, die Definition eines signifikant niedrigeren Risikos und den Vergleich von Risikoquotienten. Aus dieser ersten Analyse der TGN wurde gefolgert, dass das Verfahren deutlich klarer definiert werden muss, wenn es eine verlässliche Basis darstellen soll für die Substitution eines Biozidprodukts, welches andernfalls zulassungsfähig wäre.

Im nächsten Schritt wurden beispielhafte vergleichende Analysen durchgeführt, die die Beschränkungen, Probleme und Lücken der bestehenden Leitlinien aufzeigen sollten. Für diese Fallstudien wurden Holzschutzmittel und Ameisenbekämpfungsmittel als Vertreter zweier verschiedener Produktarten (product types, PTs) ausgewählt. Für jeden der beiden PTs wurden drei verschiede Anwendungen einer beispielhaften vergleichenden Bewertung unterzogen. Die zu prüfenden relevanten Produkte und deren Alternativprodukte wurden aus den für die entsprechenden Anwendungen zugelassenen Produkten ausgewählt, für die Zulassungsdossiers oder zumindest Zusammenfassungen von Produkteigenschaften (Summaries of Product Characteristics, SPCs) im Umweltbundesamt verfügbar waren. Da die in diesem Projekt berücksichtigten Produkte aber nicht alle auf dem Markt verfügbaren

Alternativprodukte umfassen, sind die durchgeführten vergleichenden Bewertungen als rein beispielhaft anzusehen und haben keine regulatorischen Auswirkungen. In diesem Zusammenhang ist es wichtig festzuhalten, dass die vergleichenden Bewertungen sich auf die angestrebten Anwendungen beziehen, nicht auf die Produkte als solche. Die Verfahrensschritte der Bewertung der nichtchemischen Alternativen, von wirtschaftlichen Nachteilen, und die Bewertung des Gesamtrisikos inklusive des Risikos für die menschliche Gesundheit und die Tiergesundheit wurden in diesen Fallstudien nicht durchgeführt, da sie außerhalb der Aufgabenstellung des Projektes waren. Um möglichst viel Erfahrung zu sammeln, wurden die Verfahrensschritte in jedem Fall bis zum letzten Schritt (Tier I-B) durchgeführt, auch wenn Abbruchkriterien wie zum Beispiel eine ungenügende chemische Diversität im Screening-Schritt das Verfahren eigentlich schon früher beendet hätten.

Für die Holzschutzmittel wurden die folgenden drei angestrebten Anwendungen, definiert gemäß den Vorgaben des TGN, für die vergleichenden Bewertungen ausgewählt: 1) Bekämpfung von holzzerstörenden Pilzen - Nutzungsklasse 3 - Nichtberufliche Anwender - Anwendung durch Streichen; 2) Bekämpfung von holzzerstörenden Pilzen - Nutzungsklasse 3 - Berufliche Anwender - Anwendung durch Streichen; 3) Bekämpfung von holzverfärbenden Pilzen - Nutzungsklasse 3 - Industrielle Anwendung - Anwendung durch Tauchen. Für die angestrebten Nutzungen 1 und 2 wurde das gleiche relevante Produkt ausgewählt, für die angestrebte Nutzung 3 ein anderes. Die relevanten Produkte enthielten alle den als CFS eingestuften Wirkstoff Tebuconazol, welcher ebenfalls in einigen der Alternativprodukte enthalten war. Die Anzahl an Alternativprodukten variierte zwischen zwei und fünf. In dem Bewertungsschritt Tier I-A nach TGN wurde keines der relevanten Produkte als Ausreißer eingestuft, d.h. sie hatten nach TGN kein „signifikant schlechteres Profil“ als die Alternativprodukte. Ein quantitativer Vergleich (Tier I-B) nach TGN konnte für die Holzschutzmittel nicht durchgeführt werden, weil für keine der drei Nutzungen Risikoquotienten für das relevante Produkt und zugleich für die Alternativprodukte verfügbar waren, die sich auf das gleiche Umweltkompartiment bezogen und mit dem gleichen Grad an Verfeinerung berechnet wurden.

Für die vergleichenden Bewertungen von Ameisenbekämpfungsmitteln wurden drei Anwendungen ausgewählt, alle mit der schwarzen Gartenameise *Lasius niger* als Zielorganismus: 1) Außenanwendung durch nichtberufliche Anwender mittels direkter Anwendung am Ameisennest; 2) Innenanwendung durch nichtberufliche Anwender als Köderbox; 3) Außenanwendung durch berufliche Anwender als Gelköder. Das relevante Produkt in der angestrebten Anwendung 1 enthielt als CFS den Wirkstoff Spinosad, während die relevanten Produkte in den Anwendungen 2 und 3 den Wirkstoff Fipronil als CFS enthielten. Spinosad war ebenfalls in manchen Alternativprodukten enthalten, während Fipronil in keinem der Alternativprodukte enthalten war. Die Anwendungsmethode wurde nicht als Kriterium für die Auswahl der Alternativprodukte verwendet, so dass auch Produkte mit abweichenden Anwendungsmethoden als Alternativprodukte identifiziert wurden. Die Anzahl der Alternativprodukte variierte zwischen vier und acht. Für keine der Anwendungen führte der Bewertungsschritt Tier I-A nach TGN zu einer eindeutigen Entscheidung, ob das relevante Produkt ein Ausreißer war oder nicht. Um eine quantitative vergleichende Bewertung im Schritt Tier I-B zu ermöglichen wurden Risikoquotienten für das Bodenkompartiment neu berechnet, unter Verwendung des gleichen Szenarios und mit weitgehend einheitlichen Annahmen. Für das relevante Produkt in Anwendung 1 ergab sich ein Unterschied im Risikoquotienten von mehr als Faktor 10 zu den Alternativprodukten. Für die Anwendungen 2 und 3 war dies nicht der Fall. Dieses Ergebnis deutete darauf hin, dass für die Anwendung 1 eine Substitution des relevanten Produkts zur Ameisenbekämpfung gerechtfertigt sein könnte. Allerdings blieb dabei offen, ob der Vergleich von Produkten, deren Anwendungsmethoden sich stark voneinander unterscheiden anhand von stark vereinheitlichten Annahmen als angemessen angesehen werden kann. Die Hauptursache für diese Ergebnisse waren die Unterschiede in der Anwendungsmethode, also die umweltoffene Ausbringung durch direkte Anwendung am Ameisennest im Vergleich zur eher geschlossenen Anwendung mittels Köderdose. Somit wurde die Substitutionsentscheidung im Wesentlichen durch die Anwendungsmethode bestimmt, nicht aber durch die Eigenschaften die zur Einstufung des Wirkstoffs als CFS führten.

Insgesamt wurde bei der Zusammenstellung der relevanten Daten für die qualitative vergleichende Bewertung festgestellt, dass die für die RMMs verwendeten Formulierung noch nicht ausreichend zwischen den verschiedenen Produkten, Produktarten und zuständigen Behörden harmonisiert sind. Der Vergleich der Schärfe der RMMs war dadurch stark auslegungsabhängig. Deshalb wird die Harmonisierung der für RMMs verwendeten Formulierungen voraussichtlich auch für zukünftige vergleichende Risikobewertungen hilfreich sein. Ein weiteres Ergebnis aus den Fallstudien war die Tatsache, dass RMMs oft nicht alleine auf der Basis des SPC identifiziert werden konnten und es oft nicht klar war, ob es sich formal um RMMs handelte, die durch eine Behörde aufgrund eines identifizierten Risikos festgelegt wurde, oder ob sie als Anwendungsbestimmungen vom Antragsteller festgelegt wurde. Die gleiche Anforderung (zum Beispiel die Verwendung eines Schutzanstrichs nach Anwendung eines Holzschutzmittels) war im Fall eines Produktes eine formell durch die Behörde auf der Basis eines identifizierten Risikos festgelegte Risikominderungsmaßnahme, und im Fall eines anderen Produktes eine vom Anwender festgelegte Anwendungsbestimmung. Im Falle dieses anderen Produktes blieb offen, ob die Risikoanalyse ohne Berücksichtigung dieser Anwendungsbestimmung zur Festlegung dieser Bestimmung als RMM geführt hätte. Deshalb erscheint eine Unterscheidung zwischen Anwendungsbestimmungen und RMMs eher willkürlich bzw. fragwürdig im Kontext einer vergleichenden Bewertung.

Basierend auf einer detaillierten Defizitanalyse wurden im Rahmen des Projektes einige Empfehlungen zur Erhöhung der Transparenz und zur Verminderung der Abhängigkeit von Experteneinschätzungen in zukünftigen vergleichenden Bewertungen erarbeitet. Der mehrstufige Ansatz der TGN, der darauf abzielt, die Anzahl komplexer quantitativer Risikobewertungen zu reduzieren indem ein Filterschritt vorgeschaltet wird, wird voll unterstützt. Allerdings könnte die Komplexität des bestehenden Schemas reduziert werden, indem das Verfahren auf drei Schritte (Screening, Tier I und Tier II) reduziert wird, und weniger Möglichkeiten des Verfahrensablaufes gemäß den Fließschemata der einzelnen Schritte vorgesehen werden.

Ein erheblicher Aufwand wurde im Projekt bereits für den ersten Schritt der vergleichenden Bewertung, die Zusammenstellung der in Frage kommenden Alternativprodukte, notwendig. Daraus resultiert die Empfehlung, die in der Beschreibung der Anwendung verwendeten Begriffe, die gemäß TGN in sechs Kategorien gegliedert sind, stärker zu harmonisieren bzw. zu standardisieren. Die Zusammenstellung von Alternativprodukten stellt einen entscheidenden Schritt in der vergleichenden Bewertung dar. Hier kann auch der Aufwand, der in den weiteren Schritten betrieben werden muss, beträchtlich reduziert werden. Zu diesem Zweck wird weiterhin empfohlen, noch zusätzliche Informationen in die Anwendungsbeschreibungen aufzunehmen. Am wichtigsten sind hierbei das Anwendungsziel, das mit den Wirksamkeitsdaten zusammenhängt, sowie Einschränkungen des Anwendungsgebietes. Beide Kriterien können dazu führen, dass ein mögliches Alternativprodukt als Alternative ausgeschlossen wird. Der Ausschluss von solchen Produkten so früh wie möglich im Verfahren verbessert nicht nur die Verfahrenseffizienz, sondern hilft auch dabei, fehlerhafte Entscheidungen zum Beispiel im Hinblick auf die verbleibende chemische Diversität zu vermeiden. Um diese Verbesserung zu erreichen, wird als angemessenste Maßnahme die Umsetzung in einer Datenbank angesehen, in die die vereinheitlichten Anwendungsbeschreibungen aller Anwendungen von neu zugelassenen Produkten eingetragen werden. Die Verfügbarkeit der vorgeschlagenen zusätzlichen Informationen in einer Datenbank würde helfen, die Anzahl der zu bewertenden Alternativprodukte zu verringern und die Anforderungen an nichtchemische Alternativen festzulegen.

Die chemische Diversität wird gemäß TGN als Kriterium verwendet, anhand dessen die vergleichende Bewertung im Screening-Schritt abgebrochen werden kann, basierend auf dem Argument, dass Resistenzbildungen vermieden werden sollen. Die TGN empfiehlt, dass drei Wirkstoff/Wirkmechanismus-Kombinationen als ausreichende chemische Diversität anzusehen sind. Es wird empfohlen, dass dieses Kriterium genauer spezifiziert wird, indem festgehalten wird, dass die Einschränkung des Gebrauchs des relevanten Produkts die chemische Diversität nicht unter das als ausreichend angesehene Niveau reduzieren sollte. Durch diese Formulierung würde verhindert, dass die vergleichende Bewertung

abgebrochen wird, wenn die chemische Diversität bereits niedrig ist, aber eine ausreichende Anzahl der Alternativprodukte in Frage kommen, die den gleichen Wirkmechanismus abdecken der vom relevanten Produkt abgedeckt wird, so dass die chemische Diversität durch die Einschränkung nicht verändert würde. Zusätzlich sollte das Kriterium der chemischen Diversität allgemeiner als `Diversität` bezeichnet werden, so dass auch Mikroorganismen eingeschlossen sind, die als Wirkstoffe gemäß der BPR zugelassen sind.

Das Ziel von Tier I-A gemäß der TGN ist es, zu bestimmen ob das Verfahren mit Tier I-B oder Tier II weitergeführt wird. Ein Abbruch der vergleichenden Bewertung in Tier I-A ist nicht vorgesehen. Um Komplexität und Redundanzen in den bestehenden Fließschemata zu reduzieren, wird empfohlen, das Verfahren am Ende des Screening-Schritts entweder in Tier I oder Tier II weiterzuführen, und Tier I-A auszulassen. Tier I-A basiert alleine auf RMMs und H- und P-Sätzen. Die Verwendung von RMMs als Basis für eine vergleichende Bewertung wurde als ungeeignet befunden. Erstens enthalten RMMs keine Informationen über das nach der Umsetzung der RMMs verbleibende Risiko, welches aber nach TGN Gegenstand der vergleichenden Bewertung sein sollte. Zweitens sind die RMMs gegenwärtig kaum standardisiert und harmonisiert, was ihre Verwendung und insbesondere ihre Einordnung bezüglich der Strenge sehr aufwändig und auslegungsabhängig macht. Drittens können RMMs oft nicht von Anwendungsbestimmungen unterschieden werden und es erscheint äußerst fraglich, ob solch eine Unterscheidung im Kontext einer vergleichenden Bewertung sinnvoll ist. Aus diesen Gründen wird von einer Verwendung von RMMs in der vergleichenden Bewertung von Biozidprodukten abgeraten.

Anstelle von Tier I-A wird eine gefährdungsbasierte Bewertung als erster Filter-Schritt in Tier I empfohlen. Ein entsprechendes System zur Bewertung und Einordnung der Produkte wurde im Rahmen des Projektes entworfen und auf die gleichen angestrebten Anwendungen angewandt, die in den Beispiel-Assessments untersucht wurden. Die gefährdungsbasierten Kriterien schlossen ein: PBT Kriterien aller Wirkstoffe, mögliche (Nicht-)-Einstufungen der Wirkstoffe als endokrine Disruptoren in Bezug auf die Umwelt, umweltbezogene H-Sätze der Produkte, und die Anzahl der bedenklichen Beistoffe (`Substances of Concern`) im Hinblick auf die Umwelt im Produkt. Zusätzlich wurde der Grad der umweltoffenen Ausbringung berücksichtigt, wenn Produkte mit verschiedenen Anwendungsmethoden für eine Anwendung in Frage kamen. Die Bewertungspunkte für die verschiedenen Kriterien wurden willkürlich festgelegt, mit dem Ziel einer relativen Gewichtung. Ebenso wurde der Schwellenwert für den Rang des Produktes, der darüber entscheidet ob eine quantitative Risikoanalyse nachgeschaltet wird oder das Verfahren abgebrochen wird, willkürlich festgelegt. Die Anwendung dieses Bewertungssystems auf die Fallstudien dieses Projektes zeigte, dass alle drei vergleichenden Bewertungen von Holzschutzmitteln zum quantitativen Vergleich weitergeführt würden, was im Widerspruch zu dem Ergebnis steht welches in Tier I-A gemäß TGN erzielt wurde. Für die Ameisenbekämpfungsmittel würde nur die Bewertung der Anwendung 1 in den quantitativen Vergleich weitergeführt werden, während Tier I-A nach TGN keine eindeutige Entscheidung ergeben hatte. Dieses Ergebnis wurde allerdings nur erzielt, indem die umweltoffene Anwendung der direkten Nestapplikation berücksichtigt wurde. Insgesamt zeigte das gefahren-basierte Bewertungssystem nur eine geringe Trennschärfe auf. Möglicherweise zeigt sich darin ein beschränkter Nutzen eines solchen Systems als Filter-Schritt in Tier I. Somit müssten auch die Bewertungspunkte und der Schwellenwert für die Weiterführung des Verfahrens noch weiter diskutiert, angepasst, und anhand weiterer Fallstudien geprüft werden, bevor es als effizienter Filter vor einer quantitativen vergleichenden Bewertung angesehen werden kann.

Ein quantitativer, risikobasierter Vergleich von Biozidprodukten erfordert nach den Erkenntnissen des Projektes die Neuberechnung aller relevanten Risikoquotienten. Die folgenden Empfehlungen wurden für ein solches risikobasiertes Verfahren erarbeitet:

- Bei der Neuberechnung der Risikoquotienten sollten vereinheitlichte Standardszenarien der bereits etablierten Emission Scenario Documents (ESD) mit identischen Annahmen und Eingangsparametern verwendet werden.

- Die Neuberechnung von Risikoquotienten sollte sich auf die Szenarien und Kompartimente beschränken, die basierend auf den bestehenden Bewertungsberichten als relevant identifiziert wurden.
- Unterschiede zwischen den Produkten bezüglich der Anwendungsrate und -häufigkeit sowie der Risikominderungsmaßnahmen sollten bei der Neuberechnung berücksichtigt werden.
- Die Abbaubarkeit sollte bei den Berechnungen für alle relevanten Substanzen in allen Produkten einheitlich berücksichtigt werden, da Persistenz ein entscheidender Parameter für die Einstufung als CFS ist und vermutlich in vielen Fällen die vergleichende Bewertung ursprünglich auslöst.
- Mischungstoxizität sollte entsprechend dem kürzlich verabschiedeten entsprechenden Leitfaden für Biozidprodukte berücksichtigt werden.
- Die weitere Verwendung der neuberechneten Risikoquotienten ist ein entscheidender Punkt, der in weiterführenden detaillierten Fallstudien und Diskussionen evaluiert werden sollte. Es wird empfohlen, das Vorgehen für Biozidprodukte mit dem derzeit in Entwicklung befindlichen Ansatz für Pflanzenschutzmittel abzugleichen. Das würde unter anderem bedeuten, dass ein Unterschied von mindestens Faktor 10 zwischen zwei Risikoquotienten als Kriterium für ein signifikant unterschiedliches Risiko übernommen werden würde.

Es wird eingeräumt, dass die hier vorgeschlagenen Empfehlungen bezüglich der Kriterien für die Wirkstoff-Diversität die Anzahl der durchzuführenden quantitativen risikobasierten Vergleiche erhöhen würden. Diesem erhöhten Arbeitsaufwand könnte entgegengewirkt werden durch die vorgeschlagene präzisere Definition der zu vergleichenden Anwendung, da diese voraussichtlich die Anzahl der Alternativprodukte reduzieren wird. Zusätzlich zu der möglicherweise größeren Anzahl der quantitativ zu vergleichenden Produkte würde die Empfehlung, Risikoquotienten neu zu berechnen den Aufwand für vergleichende Bewertungen insgesamt erhöhen. Dieser Aufwand könnte zumindest teilweise ausgeglichen werden durch die Schaffung einer Datenbank-basierten Softwarelösung, die eine automatische Kalkulation von Risikoquotienten ermöglicht und diese für spätere Vergleiche speichert.

1 Introduction

Authorisation of biocidal products in the European Union (EU) is a two-stage process, where the biocidal active substances are approved in a first step on European level, and the biocidal products are authorised in a second step at member state level. This scheme was first introduced by the Biocidal Product Directive in 1998 (European Communities 1998), in analogy to the Plant Protection Product Directive from 1992. In 2013, the Biocidal Product Directive was replaced by the Biocidal Product Regulation (BPR, European Union 2012). The BPR also introduced the possibility of a Union authorisation for certain biocidal products. For biocidal products authorised at Union level, authorisation in the member states is not necessary.

Depending on certain criteria specified in Article 10 of the BPR, an active substance (a.s.) can be designated as Candidate for Substitution (CFS) during the (re-)approval process at European level. These criteria are based on properties like persistence, potential for bioaccumulation, ecotoxicity, potential for endocrine disruption, toxicity towards humans, potential to be transferred to groundwater, or purity of the technical active substance.

If an a.s. is designated as a CFS, Article 23 of the BPR requests that during the authorisation of biocidal products containing this CFS, a comparative assessment is carried out, including a risk-based comparison of environmental effects. Other aspects that are assessed in this step are the availability and feasibility of other, potentially non-chemical methods and the chemical diversity of the remaining biocidal products, in order to minimize the risk of resistance development in the target organisms.

Article 24 of the BPR tasks the European Commission to develop technical guidance notes (TGN) to facilitate the implementation of this procedure. The TGN from May 2015 (European Commission 2015) proposes a tiered scheme that aims to limit the complexity of the comparative risk assessments procedure in order to not place too much burden on member state authorities as complex comparative assessments for a large number of products may jeopardize the time schedules defined in the BPR.

While the TGN provides a general scheme and some useful definitions and many additional details compared to the BPR, the comparative assessment procedure described therein remains vague and general in many places. This entails a risk of diverging interpretations between the different member states and applicants in the interpretation of the TGN.

Therefore, the aim of the current project was to evaluate the practicability of this existing guidance by conducting a number of exemplary comparative assessments. Based on this experience an improved guidance should be developed particularly with respect to environmental hazard and risks, so that the reliance on expert judgement is minimised. The resulting proposal could be passed on by the German Environment Agency (Umweltbundesamt, UBA) to the consultation process between member states and the European Commission.

The project is structured in four work packages (WPs), with the following content:

- WP 1: Analysis of the status quo
- WP 2: Evaluations of the existing guidance based on example products
- WP 3: Analysis of deficits in the existing guidance
- WP 4: Development of recommendations for the comparative environmental assessment

2 WP 1: Analysis of the status quo

Comparative assessments are a relatively new instrument in the context of product authorisation. Traditionally, environmental risk assessments address individual products that are evaluated separately according to defined thresholds for acceptability of risk that apply equally for all products. As a consequence, methods and decision criteria for comparative assessments of environmental risks are not well developed, harmonised and established for practical use by regulatory authorities.

In the following subsections, the situation at the start of the project is characterised. At first, some general remarks about comparison methods are made. Then, the legal requirements of the BPR regarding the comparison procedure, and the recommendations specified in the TGN are listed. In the third subsection, the existing legal requirements and recommendations in the area of comparative assessment of chemicals regulated under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and plant protection products are described and related to the situation for biocidal products.

Finally, in the fourth subsection, project relevant conclusions are drawn from this analysis.

2.1 Preliminary remarks on comparison methods

When two or more options are compared in a formalized comparative assessment, a procedure for dealing with conflicting objectives has to be defined, as different protection goals like human health, animal health and the environment (each of which again has many aspects) may be affected in different ways by different products.

At least, two ways of dealing with such a situation can be distinguished for our case of substitution based on comparative assessment of biocidal products:

a) A single integrated measure of the overall impact or overall risk is constructed, and a CFS-containing product with a significantly higher overall impact or risk than the alternatives is substituted.
b) For each impact category, a significance level is defined, and a CFS-containing product posing a significantly higher risk in one category than the alternatives is only substituted if the alternative product does not pose a significantly higher risk in the other categories.

In case a), a relative weighting of the different categories and a significance criterion for the overall risk is necessary, while in case b) the definition of "significant differences" within each of the impact categories will be required.

Further, it has to be kept in mind that any proposal for a comparative assessment scheme has to be

- practicable - Therefore it should be mainly or exclusively based on information available from the existing regulatory process and its complexity must be limited
- robust - Therefore subjective influences like expert judgement should be kept to a minimum, an unambiguous scheme should be used and transparency should be ensured.

2.2 Predefined requirements for the comparative assessment of biocides

In the following subsections, the methodological decisions and procedures that have already been established (in the BPR and TGN) are listed and analysed, with special emphasis on the environmental assessment.

2.2.1 Requirements specified in the BPR

2.2.1.1 Recital (15)

In the introductory part of the BPR, it is stated in Recital (15) that biocidal products containing a CFS should be restricted when other authorised biocidal products or alternative methods present a significantly lower overall risk for human health, animal health and the environment, are sufficiently effective and present no other significant economic and practical disadvantages.

> *... As a result of such a comparative assessment, a biocidal product containing active substances identified as candidates for substitution should be prohibited or restricted where it is demonstrated that other authorised biocidal products or non-chemical control or prevention methods that present a significantly lower overall risk for human health, animal health and the environment, are sufficiently effective and present no other significant economic or practical disadvantages ...*

Here, clearly an integrated view of the risk for human health, animal health and the environment is required ("overall risk"). Sufficient efficacy of a product is necessary for authorisation in any case. However, different uses can still have different efficacy requirements (compare *e.g.* European Commission 2013, p. 19), which may not all be fulfilled by every authorised product and may thereby limit the number of possible alternative products.

For the assessment of economic or practical disadvantages, a significance level is supposed and must be defined as a basis for deciding if there is a significant conflict of goals, preventing the substitution.

2.2.1.2 Article 23

This article contains the most detailed information about the comparative assessment, specifying, among other aspects, who is conducting the comparative assessment (member state competent authorities), what products are affected (biocidal products containing a CFS), who will review the assessment (other member states, the European Chemicals Agency (ECHA), for Union authorisations also the European Commission) and how it should be conducted (in accordance with the TGN referred to in Article 24).

Furthermore, the criteria for the comparative assessment are defined. The phrasing from Recital (15) shown above is repeated concerning human health, animal health, the environment, efficacy and economic and practical disadvantages.

As an additional criterion, maintaining an adequate chemical diversity among authorised products is required.

2.2.2 Requirements specified in the TGN

In the following subsections, additional information given in the TGN on the comparative assessment, further specifying how it should be carried out, is summarised. For details, please refer to the original document (European Commission 2015). In the following, the biocidal product which is being evaluated is termed the relevant biocidal product (BP), and the alternatives that were found to have the same use are termed the eligible alternative BPs.

2.2.2.1 Definition of "significantly lower overall risk"

The term "significantly lower overall risk" is used in Recital (15) as well as in Article 23, paragraph 3(a) of the BPR and describes the central decision criterion for the comparative assessment.

In paragraph (17) of the TGN, the term "overall risk for human health, animal health and for the environment" is further specified for biocidal products to be the "overall integration of the conclusions", i.e. to cover all aspects of the dossier evaluation according to Annex VI of the BPR that relate to immediate or delayed effects on the health of humans, animals and the environment. In paragraphs (18) and (19) of the TGN, it is specified that the overall risk is to be seen as significantly lower if there is a significantly "better profile" for one of the three aspects human health, animal health and the environment, but not at the same time significantly worse in the remaining aspects.

This means, referring to the considerations shown in section 2.1 of this report, that the risk is not integrated into a single measure over the three areas of human health, animal health and environment. Hence, the three areas can be evaluated separately without any weighting.

It is worth noting that for defining the term "significant", it is referred to the concept "biological significance". Biological significance, a term that has been coined in order to address problems with the concept of "statistical significance", is then defined as

- to require expert judgement and
- an estimate of the biological relevance of an observed difference between two results or observations subject to comparison, with respect to whether that difference has *potential consequences*, *affecting the* functioning of and *risks to* humans, animals or the environment.

This "definition" of biological significance in this context is so vague that it leaves the question completely open, on how the determination of such significance can be operationalised in practice. In effect, the chain of definitions given in paragraphs (17) to (21) is circular, as it boils down to the statement that there is a significantly lower risk, if the difference in risk is such that it has potential consequences for the risk.

This somewhat circular chain of definitions does not provide very practicable support for an unambiguous and transparent comparative risk assessment of products.

In the Plant Protection Product Regulation (PPPR, European Commission 2009), a significant difference in the context of a comparative product risk assessment has been defined as a factor of at least 10 between the toxicity/exposure ratios (TER) of different plant protection products. While there are practical problems applying this approach (see section 2.3), this provides a clear starting point. No such definition of a significant difference is given in the BPR.

2.2.2.2 Mapping of alternatives

In order to decide which of the possible alternative biocides should be assessed in the comparative assessment procedure, the TGN lists the following six criteria that define a specific use of a biocidal product:

1. Product type
2. Where relevant, an exact description of the authorised use
3. Target organism(s) (including development stage)
4. Field of use
5. Category(ies) of users
6. Application method(s)

Key is to identify alternative products that resemble in their combination of the six criteria the specific use of the relevant product.

The TGN specifies in paragraph (32), that each use can comprise more than one target organism, user category or field of use. This means, that a use defined for the relevant biocidal product can be a subset or a superset of the use defined for an eligible alternative biocidal product. In other words, the uses U_a

of alternative biocidal products mapped to a specific use U_r of a relevant product can either a) cover only a part of this use ($U_a \subset U_r$), or b) cover the use completely ($U_a \supseteq U_r$).

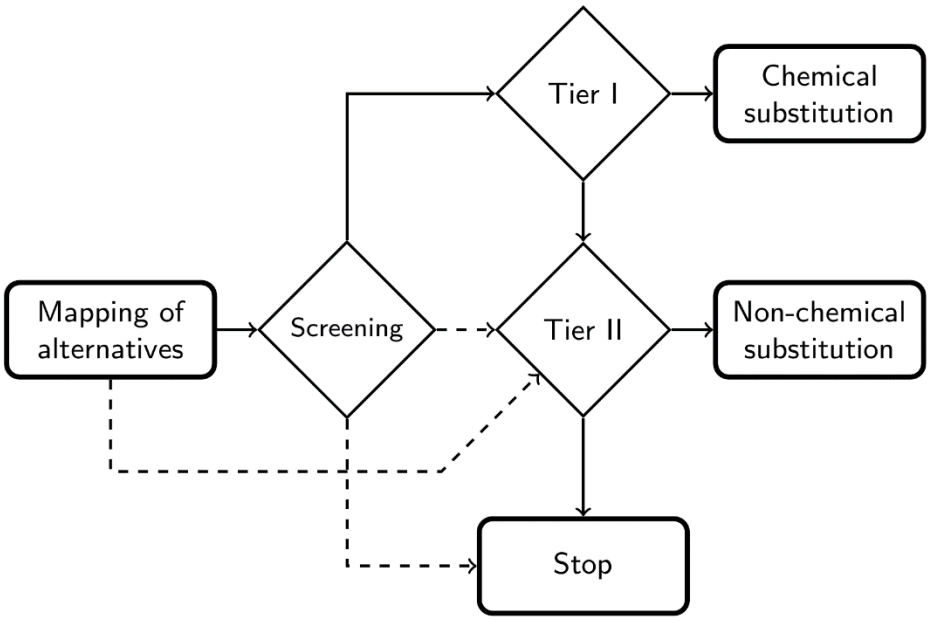
Different application methods (criterion 6) do not generally establish different uses for the purpose of the comparative assessment.

2.2.2.3 Tiered approach

The workflow of a comparative assessment is further specified in a so-called tiered approach which consists of several steps as shown in Figure 1. The approach starts with the mapping of existing alternatives to the uses of the relevant biocidal product identified according to the criteria given above (Section 2.2.2.2). If substitution by non-chemical alternatives appears feasible for a specific use, the assessment can proceed directly to their assessment (Tier II). As default, however, the specific use of the relevant product is defined, a list of potential alternative products accordingly generated, and the assessment proceeds to the screening step.

In the screening step, the chemical diversity of active substances among the alternative products is checked and the question is answered, if one of the a.s. in the relevant product fulfils one or more of the exclusion criteria. If the chemical diversity is not sufficient and none of the a.s. contained in the relevant product fulfils any of the exclusion criteria as defined in article 5 of the BPR, the comparative assessment is stopped immediately. Otherwise, the assessment proceeds with Tier I (or Tier II, if non-chemical alternatives are already known).

Figure 1: Simplified flow chart for comparative assessments based on the TGN



Source: Modified after Ranke et al. (2017) Proceedings of the SETAC Europe 27th Annual Meeting in Brussels

The TGN describes a subdivision of the comparison with chemical alternatives (Tier I) into Tier I-A and Tier I-B. At Tier I-A, there is a qualitative comparison with the eligible alternative BPs, as well as an assessment of their practical and economic disadvantages. At Tier I-B, there is a quantitative comparison with the eligible alternative BPs, and again, if not already done, an assessment of practical and economic disadvantages.

If an a.s. in the relevant product meet the exclusion criteria, the Tier I-B is reached directly from the screening step. Otherwise, Tier I-B can be triggered depending on the outcome of Tier I-A. At Tier I-B, it is finally decided if chemical alternatives with a significantly lower overall risk, but without signifi-

cant economic or practical disadvantages exist. If this is the case, the use of the relevant product will be restricted or prohibited. If this is not the case, the assessment proceeds to Tier II.

From Tier I-A, the assessment proceeds to Tier I-B only if the qualitative comparison shows that alternatives with a significantly lower overall risk are available, and no significant practical or economical disadvantages exist. Otherwise, the assessment proceeds to Tier II.

At Tier II, the efficacy of the non-chemical alternatives is checked, then the assessment of practical and economic disadvantages is carried out, and finally, the overall risk of the non-chemical alternatives is compared to the relevant BP. Tier II may also lead to a use restriction of the biocidal product being evaluated.

2.2.2.4 Area of the main concern

In paragraph (48), the TGN proposes that the comparative assessment of the overall risk of a relevant BP should start with the area of concern defined by the CFS that is/are contained.

Therefore, at Tier I-A and Tier I-B, the environment only needs to be considered when a) one of the main concern of the CFS is the environment or b) the main concern is either human health or animal health but not the environment, but there are sufficient eligible alternative BPs with a lower risk in the main area(s) of concern.

In this context, it is notable that the only substitution criteria relevant at Tier I-A according to the TGN (62) are "respiratory sensitizer" and "two out of the PBT properties".

2.2.2.5 Sufficient chemical diversity

The TGN proposes that in general, sufficient chemical diversity is given if at least three "active substances/mode of action" combinations remain on the market, meaning that representatives of three different modes of action should remain.

However, it is not clarified in the TGN, if microorganisms (in the sense of the BPR) count as a separate MoA in case alternative products concerning microorganisms are available.

2.2.2.6 Outliers

For the assessment at Tier I-A as well as for the assessment at Tier I-B, the TGN proposes that the assessment should be oriented to conclude whether the relevant BP can be considered as outlier (paragraphs (61) and (81)). It is implied that use restrictions should only be applied to outlier products. For Tier I-A, the term Outlier BP is used (paragraph (22)), for Tier I-B, the term Outlier value. In both cases, the term outlier is used for products or values that are distinct from the majority.

The outlier concept is introduced completely independent from the requirements specified in the BPR. It has been introduced with the purpose of streamlining the assessment, *i.e.* for pragmatic reasons.

One case that should be clarified would be when there are two groups of BPs, one smaller group with a significantly lower risk than the other, larger group. Adherence to the BPR requirements would dictate that the larger group with the significantly worse risk profile should be restricted. However, according to the outlier concept, this would not be necessary.

2.2.2.7 Decision criteria for economic and practical disadvantages

The TGN propose that these disadvantages should be evaluated on the user level and not in terms of a wider socioeconomic analysis, for pragmatic reasons. Some hints are given on how to evaluate these potential disadvantages, notably the terms "very high efforts" and "disproportionate costs" are used. Also, sources of information are specified.

In the Annexes, there are flow charts for Tier I-A and Tier I-B that illustrate the assessment of these disadvantages.

2.2.2.8 Decision criteria for environmental risk at Tier I-A

At Tier I-A, the TGN foresees to use only Hazard and Precautionary (H/P) statements and risk mitigation measures (RMMs) as decision criteria. As difficulties are foreseen in the TGN, it is proposed to use expert judgement to define significant differences between products.

It should be noted that while H/P-statements are a well-defined set, the list of harmonized RMMs that became available during the project is still quite new and has not been used in older authorisations. Also, it does not cover all potential RMMs and does not indicate comparability or severity of the sentences, so expert judgement will still be necessary.

In the Annex to the TGN (chapter 7.2.1), there are example assessments aiming to identify outlier BPs. In the first example, the absence of two P statements and one RMM for alternative biocidal products leads to the conclusion that the relevant BP is an outlier product, and Tier I-B, i.e. a more detailed, quantitative comparison, is warranted.

In the second example, there are no P statements, but three RMMs are necessary for the relevant BP. Among the eligible alternative BPs, there are two which only need two out of those three RMMs. The conclusion in the TGN is such that the relevant BP is not an outlier BP and Tier I-B is not necessary.

Thus, the decision rules for Tier I-A are only vaguely defined by the use of two rather artificial examples, and in practice, expert judgement will be needed in every case.

Also, it is questionable if the information used at Tier I-A is sufficient to decide if the difference in environmental risk is significant.

2.2.2.9 Decision criteria for environmental risk at Tier I-B

Regarding the decision criteria in Tier I-B, the TGN lists exclusion/substitution criteria, for which "associated data" will have to be compared. Regarding the environment, only properties relating to Persistence, Bioaccumulation and Toxicity (PBT) are listed.

This means that data associated with PBT properties should be assessed. Therefore, it seems that comparisons of half-lives, bioconcentration factors or effect data should be made. However, further down, the possibility to compare quantitative data like risk quotients (RQs) is discussed, illustrating that "associated data" is used in a wide sense.

Notably, data regarding endocrine disruption are not listed as concerning the environment, but under the point human health. Also, a significant proportion of non-active isomers or impurities are not listed as an environmental concern, but as a separate category of concerns regarding the identity of the substance, so it is unclear if this should be discussed with a view to potential consequences for the environment.

As a criterion for a significant difference, a formulation similar to definition of biological significance is given in paragraph (84), just the term "functioning of" is left out. The same criticism as put forward in section 2.2.2.1 applies.

2.3 Comparison to existing guidance on alternatives assessment

The first use restrictions (e.g. ban of arsenicals in German vineyards 1942) and complete bans of chemicals (German DDT law from 1972) based on risks for man and environment did not involve an assessment of alternatives. Meanwhile, the widespread integration of the principle of substitution into international agreements and European legislation has led to a considerable number of assessment methods supporting the evaluation of alternatives (Lohse *et al.* 2003, Tickner and Jacobs 2016).

For such an evaluation of alternatives, the term "alternatives assessment" is being used in the discussions within the Organisation for Economic Co-operation and Development (OECD) as documented in a so-called meta-review on such methods (OECD 2013a), developed in the context of the Inter-Organisation Programme for the Sound Management of Chemicals.

It was found that these methods for alternatives assessment can be based on a broad set of attributes, including, but not limited, to hazard, fate, physical-chemical properties, technical feasibility, product performance, use-based exposure and risk, cost and availability. A large number of tools is based on so-called intrinsic properties (hazard and fate), while a smaller number of tools uses attributes such as cost and availability, use-based exposure or risk, technical feasibility and product performance (OECD 2013a, p. 19).

In addition to these methods for alternatives assessment specifically tailored to substitution of hazardous substances, there is a large number of methods and tools for Life Cycle Assessment (LCA), which often include the effects of toxicants on men and environment as an impact category. Such LCA methods could therefore also be used for the assessment of chemical alternatives. However, a review of chemical impact assessment methods in LCAs is beyond the scope of this project.

2.3.1 Assessment of alternatives as part of the authorisation procedure under REACH

The identification of substances of very high concern (SVHC) and the authorisation procedure under REACH have been identified as main drivers of substitution of hazardous chemicals in the European Union (Tickner and Jacobs 2016). An alternatives assessment is part of two different procedures under REACH.

The first procedure is a comparative risk assessment of alternatives (chemical or non-chemical) that needs to be part of Annex XV dossiers prepared by authorities proposing restrictions (ECHA 2007). While many suggestions for the alternatives assessment are made and some information is mandatory, most aspects are formulated in a liberal manner, leaving the final decision on how to conduct and present such assessments to the authority writing the dossier. When it comes to trade-off between different types of hazards or risks, the authorities are requested to decide whether the risks introduced by the alternatives are acceptable and why. While a tiered scheme with six tiers is described, no guidance on how to deal with such risk-risk trade-offs is given (Annex VI to ECHA 2007).

The second procedure where alternatives assessment is required is the authorisation procedure. The corresponding, more elaborate guidance on alternatives assessment is part of the guidance on applications for authorisation of substances listed on Annex XIV. This document devotes one chapter with about 50 pages to the analysis of alternatives required by all such applications according to article 62(4)(e) of the REACH regulation (ECHA 2011).

The document proposes a two-stage process, with the comparison of hazards being the first step and a more detailed comparison of risks as the second step. In the second step, a potential need for integrating "wider implications" such as energy consumption or production of hazardous waste into the assessment is identified. The similarity of the resulting task to the LCA of products or processes is acknowledged. While many approaches and methods are mentioned, no authoritative advice is given on which scheme or method should be used. Instead, it is stated that the applicant should decide if and why the risks introduced by alternative chemical substances or technologies are acceptable and why.

The guidance states that no fully quantitative comparison will normally be possible. Nevertheless, the documentation of the assessment should be clear and transparent.

Both cases of alternatives assessment under REACH are different from the case of biocidal products, as the alternatives for biocidal products have already undergone a complete evaluation based on the same data requirements. Therefore, the database for the relevant BP and the eligible alternative products is equivalent in principle, even if tiered risk assessments and mitigations may have led to additional data and refined assessment scenarios only for some products.

Another relevant difference of alternatives assessment under REACH to comparative assessments under the BPR is in the scope of the assessments. While the scope of the comparative risk assessment in the REACH guidance described above extends to "wider implications" of a technology change and includes the same impact categories commonly considered in LCA, the scope of comparative assessments under the BPR is confined to the risk for human health, animal health and the environment caused by exposure to ingredients of the biocidal products, in combination with a chemical diversity assessment for resistance management and an assessment of economic and practical disadvantages.

Generally, the available documents are not of direct, practical use for comparative assessment of biocidal products required under the BPR, but they rather illustrate, that no general, unified method is available for alternatives assessment under REACH.

2.3.2 Comparison to regulations and guidance for plant protection products

In article 50 of the PPPR (European Commission 2009), the requirement to perform a comparative assessment of risks for humans and the environment is specified for plant protection products. This assessment may lead to non-authorisation of a plant protection product (PPP) if it is

(i) 'containing a candidate for substitution' and if

(ii) 'an authorised plant protection product, or a non-chemical control or prevention method, already exists for the uses specified in the application' 'which does not present significant economic or practical disadvantages', 'the consequences on minor use authorisations are taken into account' and if

(iii) 'the chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism' and if

(iv) the alternative 'is significantly safer for human or animal health or the environment'.

A comparison to the rules for BPs specified above shows that the two schemes have the following common elements:

- the idea of active substances as CFS
- comparison to existing chemical and non-chemical alternatives
- resistance management by protecting chemical diversity
- avoidance of significant economic or practical disadvantages
- the idea of significant risk/safety differences for human health, animal health and the environment

A minor difference is that for PPPs, there is a notion of a "minor use" which needs to be taken into account separately.

In contrast to the BPR, the PPPR gives a quantitative definition of a significant difference in environmental risk. Here, Annex IV to the PPPR specifies that 'For the environment, if relevant, a factor of at least 10 for the TER of different PPPs is considered a significant difference in risk'.

The European Commission has issued a Draft Guidance Document on Comparative Assessment and Substitution of Plant Protection Products (European Commission 2014), clarifying some procedural

aspects. However, it is not specified how to deal with the fact that the environmental risk assessment consists of a number of separate assessments for different groups of organisms (alga, fish, bees etc.) and for different time periods (acute, chronic), so there is not a single TER, but one TER for each of the risk assessments[1].

This guidance document was available from the website of the European Commission[2] . Irritatingly, the document was not available at the time of this writing (29 September 2016).

In an unpublished project report resulting from a project previously commissioned by the German Environment Agency (Altenburger et al. 2015), some principles were proposed for an operational definition of "significant difference in environmental risk". These principles were formulated as follows:

- The comparative assessment is performed on the basis of full risk profiles, including all relevant endpoints for the regulatory environmental risk assessment of PPPs for which comparable TER values or equivalent risk indicators are available;
- The decision to assess a significantly reduced risk of an alternative PPP is to be taken if a significant reduction for one or more endpoints and no significant risk increase for any endpoint is found. A significant difference in risk requires a factor of at least 10 for the toxicity exposure ratio or an equivalent risk indicator;
- Exemptions can be granted for borderline cases or extreme situations where expert judgement should be included;
- In case of doubt the comparative assessment should not claim a significant difference in risk.

These principles were tested using five candidate products in binary comparisons to alternative products, with a total of ten binary product comparisons. While some weaknesses of the approach were discovered during these case studies, a clear discriminatory power was found, as a significant difference in risk was found in 6 out of the 10 product comparisons.

Note that while 42 regulatory endpoints were identified for the comparison of PPPs (15 for birds and mammals, 8 for aquatic organisms, 19 for terrestrial organisms), quantitative comparisons were only possible for 8 to 19 endpoints in the 10 case studies investigated by Altenburger et al. (2015).

Regarding the comparability of TER values between different assessments, already the Draft Commission Guidance Document (European Commission 2014) noted that comparisons should only be made based on "conceptually equivalent" TER values. However, such a conceptual equivalence is not further specified. For example, TERs are typically only calculated for the most sensitive species, which are often different for the different a.s. or products. Furthermore, TER values, and generally risk quotients are only strictly comparable when the same assumptions were used for their calculation. Therefore, the comparison of TER values at different refinement levels should be avoided. Based on their case studies, Altenburger et al. (2015, p. 116) note that "for developing an advanced and consented regulatory procedure for comparative risk assessments, detailed rules remain to be established for distinguishing between comparable and incomparable risks". It is proposed later that comparisons could exclusively be based on RQ calculations without any specific risk mitigations measures, but no final conclusion was reached on this point (Altenburger et al. 2015, p. 162).

2.4 Preliminary conclusions from the analysis of the status quo

As detailed in section 2.2, a number of legally binding (section 2.2.1) and officially recommended (section 2.2.2) characteristics of a comparative assessment of biocidal products under the BPR have been defined. However, the comparative assessment of alternatives to the use of hazardous substances is a

[1] The acute risk assessment for bees is not based on the calculation of a TER but on the calculation of a hazard quotient.

[2] http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/comparative_assessment_substitution_rev_1107-2009.pdf

potentially very complex task, and existing methods and approaches suffer from a number of problems (Fantke et al. 2015, Tickner and Jacobs 2016) that are partially also valid for comparative assessments under the BPR.

Even before the attempt to apply the existing guidance in WP 2, several conclusions can be drawn from the analysis of the available documents. These are listed in the following subsections.

2.4.1 Definition of uses

An efficient selection of eligible alternative BPs for a certain use depends on a harmonized system of

- Product type
- Possible authorised uses within each product type
- Categories of target organisms
- Possible fields of use
- User categories
- Categories of application methods

in the sense of paragraph (31) of the TGN. Even if the comparative assessment is performed by each member state separately, the procedure should be harmonized across Europe. Therefore, it is desirable to establish such a system under consultation with other member states. Eventually, it could be integrated into the Register for Biocidal Products (R4BP), which would facilitate an automated selection to a high degree.

In order to be useful for comparative assessments, aspects of the use that have an impact on the comparability of uses should be differentiated in such a system. This will be investigated in WP 2.

Just from an analysis of the guidance it is clear that mapping the uses of a relevant product to the uses of eligible alternative products may require splitting up use definitions that comprise different target organisms, different fields of use, different user categories or even different application methods, if they have an impact on the possibility of equivalent substitution.

2.4.2 Chemical diversity

It needs to be clarified if microorganisms in the sense of the BPR should count as a separate class of substances or MoA in the screening phase of the assessment.

2.4.3 Main area of concern

It appears possible that the main area of concern is human or animal health, but no products with a significantly better risk profile regarding this area of concern can be found. According to the TGN, the environmental risk would not have to be evaluated in this situation.

2.4.4 Database of risk relevant properties to support ranking

For the comparative assessment at Tiers I-A and I-B, as described in the TGN, it would be convenient to have the relevant information in list stored in a database system that allows for instant ranking of biocidal products.

For a Tier I-A according to the TGN, this system should contain the H/P statements and the RMMs. The latter requires the establishment of a harmonized system of risk mitigation measures, which is already under development.

At Tier I-B, the system would store the relevant risk information, i.e., for the environment, the data associated with PBT, i.e. endpoints from degradation tests, endpoints relevant for bioaccumulation and ecotoxicity endpoints. As the TGN specifically mentions also RQs, such information could also be integrated. However, if the procedure should be automated in any way, RQs should only be stored together with the information necessary to decide if the RQs are comparable or not. This comprises the guid-

ance documents and models used, any refinements used in the risk assessment, and the exposure pattern (scenario) for which the RQ was obtained.

As the Summaries of Product Characteristics (SPCs) and Product Assessment Reports (PARs) from which the data were extracted are currently not publicly available, the access to the corresponding contents of the database will also have to be restricted for the time being.

Within the project, it was agreed that the information about the specific uses and the risk relevant properties should be collected in spreadsheets and/or a database, in order to gain experience on how this data should be structured.

2.4.5 Outlier products and outlier values

Based on the criticism on the concept of outlier products and outlier values proposed in the TGN, it should be checked if the intention of finding significant differences in environmental risk could not be achieved in a better, more consistent way without using the concept of outliers.

2.4.6 Tiered assessment scheme

As it was questioned if the information used at Tier I-A is sufficient to decide if the difference in environmental risk is significant, it was agreed in the Kick-off meeting of this project that during WP 2, Tier I-B will always be carried out, independent of the outcome of Tier I-A.

2.4.7 Decision criteria at Tier I-A

The examples shown for the assessment at Tier I-A do not result in a clear scheme on how a significant difference at this step should be defined. Neither the definition of the term significance given in the TGN, nor the introduction of the outlier concept provide guidance that is directly applicable in practice in an unambiguous way. Therefore, it should be checked, if a clear and unambiguous scheme could be defined.

2.4.8 Decision criteria at Tier I-B

No definitive decision criteria are specified at Tier I-B. For the environmental part of the assessment, the requirement to assess properties associated with the PBT criteria raises the question, how the decisive information (such as single media half-life values) can be aggregated to form the basis of the required quantitative comparison. Also, PBT properties are typically assessed for each active ingredient, while products may contain two or more active ingredients with different PBT related properties. The TGN remains completely silent on these questions.

Furthermore, it is left open if RQs should be part of the assessment at Tier I-B at all. For the case that a competent authority (CA) decides to use this type of information at Tier I-B, not only it has to decide on the principal comparability of RQs (i.e. they may not be comparable because different refinement levels were used), it is also not clarified if all RQs should have the same weight in a comprehensive risk comparison. For example, should a RQ resulting from a local risk assessment for the soil in the immediate vicinity of a fence post have the same weight as a RQ for agricultural fields, resulting from the presence of a contaminant in sewage sludge that is applied on such fields?

2.4.9 General conclusion from WP 1

In general, it can be stated that comparative assessments, even if only comparisons with chemical alternatives (Tier I-A and Tier I-B) with regard to the environment are considered, will have to heavily rely on *ad hoc* decisions. While it may be possible to document them in a clear and transparent way, it can be anticipated that it is very likely that different authorities will come to different conclusions, not to speak of applicants that may wish to dispute the outcome of the assessment in the case it leads to non-authorisation or restrictions for their product. Therefore, it appears that the assessment method will have to be defined much clearer if comparative assessments are to provide a robust basis for substitution based on article 23 of the BPR.

3 WP 2: Evaluation of the existing guidance based on example products

The aim of this WP was to exemplarily conduct comparative assessments strictly according to the existing TGN (European Commission 2015). By this exercise, limitations, problems and gaps of the current guidance should be identified. In subsequent work packages, the findings will be compiled and discussed (WP3) and identified shortcomings will be considered in developing recommendations for an improved guidance (WP4).

Two product types, PT 08 (wood preservative products) and PT18 (insecticides, acaricides and products to control other arthropods) were selected for the exemplary comparative assessments, because numerous products from these PTs are authorised in Germany with available dossiers. Within these PTs, information on products authorised for the German market and with available regulatory documentation (Summary of Product Characteristics, SPC, and Product Assessment Reports, PARs) were compiled by UBA and reviewed within the project. Based on this information, the relevant BPs for the exemplary comparative assessment were selected during the first project meetings. This selection took into consideration the presence of CFS in the products, amount of available information and expected representation of various use patterns. Alternative products were selected from the same pre-selected pool of products. Since this pool did not represent all potentially available alternative products on the market, the comparative assessment is clearly an exemplary exercise without implying any regulatory consequences for individual products. In total, three different intended uses per product type were taken through such an exemplary comparative assessment. These assessments will be detailed in the following, separately for the two product types. It is important to note that the comparative assessment relates to the intended uses, not to the product as such. The steps of assessing non-chemical alternatives and economic disadvantages were omitted as this was beyond the scope of the present project.

3.1 Wood preservative products

Four among the eight wood preservative products reviewed in the selection process for the relevant BP contained the active substance tebuconazole, which was identified during the review process at EU level as a potential CFS because of P (persistence) and T (toxicity) properties. No other (potential) CFS were present in the pre-selected wood preservative products. Hence, two products with tebuconazole were selected to serve as relevant BP, i.e. as BP being the subject of an exemplary comparative assessment.

3.1.1 Intended uses of the relevant BP and mapping of alternatives

The definition of the intended uses is already part of the comparative assessment as it determines which alternative products will be taken into account. According to the TGN, intended uses within PTs are defined by the combination of six elements: product type, exact description of authorised use (where relevant), target organism(s), field of use, category of user, and application method. These shall be seen in connection with the respective RMMs and 'instructions for use' (TGN, 5.1 (31)). As example for wood preservative products, the TGN states the combination of 'wood staining fungi – professional users – spraying – outdoor' as one intended use. The definition of the intended uses for a comparative assessment shall be based on the SPC of the product, which in turn shall be based on the *Application Code Document* for the respective PT to ensure consistency as stated in the TGN. For wood preservatives, the *Application Code Document* (TM 2004) lists eight categories of which five (target organisms, their developmental stages, field of use, user category, and method of application) directly relate to those mentioned in the TGN for defining the intended use. Two of the remaining three categories can be seen to relate to the TGN category 'authorised use' (i.e., 'function/mode of action' and 'application aim'), while the third one ('type of formulation') is apparently not reflected in the six aspects considered for the definition of the intended use in the TGN.

The intended uses selected for the exemplary comparative assessments were defined as summarised in Table 1. In the SPC of both relevant BPs, the TGN category "Where relevant, exact description of the authorised use" was not explicitly stated. It is not clear, however, which type of information is foreseen for this category. Wood destroying fungi (Basidiomycetes) were listed as target organisms for product 1. For product 2, wood rotting fungi as well as wood disfiguring (discolouring) fungi were stated. Wood destroying fungi are not explicitly mentioned in the relevant *Application Code Document* (TM 2004). It is assumed here that 'destroying' is a synonym for 'rotting', which is the term used in the *Application Code Document*. According to this document, soft rot fungi belong to the wood rotting fungi, but not to the Basidiomycetes. Hence, soft rot fungi would not be considered as target organisms of product 1, which needs to be taken into account for the identification of alternative products. Wood disfiguring fungi (target organisms of product 2 selected for the intended use) include blue stain, sap staining, and mould fungi (TM 2004). For both products, only preventive use is stated as application aim in the SPC. Product 1 is authorised only for outdoor use but for wood without ground contact (use class 3), while product 2 is authorised for use class 3 and use class 2 (outdoors under cover with only occasional wetting). The difference between the intended use 1 and 2 is the user category, since this was the only category of product 1 with different entries. The only authorised application method for product 1 is brushing. For the intended use 3, industrial users were selected in the user category for this exemplary exercise. In the *Application Code Document* (TM 2004), the term 'specialised user' is mentioned, which is translated to '*sachkundiger Verwender*'. Yet, this appears to be a misleading translation given the more detailed descriptions in the PAR and particularly the descriptions and definitions in *Transitional Guidance on Efficacy Assessment for Product Type 8* (ECHA 2015). In this guidance, 'industrial' but not 'specialized professional' is stated as user category. Dipping was selected for the exemplary comparison as application method among a number of authorised application methods for the industrial user. Use class 3 was selected as field of use, as no environmental risk assessment was conducted specifically for use class 2 in the PAR of the product.

Table 1: Three intended uses of the wood preservative products selected for the exemplary comparative assessment, solely based on their SPC

	Product 1		Product 2
Intended Use	**Use 1**	**Use 2**	**Use 3**
Exact description of authorised use, where relevant [a]	*not explicitly specified*	*not explicitly specified*	*not explicitly specified*
Target organism (s), including developmental stages [a]	wood destroying fungi (Basidiomycetes)	wood destroying fungi (Basidiomycetes)	wood disfiguring (wood discolouring) fungi
Field of use [a]	use class 3 (outdoors, but not in ground contact)	use class 3 (outdoors, but not in ground contact)	use class 3 (outdoors, but not in ground contact)
Category of users [a]	non-professionals	Professionals	specialised professionals (industrial)
Application method [a]	brushing	Brushing	dipping
Function/mode of action [b]	*not explicitly specified*	*not explicitly specified*	fungicide
Application aim [b]	preventive	preventive	preventive
Formulation type [b]	oil-based with water as main solvent		solvent-based

[a] Category used for definition of intended use in the TGN; [b] other categories listed in the application code document for wood preservative products

In Table 2, the relevant as well as the eligible alternative products for the three different intended uses are listed based on the exact descriptions given in their respective SPCs. For those products among the eight pre-selected ones that were not eligible as alternative BP, reasons for this decision are stated.

Based on the available information (SPC and PAR, including the outcome of the risk assessment), products 2 and 4 appear to be identical. Therefore, product 4 was not further considered here as al-

ternative for any of the intended uses. Product 8 was not eligible as alternative because dipping was not among the application methods for the only authorised user category, industrial users.

Table 2: Shortened intended use description for the relevant (intended use in bold) and the eligible alternative wood preservative products based on the respective SPCs

Product (active substances)	Intended Use 1	Intended Use 2	Intended Use 3
Product 1 (tebuconazole)	**wood destroying fungi – use class 3 – non-professionals – brushing – preventive – water-based**	**wood destroying fungi – use class 3 – professionals – brushing – preventive – water-based**	*not against wood disfiguring fungi, no industrial use, no dipping*
Product 2 (tebuconazole, IPBC)	wood rotting fungi – use class 3 – non-professionals – brushing – preventive – solvent-based formulation	wood rotting fungi – use class 3 – professionals – brushing – preventive – solvent-based formulation	**wood disfiguring fungi – use class 3 – industrial – dipping – preventive – solvent-based**
Product 3 (propiconazole, IPBC)	wood rotting fungi – use class 3 – non-professionals – brushing – preventive – solvent-based	wood rotting fungi – use class 3 – professionals – brushing – preventive – solvent-based	wood disfiguring fungi – use class 3 – industrial – dipping – preventive – solvent-based
Product 4 (tebuconazole, IPBC)	*Apparently identical to product 2; therefore, not further considered*		
Product 5 (propiconazole, IPBC)	*no non-professional use*	wood rotting fungi – use class 3 – professionals – brushing – preventive – solvent-based	wood disfiguring fungi – use class 3 – industrial – dipping – preventive – solvent-based
Product 6 (propiconazole)	*no non-professional use*	wood destroying basidiomycetes – use class 3 – professionals – brushing – preventive – water-based concentrate	sap stain fungi, blue stain fungi, moulds – use class 3 – industrial – dipping – preventive – water-based concentrate
Product 7 (IPBC)	*no non-professional use against wood destroying fungi*	wood rotting basidiomycetes – use class 3 – professionals – brushing – preventive – solvent-based	*only against blue stain fungi*
Product 8 (Copper carbonate, propiconazole, tebuconazole)	*no non-professional use*	*no professional use*	*no dipping*

The terminology regarding target organisms was not always consistent among the product SPCs. As stated above, the frequently used term “rotting” was considered as synonym for “destroying”, which enabled identifying alternative products for the intended uses 1 and 2. Target organism(s) can be linked to the user category as illustrated by product 7 for which the SPC explicitly states wood destroying fungi as target organisms only for professional and industrial use. As target organisms of product 6 “sap stain fungi”, “blue stain fungi” and “moulds” were specified, which together represent “wood disfiguring fungi” according to the application codes document. The SPC of product 7 (which relates to a generic product family) listed only blue stain fungi as target organism, which renders this product not eligible as alternative for the intended use 3. However, “wood disfiguring fungi” in general were stated as target organisms in the PAR of product 7, which would turn it into an eligible alterna-

tive. The product was, however, not further considered as alternative product for the use 3 in the present study.

The formulation type of the alternative products was not always identical with that of the relevant BP. However, it was not considered here as criterion in the definition of the intended use, which is in accordance with the TGN.

Two alternative products were identified for the intended use 1, while the same plus three more alternative products were identified for the intended use 2 (Table 2). For the intended use 3, three alternative products were identified. Product 2, the relevant product for the selected intended use 3, was identified as alternative product for the intended uses 1 and 2. This is in accordance with the TGN as products are eligible as alternative even if they contain components listed as CFS themselves.

3.1.2 Screening phase

The screening phase according to TGN provides an early filter step meant to reduce the number of complex and laborious comparative assessments. To this end, the comparative assessment process shall immediately stop if the diversity of authorised products is deemed not sufficient for minimizing resistance development of the target organisms unless the relevant BP contains one or more active substances that meet the exclusion criteria.

Tebuconazole is the active substance identified as potential CFS in the two relevant products, while none of the other active substances in the pre-selected products fulfil the substitution criteria. According to the fungicide resistance action committee (FRAC 2008), the MoA of tebuconazole is the inhibition of the C14-demethylase in the ergosterol biosynthesis pathway of fungi (demethylase inhibiting fungicide, DMI). Several of the alternative products also contain tebuconazole or the structurally related azole propiconazole, which has the same MoA as tebuconazole. All of the identified alternative products (except one) contain IPBC, mostly in combination with an azole. IPBC is a carbamate that targets cell membranes and represents thereby a different MoA than the two azoles propiconazole and tebuconazole. The TGN states that at least three active substance/mode of action combinations are required to assume adequate chemical diversity. Yet, the term “active substances/mode of action combination” is not further defined, and it is hence unclear if propiconazole and tebuconazole, both having the same MoA, shall be considered as two different “active substance/mode of action combinations” in the meaning of the TGN. In terms of resistance development presumably rather not, because cross-resistance among azoles can be assumed given the identical target site (SCC 2002, Chakrabarti 2011). Hence, the a.s. in the relevant and alternative products together represent two different MoA, which constitutes even before substitution insufficient chemical diversity. Substitution of the tebuconazole-containing two relevant products would not (further) reduce the chemical diversity as for each intended use there are alternative products with IPBC and/or a DMI fungicide available. However, it is unclear from the TGN if the comparative assessment should also stop if inadequate chemical diversity is not created through substitution but already present without substitution.

None of the three a.s. in the products meets the exclusion criteria (labelled as carcinogen, mutagen or toxic for reproduction (categories 1A or 1B), endocrine-disruptor, PBT, or very persistent and very bioaccumulative, vPvB). Therefore, continuation of the comparative assessment would not be trigged by this criterion.

The active substance/mode of action combinations among the eight pre-selected products in the present study do not necessarily mirror the full chemical diversity of authorised products as discussed above. Hence, independent of the question regarding adequate chemical diversity before substitution, the exemplary comparative assessment for all three intended uses proceeds to Tier I-A.

3.1.3 Tier I-A

Tier I-A represents another filter step, where the comparative assessment is directed either to a comparison with non-chemical alternatives (Tier-II) or a detailed quantitative comparative assessment (Tier I-B). According to the TGN, the assessment at Tier I-A shall be carried out based on the information available at the SPC level, namely RMMs and/or H/P statements. Such information was collected from the SPCs of the relevant and alternative products. Only phrases regarding the environment were considered since the focus of the project was on the environment part of the comparative assessment. It was not explicitly stated, but can be assumed that such phrases would be related in some way to the persistence and toxicity properties of tebuconazole as required pre-condition for usage in Tier I-A according to the TGN (6.2.1.1.1)

3.1.3.1 Risk Mitigation Measures

The definition of a RMM follows here the understanding of the UBA according to which a RMM must be formally established to reduce a risk identified in an environmental risk assessment (ERA), i.e. an ERA without the RMM must be available and indicate unacceptable risk. The first key observation when starting with Tier I-A was that, with the exception of product 7, none of the SPC documents contained an explicit section listing RMMs. Phrases regarding the protection of the environment were instead collected from various sections of the SPC such as “Measures to protect the environment”, “Conditions of use”, “Measures for cleaning/collecting”, “Instructions for safe use of the product”, and “Instructions for safe disposal of the product and its packaging”. This variety was apparently due to the non-standardized structure of SPCs from different CAs. The following tables list all phrases present in any of these sections in the SPCs that relate to the protection of the environment and that are linked to the intended use in question. For the sake of clarity and brevity, they were shortened for display in the tables. In order to identify which phrase actually resulted from a risk identified in the environmental risk assessment and, hence, indeed represented a formal RMM, it was necessary to consult the respective PAR. Phrases that were clearly identified as RMMs based on the additional information from the PAR are indicated in bold in the following tables. Collected phrases are summarised in the following tables by grouping those with a (presumably) similar meaning in the same lines. This was relatively easy for products that were assessed by the same CA, but more difficult for phrases from SPCs assessed by different CAs, which illustrates the current lack of standardization of such phrases.

Intended Use 1

For the intended use 1 (Table 3), the number of phrases in the SPCs of the alternative products appeared to exceed that of the relevant BP. Yet, this was due to the fact that the phrases regarding the avoidance of soil and surface water contamination for the alternative products were more specific and somewhat redundant. The first phrases of the relevant BP regarding prevention of soil and surface water contamination resulted from identified risks in the (refined) house and bridge-over-pond scenario. Hence, they represent RMMs established based on identified risks. Almost similar phrases were found for the alternative BPs. Yet, they are more general (‘Do not contaminate soil and surface water’). Consultation with the PAR revealed that only for product 3 the phrase relating to soil is based on identified risk, i.e. represents an RMM. In-situ application to wood near water is not explicitly prohibited in the SPC; it is rather left to the user how the contamination of surface water can be avoided during such application. Yet, consultation with the PAR reveals that in-situ brushing (professional or non-professional) in the vicinity of water courses is deemed as being excluded in the labelling of the alternative product 3. Therefore, no RQs were calculated in the PAR for the scenario bridge-over-pond for in-situ brushing. Hence, the phrases in the SPCs regarding usage of the product near water only appears slightly less restrictive in the case of product 3, but in fact the same restrictions as for the relevant product apply (no in-situ brushing of wood near to surface water at all). Hence, based on the SPC only it could be argued that the phrases listed in the first row of Table 3 are stricter for the relevant

than for the alternative BPs, but in fact they are not. The phrases for the alternative product relate not only to the application of the product, but also to the drying time of the treated wood, whereas the phrases for the relevant BP require generally the prevention of run-off. It is not obvious, which of these phrases should be deemed more restrictive.

Table 3: Intended Use 1: Phrases regarding protection of the environment in the SPC of the relevant and the alternative wood preservative products

Relevant BP (product 1)	Alternative BP (product 2)	Alternative BP (product 3)
Cover soil during application. Product must not be used near surface water; prevent run-off to surface water [a, b]	Do not contaminate soil and surface water during in-situ application and while surface is drying [c]	**Do not contaminate soil** and surface water **during in-situ application and while surface is drying** [b, c]
No use on materials in direct contact with water or soil [a, b]	For use on timbers not in ground contact, not in permanent contact with fresh or salt water, and not permanently exposed to weather [c]	
Prevent entering drains or watercourses [a]	Do not empty into drains [c]	
Disposal as hazardous waste [a]	Disposal of material and container in a safe way [c]	
To comply with efficacy claim, apply topcoat within 1 month [c]	**Product must always be overcoated with non-biocidal topcoat when exposed to weathering** [b]	-
-	Do not contaminate ground, waterbodies or watercourses with chemicals or used container [c]	
-	Do not contaminate plant life, and cover fish bowls/ponds, aquariums and all water storage tanks aquariums before application [c]	
-	Keep away unprotected persons and animals for 48 h or until surfaces are dry [c]	
-	Dangerous to bats [c]	

[a] listed under 'Measures to protect environment' in the SPC; [b] **resulting from environmental risk assessment as stated in the PAR**; [c] listed under 'Conditions of use' in SPC

The phrase "No use on materials in direct contact with water or soil" was listed in the SPC of the relevant BP 1, and was established as RMM based on the risk assessment in the bridge-over-pond scenario in the PAR (refined risk quotients above 1 for time 1 and time 2). Similar phrases were found in the SPCs of the alternative products without representing RMMs as they were not formally triggered by the risk assessment in the PARs. Hence, the relevant product appears to have an RMM that the alternative products do not have. However, this phrase or RMM simply reflects the use class 3 for this product (as part of the definition of the intended use). Therefore, this phrase should not be used in the comparative assessment.

For the relevant product 1, application of a top coat is required "to comply with the efficacy claim" as stated in the SPC. Since this top coat requirement did not result from an environmental risk assessment (which was based on an exposure estimate obtained without top coat), it represents not an RMM to be used in the comparative assessment at Tier I-A. For one of the alternative products, in contrast, application of a top coat was required as consequence of the risk assessment. In addition, both alternative products were labelled as "dangerous to bats", likely resulting from a national regulation that did not apply for the relevant product which was assessed by a different CA.

Overall, the case of the intended use 1 illustrates the problem of distinguishing between conditions of use and RMMs in Tier I-A. If all restrictions, regardless if they represent RMMs established due to identified risks or not, are taken into account, the relevant and the alternative products hardly differ as long as the wording 'do not contaminate surface water during in-situ application' is deemed similar in meaning to 'product must not be used near surface water'. In fact, the consultation of the PAR revealed

that the meaning is indeed similar. If only formally established RMMs are taken into account, the relevant BP has one stricter RMM (no use near surface water) and one RMM less than one of the alternative BPs. This is the top coat requirement, which is formally not an RMM since it did not result from an identified environmental risk.

For the second intended use of product 1, three more products were identified as alternatives in addition to product 2 and 3. The phrases from the respective SPCs were collected in a similar way as for the intended use 1 and listed in Table 4. The alternative product 7 is the only one that has no RMMs established (and the only one with a formal RMM section in the SPC, which does not contain any phrases regarding the environment). For two alternative products, application of a top coat is required as consequence from the ERA (i.e., as RMM), and two of the five alternatives have a similar RMM established regarding protection of soil and water. Another one (product 6) has a similar RMM but only with regard to water, but not to soil. Hence, it could be argued that two of the five alternative products (product 6 and 7) have slightly less restrictive RMMs (as identified with the help of the PAR) than the relevant product 1. Yet, two out of five alternative products do not represent a majority and according to the TGN, the relevant product would not be considered an outlier therefore. In addition, the RMMs were only identifiable from the PAR. Based only on the phrases stated in the SPCs, no difference was seen in restrictiveness, except the non-protection of soil in the SPC of product 6.

Intended Use 2

Table 4: Intended Use 2: Phrases regarding protection of the environment in the SPC of the relevant and the alternative wood preservative products

Relevant BP (product 1)	Alternative BP (product 2)	Alternative BP (product 3)	Alternative BP (product 5)	Alternative BP (product 6)	Alternative BP (product 7)
Cover soil during application. Product must not be used near surface water; prevent run-off to surface water [a, b]	Do not contaminate soil and surface water during in-situ application and while surface is drying [c]	**Do not contaminate soil** and surface water **during in-situ application and while surface is drying** [b, c]	**Do not contaminate soil and surface water during in-situ application and while surface is drying** [b,c]	**-**	Do not allow the product to enter ground/soil or surface water [a]
No use on materials in direct contact with water or soil [a, b]	For use on timbers not in ground contact, not in permanent contact with fresh or salt water, and not permanently exposed to weather [c]			**No use of treated wood over or near water bodies** [b,c]	-
Prevent entering drains or watercourses [a]	Do not empty into drains [c]			Do not allow product to reach sewage system or water bodies [a]	Do not allow product to reach sewage system or water bodies [a]
Disposal as hazardous waste [a]	Disposal of material and container in a safe way [c]			Dispose of in a manner approved by Local Authority	-
To comply with efficacy claim, apply topcoat within 1 month [c]	**Product must always be overcoated with non-biocidal topcoat when exposed to weathering** [b]	-	**Apply non-biocidal topcoat, when exposed to weathering** [b,c]	-	-
-	Do not contaminate ground, waterbodies or watercourses with chemicals or used container [c]			-	Prevent from spreading [a]
-	Do not contaminate plant life, and cover fish bowls/ponds, aquariums and all water storage tanks aquariums before application [c]			-	-
-	Keep away unprotected persons and animals for 48 h or until surfaces are dry [c]			-	-
-	Dangerous to bats. [c]			-	-

[a] listed under 'Measures to protect environment' in the SPC; [b] **resulting from environmental risk assessment as stated in the PAR**; [c] listed under 'Conditions of use' in the SPC

Intended Use 3

Similar to the finding for intended use 1 and 2, the phrases in the SPC of the products evaluated for the intended use 3 are partly identical and partly a (presumably) similar meaning is expressed in different wordings (Table 5). Regarding the RMMs as identified based on the PARs, application of a top coat was only required for the relevant product 2 and product 5 as one of the three alternative products.

Phrases regarding the prevention of the contamination of soil and water during application *in-situ* were not considered, because this is not relevant for industrial use where application takes place in an industrial facility in a contained area.

Table 5: Intended Use 3: Phrases regarding protection of the environment in the SPC of the relevant and the alternative wood preservative products

Relevant BP (product 2)	Alternative BP (product 3)	Alternative BP (product 5)	Alternative BP (product 6)
For use on timbers not in ground contact, not in permanent contact with fresh or salt water, and not permanently exposed to weather [a]			**No use of treated wood over or near water bodies** [b, c]
Freshly treated timber must be stored under shelter or on an impermeable hard standing to prevent direct losses to ground or water. Any losses (plus rainwater) must be collected for reuse or disposal [a, b]	**Storage of treated wood must either be undercover with a recovery system in place or on impermeable hard standing and bunded to prevent run-off with a recovery system in place** [a, b]	**Storage of treated wood must either be undercover with a recovery system in place or on impermeable hard standing and bunded to prevent run-off with a recovery system in place** [a, b]	**Freshly treated timber must be stored under shelter or on an impermeable hard standing to prevent direct losses to ground or water. Any losses must be collected for reuse or disposal** [b, c]
Do not contaminate ground, waterbodies or watercourses with chemicals or used container [a]			Do not allow the wash water to run off into any sewer, stream, well or pond. Soak up spilled material with absorptive material; prevent product from spreading [d]
Dispose of surplus chemical, contaminated materials (including sawdust) and the empty container safely using a method approved by the waste disposal authority [a]			Dispose of in a manner approved by Local Authority; Spilled product cannot be used and must be disposed of; Dispose of empty containers in an incinerator approved for chemicals [d]
Product must always be overcoated with non-biocidal topcoat when exposed to weathering [a, b]	-	**A non-biocidal top-coat (minimum of three coats) must be applied to use of the treated timber in situations where exposed to weathering** [a, b]	-
-	Application processes must be carried out within a contained area, situated on impermeable hard standing, with bunding to prevent run-off and a recovery system in place [b]		-

[a] listed under 'Conditions of use' in SPC; [b] **resulting from environmental risk assessment as stated in the PAR;** [c] listed under 'Instructions for safe use of the product'; [d] listed under 'Instructions for safe disposal of the product and its packaging

All products have the same RMM stating that freshly treated timber must be stored under a roof or placed on impermeable hard standing. The application of a top coat as RMM is prescribed for the relevant product 2 as well as for the alternative product 5. In contrast to all other products, wood treated with product 6 is not allowed to be used near or over water bodies based on an environmental risk identified in the bridge-over-pond scenario in the PAR. Hence, one stricter RMM is established for the alternative product 6 compared to the relevant product 2, while the relevant and one alternative BP have one stricter RMM compared to all other alternatives. Overall, this does not indicate that the relevant product 2 is an outlier in terms of RMMs related to the environment.

3.1.3.2 H/P statements

H/P statements were collected from the most recent SPCs of the products, and additionally cross-checked with the PARs. The classification and labelling for the various products was derived from different regulations, i.e. as risk and safety phrases according to Directive 67/548/EWG (European Communities 1967) or as hazard and precautionary statements according to Regulation EC 1272/2008 (European Council 2008). They were mostly stated in their abbreviated form (e.g. H411), and rarely only in the respective longer term (e.g. "Harmful to aquatic life with long lasting effects").

Intended Use 1 and 2

There are no H/P statements concerning the environment listed in the most recent SPC of the relevant product 1 (Table 6). In an earlier version, the product was classified due to the presence of a substance of concern (SoC), which has been substituted in the meantime. No H/P statements regarding the environment are established for the alternative product 2, neither in the SPC nor in the PAR. Product 3 is classified as "Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment" (R52/53) in the SPC (and the PAR) and in addition the safety phrase S61 (avoid release to the environment) is stated. S61 should always be stated if R52/53 is stated according to Directive 67/548/EWG Annex VI (European Communities 1967). Hence, S61 does not provide any additional information for a comparative assessment.

For the three additional alternative products considered for the professional use of product 1 (intended use 2), H/P statements are established (Table 6). For product 7, H/P statements are given as full text in the SPC, but they are not mentioned in the PAR. Overall, the relevant product 1 does not have stricter but rather less strict H/P statements than the alternative products.

Table 6: Intended Use 1 and 2: H/P statements for the relevant and the alternative wood preservative products

Relevant BP (product 1)	Alternative BP (product 2)	Alternative BP (product 3)	Alternative BP (product 5)	Alternative BP (product 6)	Alternative BP (product 7)
-	-	R52/53 [a]	R52/53 [a]	R51/53, H411 [a]	Aquatic Chronic 3; Harmful to aquatic life with long lasting effects [b]
-	-	S61 [a]	S61 [a]	S61 [a]	Avoid release to the environment [b]
-	-	-	-	P273, P391, P501 [a]	-

[a] listed in the SPC (and in the PAR); [b] listed only in the SPC

Intended Use 3

Since product 2 was the only one among the considered products without any H/P statement related to the environment it appears to be a 'positive' outlier in terms of less restrictive statements (Table 7).

Table 7: Intended Use 3: H/P statements for the relevant and the alternative wood preservative products

Relevant BP (product 2)	Alternative BP (product 3)	Alternative BP (product 5)	Alternative BP (product 6)
-	R52/53 [a]	R52/53 [a]	R51/53, H411 [a]
-	S61 [a]	S61 [a]	S61 [a]
-	-	-	P273, P391, P501 [a]

[a] listed in the SPC (and in the PAR)

3.1.3.3 Conclusion of Tier I-A

The RMMs and the H/P statements related to the environment were not stricter for the relevant products 1 and 2 than those of the majority of the alternative products. Hence, the relevant products cannot be considered 'outliers' in the meaning of the TGN. The comparative assessment should therefore continue with Tier II, i.e. comparison with non-chemical alternatives. Yet, in the course of the present project an exemplary quantitative comparative assessment according to Tier I-B was conducted nevertheless.

Key findings from the exemplary Tier I-A assessment are:

- RMMs cannot be identified from the SPC alone, but only with the additional consultation of the PAR as illustrated by several examples
- RMMs and H/P statements are not well standardized in terms of wording across different products and competent authorities. This renders the comparison of the strictness of the requirements rather ambiguous.
- RMMs and conditions of use remain even after consultation of the PAR as sometimes hard to distinguish from each other. The same requirement (application of a top coat or no use of product near surface water) can represent a condition of use or a formal RMM resulting from identified risk in the PAR. However, it remains open if a risk assessment without the consideration of this conditions of use would have resulted in a respective RMM. In other words, by not evaluating certain scenarios in the PAR based on restrictions in the condition of use, the formal establishment of an RMM can be avoided. Therefore, the differentiation between condition of use and RMM is arbitrary and rather questionable.
- Definition of a 'majority' and, hence, the 'outlier' status of the relevant BP appears highly questionable if only few alternative products are available

3.1.4 Tier I-B

According to the TGN, the assessment in Tier I-B should focus on the area of concern for the CFS of the relevant product, and take only into account data available in the PAR that relate to these criteria. With regard to the environment, only data relating to PBT properties would be relevant according to the TGN.

The environmental area of concern of the CFS tebuconazole in the present exercise is persistence (P) and toxicity (T). Hence, the relevant products will be compared with the identified alternative products with regard to values/data in the PAR that relate to these properties. The TGN does not specify which values or data are deemed appropriate for a qualitative or quantitative comparison at Tier I-B. As examples, only RQs or risk characterisation ratios are named (TGN 6.2.2 (83)). Since the relevant environmental data for the classification as P and T are degradation half-lives in environmental compartments and aquatic chronic toxicity, respectively, these data were compiled for the comparison. The comparative assessment relates to products, i.e. mixtures of various substances, while the PBT criteria only apply to individual substances. In order to account for the mixture property, the data were compiled for all a.s. in the relevant and alternative products, as far as possible. In addition, RQs determined for the relevant scenarios of the intended uses were compiled. The relevant scenarios were based on the Emission Scenario Document (ESD) for each intended use.

3.1.4.1 Values relating to P and T properties

For the active substances, data regarding persistence and toxicity properties (Table 8) were compiled from the Competent Authority Reports (CARs) prepared for active substance approval. With regard to values related to persistence, it was sometimes not clear from the PAR to what the reported degradation/dissipation half live (DT_{50}) referred (primary or ultimate degradation or just dissipation from the respective compartment). In Table 8, these different estimates will be separated as far as possible by using $DegT_{50}$ for (primary) degradation half-lives and $DissT_{50}$ for dissipation half-lives. The values compiled in Table 8 are taken from the CARs and therefore usually relate to values that were re-calculated to 12°C.

Table 8: Values for persistence (P) and toxicity (T) related properties compiled from the list of endpoints of the CAR for the respective active substance

Property	Tebuconazole	IPBC	Propiconazole
Degradation half-life marine water	n.a.	n.a.	n.a.
Degradation half-life fresh water	198 days ($DegT_{50}$)	3.1 hours ($DegT_{50}$)	12.1 days ($DissT_{50}$)
Degradation half-life marine sediment	n.a.	n.a.	n.a.
Degradation half-life freshwater sediment	1 year ($DissT_{50}$)	3.3 hours (DT_{50})	> 1 year ($DegT_{50}$) whole system
Degradation half-life soil	> 1 year ($DegT_{50}$)	4.7 hours ($DegT_{50}$)	82 days (DT_{50})
Aquatic long-term NOEC (mg/l)	0.01 (*Daphnia*)	0.0046 (algae)	0.068 (fish)
Categorized as cancerogenic (1A or 1B), mutagenic (1A or 1B), or toxic for reproduction (1A, 1B, or 2)	Classified as toxic for reproduction, category 2	no	no
$PNEC_{water}$ (mg/l)	0.001 (AF of 10)	0.0005 (AF of 10)	0.0068 (AF of 10)
$PNEC_{sediment}$ (mg/kg w.w.)	0.55 (AF of 100)	n.a.	0.054
$PNEC_{soil}$ (mg/kg soil d.w.)	0.114 (AF of 50)	n.a.	n.a.
$PNEC_{soil}$ (mg/kg soil w.w.)	0.1 (AF of 50)	0.005 (AF of 1000)	0.02 (AF of 50) [a]

AF: Assessment Factor; n.a.: not available; $DegT_{50}$ degradation half-life; $DissT_{50}$ dissipation half-life; DT_{50} degradation or dissipation half-life, d.w. dry weight; w.w. wet weight; [a] PNEC of 0.1 mg/kg used in one PAR based on new chronic plant toxicity study

The most recent CAR for tebuconazole relates to its authorisation in PT07 (film preservatives). In this CAR (SC 2013), tebuconazole is classified as very persistent (vP) and toxic (T). The T classification relies on the classification as toxic for reproduction, category 2, while the T-criterion relating to aquatic toxicity (No Observed Effect Concentration (NOEC) or EC_{10} (concentration with 10% effect) for aquatic long-term toxicity below 0.01 mg/l) is just not fulfilled by tebuconazole (lowest NOEC reported for *Daphnia* reproduction with 0.01 mg/l).

The most recent CAR for propiconazole also relates to its authorisation in PT07 (film preservatives). In this CAR (SC 2015a) and the related EU Commission decision (EU 2015), propiconazole is classified as very persistent (vP). Propiconazole is not classified as toxic (T), because the lowest aquatic long-term NOEC (0.068 mg/l, chronic fish toxicity) is higher than the T-criterion, and no other T-criteria are met. The former lowest aquatic NOEC of 0.016 mg/l related to green algal toxicity (SC 2007), and was replaced apparently by the higher NOEC derived with fish. The former lower NOEC value was applied in the risk assessment in the dossiers for wood preservative products used in the present study.

IPBC does not fulfil the PBT or vPvB criteria (SC 2008, SC 2015b), but is considered as toxic since the aquatic long-term NOEC is below 0.01 mg/l.

3.1.4.2 Risk ratios

The ESD specifies in Chapter 6 (*in-situ* treatment) the emission estimation for non-professional and professional use. For use class 3 and outdoor treatment by brushing (both intended uses of the relevant product 1), the scenarios fence, house, and bridge-over-pond have to be considered. Emissions are calculated for the application phase as well as for the treated wood after application. Considered receiving compartments are water and soil. The noise barrier scenario is only relevant for emissions from treated wood in service and assumes the usage of industrially treated wood. This scenario was hence not considered for non-professional and professional outdoor in-situ treatment (intended use 1 and 2). In Tier 1, dissipation and degradation is not considered while Tier 2 represents a refinement step that considers the fate of the compounds in the environment. Predicted environment concentrations (PECs) are calculated for two time-points and set in relation to Predicted No Effect Concentrations (PNECs), resulting in the risk quotient PEC/PNEC.

For industrial use, the emission scenario document describes in Chapter 4 (industrial preventive applications) and Chapter 5 (wood-in-service) the emission estimation for industrial use. For the application by dipping (intended use 3) the compartments sewage treatment plant (STP), surface water, soil and ground water have to be considered.

It was beyond the scope of the present study to recalculate the emissions of the a.s. for the various products in the scenarios. Therefore, respective risk ratios were just compiled from the PARs as far as they were available. This is the process that is also foreseen by the TGN, where no re-calculation of environmental risk assessments is mentioned.

Intended Use 1

In the PAR of the relevant product 1, no fence scenario was calculated which is in accordance with the ESD (ESD Part II, 5.4.1). In this case, the house scenario is regarded as worst-case. Accordingly, the scenarios considered for a comparative assessment of the intended use 1 are the house and the bridge-over-pond scenario. The risk ratios for these scenarios are shown in Table 9 as far as they were available in the PARs of the relevant and the alternative products.

For the relevant product, IPBC was not included in the risk assessments in the PAR as it was declared as an a.s. from a different PT. The risk identified in the bridge-over-pond scenario, remaining after refinement, resulted in the RMM ‘No use of product near surface water’.

For one alternative BP, product 2, the environmental risk assessment in the PAR completely relied on a dossier submitted and accepted for another product. Hence, no data were available in the PAR of the alternative BP that could be used for the comparative assessment in Tier I-B.

Table 9: Risk quotients for the relevant emission scenarios as compiled from the PARs considered for the intended use 1 of wood preservative products

Scenario	Compartment	Tier	Relevant BP (product 1) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 2) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 3) for time 1 and time 2 (30 d / 1825 d)	
			Tebuconazole	IPBC	Tebuconazole	IPBC	Propiconazole	IPBC
House	Soil	1	**5.1** / **17.9**	n.a.	n.a.	n.a.	**4.3** / **1.2**	**5.30** / 0.09
House	Soil	2	**4.0** / 0.8	n.a.	n.a.	n.a.	**1.03** / 0.62	n.a.
Bridge over pond	Water	1	**43.5** / **152**	n.a.	n.a.	n.a.	n.a.	n.a.
Bridge over pond	Water	2	**27.7** / **3.9**	n.a.	n.a.	n.a.	n.a. [a]	n.a.
Bridge over pond	Sediment	1	**1.8** / **6.2**	n.a.	n.a.	n.a.	n.a. [a]	n.a. [a]
Bridge over pond	Sediment	2	**1.7** / 0.8	n.a.	n.a.	n.a.	n.a. [a]	n.a.

[a] only available for industrially treated wood in service; n.a.: not available in PAR

For the second alternative BP, product 3, *in-situ* brushing (professional or non-professional) in the vicinity of water courses was excluded in the labelling of the product. Therefore, no risk quotients were calculated in the PAR for the scenario bridge-over-pond for this use. Available were, however, RQs for wood-in-service for the bridge-over-pond scenario assuming the use of industrially treated wood. Yet, these RQs do not relate to the intended use considered for the comparative assessment. With regard to soil, the PNEC of the a.s. propiconazole was refined based on newly available data. A refined assessment (Tier 2) was only conducted for propiconazole but not for the other a.s., IPBC. For none of the products, a mixture assessment was conducted in the dossiers.

Intended Use 2

Emission estimates differ between non-professional and professional use because a higher loss during brushing is assumed for the non-professional users. Hence, compared to the intended use 1 other RQs result for the intended use 2, which are summarised in Table 10. The reasons for the lack of RQs for several scenarios or products remain unchanged, however.

Intended Use 3

For the relevant product 2 of the intended use 3, no RQs were available as the ERA completely relied on the (not available) dossier of another product. Among the alternative products for the intended use 3, there was only one for which RQs for all scenarios and the two different tiers were available (product 3). As in the previous cases, scenarios were sometimes not considered because respective restriction of the use were established (e.g. storage under shelter).

3.1.4.3 Conclusion of Tier I-B

The compilation of the RQs for the different scenarios from the PARs of the products clearly illustrated the diversity within the assessments. It was often rather difficult to identify the finally used input values and resulting output values for a given scenario and whether it included a refinement step or not.

The PARs strongly differed in their format, and their structure (or lack of structure) resulted in considerable efforts needed to identify the required risk quotients and their assumptions.

The overall finding was that for all three of the intended uses risk quotients were lacking for at least some of the products for a given scenario. Even if comparability of risk quotients (i.e., resulting from similar refinement assumptions and adaptations of the scenarios) were not taken into account, there were not a sufficient number of products with risk quotients enabling a comparative assessment.

Table 10: Risk quotients for the relevant emission scenarios as compiled from the PARs considered for the intended use 2 of the wood preservative products

Scenario	Compartment	Tier	Relevant BP (product 1) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 2) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 3) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 5) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 6) for time 1 and time 2 (30 d / 1825 d)	Alternative BP (product 7) for time 1 and time 2 (30 d / 1825 d)
			Tebuconazole	IPBC	Tebuconazole	IPBC	Propiconazole	IPBC	Propiconazole	IPBC	Propiconazole	IPBC
House	Soil	1	**3.3** / **16.1**	n.a.	n.a.	n.a.	**3.3** / **1.1**	**5.2** / 0.08	n.a.	n.a.	**3.9** / 0.8	n.a.
House	Soil	2	**2.6** / 0.8	n.a.	n.a.	n.a.	**1.0** / 0.62	n.a.	< 0.01 / 0.01	n.a.	n.a.	**1.7** / 0.04 [c]
Bridge over pond	Water	1	**28.2** / **137**	n.a.	n.a.	n.a.	0.22 / 0.014[a]	**3.0** / 0.05 [a]	n.a.	n.a.	**3.5** / 0.2 [a]	n.a.
Bridge over pond	Water	2	**18.3** / **3.9**	n.a.	n.a.	n.a.	< 0.01 / < 0.01 [b]	n.a.	< 0.01 / < 0.01	n.a.	n.a.	0.2 / < 0.01 [c]
Bridge over pond	Sediment	1	**1.1** / **5.6**	n.a.	n.a.	n.a.	**12.7** / **21.2** [a]	**56** / 0.9 [a]	n.a.	n.a.	**7.4** / **17.6** [a]	n.a. [d]
Bridge over pond	Sediment	2	**1.1** / 0.8	n.a.	n.a.	n.a.	< 0.01 / < 0.01 [b]	n.a.	< 0.01 / < 0.01	n.a.	n.a.	n.a. [d]

[a] tier not specified, professional brushing, wood in-service; [b] application & wood in-service, including degradation, professional; [c] values for PBC; [d] covered by surface water; n.a.: not available in PAR

Table 11: Risk quotients for the relevant emission scenarios as compiled from the PARs for the intended use 3 of the wood preservative products

Scenario	Com-part-ment	Tier	Relevant BP (product 2) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 3) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 5) for time 1 and time 2 (30 d / 1825 d)		Alternative BP (product 6) for time 1 and time 2 (30 d / 1825 d)
			Tebuconazole	IPBC	Propiconazole	IPBC	Propiconazole	IPBC	Propiconazole
House	Soil	1	n.a.	n.a.	**1.7** / 0.4	**5.1** / 0.03	n.a.	n.a.	**2.0** / 0.3 [a]
House	Soil	2	n.a.	n.a.	**1.0** / 0.4	n.a.	< 0.01 / 0.01	n.a.	
Industrial application	STP	1	n.a.	n.a.	0.11 [b]	n.a.	0.09 [b]	n.a.	n.a.
Industrial application	STP	2	n.a.	n.a.	0.11 [b]	n.a.	n.a.	n.a.	n.a.
Industrial application (including storage)	Water	1	n.a.	n.a.	**3.5** [b]	n.a.	n.a.	n.a.	n.a.
Industrial application (including storage)	Water	2	n.a.	n.a.	**3.5** [b]	n.a.	**2.7** [b]	n.a.	n.a.
Industrial application (including storage)	Sediment	1	n.a.	n.a.	**1.6** [b]	n.a.	n.a.	n.a.	n.a.
Industrial application (including storage)	Sediment	2	n.a.	n.a.	**1.6** [b]	n.a.	**1.25** [b]	n.a.	n.a.
Industrial storage	Soil	1	n.a.	n.a.	**2.5 / 460**	n.a.	< 0.01 / **1.3**	n.a.	n.a.
Industrial storage	Soil	2	n.a.	n.a.	**2.5 / 460**	n.a.	n.a.	n.a.	n.a.
Noise Barrier	Soil	1	n.a.	n.a.	0.7 / 0.01	**1.9** / 0.01	n.a.	n.a.	0.08 / 0.01 [a]
Noise Barrier	Soil	2	n.a.	n.a.	**1.3 / 0.5**		< 0.01 / 0.01	n.a.	n.a.
Noise Barrier	STP	1	n.a.	n.a.	< 0.01 / < 0.01	0.02 / <0.01	< 0.01 / < 0.01	n.a.	< 0.01 / < 0.01 [a]
Noise Barrier	STP	2	n.a.	n.a.	< 0.01 / < 0.01	n.a.	n.a.	n.a.	n.a.
Noise Barrier	Water	1	n.a.	n.a.	0.11 / < 0.01	**1.92** / 0.01	n.a.	n.a.	0.07 / < 0.01 [a]
Noise Barrier	Water	2	n.a.	n.a.	0.04 / < 0.01		< 0.01 / < 0.01	n.a.	n.a.
Noise Barrier	Sediment	1	n.a.	n.a.	0.07 / < 0.01	**1.7** / 0.01	n.a.	n.a.	0.04 / < 0.01 [a]
Noise Barrier	Sediment	2	n.a.	n.a.	n.a.		< 0.01 / < 0.01	n.a.	n.a.
Bridge over pond	Water	1	n.a.	n.a.	0.22 / 0.005	**3.0** / 0.02	n.a.	n.a.	**3.5** / 0.09 [a]
Bridge over pond	Water	2	n.a.	n.a.	< 0.01 / < 0.01	n.a.	< 0.01 / < 0.01	n.a.	n.a.
Bridge over pond	Sediment	1	n.a.	n.a.	**12.7** / **12.2**	**56** / 0.3	n.a.	n.a.	**7.4** / **10.4** [a]
Bridge over pond	Sediment	2	n.a.	n.a.	0.002 / < 0.01	n.a.	< 0.01 / < 0.01	n.a.	n.a.

[a] Tier not specified; [b] daily; n.a.: not available in PAR

3.2 Ant control products

Information on 13 ant control products (ACPs) which are authorised in Germany, containing six different active substances was provided by the UBA. The products are listed in Table 12, sorted from newer to older authorisations. For all of these products, either an authorisation letter containing an SPC in an appendix, or an SPC issued by ECHA was available. For two products (ACP 3 and ACP 4), both documents were available.

Table 12: Overview of authorised ant control products selected for the present project

Product	Active substance	Application method(s)
ACP 13	spinosad	nest application
ACP 12	imidacloprid	bait box, gel bait
ACP 11	fipronil	bait box, gel bait
ACP 10	fipronil	bait box
ACP 9	spinosad	gel bait
ACP 8	deltamethrin	nest application
ACP 7	spinosad	gel bait
ACP 6	spinosad	bait box
ACP 5	spinosad	bait box
ACP 4	spinosad	bait box
ACP 3	spinosad	bait box
ACP 2	spinosad	bait box
ACP 1	indoxacarb	bait box, gel bait

ACP: Ant Control Product

3.2.1 Intended uses of the relevant BP and mapping of alternatives

To find out which products have a comparable use in the sense of the TGN, the use descriptions for these products were analysed. Briefly, the information given on the elements of a use description according to section 5.1 of the TGN on comparative assessment was collected from the authorisation letters and SPCs. These use description elements are listed in Table 13, numbered from 1 to 6. As the way in which this information was given was highly variable, harmonised possible entries for the use description elements were formulated, listed in Table 13.

Table 13: Elements of the use description for ant control products with proposed harmonised possible entries

N°	Element	Proposed possible entries
1	Product Type	PT 18
2	Where relevant, an exact description of the authorised use	-
3	Target organism(s) (including development stage)	*Lasius niger* *Linepithema humile* *Monomorium pharaonis*
4	Field of use	Indoor Outdoor
5	Category(ies) of users	Professionals Non-professionals
6	Application method(s)	Nest application (see text) Bait box Gel bait

According to the definition given in the TGN, each use can list more than one entry in each element, e.g. indoor and outdoor or professionals and non-professionals. However, when it comes to finding comparable products, the TGN suggests that elements 1-5 are critical, which means that uses with different use characteristics regarding these elements cannot be compared (e.g. indoor use cannot be compared to outdoor use). For element 6 (application methods), it is left to the competent authority to decide if different application methods lead to incomparable uses or not.

Due to the very general nature of element 2 ("Where relevant, an exact description of the authorised use"), the information given there was not helpful in the search for comparable products sharing the same use. In fact, only few SPCs provided information for this element, and the information was not comparable.

Regarding use description element 3 (target organism), all but one of the products were shown to be effective against ants including the garden ant *Lasius niger*. The exception (ACP 12) is aimed at tropical ants (*Linepithema humile* and *Monomorium Pharaonis*) and was therefore not considered for the case studies.

Regarding the field of use, the information given there appeared to be easily categorized as "Indoor" (including a use designated for "food/feed storage") or "Outdoor". At a later stage of the assessment, it became clear that especially for bait products against ants, there is a category "in and around buildings", which includes indoor use and outdoor use on balconies and terraces. In the following, the field of use "outdoor" is meant to cover outdoor use on terraces and balconies, as this is the use that is actually assessed in the risk assessments, with the exception of the products ACP 8 and ACP 13 which are used directly on ant nests and may therefore also be used directly on soil (spot application). The question of the comparability of the products with nest application with the other ant control products will be discussed further in the course of the assessment and is assumed to be given at this point. A first conclusion, congruent with the experience made in the comparative assessment of wood preservative products, is that it is critical for a correct assessment to get the use definitions right, and that it may be necessary to take into account information not only from the SPC, but also from the PAR, because this is where it is made clear which emission scenarios are actually relevant for the product.

The information on user categories could be classified as "Professionals" and "Non-professionals". The term "Sachkundiger Verwender" (professional user that has received special training) was used in one case, but as professionals were also listed, a special training did not appear to be mandatory even in this case and therefore no separate category was used for this (compare Table 13).

The most difficult categorisation was the one for use description element number 6, the application method. Here, a lot of detail was often given in the SPCs, *e.g.* dosage instructions or a listing of possible places where the products could be applied. After consulting the respective guidance for efficacy testing (European Commission 2013), it is proposed to differentiate between application directly on ant nests ("Nest application") by drenching or scattering, application in bait boxes ("Bait box") or application as unprotected gel bait ("Gel bait").

Nest application is proposed as a distinct application method in the context of the use definition because it is only possible when the location of the nest is known, and because it was explicitly requested for one of the products. The efficacy guidance does not differentiate between different forms of bait applications. Here, bait applications were distinguished in protected ("bait box") and unprotected gel bait applications assuming that using unprotected bait is not feasible under some circumstances, *e.g.* in the presence of small children.

The result of the classification of the products according to this scheme can be seen in Table 14. Each row in the table is a unique use definition. Only unique uses with more than one registered product are listed. All of these unique uses had *Lasius niger* as target organism, so the target organism is not listed in the table.

Table 14: Unique uses for the selected ant control products targeting *Lasius niger* when also considering the application method

Field of use	User	Method	n	Products
Indoor	Non-professionals	Bait box	6	ACP 2, ACP 3, ACP 4, ACP 5, ACP 6, ACP 10
Outdoor	Non-professionals	Bait box	6	ACP 2, ACP 3, ACP 4, ACP 5, ACP 6, ACP 10
Indoor	Professionals	Bait box	5	ACP 1, ACP 2, ACP 3, ACP 4, ACP 11
Outdoor	Professionals	Bait box	5	ACP 1, ACP 2, ACP 3, ACP 4, ACP 11
Indoor	Non-professionals	Gel bait	2	ACP 7, ACP 9
Indoor	Professionals	Gel bait	2	ACP 1, ACP 11
Outdoor	Non-professionals	Nest application	2	ACP 8, ACP 13
Outdoor	Professionals	Gel bait	2	ACP 1, ACP 11

For the purpose of this project, comparative assessments for a unique use were only eligible for the case studies when there were at least three authorised products. Based on the proposed use classification scheme, this would only be the case for the four versions of bait box applications (the four combinations of Indoor/Outdoor and Professionals/Non-professionals).

If the application method is not considered in the mapping of alternative products, the four combinations of Indoor/Outdoor and Professionals/Non-professionals remain as uses for which at least three products are authorised. The resulting unique uses are shown in Table 15.

Table 15: Unique uses for the selected ant control products when not considering the application method, with active substances

Field of use	User	n	Products	Active substance
Outdoor	Non-professionals	9	ACP 2, ACP 3, ACP 4, ACP 5, ACP 6, ACP 7, ACP 13	Spinosad
			ACP 8	Deltamethrin
			ACP 10	Fipronil
Indoor	Non-professionals	8	ACP 2, ACP 3, ACP 4, ACP 5, ACP 6, ACP 7, ACP 9	Spinosad
			ACP 10	Fipronil
Indoor	Professionals	5	ACP 2, ACP 3, ACP 4	Spinosad
			ACP 11	Fipronil
			ACP 1	Indoxacarb
Outdoor	Professionals	5	ACP 2, ACP 3, ACP 4	Spinosad
			ACP 11	Fipronil
			ACP 1	Indoxacarb

Based on this table, the product groups shown in Table 16 were selected for the further evaluations in this project.

Table 16: Intended uses of ant control products selected as examples for a comparative assessment

No	Intended Use Definition	Products[a]	Active Substance
1	Outdoor use by non-professionals against *Lasius niger*	ACP 2, ACP 3, ACP 4, ACP 5, ACP 6, ACP 7, **ACP 13**	Spinosad
		ACP 8	Deltamethrin
		ACP 10	Fipronil
2	Indoor use by non-professionals against *Lasius niger*	ACP 2, ACP 3, ACP 4, ACP 5, ACP 6, ACP 7, ACP 9	Spinosad
		ACP 10	Fipronil
3	Outdoor use by professionals against *Lasius niger*	ACP 2, ACP 3, ACP 4	Spinosad
		ACP 11	Fipronil
		ACP 1	Indoxacarb

[a]The relevant product is highlighted in bold

For intended use 1, ACP 13 (spinosad, nest application) was selected as the relevant biocidal product. Its only active ingredient spinosad is classified as persistent and toxic (PT) in the (unpublished) list compilation of exclusion and substitution criteria (ECHA 2016), so it is considered a CFS. For intended use 2, ACP 10 (fipronil, bait box) was selected as the relevant product. Its only active ingredient fipronil is also classified as PT according to the available list (ECHA 2016) and it is the product with the most recent authorisation date in this group. For intended use 3, ACP 11 (fipronil, gel bait or bait box) was selected as it was the most recent product containing a CFS.

3.2.2 Screening phase

According to the TGN, two questions need to be answered in the screening phase, one regarding the chemical diversity of all authorised BPs, and one concerning the question if the CFS in the product is targeted by the exclusion criteria in the BPR. According to an unpublished list (ECHA 2016), none of the active substances in the ACPs described above fulfil the exclusion criteria. For the a.s. in question, information on the substitution criteria and their MoA are listed in Table 17.

Table 17: Information about the active substances in the ant control products relevant at the screening stage

Active substance	PBT classification[a]	Respiratory sensitiser[a]	Candidate for substitution[a]	Mode of action (IRAC main group[b])
Indoxacarb	-[c]	-	No[c]	Voltage-dependent sodium channel blocker (22A)
Spinosad	PT	-	Yes	Nicotinic acetylcholine receptor allosteric modulator (5)
Deltamethrin	(P)T	-	(Yes)	Sodium channel modulator (3A)
Fipronil	PT	-	Yes	GABA-gated chloride channel blocker (2B)

[a] Based on an unpublished list (ECHA 2016). (P) means potential P
[b] IRAC (2017)
[c] Not identified as PT according to the available list (ECHA 2016).

3.2.2.1 Intended use 1: Outdoor use by non-professionals

In intended use 1, most of the available products contain spinosad as the only a.s. In addition, there is one product containing deltamethrin, and one containing fipronil (Table 16). The TGN proposes that three different active substance/mode of action combinations 'should remain through authorised BPs for a given use'. It was agreed within the project that this simply means that active substances with three different modes of action need to be present in the products to satisfy this TGN requirement.

According to IRAC mode of action classifications, spinosad is an allosteric modulator of the nicotinic acetylcholine receptor, while deltamethrin is a sodium channel modulator, and fipronil is a GABA-gated chloride channel blocker, so the three a.s. in Intended use 1 clearly have three different modes of action.

As there are a number of alternative products containing spinosad, the same chemical diversity would still be given if the relevant BP was not to be authorised.

As the relevant BP only contains the active substance spinosad, and spinosad does not meet any of the exclusion criteria (ECHA 2016), the assessment continues to Tier I-A. In a real assessment performed by a competent authority, it could also continue to Tier II if this would seem more appropriate in the interest of an economic use of administrative resources, but Tier II is out of the scope of this project.

3.2.2.2 Intended use 2: Indoor use by non-professionals

In intended use 2, the only available product not containing spinosad as the only a.s. is ACP 10 which contains fipronil. Therefore, the available BPs do not provide adequate chemical diversity when judged by the rule proposed in the TGN (but note the discussion under section 3.2.2 about the possibility to waive this rule for certain products). The relevant product contains only fipronil as a.s., and fipronil does not meet the exclusion criteria (ECHA 2016).

Non-authorisation the relevant product would lead to a further reduction of the chemical diversity of products on the market. Therefore, if resistance management was considered important for this use, the assessment would stop here. In any case, Tier I will be performed here in the interest of the project goals.

3.2.2.3 Intended use 3: Outdoor use by professionals

In intended use 3, the relevant product contains fipronil, one eligible alternative product contains indoxacarb and the two remaining eligible alternative BPs contain spinosad (Table 16). Fipronil has a different MoA than the other two a.s.

Therefore, if the relevant product were not to be authorised, the chemical diversity would be reduced below the rule proposed in the TGN. Therefore, if the necessity of a resistance management would not be waived by the competent authority based on TGN Article 58 (see the discussion in section 3.2.2), the assessment would stop here, as fipronil does not meet the exclusion criteria based on the available list (ECHA 2016). In any case, Tier I will be performed here in the interest of the project goals.

3.2.3 Tier I-A

In a first step, all RMMs listed in the respective sections of the SPCs were collected with their exact original wording from the SPC section entitled "Risk mitigation measures". Only for some of the earliest authorisations, no such section was present, and RMMs were collected from other suitable sections as in the case study for the wood preservative products. For example, in the case of ACP 1, RMMs were taken from the sections "Anwendungsbestimmungen" (conditions of use) and "Sicherheitsdatenblatt" (safety data sheet). In the conditions of use, there was additionally a restriction to professional users, which was not considered an RMM because it was already taken into account in the use definition. Also, there were several references to technical rules for hazardous substances and similar documents that were not considered usable for the Tier I-A assessment. Similar decisions had to be made for other products as well. Sometimes, information that was found in the RMM section of the SPC was not considered to be an RMM in the strict sense, like information on the storage stability of the product, or hazard phrases like "Hazardous for bees". Information on waste disposal was also ignored when collecting RMMs. For the products ACP 2, ACP 3, ACP 4, ACP 5, RMMs were extracted from the section "Anwendungsbestimmungen" (conditions of use), subsection "Gebrauchshinweise" (use directions) of the authorisation letters. Starting from the documents for ACP 6, a dedicated section for RMMs was always available, even though it often only contained a reference to the conditions of use where the RMMs were then listed. In some cases, like e.g. in the case of ACP 9, both sections contained information. In such cases, only the information from the explicit RMM section was used. Sentence "Avoid release to the environment" is not listed among the RMMs, as both products that mentioned it also had S61 or P273, which is identical with this phrase.

When the collection of the RMMs with their original wording was finished, they were compared to the list of sentences agreed among the EU Member States. If for a given sentence a similar EU-agreed sentence existed (Sentences for discussion, version from 25 Nov 2016), this was used for the Tier I-A assessment. As an example, Table 18 shows five different wordings that were considered equivalent to the EU agreed sentence N-121.

Table 18: Original German wordings considered equivalent to RMM N-121: Apply only in areas that are not liable to submersion or becoming wet *i.e.* protected from rain, floods and cleaning water

Original wording
Bei der Anwendung im Außenbereich ist sicherzustellen, dass das Produkt in Bereichen ausgebracht wird, die vor Regen geschützt sind bzw. die nicht für Wasser von Reinigungsarbeiten zugänglich sind.
Die geöffnete Köderdose auf die Laufwege der Ameisen stellen. Wählen Sie einen trockenen Platz und lassen Sie die Köderdose über eine längere Zeit stehen. Die Ameisen-Köderdose muss während der Anwendung vor Regen und Feuchtigkeit geschützt werden.
Bei der Verwendung ist sicherzustellen, dass das Produkt in geschützten Bereichen (Spalten und Ritzen) angewendet wird oder nur in Bereichen, die nicht nass gereinigt werden.
Bei der Anwendung um Gebäude nicht in der Nähe von Abflüssen aufstellen. Wenn der behandelte Bereich mit einem Regenwasserabfluss oder der Kanalisation verbunden ist, nur in Bereichen anwenden, die nicht überflutet oder nass werden können, d.h. die von Regen, Überschwemmung und Spülwasser geschützt sind.
Nicht anwenden in Bereichen, die überschwemmt oder nass werden können, d. h. geschützt vor Regen, Überschwemmung und Reinigungsflüssigkeiten.

For many RMMs, no harmonised wording was available. For the purpose of this project, these were translated to English. For example, less restrictive versions of N-121 were given for three products as listed in Table 19.

Table 19: Original wordings subsumed under “If possible, apply only in areas that are not liable to submersion or becoming wet *i.e.* protected from rain, floods and cleaning water”

Original wording
Wenn möglich sollte das Produkt bei der Anwendung im Außenbereich nur in Bereichen angebracht werden, die vor Regen geschützt sind bzw. die nicht für Wasser von Reinigungsarbeiten zugänglich sind
Wenn möglich, sollte das Produkt bei der Anwendung auf Terrassen und Balkonen nur in Bereichen ausgebracht werden, die vor Regen und Feuchtigkeit geschützt sind.
Wenn möglich, sollte das Produkt bei der Anwendung auf Terrassen und Balkonen nur in Bereichen ausgebracht werden, die vor Regen und Feuchtigkeit geschützt sind.

In a few more cases, the meaning of two risk mitigating sentences used for different products was considered equivalent, so that a common wording was used, as illustrated in Table 20. Note that also in this case, a subtle difference in the degree of restriction could also be considered (“soll” versus “sollte”).

Table 20: Original wordings subsumed under “Keep birds from feeding on target animals”

Original wording
Das Produkt soll nicht in Bereichen angewendet werden, in denen sich bekanntermaßen Vögel von den behandelten Ameisen ernähren würden, außer der Zugang von Vögeln zu diesen Behandlungsflächen wird verhindert, z.B. durch Abdeckung mit Netzen.
Im Sinne einer nachhaltigen Nutzung sollte der Zugang von Vögeln zu den Behandlungsflächen verhindert werden.

Finally, only RMMs were considered relevant for Tier I-A of this case study that appeared to be relevant for the ERA documented in the PARs. However, it should be noted that in many cases, it was not possible to derive the reason why a specific sentence was considered necessary from the available information. The RMMs relevant for this case study are listed in Table 21.

Table 21: List of relevant RMMs for ant control products

Acronym	Harmonised risk mitigation measure
N-121	Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water
N-133	Do not use when rain is expected in the next 24 hours
N-143	Do not use where release to drains (sewer) and/or surface water cannot be prevented
N-173	Place inaccessible to children, companion animals and non-target animals
N-227	Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children
-	Keep birds from feeding on target animals
-	Wait 7 days before next application
-	Do not use more than two bait boxes per household
-	Do not use more than two bait boxes per nest
-	Remove the product after use
-	Do not use more than two bait boxes per site
-	Wait 28 days before the next application
-	Only apply directly on ant nests. Do not apply on ant trails on hard surfaces or bare soil
-	Only use in cracks or crevices
-	Remove spilled or leftover gel bait after use with a paper towel
-	For outdoor use, only use in bait stations. Where this is not possible, only use in cracks or crevices with a maximum diameter of 5 mm
-	Wait 7 days before the next application after an application of 28 days
-	If possible, apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water

Note that in some cases, RMMs are only applicable for a specific part of the use definition. This has to be considered in the Tier I-A assessments.

As evident from the examples shown above, the wording can vary considerably, so in some cases it can be debated if all the intended information is kept, and if the harmonized RMM is not stricter than intended. In some cases, *e.g.* when the original RMMs were very long and complex, more than one harmonised RMM was derived. However, no loss of relevant information is considered to be caused by the harmonisation process. Similar tables can be found for all harmonised mitigation measures in the confidential appendix of this report.

Finally, a distinction was made between RMMs that are assumed as formal RMMs resulting from an identified risk and established by the CA (strict definition), and a loose definition of RMMs including those where the identification of risk was unclear or where the measure was established by the applicant. In numerous cases, it could not be concluded whether a statement was formally a RMM or not. RMMs according to the strict definition are indicated in the following tables with the letter “a” (for

authority). If an RMM did not fulfil the strict definition, it is either indicated with the letter "p" (introduced by a**p**plicant) or "u" (for **u**ncertain, origin or the reason for an RMM was unclear). In the first case ("p"), the RMM was adopted from a proposal by the applicant without a formal risk assessment to support it, and in the second case ("u"), either the origin of the RMM was unclear or it was introduced by the authority but not formally established based on a risk assessment.

The H/P statements were also collected from the SPCs. In some cases, the authorisation letter (Zulassungsbescheid, ZB) gave different H/P statements. In these cases, the H/P-statements as shown in the ZB were used, as the ZB is the authoritative communication to the authorisation holder. The H/P-statements that occurred in these SPCs are listed in Table 22.

Table 22: H/P-statements for ant control products

Acronym	H/P-statement
EUH208	Contains .... May produce an allergic reaction
EUH401	To avoid risks to human health and the environment, comply with the instructions for use
H410	Very toxic to aquatic life with long-lasting effects
H412	Harmful to aquatic life with long-lasting effects
P102	Keep out of reach of children
P273	Avoid release to the environment
P391	Collect spillage
P501	Dispose of contents/container to ... in accordance with local/regional/national/international regulation

Out of these eight H/P-statements, only H410, H412 and P273 and P391 were considered relevant for the comparative environmental assessment.

In the following three subsections, the H/P-statements and RMMs are shown and discussed for each of the three assessments A, B and C defined in Table 16.

3.2.3.1 Intended use 1: Outdoor use by non-professionals

H/P-statements and risk mitigation measures of the relevant product ACP 13 (nest application) used only directly on ant nests ("nest application") and its alternative products for the outdoor use by non-professionals are listed in Table 23, together with the information if the same or equivalent sentences were given for the eligible alternative products.

The RMM "Wait 28 days before the next application" was considered to satisfy the strict definition, because a 28-day time weighted average concentration was assumed in several refined risk assessments in order to address risk quotients greater than 1. The link between the RMM and this refinement was not explicitly stated in the PAR, but it was assumed that this necessary refinement lead to the RMM. Note that this RMM should also be seen as part of the dosing instructions, as it restricts the quantity of the product applied in a specific time period.

Table 23: H/P-statements and RMMs of relevant (ACP 13) and alternative products, intended use 1

Acronym	Sentence	13	2	3	4	5	6	7	8	10
H410	Very toxic to aquatic life with long-lasting effects								+	
H412	Harmful to aquatic life with long-lasting effects	**+**	+	+	+	+	+	+		+
P273	Avoid release to the environment	**+**	+	+	+	+	+	+		+
P391	Collect spillage								+	
N-121	Apply only in areas that are not liable to submersion or becoming wet *i.e.* protected from rain, floods and cleaning water					a				a
N-133	Do not use when rain is expected in the next 24 hours								a	
N-143	Do not use where release to drains (sewer) and/or surface water cannot be prevented	**u**				a	u	p	u	
N-173	Place inaccessible to children, companion animals and non-target animals						p	p	u	
-	Keep birds from feeding on target animals		u							
-	Wait 7 days before next application							a		
-	Do not use more than two bait boxes per household						p			
-	Wait 7 days before the next application after an application of 28 days						a			
-	Do not use more than two bait boxes per nest					p				
-	Remove the product after use					p				u
-	Do not use more than two bait boxes per site			p						
-	Wait 28 days before the next application	**a**								
-	Only apply directly on ant nests. Do not apply on ant trails on hard surfaces or bare soil	**a**								
-	If possible, apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water		u	u	u					

a: RMM according to strict definition
p: RMM established by applicant
u: RMM origin or reason unclear

In a next step, the information from Table 23 was processed by determining similar H/P statements and RMMs for the relevant product (Table 24). H410 and H412 clearly belong to the same group, with H410 being a more severe H statement than H412. P273 is a very general P statement that was made for all products in the three assessments, with the exception of ACP 8. ACP 8 does not have P273, although it has H410, presumably because the authorised use is not possible without release to the environment.

RMMs N-121 and N-143 were considered similar in the sense that they both restrict the area where the products can be placed. As N-121 requires protection from sources of runoff water (rain, floods and cleaning water), it was considered more restrictive than N-143 where only release to drains and/or surface water has to be prevented. Therefore, alternative products with N-121 have the entry

"no (worse)" in Table 25. On the other hand, the conditional version of N-121 ("If possible, apply only…") is considered less restrictive compared with N-143, because it is only optional. Therefore, the corresponding alternative products have the entry "yes (better)".

The RMM "Wait 28 days before the next application" was considered similar to the other two mitigation measures that provide restrictions regarding repeated applications. The alternative products ACP 6 (bait box) and ACP 7 (gel bait) also have RMMs restricting regarding repeated applications, but due to their different application methods and differences in wording (the length of the application is only specified in one case) it is not clear if any of these RMMs have to be considered more restrictive than the others. In Table 24, the outlier analysis is shown when only considering RMMs according to the strict definition.

Table 24: Outlier analysis of H/P-statements and RMMs (strict definition), intended use 1 of ant control products

Acronym	Sentence	Do alternative BPs have better H/P statements or RMMs?							
		2	3	4	5	6	7	8	10
H412	Harmful to aquatic life with long-lasting effects	no (same)	no (same)	no (same)	no (same)	no (same)	no (same)	no (worse)	no (same)
-	Wait 28 days before next application	yes (none)	yes (none)	yes (none)	yes (none)	no (similar)	no (similar)	yes (none)	yes (none)

With this definition of RMMs, there are five (ACP 2, ACP 3, ACP 4, ACP 5 and ACP 10) out of eight eligible alternative products that have a better profile, as they do not have the RMM of the relevant product. ACP 8 is also better in this aspect, but worse with respect to the H statement. As these five alternative products represent a majority, the relevant product would be identified as an outlier. However, it has to be kept in mind that in Table 24, additional RMMs of these alternative products are not listed, based on the two example tables in the Appendix to the TGN (Appendix 7.2.1, p. 27) that was interpreted to suggest that only H/P-statements and RMMs of the relevant product should be tabulated for the outlier analysis. As the additional RMMs of the alternative products are clearly relevant at Tier I-A as well, these were considered below as part of the analysis of significant practical disadvantages in this case study. In Table 25, the analysis is repeated, additionally considering RMMs not fulfilling the strict definition.

Table 25: Outlier analysis of H/P-statements and RMMs (loose definition), intended use 1 of ant control products

Acronym	Sentence	Do alternative BPs have better H/P statements or RMMs?							
		2	3	4	5	6	7	8	10
H412	Harmful to aquatic life with long-lasting effects	no (same)	no (same)	no (same)	no (same)	no (same)	no (same)	no (worse)	no (same)
N-143	Do not use where release to drains (sewer) and/or surface water cannot be prevented	yes (better)	yes (better)	yes (better)	no (worse)	no (same)	no (same)	no (same)	no (worse)
-	Wait 28 days before next application	yes (none)	yes (none)	yes (none)	yes (none)	no (similar)	no (similar)	yes (none)	yes (none)

From the five alternative products identified above to have a better profile (using the strict RMM definition, two (ACP 5 and ACP 10) have a more restrictive RMM regarding the areas where the product can be placed. However, when using the loose RMM definition, only three alternative products (ACP 2, ACP 3 and ACP 4) are either equal or better with respect to all three criteria, which is not the majority, so the relevant product would not be an outlier when this decision rule would be used.

In the next step, the question needs to be answered if the alternative products that potentially have a better profile would have significant economic or practical disadvantages. None of the information sources mentioned in the flow chart in Appendix 7.2.2 of the TGN were available for this project. As a substitute, the available information on the alternative BPs was reviewed with respect to significant practical disadvantages for this case study.

Potential sources of disadvantages identified were the "inability to maintain sufficient control of the target organism", TGN Article 27a), use restrictions resulting from additional RMMs of alternative products (compare Table 23), or other conditions of use motivated *e.g.* by efficacy requirements as well as potential disadvantages of different application methods.

Regarding the ability to maintain sufficient control of the target organism, it is worthy to note that ACP 2 did not maintain its nest kill claim during the authorisation procedure. Even though the competent authority decided that the efficacy of the product was sufficient for authorisation, the lack of the nest kill claim is surely a practical disadvantage, and could even potentially be seen as an "inability to maintain sufficient control of the target organism" for this alternative product.

In the next paragraphs, the question is discussed if practical disadvantages caused by the additional H/P-statements or RMMs of the alternative products should be considered significant practical disadvantages in the sense of the BPR.

P391 ("Collect spillage") is only given for ACP 8. While being a practical disadvantage, it would probably not be regarded a significant practical disadvantage in the sense of the BPR.

"Keep birds from feeding on target organisms" is only given for ACP 2, which is a spinosad containing bait box. If taken seriously, this RMM could indeed entail a practical disadvantage, because potential measures to keep birds from feeding on the ants that have taken up the bait would appear to either cover the entire area where these ants live *e.g.* with nets, or to somehow deter birds as soon as they enter this area *e.g.* with a noise. The question if there is a valid reason why this spinosad containing bait box product has this RMM while other spinosad containing products with bait box as application method do not (ACP 3, ACP 4, ACP 5, ACP 6) is not within the scope of this project. However, the fact that it is often not clear if competent authorities use the same criteria to establish RMMs is discussed in WP 3.

There are three different sentences restricting the maximum amount of bait boxes to be used. Again, as the authorisation procedure should have ensured that the products are sufficiently effective under these conditions this is not seen as a significant practical disadvantage.

"Remove the product after use" given for two of the alternative products is not applicable for the relevant product, as it is scattered or poured directly onto ant nests. The additional effort to remove *e.g.* bait boxes or gel baits after use would probably not be seen as a significant practical disadvantage as well.

Sentence N-133 ("Do not use when rain is expected in the next 24 hours") is listed as an RMM for ACP 8 which is the only alternative product also used directly on ant nests ("nest application"). Even though designated as an RMM in the authorisation letter, it is motivated by efficacy data and not by a risk. In any case, it could potentially be regarded a significant practical disadvantage, especially in regions areas where there are prolonged periods of rain.

Sentence N-173 ("Place inaccessible to children, companion animals and non-target animals", ACP 6, ACP 7 and ACP 8) may also be practically difficult to implement, and may therefore be regarded to result in a significant practical disadvantage.

In summary, the analysis of additional RMMs of the alternative products suggests that N-173 (no RMM according to the strict definition), "Keep birds from feeding on target organisms" (due to the efforts required, no RMM according to strict definition) as well as N-133 (due to a potential inability to maintain sufficient control of the target organism, no RMM according to strict definition) may be viewed as significant practical disadvantages.

If only RMMs according to the strict definition were considered, the relevant product would still be considered an outlier as potential significant practical disadvantages would only be identified for ACP 2 (no nest kill effect can be claimed). If the loose definition is used in the way described above, the relevant product would not be identified as an outlier, so the question of practical disadvantages of the alternatives is not relevant.

Within the project, it was also discussed if the different application methods would entail significant practical disadvantages under certain conditions. However, as this project focusses mainly on the comparative assessment of environmental risks, such an in-depth analysis of practical disadvantages was considered out of scope.

As exemplary conclusion of Tier I-A for intended use 1, no unequivocal decision on the outlier status of the relevant product could be derived, as it depends on the definition of a risk mitigation measure as well as of the assessment of practical disadvantages. Potential significant practical disadvantages of alternative products were identified for ACP 2, ACP 6, ACP 7 and ACP 8. In any case, for the purpose of this project, the assessment proceeds to Tier I-B.

3.2.3.2 Intended use 2: Indoor use by non-professionals

H/P-statements and RMMs of the relevant product ACP 10 (a ready-to-use bait box) for the indoor use by non-professionals are listed in Table 26, together with the information if the same or equivalent sentences were given for the eligible alternative products.

Again, the information was processed by grouping similar H/P statements and RMMs. P273 is disregarded in the following as it adds no further information to H 412 in the context of the comparative assessment and N-121 was considered more restrictive than N-143 and also more restrictive than the conditional version of N-121 ("If possible, apply only…", see the related discussions for intended use 1 above). In addition, N-173 and N-227 were regarded similar for the purpose of the Tier 1-A assessment.

In Table 27, the outlier analysis is shown when only considering RMMs that satisfy the strict definition.

As all alternative products also have H412, there is no difference regarding H/P-statements. Regarding the only RMM (N-121) of the relevant product that satisfies the strict definition, there are five products that do not have it, and therefore qualify to have a better profile at Tier I-A. As there are seven alternative products all in all, these five represent a majority, and therefore the relevant product would be identified as an outlier according to this analysis.

However, the applicability of N-121 for the indoor use of the relevant product is questionable. In fact, it was introduced by the authority on the basis of the assessment of the outdoor use. While it was not formally specified by the authority to be specific to the outdoor use, it appears unreasonable to use it as the basis for qualifying the relevant product as an outlier for the comparative assessment for indoor use. In addition, it should be noted that even for the outdoor use, many assessments of alternative products did not calculate a risk assessment for surface water, as this route of exposure is not considered relevant in the ESD.

Table 26: H/P-statements and RMMs of relevant (ACP 10) and alternative products, intended use 2 of ant control products

Acronym	Sentence	10	2	3	4	5	6	7	9
H412	Harmful to aquatic life with long-lasting effects	**+**	+	+	+	+	+	+	+
P273	Avoid release to the environment	**+**	+	+	+	+	+	+	+
N-121	Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water	**a**				a			a
N-143	Do not use where release to drains (sewer) and/or surface water cannot be prevented					a	u	p	
N-173	Place inaccessible to children, companion animals and non-target animals						p	p	
N-227	Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children	**u**							
-	Keep birds from feeding on target animals		u						
-	Wait 7 days before next application							a	
-	Do not use more than two bait boxes per household						p		
-	Wait 7 days before the next application after an application of 28 days						a		
-	Do not use more than two bait boxes per nest					p			
-	Remove the product after use	**u**				p			
-	Do not use more than two bait boxes per site			p					
-	If possible, apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water		u	u	u				

a: RMM according to strict definition
p: RMM established by applicant
u: RMM origin or reason unclear

Table 27: Outlier analysis of H/P-statements and RMMs (strict definition), intended use 2 of ant control products

Acronym	Sentence	Do alternative BPs have better H/P statements or RMMs?						
		2	3	4	5	6	7	9
H412	Harmful to aquatic life with long-lasting effects	no (equal)	no (equal)	no (equal)	no (equal)	no (equal)	no (equal)	no (equal)
N-121	Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water	yes (none)	yes (none)	yes (none)	no (equal)	yes (none)	yes (none)	no (equal)

Table 28: Outlier analysis of H/P-statements and RMMs (loose definition), intended use 2 of ant control products

Acronym	Sentence	Do alternative BPs have better H/P statements or RMMs?						
		2	3	4	5	6	7	9
H412	Harmful to aquatic life with long-lasting effects	no (equal)	no (equal)	no (equal)	no (equal)	no (equal)	no (equal)	no (equal)
N-121	Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water	yes (better)	yes (better)	yes (better)	no (equal)	yes (better)	yes (better)	no (equal)
N-227	Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children	yes (none)	yes (none)	yes (none)	yes (none)	no (similar)	no (similar)	yes (none)
-	Remove the product after use	yes (none)	yes (none)	yes (none)	no (equal)	yes (none)	yes (none)	yes (none)

When all RMMS according to the loose definition are considered as shown in Table 28, it can be argued that that all alternative BPs have less restrictive RMMs (all of them are missing at least one RMM that the relevant product has), and therefore the relevant product could be seen as an outlier with regard to its Tier I-A profile. However, also in this case, there are caveats.

At first, the same remark regarding the applicability of N-121 to the indoor use applies here.

Furthermore, the reasons why the RMMs N-227 and "Remove the product after use" were given for the relevant product were not obvious from the PAR. Therefore, it is not clear why other products were not assigned this RMM, especially the gel bait products ACP 7 and ACP 9, but also the other alternative bait box products (ACP 2, ACP 3, ACP 4, ACP 5 and ACP 6). Therefore, an outlier analysis using these RMMs could be misleading.

The relevant product would be seen as an outlier when only regarding the strict definition of RMMs as in Table 27, but not if N-121 would be seen as not applicable to the indoor use. Also, note that additional RMMs of alternative products are not considered there. When the loose RMM definition is used, the outcome also depends on the use of N-121, but additionally on the use of N-227.

Regarding significant practical disadvantages, again a potential inability to control the target organisms and additional RMMs were reviewed. Regarding the first point, only ACP 2 appears to have a potential significant practical disadvantage, as the nest kill claim was not approved by the CA.

Table 26 shows several additional RMMs of alternative products that the relevant product does not have. While "Keep birds from feeding on target animals" (ACP 2 only) may entail a significant practical disadvantage due to the effort required, there are two restrictions regarding repeated applications and three limitations of the number of bait boxes to be placed that are not seen as significant disadvantages within this project (compare the discussion of these RMMs in intended use 1). Also, the optional version of N-121 ("If possible, apply only") is not seen as a significant practical disadvantage in this case study.

Thus, significant practical disadvantages were only identified for ACP 2, so the relevant product could still be seen as an outlier according to this assessment if N-121 would be deemed applicable, for the strict RMM definition but potentially also for the loose RMM definition. If N-121 is not considered applicable to this assessment, the relevant product would not be seen as an outlier when using the strict

RMM definition. Using the loose RMM definition, still different outcomes of the assessment are possible as discussed above.

3.2.3.3 Intended use 3: Outdoor use by professionals

H/P-statements and RMMs of the relevant product ACP 11 (used as gel bait or in a bait box) and its alternative products for this use are listed in Table 29, together with the information if the same or equivalent sentences were given for the eligible alternative products.

Table 29: H/P-statements and RMMs of relevant (ACP 11) and alternative products, intended use 3 of ant control products

Acronym	Sentence	11	1	2	3	4
H410	Very toxic to aquatic life with long-lasting effects		+			
H412	Harmful to aquatic life with long-lasting effects	**+**		+	+	+
P273	Avoid release to the environment	**+**	+	+	+	+
N-121	Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water	**a**	p			
N-143	Do not use where release to drains (sewer) and/or surface water cannot be prevented		p			
N-173	Place inaccessible to children, companion animals and non-target animals		p			
N-227	Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children	**u**				
-	Keep birds from feeding on target animals		a	u		
-	Do not use more than two bait boxes per site				p	
-	Remove spilled or leftover gel bait after use with a paper towel		p			
-	For outdoor use, only use in bait stations. Where this is not possible, only use in cracks or crevices with a maximum diameter of 5 mm	**a**				
-	If possible, apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water			u	u	u
-	Cover bait to ensure access by non-target animals is minimised		a			

a: RMM according to strict definition
p: RMM established by applicant
u: RMM origin or reason unclear

H410 and H412 belong to the same group, with H410 being a more severe H statement than H412. P273 is not used in the following, as it provides no additional information in this context.

Again, N-121 was considered more restrictive than N-143 (see the discussion above) and the conditional version of N-121 ("If possible…") is considered less restrictive ("better"). RMM N-173 and N-227 were regarded similar for the purpose of the Tier 1-A assessment.

RMM N-121 is clearly derived based on the risk assessment for the sediment compartment by the competent authority for the relevant product, and therefore satisfies the strict RMM definition. The RMM N-227 is mentioned in the risk assessments for children and infants described in the PAR for the relevant product ACP 11. However, it is not clear if there would be a risk if this RMM would not be imposed. Therefore, it is not considered to satisfy the strict definition for this product.

This is not quite clear for the RMM "For outdoor use, only use in bait stations. Where this is not possible, only use in cracks or crevices with a maximum diameter of 5 mm", because the RMM does not appear to have been derived from a quantitative risk assessment but rather from a qualitative one. Here, this is still considered to be the result of a risk analysis, even if only a qualitative one, and therefore this RMM is considered to satisfy the strict definition. In any case, it has to be kept in mind that this RMM is specific for gel baits and does not make sense for bait boxes. All alternative products in this assessment (ACP 1, ACP 2, ACP3 and ACP 4) are authorised only for application in or as a bait box.

Table 30: Outlier analysis of H/P-statements and RMMs (strict definition), intended use 3 of ant control products

Acronym	Sentence	Do alternative BPs have better H/P statements or RMMs?			
		1	2	3	4
H412	Harmful to aquatic life with long-lasting effects	no (worse)	no (equal)	no (equal)	no (equal)
N-121	Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water	no (equal)	yes (none)	yes (none)	yes (none)
-	For outdoor use, only use in bait stations. Where this is not possible, only use in cracks or crevices with a maximum diameter of 5 mm	yes (none)	yes (none)	yes (none)	yes (none)

When only the RMMS of the relevant product according to the strict definition are considered (Table 30), the relevant product would be identified as an outlier, as the majority of products (three out of a total of five products in this use) do not have any of these RMMs.

Table 31: Outlier analysis of H/P-statements and RMMs (loose definition), intended use 3 of ant control products

Acronym	Sentence	Do alternative BPs have better H/P statements or RMMs?			
		1	2	3	4
H412	Harmful to aquatic life with long-lasting effects	no (worse)	no (equal)	no (equal)	no (equal)
N-121	Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water	no (equal)	yes (better)	yes (better)	yes (better)
N-227	Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children	no[a] (similar)	yes (none)	yes (none)	yes (none)
-	For outdoor use, only use in bait stations. Where this is not possible, only use in cracks or crevices with a maximum diameter of 5 mm	yes (none)	yes (none)	yes (none)	yes (none)

[a] Note that both the relevant product ACP 11 and ACP 1 can be applied directly as gel bait, but also in a bait box. RMMs N-227 and N-173 (similar RMM given for ACP 1) are only applicable to its application as gel bait

When the loose RMM definition is used, the alternative products ACP 2, ACP 3 and ACP 4 are better than the relevant product with respect to N-121. In addition, the same products are also better with respect to N-227 and the RMM "For outdoor use, …". Therefore, the relevant product would be considered an outlier also according to this analysis.

Regarding significant practical disadvantages, again a potential inability to maintain sufficient control of target organisms and additional RMMs of alternative products were reviewed. Again, ACP 2 can be potentially considered to have a significant practical disadvantage, as the nest kill claim was not approved by the CA.

There are three remaining additional RMMs of the alternative products. Out of these, "Keep birds from feeding on target animals" may pose a significant practical disadvantage, which affects the alternative BPs ACP 1 (also using the strict RMM definition) and ACP 2 (only when the loose definition of RMMs is used).

The sentence "Do not use more than two bait boxes per site" is a limitation of the number of bait boxes that should have not negative practical implications as discussed in intended use 1. The sentence "Remove spilled or leftover gel bait after use with a paper towel" is specific to gel baits. While it does mean a bit of an additional effort, this would probably not be seen as a "very high effort" in the sense of the TGN (Appendix 7.2.2), and would therefore probably not be seen as significant for the Tier I assessment.

In summary, the relevant product could be seen as an outlier in the sense of the TGN based on Table 30. Potential significant practical disadvantages of the alternative products were identified for ACP 1 and ACP 2. The two products ACP 3 and ACP 4 for professional indoor use would remain, that do have better RMMs base on the outlier analysis shown in Table 30, and for which no indications of significant practical disadvantages were found. The TGN does not indicate if an updated chemical diversity assessment is recommended at this stage.

In any case, intended use 3 also proceeds to Tier I-B for the purpose of this project.

3.2.4 Tier I-B

For the comparative assessments at Tier I-B, the available information designated to be relevant in the TGN was extracted from the PAR documents for the relevant and eligible alternative products. As detailed in the case study with wood protection products, the TGN only explicitly mentions PEC/PNEC ratios and RQs as information relevant at Tier I-B.

As it is unclear how other information e.g. from the PBT assessment (DT_{50} values or effect values) would finally be used in a comparative product risk assessment at Tier I-B, this case study focusses on risk quotients, which are calculated as PEC/PNEC ratios in the context of the ERA of the BP. Furthermore, due to the large number of RQs calculated in the PAR for the different products, an effort was made to identify the most relevant emission scenario and the most relevant exposed compartment for the risk assessment for each of the three uses assessed.

For each of these uses, the first step was therefore to review all risk quotients in the PAR documents and to select the ones considered most relevant. In order to keep the task manageable, scenarios where the RQs for all products were below 0.1 were not considered further. Also, no indication was found in the PARs that the risk to groundwater would need to be considered for the comparative assessment.

For the outdoor uses in assessments A and C, the risk assessments in the PAR suggest that the direct emission to soil due to either direct application on ant nests, or due to the use of gel bait or bait boxes on terraces are the most relevant scenario, with RQs frequently exceeding 1, at least at the first tier without refinements (see the more detailed discussion in each of the assessments). The comparative assessment for these uses was therefore focussed on this scenario. In parallel, information on other scenarios leading to risk quotients of at least 0.1 was collected.

Regarding the comparison of RQs, it quickly became clear that in many (if not in all) cases, the direct comparison of the RQs documented in the PARs would lead to invalid risk comparisons, because a) for two products the scenario was not considered relevant at all (ACP 3 and ACP 4) as simply no emissions

to the environment were assumed, even though the use and the application method is the same as for other bait box products, b) different assumptions regarding the scenario were made, notably the area of the soil exposed, leading to a different dilution of the amount entering the soil, often for exactly same use, and c) different data were used for deriving the PNEC in soil, although the same active ingredient was assessed.

In order to be able to transparently deal with these differences, emission estimates, soil area exposed, PNEC soil and risk quotient in soil were collected for all outdoor uses in the R scripts embedded in the source code generating the confidential Annex to this report.

Regarding the area of soil exposed, some assessments of the use on terraces assume that the amount washed off from the terrace enters a soil area of 0.25 m^2, which is the area specified in the ESD (OECD 2008) for spot application directly on ant nests (ACP 1, ACP 5, ACP 6, ACP 7, ACP 13). Other assessments use various assumptions about the geometry of the soil area exposed, based *e.g.* on an assumed geometry of the terrace and obtain various results (ACP2: 1.5 m^2, ACP 8: 5 m^2, ACP 10: 8.72 m^2, ACP 11: 26 m^2). Only in the case of ACP 8, a reason specific to the product was identified for the soil area exposed, as the efficacy assessment called for a treated area of 5 m^2, which would lead to an equal area of soil exposed, if the treatment was directly on soil, and not on adjacent hard surfaces.

Regarding the PNEC in soil, various PNEC values were used for the a.s. spinosad. While the value used in the CAR for spinosad of 2.27 µg/kg wet weight was used in most assessments, one assessment assumed a different soil water partition coefficient Kpsoil for the equilibrium partitioning calculation, one assessment deviated from the European Assessment by using experimental data that was rejected in the CAR, because newer discussions at Technical Meetings would allow making use of the data, and a third assessment used new studies not available in the European risk review process to derive a refined PNEC.

It is evident that using a different area of soil exposed in the same scenario or using a different PNEC soil for the same compound leads to risk quotients that cannot be compared in a meaningful way in the context of a comparative risk assessment. Therefore, an attempt was made to recalculate these risk quotients using the same assumptions for all products. As shown below, this was done for the exposure of soil via runoff or direct nest application due to outdoor use.

3.2.4.1 Intended use 1: Outdoor use by non-professionals against *Lasius niger*

For the relevant product ACP 13 in intended use 1, the risk assessments for the following combinations of protection goals and exposure pathways were considered potentially relevant for the comparative environmental assessment based on the PAR:

1. Soil organisms
    a. active substance spinosad
    b. transformation products spinosyn B and N-demethylated spinosyn D
2. Birds and mammals
    a. acute risk due to primary poisoning
    b. chronic risk due to primary poisoning
    c. chronic risk due to feeding on contaminated ants
    d. chronic risk due to feeding on contaminated earthworms

The risk to soil organisms due to exposure to the active substance spinosad can be quantitatively compared with the respective risk of using the alternative products (see below). A similar comparison for the two major transformation products in soil is not possible, as these have only been considered in very few assessments of alternative products. However, as transformation to these metabolites is only

assumed to take place after the a.s. has entered soil, the additional risk due to the formation of these metabolites can be assumed to be proportional to the risk caused by the a.s., and therefore, for the purpose of the comparative assessment, it is sufficient to compare the risk due to soil exposure to the a.s. when the product contains the same a.s. and no additional substances of concern. For comparison with products containing other a.s., the additional contribution of the primary metabolites of spinosad components must be kept in mind.

In Table 32, original RQs for the soil organisms (without refinements) due to exposure to the a.s. are shown together with the parameters used in their calculation. As noted above, these assessments are not usable for a comparative assessment, as incompatible assumptions have been made for the different products. When more than one application scheme was treated in the PAR, the worst-case application scheme out of those that were finally authorised was selected. Thus, application by drenching is shown for ACP 13, and application of two bait stations for ACP 6. For ACP 3 and ACP 4, no soil scenario was calculated in the PAR. Numbers were rounded to three significant digits.

Table 32: Risk quotients for soil organisms as given in the PARs of ant control products of intended use 1 and related assumptions for the calculations, not considering any refinements

	ACP 13	ACP 2	ACP 3	ACP 4	ACP 5	ACP 6	ACP 7	ACP 8	ACP 10	Unit
Emission to soil	88.9	1.6	0	0	2.56	3.56	8.33[a]	150	4.21	mg
Soil area exposed	0.25	1.5	-	-	0.25	0.25	0.25	5	8.72	m^2
Soil depth	0.5	0.5	-	-	0.5	0.5	0.5	0.5	0.5	m
PEC soil	418	1.25	-	-	12.0	16.8	39.2[a]	35.3	0.568	µg/kg w.w.
PNEC soil	77.6	2.27	-	2.27	2.27	2.27	2.27	75	123	µg/kg w.w.
RQ soil	5.39	0.551	-	-	5.31	7.38	17.3[a]	0.471	0.0046	

[a] Sum of emission for four subsequent applications, RQ not calculated in the PAR

As a next step, RQs for refined risk assessments and their assumptions are shown for those products where a refinement was conducted (Table 33). These are the RQs that finally lead to product authorisation. Note that for ACP 6, no RQ of the final refinement step (higher PNEC based on different soil partitioning) is available for the use finally authorised product (two bait stations). An RQ with this refinement was only calculated for the use of four bait stations which was not authorised.

Table 33: Refined risk quotients for soil organisms as given in the PARs of ant control products of intended use 1 and related assumptions for the calculations

	ACP 13	ACP 2	ACP 3	ACP 4	ACP 5	ACP 6	ACP 7	ACP 8	ACP 10	Unit
Emission to soil	88.9	-	-	-	2.56	3.56	8.33	-	-	mg
Soil area exposed	0.25	-	-	-	0.25	0.25	0.25	-	-	m^2
Soil depth	0.5	-	-	-	0.5	0.5	0.5	-	-	m
PEC soil	62.4[a]	-	-	-	12.0	2.5[a]	6.08[b]	-	-	µg/kg w.w.
PNEC soil	77.6	-	-	-	34.2	7.53[c]	7.53[c]	-	-	µg/kg w.w.
RQ soil	0.80	-	-	-	0.35	-	0.81	-	-	

[a] 28 day time weighted average concentration; [b] 28 day time weighted average concentration for four applications with an interval of seven days; [c] PNEC based on different soil partitioning data with stronger sorption

Finally, in Table 34, the comparative risk assessment for soil organisms due to exposure to the a.s. from spot application (application method "Nest application") or runoff from terraces (application method "Gel bait" or "Bait box") is shown using the following unified assumptions: a) for the soil area exposed, an area of 0.25 m^2 was assumed, as this was the value used in most existing assessments and b) for spinosad, the PNEC of 2.27 µg/kg wet weight given in the CAR was used for all products with spinosad, including the relevant ACP 13. Please refer to the confidential appendix of this report for a detailed comparison of each recalculated risk assessment with the respective risk assessment given in the PAR.

An exception from the unified assumptions was made for the soil area exposed in the case of ACP 8, which is the only alternative product that is also applied directly on ant nests ("Nest application"). Here, the exposed area of 5 m^2 was derived from the efficacy assessment, as it was found important that all entrances to the ant nest were treated, and the same area was used for the calculation of the applied amount, as the application rate was given in mg active substance per m^2 for the exposure calculations. This exception must be kept in mind, as the area exposed assumed for the relevant product is smaller by a factor of 20, although the use is quite similar.

Table 34: Recalculated risk quotients for soil organisms for ant control products of intended use 1 and related unified assumptions for the calculations, not considering any refinements

	ACP 13	ACP 2	ACP 3	ACP 4	ACP 5	ACP 6	ACP 7	ACP 8	ACP 10	unit
Emission to soil	88.9	1.6	0.664	0.664	2.56	3.56	8.33[a]	150	4.21	mg
Soil area exposed	0.25	0.25	0.25	0.25	0.25	0.25	0.25	5	0.25	m^2
Soil depth	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	m
PEC soil	418	7.53	3.12	3.12	12	16.8	39.2	35.3	19.8	µg/kg w.w.
PNEC soil	2.27	2.27	2.27	2.27	2.27	2.27	2.27	75	123	µg/kg w.w.
RQ soil	184	3.32	1.38	1.38	5.31	7.38	17.3	0.471	0.16	

[a] Sum of emission for four subsequent applications, RQ not calculated in the PAR

The recalculated RQs shown in Table 34 suggest that all alternative products entail a lower risk to soil organisms by at least a factor of 10. However, the following caveats need to be kept in mind: As a much larger exposed soil area was assumed for ACP 8, it is not clear if the comparison is valid. The treated soil area for the relevant product, with the same application method "Nest application" is not specified for this product, so it is possible that the area treated and therefore the area exposed may be larger also for this product. In order to make it possible to obtain a clearly defined and fair risk comparison for these products, the scenario definition in the ESD apparently would need to be further improved, and the way to specify the applied amount in the PARs would need to be unified. Currently, some SPCs give an amount per m^2, some per ant nest, some per m of ant trail, some per terrace/building, and some give several of the above. Clarifying the scenario and harmonizing the way to specify the application rate is beyond the scope of this project but will be discussed in the deficit analysis and the recommendations. In view of this uncertainty, ACP 8 is not considered to have a significantly better profile than the relevant product ACP 13.

The second caveat is that there are two products that do not contain spinosad as active substance: ACP 8 (deltamethrin) and ACP 10 (fipronil). However, as the risk due to exposure to transformation products is not reflected in the risk quotients given above, but risks of the transformation products of these alternative a.s. are negligible in the soil compartment, the relative risk due to spinosad exposure is still underestimated for the spinosad containing products, compared to the alternatives. Soil organism risk quotients for deltamethrin metabolite Br2CA are about a factor 100 below risk quotients for the parent for ACP 8, and in the case of fipronil the risk assessment of soil metabolites is considered covered by the risk assessment of the parent compound based on the CAR.

Overall, the exemplary comparative assessment based on re-calculated RQs without any refinement suggests that there are a number of alternative products with a risk for soil organisms lower by more than a factor of 10. However, all of them except ACP 8 have a different application method (bait application instead of direct next application). For ACP 8, it could be questioned whether assuming an exposed soil area of 5 m^2 (according to the dossier) is appropriate in comparison to 0.25 m^2 for ACP13.

Regarding birds and mammals, comparable assessments have only been made for few alternative products. For ACP 7 (Gel bait), comparable assessments were discussed but yielded RQs < 0.1 (secondary poisoning). For other products where exposure of birds and mammals has been assessed, no RQs above 0.1 were found in the available PARs.

The analysis of practical disadvantages shown in Tier I-A has shown that an equivalent efficacy claim of nest kill has not been approved for ACP 2. In addition, ACP 2 and ACP 8 have RMMs that may pose significant practical disadvantages. The risk comparison to ACP 8 is also considered uncertain due to the different assumptions concerning the soil area exposed. Nevertheless, there are seven alternative products that have a recalculated risk quotient in the most relevant scenario that is lower by more than a factor of ten compared to the relevant product. Metabolites of the alternative active substance do not significantly contribute to the risk, while the risk due to spinosad metabolites in the relevant product is of a similar magnitude as the risk due to the a.s. No other SoC were mentioned in the PARs.

Also, the relevant product showed some risks to birds and mammals due to primary or secondary poisoning, even if they were considered acceptable by the competent authority. Due to the complexity of the respective assessments, these are not quantitatively compared with corresponding risks of the alternative products here, but as no risk quotients greater than 0.1 were encountered for birds and mammals in the PARs of the alternative products, there are no indications that the risk for birds and mammals could be greater for the alternative products.

In conclusion, the quantitative comparative environmental risk assessment at Tier I-B indicates that there may be at least seven alternative products that entail a significantly lower environmental risk, when based on a recalculated risk assessment using similar assumptions. This would depend on either some operational definition of significance which is not given in the TGN, or on expert judgement re-

garding this significance. For three of these products (ACP 3, ACP 4, ACP 5, compare Tier I-A), no indications of significant practical disadvantages were identified, if practical disadvantages that may result from the different application methods are considered negligible.

Note that the relevant product was not necessarily identified as an outlier at Tier I-A in this assessment. Also, if bait applications were per se not considered as comparable to nest applications, this result would not have been obtained.

3.2.4.2 Intended use 2: Indoor use by non-professionals

For the relevant product ACP 10 (ready-to-use bait box) in intended use 2, the risk assessments for the following combinations of protection goals and exposure pathways were considered potentially relevant for the comparative environmental assessment based on the PAR:

1. Emissions to the environment via STP
    a. STP microorganisms
    b. Surface water
    c. Sediment
    d. Soil via sludge application
    e. transformation products spinosyn B and N-demethylated spinosyn D

Direct emissions to soil as well as primary or secondary poisoning were not considered relevant in the respective PARs of the relevant and the alternative products. For the relevant product ACP 10, no emissions to the environment were assumed for the indoor use, as it is a ready-to-use bait box. For the alternative products ACP 2, ACP 3, ACP 5 and ACP 6, emissions to the environment were also considered negligible for the indoor use, as they are also ready-to-use bait boxes. The alternative products ACP 4, ACP 7 and ACP 9 are gel baits that can either be used to refill bait boxes (ACP 4) or directly as gel baits (ACP 7 and ACP 9). In both cases, emissions to STP via cleaning activities have been assessed. However, as the environmental risk of the relevant product has been considered negligible in accordance with the ESD, the question whether the alternative product has a better profile with respect to environmental risks does not really arise. Hence, the ambiguous outcome of Tier I-A according to TGN contrasts with the negligibility of environmental risks of the relevant products in Tier I-B.

3.2.4.3 Intended use 3: Outdoor use by professionals

For the relevant product ACP 11 (used as gel bait or in a bait box) in intended use 3, the risk assessments for the following combinations of protection goals and exposure pathways were considered potentially relevant for the comparative environmental assessment based on the PAR:

1. Soil organisms
    a. active substance

No risk due to primary or secondary poisoning was identified in the PAR. The risk due to exposure of surface water (RQ > 0.1) and sediment (RQ > 1) was addressed by RMM N-121 (“Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water”) and is not considered further in the comparative assessment.

The risk to soil organisms due to exposure to the a.s. (fipronil) can be quantitatively compared with the respective risk of using the alternative products (see below). No risk assessment for soil metabolites was made as this was considered covered by the risk assessment for the a.s.

In Table 35, original RQs for the soil organisms due to exposure to the a.s. are shown together with the parameters used in their calculation. As noted above, these assessments are not usable for a comparative assessment, as incompatible assumptions have been made for the different products. When more

than one application scheme was treated in the PAR, the worst-case application scheme out of those that were finally authorised was selected. As an exception to this rule, the house scenario was selected for ACP 11, as this is more like the scenario used for the other products. However, the alternative scenario (large building) gave almost the same results. No refined risk assessments were performed for these products, as the risk quotients were already below 1 at the first tier.

Table 35: Risk quotients for soil organisms as given in the PARs of ant control products of intended use 3 and related assumptions for the calculations, not considering any refinements

	ACP 11	ACP 1	ACP 2	ACP 3	ACP 4	Unit
Emission to soil	0.473	0.0754	1.6	0	0	mg
Soil area exposed	26	0.25	1.5	-	-	m^2
Soil depth	0.5	0.1	0.5	-	-	m
PEC soil	0.0214	1.77	1.25	-	-	µg/kg w.w.
PNEC soil	123	46.6	2.27	-	2.27	µg/kg w.w.
RQ soil	0.0002	0.0381	0.553	-	-	

In Table 36, the comparative risk assessment for soil organisms due to exposure to the a.s. from runoff from terraces (application method "Gel bait" or "Bait box") is shown using the following unified assumptions: a) for the soil area exposed, an area of 0.25 m^2 was assumed, as this was the value used in most existing assessments and b) for spinosad, the PNEC of 2.27 µg/kg wet weight given in the CAR was used. Please refer to the confidential appendix of this report for a detailed comparison of each recalculated risk assessment with the respective risk assessment given in the PAR.

The assessment of ACP 1 in the PAR assumes an application rate of five spots of 0.1 g per m^2, resulting in only 0.5 g/m^2, while the ZB lists a maximum application rate of 2.5 g/m^2. Furthermore, the assumption that 0.25 m^2 on the terrace are treated is questionable, as this is the area treated for a spot application on soil. The area treated on a terrace is not given in the ESD, therefore the application rate per terrace appears to be ill-defined for this product. Based on the assumptions used in the risk assessment in the PAR, the application would have to be restricted to six spots of 0.1 g per terrace. Due to these complications, no risk quotient was calculated for ACP 1 for the quantitative risk comparison.

Table 36: Recalculated risk quotients for soil organisms for ant control products of intended use 3 and related assumptions for the calculations, not considering any refinements

	ACP 11	ACP 1	ACP 2	ACP 3	ACP 4	Unit
Emission to soil	0.473	-	0.16	0.664	0.664	mg
Soil area exposed	0.25	0.25	0.25	0.25	0.25	m^2
Soil depth	0.5	0.5	0.5	0.5	0.5	m
PEC soil	2.23	-	7.53	3.12	3.12	µg/kg w.w.
PNEC soil	10.6	46.6	2.27	2.27	2.27	µg/kg w.w.
RQ soil	0.21	-	3.32	1.38	1.38	

The recalculated RQs shown in Table 36 suggest that the spinosad containing alternative products ACP 2, ACP 3 and ACP 4 have a higher risk to soil organisms by a factor of 6.5-16 compared to the relevant product. If the additional risk of the spinosad metabolites would be taken into account, this would be even more pronounced. Therefore, the exemplary comparative assessment at Tier I-B does not suggest that there are alternative products with a lower risk for soil organisms due to wash-off from terraces, while Tier I-A did not result in an unambiguous decision. Note that all considered products had a similar application method (bait application, no direct nest application).

4 WP 3: Analysis of deficits in the existing guidance

The deficits in the existing guidance derived from the analysis performed in WP 1 and from the two case studies in WP 2 are described in this chapter. In general, a comparative assessment of biocidal products has to face some generic problems that are intrinsic to comparative ERAs and for which no easy solutions exist. These are not specific to the propositions and the guidance given in the BPR and the TGN but are rather common for assessment methods that try to compare environmental impacts of products, *e.g.* the assessment methods described by Hungerbühler *et al.* (1999) or the methods of alternatives assessment discussed in the context of substitution under REACH previously.

In particular, there are always conflicts between the different assessment objectives (e.g. risk for humans, animals and the environment) that are not quantitatively comparable on a common scale. The procedure proposed in the TGN does not provide a common scoring system of risks for humans, animals and the environment (and also for economic or practical disadvantages) by evaluating these aspects separately, and if alternative products are better *e.g.* for the environment, this will be neglected if they are significantly worse for *e.g.* humans. This places a lot of weight on the determination of significant differences. As detailed in WP 1 (Section 2.2.2.1), the definition of such significant differences in the TGN is not clear enough that it could simply be applied in the form of a recipe that could be used to assess significance. Therefore, the competent authority currently needs to come up with *ad hoc* methods and decisions which make it hard to establish a robust comparative assessment.

In the following sections, deficits identified along the different steps of the assessment scheme are described. Many of these deficits are related to a low degree of standardization and change over time of SPC and PAR documents. Although the ERAs of the different products are based on the same ESD documents, they contain specific adaptations to a considerable degree (see for example the comparison of risk quotient calculations in Table 32). Also, the format of the dossier is hardly standardized and sometimes contains the applicants risk assessment followed by corrections of the competent authority in individual sections. This makes many dossiers highly complex and hinders an easy access and identification of the data that are finally the basis for regulatory decisions. Also, dossiers may be updated, *e.g.* due to substitution of additives identified as SoC, which requires additional efforts to ensure that only most recent versions are used for a comparative assessment.

4.1 Deficits in the definition of the intended use

The definition of the intended use is the basis for mapping alternative products to the relevant product. Several shortcomings of the current way of defining the intended use with regard to a comparative assessment have been identified.

Lack of harmonisation of use descriptions

As noted in WP 1 (Section 2.4.1) and in the case studies in WP 2, a system of harmonised terms for the use description elements listed in the TGN would make the mapping of alternatives much easier and more efficient. In each of the case studies, a system of use descriptions had to be established *ad hoc* for the purpose of the project, in order to be able to transparently map alternative products to the uses of the relevant products.

Efficacy claims are currently not part of the use description

For alternative products to be comparable to the relevant product, it is essential that they do not only have the same target organism, but also the intended effect on the target organism to qualify as substitute. As mentioned in Section 2.2.1.1 different uses and different claims can have different efficacy requirements (compare *e.g.* European Commission 2013, p. 19). In the efficacy guidance for ant control products it is stated that label claims contain two types of information, the target species and effects

(European Commission 2013, p. 58/59). If two products are effective against the same target organism, but the efficacy claims are different, they may both pass the efficacy assessment, but are still not able to replace each other.

An example from the case study on wood preservative products is the differentiation between preventive and curative use, which requires a different type of efficacy.

In the case study for ant control products, an assessment of the effect (label claims) was carried out at Tier I-A in order to address the question of practical disadvantages. However, if this assessment would have taken place at the mapping step, it could have been avoided to work with products in the screening step and at Tier I-A which do not really serve the purpose in the sense of the kind of control that is achieved by the products. An example would be ACP 2, for which the competent authority has not granted the label claim of nest kill (equivalent to colony control). If this label claim would be part of the use definition, this would have been noted already at the mapping step, and some work at Tier I-A could have been avoided. Also, if products are considered eligible alternatives that do not have an equivalent efficacy claim, the chemical diversity assessment in the screening step may lead to wrong conclusions.

4.2 Deficits in the screening step

In the following subsections, deficits identified in this project regarding the screenings steps are listed.

Formal deficits

The wording “three different substance/mode of action combinations” of the proposed criterion for sufficient chemical diversity is confusing. Presumably, the intended meaning is that there should be a.s. with three different modes of action in the set of products available for a specific use.

There are no references to the MoA definitions of the resistance action committees (IRAC, HRAC and FRAC), which are a very helpful source of information in the context of chemical diversity assessment.

Also, it is not clear if microorganisms in the sense of the BPR should count as a separate class of substances or MoA in the screening phase of the assessment.

Necessity of resistance management

For ant control products, in the course of the review of the PAR for one of the eligible alternative products in this assessment, the question came up, if the chemical diversity requirement to have representatives of three different modes of action is really applicable. The competent authority for the respective product argued that a) there are only few reproductive individuals (the queens) and the application of the product will kill these individuals so that resistance is unlikely to develop within the nest or colony, and b) nests further away from human dwellings are not affected by the treatment. Therefore, resistance development is seen as being unlikely.

Taking into consideration that the TGN allows for exceptions to the general rule of three different modes of action (Article 58), it would be possible to argue that the chemical diversity requirement is not necessary in this case. However, chemical diversity may be a goal on its own, in order to prevent development of resistance which cannot be foreseen based on currently available knowledge. Besides resistance development prevention, chemical diversity can be considered warranted in an economic perspective, i.e. fostering a competitive market and preventing monopolisation.

Chemical diversity can be insufficient but unaffected by non-authorisation

The TGN proposes to stop the assessment if the chemical diversity is insufficient in the screening phase (flow chart p. 25), while Article (57) specifies that at least three different MoA should ‘remain

available through authorised products'. There is no specification for the case that the chemical diversity is already inadequate before the comparative assessment and restriction of one product would not further reduce the diversity. For example, if the relevant product contains active substance A and all the alternative products also contain active substance A, non-authorisation of the relevant product would not lead to a reduction of the chemical diversity.

4.3 Deficits identified for Tier I-A

Based on the TGN, the information available at Tier I-A is limited to the contents of the SPC. As the SPC does not contain the results of the risk assessments, such an assessment cannot really be a risk comparison according to the usual definition of environmental risk, but rather a pragmatic assessment of the question if there are indications in the SPC that alternative products may have a better risk profile.

Also, the TGN (6.2.1.1.1) requires that only RMMs and H/P statements associated to the substitution criteria respiratory sensitizer and PBT shall be considered in Tier I-A based at the level of the SPC. It became evident from the case studies in WP2 that this information is not available at the level of the SPC, in particular the distinction between conditions of use and RMMs requires consultation of the PAR. It is also not clear if RMMs regarding the environment result directly *e.g.* from a persistence labelling of the CFS in question, but it can only be assumed.

The term risk mitigation measure is not clearly defined

As mentioned in WP2, there was no dedicated RMM section in the SPC documents for the older product authorisations. After the RMM section had been introduced, it often contained a reference to the section "Instructions for use", so no formal difference between the two was made. Therefore, the location in the SPC in many cases did not clearly indicate if a sentence was a RMM.

Secondly, there is no generally agreed definition of a 'risk mitigation measure'. The working hypothesis that a formal RMM must result from an environmental risk being identified in the PAR could not be kept as there were several ambiguous cases where RMMs were specified as a precautionary measure, e.g. to address a hazard, or an unquantified risk e.g. by excluding a certain emission pathway. In a number of cases, it was not indicated in the PAR at all why a certain RMM was established.

Risk mitigation measures are not fully harmonized

As illustrated in both case studies, RMMs are listed in various sections in the SPCs (only from a certain point in time, there is an RMM section, see above), while conditions of use, *e.g.* based on efficacy requirements, are sometimes listed in the RMM section (e.g. N-133 "Do not use when rain is expected in the next 24 hours").

While harmonised phrases have been developed lately, the wording in the existing SPCs regarding RMMs is very variable and it requires a large effort to assign them to the new harmonised phrases. In several cases, it was questionable whether two RMMs express the same meaning and are actually meant to express the same meaning. Examples from the wood preservatives are the phrases "Do not contaminate soil and water during application and drying time" and "Do not contaminate surface water and prevent run-off": one was a condition of use and the other a RMM set due to identified risk. In both cases, the impact on the user is the same: no application on wood that is near surface water (e.g. a bridge over a pond). Furthermore, a decision whether a specific RMM is stricter than another one is not straightforward but could likely give reason for controversial debates: it was just not established formally as RMM because the scenario was not calculated due to restrictions in usage. Therefore, the ongoing efforts to harmonise the sentences used to express RMMs were very helpful, at least in the case study with the ant control products.

Also, if RMMs are only applicable for a specific application method, the absence of those measures for an alternative product with a different application method may or may not appear meaningless (see subsection "Use specific risk mitigation measures" below). Hence, simply counting the number of case with 'better' versus 'worse' or 'similar' RMMs and H/P statements is highly questionable. A simple counting of the number of RMMs does not take into account the weight of H/P-statements and RMMs. Yet, if and how to apply any weighting is not defined in the TGN.

As the TGN states that Tier I-A should only use information listed in the SPC, it is not possible to know if different competent authorities used the same decision rules to decide if a specific RMM is necessary. However, if this is not the case, the assessment may lead to wrong conclusions. Therefore, the rules leading to the use of an RMM should be clarified in the process of their harmonisation (compare the recommendations in WP 4). It also became clear within WP2 that by establishing certain conditions of use (e.g., no application near surface), the formal establishment of a respective RMMs can be avoided. The implication for the user and the environmental risk, however, may be similar. Therefore, the comparative assessment in Tier I-A on formally established RMMs and H/P statements only may fall too short.

As the assessments forming the basis of the authorisations of the available alternative products may have been performed years ago, the standards of the authorities may have changed, which may lead to erroneous conclusions at Tier I-A. This problem is not addressed in the TGN.

Risk mitigation measures are not intended to be risk indicators

The purpose of RMMs is to mitigate risks that have been identified in the product risk assessment based on use definition and the conditions of use proposed by the applicant. However, they do not provide information about the risk that remains after they have been implemented, which should be assessed according to the TGN (compare TGN Article 63 a). In the simplest case, an RMM prohibits certain applications (e.g. near surface water) and is thereby expected to eliminate any remaining risk for the aquatic compartment (which has then consequently not been further assessed in such dossiers).

Therefore, they do not provide a good fit to the assessment goal and their use as risk indicators for a comparative assessment at Tier I-A as prescribed by the TGN is questioned. This is further illustrated in the two following subsections.

Risk mitigation measures limiting dosing or application timing

The risk assessment performed by the competent authority may lead to a restriction in the application rate or dosing of the product which was frequently stated in the category "risk mitigation measures" in the case of ant control products. However, if the same limitation was already anticipated by the applicant for a comparable product, this could be part of the dosing instructions and no corresponding RMM would be specified. Therefore, the dosing-limiting RMM alone may not be a reliable parameter to be used in a comparison of the risks remaining after implementation of RMMs.

Risk mitigation measures limiting use

A similar situation can be found when risk mitigation measures have been specified that restrict the authorised uses of the product and thereby affect the use definition. An example for such a case is the top coat requirement illustrated in the intended use 1 of the wood preservative products. For the relevant BP, the top coat was established as condition of use related to the efficacy claim. Consequently, no risk assessment based on leaching from treated wood without top coat was performed. Yet, it remains open whether such an assessment would have resulted in an RMM requiring a top coat.

Additional risk mitigation measures of alternative BPs

The example scheme for the outlier analysis at Tier I-A in the TGN shown in Appendix 7.2.1 of the guidance is based on "RMMs and H/P-statements in the relevant BP linked to the substitution criterion met by the CFS contained therein". For each such RMMs or H/P-statements it is checked if the alternative BPs have better RMMs or H/P-statements.

On the other hand, alternative products will often also have H/P-statements or RMMs that cannot be compared to the ones of the relevant product. In the case study with wood protection products, these were included in the discussion of the risk profile at tier I-A, while they were not considered at this stage in the case study with ant control products. In the case study with ant control products, these were then used for answering the question if there are significant practical disadvantages. The TGN appears not to be clear at which stage of the assessment the RMMs of the alternative products shall be taken into account. While it is stated in the main text of the TGN regarding Tier I-A (64a) that number and relevance of the relevant and the alternative products are taken into consideration, the example in the appendix only looks at the RMMs of the relevant product.

Lacking operational definition of an outlier

As briefly discussed already in WP 1 the term outlier is used in the TGN for products or values that are distinct from the majority. One point to be clarified (compare Section 2.2.2.6 of this report) is the question, if a smaller group of alternative products that are significantly better than a larger group should not also be sufficient for non-authorisation of a relevant product, provided that the other conditions (sufficient chemical diversity and absence of significant economic or practical disadvantages) are met.

Another deficit identified for the application of the outlier concept at Tier I-A was that the decision rules regarding the number (and severity) of RMMs and H/P-statements are not clearly defined (Section 2.2.2.8 of this report). In particular, there is no indication in the TGN how to deal with cases where the relevant product is worse than most other products with respect to one particular RMM, but better with respect to other RMMs. Due to the large number of RMMs that are often specified (compare the case study of ant control products), this severely limits the potential for unambiguous decisions at Tier I-A.

This lack of a clear operational definition was also found at Tier I-A in the case studies, where it was often not unambiguous if the relevant product should be seen as an outlier or not (see WP 2). Consequently, the respective conclusions had to be formulated rather carefully.

Lack of information on economic and practical disadvantages

The information sources mentioned in section 7.2.2 of the TGN (Public consultations according to BPR article 10(3), sector specific consultations, critical review of alternative BPs submitted by the applicant) were not available for the case studies. The availability to CAs and the quality and appropriateness of such data could not be checked.

The terms "sufficient control" and "very high efforts" used for determining the significance of economic or practical disadvantages (TGN article 27) are not defined to a sufficient degree. While it may turn out to be impossible to provide an unambiguous, operational definition, this is in conflict with the requirement that the comparative assessment should have an objective basis that cannot reasonably be disputed by the applicant, resulting from the fact that the burden of proof is with the CA proposing non-authorisation.

4.4 Deficits in the definition of Tier I-B

In general, the assessment procedure at Tier I-B was found to be the part of the scheme that was defined in the least detail. Especially the lack of explicitly defining which parameters (only risk quotients or also other data) should be quantitatively compared (see next subsection) must be seen as a serious deficit, as no unambiguous basis for the assessment is given.

Lack of harmonisation of the risk assessments

Although the ERAs of the different products were based on the relevant ESD documents, they contained notable degrees of specific adaptations and the risk assessments are documented in very different ways which makes it very hard to extract the information relevant for a comparative assessment. An extreme example is the way in which method and rate of application were described for the ant control products. During the attempt to recalculate risk quotients in order to make a quantitative comparison possible, there was at least one case where the dosing of the product was specified in a way that was incomparable to the other products. This made it impossible to provide comparable risk quotients for ACP 1 in intended use 3.

Should other values except for risk quotients be used?

While the TGN states that RQs and PEC/PNEC ratios could be used at Tier I-B, it leaves the possibility that other "values" are relevant as well. Potentially, this could mean the PBT/vPvB classification, as this is directly related with the area of concern leading to an a.s. in the product being a CFS. On the other hand, the comparative assessment, as per the definition in the BPR (Article 23a), is designated to be a comparison of risks, rather than hazards. Therefore, hazard indicators such as PBT or single compound specific values as soil DT_{50} values or aquatic EC_{50} values cannot be used in isolation to indicate such a risk.

Given that the PBT criteria apply to individual substances, it remains open how a comparative assessment of products containing several substances can be conducted. How to weight a product that contains one PT substance against a product that contains two PT substances or one PBT substance? How to consider in this weighting SoC contained in the individual products?

Risk quotients as documented in the PARs are not comparable

In both case studies it was evident that the RQs extracted from the PARs were not comparable in the sense of a quantitative risk comparison, because they often resulted from adapted risk scenarios and/or refined assessments. Different assumptions were made in the calculations of PEC values regarding degradation/no degradation, or different compartment dimensions, but also different PNEC values were used for the same a.s. The latter may also be caused by new data that have become available between different authorisation processes or that are only accessible for a subset of the applicants.

Some of these differences were caused by the different ways in which the ESDs were interpreted. While a lot of effort has been made at Working Group Meetings and in different projects to improve these, the comparative assessment will always have to deal with assessments that have been carried out at different times by different authorities.

Emission scenarios are often adapted to local, national or application-specific circumstances. This is in consistence with e.g. the ESD for wood preservatives which states on page 2, Part 1 that "default values [of the ESD] are not "fixed in concrete" and if users of this ESD have other, more valid values, then these should be used instead".

Such more valid values established by one applicant (and accepted by authorities) may, however, not be used for other applicants in order to standardise the risk assessments for the comparison as this

may create issues with data protection and confidentiality. Accepting different values being used in emission calculations will strongly affect the comparability of calculated risk quotients.

Number of risk quotients potentially available for a comprehensive assessment

In practice, there is a large number of RQs in each PAR that could potentially enter the comparative assessment (compare e.g. the overview in the case study of wood preservative products). In the TGN, it is not specified whether they should be all treated as equally important, regardless if they are on the order of magnitude of 10^{-3} or around 1. As no cut-off is defined in the TGN, the assessment becomes very difficult to handle.

No significance threshold for comparable risk quotients

In the case that it was possible to recalculate risk quotients for an example assessment that did not have any obvious deficits regarding their comparability (Assessments A and C in the case study for ant control products), a significance threshold or another operational definition of the outlier concept would be needed in order to decide if there are sufficient alternative products with a significantly lower overall risk.

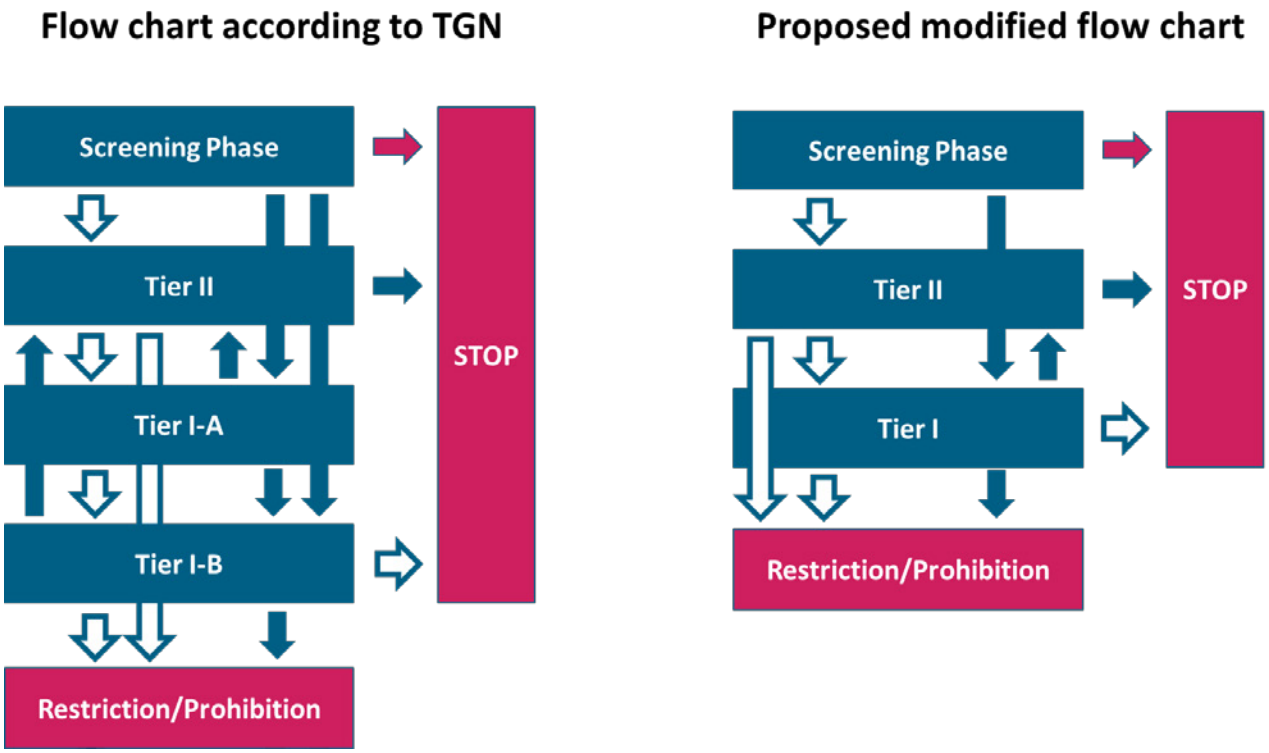
Tier I-A may produce false negatives

The assessment of the outdoor use by non-professional users of ant control products against *Lasius niger* (Intended use 1 in the second case study) showed that a relevant product may not be assessed as an outlier at Tier I-A, although it shows a higher comparative risk at Tier I-B in comparison to most alternative products. However, this appears to depend to a larger degree on the definition of an 'outlier' and the sound comparability of the established RMMs in terms of their strictness.

5 WP 4: Development of recommendations for the comparative environmental assessment

It was agreed during the course of the project that no new concept for a comparative assessment of biocidal products should be developed from scratch, but that rather more detailed recommendations and guidance shall be developed based on the existing TGN document of the European Commission (European Commission 2015). The tiered approach of the TGN that aims at reducing the number of complex quantitative comparative assessments based on risk by setting filtering steps is fully supported. However, the overall complexity of the tiered approach is high as illustrated in Figure 2. There are numerous paths among the tiers that can be followed through the framework suggested by the TGN. The here proposed slightly simplified overall flow chart would involve three tiers (screening phase, Tier I, and Tier II), and from each of them the comparative assessment could be stopped under defined conditions. A decision for restriction/prohibition can be reached from either Tier I or Tier II, eventually after the other tier has been completed first without reaching the decision for restriction or prohibition. The proposed modifications are discussed in the following sub-chapters in more detail.

Figure 2: Flow chart of the overall tiered approach according to the TGN (left) and modified as proposed in the present project (right)



Source: own figure based on TGN, ECT Oekotoxikologie GmbH

5.1 Definition of the intended use and mapping of alternatives

According to the BPR (European Union 2012) as the underlying law and the TGN (European Commission 2015), a comparative assessment relates to specific uses of the relevant product, not to the product as such. It is therefore essential to clearly define the specific uses (i.e., each *intended use*) and identify accordingly alternative products with an identical intended use. Any restrictions resulting from a comparative assessment may relate to one or more intended uses of the relevant product.

Substantial efforts were required to compile information and define the intended uses of the relevant and possible alternative products in WP2. This was, among others, due to non-standardised descrip-

tions of the required information, often scattered across various sections of the SPC and the PAR. As a consequence, a greater degree of harmonisation and standardisation is strongly recommended for the terms in the use description within the six categories defined by the TGN. This harmonisation should also include the different member states, as differences among the member states appeared to be another source of variation regarding terminology in the use description. A digital system that would enable selecting among pre-defined terms for the six categories of the use description when entering a product into a database, would enable a more efficient way of identifying alternative products for a comparative assessment. The resulting standardised and harmonised use description could then be summarised in an own section at the beginning of each SPC, and become part of the *Register for Biocidal Products* (R4BP) database. The pre-defined terms would differ to some degree among PTs, but their establishment per PT may despite the considerable initial effort increase the efficiency of comparative assessments in the future, where needed. Any digital compilation of this information must already relate to each individual intended use (i.e. as defined by combinations of the entries), because the entries for different categories cannot be freely combined. One simple example described in WP2 is the case of the wood preservative product 7 for which professional but no non-professional usage against Basidiomycetes is authorised. For the examples addressed in WP2, i.e. wood preservative and ant control products, proposed pre-defined terms are listed in Table 37.

Table 37: Pre-defined possible entries for the proposed categories that describe the intended use of a biocidal product

	Wood preservative products	Ant control products
Product type [a]	PT 08	PT18
Exact description of authorised use, where relevant [a,b]	*Example*: Fungicide of use class 2 targeting wood destroying fungi and applied by brushing for preventive treatment of wood, but not near surface water	*Example*: Insecticide for outdoor use targeting black garden ants and applied by gel baits, but not close to blooming plants/cultures
Target organism (s), including developmental stages [a] **Function, taxonomic group and species of target organism (s), and their developmental stages** [a]	1: Fungicide; 2: Insecticide; 3: Molluscicide; 4: Bactericide; 5: Algicide; 1.1: Wood destroying (=rotting) fungi (Basidiomycetes); 1.2: Soft rot fungi; 1:3: Wood disfiguring (discolouring) fungi (blue stain, sap staining and/or mould fungi); 1.4: [species name or taxonomic group for insects, molluscs, bacteria, algae, according to the Application Code Document, TM 2004]	1: Insecticide 1.1: Ants 1.1.1: Garden ants (*Lasius niger*); 1.1.2: Tropical ants (*Linepithema humile*); 1.1.3: Tropical ants (*Monomorium phar-aonis*); [further species name or taxonomic group for ants and termites according to the Application Code Document, TM 2008]
Field of use [a]**, including any restrictions in the field of use** [b]	1: Indoor 1.1: use class 1 or 2; 2: Outdoor 2.1: use class 2, 3, 4, or 5; 3: Restrictions such as no application near surface water	1: Stored product protection/food protection; Health protection; 2: Outdoor; indoor; 3: Restrictions such as no application in areas that are liable to submersion or becoming wet
Category of users [a]	Non-professionals; Professionals; Industrial	Non-professionals; Professionals
Application aim (efficacy claim) [b] **Application method** [a]	1: Preventive; Curative 2: Brushing; spraying;… [according to Application Code Document, TM 2004]	1: Control/reduction; Nest kill 2: Nest application; Bait box; Gel bait

[a] Category used for the definition of intended use in the TGN; [b] proposed modification

It is further proposed to extend the information in the categories established in the TGN in order to better define the intended use. One proposed additional information is the function of the a.s. (i.e. the broad group of targeted organisms to substitute for cases where the targeted organisms are not identified at higher taxonomic levels). 'Function' could be combined with target organisms and their developmental stages, and the information in this category should be ordered hierarchically from 'Function' to 'Taxonomic group', 'Species' and finally 'Developmental stage'.

One more piece of additional information that is recommended to be included is the application aim. Application aim, function, and target organism(s) are closely linked to the efficacy claims for a biocidal product. Therefore, PT-specific guidance documents for efficacy assessment should be taken into account when pre-defining the possible entries in the intended use description of a product. This is already stated in the TGN to some degree (see example of cockroaches in 5.2 (37) of the TGN), but not clearly reflected in the definition of the intended uses. For any biocidal product, the claim for the target organisms in combination with the application aim and application method must be supported by appropriate efficacy data. For wood preservative products, for example, a transitional guidance document (ECHA 2015) describes in detail which data must be provided to support respective claims. A product can only be considered as an alternative for an intended use in question if it has equivalent efficacy claims, supported by appropriate data, as the relevant product. The application aim in combination with the efficacy claim could best be added to the 'application method' category. The category 'Exact description of authorised use, where relevant' could carry a short description of the intended use, i.e. basically the combination of the terms in the other categories to serve for quick orientation. Again, all entries should be standardised as much as possible, because free text entries would not support a fast identification of eligible alternative products in the database.

A product cannot be considered as an alternative if its field of use is more restricted than that of the relevant product. For example, a product for which the *in situ* application to wood close to surface water is excluded (e.g. by a RMM) cannot be considered an alternative for a product for which this use is authorised. Hence, any established conditions of use or RMMs that prohibit application in certain areas should be integrated into the category 'Field of use'. This is recommended, because application restrictions such as 'No application near surface water' or 'Apply only in areas that are not liable to submersion or becoming wet' prevent the eligibility as alternative product for a relevant product that does not have this restriction. In fact, application code documents (e.g. that for PT18) differentiate at a much greater level of detail the field of use than it is foreseen in the TGN. Hence, being more specific in this category in the mapping step is in full accordance with application code documents. A full list of possible entries for this extended category can probably not be provided yet as it would require the list of standardised RMMs for all PTs regarding field of use discussed above. It is acknowledged that the category "Exact description of authorised use, where relevant" foreseen in the TGN might have been established to contain such information. However, if this is indeed the intention of this category, it was not made clear in the guidance.

Including application aim, efficacy claim and use restrictions in the definition of the intended use and, hence, the mapping of alternative products, would reduce uncertainties and problems later on in the assessment. Particularly complex considerations as exemplified in WP2 for ACPs regarding technical disadvantages due to use restrictions and similar efficacy claims can be avoided.

The application method is one of the categories foreseen by the TGN for the definition of the intended use. However, the TGN also states that products with a different application method than the relevant product can still be considered as alternatives. Only in a later stage, the consideration of 'significant economic or practical disadvantages' (TGN, 5.21 (39)) can render a potential alternative product a non-suitable alternative. The definition of 'significant economic or practical disadvantages' is relative vague in the TGN. More guidance on this aspect would reduce foreseeable conflicts and disputes. In the present case study with ACPs, the question whether bait application is a suitable method to substitute for direct nest application was critical for the outcome of the comparative assessment. Guidance on the

suitability of various methods to replace each other should be developed and integrated into the PT-specific efficacy guidance documents. The application method is directly linked to efficacy claims, as efficacy must be demonstrated by appropriate tests for each proposed application method.

It can of course be discussed and changed in which of the six categories foreseen by the TGN the proposed additional information shall be added, e.g. based on technical or practical reasons. However, it is essential to standardise how this information shall be entered in a future database. Key is in fact having the proposed additional information available in an easily accessible way already for the first step of a comparative assessment, i.e. the mapping of alternatives, would considerably help in quickly narrowing down the number of potential alternatives. Hence, any effort that is invested into clearly defining the intended use(s) of all authorised products in a harmonised way during the authorisation process reduces the work load of potentially necessary comparative assessments later on. Narrowing down the number of eligible alternative products reduces specifically the work load in the more complex later steps of the comparative assessment, i.e. those based on qualitative and quantitative aspects. A clear and concise description of the intended use would also support the search for potential non-chemical alternatives.

5.2 Screening Phase

The condition of sufficient chemical diversity stated in the TGN is solely based on the argument of preventing resistance development. On a case-by-case basis, resistance management can be deemed not necessary by the CA, which would allow to overrule the requirement of adequate chemical diversity. Overruling this screening step condition by using this argument appears potentially problematic, because availability of different MoA can be seen as warranted in view of a precautionary resistance prevention scheme as the potential for resistance development may just not be known yet for the MoA in question. In addition, diversity of biocidal treatment methods for a given intended use can be seen desirable also due to economic reasons (e.g. prevention of market monopolisation).

On the other hand, the limitation to chemical diversity alone appears too restrictive. Micro-organisms as active substances of authorised biocidal products should be considered as well in this context. This is not fully in agreement with the BPR that states “other authorised biocidal products” in general as eligible alternatives, but also requests specifically adequate chemical diversity to minimise occurrence of resistance (Article 23(b), BPR). Hence, there is no reason to limit alternative products *per se* to those with chemical active substances, but micro-organisms authorised as active substances according to the BPR are not acknowledged as a means to manage resistance of target organisms to chemical agents. There may be few cases currently where a micro-organism qualifies as a suitable substitute for a chemical a.s. with regard to efficacy and technological effort. One example could be the gram-positive bacterium *Bacillus thuringiensis* used as insecticidal agent e.g. for mosquito control (Palma et al. 2014). However, the area of ‘biopesticides’ is developing, which may result in more products as eligible alternatives to chemical active substances in the future. Hence, the limitation of the BPR to adequate chemical diversity is deemed as too short-sighted, and it is recommended to require in the screening phase the existence of authorised products for the relevant intended use with a sufficient number (e.g. three) of a.s. with a different MoA, regardless whether they are chemical substances or micro-organisms. Considering micro-organisms authorised as active substances as non-chemical alternative to chemical a.s. may be seen as another option, but appears not as a practical solution. This is mainly because resistance development is not only an issue for chemical a.s., but also for micro-organisms used as actives. Hence, one authorised micro-organism cannot represent an eligible non-chemical alternative, but must be scrutinized for diversity in view of preventing resistance development similarly to a chemical active substance.

As discussed in WP3 and apparent from examples in the present studies (i.e. authorisation dossiers of products with a.s. classified as CFS that contained a comparative assessment), the requirement of chemical diversity is interpreted in a way that it must be fulfilled before the assessment or regardless

of the number of authorised products with different a.s. that remain after a potential restriction of the relevant product. According to this interpretation, the comparative assessment stops in the screening phase if, for example, all authorised products for an intended use contain a.s. of only two different MoA groups. Yet, the restriction of the relevant product in such a case does not necessarily result in a reduction of chemical diversity as alternative products with the same a.s. or other a.s. with the same MoA could remain on the market. The TGN states that it is in principle possible that a product with an a.s. classified as CFS can serve as an alternative product (Article 5.2(36)). This is stated without a specific justification, but likely relates to the argument that the possible alternative product containing a CFS as well may still have a better overall risk profile than the relevant product. The same line of argumentation would hold for a product that contains the same a.s. as the relevant product. This possible alternative product could in principle have a better risk profile than the relevant product, e.g. due to lower concentrations and/or a different application method resulting in lower PECs or due to fewer formulation additives being classified as SoC.

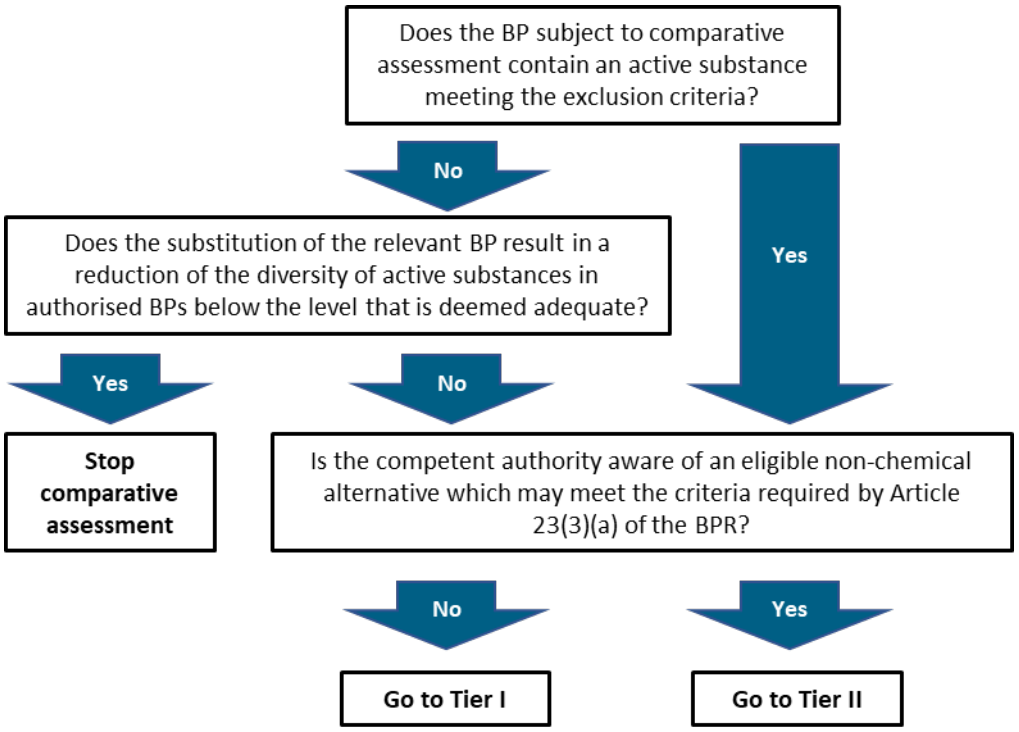
Taking all these arguments into account, it is recommended not to stop the comparative assessment in the screening phase due to inadequate diversity (three or less a.s. with different MoA in authorised products) as long as the relevant product is not the only representative for one of the MoA groups. The comparative assessment should instead only stop in the screening phase if the substitution of the relevant product would lead to the reduction of different MoA groups being represented in authorised products below the number deemed adequate (i.e., three according to the TGN). In the borderline case that three or less MoA groups are represented by a.s. in authorised products, at least one product of the MoA group that contains the relevant product should remain on the market due to the requirement of diversity. It is recommended that in this case the relevant product be only compared with the alternative products that contain a.s. with the same MoA, i.e. the comparative assessment be conducted within one MoA group. This is to ensure that the remaining product in the MoA group of the relevant product is the one with the best overall risk profile. If the relevant product would be restricted because of a better profile of an alternative product from a different MoA group, it could happen that a product from the same MoA group as the relevant product would be subject of a comparative assessment later on that may be stopped because it is the only representative of this MoA group then. In consequence, it could happen that from two products containing a CFS from the same MoA group, the product with the later authorisation date would remain on the market instead of the product with the better risk profile.

5.3 Tier I-A and the proposed modified screening phase

The aim of the current Tier I-A is to direct the comparative assessment either to Tier I-B or Tier II, while stopping the comparative assessment in Tier I-A is no option according to the TGN. It is questionable whether such a sorting step is indeed meaningful and efficient. In the current flow charts, there are numerous options how Tier I-B and Tier II as steps of an actual comparative assessment can be reached with options stated as footnotes how the flow can be changed.

In order to reduce this complexity and redundancy of the current flow charts, it is recommended to direct a continuing comparative assessment at the end of the screening phase either to Tier I or Tier II as illustrated in Figure 3, and omit Tier I-A as an additional sorting step. It is anyway an option in the screening phase to move to Tier II instead of Tier I-A if the competent authority is aware of eligible non-chemical alternative that may meet the criteria (Annex 7, TGN). The proposed modified flow chart for the screening phase also includes changes in the flow so that most easily available information is required first.

Figure 3: Proposed flow chart for a modified screening phase



Source: own figure based on TGN, ECT Oekotoxikologie GmbH

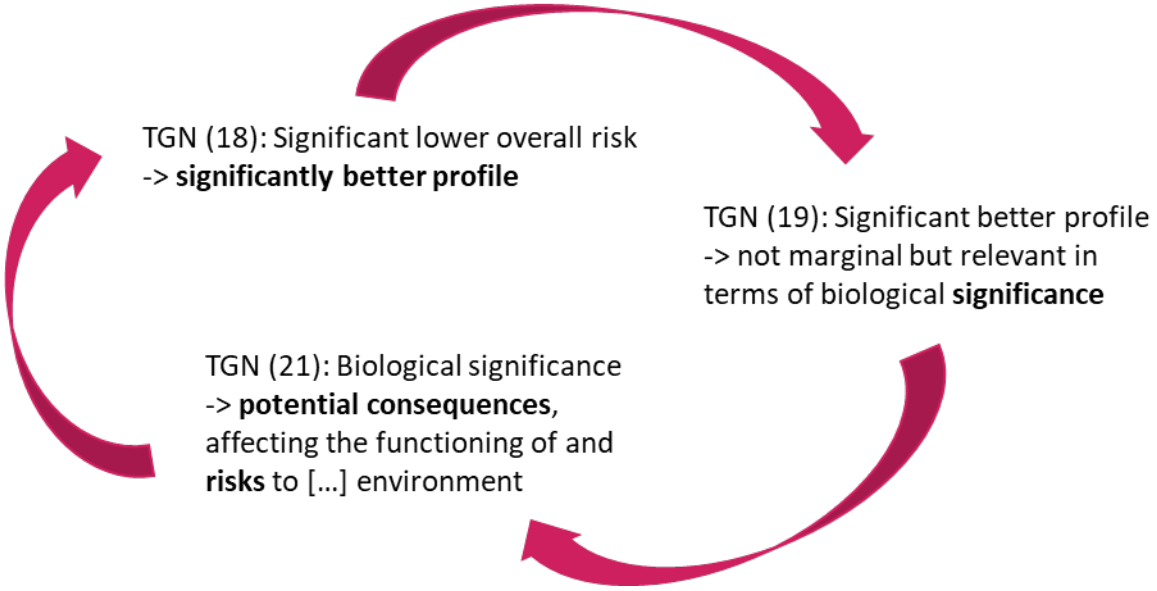
5.4 Tier II

Evaluation and development of recommendations for Tier II (comparison with non-chemical alternatives) was beyond the scope of the present project. The outcome of a Tier II assessment according to the TGN is either to restrict the relevant product or stop the comparative assessment if Tier I-B had already been conducted. The assessment would not stop but move to Tier I-B if Tier II had been entered first, however. The proposed change in the screening phase would not alter this as the outcome of Tier II should still be either restriction of the relevant product or further assessment in Tier I unless this has been conducted first with the result to continue the assessment in Tier II. The only change would be the initial question of the current Tier II (availability of possible non-chemical alternatives) that would be moved to the screening phase.

5.5 Proposed modified Tier I

The TGN provides a somewhat circular definition of 'significant lower risk' (Figure 4) that is supposed to allow identifying the relevant BP as outlier in Tier I-B, and thereby enable a substitution decision. In effect, the difference in risk is defined as significant if it entails potential consequences for the environment. The underlying intention of these definitions may be to relate a 'significant lower risk' to differences in regulatory consequences, although that is not explicitly stated in the TGN. In this case, a 'significantly worse profile' would be indicated by stricter PBT classification or stricter RMMs or H/P statements. Consequently, the Tier I-B assessment would be reduced to a Tier I-A assessment, which is based on exactly these parameters. Hence, Tier I-A and Tier I-B could be combined into a Tier I assessment based on weighted or ranked qualitative criteria. Yet, this would imply to fully omit a comparison of risks remaining after implementation of RMMs, which should be based e.g. on risk quotients according to the TGN.

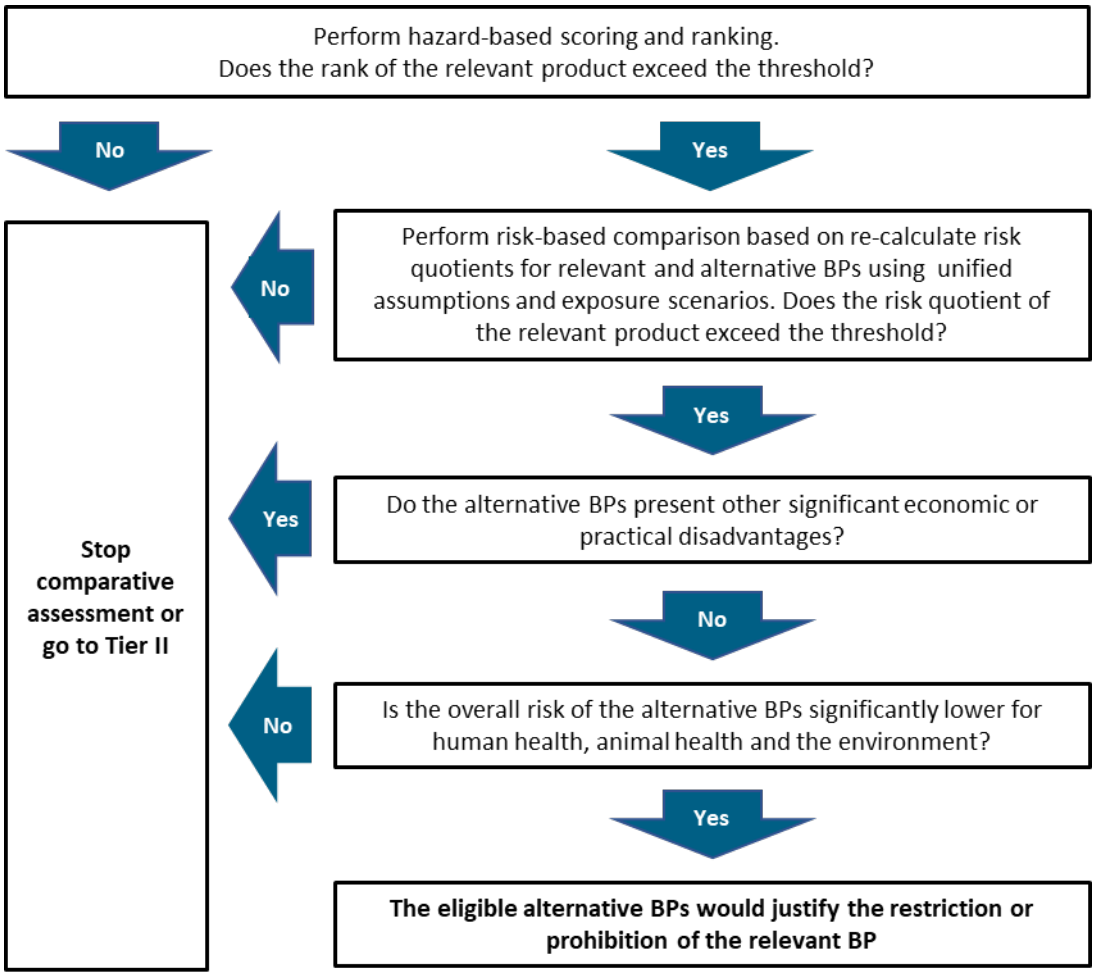
Figure 4: Scheme of the circular definition of 'significant lower risk'



Source: own figure based on TGN, ECT Oekotoxikologie GmbH

As a consequence, a modified Tier I is proposed that keeps the idea of Tier I-A as a hazard-based filtering step, a final assessment based on quantitative risk indicators, and that also suggests quantitative thresholds for a 'significantly lower overall risk'. The flow chart for the proposed modified Tier I is shown in Figure 5.

Figure 5: Proposed flow chart for modified Tier I



Source: own figure based on TGN, ECT Oekotoxikologie GmbH

5.5.1 Hazard-based ranking as filtering step in a modified Tier I

Compiling RMMs for the relevant and the alternative products was an initial step in WP2 that turned out to be far more complicated than expected. As discussed in the deficit analysis, it was not possible to identify RMMs based on the SPCs alone (as foreseen by the TGN). Even with the help of the PAR, it was often not possible to unambiguously decide whether a phrase relating to protection of the environment was indeed a RMM according to the working hypothesis (i.e., established due to identified risk) or whether it was a condition of use. There is no definition of a RMM that is agreed among the member states, and as stated already in earlier projects and workshops (Gartiser et al. 2012, Gartiser and Jäger 2013, Gartiser et al. 2015), there is a strong need to standardise and harmonise the terminology of RMMs as well as the criteria for their establishment among member states. Without such a harmonisation and standardisation, reaching back also to existing authorisations, it appears impossible to consider RMMs currently in the comparative assessment from a practical point of view. If RMMs are to be kept as criteria within the comparative assessment, not only those formally established due to an identified risk in the assessment should be considered, but equally any restriction in the condition of use listed in the SPC that has a similar impact on environmental exposure or effects. Examples from WP2 are the top coat requirement and the instruction for minimum intervals before repeated applications. They were established as conditions of use by the applicant and taken into account in the ERA. Considering RMMs and conditions of use equally would at least allow an initial assessment such as Tier I-A based on the SPC only as foreseen in the TGN, i.e. without consultation of the PAR.

Beyond the practical aspect of poorly standardised RMMs, the issues with using RMMs as decisive step in the comparative assessment outlined in WP2 and WP3 appear as inherently problematic and rather difficult to solve. Therefore, it is recommended at least for the time being to omit RMMs from the comparative risk assessment for the following reasons:

- The practical exercise in WP2 revealed that a ranking of RMMs based on their strictness and severity is ambiguous. This problem may remain even after improved standardisation and harmonisation.
- RMMs for different application methods (e.g. direct nest application versus bait application) may not be comparable.
- There is no clear threshold established by the TGN for classifying a BP as an outlier, and it appears impossible to propose on a scientific basis such a quantitative threshold when using RMMs.
- The TGN states that risks remaining after established mitigation measures should be taken into account in Tier I-A (62a). This is in fact to some degree contradictory to the requirement of considering RMMs based on their strictness. A RMM that prohibits for example any application close to surface water and thereby excludes contamination of this compartment can be seen as rather strict in view of the impact on possible uses. However, it appears not appropriate to consider this RMM in the comparative assessment as there is no remaining risk (due to non-exposure) of surface water. Overall, the existence of RMMs can be seen as an indicator for hazard or for unacceptable environmental risk in case of non-compliance, but certainly not as a qualitative or quantitative estimate for remaining risks.

The idea of an initial filtering step should be kept in Tier I in order to reduce the number of relevant products for which the most detailed risk-based comparison needs to be applied. Using a hazard-based filtering step (as partly attempted by the TGN) appears logical, because hazard-based criteria (i.e. PBT properties or reasons for concern despite restrictive RMMs) triggered in the first place the labelling as CFS with regard to the environment. It can be expected, hence, that the relevant product (not only the a.s. therein) should indeed have a worse hazard profile than the alternative products to justify substitution. Accordingly, a scoring system based on hazard indices relevant to the environment is proposed in Table 38.

The proposed scoring system includes the hazard indices addressed in the TGN (i.e., PBT properties and H statements). In addition, classification of the a.s. as endocrine disruptor with regard to wildlife and presence of SoC (with regard to the environment) is considered. The latter two aspects are currently neglected in the TGN but do appear relevant for comparative assessments with regard to the environment.

Table 38: Possible scoring system for a hazard-based comparative assessment of biocidal products in Tier I with regard to the environment

	Criterion assessed	Resulting score
Assessed per active substance		
Persistent, bioaccumulative and toxic	None of 3 PBT criteria met	0
	Classified as PB or PT or BT	3
	Classified as vPT or vBT	5
	Classified as PBT	10
	Classified as vPvB	10
	Classified as PBT and vPvB	20
Classified as endocrine disruptor	No	0
	Yes	10
Assessed per product		
Established H statements [a]	None	0
	H400 (R50): Very toxic to aquatic life	3
	H413 (R53): May cause long-lasting harmful effects to aquatic life	1
	H412 (R52-53): Harmful to aquatic life with long-lasting effects	2
	H411 (R51-53): Toxic to aquatic life with long-lasting effects	3
	H410 (R50/53): Very toxic to aquatic life with long-lasting effects	4
	H420: Harms public health and the environment by destroying ozone in the upper atmosphere	1
Substance of concern (SoC)	Number of contained SoC with regard to environment	1 per SoC
Degree of open application	Contained application method	0
	Environmentally open method	5
Sum of scores [b]		

[a] According to European Council (2008) and GHS only those related to environment at this step; [b] summed per a.s. in the product and the product itself

In addition, one more parameter could be included in the scoring system that relates to the 'hazard of emission'. This additional parameter makes only sense if within the same intended use application methods are represented that can be differentiated with regard to a more environmentally open or a more contained application. One example from the assessment of the ant control products is the direct application of a (diluted) product by pouring onto soil (or the ant nest entries, rather) in contrast to a more contained application in a bait box. A similar example may be found in the case of rodenticides where baits could formerly be applied openly or more contained in boxes, i.e. protected from other animals or rain, which is nowadays the standard application method. In the case of wood preservative products applied *in situ* outdoors, methods such as brushing and painting could be assumed both as open applications. Hence, no differentiation would be required here for the ranking. Hence, the pa-

rameter 'degree of open application' would only be required on a case-by-case basis for some PTs or intended uses.

The scores would be calculated for each a.s. in each product, summed and added to the score obtained for the product, based on H statements and number of contained SoC. The relevant and the alternative products would be ranked based on their total scores. Such a scoring and ranking system would be transparent and easy to calculate.

The most critical point is obviously the scores attributed to the different properties and their relative weighting to each other. The scores proposed in Table 38 weight the fulfilment of exclusion criteria (PBT, vPvB, or endocrine disruptor) rather high, since it is foreseen in the TGN that if the CFS meets the exclusion criteria, the comparative assessment shall proceed directly to Tier I-B, i.e. Tier I-A is omitted. Proposed scores for the other criteria are lower and take into account the severity of, for example, the H statements.

The second critical point is the proposed threshold for the rank of the relevant product that leads either to the stop of the comparative assessment or to continuing based on re-calculated RQs. Obviously, this threshold should be set in a way that it indeed works as a filtering step, but at the same time directs relevant products with a clearly higher hazard profile towards the next step of the comparative assessment. The preliminary pragmatic proposal is that the comparative assessment should continue if the relevant product ranks among the 10% of products with the highest scores (i.e. those with the worst hazard profile). This could also be operationalised by checking if the score of the relevant product is at or above the 90th percentile of the scores of all products available for the intended use.

Both, the quantitative values for the scores and the threshold proposed here must be seen as basis for discussion and not as fixed values. The consequences of using these scores and thresholds are illustrated in the following using the examples from WP2, which allows at the same time a comparison of the outcome with that of Tier I-A based on the TGN. The score for the number of contained SoC is based on the available information for the formulation of the products, which may not have been complete in all cases, or SoC identification may not have been conducted in all cases, particularly in older dossiers.

Applying the proposed scoring and ranking scheme to the example of the three intended uses of the wood preservative products results in the relevant product being ranked in all three cases among the top 10% with the highest scores (Table 39, 40, and 41). The relatively high applied weight for the substitution criteria (i.e. PBT properties) overrides the influence of hazard statements established for the products, and there are no known environmental SoC in the selected set of products contributing to their total score. Hence, the hazard profile of the relevant products based on the proposed scheme is worse than or equally bad as that of the alternative products. In all three cases, the comparative assessment would hence continue towards a risk-based assessment. This outcome is in contrast to the outcome of Tier I-A according to the TGN, where no further comparison based on quantitative risks was indicated for any of the three products. This indicates that the proposed hazard-based scoring and ranking system in its current form may generally not be strict enough to serve as an efficient filtering step, since the comparative assessment would have to be continued for all three cases.

Table 39: Possible scoring system for a hazard-based comparative assessment applied to the *Intended Use 1* of the wood preservative products

	Score of relevant BP	Scores of alternative products	
Product	**1**	**2**	**3**
Assessed per active substance	Tebuconazole	Tebuconazole & IPBC	Propiconazole & IPBC
PBT	5	5+0	0+0
Classified as endocrine disruptor	0	0	0
Assessed per product			
Established H statements	0	0	2
Substances of concern (SoC)	0	0	0*
Sum of scores	**5**	**5**	**2**

* Information on SoC not available or not clear whether classified because of environmental concern

Table 40: Possible scoring system for a hazard-based comparative assessment applied to the *Intended Use 2* of the wood preservative products

	Score of relevant BP	Scores of alternative products				
Product	**1**	**2**	**3**	**5**	**6**	**7**
Assessed per active substance	Tebuconazole	Tebuconazole & IPBC	Propiconazole & IPBC	Propiconazole & IPBC	Propiconazole	IPBC
PBT	5	5+0	0+0	0+0	0	0
Classified as endocrine disruptor	0	0	0	0	0	0
Assessed per product						
Established H statements	0	0	2	2	3	2
Substances of concern (SoC)	0	0	0*	0*	0	0*
Sum of scores	**5**	**5**	**2**	**2**	**3**	**2**

* Information on SoC not available or not clear whether classified because of environmental concern

Table 41: Possible scoring system for a hazard-based comparative assessment applied to the *Intended Use 3* of the wood preservative products

	Score of relevant BP	Scores of alternative products		
Product	**2**	**3**	**5**	**6**
Assessed per active substance	Tebuconazole & IPBC	Propiconazole & IPBC	Propiconazole & IPBC	Propiconazole
PBT	5+0	0+0	0+0	0
Classified as endocrine disruptor	0	0	0	0
Assessed per product				
Established H statements	0	2	2	3
Substances of concern (SoC)	0	0*	0*	0
Sum of scores	**5**	**2**	**2**	**3**

* Information on SoC not available or not clear whether classified because of environmental concern

Applying the scheme to the example of the Intended Use 1 of the ant control products achieves almost the same sum of scores for the relevant and all alternative products when looking at PBT properties of active substances and H-statements for the product (Table 42). A SoC was only identified for one alternative product. This lack of differentiation is removed when the proposed indicator for the degree

of environmentally open application is taken into account. Nest application and gel baits are considered as environmentally open applications, while bait boxes are considered a contained application method. Hence, the comparative assessment would be continued for the Intended Use 1 of the ant control products. Similar to the outcome of the assessment according to TGN, this was exclusively triggered by the application method of the relevant product.

Table 42: Possible scoring system for a hazard-based comparative assessment applied to the *Intended Use 1* of the ant control products

	Score of relevant BP	Scores of alternative products							
Product	**13**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**10**
Assessed per active substance	Spinosad	Spinosad	Spinosad	Spinosad	Spinosad	Spinosad	Spinosad	Deltamethrin	Fipronil
PBT	3	3	3	3	3	3	3	0	3
Classified as endocrine disruptor	0	0	0	0	0	0	0	0	0
Assessed per product									
Established H statements	2	2	2	2	2	2	2	4	2
Substances of concern (SoC)	0	1	0	0	0	0	0	0	0
Degree of open application	5	0	0	0	0	0	5	5	0
Sum of scores	**10**	**6**	**5**	**5**	**5**	**5**	**10**	**9**	**5**

For Intended Use 2, the total score of the relevant product is not among the top 10% of the available products (Table 43), therefore the assessment would stop here according to the proposed scheme.

Table 43: Possible scoring system for a hazard-based comparative assessment applied to the *Intended Use 2* of the ant control products

	Score of relevant BP	Scores of alternative products						
Product	**10**	**2**	**3**	**4**	**5**	**6**	**7**	**9**
Assessed per active substance	Fipronil	Spinosad	Spinosad	Spinosad	Spinosad	Spinosad	Spinosad	Deltamethrin
PBT	3	3	3	3	3	3	3	0
Classified as endocrine disruptor	0	0	0	0	0	0	0	0
Assessed per product								
Established H statements	2	2	2	2	2	2	2	4
Substances of concern (SoC)	0	1	0	0	0	0	0	0
Degree of open application	0	0	0	0	0	0	5	5
Sum of scores	**5**	**6**	**5**	**5**	**5**	**5**	**10**	**9**

For Intended Use 3, the relevant product ACP 11 can be used in a bait box or as gel bait. As the indicator for environmentally open application differentiates between these two application methods, they

were assessed as different uses. For the use of the relevant product as a bait box, ACP 11 is not among the 10% of highest ranked products scores (Table 44). For its use as gel bait, it is ranked at the top and the comparative assessment would therefore continue for this application method. This difference demonstrates that it is essential to include the application method in the definition of the intended use at least for the relevant product. Note however, that for the mapping step, the proposed relevant criterion is an equivalent efficacy claim (application aim), not the application method.

Table 44: Possible scoring system for a hazard-based comparative assessment applied to the *Intended Use 3* of the ant control products

	Score of relevant BP		Scores of alternative products				
Product	**11**		**1**		**2**	**3**	**4**
	bait box	**gel bait**	**bait box**	**gel bait**	**bait box**	**bait box**	**bait box**
Assessed per active substance	Fipronil		Indoxacarb		Spinosad	Spinosad	Spinosad
PBT	3		0		3	3	3
Classified as endocrine disruptor	0		0		0	0	0
Assessed per product							
Established H statements	2		4		2	2	2
Substances of concern (SoC)	0		0		1	0	0
Degree of open application	0	5	0	5	0	0	0
Sum of scores	**5**	**10**	**4**	**9**	**6**	**5**	**5**

Applying the hazard-based scoring and ranking system to the intended uses addressed in WP 2 demonstrated very low discriminatory power based on hazard criteria (PBT, H statement, SoC, and endocrine disruptor property). Only based on the additional criterion of environmentally open application, the relevant product could be differentiated from the alternatives with the consequence to continue the assessment. This is congruent to the finding in WP 2 that the application method was decisive for the comparative assessment. As a consequence, it should be considered to address environmental concerns related to the direct nest application method of ant control products in a different regulatory way than via the laborious comparative assessment. It remains open whether the proposed hazard-based scoring and ranking system would show a greater discriminatory power if more alternative products with a greater diversity in a.s. were to be compared with the relevant product. If not, a hazard-based entry step in Tier I would be useless, and the comparative assessment could as well directly move from the screening phase to a quantitative risk-based comparative assessment.

5.5.2 Risk-based final comparative assessment in Tier I

In accordance with the TGN, the comparison of quantitative values should represent the decisive step of the comparative assessment (Figure 4), which is followed by the assessment of practical and economical disadvantages and by an overall assessment of the risk for environment, human health and animal health. These last two steps are beyond the scope of the present project.

The TGN states PEC/PNEC ratios and risk characterisation ratios (i.e. RQs) as example for the quantitative values to be used in Tier I-B. It is acknowledged in the TGN that several issues, as already discussed in WP1 and WP3, should be 'taken into consideration' when comparing RQs provided in the dossiers of different products. The key issue is basically the lack of comparability of RQs that have been calculated using different assumptions for PEC estimation, different effect data for PNEC derivation or different calculation methods in general due to changes in the respective guidance or exposure

models over time. It is left to expert judgement in the TGN how these issues should be taken into account. Based on discussions within the project and the work conducted in WP2, it was concluded that there is no sound way to take these issues 'into account' when using the RQs provided in the dossiers of the different products. The only solution to obtain indeed comparable RQs for the relevant and alternative products is a re-calculation of RQs based on truly unified scenarios and common assumptions. Particularly with regard to exposure estimates, the exercise conducted in WP2 with ACP of the intended use 1 demonstrated how variable and diverse the assumptions in different dossiers can be, even for the same application scenarios. It is beyond the scope of the present project to develop unified exposure and effect assessment frameworks for the biocidal products in general or the PTs considered here in detail. However, some recommendations regarding such unified scenarios can be provided:

- The unified standard scenarios should be based as much as possible on the already established ESDs that are available for each PT.
- In contrast to the usage of the ESD in typical biocide dossiers, the unified scenario for each intended use and related application method must not allow any deviation from the standard assumptions and default parameters, except for the reasons stated below. Defining unified scenarios for different application methods within the same intended use may present a challenge in view of achieving a comparability of resulting risk quotients. For example, in the case of ant control products, the area exposed for nest application is not clearly defined and different values were used by different authorities so this would need to be standardised. Furthermore, the simple comparison of risk quotients is questionable if the spatial extent of the exposed ecosystem is different. To illustrate this, the question can be asked if the risk to the environment is really the same, when a risk quotient of e.g. 0.9 is calculated for an exposed area of one square meter in one case, and for an exposed area of one hundred square meters in another case.
- Refinements applied to the ERA of one products should be applied similarly to the ERA of all products in the comparison in order to achieve comparability of resulting RQs. This includes products for which the RQs were already indicating acceptable risk without refinement. If, for example, time-weighted average concentrations based on dosing instructions are used for PEC calculations, this should be done similarly for all products with such dosing instructions.
- Exposure estimates in the unified standard scenarios should take into account degradability in all cases. This holds even if in the dossier of the applicant no such calculations were made, because a PEC/PNEC ratio below 1 was achieved without such considerations. This is essential in order to treat different a.s. (and products) equally. More importantly, degradability should be considered particularly because persistence is one of the criteria leading to the status as CFS. Not considering degradability would be in strong contradiction to the basic motivation of the comparative assessment. In this case, problems will arise when inorganic a.s. are to be compared to organic a.s. since degradation is no meaningful concept for inorganic compounds.
- Exposure estimates in the unified standard scenario should take into account established RMMs and conditions of use such as for example dosing regime and top coat application. This appears necessary to compare risks remaining after implementation of RMMs, as required by the TGN.
- Estimates for effects (i.e. PNECs) should be identical for the same a.s. across all products with this a.s., regardless of the actually used values in the individual authorisation dossier. This is again to treat all products equally, and to account for updates and new data being possible developed and used in more recent authorisations.

A key point is the usage of the resulting comparisons. What should be established as a quantitative threshold for a significantly higher risk of the relevant product? There is no guidance on this in the TGN, which means that the decision is left to the expert judgement of the CAs.

The most reasonable and straightforward approach would be to harmonise this last critical step of the comparative assessment with other regulatory frameworks, and to reach common agreement among member states on this.

In the regulatory framework dealing with the authorisation of PPP, comparative assessment of products is also required. Based on research projects (Faust et al. 2014, Altenburger et al 2015) and discussions within UBA, preliminary concepts have been developed, which also involve the recalculation of RQs. In the PPPR, a factor of at least 10 between the RQs of different products is defined as 'significant difference in risk'. This factor of 10 could be adopted for the RQs obtained for biocidal products. It could be either established in a way that the factor of 10 difference applies for any eligible alternative product or with regard to e.g. the median of the RQs of all alternative products. The first condition (difference of 10 to any product) appears not very strict, i.e. would favour restriction/prohibition of the relevant product, while the second option (difference of factor 10 to median) appears stricter, i.e. less in favour of restriction/prohibition. However, relating the requirement of factor of 10 difference to the median of a group of products without any information on the range of RQs among these products may result in unexpected outcomes. If RQs stretch over a great range, it could theoretically be possible that the RQ of the relevant product is tenfold greater than the median (i.e., 50% or more products have a tenfold smaller RQ), but that still the remaining 50% (or less) of the alternative products have a greater RQ than the alternative product. In such a case, the relevant product ranges relatively close to the median (i.e., the majority of products), although not in absolute numbers, and restriction/prohibition may appear not justified. As additional requirement, it is proposed in the PPP framework that the relevant product must not only differ in its RQ from an alternative product by at least factor 10 in at least one evaluation area, but that at the same time that this alternative product may not have a RQ more than factor 10 greater in any other evaluation area than the relevant product. This appears as a reasonable condition, which is in line with the requirements of the TGN.

A possible procedure for a risk-based comparison for one specific use, based on the experience made in the case study on ACP, is roughly lined out below.

1. Identify relevant scenarios and compartments based on the RQs documented in all PARs. It is proposed only to consider RQs above 0.1 (for any of the products) to be relevant for this step. This results in *n* relevant evaluation areas (combinations of emission scenarios and receiving compartments)
2. Identify all metabolites/transformation products that are relevant for the respective evaluation areas for each product. Identify all substances (e.g. SoC) that are relevant for a mixture assessment according to the guidance on mixture toxicity assessment for biocidal products (ECHA 2017)
3. For each evaluation area and relevant substance, recalculate exposure estimates (PECs) using unified assumptions. Take into account product-specific conditions of use and RMMs in these recalculation
4. For each evaluation area and relevant substance, identify the relevant PNEC to be used for identical substances in all of the products
5. For each evaluation area, recalculate RQs applying the concepts described in the guidance on mixture toxicity assessment for biocidal products (ECHA 2017).
6. Compare the RQs of the relevant product to the RQs of the alternative products for each evaluation area
7. Check whether the following conditions are met to justify restriction/prohibition of the relevant product:
    a. The recalculated RQ of the relevant product is at least by a factor of 10 greater than the RQ of at least one eligible alternative product (with the same MoA if diversity is becoming critical) in at least one evaluation area
    b. The recalculated RQ of this alternative product is not by a factor of 10 greater than that of the relevant product in any other evaluation area

5.6 Outlook and Recommendations in a nutshell

The here proposed scheme of a hazard-based filtering combined with a risk-based decisive comparative assessment and, particularly, the proposed thresholds must be seen as preliminary. It is considered necessary to conduct additional in-depth case studies in order to check the feasibility of this scheme. The here conducted case studies were relatively simple due to the low number of possible alternative products, few a.s. per product, few or no SoC, and non-consideration of transformation products. Only one compartment for one emission scenario was identified as relevant for the comparative risk-based assessment of the ACP. It is assumed that most real cases of comparative assessments would be considerably more complex, which would involve a considerable workload, anticipating that risk-based comparative assessments would frequently be triggered. The workload could in turn be alleviated by establishing a database-driven system for the parallel calculation of these RQs and their storage for future comparative assessments.

The here developed recommendations can be summarised as follows:

- Establish digital database of the intended use(s) of all biocidal products, described in standardised and harmonised terms, to be prepared during product authorisation
- Extend required information in the categories for the description of the intended use(s) to include function of the a.s., application aims, and application restrictions, in consistence and closely linked to other relevant information such as *Application Code Documents* and efficacy claims.
- Extend requirement for adequate chemical diversity to include micro-organisms that are authorised as active substances under the BPR. The requirement would, hence, relate to an adequate number of different active substances in authorised products, regardless whether chemical or microbial agents.
- Specify that the requirement of diversity means that the restriction of the relevant product may not reduce the number of different active substances in authorised products below the number deemed adequate. It does not mean that the comparative assessment automatically stops if the number is initially already below the threshold.
- Develop some more guidance on when a resistance management can be deemed not necessary and, hence, the requirement of diversity can be overruled. This should keep in mind that diversity can be deemed warranted for other reasons, e.g. with regard to prevention of market monopolisation or prevention of the development of yet unknown resistance mechanisms.
- Specify that if only a.s with three different MoA are represented among the products authorised for the intended use in question, the relevant product should only be compared to those products that compare the same a.s. classified as CFS.
- Modify the screening phase in order to reach at a decision for stop of the comparative assessment, moving to Tier I or Tier II.
- Omit the use of RMMs in the comparative assessment
- Establish a hazard-based scoring and ranking system as a filtering step in Tier I of the comparative assessment.
- Develop unified exposure scenarios for the different uses in each PT to be used in a risk-based comparative assessment in the final step. Strictly apply uniform assumptions to all products, and consider degradation quantitatively when calculating RQs, because persistence was the reason for starting a comparative assessment after all.
- Apply mixture toxicity concepts as described in the respective guidance when re-calculating RQs for the risk-based comparative assessment
- Establish quantitative thresholds for decision making in the risk-based comparative assessment. This could be done in analogy and consultation with other regulatory frameworks, namely the plant protection product regulatory field.

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7 Annex

This Annex aims to serve as a discussion paper facilitating the transfer of the results of the present project into the discussion among competent authorities and subsequently into regulatory praxis.

7.1 Background

The legislative establishment of a comparative assessment for biocidal products (BPs) containing a candidate for substitution (CFS) can be seen as a chance to better protect environmental quality by replacing biocidal products with alternatives that have a lower environmental impact. At the same time, disadvantages in other areas must be avoided such as a loss of effective products on the market, an increased risk for humans or animals, economic or practical disadvantages, and an increased risk of resistance development.

The aim of the project was to evaluate the practicability of the procedure for a comparative assessment that are laid down in the Technical Guidance Note (TGN) published by the European Commission in 2015. A number of exemplary comparative assessments were conducted in the present project that served as basis for the development of recommendations to improve the existing guidance. In the following, the key results and the thereby inspired recommendations for improvements are summarised.

7.2 Existing guidance

In Article 23 of the BPR it is specified that biocidal products containing an active substance (a.s.) classified as CFS shall be subject to a comparative assessment. This could lead to a restriction of the product in question (the relevant product) if "another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, [….]" (Article 23, Biocidal Product Regulation, BPR). Hence, the interpretation of the term "significantly lower overall risk" plays a central role.

The TGN details this to mean "that an eligible alternative has a significantly better profile for the human or animal health or for the environment […] and not significantly worse for any of those three aspects, […]" (Article 18, TGN). The full wording in the TGN also refers to "the main concern(s) of the CFS(s)", apparently suggesting that a significantly lower overall risk is only given when a significantly better profile is found in the area of the main concerns of the CFS (e.g. the environment in the case of a CFS that is persistent and bioaccumulating).

A "significantly better profile" is given when "the observed differences between the relevant BP and the compared eligible alternative […] are not marginal but relevant in terms of biological significance […]" (Article 19, TGN). Notably, it is explicitly stated that the evaluation of biological significance requires expert judgement (Article 21, TGN). Finally, the decision about biological significance is bound to the question "whether that difference has potential consequences, affecting the functioning of and risks to humans, animals or the environment" (Article 21, TGN). With this final reference, the circle of definitions is closed, i.e. the term "significantly lower risk" from the BPR is defined referring back to the term "risk". In addition to providing a circular definition, the requirement of expert judgement is installed at a central position.

The TGN introduces a tiered assessment scheme. With the exception of the comparison with non-chemical alternatives (Tier II), which was not within the scope of the project, these steps are discussed in the next chapter. Risks for human and animal health as well as economic disadvantages were also beyond the scope of the project.

7.3 Case studies

Exemplary comparative assessments were conducted for three intended uses of each of two product types, wood preservative products and ant control products. The products selected for these case

studies were on the German market at the beginning of the project, and product assessment reports (PAR), or at least summaries of product characteristics (SPC) were available.

7.3.1 Mapping of alternatives

In the mapping step, eligible alternative products have to be identified for each intended use of the relevant product. The TGN lists six categories that shall define the intended use for a comparative assessment: product type, the exact description of authorised use, the target organism(s) and their developmental stages, the field of use, the category of user, and the application method.

In the case studies, considerable effort was necessary to extract the information for the mapping step from the SPCs and the PARs of the relevant and the potential alternative products.

In the case of the ant control products, three different application methods were represented among the products (bait box, gel bait and nest application). The TGN leaves it to the competent authority to decide if uses with different application methods can be eligible alternatives or not. For the purpose of the project, it was decided to not use the application method as a criterion in the mapping step, resulting in the need to compare products with different application methods. It turned later out that differences in the application methods were decisive for the outcome of the comparative assessment.

In both case studies, information that is required later in the comparative assessment according to the TGN was found to challenge the identification of a product as an alternative product. This includes particularly restrictions in the application or field of use that are implied by risk mitigation measures (RMMs) such as no application near surface water in the case of wood preservative products. In the case of ant control products, alternative products were found to possibly carry economic or practical disadvantages since they could not claim the same effect ("nest kill"), supported by respective efficacy data, as the relevant product. Including such information already in the definition of the intended use would prevent that possible alternative products are evaluated in detail but turn out later as not suitable alternatives.

Based on the mapping step in the case studies, the following recommendations were derived:

- Establish a digital database of each of the intended use(s) of all authorised biocidal products, described in standardised and harmonised terms. This information should be entered upon product authorisation into the database as the combination of the six categories needed in the mapping step (i.e., each defined intended use as a separate entry), because the individual entries for the six categories cannot be freely combined. Such a database would enormously simplify and speed up the task of identifying alternative products for a comparative assessment.
- Extend the required information in the categories for the description of the intended use(s) to include function of the a.s., application aims, and application restrictions, in consistence and closely linked to other relevant information such as established RMMs, *Application Code Documents* and efficacy claims.
- Develop a common understanding under which conditions and in which way different application methods within the same intended use can be compared.

7.3.2 Screening

The screening phase according to the TGN provides an early filter step meant to reduce the number of complex and laborious comparative assessments. To this end, the comparative assessment process shall immediately stop if the diversity of authorised products remaining on the market is deemed not sufficient for preventing resistance development of the target organisms. The TGN proposes three different active substance/mode of action combinations as sufficient diversity. If a.s. contained in the relevant BP meet the exclusion criteria, the criterion of diversity does not apply. It is further left to the competent authority to waive the diversity requirement on a case-by-case basis.

In the present case studies, regulatory comparative assessments would have been stopped due to a lack of diversity for all intended uses of the wood preservative and two intended uses of the ant control products, respectively.

The following recommendations were developed regarding the screening step:

- Extend the requirement for adequate chemical diversity to include micro-organisms that are authorised as active substances under the BPR. The requirement would, hence, relate to an adequate number of different a.s. in authorised products, regardless whether chemical or microbial agents. This recommendation is based on the fact that target organisms can develop resistance also against micro-organisms serving as a.s., which should therefore be treated similar to chemical a.s. and not as non-chemical alternative without any consideration of the risk of resistance development.
- Specify that the requirement of diversity means that the restriction of the relevant product may not reduce the number of different a.s. in authorised products below the number deemed adequate. This implies that the comparative assessment does not automatically stop if the number is initially already below the diversity threshold.
- Develop guidance on when a resistance management can be deemed not necessary and, hence, the requirement of diversity can be overruled. This should keep in mind that diversity can be deemed warranted for other reasons, e.g. with regard to prevention of market monopolisation or prevention of the development of yet unknown resistance mechanisms.
- Specify that if only a.s with three different MoA are represented among the products authorised for the intended use in question, the relevant product should only be compared to those products that have a.s. with the same MoA as the a.s. classified as CFS. This aims to ensure that the product with the best risk profile within a mode-of-action group remains on the market and not just the product with the earliest date of application for authorisation.

7.3.3 Tier I-A

As conceived in the TGN, Tier I-A is a qualitative comparison, exclusively based on information made available in the SPC. Specifically, this are hazard (H-) and precautionary (P-) statements as well as RMMs. According to the TGN, the relevant product must be an outlier (i.e. have a significantly worse profile than the majority of alternatives) in order to trigger the quantitative comparison at Tier I-B.

H- and P-statements are well standardized. On the other hand, a number of problems were noted regarding the use of RMMs at Tier I-A:

- The harmonisation of RMMs currently under way is not finished yet. More importantly, it does not affect the SPCs of existing authorised products. Therefore, the various phrasings of RMMs in the SPCs had to be checked for equivalence with one of the harmonised RMMs in the current list. Due to various differences in the wordings, decisions were often ambiguous.
- In many cases, it was not possible to distinguish between a RMM and a condition of use based on the SPC or even after consulting the PAR. In the case of wood preservative products, the requirement of a top coat was for example established as condition of use to ensure efficacy for one product, but for another as a RMM resulting from a risk identified in the risk assessment. Yet, since in the first case no risk assessment was conducted without the assumption of a top coat, it is not clear whether a top coat would not have been required as RMM as well. Hence, the consequences of conditions of use and RMMs can be identical with regard to environmental risk and they should therefore be taken into account in the same way.
- Even with harmonised RMMs and considering conditions of use along with RMMs, it appears difficult to rank them with regard to their strictness as required by the TGN. In addition, RMMs are not necessarily indicators for remaining risk, on which according to the TGN the comparative assess-

ment shall be based. Therefore, it is recommended to omit the use of RMMs in the comparative assessment, at least for the time being.

- A hazard-based scoring and ranking system could be established as a filtering step instead. In the present project, such a hazard-based filter step was exemplarily applied to the case studies but turned out to provide rather small discriminatory power. Further refining of such an approach would hence be necessary before it could be applied on a routine basis.

7.3.4 Tier I-B

The quantitative comparison at Tier I-B is only vaguely described in the TGN. In particular, it is not determined if only risk quotients (RQs) should be compared or if other parameters should be used in the comparison. In the absence of well-established alternative measures of environmental risk, it was decided to focus on RQs for the current project.

For both case studies, it was not possible to extract RQs from the PARs that were derived based on the same assumption, e.g. at similar levels of refinement. The TGN states that RQs derived with different assumptions cannot simply be compared, which means in consequence that they need to be re-calculated using common assumptions for a comparative assessment.

Re-calculation of RQs was conducted in the present study for the comparison of ant control products. This exercise demonstrated that numerous assumptions need to be unified for this purpose, involving a considerable work load.

Yet, the re-calculation of RQs proved to be doable in principle, and specific recommendations were developed to this end in the project. They are reported in more detail in the report and listed here only in a more general way:

- Develop unified exposure scenarios to be used in a risk-based comparative assessment. Strictly apply uniform assumptions to all products and consider RMMs as well as conditions of use in the calculations. Degradation should be quantitatively considered for all products in the same way, because persistence was presumably the reason for starting a comparative assessment after all.
- Apply mixture toxicity concepts as described in the respective guidance when re-calculating RQs.
- Establish quantitative thresholds for decision making in the risk-based comparative assessment. This could be done in analogy and consultation with other regulatory frameworks, namely the plant protection product regulatory field.

7.4 Consequences of developed recommendations

The here conducted case studies were relatively simple due to the low number of possible alternative products, few a.s. per product, few or no SoC, and non-consideration of transformation products. It is assumed that most real cases of quantitative comparative assessments would be more complex, which would involve a considerable workload for the re-calculation of RQs. However, re-calculation of RQs using unified assumptions is deemed essential to enable a reliable, transparent and defendable risk-based comparative assessment on a routine basis. The number of quantitative assessments would increase if the assessment would stop less frequently in the screening phase due to the recommended changes and specifications. The increase in workload could in turn at least be partly alleviated by establishing a database-driven system for easier identification of products with similar intended uses and allowing the storage of re-calculated RQs for future comparative assessments.