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Establishment of a concept for comparative risk assessment of plant protection products with special focus on the risks to the environment

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Establishment of a concept for comparative risk assessment of plant protection products with special focus on the risks to the environment

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Abstract

The EU regulation 1107/2009 introduces the substitution principle for the authorisation of plant protection products that contain active substances identified as candidates for substitution. For this novel regulatory principle active substances are flagged at the Commission level as candidates for substitution if they are found to meet a set of human or environmental hazard criteria. At the member state level, subsequently, comparative risk assessment for products is to be carried out if a product is to be authorised that contains a candidate for substitution. Almost one quarter of the active substances that are currently approved for use in plant protection products in the EU can be expected to be flagged as candidates for substitution and many of those will be identified for their persistence, bioaccumulation or aquatic toxicity properties. For Germany about one third of the currently authorised products would fall into the category where, upon reauthorisation, a comparative assessment with alternative products would become necessary. For about 40% of the registered uses there are alternative products which do not contain potential candidates for substitution and all potential candidates for substitution have at least one use where a potential alternative is available. Comparative environmental risk assessment of plant protection products can thus be expected to become a major additional effort in the authorisation process. To perform comparative environmental risk assessment a set of generic criteria is proposed in this report that operationalises the legal benchmark which defines ‘a factor of at least 10 for the toxicity/exposure ratio [...] a significant difference in risk’. We suggest carrying out risk comparisons for all different endpoints currently used in environmental risk assessment, while not discriminating a substitution candidate if the alternative products shows a significant increase in any other risk endpoint. For ten case studies it was shown that the current summary authorisation reports principally facilitate conducting a comparative risk assessment along the suggested principles. However, ambiguity in assessments was found where risk estimates were provided as limit values only. To organise the upcoming comparative assessments most efficiently a major resource saving factor would be to store and retrieve risk measures such as TER or HQ values electronically. We recommend establishing new data handling systems, to harmonise assessment procedures, and to achieve consent on decision rules.

Kurzbeschreibung

Die EU Verordnung 1107/2009 führt das Substitutionsprinzip für die Zulassung von Pflanzenschutzmitteln ein, die Wirkstoffe enthalten, die als Substitutionskandidaten identifiziert wurden. Für dieses neue rechtliche Verfahren werden Wirkstoffe auf Kommissionsebene als Substitutionskandidaten gekennzeichnet, wenn sie bestimmte Kriterien hinsichtlich der Gefährdung der menschlichen Gesundheit oder der Umwelt erfüllen. Nachfolgend ist auf Ebene der Mitgliedstaaten eine vergleichende Risikobewertung für Präparate vorzunehmen, falls für ein Produkt eine Zulassung beantragt wird, welches einen solchen Substitutionskandidaten enthält. Fast ein Viertel der gegenwärtig in der EU zugelassenen Wirkstoffe könnten als Substitutionskandidaten gekennzeichnet werden, und viele davon werden aufgrund ihrer Persistenz, Bioakkumulation oder aquatischen Toxizität eine Kennzeichnung erfahren. Für Pflanzenschutzmittel, die gegenwärtig in Deutschland zugelassen sind, ist zu erwarten, dass rund ein Drittel der Präparate in die Kategorie fallen würde, für die bei einer Neuzulassung eine vergleichende Bewertung mit Alternativprodukten erforderlich werden könnte. Für rund 40% aller betroffenen Anwendungsgebiete existieren Alternativprodukte die keine Substitutionskandidaten enthalten, und alle Produkte mit Substitutionskandidaten weisen mindestens ein Anwendungsgebiet auf, in dem eine potentielle Alternative vorhanden ist. Die vergleichende Umweltrisikobewertung von Pflanzenschutzmitteln kann daher absehbar einen wesentlichen zusätzlichen Aufwand im Zulassungsprozess bewirken. Für die Durchführung einer vergleichenden Umweltrisikobewertung wird aus diesem Projekt heraus ein Satz von generischen Kriterien vorgeschlagen, die die rechtliche Bezugsgröße umsetzt, wonach ein Faktor von mindestens 10 für das Toxizitäts-/Expositions-Verhältnis als ein signifikanter Risikounterschied aufzufassen sei. Wir schlagen weiterhin vor, Risikovergleiche für alle unterschiedlichen Endpunkte vorzunehmen, die gegenwärtig in der Umweltrisikobewertung verwendet werden, und keinem Substitutionskandidaten die Zulassung zu verweigern, falls sich für das Alternativprodukt eine signifikante Risikoerhöhung in irgendeinem anderen Risikoendpunkt zeigt. Für zehn Fallstudien konnte dargelegt werden, dass mit Hilfe der verfügbaren zusammenfassenden nationalen Bewertungsberichte eine vergleichende Risikobewertung auf der Basis der vorgeschlagenen Prinzipien prinzipiell vorgenommen werden kann. Allerdings können bei Risikowerten, die nur als Grenzwertangaben vorliegen, beim Risikovergleich uneindeutige Befunde erzeugt werden. Um die bevorstehenden vergleichenden Bewertungen möglichst effizient vornehmen zu können, wäre es aus Ressourcensicht besonders lohnend, Risikomaße wie TER- oder HQ-Werte elektronisch zugänglich zu machen. Wir schlagen daher vor, die Etablierung von elektronischen Datenbasen vorzusehen, Bewertungsprozeduren zu harmonisieren und Konsens über Entscheidungsregeln herzustellen.

Disclaimer

The findings and conclusions in this paper are those of the authors and do not necessarily represent the view of the German Federal Environment Agency (UBA).

Document history

- Project work started: October 2012
- End of project performance (data analyses completed): December 2014
- Draft final report: May 2015
- Approval of revised final report: October 2015

Table of Contents

List of Figures

List of Tables

List of Abbreviations

ADI	Acceptable Daily Intake
AOEL	Acceptable Operator Exposure Level
AS	Active Substance
B	Bioaccumulation
BCF	Bioconcentration Factor
BVL	Federal Office of Consumer Protection and Food Safety
CAS No	Chemical Abstract Service Number
CFS	Candidate for substitution
DT	Degradation time
EC	European Commission
EC50	Median effective concentration
EFSA	European Food Safety Authority
ESIS	European chemical Substances Information System
EU No	Active substance number according to Regulation (EC) No. 1107/2009
FCEC	Food Chain Evaluation Consortium
GW	Ground water
HC5	Hazardous concentration for 5% of the species
HQ	Hazard Quotient
LC50	Lethal effective concentration
LOEC	Lowest observed effect concentration
Log POW	N-octanol-water partition coefficient
Log *K*OW	Octanol-water partition coefficient at pH 7, 20°C
MS	Member State(s) (of the European Union)
NOEC	No-observed effect concentration
P	Persistence
PEC	Predicted Environmental Concentration
pF	the force with which soil particles hold water
PNEC	Predicted No Effect Concentration
PPDB	Pesticide Properties Database
POP	Persistent Organic Pollutant
PBT	persistent, bioaccumulative and toxic
PPP	Plant Protection Product
PRI	Pesticide Risk Indicator
PSM	Pflanzenschutzmittel
PT	Proportion of an animal's daily diet obtained in habitat treated with pesticide
RQ	Risk Quotient
R-Score	Risk-Score (derived from risk mitigation requirements)
T	Toxicity
TER	Toxicity-Exposure Ratio
TERac	TER for acute toxicity
TERl	TER for long-term toxicity
TERs	TER for short-term toxicity
UBA	German Federal Environmental Agency
vPvB	very persistent and very bioaccumulative

1 Summary

The Commission of the European Communities in 2001 suggested in its strategy for a future chemical policy (CEC 2001, 88 final) that the substitution of hazardous chemicals by less dangerous substances should be encouraged. Subsequently, suggestions were brought forward to support the establishment of the substitution principle and to propose approaches that allow comparison of different chemicals regarding associated hazards and risks (KEMI 2007). Moreover, the focus was placed onto compounds that do not require immediate withdrawal or phasing out under the current risk legislation but those that may still be considered as of high levels of concern, e.g. requiring specific risk mitigation measures.

The requirement to perform comparative assessment of risks for humans and the environment with the option to allow product substitution became recently implemented into chemical legislation with the novel regulations for plant protection products (PPPs) (Regulation EC 1107/2009) and biocides (Regulation EU 528/2012). The regulation 1107/2009 specifies in its article 50 that a PPP may not be authorised for use 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'.*

Annex IV further specifies that *'For the environment, if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk'.*

Candidates for substitution are to be identified at Community level, while Member States shall regularly examine PPPs containing such active substances *'with the aim of replacing them by plant protection products containing active substances which require less risk mitigation or by non-chemical control or prevention methods*'. A first list of candidates for substitution was announced for 14.12.2013 but had not been published by the end of the period of performance of this project (31.12.2014) and was finally established in March 2015 only.

The objective of this project was to develop a concept for comparative assessment of plant protection products (PPPs) with regard to comparison of risks to the environment and to test this approach for selected cases. From the lack of an established list of candidates of substitution at the onset of this project, resulting in ignorance regarding the PPPs for which alternatives have to be considered, and also from the absence of guiding principles for comparative assessments of environmental risks of PPPs, the need arose for performing all these steps within the project prior to actually developing an approach for comparative assessment. The project work plan was therefore necessarily run in parallel to activities by the EU and other institutions. It was tried to accommodate as far as possible results from those parallel initiatives by iterative efforts on our side. In a stepwise manner we first undertook to identify potential candidates for substitution for active substances approved at the EU level and

subsequently identified plant protection products authorised for use in Germany and containing those potential candidates for substitution. Further, we collated possible alternatives without candidates for substitution. In a subsequent step we analysed the literature and the meanwhile available EU draft guidance document for methods of comparative risk assessment and derived generic principles for comparative environmental risk assessment of products. For ten case studies that were selected from the list of plant protection products authorised for use in Germany these proposed principles were applied using information from the national summary risk assessment reports. The findings are collated and results from all these steps are synthesised into a proposal for an approach for comparative environmental risk assessment. The major findings and issues will be detailed in the following.

CFS identification

For identifying candidates for substitution, a list of respective criteria concerning both human and environmental risks is described in the Annex II, point 4 of the Regulation (EC) No 1107/2009. Out of this list, the present report focuses on the substitution criterion relevant for the environment; namely a candidate for substitution is any active substance if it meets two of the criteria that render a substance to be considered as persistent, bioaccumulative and toxic (PBT substance). While the legal definition of the T criterion comprises indicators of human toxicity (T_{HUMAN}) and aquatic toxicity (T_{AQUA}), our search for potential substitution candidates was confined to substances that meet the T criterion for reasons of environmental protection (T_{AQUA}). This approach was applied to a list of 375 active substances that were approved for use in the EU at the beginning of project work in November 2012. Biological agents were removed from this list, and where the approval of a chemical agent applies to a group of similar compounds with different CAS numbers (e.g. different salts and esters of a parent molecule), a single representative was selected. This resulted in a consolidated list of 344 active substances for which we compiled information about their P, B, and T_{AQUA} properties. The data were retrieved by means of sequential searches in the Pesticide Properties database (PPDB), the European Chemical Substances Information System (ESIS), the EU Pesticides database and eventually the risk assessment reports that are publicly available via the European Food Safety Authority (EFSA) website. We followed a stepwise approach for the data enquiry, searching the databases in the above mentioned order. In case where the necessary data for an active substance were already found in the first, second or third database, the subsequent information sources were not checked further.

Using the outlined strategy, data could be retrieved for most substances and criteria except for the bioaccumulation criterion. In detail, values for soil persistence were found for 300 of the 344 compounds, 270 for water/sediment system persistence, and 272 for the water phase of water/sediment systems. For the bioaccumulation criterion data were retrieved for only 188 of the 344 (55%) compounds from the searched databases. This lower fraction of compound information is probably due to the tiered scheme of data requirements for this criterion in the approval process for active substances, which does call for bioaccumulation data only for compounds which are expected to show strong partitioning into lipids. Regarding the aquatic toxicity criteria, we obtained information for 317 of the 344 active substances amounting to 92%.

The Regulation (EC) No 1107/2009 of the European Parliament and of the Council of the EU lays down approval criteria for active substances, including requirements relating to ecotoxicology and fate in the environment. The criteria for persistence are defined by cut-off values fixed in Annex II, point 3.7.2.1. An active substance is considered to be persistent if the half-life in marine, fresh or estuarine water, marine, fresh or estuarine sediment or soil is

higher than 40 to 180 days as specified for the respective compartment. Furthermore, an active substance is considered to be “bioaccumulative”, according to the Regulation (EC) No 1107/2009, section 3.7.2.2, if the bioconcentration factor exceeds a value of 2000. To evaluate the bioaccumulation potential of an active substance, measured BCF values for fresh and marine water organisms are to be taken into account. Regarding the toxicity criterion, according to regulation (EC) No 1107/2009, the substance has to be classified accordingly, if the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is lower than 0.01 mg/L. Additional guidance for the corresponding use of available data is provided and specified in the DG SANCO Working Document (COM 2012).

Applying these PBT-criteria to the data retrieved here, 33 (9.6%) of the investigated 344 active substances were found to meet at least two of the three PBT criteria. These could thus be classified as potential candidates for substitution. Most of these compounds were flagged by the combination of the persistence and the toxicity criterion, while there was only one compound indicated through a combination of the persistence and the bioaccumulation criterion. Interestingly the 33 active substances flagged as potential candidates for substitution came from 26 different chemical classes and covered all major use groups, i.e. herbicides, fungicides, insecticides and acaricides. The following chemical classes were represented with more than one compound: pyrethroids, sulfonylureas and triazoles. The 33 active substances identified in this process formed the initial training set for the project activities in evaluating how many products and which settings regarding uses and indications can be expected to emerge for potential comparative environmental risk assessment.

Parallel to the efforts of this project, the EU Commission commissioned a contract study to a consultant to provide necessary preparatory work for the Commission’s task of establishing an initial list of Candidates for Substitution (CFS) by the end of 2013, based on a set of seven criteria, among which one consists of the PBT criterion discussed here. A work report of this activity became available to the member states and subsequently to this project which allowed compiling a draft list of potential candidates for substitution. Herein 98 different approved active substances were identified as probable CFS. The analyses made in this project were confined to substances fulfilling two of the three criteria P, B, and T. Thus, the figure of 31 congruent findings cannot be compared to the whole number of 98 probable CFS, but only to those 70 substances that are identified in the consultant report to the Commission as compounds meeting two of the three criteria P, B, and T_{AQUA}. There are a number of reasons identified and discussed why it is reasonable that the number of CFS identified by the PBT criteria in the efforts of this project are lower than in the consultant report. In particular, the fact that the evaluation of the toxicity criterion was limited here to the standard algal, daphnids and fish toxicity endpoint that were available from the PPBD database explains some of the deviations. The consultant work, in contrast, included data for a much broader spectrum of aquatic species and endpoints that are available from the official documents for substance approval. Nevertheless, the large difference of 40 substances that were positively identified by the PBT_{AQUA} criterion in the consultant report, but undetected in our report is somewhat surprising. Furthermore, we were particularly surprised to see that two of the substances identified as potential CFS with the approach of this project, namely beflubutamid and deltamethrin, were not at all identified as potential CFS in the consultant report.

With more than a year delay, the final official list of CFS was established by the European Commission in March 2015 only, after of all data analyses performed within this project had already been finalized. The official list now includes a slightly reduced number of 77 CFS, 52 of which were identified for environment-related concerns (Commission Implementing Regulation (EU) 2015/408).

Products with potential substitution candidates

The goal of this working step was to obtain an overview about plausible numbers and types of plant protection products (PPPs) that may become subject to comparative assessments in the future due to the presence of candidates for substitution which were yet to be defined at the time of conducting these analyses in the project. Also, it was tried to anticipate the distribution of these potential candidate products over the different intended uses in order to anticipate for which cases comparative risk assessments will have to be conducted. The guiding hypothesis was that any restriction in the scope or number of potential cases for comparative assessment could help to simplify the foreseeable tasks of comparative environmental risk assessment.

To achieve these goals, the PPP database of the German Federal Office of Consumer Protection and Food Safety (BVL) was employed to identify PPPs containing potential substitution candidates and their distribution across cultures, target organisms and authorised intended uses. Additionally, the availability of potential alternative PPPs was checked for each of the relevant intended uses. As potential alternatives we focused on PPPs that did not contain potential candidates for substitution themselves.

For the first phases of the project we worked with the list of 33 potential CFS that we generated by checking P, B, and T_{AQUA} properties only, as described above. When the results from the Commission's contract study became available that addressed all criteria for identifying candidates for substitution, we decided to switch to the resulting list of 98 probable CFS as a basis for identifying PPPs with and without potential CFS. The rationale for this decision was that replacement of a product containing CFS identified for environmental reasons by a product containing CFS identified for other reasons was not considered a meaningful option. The official list of candidates for substitution only became available after all analyses within this project had been accomplished; hence, the respective results as documented in this report are considered to be preliminary and prone to minor alterations in the future.

The BVL database in its version of May 2013 lists 374 active substances and 1378 authorised plant protection products (PPPs) covering 3606 different intended uses regarding the authorised application of a PPP against a specific pest in a defined crop. For 65 out of the list of 98 active substances considered here as potential candidates for substitution, data entries were found in the German BVL database. 351 of the 1378 PPPs listed by the BVL contained at least one potential candidate for substitution, i.e. about 25% of the PPPs authorised for use in Germany would possibly require a comparative risk assessment if they were to be authorised under the current PPP Regulation. The identified potential candidates for substitution are unevenly distributed across authorised PPPs, while 11 active substances are found in more than 10 products; there are 17 active substances that are found in only one product. PPPs containing potential candidates for substitution are recruited from all major use categories, namely herbicides (37 % of the PPPs containing CFS), fungicides (36%), and insecticides (20%). The PPPs containing potential candidates for substitution are used against 264 out of 477 defined pests in 209 out of 309 different crops considered. All in all, they are authorised for about half of all 3606 intended uses. Of the 351 products containing potential candidates for substitution, 100 are used in a single crop, while 43 products are authorised for use in more than 10 different crops. Thus, contrary to the starting hypothesis of this project we could not identify any specific pattern from the occurrence of PPPs with potential candidates for substitution that would give reason to focus future comparative risk assessment on specific active substances, product use groups, crops, or intended uses.

The 351 identified PPPs authorised for use in Germany that were identified to contain potential candidates for substitution were authorised for a total of 1863 intended uses. This means that a

typical PPP containing a potential substitution candidate is authorised for several (on average 3) intended uses: For each of these uses one or more alternative PPPs without potential substitution candidates need to be considered if available. In this study, PPPs that did not contain any candidate for substitution as an active substance and which are assigned to the same intended use as the PPP that may be considered for substitution, were regarded as the primary potential alternative. Of the 1863 intended uses where PPPs with potential candidates for substitution are used in 1096 cases no products without any candidates for substitution are currently available from the BVL database. These typically are found to occur in specialised uses such as dicotyledonous weed treatment on lawn. The remaining 40% of cases, however, cover all major crops and widespread pests. Here, on average 3 potential alternative PPPs without candidates for substitution are available. Thus, it can be anticipated that a comparative assessment of environmental risks will be performed by pairwise comparisons at least until a 'significant difference in risk' is found. The total number of comparative assessments that eventually will have to be performed over a full cycle of PPP authorisations, which under the current regime would require about a decade, may therefore easily account for several thousand cases. Moreover, regarding the spectrum of authorised uses of PPPs containing potential candidates for substitution, our analysis showed that at least for one of the authorised uses of any candidate product a CFS-free alternative appears to be available and thus the need for performing a comparative risk assessment may indeed be anticipated for every CFS-containing PPP currently authorised for use in Germany.

Generic comparative assessment of environmental risks

The novel regulation for plant protection products (PPPs) (Regulation EU 1107/2009) specifies in its Article 50 that member states 'shall not authorise or shall restrict the use of plant protection products containing an active substance approved as a candidate for substitution [...] where comparative assessment of risks and benefits [...] demonstrates that [...] for the uses specified [...] an authorised plant protection product [...] exists which is significantly safer for human or animal health or the environment'. Additional agronomic, technological and economic criteria come into play during the assessment process, but the central issue for the requested comparative health and environmental considerations of PPP alternatives for the same use, is their comparison to assess whether the alternative is 'significantly safer'. Annex IV of that regulation further specifies that a 'significant difference in risk shall be identified on a case-by-case basis by the competent authorities.' Moreover, guidance is provided for what constitutes a significant risk difference: 'For the environment, if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk.'

The task of this project therefore was to derive generic principles and to set up a scheme fulfilling these legal requirements. A review of available literature on approaches suggested for comparative assessment and substitution of chemical reveals that the current available discussion in its majority deals with comparison of hazards rather than risks as is requested here. The draft guidance document provided by SANCO document 11507/2013 in order to support the member states in carrying out future comparative assessment of PPPs (COM 2014) can be considered the most relevant document in this context. In particular, it offers suggestions of how to organise the whole process of comparative assessment in a sequential order. Therein, the agronomical consideration of appropriate alternatives is suggested to come prior to the comparative risk considerations. A limitation of the proposed SANCO approach lies in that no guidance is provided in how to deal with the various areas of environmental and human risk assessment that are currently assessed independently. Implicitly, it may seem as if

there were single risk aggregate measures that allowed comparisons between different PPPs. However, neither the scientific literature nor any piece of regulation to the knowledge of the authors allows meaningful aggregation of risk estimates in such separate areas as e.g. risk for soil organisms, birds and mammals, or aquatic organisms. Rather the different risk assessment endpoints from a scientific perspective seem mutually exclusive.

Given this situation, we propose a set of generic principles that account for the typical information produced for the environmental assessment of individual PPPs (the summary authorisation reports), that allow to meet the legal definition of a 'significant difference in risk' from the PPP regulation. The principles proposed comprise:

- 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.

Case studies for plant protection products

In order to study the practicability, suitability and performance of the proposed generic principles for comparative environmental risk assessments of PPPs we investigated a set of case studies. Five different PPPs, each containing one of three potential candidates for substitution, a phenylurea herbicide, a triazol fungicide, and a pyrethroid insecticide, where compared to selected alternative products not containing any potential CFS but authorised for the same use in terms of crops and target pests. All in all, ten such cases where studied. Summary authorisation reports of the UBA were used as the sole data source. Risk indicators to generate the multiple risk profiles consisted of the documented TER and HQ values or were derived from the relevant toxicity and exposure values and covered the three different environmental assessment areas: terrestrial organisms, birds and mammals and aquatic environment. Decisions on the level of retrieved details and rescaling (e.g. transferring HQ into TER values) were taken to allow consistent presentations of risk profiles. As a potential surrogate for actual TER values, we additionally explored the use of risk scores derived from applicable risk mitigation measures as fixed in the authorisation decision for a PPP. Scores were calculated according to a proposal of the UBA.

The risk profiles for the individual PPPs were subsequently compared based on calculating the ratio between the value for the considered alternative and the candidate product for each given risk characterisation endpoint. These differential risk profiles were also graphically represented to provide an overview of risk differences for each assessment area. The risk profiles and comparisons could be generated in all ten investigated cases from the information in the underlying summary authorisation reports; however, it required various ad hoc operationalisations of the proposed generic principles for comparative environmental risk assessments. Most importantly where TER or 1/HQ values were not provided as exact values but defined as inequalities that signalled the exceedance of a limit value, the risk difference cannot

in all cases be quantified. In particular, risk endpoints regarding toxicity against honeybees, earthworms and plants suffered from this restriction. Moreover, the data basis proved to be heterogeneous so that risk comparisons for the same nominal assessment endpoint were occasionally based on different effects, including comparisons of higher with lower tier test findings. Because risk indicators and risk descriptions varied between PPP authorisation reports, the quantitative comparison of risks could not always be performed for all indicators or for the same set of indicators, e.g. due to the fact that if a PPP does not show a substantial risk in a specific area no quantitative risk quotient may be reported. As a consequence, significant risk differences may potentially remain unnoticed.

The outlined procedure for risk profiling and risk comparison generated a differential spectrum of risk indicators for quantitative comparisons in the three different areas of environmental risk assessment with some 250 categories of comparable TER and 1/HQ values. Aggregated to a level were missing data were minimised, comparisons of risk profiles for birds and mammals comprised TER values for a maximum of 15 different regulatory endpoints. Considering aquatic ecotoxicology, risk comparisons could be performed on the basis of TER values for the most sensitive test species for a maximum of three different exposure routes and different exposure refinements resulting in a total of 8 assessment endpoints. With respect to terrestrial ecotoxicology, comparable HQ or TER values were available for a maximum of 19 different regulatory endpoints. All in all, risk indicators for a maximum of 42 different regulatory endpoints were included in the comparisons of risk profiles. In the 10 cases studied, quantitative risk comparisons for 8 to 19 of these 42 possible endpoints were in fact supported by data.

Applying the criterion of a significant risk reduction in at least one assessment endpoint and no significant deterioration in any other risk endpoint, we found for 6 of the 10 binary product comparisons alternatives with significantly less environmental risk regarding one or more assessment endpoints. For 3 of the remaining 4 cases the alternative product despite not containing a candidate for substitution demonstrated a significantly larger risk at least for one endpoint. In the one remaining case we obtained conflicting findings resulting from the use a of a risk mitigation scenario within risk assessment which calls for refinement of the decision rules. Thus, for the case studies it could be demonstrated that the simple set of suggested principles for risk comparison and assessment can be made operational. Moreover, it showed clear discriminatory power and the significant risk differences detected provide a clear basis for regulatory decision making. However, ambiguity of risk comparison findings particularly in the assessment areas for terrestrial organisms remains to be addressed.

Synthesis of findings

Almost one quarter of the active substances currently approved for use in plant production products in the EU can be expected to be labelled as candidates for substitution (CFS) in the foreseeable future. For products containing such CFS, member states will have to carry out comparative risk assessments during the authorisation process with the goal to withhold authorisation if an alternative product with significantly lower risk is available for the same use. Of the potential candidates for substitution the majority is indicated for environmental concerns, so environmental risk assessment can be expected to become a central issue in future comparative risk assessment efforts. For plant protection products currently authorised for use in Germany about one third of the products would fall into the category where comparative risk assessment would be required if the product required re-authorisation. All major chemical compound classes of active substances use groups, and application areas are concerned. For many uses alternative products that do not contain potential candidates for substitution exist.

The principles for performing comparative risk assessment for alternative plant protection products can be based on the legal setting that 'a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk'. Additionally, we propose carrying out the risk comparison for all different endpoints used currently in environmental risk assessment and we suggest discriminating no substitution candidate if the alternative product shows a significant increase in any other risk endpoint. For ten case studies it was shown that based on current summary authorisation reports for environmental risk assessment a comparative risk assessment could be performed, though unambiguity in findings could be reduced.

Five recommendations for setting up a process for comparative environmental risk assessment of plant protection products can be provided based on the results of the project:

- First of all, a consensus on the principles for comparative risk assessment is needed in order to devise a coherent process scheme of how to perform comparative assessments. The needs for exemptions and special cases, by contrast, are expected to emerge from first practical experience, for which the general principle of allowing expert judgement for borderline cases would suffice at the beginning.
- Secondly, as identified during the case study investigations, it would be highly advisable to plan a process whereby data access would be simplified. This relates to necessary risk information which is generated during the ongoing authorisation of plant protection products. Two issues can be raised here. The ease of product comparison would substantially improve if the risk assessment report provided a more coherent reporting structure. Moreover, an electronic data base and retrieval of risk measures such as TER or HQ values could render risk comparisons a semi-automated and thus effort-optimised process.
- Thirdly, in view of the zonal authorisation that is called for in the current plant protection regulation and in response to already raised business concerns about unfair product discrimination we advise to seek harmonisation of approaches for comparative PPP assessment at least within the same authorisation zone.
- Fourth, acknowledging that comparative risk assessment is also called for under the biocides directive as well as for REACH compounds that require authorisation this seems an opportunity to save future resources and ensure coherent regulatory strategies by devising consistent principles and possibly even similar approaches across chemical risk assessment under different regulations.
- Fifth, it may prove a substantial simplification for the process of comparing products to plan and establish reference cases for major indications. As there are many PPPs available for major pests and crops one may else be faced with repetitive binary product comparisons.

From the project efforts it emerges that comparative environmental risk assessment of plant protection products may become a novel cornerstone of regulatory activities that helps to improve the environmental quality by leading to substitution of less viable products.

2 Zusammenfassung

Die Kommission der Europäischen Gemeinschaften hat im Jahre 2001 in ihrem Weißbuch zur Strategie der zukünftigen Chemikalienpolitik (CEC 2001, 88 final) vorgeschlagen, dass die Substitution von gefährlichen Chemikalien durch weniger bedenkliche gefördert werden sollte. In der Folge wurden Vorschläge für die Etablierung des Substitutionsprinzips unterbreitet und Vorgehensweisen entwickelt, die Vergleiche von verschiedenen Chemikalien hinsichtlich assoziierter Gefährdungen und Risiken (KEMI 2007) erlauben. Der Fokus wurde dabei auf Stoffe gelegt, für die nach dem gegenwärtigen Risikorecht keine unmittelbaren Managementmaßnahmen wie der Entzug einer Autorisierung oder das Auslaufen der Genehmigung erforderlich sind, die aber dennoch als von besonderer Besorgnis gelten können, z.B. aufgrund der Erfordernis von spezifischen Risikominderungsmaßnahmen.

Die Anforderung eine vergleichende Risikobewertung für Menschen und die Umwelt vorzunehmen, inklusive der Option einer Produktsubstitution, wurde kürzlich mit den neuen europäischen Verordnungen für Pflanzenschutzmittel (PSM) (Verordnung EG Nr. 1107/2009) und Biozide (Verordnung EU Nr. 528/2012) in das Chemikalienrecht eingeführt. Die Verordnung 1107/2009 spezifiziert in ihrem Artikel 50, dass PSM nicht zur Anwendung zugelassen werden dürfen, wenn folgende Bedingungen erfüllt werden:

(i) Das Pflanzenschutzmittel enthält einen Wirkstoff, „*der als Substitutionskandidat zugelassen ist*“, und

(ii) *„für die im Antrag genannten Verwendungen“* besteht *„bereits ein zugelassenes Pflanzenschutzmittel oder eine nichtchemische Bekämpfungs- oder Präventionsmethode“* das/die *„keine wesentlichen wirtschaftlichen oder praktischen Nachteile aufweist“,* wobei *„die Auswirkungen auf die Zulassungen für geringfügige Verwendungen berücksichtigt werden“,* und

(iii) *„die chemische Vielfalt der Wirkstoffe oder die Methoden und Verfahren der Kulturführung und der Schädlingsprävention“ sind gegebenenfalls „ausreichend (...), um das Entstehen einer Resistenz beim Zielorganismus zu minimieren“,* und

(iv) das alternative Mittel oder Verfahren ist *“für die Gesundheit von Mensch oder Tier oder für die Umwelt deutlich sicherer”.*

Anhang IV spezifiziert weiterhin: „*Für die Umwelt ist gegebenenfalls ein Faktor von mindestens 10 für das Verhältnis Toxizität/Exposition (Toxicity/Exposure Ratio — TER) der verschiedenen Pflanzenschutzmittel als signifikanter Unterschied im Risiko anzusehen.*“

Welche Wirkstoffe Substitutionskandidaten sind, wird auf Gemeinschaftsebene festgelegt, während es die Aufgabe der einzelnen Mitgliedsstaaten ist, diejenigen Pflanzenschutzmittel, die solche Wirkstoffe enthalten, regelmäßig zu prüfen, und zwar „*mit dem Ziel (...), sie durch andere Pflanzenschutzmittel, die Wirkstoffe enthalten, die weniger Risikominderung erfordern, oder durch nichtchemische Methoden der Bekämpfung oder Prävention zu ersetzen“* (Erwägungsgrund 19 der Verordnung). Eine erste Liste mit Substitutionskandidaten war für den 14.12.2013 angekündigt, sie lag aber bis zum Ende der Durchführungsphase dieses Projektes (31.12.2014) noch nicht vor und wurde schließlich erst im März 2015 veröffentlicht.

Die Zielstellung für dieses Vorhaben war es, ein Konzept für die vergleichende Bewertung von Pflanzenschutzmitteln (PSM) zu entwickeln, und zwar im Hinblick auf Risiken für die Umwelt. Weiterhin sollte dieses Konzept für ausgewählte Fälle erprobt werden. Aus dem Fehlen einer etablierten Liste von Substitutionskandidaten bei Beginn des Vorhabens ergab sich die Unkenntnis über PSM, für die zukünftig ggf. Alternativen zu betrachten sind. Weiterhin lagen

keine leitenden Prinzipien für die vergleichende Bewertung von Umweltrisiken von PSM vor. Aus den beiden vorgenannten Punkten folgte, dass diese Schritte zunächst durchgeführt werden mussten, bevor tatsächlich eine Vorgehensweise für die vergleichende Bewertung entwickelt werden konnte. Der Arbeitsplan des Vorhabens verlief daher zwangsläufig parallel zu Aktivitäten der EU und anderer Institutionen. Es wurde soweit wie möglich versucht, die Ergebnisse dieser parallelen Aktivitäten durch ein iteratives Vorgehen in diesem Vorhaben zu berücksichtigen. Bei dem gewählten schrittweisen Vorgehen haben wir es zunächst unternommen, potentielle Substitutionskandidaten aus der EU-Liste der zugelassenen Wirkstoffe zu identifizieren, um anschließend jene Pflanzenschutzmittel zu erfassen, die derartige Wirkstoffe enthalten und die für eine Anwendung in Deutschland autorisiert sind. Weiterhin wurden mögliche alternative Produkte ausgewiesen, die keine potentiellen Substitutionskandidaten enthalten. In einem nächsten Schritt analysierten wir die Literatur sowie einen zwischenzeitlich verfügbar gewordenen Entwurf der Kommission für einen Leitfaden (draft guidance document) zur Durchführung der vergleichenden Risikobewertung und leiteten daraus generische Prinzipien für die vergleichende Umweltrisikobewertung von Pflanzenschutzmitteln ab. Für zehn Fallstudien, ausgewählt aus der Liste von aktuell in Deutschland autorisierten Pflanzenschutzmitteln, wurden auf Basis der Informationen aus den zusammenfassenden nationalen Bewertungsberichten die vorgeschlagenen Bewertungsprinzipien angewendet. Die Befunde wurden zusammengestellt und die Ergebnisse aller Schritte wurden zusammengeführt in einen Vorschlag zur vergleichenden Umweltrisikoverwertung. Die wesentlichen Befunde und die zu berücksichtigende Aspekte werden im Folgenden näher dargestellt.

CFS Identifizierung

Für die Identifikation von Substitutionskandidaten gibt die Verordnung (EG) Nr. 1107/2009 im Anhang II, Punkt 4 eine Liste von Kriterien für die relevanten zu betrachtenden Risiken für die menschliche Gesundheit und die Umwelt vor. Von dieser Liste fokussiert dieser Bericht auf die Kriterien, die für die Umwelt relevant sind. Danach gilt als Substitutionskandidat jeder Wirkstoff, der zwei der drei Kriterien erfüllt, die einen Stoff als persistent, bioakkumulativ und toxisch (PBT-Substanz) kennzeichnen lassen. Während die Legaldefinition des T-Kriteriums sowohl Indikatoren aus den Bereichen der Humantoxizität (T_{HUMAN}) und der aquatischen Toxizität (T_{AQUA}) umfasst, beschränkte sich unsere Suche nach potentiellen Substitutionskandidaten auf solche Stoffe, die aus Gründen des Umweltschutzes (T_{AQUA}) das T-Kriterium erfüllen. Dieser Ansatz wurde für eine Liste von 375 Wirkstoffen verfolgt, die am Beginn des Vorhabens im November 2012 in der EU als zugelassene Wirkstoffe galten. Biologische Agenzien wurden aus dieser Liste entfernt und in Fällen, in denen die Zulassung sich auf Chemikalien bezog, die eine Gruppe von ähnlichen Verbindungen mit verschiedenen CAS-Nummern umfasste (etwa verschiedene Salze und Ester einer Ausgangsverbindung), wurde ein Repräsentant ausgesucht. Dies resultierte in einer konsolidierten Liste von 344 Wirkstoffen, für die dann Informationen zu ihren P-, B- und T_{AQUA}-Eigenschaften zusammengetragen wurden. Diese Daten wurden in Form von sequentiellen Suchen in den Datenbanken Pesticide Properties Database (PPDB), European Chemical Substances Information System (ESIS) und EU Pesticides Database erschlossen. Schließlich wurden auch noch die ‘Risk Assessment Reports’ der European Food Safety Authority (EFSA) über die EFSA-Webseite erschlossen, sofern zuvor keine relevanten Informationen zu den Stoffen gefunden wurden. Die gewählte schrittweise Datenerschließung bedeutet, dass, falls die gesuchten Informationen für einen Wirkstoff bereits in der ersten, zweiten oder dritten Quelle gefunden wurden, keine weitergehende Suche in den nachrangigen Quellen erfolgte.

Mit der beschriebenen Strategie konnten Daten für die meisten Stoffe und Kriterien mit Ausnahme des Bioakkumulationskriteriums gefunden werden. Im Einzelnen wurden für 300 der 344 Stoffe Boden-Persistenz-Werte ausgemacht, 270 aus Wasser/Sediment-Systemen, 277 für die Wasserphase von Wasser/Sediment-Systemen. Für das Bioakkumulationskriterium wurden für lediglich 188 der 344 betrachteten (55%) Stoffe Informationen in den durchsuchten Datenbasen gefunden. Dieser niedrigere Anteil an Stoffinformationen ist vermutlich auf die gestaffelten Datenanforderungen für dieses Kriterium im Zulassungsverfahren zurückzuführen. Hier werden Bioakkumulationsinformationen nur für Stoffe verlangt, die eine stärkere Partitionierung in die Lipidphase erwarten lassen. Für das Kriterium zur aquatischen Toxizität schließlich ergaben sich Informationen für 317 der 344 betrachteten Wirkstoffe, mithin für 92%.

Die Verordnung (EG) Nr. 1107/2009 des Europäischen Parlamentes und des Europäischen Rats legt die Zulassungskriterien für Wirkstoffe fest. Diese enthalten auch Anforderungen zur Ökotoxikologie und zum Verhalten von Stoffen in der Umwelt. Die Persistenz-Kriterien sind über Ausschlusswerte in Anhang II im Punkt 3.7.2.1 festgelegt. Ein Wirkstoff wird hiernach als persistent betrachtet, wenn seine Halbwertszeit in Salz-, Süß- oder Brackwasser, im Sediment von Gewässern (Salz-, Süß- oder Brackwasser) oder im Boden, je nach Kompartiment, mehr als 40 bis 180 Tage beträgt. Weiterhin wird ein Wirkstoff entsprechend der Verordnung (EG) Nr. 1107/2009, Anhang II, Abschnitt 3.7.2.2 als bioakkumulativ betrachtet, wenn sein Biokonzentrationsfaktor einen Wert von 2000 überschreitet. Um das Bioakkumulationspotential eines Wirkstoffes einzuschätzen, werden gemessene BCF-Werte für Süß- und Salzwasserorganismen betrachtet. Im Hinblick auf das Toxizitätskriterium werden nach der Verordnung (EG) Nr. 1107/2009 chronische ‘No-Observed Effect Concentrations’ (NOEC) für marine Organismen oder Süßwasser-Organismen betrachtet und Stoffe dann als toxisch eingestuft, wenn ein Wert von unter 0,01 mg/L auftritt. Zusätzliche Hinweise für die Nutzung von anderen verfügbaren Daten in diesem Zusammenhang sind in einem DG SANCO Working Document (COM 2012) zusammengestellt.

Die Anwendung der genannten PBT-Kriterien auf die zusammengestellten Daten ergab, dass für 33 (9,6%) der betrachteten 344 Wirkstoffe mindesten zwei der drei PBT-Kriterien erfüllt waren. Diese könnten somit als potentielle Substitutionskandidaten klassifiziert werden. Über die Kombination aus Persistenz- und Toxizitätskriterium wurden die meisten Stoffe identifiziert, wohingegen nur eine Verbindung durch das gleichzeitige Erfüllen des Persistenz- und des Bioakkumulationskriteriums indiziert wurde. Bemerkenswerterweise stammen die so identifizierten 33 potentiellen Substitutionskandidaten aus 26 unterschiedlichen chemischen Stoffgruppen und decken auch alle wichtigen Pflanzenschutzwirkungstypen, wie Herbizide, Fungizide, Insektizide und Akarizide ab. Folgende chemische Stoffklassen sind mit jeweils mehr als einem Stoff vertreten: Pyrethroide, Sulfonylharnstoffderivate und Triazolverbindungen. Die 33 Wirkstoffe, die durch dieses Verfahren identifiziert wurden, dienten in der Folge als Trainings-Set für die Projektarbeiten, um herauszufinden wie viele Produkte und welche Charakteristika hinsichtlich Anwendungen und Einsatzgebieten für eine zukünftige vergleichende Umweltrisikobewertung auftreten können.

Zeitlich parallel zu den Arbeiten an diesem Projekt vergab die EU-Kommission eine Auftragsstudie an einen Berater, um die notwendigen vorbereitenden Arbeiten für die Kommissionsaufgabe der Etablierung einer initialen Liste an Substitutionskandidaten (engl. candidates for substitution) (CFS) bis Ende 2013 zu erledigen. Diese Studie beinhaltete die Datenbeschaffung für einen Satz von sieben Kriterien, von denen eines die hier diskutierte Kombination von PBT-Kriterien war. Ein Arbeitsbericht über diese Aktivität wurde den Mitgliedsstaaten und nachfolgend auch diesem Projekt zugänglich, woraus eine Entwurfsliste

der potentiellen Substitutionskandidaten der EU Kommission ableitbar war. Danach sind 98 verschiedene zugelassene Wirkstoffe als wahrscheinliche CFS für die Kommission identifiziert worden. Die Analysen aus dem hier vorliegenden Vorhaben hingegen beschränkten sich auf die Betrachtung der PBT-Kriterien, von denen je zwei erfüllt sein müssen, um einen Wirkstoff als Substitutionskandidaten zu betrachten. Von daher kann die Zahl von 30 übereinstimmenden Befunden nicht mit der Gesamtzahl von 98 wahrscheinlichen CFS verglichen werden, sondern muss auf die 70 Stoffe bezogen werden, die in dem Bericht des Beraters an die Kommission als zwei der drei PBT-Kriterien erfüllend gelistet wurden. Vergleichend werden in diesem Bericht eine Reihe von Gründen identifiziert und diskutiert, warum es nachvollziehbar sein kann, dass die Zahl der durch die PBT-Kriterien identifizierten CFS in diesem Bericht gegenüber dem Bericht an die Kommission deutlich geringer ausfiel. Insbesondere die Tatsache, dass die Evaluation des Toxizitätskriteriums in dieser Arbeit auf Daten aus der PPBD Datenbank zu Standardtoxizitätsuntersuchungen an Algen, Daphnien und Fischen beschränkt blieb, erklärt einige der Abweichungen. Die Datenerfassung der Beraterarbeit umfasste demgegenüber nämlich ein viel breiteres Spektrum an aquatischen Spezies und Endpunkten, die aus den offiziellen Dokumenten für die Stoffzulassung verfügbar waren. Nichtsdestotrotz ist die große Differenz von 40 Verbindungen, die ausschließlich in dem Bericht der Kommissionsberater aufgrund der PBT-Kriterien als positiv identifiziert wurden, überraschend. Noch unerwarteter war allerdings der Befund, dass zwei Substanzen, die mit den Verfahren dieses Projektes als potentielle CFS identifiziert wurden, nämlich Beflubutamid und Deltamethrin, beide nicht als potentielle CFS in dem Bericht der EU-Beraterkommission auftraten.

Mit einer Verzögerung von mehr als einem Jahr wurde die offizielle Liste von Substitutionskandidaten von der Europäischen Kommission im März 2015 festgelegt, nachdem bereits alle Datenanalysen in diesem Projekt abgeschlossen waren. Die offizielle Liste umfasst jetzt eine etwas reduzierte Zahl von 77 Substitutionskandidaten, von denen 52 nach Maßgabe umweltrelevanter Kriterien identifiziert wurden (Durchführungsverordnung (EU) 2015/408 der Kommission).

Präparate mit potentiellen Substitutionskandidaten

Das Ziel dieses Arbeitsschrittes bestand darin, einen Überblick zur Anzahl und den Typen von Pflanzenschutzmitteln zu erlangen, die möglicherweise in der Zukunft Gegenstand von vergleichenden Risikobewertungen werden könnten, weil sie Substitutionskandidaten enthalten, die zum Zeitpunkt der Durchführung der Analysen noch nicht offiziell festgelegt waren. Weiterhin wurde angestrebt, die Verteilung dieser potentiellen Kandidatenpräparate auf die verschiedenen Anwendungsfelder zu antizipieren, um typische Fälle zu charakterisieren, für die eine vergleichende Risikobewertung vorzunehmen sein würde. Die leitende Hypothese war hierbei, dass jede absehbare Einschränkung hinsichtlich der betroffenen Felder oder Anwendungszahlen helfen könnte, den absehbaren Aufwand für die vergleichende Umweltrisikobewertung zu reduzieren.

Zur Erreichung dieser Ziele wurde die PSM-Datenbank des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit (BVL) genutzt und damit sowohl die PSM identifiziert, die potentielle Substitutionskandidaten enthalten, als auch eine Charakterisierung der Verteilung dieser Präparate über die Nutzpflanzenkulturen, Schädlingsarten und Anwendungsgebiete vorgenommen. Darüber hinaus wurde die Verfügbarkeit von alternativen PSM für jedes der verschiedenen Anwendungsgebiete geprüft. Als potentielle Alternativen betrachteten wir vorrangig Präparate, die keinen potentiellen Substitutionskandidaten enthalten.

In den ersten Projektphasen arbeiteten wir mit der Liste von 33 potentiellen CFS, die wir durch die P, B, T_{AQUA}-Eigenschaften, wie zuvor beschrieben, generiert hatten. Nachdem die Ergebnisse der EU-Kommissions-Kontraktstudie verfügbar wurden, entschieden wir, mit der resultierenden Liste von 98 wahrscheinlichen CFS als Basis für die Identifikation von PSM mit und ohne CFS weiterzuarbeiten. Die Überlegung hinter dieser Entscheidung war, dass wir die Substitution eines Produkts mit einem aus Gründen einer Umweltgefährdung identifizierten CFS durch ein Produkt mit einem aus anderen Gründen identifizierten CFS nicht als sinnvolle Option einschätzen. Die offizielle Liste an Substitutionskandidaten wurde erst verfügbar, nachdem die Analysen innerhalb des Projekts abgeschlossen waren, sodass alle im Bericht dokumentierten entsprechenden Ergebnisse als vorläufig zu betrachten sind und vermutlich geringfügige Änderungen in der Zukunft zu erwarten sind.

Die BVL-Datenbank in ihrer Version von Mai 2013 enthält 374 Wirkstoffe und 1378 autorisierte Pflanzenschutzmittel, die 3606 unterschiedliche Anwendungsgebiete hinsichtlich spezifizierter Schädlinge und Pflanzenkulturen beschreiben. Für 65 der Wirkstoffe aus der Liste der 98 Wirkstoffe, die hier als potentielle Substitutionskandidaten betrachtet wurden, konnten Einträge in der BVL-Datenbank gefunden werden. 351 der 1378 PSM, die vom BVL zum Stichdatum erfasst waren, enthielten zumindest einen potentiellen Substitutionskandidaten. D.h. ungefähr 25% der in Deutschland zur Anwendung zugelassenen PSM würden vermutlich eine vergleichende Risikobewertung erfordern, sollten sie unter der gegenwärtig gültigen PSM-Verordnung zuzulassen sein. Die identifizierten potentiellen Substitutionskandidaten sind ungleich über die zugelassenen Präparate verteilt. Während 11 der CFS-Wirkstoffe in mehr als 10 Präparaten gefunden werden können, sind 17 potentielle CFS in nur einem Präparat enthalten. PSM, die potentielle Substitutionskandidaten enthalten, stammen aus allen Wirktypgruppen, nämlich Herbizide (37% der PSM enthalten CFS), Fungizide (36%) und Insektizide (20%). Die Präparate, die potentielle Substitutionskandidaten enthalten, werden gegen 264 der 477 gelisteten Schädlinge in 209 der 309 geführten Kulturen eingesetzt. Insgesamt werden die ggf. zur vergleichenden Bewertung anstehenden Produkte für die Hälfte aller Anwendungsgebiete geführt. Von den 351 Präparaten, die einen potentiellen Substitutionskandidatenwirkstoff enthalten, waren 100 in nur einer Kultur aber 43 Präparate für die Anwendung in mehr als 10 verschiedenen Kulturen zugelassen. Im Unterschied zu unserer Ausgangshypothese konnten wir mithin keinerlei Muster zum Auftreten von PSM, die potentielle Substitutionskandidaten enthalten, finden, welche es erlaubt hätten, die zukünftige vergleichende Risikobewertung auf spezifische Wirkstoffe, Produktgruppen, Kulturen oder Anwendungsgebiete einzuschränken.

Die 351 Präparate, die am Stichdatum in Deutschland zur Anwendung zugelassen waren und dabei einen potentiellen Substitutionskandidaten als Wirkstoff enthielten, waren für 1863 verschiedene Anwendungsgebiete zugelassen. Das heißt, dass ein typisches Präparat mit einem CFS für verschiedene (im Durchschnitt 3) Anwendungsgebiete zugelassen ist. Für jedes dieser Anwendungsgebiete müsste ggf. eine Substitution geprüft werden, sofern eine Alternative verfügbar ist. In dieser Untersuchung wurden solche Präparate als primäre potentielle Kandidaten für einen alternativen Einsatz angesehen, die keine Substitutionskandidaten enthielten aber für das gleiche Anwendungsgebiet eine Zulassung aufwiesen. Von den 1863 Anwendungsgebieten mit Präparaten, die CFS enthalten, konnten in 1096 Fällen keine Produkte ohne Substitutionskandidaten in der BVL-Datenbank identifiziert werden. Diese Fälle umfassen typischerweise Spezialanwendungen, wie etwa die Bekämpfung dikotyler Unkräutern auf Rasenflächen. In den verbleibenden 40% der Fälle sind alle Hauptkulturen und weitverbreiteten Schädlinge enthalten. In dieser Kategorie sind im Durchschnitt 3 alternative Präparate verfügbar, die keinen potentiellen Substitutionskandidaten enthalten. Daher kann angenommen werden, dass eine vergleichende Bewertung der Umweltrisiken paarweise

vorzunehmen ist, zumindest so lange bis eine ‚signifikante Risikoreduktion' gefunden wird. Die Gesamtanzahl an vergleichenden Bewertungen, die ggf. im Verlaufe einer kompletten Neubewertung aller PSM vorzunehmen sein würde, also bei gegenwärtiger Zulassungsdauer für Produkte etwa im Zeitraum einer Dekade, könnte nach dieser Betrachtung also gut mehrere tausend Fälle erreichen. Bei Betrachtung des Spektrums an zugelassenen Anwendungen für PSM mit CFS zeigt unsere Analyse, dass für jedes betroffene Produkt mindestens ein Anwendungsgebiet existiert, für das ein CFS-freies Präparat autorisiert ist, sodass in der Tat in Deutschland für jedes Produkt, das einen Substitutionskandidaten enthält, auch eine vergleichende Risikobewertung erforderlich werden könnte.

Generisch vergleichende Bewertung von Umweltrisiken

Die neue Verordnung zur Zulassung von Pflanzenschutzmittel (EU Nr. 1107/2009) regelt in Artikel 50, dass die Mitgliedstaaten „*keine Zulassung für ein Pflanzenschutzmittel*" erteilen oder „*die Verwendung eines Pflanzenschutzmittels, das einen Substitutionskandidaten enthält, auf eine bestimmte Kulturpflanze*" beschränken, „*wenn die vergleichende Bewertung der Risiken und des Nutzens (...) ergibt, dass (...) für die im Antrag genannten Verwendungen bereits ein zugelassenes Pflanzenschutzmittel oder eine nichtchemische Bekämpfungs- oder Präventionsmethode besteht, das/die für die Gesundheit von Mensch oder Tier oder für die Umwelt deutlich sicherer ist (...)*". Zusätzlich kommen agronomische, technologische und ökonomische Kriterien während des Bewertungsprozesses zum Einsatz. Der zentrale Punkt bei der erforderlichen vergleichenden Betrachtung von Risiken für Gesundheit und Umwelt bei Präparaten mit derselben Nutzung ist die Frage, ob die Alternative „*deutlich sicherer*" ist. Anhang IV der Verordnung spezifiziert weiterhin, dass ein „*signifikanter Unterschied im Risiko*" fallweise von der zuständigen Behörde festzustellen ist. Darüber hinaus wird ein Anhaltspunkt dafür gegeben, was als signifikanter Risikounterschied anzusehen ist: „*Für die Umwelt ist gegebenenfalls ein Faktor von mindestens 10 für das Verhältnis Toxizität/Exposition (Toxicity/Exposure Ratio — TER) der verschiedenen Pflanzenschutzmittel als signifikanter Unterschied im Risiko anzusehen.*"

Die Projektaufgabe bestand deshalb darin, generische Prinzipien abzuleiten und ein Verfahrensschema zu entwickeln, wie die bestehenden rechtlichen Anforderungen umgesetzt werden könnten. Mittels einer Sichtung der verfügbaren Literatur über vorgeschlagene Vorgehensweisen der vergleichenden Bewertung und der Substitution von Chemikalien kann gezeigt werden, dass sich der Schwerpunkt der geführten Diskussion um den Vergleich von Gefahren und nicht um den hier geforderten Vergleich von Risiken dreht. Der Entwurf des von der Generaldirektion SANCO (Gesundheits- und Verbraucherschutz) bereitgestellten Leitfadens (Draft Guidance Document SANCO/11507/2013 final) (COM 2014) für die Unterstützung der Mitgliedsstaaten bei der Durchführung der zukünftigen vergleichenden Bewertung von PSM kann in diesem Kontext als das wichtigste Dokument betrachtet werden. Dieses Dokument unterbreitet insbesondere Vorschläge dazu, wie der gesamte Prozess der vergleichenden Bewertung in sequentieller Abfolge organisiert werden kann. Agronomische Überlegungen zu angemessenen Alternativen stehen diesem Vorschlag zufolge vor der eigentlichen vergleichenden Risikobewertung. Eine Limitierung in dem von SANCO vorgeschlagenen Vorgehen besteht darin, dass keine Empfehlungen gegeben werden, wie mit den verschiedenen, gegenwärtig unabhängig beurteilten Feldern der Umwelt- und Gesundheitsrisikobewertung umzugehen ist. Implizit könnte der Eindruck entstehen, als ob es einzelne aggregierte Risikokenngrößen gäbe, die einen Vergleich von verschiedenen PSM zuließen. Nach Kenntnis der Autoren erlaubt jedoch weder die wissenschaftliche Literatur noch irgendein etabliertes Verfahren innerhalb des Chemikalienrechtes eine sinnvolle Aggregation

von Risikokenngrößen aus so unterschiedlichen Feldern wie Risiken für Bodenorganismen, Säugern und Vögeln oder aquatischen Organismen. Aus wissenschaftlicher Perspektive scheinen sich diese unterschiedlichen Risiko-Beurteilungsendpunkte im Gegenteil eher gegenseitig auszuschließen.

In dieser Situation schlagen wir daher eine Reihe von generischen Prinzipien vor, die es erlauben, unter Berücksichtigung der Informationen, die für die bestehende Umweltrisikobewertung von einzelnen Präparaten typischerweise erzeugt werden (zusammenfassenden Risikozulassungsberichte), die rechtliche Definition eines signifikanten Risikounterschiedes nach der PSM-Verordnung einzulösen. Die vorgeschlagenen Prinzipien umfassen vier Hauptpunkte:

- Die vergleichende Bewertung erfolgt auf der Basis vollständiger Risikoprofile, die alle der regulatorische Umweltrisikobewertung von Pflanzenschutzmitteln zugrundeliegenden Endpunkte berücksichtigen, für die vergleichbare TER-Werte oder äquivalente Risikoindikatoren verfügbar sind.
- Die Entscheidung, eine Risikoreduktion durch ein alternatives Präparat als signifikant zu bewerten, wird vorgenommen, falls eine signifikante Reduktion für einen oder mehrere Endpunkte gefunden wird und keine signifikante Risikoerhöhung für irgendeinen anderen Endpunkt festgestellt wird.
- Ausnahmen können für Grenzfälle vorgesehen werden. In diesen Fällen sollten Expertenurteile vorgesehen werden.
- Im Zweifelsfall sollte sich aus einer vergleichenden Risikobewertung keine Festlegung auf einen signifikanten Risikounterschied ergeben.

Fallstudien für Pflanzenschutzmittel

Um die Praktikabilität, Angemessenheit und Leistungsfähigkeit der vorgeschlagenen generischen Prinzipien für die vergleichende Umweltrisikobewertung von PSM zu studieren, wurde ein Satz an Fallstudien untersucht. Fünf verschiedene PSM, jedes mit einem von drei potentiellen Substitutionskandidaten, nämlich ein Phenylharnstoff-Herbizid, ein Triazol-Fungizid und ein Pyrethroid-Insektizid, wurden mit ausgewählten alternativen Präparaten verglichen. Diese enthalten einerseits keinen CFS und sind andererseits für dasselbe Anwendungsgebiet hinsichtlich Kulturpflanze und zu bekämpfendem Schädling zugelassen. Insgesamt wurden 10 solcher Fälle untersucht. Als einzige Datenquelle wurden die zusammenfassenden Zulassungsberichte des UBA genutzt. Um die multiplen Risikoprofile zu erstellen, wurden die dokumentierten TER- und HQ-Werte dargestellt oder die entsprechenden Risikoindikatoren aus den relevanten Toxizitäts- und Expositionswerten abgeleitet. Die Risikoindikatoren umfassten die drei unterschiedlichen Umweltbewertungsbereiche terrestrische Organismen, Säuger und Vögel sowie aquatische Umwelt. Um zu einer konsistenten Darstellung der Risikoprofile zu gelangen, mussten Entscheidungen über den Grad der detaillierten Betrachtung der zu berücksichtigenden Informationen sowie zur Re-Skalierung (z.B. Umwandlung von HQ in TER-Werte) getroffen werden. Als potentielles Surrogat für TER-Werte wurde zusätzlich die Verwendung von Risiko-Score-Werten betrachtet, die aus den anzuwendenden Risikominderungsmaßnahmen aus der Zulassungsentscheidung für ein PSM abgeleitet werden können. Diese Rückrechnung erfolgte entsprechend eines UBA-Vorschlages.

Die Risikoprofile für die einzelnen PSM wurden anschließend durch Berechnen der numerischen Verhältnisse zwischen den korrespondierenden Werten für das betrachtete

Alternativpräparat und das Kandidatenprodukt für jeden möglichen Risikoendpunkt verglichen. Diese differentiellen Risikoprofile wurden auch grafisch dargestellt, um einen Überblick der Risikodifferenzen für alle Riskobewertungsbereiche zu geben. Die Risikoprofile und Vergleiche konnten für alle 10 untersuchten Fälle aus den Informationen der zugrundeliegenden zusammenfassenden Zulassungsberichte erzeugt werden. Es erwiesen sich jedoch einige Ad-hoc-Operationalisierungen der vorgeschlagen generischen Prinzipien der vergleichenden Umweltrisikobewertung als erforderlich. Die wichtigste Schwierigkeit zeigte sich für Fälle, in denen ein TER- oder 1/HQ-Wert nicht als exakte Zahlenangabe, sondern als Ungleichheit angegeben war, d.h. als Wert, der die Überschreitung oder Unterschreitung eines Grenzwertes anzeigt (< x oder > x). In dieser Situation kann nämlich ein Risikounterschied nicht in allen Fällen wie erforderlich quantifiziert werden. Insbesondere Risikoendpunkte zur Toxizität gegenüber Bienen, Regenwürmern und terrestrischen Pflanzen waren hiervon betroffen. Eine weitere Schwierigkeit lag darin begründet, dass die Datenbasis heterogen zusammengesetzt war, sodass Risikovergleiche für nominell gleiche Bewertungsendpunkte mitunter auf verschiedenen Effekten beruhten, insbesondere auch auf Vergleichen zwischen niedrig- und höherstufigen Testergebnissen. Da Risikoindikatoren und Risikobeschreibungen zwischen den Zulassungsberichten variierten, konnte der quantitative Risikovergleich nicht immer für alle Indikatoren oder nicht immer für den gleichen Satz an Indikatoren vorgenommen werden, da z.B. im Fall, dass ein PSM in einem spezifischen Bewertungsbereich offensichtlich kein substantielles Risiko aufweist, ein Risikoquotient im Bewertungsbericht auch nicht quantifiziert worden ist. Aus dieser Situation heraus könnten durchaus einzelne signifikante Risikodifferenzen übersehen werden.

Das entworfene Verfahren für eine Risikoprofilierung und einen Risikovergleich erzeugt ein differentielles Spektrum an Risikoindikatoren für den quantitativen Vergleich in den drei unterschiedlichen Bereichen der Umweltrisikobewertung mit 250 verschiedenen Kategorien und prinzipiell vergleichbaren TER- und 1/HQ-Werten. Nach Aggregation auf ein Niveau, bei dem die Matrix hinsichtlich fehlender Werte minimiert wurde, umfasste der Vergleich von Risikoprofilen für Vögel und Säuger TER-Werte für ein Maximum von 15 verschiedenen regulativ bedeutsamen Endpunkten. Im Bereich der aquatischen Ökotoxikologie konnten Risikovergleiche auf der Basis von TER-Werten für die empfindlichste Testspezies unter Betrachtung von drei verschiedenen Expositionspfaden und verschiedenen Verfeinerungen der Expositionskonzentration für maximal 8 Beurteilungsendpunkte vorgenommen werden. In der terrestrischen Ökotoxikologie waren vergleichbare HQ- oder TER-Werte für maximal 19 verschiedene regulatorische Endpunkte verfügbar. Insgesamt ergaben sich Risikoindikatoren für maximal 42 verschiedene regulatorisch relevante Endpunkte, die in den Vergleich von Risikoprofilen einbezogen werden konnten. In den 10 Fallstudien, konnten schließlich tatsächlich für 8 bis 19 dieser 42 Endpunkte Risikovergleiche datengestützt vorgenommen werden.

Bei Anwendung des Kriteriums einer signifikanten Risikoreduktion in dem Fall, dass mindestens ein Bewertungsendpunkt eine numerisch signifikante Reduzierung und kein anderer eine signifikante Risikoverschlechterung ausweist, konnten wir für 6 der 10 paarweisen Präparate-Vergleiche Alternativen mit signifikant geringerem Umweltrisiko ermitteln. Die gefundenen Verbesserungen fußten auf einem oder mehreren Endpunkten, in denen signifikante Unterschiede gefunden wurden. Für 3 der verbleibenden 4 Fälle wies das alternative Präparat, obwohl es keinen CFS enthielt, ein signifikant erhöhtes Risiko in wenigstem einem Endpunkt aus. In dem verbleibenden letzten Fall ergaben sich widersprüchliche Befunde, die sich aus der Nutzung von Risikominderungsmaßnahmen in der Risikobeurteilung ergaben. Hier könnte eine Verfeinerung der vorgeschlagenen Entscheidungsregeln vorgenommen werden. Für die untersuchten Fallstudien konnte mithin

gezeigt werden, dass der vorgeschlagene Satz aus einfachen Prinzipien für Risikovergleich und Bewertung operationalisiert werden kann. Weiterhin zeigte sich eine klare Unterscheidungsfähigkeit für die Bewertung, d.h. die als signifikant detektierten Risikodifferenzen liefern eindeutige Entscheidungsrundlagen für die vergleichende Bewertung. Ein zu klärender Interpretationsbedarf für die vergleichende Risikobewertung besteht allerdings im Hinblick auf den Bereich der terrestrischen Risikobewertung.

Synthese der Ergebnisse

Rund ein Viertel der gegenwärtig in der EU zur Formulierung in Pflanzenschutzmitteln zugelassenen Wirkstoffe könnten als Substitutionskandidaten (CFS) in der näheren Zukunft ausgewiesen werden. Für Produkte, die derartige CFS enthalten, werden die Mitgliedsstaaten während des Zulassungsverfahrens eine vergleichende Risikoverwertung vornehmen müssen, mit der Zielstellung die Zulassung zu verwehren, falls ein alternatives Präparat mit signifikant geringerem Risiko für denselben Zweck verfügbar ist. Von den potentiellen Substitutionskandidaten wird die Mehrzahl aus Umweltbedenken heraus identifiziert, weshalb der Umweltrisikobewertung eine zentrale Bedeutung in zukünftigen vergleichenden Risikobewertungsanstrengungen zukommen dürfte. Von den Pflanzenschutzmitteln, die gegenwärtig in Deutschland zur Anwendung zugelassen sind, würde etwa ein Drittel aller Präparate in die Kategorie fallen, in der eine vergleichende Risikobewertung erforderlich werden könnte, sobald das Produkt einer Neu- oder Wiederzulassung unterzogen wird. Alle wichtigen chemischen Wirkstoffklassen, Wirktypen und Anwendungsgebiete sind betroffen. Für zahlreiche Anwendungen existieren alternative Produkte, die keine potentiellen Substitutionskandidaten enthalten. Die Prinzipien zur Durchführung von vergleichenden Risikobewertungen können aus der rechtlichen Festlegung, wonach ein Faktor von mindestens 10 für das Toxizitäts-zu-Expositions-Verhältnis (TER) von verschiedenen Pflanzenschutzmitteln als signifikanter Risikounterschied zu betrachten ist, hergeleitet werden. Zusätzlich schlagen wir vor, den Risikovergleich für alle unterschiedlichen Endpunkte durchzuführen, die gegenwärtig in der Umweltrisikobewertung gebräuchlich sind. Auch schlagen wir vor, kein Produkt rechtlich begründet zu substituieren, wenn das alternative Präparat eine signifikante Risikozunahme in einem anderen Risikoendpunkt ausweist. Für zehn Fallstudien konnte gezeigt werden, dass eine vergleichende Risikobewertung basierend auf den Informationen aus den gegenwärtigen zusammenfassenden Zulassungsberichten zur Umweltrisikobewertung vorgenommen werden kann, auch wenn die Eindeutigkeit der Ergebnisse noch verbessert werden könnte.

Fünf Empfehlungen für die Etablierung eines Verfahrens zur vergleichenden Umweltrisikobewertung von Pflanzenschutzmittel können aus den Ergebnissen des Projektes abgeleitet werden:

- Zuallererst sollte Konsens über die Prinzipien einer vergleichenden Risikobewertung hergestellt werden. Dies ist als Voraussetzung für ein kohärentes Prozessverständnis zu einem Verfahren der vergleichenden Risikobewertung notwendig. Es wird erwartet, dass die Erfordernis für abweichende Regelungen für Ausnahme- und Spezialfälle erst aufgrund von praktischen Erfahrungen erkennbar wird, und dass für die Arbeitsfähigkeit in diesem Falle zunächst das Prinzip ausreicht, wonach in Grenzfällen die Möglichkeit von Expertenurteilen vorgesehen wird.
- Als Zweites erscheint es aus den Untersuchungen der Fallstudien sehr ratsam, einen Prozess einzuplanen, wie der Zugang zu den notwendigen Datengrundlagen vereinfacht werden kann. Dieser Punkt bezieht sich auf Risikoinformationen, die in den laufenden

Zulassungsverfahren für Pflanzenschutzmittel erzeugt werden. Zwei Aspekte lassen sich dabei hervorheben: Die Einfachheit des Produktvergleiches ließe sich substantiell verbessern, wenn die Risikobewertungsberichte eine kohärentere Berichtsstruktur aufweisen würden, als dies gegenwärtig der Fall ist. Weiterhin würde eine elektronische Datenbasis mit Recherchemöglichkeit für relevante Risikokenngrößen wie TER- und HQ-Werte für PSM den halbautomatischen Risikovergleich ermöglichen und damit ein erhebliches Optimierungspotential für den Verfahrensaufwand bedeuten.

- Drittens schlagen wir mit Blick auf die zonale Zulassung von PSM, wie sie nach der aktuellen Pflanzenschutzmittel-Verordnung vorgesehen ist, vor, die Vorgehensweisen für die vergleichende Bewertung von PSM zumindest innerhalb derselben Zulassungszone zu harmonisieren, auch um bereits geäußerten Wirtschaftsbedenken hinsichtlich unfairer Produktdiskriminierung zu begegnen.
- Viertens lassen sich in dem Wissen, dass eine vergleichende Risikobewertung auch in der Biozid-Verordnung vorgesehen und für Stoffe nach der REACH-Verordnung für Chemikalien gefordert wird, die einem Zulassungsverfahren unterworfen werden, schon jetzt zukünftig notwendige Ressourcen sparen. Hierfür wären insbesondere kohärente regulatorische Strategien auf der Basis konsistenter Prinzipien notwendig, um möglicherweise sogar ähnliche Vorgehensweisen über die verschiedenen Stoffrechtsvollzüge hinweg zu entwickeln.
- Fünftens könnte es sich als großer Vorteil für die Vereinfachung des Vollzugs der vergleichenden Produktbewertung erweisen, wenn die Etablierung von Referenzfällen für Haupt-Anwendungsgebiete im Pflanzenschutz vorgesehen würde. Derartige Referenzen für gute Produktstandards für Hauptkulturen und bedeutende Schädlinge könnte die Fallzahlen wiederholt erforderlicher binärer Stoffvergleiche erheblich senken helfen.

Die bei der Bearbeitung dieses Projektes gewonnenen Erfahrungen und Erkenntnisse begründen die Annahme, dass aus der vergleichende Bewertung von Umweltrisiken für Pflanzenschutzmittel ein neuer Eckstein für regulatorische Aktivitäten zur Chemikaliensicherheit entstehen könnte, der durch die Beförderung der Substitution weniger nachhaltiger Produkte hilft, die Umweltqualität zu verbessern.

3 Introduction[1]

3.1 The substitution principle in the EU pesticides legislation

The substitution principle is a new element of the legislation on plant protection products (PPPs) in the European Union (EU). It was introduced with the new Regulation (EC) No 1107/2009 (2009), in the following shortly denoted as the PPP regulation. This replaced the old Directive 91/414/EEC on PPPs (Council Directive, 1991) in June 2011. In parallel, the substitution principle was also included in the new regulation (EU) No 528/2012 on biocidal products (Regulation (EU) No 528/2012), which came into force in September 2013. PPPs and biocidal products are collectively denoted as 'pesticides' under EU law, as has been defined in Article 3 of Directive 2009/128/EC on the sustainable use of pesticides in the European Community (EC) (Directive 2009/128/EC, 2009). As a common rule, pesticides shall not be placed on the market or used unless they have been authorised in accordance with the applicable regulations. In general, 'substitution' of pesticides means that an authorisation is refused or withdrawn in favour of an alternative product or a non-chemical control or prevention method that presents a 'significantly lower risk', according to either Annex IV of the PPP regulation (EC) No 1107/2009 or Article 23 of the biocidal products regulation (EU) No 528/2012, as applicable. In detail, the conditions, rules, and criteria for applying the substitution principle differ for PPPs and for biocidal products. In this project, we focus on substitution under the regulation for PPPs.

The inclusion of the substitution aspect in the EU pesticides legislation is an outcome of a broader and long-lasting discussion about the guiding principles of chemicals regulation under EU law. As a generic policy principle, substitution means the replacement of hazardous chemical substances and products by less hazardous alternatives (KEMI, 2007). Whether this idea should be established as a legal demand for actors in the field has been subject to heated debates. Opponents, such as the German chemical industries for instance, argued that substitution was superfluous if safe use of a hazardous chemical could be ensured by appropriate risk management measures (VCI, 2005). In 2001, during the preparation of the REACH legislation, the Commission of the European Communities (COM) considered the substitution of hazardous chemicals as one of the 'key elements' of the proposed 'Strategy for a future Chemicals Policy' (COM, 2001). Five years later, in the final REACH legislation (Regulation EC) No 1907/2006), legal requirements for feasibility analyses for substitution were, however, confined to substances of very high concern (SVHC) that are subject to authorisation (Article 55 of Regulation (EC) No 1907/2006). In all three pieces of legislation, where substitution has now been included as an element of authorisation procedures (REACH, biocidal products and PPPs), hazardous properties of chemicals serve only as a trigger for considerations for substitution, but are considered insufficient for decision making. Instead, comparative risk assessments of products have to be conducted as the basis for substitution decisions, which is novel and challenging.

Conventional risk assessments for individual PPPs, as they have been established under the old Directive 91/414/EEC, aim to ensure that regulatory acceptable exposure levels are not exceeded, but they do not provide incentives for reducing risks any further. This is changed by the complementary instrument of comparative risk assessment which supports a process of continuous improvement by identifying those PPPs that allow to achieve a desired purpose

[1] Part of this chapter has been published as Faust et al 2014.

with minimal risks at a given point in time. This is particularly favourable for environmental risks, where the authorisation requirements still allow tolerating temporary adverse effects as acceptable. Moreover, acceptable exposure levels for many pesticides on the market are only achievable by applying risk mitigation measures, such as protective equipment for workers or buffer zones between sprayed agricultural land and surface waters. Such measures may fail accidentally or may be disregarded negligently. Substitution of such products by alternatives that require fewer or less restrictive risk mitigation measures is therefore desirable and shall be supported by the new instrument of comparative assessments.

While the intended improvements are clear, the detailed procedures and methodologies for applying the substitution principle are not. Only in the Nordic countries, in particular in Sweden, the principle has been included in the national chemicals legislation since the beginning of the 1990s (KEMI, 2000). Other EU Member States (MS) have no comparable legislative tradition. Against this background, there is high uncertainty about potential impacts of this new element of EU pesticides legislation and the best way towards its efficient implementation.

3.2 Candidates for substitution (CFS)

Plant protection products contain one or more active substances. Under EU law, PPPs are authorised on the Member States level, while active substances are approved on the Community level. Approved active substances are included in a positive list established by the European Commission. Member States shall not authorise PPPs that contain active substances other than those on the positive list. Authorisations are only granted for specified uses, usually defined by a combination of a crop and a targeted pest.

The revised legislation now requires that certain active substances shall be approved by the European Commission only as 'candidates for substitution' (CFS), and listed separately from other approved active substances. Member States shall not grant authorisation to PPPs that contain such CFS, if a comparative assessment reveals that a significantly safer alternative is available for the same use.

CFS are active substances that have one or more of the hazardous properties listed in Table 1. As laid down in the PPP Regulation, their identification constitutes one task within the regular assessment of active substances on Community level. In order to speed up the process for the already approved active substances, an obligation for the European Commission (COM) was included in the PPP Regulation to establish an initial list of CFS until the end of 2013. However, completion of this task was delayed by more than a year, and the official list only became available after the project work had been finalised.

Table 1: Criteria for the identification of active substances as candidates for substitution (CFS)

No	Legal text (Regulation (EC) No 1107/2009, Annex II, point 4) [1]a	
1	—	its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories
2	—	it meets two of the criteria to be considered as a PBT substance
3	—	there are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones)
4	—	it contains a significant proportion of non-active isomers
5	—	it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3b
6	—	it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4b
7	—	if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties that may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5b,c

a The criteria apply independently, i.e. a CFS meet one or more of them.
b Points 3.6.2 to 3.6.5 of Annex II of Regulation (EC) No 1107/2009 [1] define hazard-based criteria for substances that must not be approved, so-called cut-off criteria.
c For endocrine disrupters, currently the interim criteria laid down under Point 3.6.5 of Annex II of Regulation (EC) No 1107/2009 [1] apply, i.e. substances classified as carcinogenic category 2 and toxic for reproduction category 2.

3.3 Comparative assessments

In the future, EU Member States shall perform a comparative assessment whenever they evaluate any application for authorisation of a PPP that contains a CFS, in the following shortly denoted as candidate product. A comparative assessment may be initiated by an application for the authorisation of a new candidate product, for the renewal of an existing authorisation, or for the amendment of an authorisation for new uses of a candidate product. Comparative assessments must be performed for each use of a candidate product. A candidate product shall not be authorised for a use for which an alternative chemical product or a non-chemical control method is available, if the following requirements are fulfilled (Article 50 in conjunction with Annex IV of the PPP Regulation):

(i) experience from practical use of the alternative is available,

(ii) the alternative has a comparable efficacy against target pests,

(iii) the alternative can be used without significant economic or practical disadvantages, including impacts on so-called minor uses,

(iv) the substitution does not compromise resistance management and the minimisation of the occurrence of resistance, and

(v) the alternative product or method is 'significantly safer for human or animal health or the environment'.

Thus, the comparative assessment can be divided into two major parts: a comparative agronomic assessment covering points (i) to (iv), and a comparative safety assessment as required by point (v). This project focused on the safety assessment part. In addition, it does not discuss comparisons of chemical PPPs with non-chemical protection methods (e.g. mechanical methods or bio-pesticides such as viruses and bacterial strains).

Annex IV to the PPP Regulation clarifies that the increase in safety that is achieved by a substitution shall be demonstrated in terms of a 'significantly lower risk'. In general, competent authorities shall identify such significant differences in risk 'on a case-by-case basis'. A significance level is not specified for the comparative human health risk assessment but for the environmental risk assessment: 'if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk' (Regulation (EC) No. 1107/2009).

For conducting the agronomic part of the comparative assessments, guidance has been developed by EPPO, the European and Mediterranean Plant Protection Organization (OEPP/EPPO 2011). For the risk assessment part, COM is currently working on a guidance document, based on a proposal by Sweden (COM 2014). This guidance aims to support the Member States but it will not establish detailed and legally binding rules. Basically, it will be up to the decision of the Member States how they actually conduct comparative risk assessments.

3.4 Project goals and approach

The central goals of the project are

(i) to identify the upcoming the number of cases for comparative assessments that regulatory authorities may have to face,

(ii) to devise a strategy for comparative environmental risk assessments of plant protection products that relies on available data,

(iii) to investigate the suitability of the proposed strategy for actual cases,

(iv) to derive recommendations for the establishment of a regulatory process that accommodates for the novel goal of chemical substitution.

When realising the goals in a systematic way, we initially had to overcome the lack of an established list of candidates of substitution, and consequently had to tackle the ignorance regarding the PPPs for which alternatives will have to be considered. The project approach also had to accommodate as much as possible results from those parallel initiatives by the EU and other institutions through iterative efforts on our side. In a stepwise manner we first undertook to identify potential candidates for substitution for active substances approved at the EU level. For identifying candidates for substitution, a list of respective criteria concerning both human and environmental risks is described in the Annex II, point 4 of the Regulation (EC) No 1107/2009. Out of this list, this project was asked to focus on the substitution criteria relevant for the environment namely a candidate for substitution is any active substance if it meets two of the criteria to be considered as a PBT substance.

Subsequently, it was undertaken to obtain an overview about plausible numbers and types of plant protection products (PPPs) that may become subject to comparative assessments in the future due to the presence of yet to be defined candidates for substitution. Also, it was tried to anticipate the distribution of these potential candidate products over the different intended

uses in order to anticipate for which cases comparative risk assessments will have to be conducted. The guiding hypothesis was that any restriction in the scope or number of potential cases for comparative assessment could help to simplify the foreseeable tasks of comparative environmental risk assessment. This analysis was carried out for Germany as an example. Further, we set out to collate possible alternatives without candidates for substitution. From parallel activities at EU level regarding the identification of candidates for substitution, we had different information during the analysis phase and decided to focus our comparison regarding products that may be considered as potential alternatives on those that do not contain candidates for substitution irrespective of whether they derive from environmental or human hazard indications. This was done in order to minimise possible confusion.

From the absence of guiding principles for comparatives assessment of environmental risks of PPPs at the start of the project, it followed that these steps had to be performed within the project prior to actually developing an approach for comparative assessment. We analysed the literature and the meanwhile available EU draft guidance document for methods of comparative risk assessment and then derived generic principles for comparative environmental risk assessment of products. The principles were to be operationalised and to be tested for several selected cases of authorised plant protection products for their applicability. From the experience with the cases studies we generated recommendations for a future process organisation of comparative environmental risk assessment.

4 Potential candidates for substitution

Introductory Note

All data compilations and data analyses documented in sections 4.1 to 4.7 of this chapter were completed in spring 2013. They provided a list of 33 possible candidates for substitution (CFS). As detailed in section 4.8, the work was updated when an extended list of 98 potential CFS became available during the second half of 2013 as a result of a contract study prepared for the European Commission (FCEC 2013). All subsequent data analyses in this project were based on that extended list and were completed before the end of 2014. The final official list of 77 CFS was published by the European Commission in March 2015 only and hence could not be included in the analyses performed for this project. A brief indication of the differences between the draft list of 98 potential CFS used for this project and the final official list of 77 CFS is given in section 4.9 of this chapter.

4.1 Task description

This chapter summarises the results of the first project work package which aimed to identify and to characterise active substances of PPPs which are of concern for the environment according to the criteria laid down in Annex II, point 4, of Regulation (EC) No 1107/2009 and thus were to be considered as possible candidates for substitution (CFS). This list of identified potential substitution candidates served as a training set for the development of a strategy for comparative assessment in the subsequent working steps. At the time of project start in November 2012, the generation of the official initial list of candidates for substitution by the European Commission was underway, but it did not become available before completion of all data analyses performed in the project by the end of December 2014 (Regulation (EC) No 1107/2009, Art 80 formulated a deadline as of December 2013). For the purposes of this project, it was therefore necessary to identify active substances of environmental concern that were likely to become official candidates for substitution from the end of 2013 onwards.

For identifying candidates for substitution, a list of respective criteria concerning both human and environmental risks is described in the Annex II, point 4 of the Regulation (EC) No 1107/2009. Out of these criteria, the present report focuses on the substitution criteria relevant for the environment, first of all the condition that "... a candidate for substitution [...] meets two of the criteria to be considered as a PBT substance ...". Rules for deciding whether an active substance actually fulfils the criteria for persistence (P), bioaccumulation (B), and/or toxicity (T) were derived from Annex II point 3.7.2 of Regulation (EC) No 1107/2009 and from the DG SANCO working document on "Evidence needed to identify POP, PBT and vPvB properties for pesticides" (COM 2012), which summarises the results of an expert meeting convened by the European Commission for the purpose of establishing the above mentioned initial list of candidates for substitutions.

A second CFS criterion with environmental relevance was not specifically considered for the purposes of this project, namely "critical effects (...) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; (...)". This criterion was found very difficult to interpret and it was concluded that it probably could only be meaningfully applied retrospectively on the basis of post-marketing experience (e.g. groundwater monitoring results) gathered for authorised PPPs on the Member States level, but not prospectively on the basis of the dossiers provided for approval active substances. As a consequence, it was expectable that the establishment of the initial CFS list by the European Commission would not include any

substances identified (exclusively) on the basis of this criterion. Furthermore, to our knowledge there were no initiatives of the Member States to nominate any additional CFS on the basis of groundwater monitoring results or similar relevant findings from post-marketing studies.

In order to identify potential substitution candidates, we firstly selected a list of chemicals that were approved for use as active substances of PPPs in the EU at the status of November 2012, secondly we retrieved data related to their persistence, bioaccumulation potential, and toxic properties and compiled them in a database, and thirdly we used this database to identify and characterise possible candidates for substitution.

In this chapter thus, (i) the selection of active substances of PPPs is described (section 4.2), (ii) the used data sources for database enquiries are presented (section 4.3), (iii) the established active substances database and the data enquiry strategies are explained (sections 4.4 and 4.5), (iv) the results of the data enquiry such as the amount of retrieved data is analysed (section 4.6), and (v) in the last section, the resulting set of potential candidates for substitution is characterised (section 4.7).

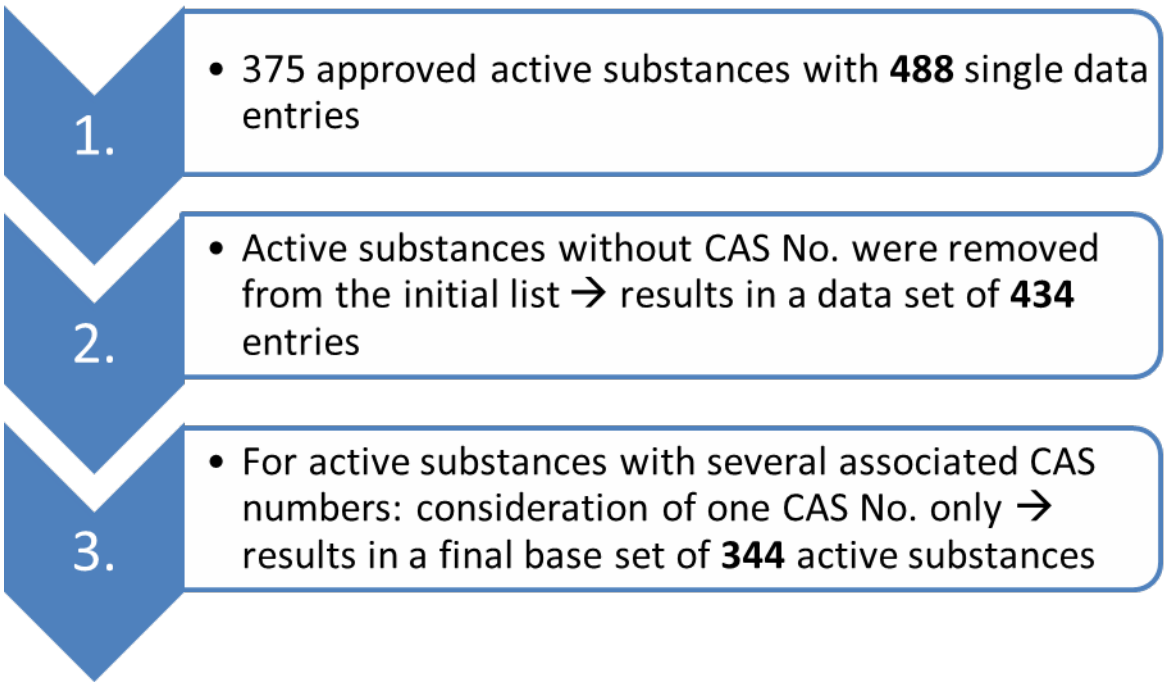
These working steps were completed in April 2013. A couple of months later, the results of a contract study became available to EU Member States' authorities, which the European Commission had commissioned in order to prepare the establishment of an initial official list of substitution candidates. Consequently, we compared our list of potential substitution candidates with the results from that contract study. The outcome of that comparison is documented in section 4.8. Finally, a brief summary of the entire exercise is given in section 4.9.

4.2 Selection of active substances approved for use in plant protection products

At the time of project start in November 2012, a total of 375 active substances were approved for use in authorised PPPs on the EU market. Legal definitions of approved active substances include groups of chemicals with different CAS numbers, such as isomers and derivatives of a parent compound. Disaggregation of these groups resulted in an initial total of 488 single data entries. This list was further processed as visualised in Figure 1.

In a first step, we excluded 54 data entries for bio-pesticides which do not have a CAS No assigned, such as viruses and bacteria. This reduced the initial list to a set of 434 entries. In a second step, a single representative parent compound with a single CAS No was selected in all cases where the legal approval refers to a group of similar compounds. This reduced the list by further 90 compounds to a final base set of 344 active substances for subsequent consideration.

Figure 1: Scheme for the selection of active substances, used for data enquiry and building the base set for the identification of potential substitution candidates.



4.3 Sources of P-, B-, and T-data on active substances

A data enquiry relating to the P-, B-, and T-properties, the classification of substances in terms of pesticide use groups and chemical substance groups, and the log K_{OW} of the 344 selected active substances was carried out with the aim to identify and characterise possible substitution candidates. The data relating to the P-, B-, and T-properties were retrieved from four publically available data sources: (1) the Footprint Pesticide Properties Database (PPDB), (2) the European Chemical Substances Information System (ESIS), (3) the EU Pesticide database, and (4) the assessment reports provided by the European Food Safety Authority (EFSA). In the following, these data sources are described briefly.

PPDB database (1)

The Pesticide Properties database (PPDB) is a comprehensive publicly available database of physicochemical and ecotoxicological data for pesticides. It has been developed by the Agriculture and Environment Research Unit (AERU) at the University of Hertfordshire with additional input from the EU-funded project FOOTPRINT (Sixth EC Framework Program).

ESIS database (2)

The European chemical Substances Information System (ESIS) is a platform of the former European Chemicals Bureau and combines different databases. Information on physicochemical properties of chemicals, data from scientific projects, IUCLID chemical data sheets, and CLP information are available on this platform.

EU Pesticides database (3)

The EU Pesticide database, summarising information from the authorisation process of PPPs, is made available through the European Commission for the purpose of informing the public. It is regularly updated.

EFSA provision of documents (4)

In compliance with relevant legislative framework, the European Food Safety Authority (EFSA) provides access to the documentation of risk assessments submitted by rapporteur Member States responsible for the peer review of active substances used in plant protection products. An online request form needs to be submitted for each active substance in order to receive an email providing access to the respective documentation.

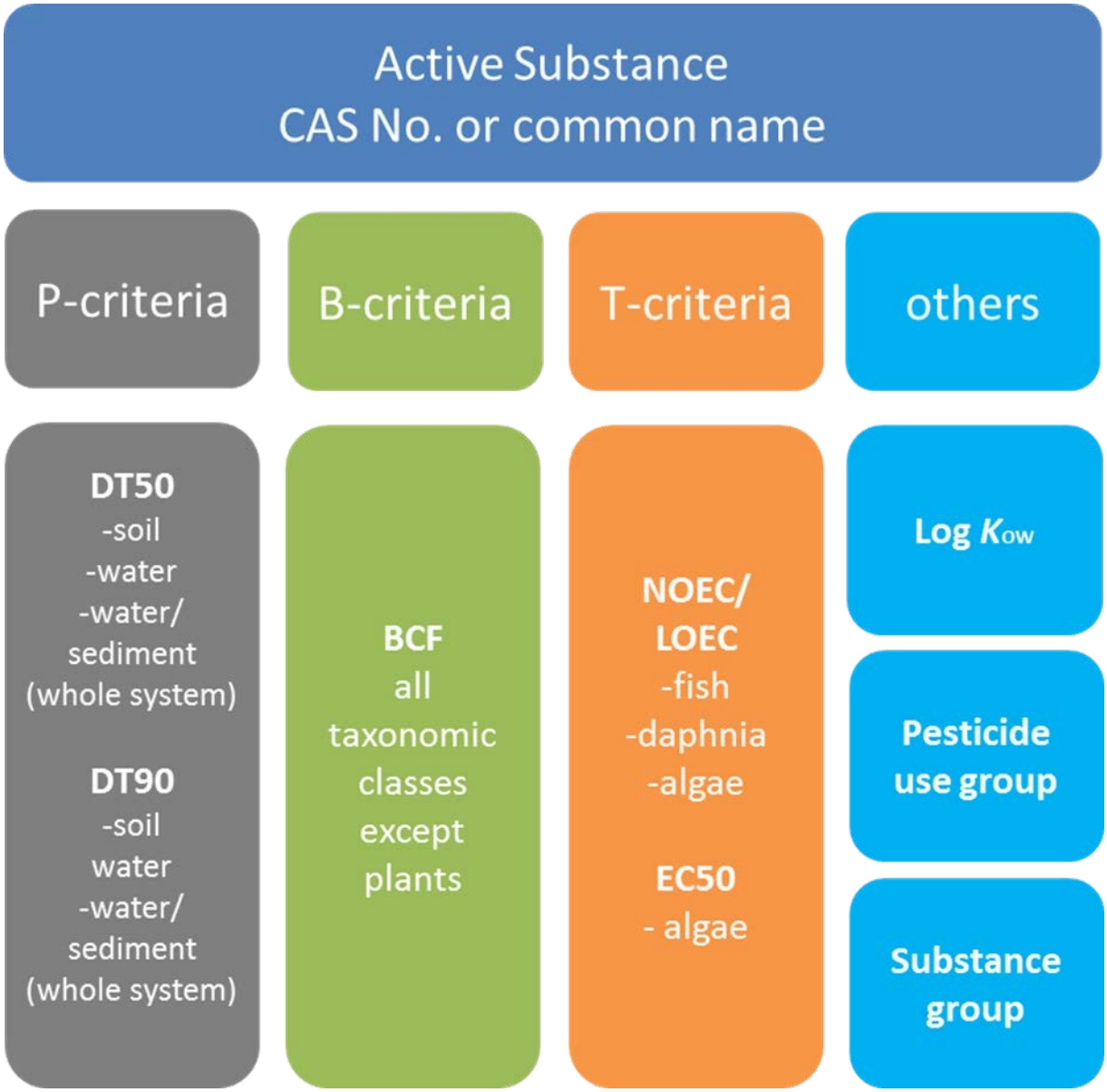
We followed a stepwise approach for the data retrieval, searching the data sources in the above mentioned order. In case that the required data for an active substance was already found in the first, second or third database, no further inquiry of the subordinated data source(s) were performed. For searches in the PPDB and ESIS databases, the active substances were identified by CAS No and confirmed by common names. For searches in the EU pesticide database as well as in the EFSA documents, the common name of the active substance had to be identified from a list of substances and the CAS No was retrospectively compared with the data file of the active substance.

4.4 Structure of the database

All compiled information was included in a database. The database was established by using the relational database management system Microsoft Access. In the Access database we created four tables (Access tables 1 to 4) which are unambiguously related to each other through a primary key, i.e. a unique number assigned to each of the 344 active substances in the database.

Next to the primary key, Access table 1 includes general information about CAS No, pesticide use group according to Regulation (EU) No 540/2011, chemical substance group, and the octanol-water-partition coefficient log K_{ow} (Footprint Pesticide Properties database). Access tables 2, 3, and 4 include data on persistence, bioaccumulation, and toxicity, respectively. In addition, information on data sources (1=PPDB, 2=ESIS, 3=EU Pesticides database, 4=EFSA) and enquire dates were included in all tables. Any relevant supplementary information was stored in commentary fields, such as specifications of values (e.g. worst case value or calculated value) or observed inconsistencies in CAS numbers given in the data sources. An overview of the retrieved data is shown in Figure 2.

Figure 2: Data enquired for the active substances database.



4.5 Procedure for data enquiry

In the following, the P-, B-, and T-criteria and their specification in the context of CFS identification under Regulation (EC) No 1107/2009 are briefly described. In addition, the search strategies are explained which were followed for obtaining a reproducible, consistent, and robust data basis for the identification of active substances that fulfil two of PBT criteria.

4.5.1 Persistence of a compound

Persistence of a substance may be understood as the duration of time necessary for a complete degradation of an active substance and its metabolites into harmless products (Shoemaker and Harris, 1979). For regulatory purposes it is defined as the time necessary for the degradation or the dissipation of 50% (DT50) or 90% (DT90) of the active substance originally applied (Craven

and Hoy, 2005). It is the result of the sum of transformation, degradation, and mineralisation processes such as microbial degradation, chemical hydrolysis, and photolysis (COM 2000). Persistence is dependent on the environmental compartment in which degradation takes place as well as the corresponding environmental factors such as soil composition and moisture, temperature, aerobic or anaerobic conditions or soil depth (Craven and Hoy, 2005). Therefore, Regulation (EC) No 1107/2009 defines different benchmark values for the three compartments soil, water, and sediments, and differently for fresh and marine waters and sediments, respectively. An active substance which exceeds at least one of these limits is considered to be persistent.

Criteria according to Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 of the European Parliament and of the Council lays down approval criteria for active substances, including requirements relating to the ecotoxicology and fate of active substances in the environment. The criteria for persistence are defined in terms of cut-off values fixed in Annex II, point 3.7.2.1. An active substance is considered to be persistent if:

- the half-life in marine water is higher than 60 days,
- the half-life in fresh or estuarine water is higher than 40 days,
- the half-life in marine sediment is higher than 180 days,
- the half-life in fresh or estuarine water sediment is higher than 120 days, or
- the half-life in soil is higher than 120 days.

Enquiry strategy

Persistence data were collected for soil, water, and whole water/sediment test systems. DT50 values for sediment were not available. Several search criteria were defined for the data enquiry in order to obtain a consistent data set.

Indicators for persistence were DT50 or DT90 values obtained under aerobic conditions at 20°C (or normalised to 20°C) in laboratory studies. If both DT50 and DT90 values were listed in a database, preference was given to DT50 values, following the guidance given in the Draft SANCO Working Document on "Evidence needed to identify POP, PBT and vPvB properties for pesticides" (COM 2012). For the retrieval of data from the PPDB database the following order of priority was used: (i) DT50 (lab at 20°C), (ii) DT90 (lab at 20°C), and (iii) DT50 (typical). For the comparison with the limit values defined in the Regulation (EC) No 1107/2009, DT90 values were divided by 3.32 (ln10/ln2), in correspondence with the Draft SANCO Working Document (COM 2012)[2]. The entry of a recalculated DT90 value in the database was recorded in the commentary field. Field dissipation studies have been excluded from the assessment, because temperature and moisture conditions during those studies were usually not documented with the data, thus not allowing normalisation to standard conditions. Kinetic models used for the derivation of DT50 or DT90 values were often not specified in the databases used. As a consequence, possible deviations from single first order kinetics could not be considered and DT50 and DT90 values were entered in the database without any correction factor. In accordance with the guidance provided in the SANCO Working Document (COM 2012), we did

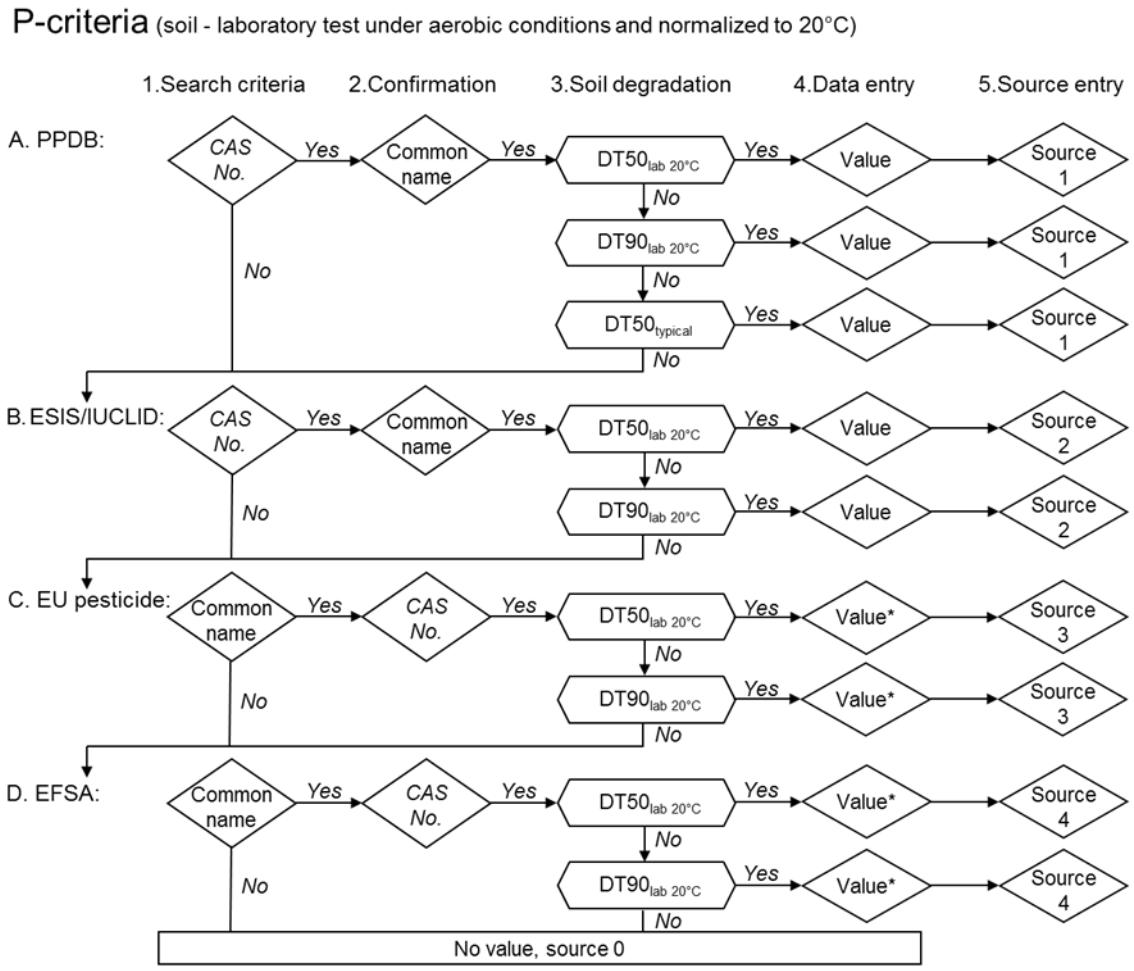
[2] The recommendation in the SANCO document is for biphasic kinetics, but the approach was used for all values since the type of the kinetic was not stated in the databases

not include metabolites or non-extractable residues in the assessment of persistence. Furthermore, data from photolysis, hydrolysis, and biodegradation assays were not taken into consideration. Where several values were available for the same endpoint, the geometric mean was calculated and entered in the database for water, whole water/sediment systems and soil, respectively, as proposed in the SANCO Working Document (COM 2012). Where studies provided a range of DT50 or DT90 values, the highest value (worst case) was selected as data entry. The range was recorded in the comment field for the corresponding data field.

Regulation (EC) No 1107/2009 defines different threshold values for persistence in fresh and marine waters and sediments. However, the type of water is usually not specified in the databases used. For this reason, a differentiation between fresh and marine water studies was not possible. Since tests with marine waters and water/sediment systems are, however, no standard requirements under the PPP regulation, there are good reasons to assume that the majority of the data has in fact been generated in freshwater studies. Therefore, the more conservative limit values for freshwater and freshwater sediments were chosen for the decision on persistence or non-persistence of a compound. DT50 values compiled for the water phase refer to the dissipation of the active substance (also denoted as DissT50)[3], which may result from its transfer into the sediment and/or degradation, while the DT50 values for the whole water/sediment test systems indeed indicate the degradation of the active substance in the whole system (also denoted as DegT50). These different meanings of the data were taken into consideration during the assessment procedure as described in detail in section 4.6.1 below. The stepwise procedure applied for the search of persistence data using the four different data sources is shown in Figure 3 for soil and in Figure 4 for water and whole water/sediment systems.

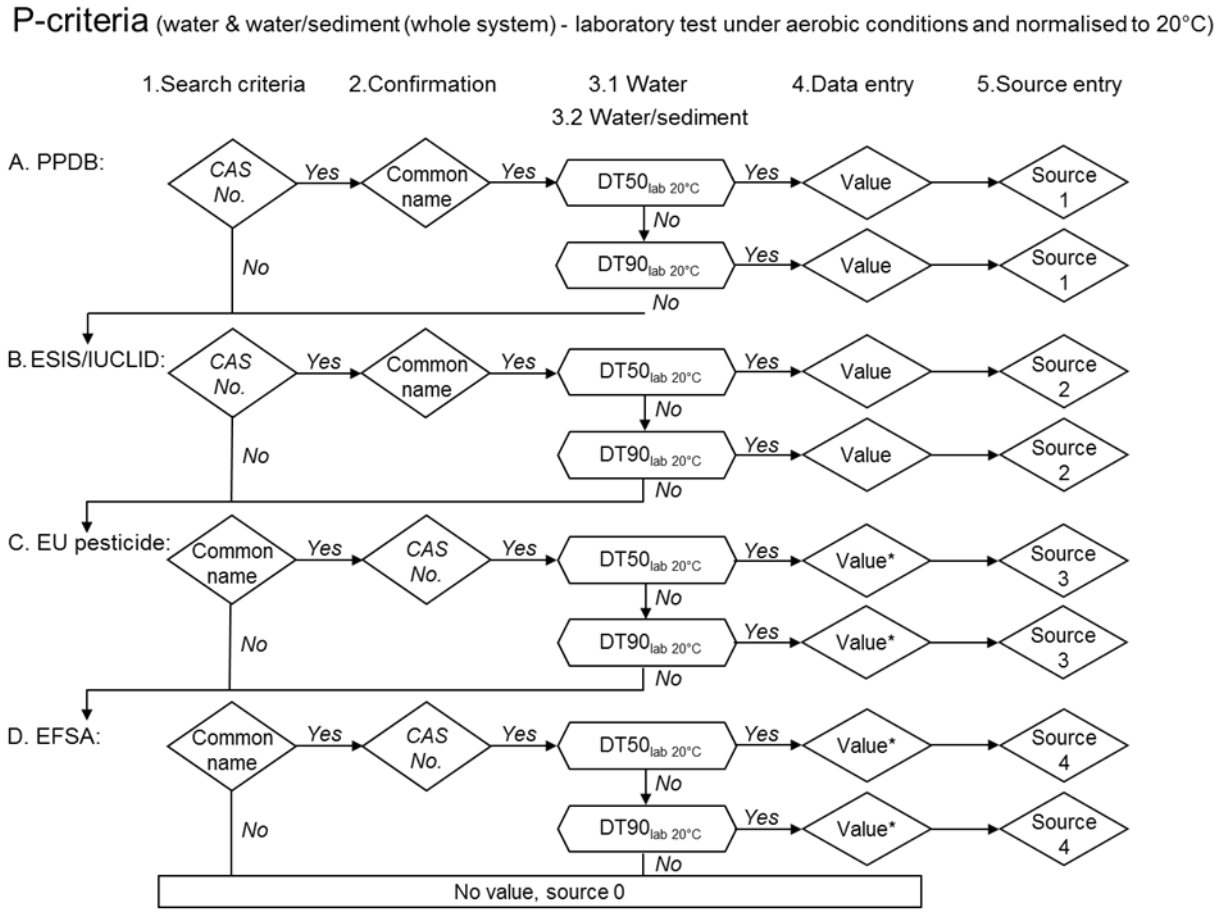
[3] DT50 values for sediment were not available, and if available in exceptional cases they would also refer to dissipation

Figure 3: Flow chart for the procedure of data retrieval for persistence data for the soil compartment.



* = if several values were listed, the geometric mean was calculated and entered in the database.

Figure 4: Flow chart illustrating the search for data on persistence in water and whole water/sediment systems.



* = if several values were listed, the geometric mean was calculated and entered in the database.

4.5.2 Bioaccumulation of a compound

Bioaccumulation of a compound is generally referred to as a mass transfer process in which the chemical concentration in an organism achieves a level that exceeds that in the ambient media (Gobas et al. 2009).

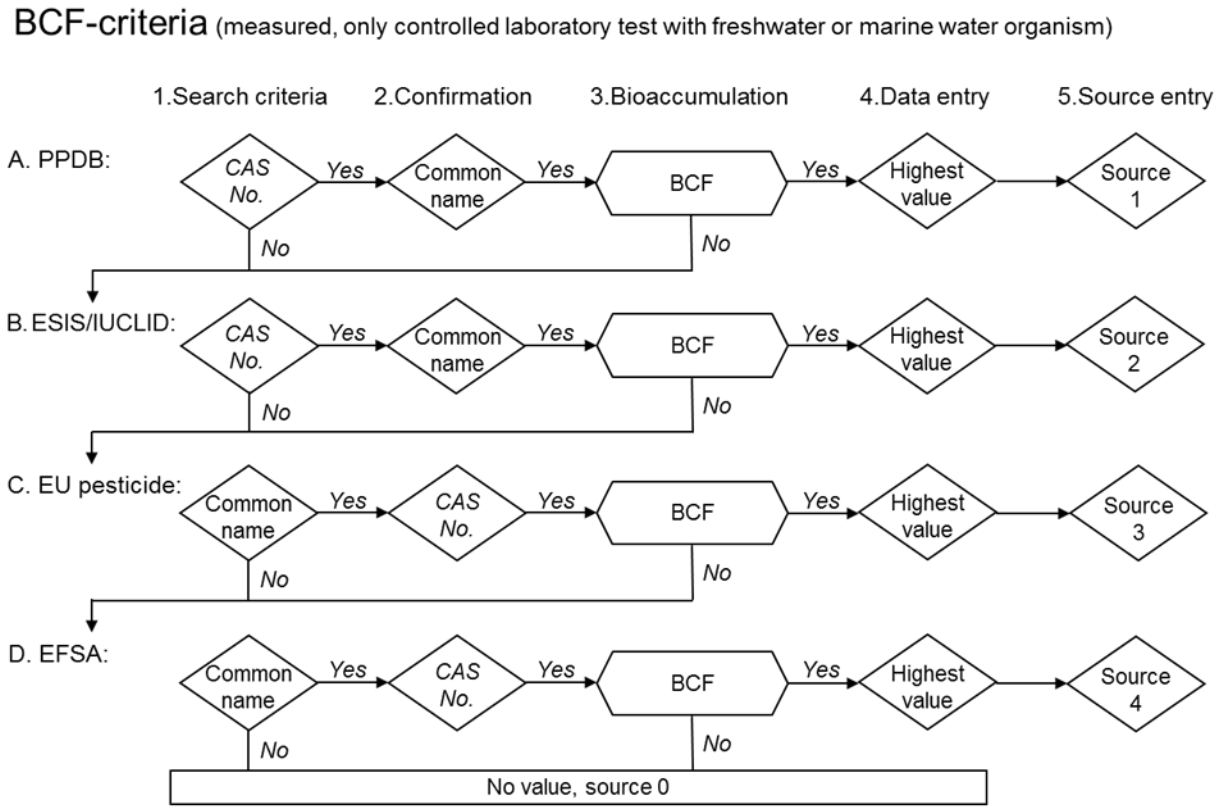
Criteria according to Regulation (EC) No. 1107/2009

According to the Regulation (EC) No 1107/2009, section 3.7.2.2, an active substance is assessed to be “bioaccumulative”, if the bioconcentration factor exceeds a value of 2000. The bioconcentration factor (BCF) is defined as the ratio of the steady state chemical concentration in an aquatic organism and the ambient medium (Gobas et al. 2009). To evaluate the bioaccumulation potential of an active substance under the PPP Regulation (EC) No 1107/2009, measured BCF values for fresh and marine water organisms were considered. However, a bioconcentration study only has to be conducted in a controlled laboratory experiment when a significant potential of the active substance to bioaccumulate is expectable. For this, a log $K_{OW} > 3$ is generally used as the trigger value (COM 2002).

Enquiry strategy

Bioaccumulation data for the 344 active substances were collected by using the four different databases described in section 3. In case of more than one bioconcentration factor being listed in the databases, we used the worst case value as a conservative estimate. If no bioconcentration factor for an active substance was found in all four databases, the log K_{ow} value was used to check whether a bioconcentration study should have been required in the regulatory context. The stepwise procedure applied for the search of bioconcentration data is depicted in Figure 5.

Figure 5: Flow chart to illustrate the procedure of data search for the bioaccumulation criterion in fresh or marine water organisms.



4.5.3 Toxicity of a compound

As described in the introductory section, considerations of the toxicity criterion were confined to ecotoxicological effects; human toxicity was out of scope. According to the Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC (COM 2002), eco-toxicity evaluation in the standard risk assessment procedure includes both long-term and acute tests with fish, aquatic invertebrates, sediment-dwelling invertebrates, and aquatic plants. With respect to the PBT criteria as defined in Annex II, point 3.7.2 of Regulation (EC) No 1107/2009, however, the ecotoxicity assessment refers only to long-term ecotoxicity studies with marine or freshwater organisms.

Criteria according to Regulation (EC) No. 1107/2009

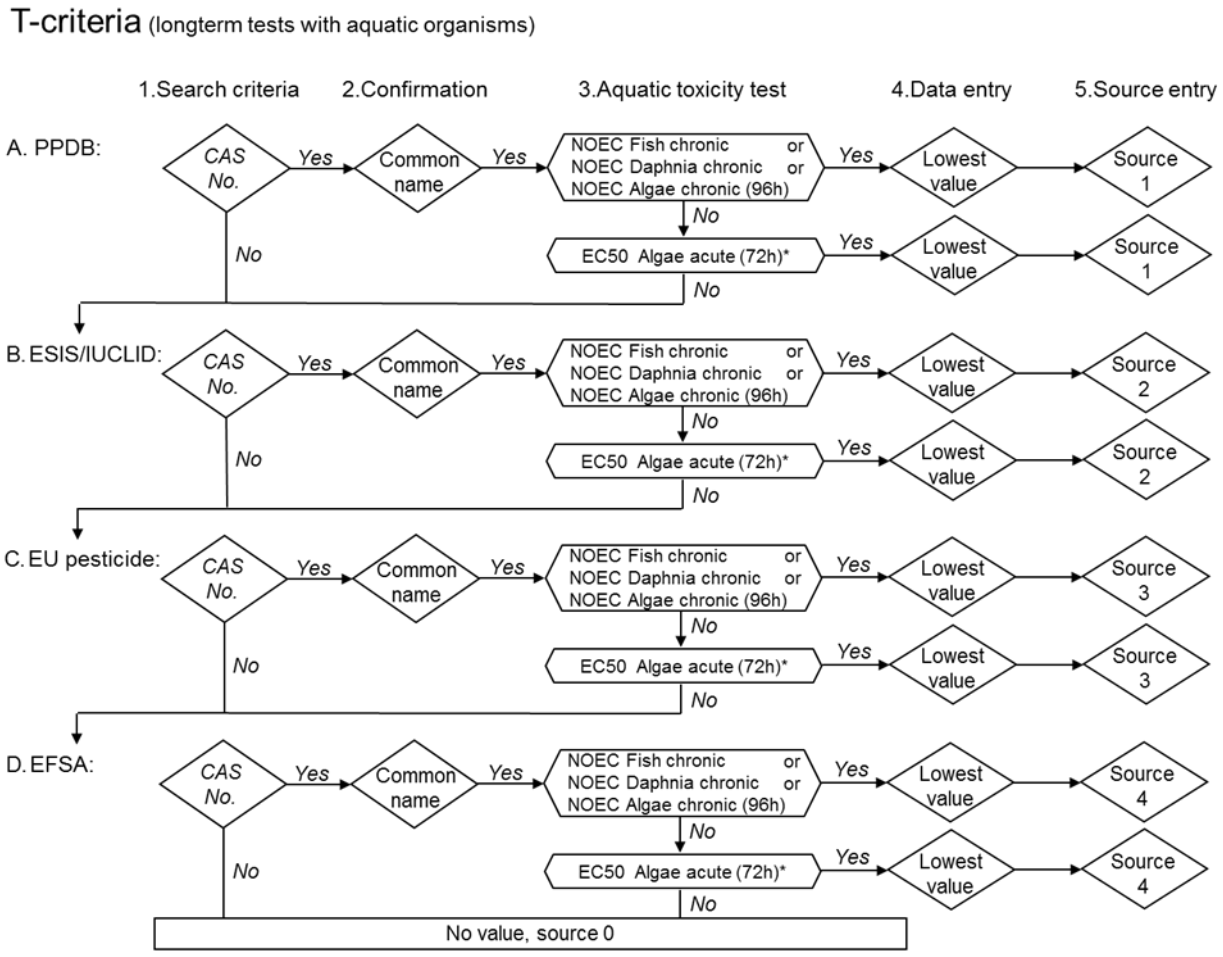
According to regulation (EC) No 1107/2009, an active substance is defined to be toxic, if the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/L. Additional guidance for the corresponding use of available data was provided and specified in the DG SANCO Working Document (COM 2012) as follows: In the absence of a relevant NOEC value, a median effective concentration (EC50 value) can be used with an assessment factor of 10 instead. When assessing the standard endpoints from algae studies, the values should be based on growth rate only rather than on biomass/yield.

Enquiry strategy

Toxicity data for all 344 active substances were retrieved from the four different data sources described in section 4.3. The stepwise procedure applied for the enquiry on the toxicity data is depicted in Figure 6. Long-term (chronic) NOEC values from fish and daphnia[4] studies and NOECs from 96h algae studies based on growth as an endpoint, and if not available EC50 values of 72h algae studies based on growth as endpoint, were searched for. If only LOEC (lowest observed effect concentration) values were available, which was true for very few cases only, then the LOEC values were retrieved. From the available fish, daphnia, and algae studies, the lowest of the available values was chosen (worst-case) and entered into the database. Additionally, the respective test species, test duration, data source, and the date of the enquiry were documented in the database. If the NOEC was smaller than 0.01 mg/L, the active substance was considered as having positively fulfilled the toxicity criterion. For EC50 values from 72h algae tests an assessment factor of 10 was applied to calculate an estimated NOEC.

[4] Concerning toxicity to aquatic invertebrates, the data available in the databases searched for the substances of concern exclusively referred to Daphnia magna.

Figure 6: Flow chart to illustrate the search for toxicity data for freshwater or marine water organisms.



* = An assessment factor of 10 was applied to EC50 values from 72h algae tests for establishing estimated NOECs.

4.6 Results of the data enquiry

4.6.1 Persistence criterion

Degradation and dissipation half live values (DT_{50}) were collected and retrieved for soil, water, and whole water/sediment systems.

Soil persistence values were found for 300 out of 344 active substances resulting in a database filling degree of 87.2% (Table 2). The majority (96%) of the data were taken from the PPDB database, eight values were derived from the EFSA documents, three from the EU Pesticides database and one from the ESIS database. For 44 active substances no soil DT_{50} values were found in any of these information sources, resulting in a lack of data for 12.8% of the compounds.

For water and whole water/sediment systems only for 272 and 270 of the 344 active substances DT_{50} values were found, respectively, resulting in a filling degree of about 79%. Again, the majority of the data were taken from the PPDB database (91.1 to 91.2%). No additional values were found in the ESIS database. A total of eight water DT_{50} values were taken from the EU

pesticides database and 16 values came from EFSA documents. For water/sediment systems seven values were derived from the EU pesticides database and 17 from the EFSA documents.

For 41 active substances no DT_{50} values for soil, water, as well as whole water/sediment systems could be found. For 32 of these active substances persistence is not relevant, because they are natural products such as phytohormons (e.g. chlormequat; CAS No. 7003-89-6), naturally occurring minerals (e.g. sodium aluminium silicate; CAS No. 1344-00-9) or natural constituents of plants or soil (e.g. indolylbutyric acid; CAS No. 133-32-4). No data are required in these cases to obtain approval of the active substance. Furthermore, two of the active substances are used as ingredients of waxes (e.g. 2,5-dichlorobenzoic acid methylester; CAS No. 2905-69-3); from such uses, no significant environmental exposure is expected to result and studies to obtain DT_{50} values are not required. For sodium hypochlorite (CAS No. 7681-52-9) no studies were available due to the rapid breakdown, and also not for sulfuryl fluoride (CAS No. 2699-79-8), because it is a permanent gas and will partition into the atmosphere. Only five out of the 41 missing data cannot be explained.

Table 2: Filling degree for DT50 data for the total of 344 actives substances resulting from the consecutive search in four information sources

Data source	Soil	Water/ Sediment	Water
1- PPDB database	288	246	248
2- ESIS database	1	0	0
3- EU Pesticides database	3	7	8
4- EFSA documents	8	17	16
1 to 4 (total in all data sources)	300	270	272
lack of data	44	74	72

According to the criteria defined in the Regulation (EC) No. 1107/2009 and the corresponding guidance given in the draft SANCO Working Document (COM 2012), identification of persistent active substances from the database was done by applying the following cut-off values: for soil DT50 > 120 d, for fresh or estuarine water sediment DT50 > 120 d and for fresh or estuarine water DT50 > 40 d. For most of the retrieved DT_{50} values, no information could be gained whether the studies had been performed with fresh or marine water. Therefore, the more conservative cut-off values for freshwater were applied. All active substances with a whole system water/sediment DT50 value of less than 40 days were considered to be not persistent, because they neither meet the persistence criteria for water nor for sediment. All substances with a whole system water/sediment DT50 value of more than 120 days were considered to be persistent, because they meet the criteria for both water and sediments anyway. For all substances with an intermediate whole system water/sediment DT50 value between 40 and 120 days it was first assessed whether the degradation can be assumed to take place mainly in the water phase or in the sediment, and then the whole system DT50 value was compared with the trigger value for the relevant compartment. To this end, criteria proposed by the German UBA were applied as follows: All active substances having a water DT50 value of higher than 12 days, were assumed to remain and mainly degrade in the water phase. Therefore, their whole system DT50 was evaluated against the more conservative criterion for water (>40 d). Substances with water DT50 values of less or equal than 12 days are considered to dissipate

quickly into the sediment where accumulation takes place. It was further assumed that these substances degrade in the sediment or dissipate back into the water but reach only very small concentration levels. Consequently their whole system DT50 was evaluated based on the sediment criterion. For substances with similar water and whole system water/sediment DT50 values (± two days) the more strict water cut-off value was used for evaluation. However, this approach presupposes that always both water DT50 and whole system DT50 values are available, if this is not the case further efforts are required. In general, one can assume that the whole system DT50 value cannot be smaller than the water DT50. Consequently, the persistence criterion can be considered to be fulfilled if the available DT50 (whether water DT50 or whole system DT50) is higher than 120 days. This was the case for two active substances, namely clopyralid (CAS No 1702-17-6) and cyproconazol (CAS No 94361-06-5). For flutriafol (CAS No. 76674-21), clomazone (CAS No. 81777-89-1) and diclofop (CAS No. 40843-25-2) further information on the degradation in water and sediment was searched for justifying decisions. The information found was added to the database and the evaluation of persistence was conducted as described above. As a result, all three active substances were considered to be persistent based on the water criterion.

By proceeding this way, 117 persistent active substances were found. A total of 45 active substances exceed the cut-off value for soil (Table 3), 24 the limit for freshwater sediment, and 77 the limit for water. There were 16 active substances above the limits for both soil and water and 13 above the limits for both soil and freshwater sediment.

Table 3: Number of identified persistent active substances

Cut-off values for persistence assessment according to Regulation (EC) No 1107/2009	Soil DT50 > 120 d	Fresh water Sediment DT50 > 120 d	Water DT50 > 40 d	Total number of persistent active substances
Number of active substances meeting the criteria	45	24	77	**117**

4.6.2 Bioaccumulation criterion

Measured bioaccumulation data were searched for the whole set of 344 active substances. For 188 out of 344 active substances bioaccumulation data were available in the information sources used, resulting in a filling degree of 54.7% (Table 4). The majority (95.2%) of bioaccumulation data were taken from the PPDB database. Two bioaccumulation values were taken from the ESIS database, one from the EU pesticides database, and six from EFSA documents. Specifications of the test organisms were available for 62 of 188 data (33%). A total of eight active substances (2.3%) fulfil the criterion of a BCF > 2000.

Table 4: Filling degree for bioaccumulation data for the total of 344 actives substances resulting from the consecutive search in four information sources, and number of identified bioaccumulative active substances.

Data sources	Number of substances for which BCF data were available
1- PPDB database	179
2- ESIS database	2
3- EU Pesticides database	1
4- EFSA documents	6
1 to 4 (total in all databases)	188
lack of data	156
BCF > 2000 L/kg (cut-off value for the B-criterion according to Regulation (EC) No 1107/2009)	**8**

For 156 (45.3%) of the 344 active substances no bioaccumulation data were found. Screening of the log *K*ow was used as a simple way of checking whether a bioconcentration test should have been performed for an active substance according to legal standard requirements. In doing so, the lack of bioaccumulation data for 98 of these 156 active substances could be explained due to their low log *K*ow < 3 indicating no significant bioaccumulation potential. The reasons for the lack of bioaccumulation data in the data sources for all the remaining substances with a higher log *K*ow remained unclear.

4.6.3 Toxicity criterion

For aquatic toxicity data (chronic fish, daphnia, and algae data), a quite high filling degree (92.2%) was achieved (Table 5). Out of the 344 active substances, a lack of data was seen for only 27 compounds. 94% of the data were taken from the PPDB database. The availability of data was highest for aquatic invertebrates (119 entries), followed by algae (107 entries) and fish (79 entries).

Table 5: Filling degree for toxicity data for the total of 344 actives substances resulting from the consecutive search in four information sources

Data source	Fish	Daphnia	Algae	All species
1- PPDB database	79	112	107	298
2- ESIS database	0	0	1	1
3- EU Pesticides database	2	3	1	6
4- EFSA documents	3	4	5	12
1 to 4 (total in all databases)	84	119	114	317
lack of data				27

The high filling degree for eco-toxicity data is an obvious consequence of the legal standard requirements: tests with green algae are required in all cases, and chronic (long-term) studies with fish or daphnids must also be carried out in all cases unless it can be justified that continued or repeated exposure is unlikely to occur.

For two substances any information on ecotoxicity was missing in all four data sources examined, namely fosetyl (CAS No. 15845-66-6) and tribenuron (CAS No. 106040-48-6). The remaining data gaps resulted from cases (i) where it was stated that full data sets were not legally required (gibberellic acids, CAS No. 77-06-5, and fatty acids, CAS No. 67701-09-1), (ii) where the available data were considered to be not valid (e.g. carbon dioxide, CAS No. 124-38-9), or (iii) where only acute data for fish and daphnids and algae data not based on growth rate as endpoint were available.

For about one third (110) of the investigated active substances, NOEC values were found to be smaller than 0.01 mg/L or EC50 values were smaller than 0.1 mg/L and they were thus classified as “toxic” according to the Regulation (EC) No. 1107/2009 (Table 6).

Table 6: Numbers of active substances fulfilling the toxicity (T-) criterion according to Regulation (EC) No 1107/2009.

Cut-off values for assessment of the T-criterion according to Regulation (EC) No. 1107/2009	Fish	Daphnia	Algae	Total number of compounds over all species
NOEC < 0.01mg/L or EC50 (72h algae test) < 0.1mg/L	26	43	41	**110**

4.7 Potential candidates for substitution due to P, B, and T properties

33 (9.6%) of the investigated 344 active substances were found to fulfil at least two of the three PBT criteria. These potential candidates for substitution are listed in Table 7 together with the corresponding parameter values for persistence, bioaccumulation, and toxicity.

Table 7: Potential substitution candidates identified by the values for persistence, bioaccumulation or/and toxicity

Common name	Persistence (DT_{50} values in soil, water/sediment, water in d)			Bioaccumulation (BCF in L/kg)	Toxicity (NOEC in mg/L)	
Aclonifen	117	14.3	4.2	2896	0.005	Fish
Azimsulfuron	64.2	112	44.5	-	0.003	Algae
Beflubutamid	59.3	57	18	230	0.005	Daphnia
Bifenthrin	104.3675	161	8	1703	0.0000013	Daphnia
Chlorotoluron	59	352	42	-	0.001	Algae
Copper hydroxide	10000	-	-	-	0.009	Algae
Cyprodinil	53	142	12.5	393	0.0088	Daphnia
Deltamethrin	26.21	65	17	1400	0.0000041	Daphnia
Difenoconazole	130	1053	3	330	0.0056	Daphnia
Diflufenican	141.8	182.5	29.7	1276	0.0001	Algae
Diquat(ion)	365	-	1	-	0.011	Algae
Epoxiconazole	226	119.8	65.8	70	0.0078	Algae
Esfenvalerate	44	71	30	3250	0.000052	Daphnia
Etofenprox	16	13.3	5.7	3951	0.000054	Daphnia
Etoxazole	26.6	79.5	1.45	2900	0.0002	Daphnia
Famoxadone	45.78	0.7	0.1	3000	0.0014	Fish
Fenbutatin oxide	389	147	1	730	0.00127	Fish
Fludioxonil	239	575	2	366	0.005	Daphnia
Flufenacet	40	81	54	71.4	0.00204	Algae
Fluopicolide	271	1117	91.4	121	0.029	Algae
Fluquinconazole	347	13.7	3.5	87	0.046	Algae
Flurtamone	130	80	23	27.5	0.02	Algae
Imazamox	109.34	142	38	0.1	0.037	Algae
Isopyrazam	244	628	2.3	441	0.00287	Fish
Lufenuron	30.21	112	112	5300	0.0001	Daphnia
Oxadiazon	502	126.5	17.9	243	0.00088	Fish
Pendimethalin	123	16	4	5100	0.003	Algae
Pirimicarb	94.6	195	33.3	24	0.0009	Daphnia
Prochloraz	223.6	359	2	371	0.0055	Algae
Prosulfuron	113	130	50	0.13	0.0089	Algae
Quinoxyfen	374	127	5	5040	0.014	Fish
Spinosad (Spinosyn A)	42	176	27	114	0.0012	Daphnia
Triasulfuron	71.69	217	217	1.3	0.035	Algae

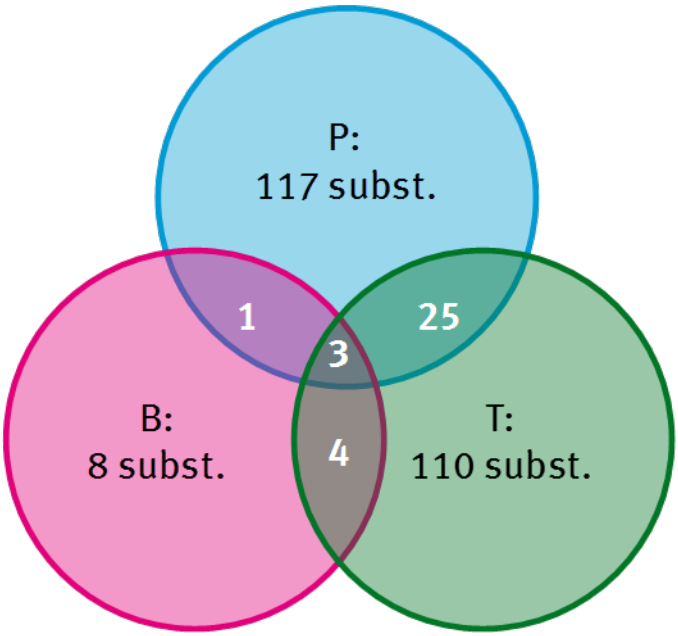
A total of 75.7% of 33 potential substitution candidates were found to meet the criteria T and P, one active substance meets the criteria B and P, and four active substances (12.2%) exceeded the trigger values for T and B. The active substances esfenvalerate, lufenuron and pendimethalin meet all three PBT criteria, according to the information sources used. The proportion of persistent, bioaccumulative and toxic active substances meeting at least two of

the criteria is illustrated by a Venn diagram in Figure 7. Table 8 summarises the criteria (BT, PT, PB, or PBT) met for each of the identified possible candidates for substitution.

Table 8: Identified potential candidates for substitution by combined P-, B-, and T-criteria.

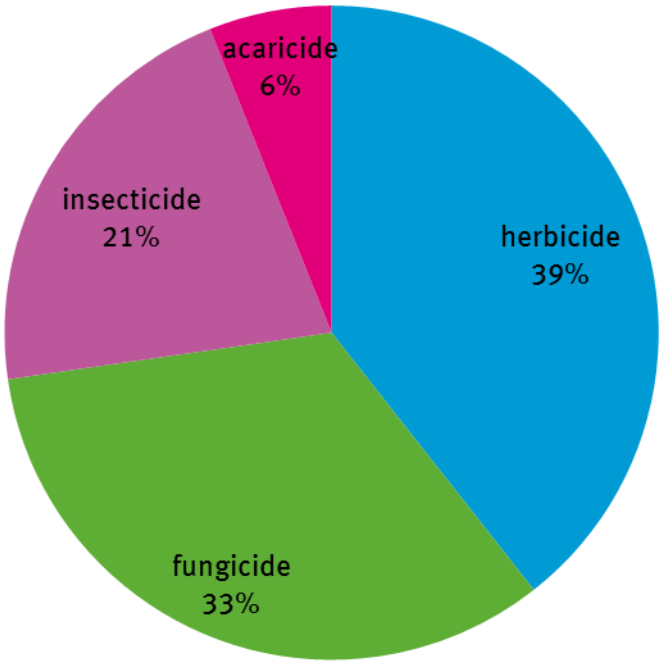
Common name	B-T	P-T	P-B	P-B-T
Aclonifen	x			
Azimsulfuron		x		
Beflubutamid		x		
Bifenthrin		x		
Chlorotoluron		x		
Copper hydroxide		x		
Cyprodinil		x		
Deltamethrin		x		
Difenoconazole		x		
Diflufenican		x		
Diquat(ion)		x		
Epoxiconazole		x		
Esfenvalerate				x
Etofenprox	x			
Etoxazole	x			
Famoxadone	x			
Fenbutatin oxide		x		
Fludioxonil		x		
Flufenacet		x		
Fluopicolide		x		
Fluquinconazole		x		
Flurtamone		x		
Imazamox		x		
Isopyrazam		x		
Lufenuron				x
Oxadiazon		x		
Pendimethalin				x
Pirimicarb		x		
Prochloraz		x		
Prosulfuron		x		
Quinoxyfen			x	
Spinosad (Spinosyn A)		x		
Triasulfuron		x		

Figure 7: Venn diagram of numbers of active substances matching the P-, B-, and T- criteria.



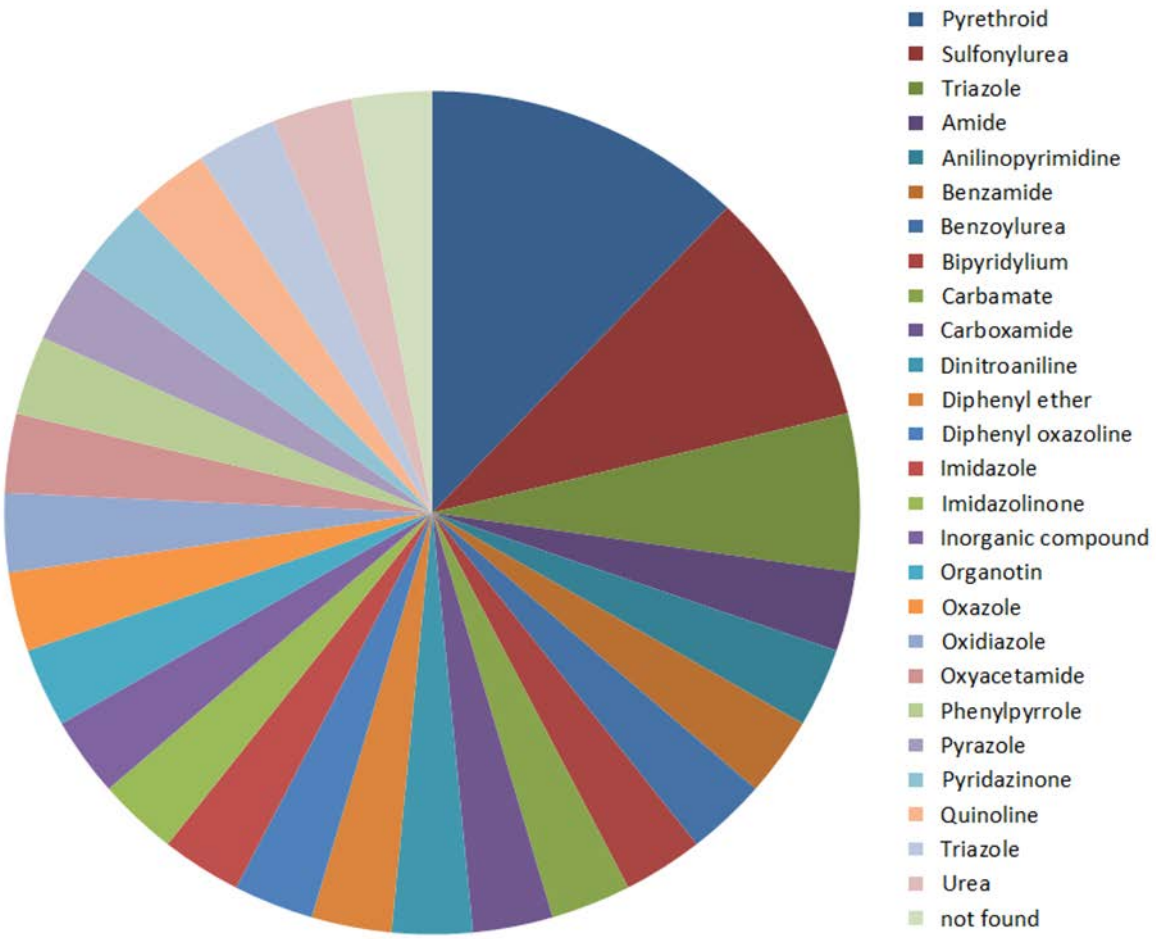
In addition, we examined the allocation of the identified potential substitution candidates to pesticides use groups. Interestingly, the 33 potential CFS are more or less evenly distributed over the three major classes of fungicides, herbicides, and insecticides plus acaricides (Figure 8, Table 9).

Figure 8: Classification of the 33 identified possible candidates for substitution by pesticide use groups.



Furthermore, we examined the allocation of the identified potential CFS to chemical substance groups. As illustrated in Figure 9, the identified 33 potential CFS represent a broad spectrum of 27 different chemical substance groups (Table 9). Most of these substance groups were represented by only one active substance in the dataset. Three substances belong to the group of sulfonylurea compounds, three to the triazoles group, and four are pyrethroids. Thus, chemical grouping has little to no indicative value for the identification of possible CFS.

Figure 9: Classification of the 33 identified possible candidates for substitution by chemical substance groups



Finally, we examined the lipophilicity of the potential CFS. As shown in Table 9, 25 of the 33 identified possible candidates for substitution have a log *K*ow ≥ 3, which is 75.8%. This proportion is high in comparison to the whole data set, where 140 out of 344 active substances have a log *K*ow ≥ 3, which is 41 % only. A high log *K*ow may therefore be considered as an alert for an active substance to become a candidate for substitution. This is not astonishing as a high lipophilicity is correlated with both a high potential for bioaccumulation (B-criterion) and a slow degradation due to strong sorption to organic material (P-criterion).

As CFS properties do not seem to be associated with specific use groups or chemical substance classes, it may be assumed that enforcement of the substitution in principle might be a viable

option, because there is a chance that for any of the possible substitution candidates an alternative from the same pesticide use group could already be available.

Table 9: List of potential substitution candidates allocated to chemical substance groups and pesticides use groups, and their log Kow.

CAS No.	Common name	Chemical substance group	Pesticide use group	Log Kow
74070-46-5	Aclonifen	Diphenyl ether	herbicide	4.37
120162-55-2	Azimsulfuron	Sulfonylurea	herbicide	-1.40
113614-08-7	Beflubutamid	Amide	herbicide	4.28
82657-04-3	Bifenthrin	Pyrethroid	insecticide, acaricide	6.60
15545-48-9	Chlorotoluron	Urea	herbicide	2.50
20427-59-2	Copper hydroxide	Inorganic compound	fungicide	0.44
121522-61-2	Cyprodinil	Anilinopyrimidine	fungicide	4.00
52918-63-5	Deltamethrin	Pyrethroid	insecticide	4.60
119446-68-3	Difenoconazole	Triazole	fungicide	4.36
83164-33-4	Diflufenican	Carboxamide	herbicide	4.20
2764-72-9	Diquat(ion)	Bipyridylium	herbicide	-4.60
135319-73-2	Epoxiconazole	Triazole	fungicide	3.30
66230-04-4	Esfenvalerate	Pyrethroid	insecticide	6.24
80844-07-1	Etofenprox	Pyrethroid	insecticide	6.90
153233-91-1	Etoxazole	Diphenyl oxazoline	acaricide	5.52
131807-57-3	Famoxadone	Oxazole	fungicide	4.80
13356-08-6	Fenbutatin oxide	Organotin	acaricide	5.15
131341-86-1	Fludioxonil	Phenylpyrrole	fungicide	4.12
142459-58-3	Flufenacet	Oxyacetamide	herbicide	3.20
239110-15-7	Fluopicolide	Benzamide	fungicide	2.90
136426-54-5	Fluquinconazole	Triazole	fungicide	3.24
96525-23-4	Flurtamone	Pyridazinone	herbicide	3.20
114311-32-9	Imazamox	Imidazolinone	herbicide	5.36
881685-58-1	Isopyrazam	Pyrazole	fungicide	4.25
103055-07-8	Lufenuron	Benzoylurea	insecticide	5.12
19666-30-9	Oxadiazon	Oxidiazole	herbicide	5.33
40487-42-1	Pendimethalin	Dinitroaniline	herbicide	5.20
23103-98-2	Pirimicarb	Carbamate	insecticide	1.70
67747-09-5	Prochloraz	Imidazole	fungicide	3.50
94125-34-5	Prosulfuron	Sulfonylurea	herbicide	1.50
124495-18-7	Quinoxyfen	Quinoline	fungicide	4.66
131929-60-7	Spinosad (Spinosyn A)	Not found	insecticide	3.91
82097-50-5	Triasulfuron	Sulfonylurea	herbicide	-0.59

4.8 Comparison with the list of potential CFS identified by a contract study for the European Commission in July 2013

As laid down in Regulation (EC) No 1107/2009, The European Commission (COM) was asked to establish an initial list of Candidates for Substitution (CFS) by the end of 2013. As a support, COM commissioned a contract study to a consultant, the Food Chain Evaluation Consortium

(FCEC). The consultant delivered his study report at the beginning of July (FCEC 2013). The report was presented to the competent authorities of the Member States (MS) on 15 July 2013 in a meeting of the Standing Committee on the Food Chain and Animal Health, section Plant Protection products – Legislation. Subsequently, it was made available to the MS via the CIRCA platform (Communication & Information Resource Centre Administrator).

It was not the task of FCEC to set up the initial list of CFS – this is the privilege of COM –, but to do the necessary preparatory work, which was

- to compile the data needed for decision making from the legally relevant documents, i.e. the documents on which the decision for approval of active substances has been based, such as Review Reports, EFSA Conclusions, and Draft Assessment Reports, and
- to explore options for the interpretation and the operationalisation of the seven Conditions for the identification of CFS defined in the Regulation (EC) No 1107/2009, where the legal text and the available data leave room for judgments and where corresponding rules for data assessments have not already been fixed in the Draft Commission Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties of Pesticides" (COM 2012).

As a consequence, the FCEC report did not include a complete list of proposed CFS, but it provided lists of substances that are considered to fulfil relevant criteria, separately for each of the 7 legal Conditions and/or for individual sub-criteria, such as P, B, and T-properties for instance. Where applicable, various versions of these lists were provided in the report, each representing the outcome of different interpretations of the legal Conditions, such as different measures and trigger values for a “significantly lower ADI” for instance. However, in these cases the final decision was not left completely open, but arguments were provided in favour of the option that was considered to be most appropriate.

Thus, by combining these individual lists, it was possible to obtain a draft list of substances that could be expected, at the time of working on our project, to be included in the initial list of CFS that COM was going to establish, but without possible changes resulting from feedback from MS.

Draft CFS list resulting from the FCEC report

The aggregated list of active substances that were considered in the FCEC report to fulfil one or more of the legal Conditions for CFS identification is provided in Table 10 below. Where different options for interpretation were developed in the FCEC report, the list is based on that option which was suggested in the report as the most appropriate one. Where the approval of an active substance in the EU includes different varieties of a parent compound (such as quizalofop-P-ethyl and quizalofop-P-tefuryl for instance) or where the approval applies to a defined group of compounds (such as copper compounds for instance) these are included in the list as a single entity.

As a result, 98 different approved active substances were identified as probable CFS, listed in Table 10 by the common names used in the FCEC report. The reasons for CFS identification that are considered to be fulfilled in the FCEC report are indicated in terms of the relevant legal conditions. The abbreviations C1 to C7 stand for:

C1 – “Its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories”,

C2 – “It meets two of the criteria to be considered as a PBT substance”,

C3 – "There are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones)",

C4 – "It contains a significant proportion of non-active isomers",

C5 – "It is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3 [of Regulation 1107/2009]",

C6 – "It is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4 [of Regulation 1107/2009]",

C7 – "on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties that may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5 [of Regulation 1107/2009]" (The interim criteria laid down in Regulation (EC) No 1272/2008 apply here).

For substances fulfilling Condition 2 it is additionally indicated in the Table 10 whether the toxicity assessment refers to aquatic species (PBT_{AQUA}) or to humans (PBT_{HUMAN}) or both. The resulting aggregated assessment is indicated by PBT_{ALL}.

The assessments for Conditions 1 to 7 were derived from the FCEC report by aggregating information as follows:

C1 – Assessments provided in the Tables A1 (ADI), A2 (ARfD), and A3 (AOEL) of the FCEC report were combined under the assumption that the following decision rule applies: values are considered to fulfil the criterion when they are below the 5% percentile of a use group as defined in the EU pesticides database.

C2 – Assessments provided in the Tables A5 (half-life in water), A7 (half-life in sediments), and A9 (half-life in soil) of the FCEC report were aggregated for assessments of persistence (P). Assessments of bioaccumulation (B) were directly taken from the corresponding Table A10 of the FCEC report. Assessments of aquatic toxicity (T_{AQUA}) were generated by combining the assessments provided in the Tables A11 (fish), A12 (algae), A13 (Daphnia), and A14 (other aquatic species) of the FCEC report. Assessments of human toxicity (T_{HUMAN}) were obtained by combining the information on CMR and STOT RE classifications provided in Tables A16 (C 1A or 1B), A20 (M 1A or 1B), A22 (R 1A or 1B), A24 (R 2), A26 (STOT RE 1), and A 27 (STOT RE2) of the FCEC report.

C3 – No substances fulfilling this Condition were identified in the FCEC report.

C4 – Assessments were directly taken from the corresponding Table A15 of the FCEC report.

C5 – No substances fulfilling this Condition were identified in the FCEC report.

C6 – Relevant information on existing and forthcoming classifications of reproductive toxicity class 1A or 1B was aggregated from the FCEC report Tables A22 and A23, respectively.

C7 – For assessments of endocrine disrupting properties according to the interim criteria laid down in Regulation (EC) No 1272/2008, i.e. substances that are classified as both C2 AND R2, the information provided in the corresponding FCEC report Tables A21 and A25 was combined accordingly.

The resulting 98 CFS are listed in Table 10 in alphabetical order of common names, but separated into three groups:

(i) Substances that are exclusively identified for ecotoxicological reasons, i.e. they fulfil two of the criteria P, B, and T_{AQUA}, but not T_{HUMAN} and none of the other six Conditions. This applies to 53 substances, i.e. slightly more than 54 % of all CFS.

(ii) Substances that are identified as a CFS both for ecotoxicological reasons and for reasons of human health protection. These are substances that fulfil two of the criteria P, B, and T_{AQUA} and additionally the T_{HUMAN} criterion or any of the other CFS Conditions. Included in this group are also two substances that fulfil Condition 4, as a "significant proportion of non-active isomers" may have relevance for both human and environmental risk assessments. 19 substances fall into this group, i.e. almost 20 % of all CFS.

(iii) The remaining substances that are identified as a CFS exclusively for reasons of human health protection. These sum up to a total of 26 substances which is slightly more than 26 % of all CFS.)

Thus, almost 75% of all probable CFS will immediately trigger comparative environmental risk assessments of the plant protection products (PPPs) in which they are contained (provided the procedure is not stopped for agronomic reasons). The remaining 25% will trigger comparative human risk assessments in the first place, but complementary environmental risk assessments may become necessary where the human risk assessments argues in favour of substitution.

Comparison of the lists of potential CFS

The last column in Table 10 indicates those substances that were concordantly identified as a potential CFS, both in the FCEC report and in this project. This applies to 31 substances out of a total of 33 substances that had been identified as potential CFS in the preceding section 4.7. One of these substances (diquat) was identified in the FCEC report exclusively for reasons of human health hazards, while our analysis in the preceding sections gave an indication for ecotoxicological reasons too. The other 30 substances were consistently identified to fulfil ecotoxicological CFS criteria. For six of them, human health criteria apply additionally.

The analyses made in the first workpackage of this project were confined to substances fulfilling two of the three criteria P, B, and T_{AQUA}. Thus, the figure of 30 congruent findings cannot be compared to the whole number of 98 probable CFS, but only to those 70 substances that are identified in the FCEC report as compounds meeting two of the PBT_{AQUA} criteria. In addition, there are a number of reasons why it was expectable that the number of CFS identified by the PBT_{AQUA} criteria in our efforts would be lower than in the FCEC report, in particular the fact that the evaluation of the toxicity criterion was limited in this study to the standard algal, daphnid and fish toxicity endpoint that were available from the PPBD database. The FCEC work, in contrast, included data for a much broader spectrum of aquatic species and endpoints that are available from the official documents for substance approval. Nevertheless, the large difference of 40 substances that were positively identified by the PBT_{AQUA} criterion in the FCEC report, but undetected in our report is somewhat surprising. Furthermore, we were particular surprised to see that two of the substances identified as potential CFS in our efforts, namely beflubutamid and deltamethrin were not at all identified as a CFS in the FCEC report.

4.9 Comparison with the final list of CFS established by the European Commission in March 2015

The final list of CFS in the Annex to Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 only became available after the project work was finished. As a consequence of the review of the CFS by notifiers of the mentioned compounds and the respective EU Rapporteur Member States, the official list now comprises 77 CFS of which 52 were identified for environment-related concerns, i.e. 68%. Compounds that were included in the FCEC list but no longer in the official list are denoted in the Table 10 by an asterisk (*). Compounds that were included in the FCEC list also for environment-related concerns and remain in the official list, but no longer for ecotoxicological reasons, are denoted by a double asterisk (**).

Table 10: 98 active substances identified as potential candidates for substitution (CFS) in the contract study prepared for the European Commission (FCEC 2013).

Where different options for the interpretation or operationalisation of the legal criteria apply, that option which was recommended in the report as the most appropriate one is shown.

Common Name	Reason for Identification as a CFS									Identified as a CFS in section 4.7
	C1	C2			C3	C4	C5	C6	C7	
		PB T_{AQUA}	PB T_{HUMAN}	PB T_{ALL}						
	n =22	n =70	n =20	n = 77	n =0	n = 2	n = 0	n = 9	n = 7	n = 31
CFS identified exclusively for ecotoxicological reasons (n = 53)										
Aclonifen	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Azimsulfuron*	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Benfluralin*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Bifenthrin	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Bispyribac*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Bromadiolone**	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Bromuconazole	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Copper compounds	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Cyprodinil	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Difenacoum	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Difenoconazole	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Diflufenican	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Esfenvalerate	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Etofenprox	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Etoxazole	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Fenbuconazole*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Fenbutatin oxide	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Fenpyroximate*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Flazasulfuron*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Fludioxonil	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES

Common Name	Reason for Identification as a CFS									Identified as a CFS in section 4.7
	C1	C2			C3	C4	C5	C6	C7	
		PB T_{AQUA}	PB T_{HUMAN}	PB T_{ALL}						
Fluopicolide	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Imazamox	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Imazaquin*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Imazosulfuron	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Isoproturon	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Isopyrazam	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Isoxaben*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
lambda-cyhalothrin	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Lufenuron	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Metribuzin	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Metsulfuron-methyl	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Nicosulfuron	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Oxadiazon	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Oxyfluorfen	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Paclobutrazol	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Pencycuron*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Pendimethalin	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Pirimicarb	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Prochloraz	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Propiconazole	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Propoxycarbazone	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Prosulfocarb*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Prosulfuron	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Quinmerac*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Quinoxyfen	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
S-metolachlor*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Spinosad*	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Sulfosulfuron*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Tebufenpyrad	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Thiabendazole*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Thifensulfuron-methyl*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO
Triasulfuron	NO	YES	NO	YES	NO	NO	NO	NO	NO	YES
Triflusulfuron*	NO	YES	NO	YES	NO	NO	NO	NO	NO	NO

CFS identified both for ecotoxicological reasons and hazards to humans (n = 19)

Chlorotoluron	NO	YES	YES	YES	NO	NO	NO	NO	YES	YES
Cyproconazole	NO	YES	YES	YES	NO	NO	NO	NO	NO	NO
Dimoxystrobin	YES	YES	YES	YES	NO	NO	NO	NO	YES	NO

Common Name	Reason for Identification as a CFS									Identified as a CFS in section 4.7
	C1	C2			C3	C4	C5	C6	C7	
		PB T_{AQUA}	PB T_{HUMAN}	PB T_{ALL}						
Epoxiconazole	NO	YES	YES	YES	NO	NO	NO	YES	YES	YES
Famoxadone	NO	YES	YES	YES	NO	NO	NO	NO	NO	YES
Fipronil**	YES	YES	YES	YES	NO	NO	NO	NO	NO	NO
Fluazinam*	YES	YES	NO	YES	NO	NO	NO	NO	NO	NO
Flufenacet	NO	YES	YES	YES	NO	NO	NO	NO	NO	YES
Flumioxazine**	NO	YES	YES	YES	NO	NO	NO	YES	NO	NO
Fluquinconazole	YES	YES	YES	YES	NO	NO	NO	NO	NO	YES
Flurtamone*	YES	YES	NO	YES	NO	NO	NO	NO	NO	YES
Haloxyfop-P	YES	YES	NO	YES	NO	NO	NO	NO	NO	NO
Linuron**	NO	YES	YES	YES	NO	NO	NO	YES	NO	NO
Mecoprop**	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO
Metalaxyl**	NO	NO	NO	NO	NO	YES	NO	NO	NO	NO
Metconazole	NO	YES	YES	YES	NO	NO	NO	NO	NO	NO
Tri-allate	NO	YES	YES	YES	NO	NO	NO	NO	NO	NO
Triazoxide**	YES	YES	NO	YES	NO	NO	NO	NO	NO	NO
Ziram	NO	YES	YES	YES	NO	NO	NO	NO	NO	NO

CFS identified exclusively for reasons of human health protection (n = 26)

1-Methylcyclopropene	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Amitrole	YES	NO	YES	YES	NO	NO	NO	NO	NO	NO
Carbendazim	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO
Clodinafop	NO	NO	YES	YES	NO	NO	NO	NO	NO	NO
Diclofop	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Dimethoate	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Diquat	YES	NO	YES	YES	NO	NO	NO	NO	NO	YES
Ethoprophos	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Fluometuron	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Flusilazole	YES	NO	YES	YES	NO	NO	NO	YES	NO	NO
Glufosinate	YES	NO	NO	NO	NO	NO	NO	YES	NO	NO
Metam	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Methomyl	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Molinate	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
Myclobutanil	NO	NO	YES	YES	NO	NO	NO	NO	NO	NO
Oxadiargyl	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO
Oxamyl	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Profoxydim	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
Propineb	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Quizalofop-P	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO

Common Name	Reason for Identification as a CFS									Identified as a CFS in section 4.7
	C1	C2			C3	C4	C5	C6	C7	
		PB T_{AQUA}	PB T_{HUMAN}	PB T_{ALL}						
Sulcotrione	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Tebuconazole	NO	NO	YES	YES	NO	NO	NO	NO	NO	NO
Tepraloxydim	NO	NO	YES	YES	NO	NO	NO	NO	YES	NO
Terbuthylazine	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO
Thiacloprid	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
Warfarin	NO	NO	NO	NO	NO	NO	NO	YES	NO	NO

* Substance no longer included in the official list of CFS
** Substance still included in the official list of CFS, but no longer for ecotoxicological reasons

4.10 Brief

An important novel element of the regulation (EC) No 1107/2009 concerning the placing of plant protection products (PPPs) on the market is that a comparative assessment shall be performed for PPPs containing active substances which are classified as of specific hazard for the environment or human health, so-called candidates for substitution. The overall aim of this project funded by the UBA (FKZ 371267406) was the development of a procedure for the comparative assessment of PPPs focusing on the aspect of environmental hazards and risks. This procedure was developed in a stepwise approach.

This chapter summarises the results on identifying potential substitution candidates with the aim of establishing a training set for the subsequent development of the methodology for comparative assessments of PPPs. To this end, persistence (P), bioaccumulation (B), and toxicity (T) criteria as defined in the Annex of Regulation (EC) No 1107/2009 were applied. Rules for deciding if an active substance is to be considered as a substance that meets two of the PBT criteria were taken from the Annex II point 3.7.2 of the Regulation (EC) No 1107/2009 and from the DG SANCO working document on “Evidence needed to identify POP, PBT and vPvB properties for pesticides” (COM 2012).

A database was created for selected active substances that were approved for use in the EU at the beginning of project work in November 2012. In this database, only approved active substances with an unambiguous CAS No. were included; bio-pesticides and chemically ill-defined complex materials and mixtures were excluded. This was the case for 344 substances. Their CAS No., common names, pesticide use group, substance group as well as available tabled parameters for persistence (P), bioaccumulation (B) and ecotoxicity (T) were collected. For data retrieval, the following four public databases were used: (1) the Footprint Pesticide Properties database (PPDB), (2) the IUCLID information of European chemical Substances Information System (ESIS), (3) the EU Pesticide database, and (4) the data provided by the European Food Safety Authority (EFSA). For each of the three P-, B-, and T-criteria, a data enquiry strategy was developed and applied to ensure coherent and consistent data.

Persistence data were collected and documented for soil, water, and water/sediment systems. For 300 out of 344 active substances soil persistence values were retrieved. For 188 out of 344 active substances, bioaccumulation data were available. Aquatic long-term toxicity data were

available for most compounds except for 27 substances. According to the retrieved toxicity data, invertebrates represented the most sensitive taxonomic group in the majority of cases, followed by algae and fish.

An active substance was selected as a possible candidate for substitution if it met two of the three criteria defining a PBT substance according to Regulation (EC) No 1107/2009. These are specified as follows: a DT50 Soil > 120 d, a DT50 Sediment > 120 d or a DT50 Water > 40 d to be classified as a persistent (P) substance; a BCF > 2000 L/kg to be classified as a bioaccumulative (B) substance; and a NOEC (long-term fish, daphnia or algae) < 0.01 mg/L or an EC50 (72h algae test) <0.1 mg/L to be classified as a toxic (T) substance. Overall, 33 (9.6%) of the studied 344 active substances were identified as possible substitution candidates due to their P, B, and T properties. Most of them fulfil the criterion to be both toxic and persistent and they are used as fungicides, herbicides, or insecticides/acaricides. As the identified possible substitution candidates belong to very diverse chemical substance groups, it can be concluded that neither the chemical group nor the intended use of an active substance provides any indication for a substance as whether or not it may fulfil the criteria for substitution candidates. This is different for the octanol water partition coefficient (log *K*ow) of the substances, which was found to be larger than three for most of the substitution candidates; hence, this information may provide an alert for an active compound of a PPP that a possible candidate for substitution is to be flagged.

The analysis was completed in spring 2013. The 33 substitution candidates identified were used as an interim training set for developing an approach to identify potential products that contain candidates for substitution and would thus lend themselves to comparative assessment. When the results of the EU initiatives for identifying CFS became available at a later project stage (late summer 2013), we compared the findings from both efforts and decided to continue the work on the basis of a consolidated and extended list of 98 potential candidates, no longer limited to substances fulfilling two PBT criteria according to selected public databases, but also considering other substitution criteria and information sources. The official EU list of CFS only became available in March 2015 after all data analyses in the project had been completed and could thus not be included in the work.

5 Potential candidate products[5]

Introductory Note

All data compilations and data analyses documented in this chapter were completed during spring 2014, well ahead of the establishment of a list of candidates for substitution (CFS) by the European Commission in March 2015. The work was based on a preliminary list of 98 potential CFS (FCEC 2013), while the final official list now includes only a sub-set of 77 active substances. As a consequence, the actual numbers of CFS containing PPPs should be somewhat lower than the estimates developed in this chapter, the description of the nature and the dimension of the problem, however, remains valid.

5.1 Task description

The goal of this working step was to obtain an overview about plausible numbers and types of plant protection products (PPPs) that may become subject to comparative assessments in the future due to the presence of a candidate for substitution (still to be legally defined at the time of conducting this analysis). Also, it was tried to anticipate the distribution of these potential candidate products over the different intended uses in order to anticipate for which cases comparative risk assessments will have to be conducted. The guiding hypothesis was that a restriction in the scope or number of potential cases for comparative assessment could simplify the subsequent tasks.

To achieve these goals the PPP database of the German Federal Office of Consumer Protection and Food Safety (BVL) was examined (section 5.3). It was subsequently employed for identifying PPPs that contain potential substitution candidates (section 5.4), and the distribution of these PPPs across cultures, target organisms and authorised intended uses, i.e. combinations of cultures and pest organisms, was analysed. Additionally, the availability of potential alternative PPPs was checked for each of the relevant intended uses (section 5.5). As potential alternatives we focused on PPPs that did not contain potential substitution candidates, irrespective of the criteria from which they were indicated as CFS. The retrieved cases were aggregated in order to obtain an estimate about the potential number of future cases for comparative assessments in section 5.6. The numbers are of course based on information that was available at the time of conducting this exercise and will change with any alteration in the designation of CFS or authorised PPPs. The order of magnitude, however, will serve to be indicative for the efforts to be expected for comparative assessments.

5.2 Potential candidates for substitution included in the analysis of the German PPP market

The following analysis to identify and describe PPPs on the German market containing potential candidates for substitution identified for reasons of human and environmental hazards refers to the list of 98 potential active substances derived from the FCEC (2013) report (Table 10, section 4.8). During the initial phases of the project we worked with the restricted list of potential candidate substances generated in this project with a focus on environmental concerns as described in sections 4.1 to 4.7. When the results of the FCEC study became available during 2013, we decided to compare the findings from both efforts (section 4.8) and to run all further analyses on the basis of the larger FCEC list of potential candidates for substitution. The rationale for this decision was that replacement of a product containing a CFS

[5] Part of this chapter has been published as Faust et al 2014

identified for environmental reasons by a product containing CFS identified for other reasons was not considered a meaningful option.

5.3 Structure and analyses of the German plant protection products database

A PPP database is available and maintained through the BVL (German Federal Office of Consumer Protection and Food Safety). It contains relevant registration data of all PPPs authorised for use in Germany at specified time points and provides information on the active substances of the PPPs. The database is updated monthly. The BVL provides the database for use by authorities and public services. The database was used as the basis for the identification of PPPs that contain potential candidates for substitution as well as to search for alternative PPPs without potential substitution candidates. The following analyses of the BVL database refer to the version published in May 2013 and hence include all PPPs that were authorised for uses in Germany at this date.

5.3.1 Structure of the BVL database

The data in the BVL database organised in 44 tables. These tables are linked to each other in most cases through the identification number [KENNNR] or the application ID [AWG_ID]. Most of the data entries are in a coded format. The keys and descriptions for all these codes are listed in the corresponding tables “Kode” and “Kodeliste”. The table “Mittel” (plant production product) contains all currently authorised PPPs with the respective first date of authorisation and the end of the authorisation period as well as the formulation type (e.g. suspension concentrate or water dispersible granulate). Use categories for all PPPs are listed in the table “Mittel_Wirkbereich”. Furthermore, active substances are listed together with the other components of the PPPs in the table “Wirkstoff_Gehalt”. This allows the identification of PPPs that contain potential substitution candidates. PPPs are authorised for so-called intended uses, which is the combination of a specific crop and a pest. The information for which crops and pests a PPP application is approved are presented in the tables “AWG_Kultur” and “AWG_Schadorg”. In addition, the table application (“AWG”) summarises information on the authorisation and the application of the PPPs. Additionally, it provides more information on the crops and pests.

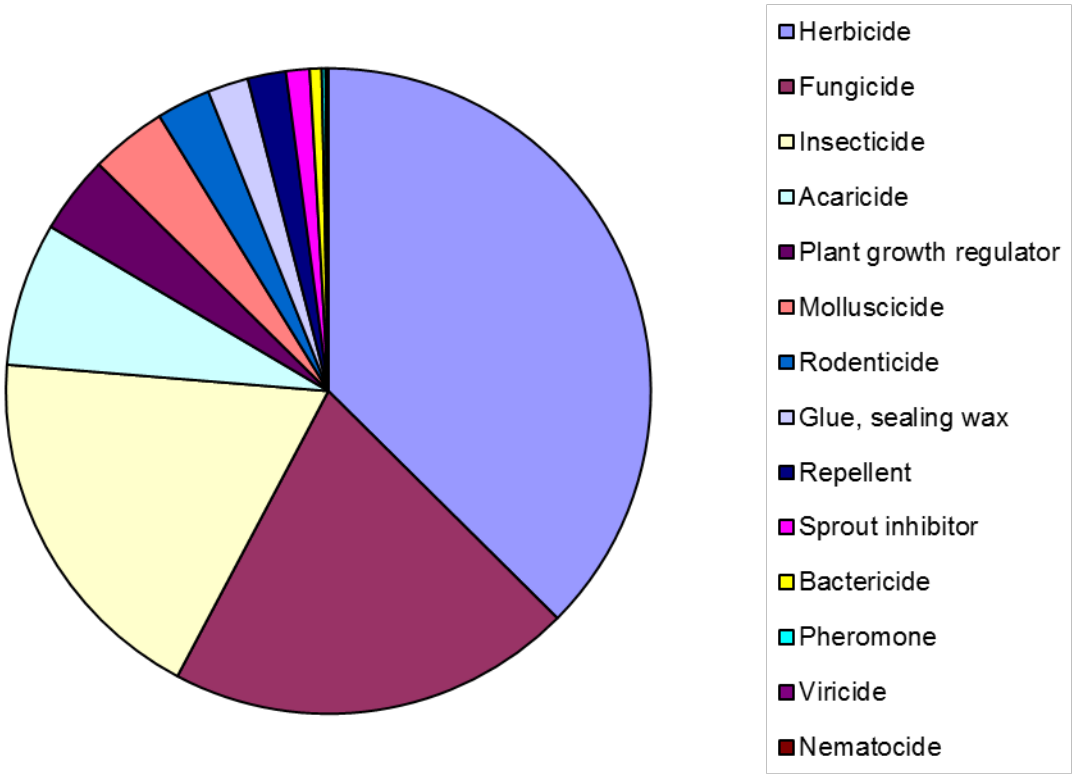
For most of the PPPs, specific risk mitigation measures such as distance requirements and measures that are fixed to reduce the dispersal of a PPP from the site of application are provided. These measures target to lower the exposure of surface water (NW requirements), groundwater (NG requirements), terrestrial non-target ecosystems (NT requirements) or honeybees (NB requirements). The risk mitigation requirements are listed in the tables “Auflage” or “Auflagen” (“requirement” or “requirements”). Additionally, the table “Auflagen_Redu” (reduction requirements) contains information on the four risk categories (A, B, C, D) indicated by different drift reduction classes for the different distance requirements that may apply to a PPP, respectively.

The data structure provided in the BVL database allows general database queries to retrieve (i) the distribution of PPPs by use categories, (ii) the number of pests and crops, and (iii) the number of intended uses as well as numbers of PPPs containing several active substances (section 5.3). Furthermore, the number of PPPs containing potential substitution candidates (section 5.4) and possible alternative PPPs with the same intended use but without a potential candidate for substitution (section 5.5) can be retrieved. Finally, database queries allow the estimation of the number of cases for which a comparative assessment of PPPs may have to be conducted.

5.3.2 Data analyses of the BVL database

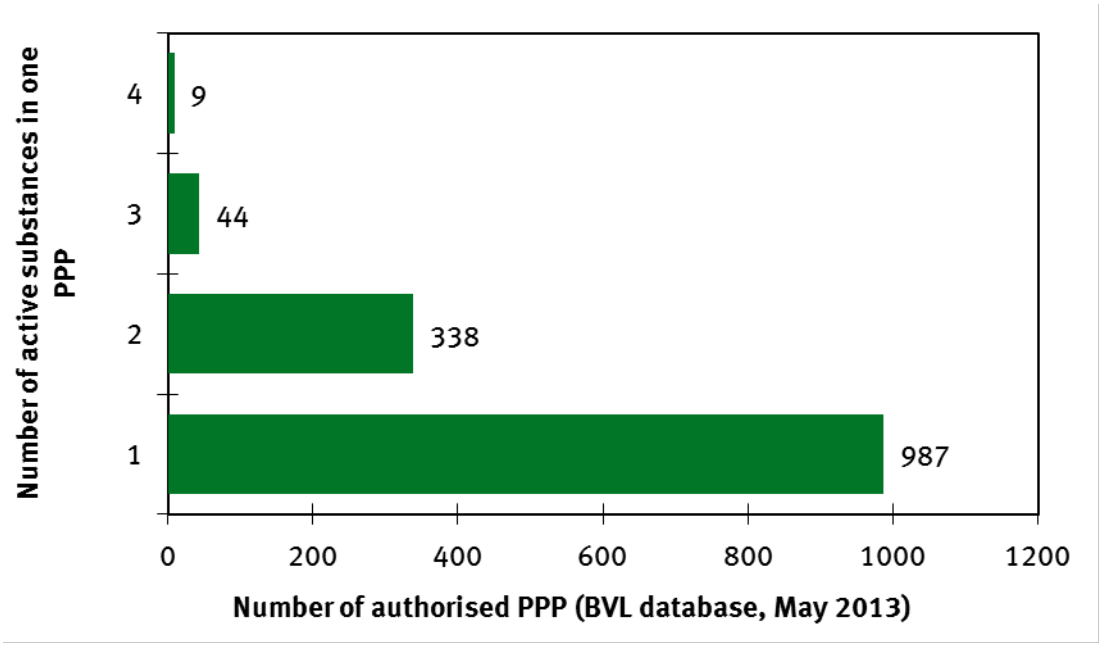
The BVL database of May 2013 contains 374 different active substances and 1378 authorised PPPs. Most of the PPPs are assigned to one of 14 use categories, 9.9% of the PPPs are allocated to more than one use categories. About one third (37.4%) of the PPPs are used as herbicides, 20.3% are fungicides, 18.5% are insecticides, and 7.2% are acaricides (Figure 10). The remaining ten use categories account for less than 5% of the total PPPs, respectively.

Figure 10: Distribution of PPPs listed in the BVL database (version May 2013) by use categories.



The majority (71.6%) of the PPPs contain only one active substance, 24.5% contain two and 3.2% three active substances (Figure 11). A total of 44 PPPs include three active compounds and nine PPPs contain four different active compounds.

Figure 11: Number of authorised PPPs containing one or more active substances

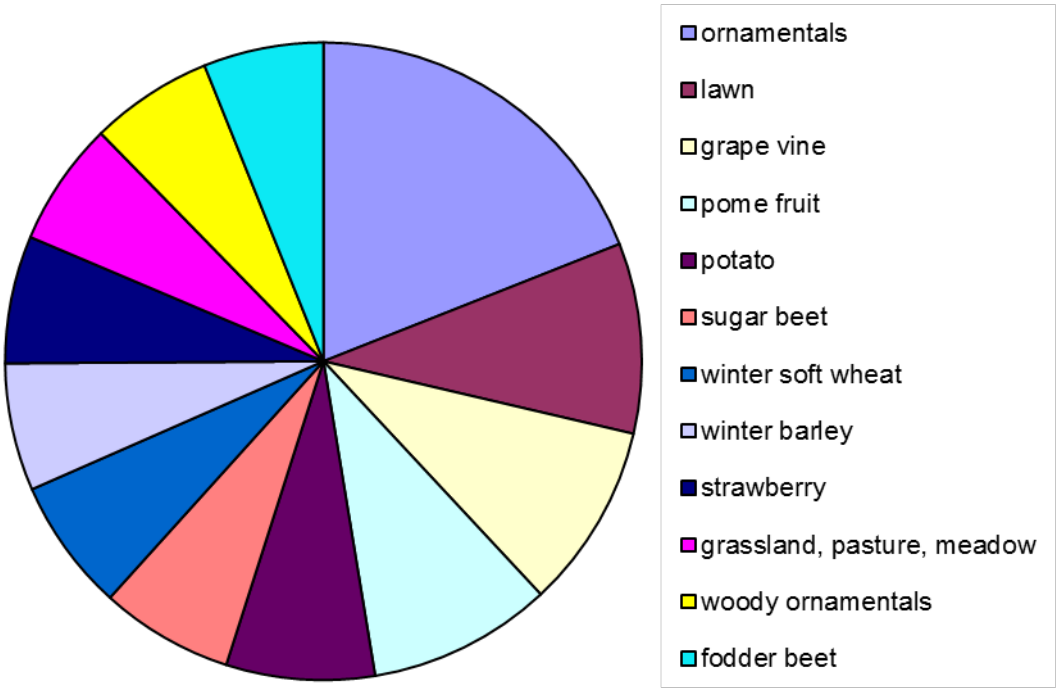


Distribution of PPPs by crops

The authorised PPPs are not equally distributed with regard to their use in different crops. The list comprises 1378 authorised PPPs with uses in 309 different crops, with an average of 30.9 (± 48.4; median = 12) different PPPs authorised per crop. However, there are 107 crops with less than five and 44 crops with only one authorised PPP. In contrast, 26 crops exist, for which more than 100 PPPs are authorised. The figures are highest for a group of 12 crops shown in Figure 12, with numbers of authorized PPPs varying between 148 for fodder beet and 461 for ornamentals. About 25% of all authorised PPPs are authorised for use in one or more of these 12 different crops (exclusively or in addition to authorisations for other crops). If the group of crops with highest numbers of authorised PPPs is extended to cover the top 34, this means that 80 or more PPPs are authorised for use in each of these 34 crops, and that the whole set of PPPs authorised for use in one or more of these 34 crops already includes 50 % of all PPPs authorised in Germany.

A total of 19 PPPs are authorised for use in more than 50 crops, with the maximal number of 85 crops applying to the PPP “Karate Zeon”. On the other hand, 419 PPPs are authorised for use in only one crop. On average one PPP is authorised for use in 6.9 (± 10.2; median = 4) different crops.

Figure 12: Crops with the highest number of authorised PPPs (25%-quantile of all PPPs).

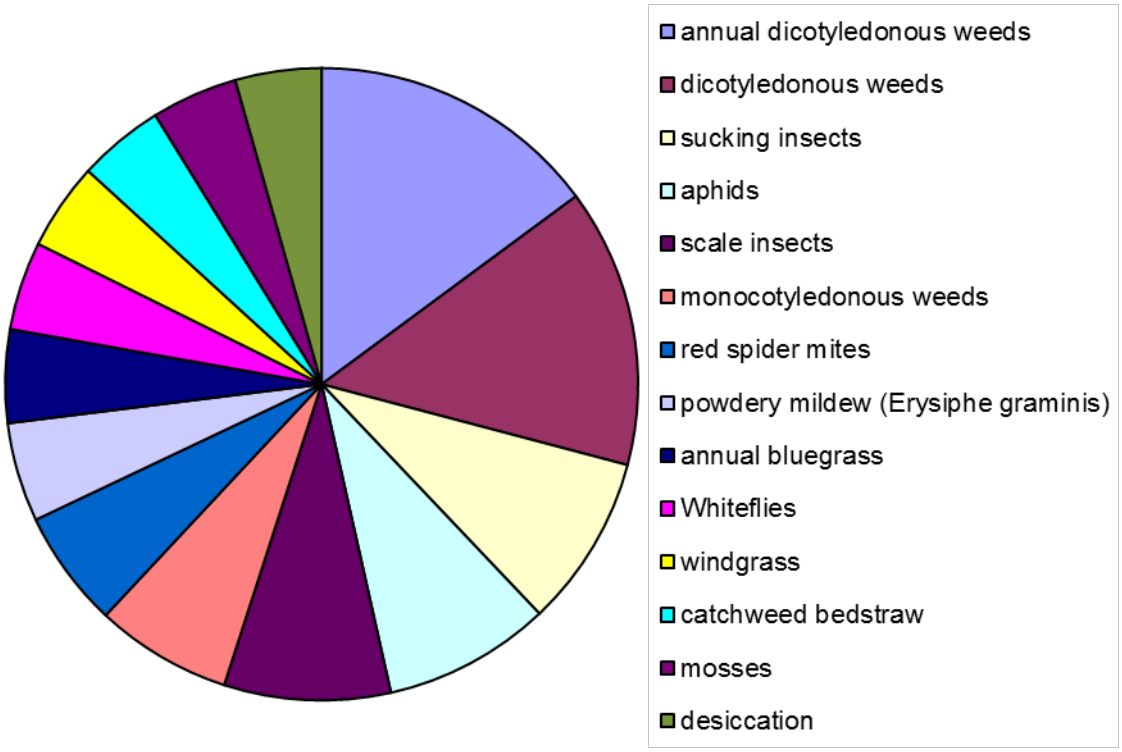


Distribution of PPPs by pests

The 1378 listed PPPs of the BVL database (version May 2013) are authorised for use against 477 different pests. On average 13.7 (± 24; median = 5) different PPPs are authorised per pest, but the distribution is highly skewed. There are 221 pests with less than five and 95 pests with indeed only one authorised PPP in Germany. However, six pests exist with more than 100 and 28 pests with more than 50 approved PPPs. The 14 pests listed in Figure 13 are those against which about 25% of all PPPs are authorised for use, and 50% of all authorisations for PPPs refer to uses against 50 different pests.

A total of 14 PPPs are authorised for use against more than 50 different pests, with a maximum number of 64 pests for the PPP “Rosen-Pilzfrei Saprol”. In contrast, 459 PPPs are authorised for use against only one single pest. On average one PPP is authorised for use against 4.7 (± 7.2; median = 3) different pests.

Figure 13: Pests with the highest number of authorised PPPs (25%-quantile of all PPPs).



Distribution of PPPs by intended uses

Each PPP is authorised for use in just one or in several different combinations of crops and pests, denoted as intended uses. The PPPs listed in the BVL database, version May 2013 cover a total of 3606 different intended uses. On average 5.6 (± 10.3; median =2) PPPs are authorised for each of the different intended uses. The maximum number of PPPs authorised for one intended use is 161, and, logically, there is at least one PPP authorised for any intended use listed in the database. More than 100 PPPs are authorised for three intended uses and 50 intended uses exist, where more than 50 PPPs are authorised. In contrast, for 2636 intended uses (73.1% of all intended uses) less than five and for 1127 intended uses (30.3%) only one PPP may legally be applied in Germany. Thus for this latter category, it would not be possible to compare a PPP with an alternative product. The intended uses with the highest numbers of authorised PPPs are shown in Table 11.

Table 11: Intended uses (combinations of crops and pests) with more than 55 authorised PPPs in Germany.

Rank	Crop	Pest	Number of author. PPPs
1	lawn	dicotyledonous weeds	161
2	ornamentals	scale insects	134
3	ornamentals	sucking insects	122
4	ornamentals	red spider mites	97
5	winter soft wheat	annual dicotyledonous weeds	91
6	pome fruit	monocotyledonous weeds	80
7	winter rye	annual dicotyledonous weeds	79
8	maize	annual dicotyledonous weeds	79
9	hard & semi-permeable paths & places with tree	dicotyledonous weeds	77
10	hard & semi-permeable paths & places with tree	monocotyledonous weeds	77
11	pome fruit	dicotyledonous weeds	76
12	ornamentals	monocotyledonous weeds	76
13	ornamentals	dicotyledonous weeds	76
14	winter barley	annual dicotyledonous weeds	74
15	wheat	powdery mildew (*Erysiphe graminis*)	73
16	ornamentals	whiteflies	71
17	barley	powdery mildew (*Erysiphe graminis*)	70
18	ornamentals	aphids	68
19	coniferous plants	monocotyledonous weeds	66
20	field crops	monocotyledonous weeds	64
21	field crops	dicotyledonous weeds	64
22	coniferous plants	dicotyledonous weeds	64
23	lawn	monocotyledonous weeds	64
24	wheat	brown leaf rust of cereals (*Puccinia*	63
25	grapevine	dicotyledonous weeds	63
26	deciduous trees	monocotyledonous weeds	62
27	grapevine	monocotyledonous weeds	61
28	grassland, pasture, meadow	dock	61
29	unproductive areas	dicotyledonous weeds	61
30	unproductive areas	monocotyledonous weeds	61
31	lawn	mosses	60
32	deciduous trees	dicotyledonous weeds	60
33	winter soft wheat	windgrass	58
34	ornamentals	slugs	58
35	rye	powdery mildew (*Erysiphe graminis*)	58
36	grassland, pasture, meadow	dicotyledonous weeds	58
37	coniferous plants	woody plants	57
38	barley	net blotch (*Pyrenophora teres*)	57
39	deciduous trees	woody plants	57
40	winter triticale	annual dicotyledonous weeds	57
41	cereals (barley, oats, rye, triticale, wheat)	desiccation	56
42	cereals (barley, oats, rye, triticale, wheat)	dicotyledonous weeds	56
43	cereals (barley, oats, rye, triticale, wheat)	monocotyledonous weeds	56
44	woody ornamentals	monocotyledonous weeds	56

5.4 Plant protection products containing potential candidates for substitution

The identification of candidates for substitution results from hazardous properties regarding human or environmental health and is assessed for the active substance. The following analyses concerning PPPs that contain potential candidates for substitution refer to the list of 98 potential CFS given in Table 10 (section 4.8).

For 33 of these 98 active substances no German common names or corresponding CAS numbers are listed in the BVL database or they were definitely not included as an ingredient in any PPP authorized in Germany at the date checked (May 2013). These potential CFS with no authorised use in Germany are Azimsulfuron, Benfluralin, Bifenthrin, Bispyribac, Bromadiolone, Bromuconazole, Etoxazole, Fenbuconazole, Fenbutatin oxide, Imazaquin, Lufenuron, Oxadiazon, Oxyfluorfen, and Thiabendazole (identified exclusively for ecotoxicological reasons); Fipronil, Linuron, Mecoprop, Metalaxyl, Tri-allate and Ziram (CFS identified both for ecotoxicological reasons and hazards to humans); and Amitrole, Diclofop, Diquat, Ethoprophos, Fluometuron, Metam, Methomyl, Molinate, Oxadiargyl, Oxamyl, Profoxydim, Propineb and Warfarin (CFS identified exclusively for reasons of human health protection).

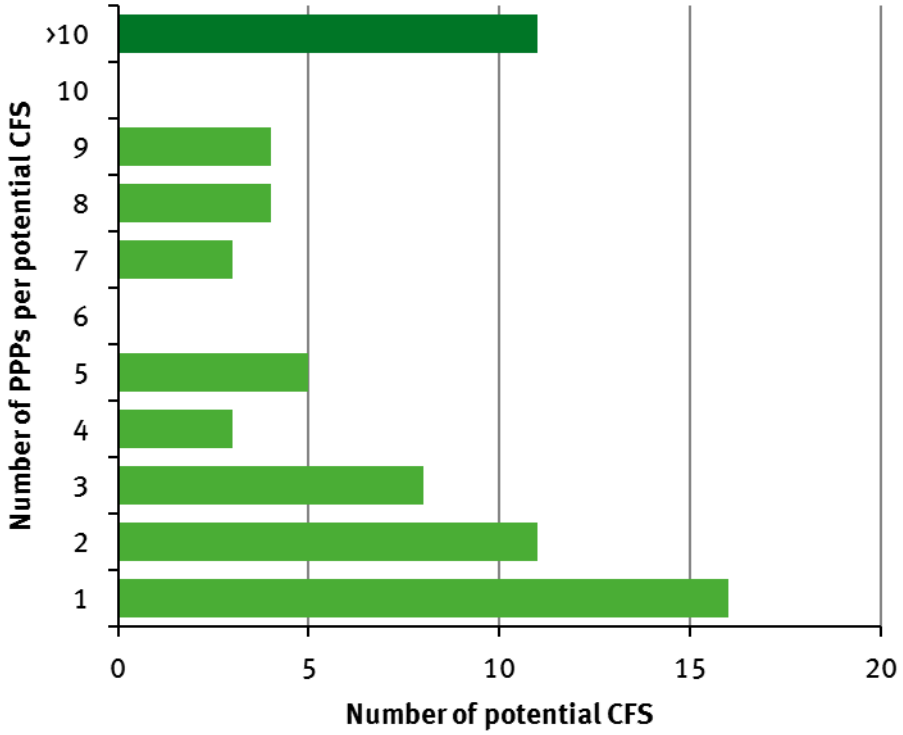
Regarding copper compounds there are 5 different compounds listed in the BVL list and three of these are actually used as a.s. in authorised PPPs.

Thus, there are eventually 65 different active substances from the list of 98 potential CFS (or 67 compounds if the three different copper salts are counted as different a.s.) that are used as ingredients of PPPs authorized for use in Germany, according to the BVL database in its version of May 2013. Of these 65 substances, 39 potential CFS would be indicated exclusively for environmental criteria, 13 would be identified for both environmental and health hazards, and 13 would be exclusively indicated from the health-related criteria. A total of 351 authorised PPPs were found in the BVL database (version May 2013) that contained any of these 65 active substances. The PPPs containing potential candidates of substitution are documented as Table A2 of the Annex and the reasons for flagging of the active substances are shown in the Table A1 of the Annex to this report.

The list comprises of the following active substances as potential candidates for substitution: 1-Methylcyclopropen, Aclonifen, Carbendazim, Chlortoluron, Clodinafop, Cyproconazol, Cyprodinil, Difenacoum, Difenoconazol, Diflufenican, Dimethoat, Dimoxystrobin, Epoxiconazol, Esfenvalerat, Etofenprox, Famoxadone, Fenpyroximat, Flazasulfuron, Fluazinam, Fludioxonil, Flufenacet, Flumioxazin, Fluopicolide, Fluquinconazol, Flurtamone, Flusilazol, Glufosinat, Haloxyfop-P (Haloxyfop-R), Imazamox, Isoproturon, Isopyrazam, Isoxaben,Copper hydroxid, Copper oxychloride, Copper sulfate (basic), lambda-Cyhalothrin, Metconazol, Metribuzin, Metsulfuron, Myclobutanil, Nicosulfuron, Paclobutrazol, Pencycuron, Pendimethalin, Pirimicarb, Prochloraz, Propiconazol, Propoxycarbazone, Prosulfocarb, Prosulfuron, Quinmerac, Quinoxyfen, Quizalofop-P, S-Metolachlor, Spinosad, Sulcotrion, Sulfosulfuron, Tebuconazol, Tebufenpyrad, Tepraloxydim, Terbuthylazin, Thiacloprid, Thifensulfuron, Triasulfuron, Triazoxid and Triflusulfuron.

On average, every potential candidate for substitution is contained in 4.9 (± 6.7; median = 2.5) different PPPs authorised in Germany. The distribution of CFS over the number of authorised PPPs is displayed in Figure 14. For instance, 17 CFS are included in only one PPP each, while 11 CFS are included in more than 10 PPPs. Dimethoate as the extreme case (CAS No 135319-73-2) is contained in 35 different PPPs.

Figure 14: Number of authorised PPPs containing active substances considered as potential candidates for substitution (CFS)

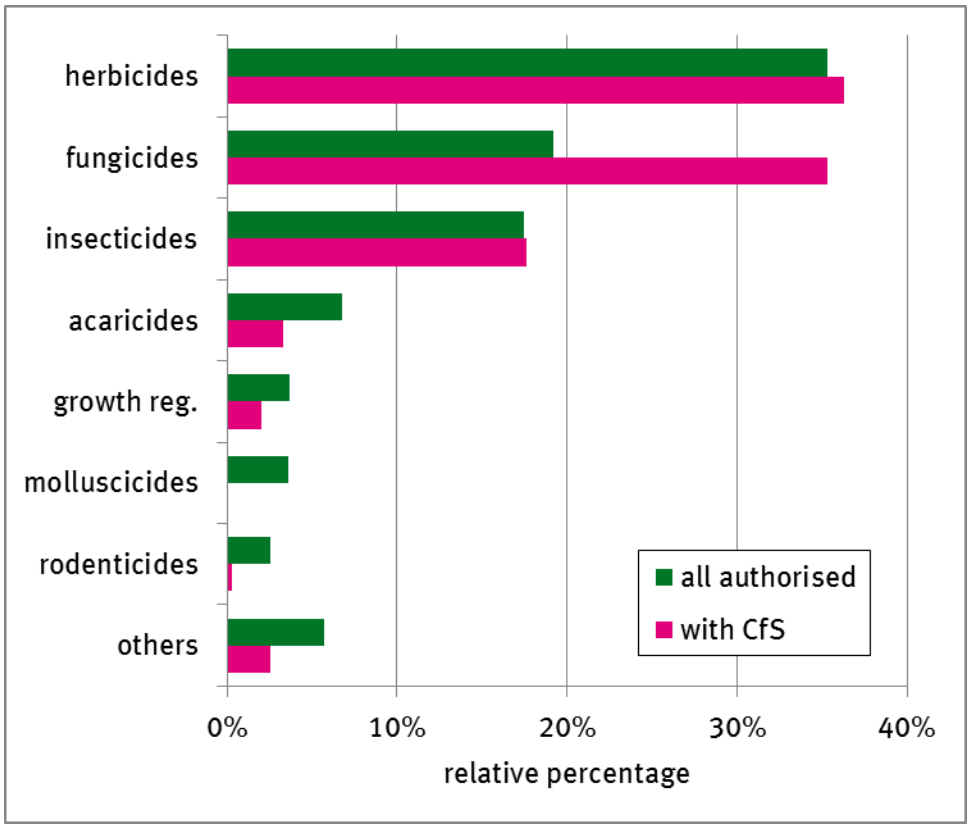


A fraction of 34.2% of the PPPs containing potential substitution candidates includes two active substances, 57.5% only one active substances, 7.4% three and 0.8% more than three active substances. The PPPs “EfA”, “JUWEL FORTE” and “EfA Universal” contain four active substances, which is the highest number of active substances for a PPP containing potential candidates for substitution. However, the majority (87.2%) of PPPs contain only one substitution candidate, 12 % contain two and the PPPs “LANDOR CT”, “Trinity” and Bacara FORTE” contain three active substances each that may be considered potential candidates for substitution.

Similar to the allocation to use categories observed for the whole of all authorised PPPs, most of the 351 PPPs containing potential substitution candidates are herbicides (37.3%). Fungicides (36.2%) are the second most frequent use category regarding the occurrence of potential candidates for substitution. Furthermore, 69 PPPs with potential substitution candidates are used as insecticides and 13 PPPs belong to the acaricide use category. Almost 5% of the 351 PPPs belong to the combined use categories fertiliser and plant growth regulator. Only one PPP is assigned to the use categories of rodenticides and bactericides, respectively (Figure 15). 29 PPPs containing potential candidates for substitution are applied in more than just one use category.

The percentages of potential CFS-containing PPPs used as herbicides or insecticides agree quite well with the corresponding shares of all PPPs (somewhat more than 35% used as herbicides and almost 18% used as insecticides, respectively). Interestingly, however, the situation is different for the third major use category, namely fungicides. While only around 19% of all PPPs are used as fungicides, about 35% of those PPPs that contain a potential CFS fall into this use category.

Figure 15: Distribution of the 351 PPPs containing potential CFS by use categories, compared to the corresponding distribution of all authorised PPPs



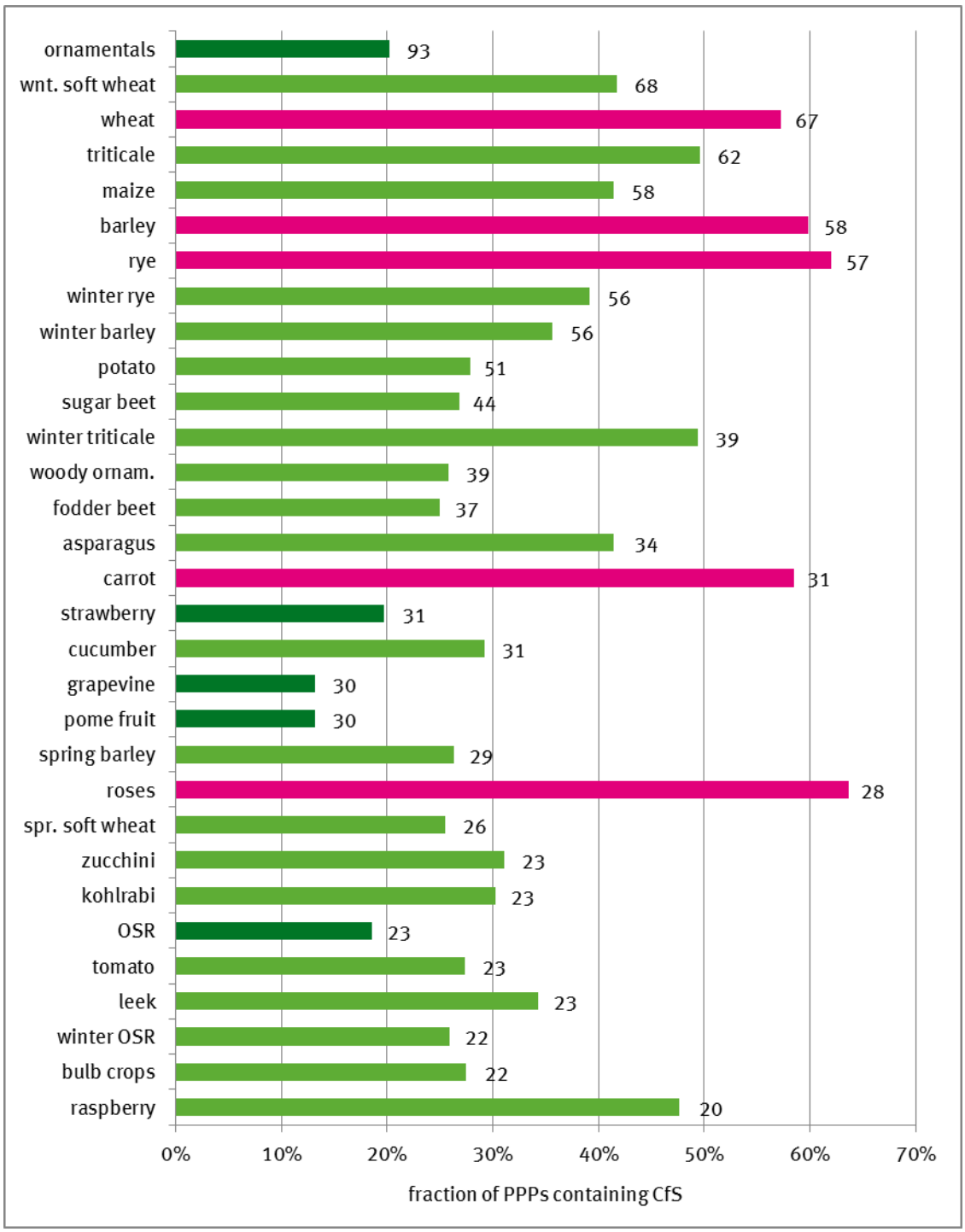
5.4.1 Distribution by crops

The 351 listed PPPs containing potential substitution candidates are authorised for use in 209 out of the total of 309 different crops. For each of the concerned crops on average 11.6 (± 14.5; median = 6) different PPPs containing potential substitution candidates are authorised. The crops for which the use of 20 or more PPPs containing potential substitution candidates have been authorised are shown in Figure 16. Ornamentals are the crop group with the highest number of authorised PPPs containing potential substitution candidates (93). However, for 69.8% of the concerned crops less than five PPPs containing candidates for substitution are authorised.

A total of 43 PPPs containing potential substitution candidates are authorised for more than 10 different crops each, the PPP “Karate Zeon” is even authorised for a maximal number of 85 different crops. In contrast, about 100 PPPs are authorised for use in only one single crop each. On average the PPPs are authorised for use in 6.9 (± 11.3; median = 4) different cultures.

Figure 16: Fraction of potential CFS-containing PPPs authorised for use in 31 different crops

The figure includes all crops for which 20 or more PPPs are authorised that contain one or more potential CFS. Percentages of potential CFS-containing products refer to the whole number of PPPs authorised for use in a single given crop. Absolute numbers of potential CFS-containing products are given as labels to individual bars.



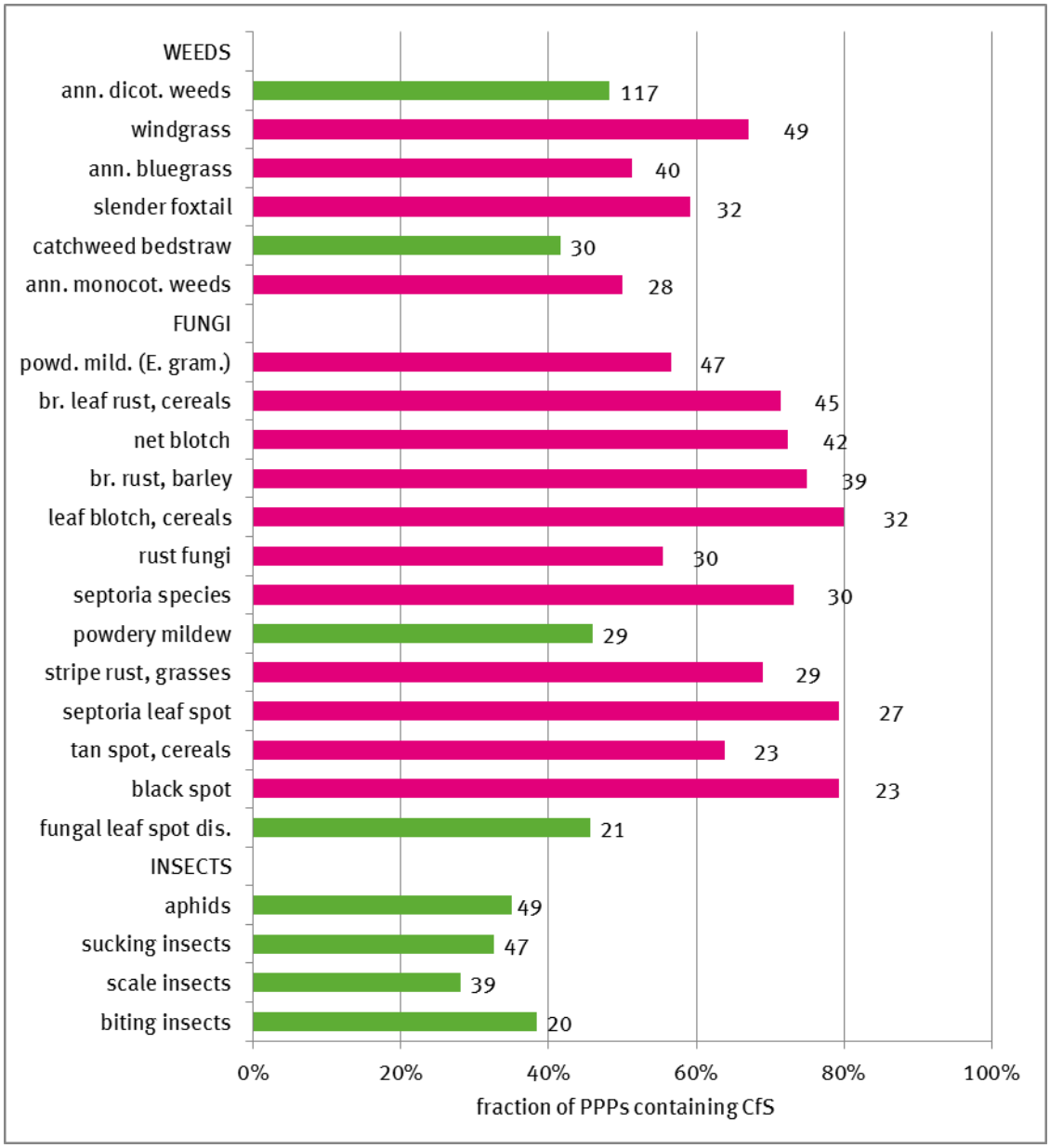
5.4.2 Distribution by pest organisms

The 351 PPPs containing potential substitution candidates are approved for use against 264 out of 477 different pests. On average 7 (± 11.6; median = 3) different PPPs containing potential substitution candidates are authorised for use against a specific pest. Those pests, for which uses of 20 or more different PPPs containing potential substitution candidates are authorised, are shown in Figure 17. Annual dicotyledonous weeds constitute the pest group against which the highest number of all PPPs (243) is authorised. Thus, it is not surprising that this is also the pest group with the highest corresponding number of authorised PPPs containing potential substitution candidates (117). However, for 62.2% of the listed pests less than five PPPs containing potential candidates for substitution are authorised.

A total of 43 PPPs containing potential substitution candidates are authorised for use against more than 10 pests, with the maximum number of 39 different pests for the PPP “SCORE”. In contrast, about 209 PPPs containing potential substitution candidates are authorised for use against less than five pests and 56 PPPs are authorised for use against only one pest each. On average the PPPs containing potential substitution candidates are authorised for use against 5.2 (± 5.1; median = 4) different pests.

Figure 17: Fraction of potential CFS-containing PPPs authorised for use against 23 different pests

The figure includes all pests for which 20 or more PPPs are authorised that contain one or more potential CFS. Percentages of potential CFS-containing products refer to the whole number of PPPs authorised for use in a single given crop. Absolute numbers of potential CFS-containing products are given as labels to individual bars.



5.4.3 Distribution by intended uses

The PPPs containing potential substitution candidates are authorised for 1863 (51.7%) out of the total of 3606 different intended uses listed in the BVL database. For each of the concerned intended uses (combination of crop and pest) on average 17.4 (± 32.6; median =9) PPPs containing potential substitution candidates are authorised. For the combination of winter soft wheat as the crop and annual dicotyledonous weeds as the pest species a maximal number of 52 PPPs containing potential candidates for substitution were authorised. For about 71

intended uses more than ten PPPs and for 212 intended uses more than five PPPs containing potential candidates for substitution were authorised. On the other end, for 268 (10.7%) of all intended uses only one PPP containing potential substitution candidates is authorised in Germany. The intended uses with the highest numbers of authorised PPPs containing potential substitution candidates are shown in Table 12. A complete list of all intended uses for which PPPs containing potential substitution candidates are authorised is given in Table A2 of the Annex. There are 14 uses for which more than 50 PPPs which do not contain a potential candidate for substitution are authorised. These may be considered as alternative products in comparative assessment. However, for 1096 of the 1863 uses no potentially alternative PPP not containing a substitution candidate was available. This applies for instance to the control of annual bluegrass in winter barley or powdery mildew (Erysiphe betae) in fodder beet.

Table 12: Intended uses (combinations of culture and pest organisms) for which twenty or more PPPs containing potential candidates for substitution (CFS) are authorised in Germany

Intended use		Number of PPPs with CFS	Total number of PPPs	Rel. prop. of PPPs containing CFS (%)
Crop	Pest			
winter soft wheat	annual dicotyledonous weeds	52	91	57.1
maize	annual dicotyledonous weeds	51	79	64.6
winter soft wheat	windgrass	46	58	79.3
wheat	brown leaf rust of cereals (*Puccinia recondita*)	45	63	71.4
ornamentals	sucking insects	42	122	34.4
winter rye	annual dicotyledonous weeds	42	79	53.2
winter barley	annual dicotyledonous weeds	42	74	56.8
wheat	powdery mildew (*Erysiphe graminis*)	41	73	56.2
barley	net blotch (*Pyrenophora teres*)	41	57	71.9
winter rye	windgrass	41	53	77.4
ornamentals	scale insects	39	134	29.1
barley	brown rust of barley (*Puccinia hordei*)	39	52	75.0
rye	brown leaf rust of cereals (*Puccinia recondita*)	39	50	78.0
barley	powdery mildew (*Erysiphe graminis*)	37	70	52.9
winter barley	windgrass	34	39	87.2
rye	powdery mildew (*Erysiphe graminis*)	32	58	55.2
ornamentals	aphids	31	68	45.6
barley	leaf blotblotch of cereals	31	39	79.5
winter triticale	annual dicotyledonous weeds	30	57	52.6
wheat	stripe rust of grasses (*Puccinia striiformis*)	28	41	68.3
winter soft wheat	slender foxtail	28	37	75.7
triticale	Septoria species (*Septoria spp.)*	27	37	73.0
wheat	Septoria leaf spot (*Septoria nodorum*)	27	34	79.4
rye	Leaf blotch of cereals	26	31	83.9
ornamentals	powdery mildew	24	49	49.0
ornamentals	rust fungi (*Uredinales*)	24	46	52.2
winter rye	slender foxtail	24	32	75.0
winter triticale	windgrass	24	31	77.4
wheat	tan spot of cereals (*Drechslera tritici-repentis*)	23	36	63.9
roses	Black spot (*Diplocarpon rosae*)	23	29	79.3
winter soft wheat	annual bluegrass	23	28	82.1
winter rye	annual bluegrass	23	27	85.2
winter barley	annual bluegrass	22	22	100

5.5 Plant protection products containing no candidates for substitution

The 351 identified PPPs containing potential substitution candidates are authorised for a total of 1863 different uses. This means that such PPPs are typically authorised for several uses (mean 3.1). Consequently, there will be a need for identification of one or more alternative PPPs without potential substitution candidates in a comparative risk assessment, and it is likely that for a PPP being authorised in several intended uses, eventually, also several PPPs without potential substitution candidates will have to be considered.

In this study, PPPs without candidates for substitution, which are authorised for the same intended use as the PPP under assessment for substitution, were considered as primary potential alternative PPPs. For these a comparative assessment would eventually become necessary.

From this, it can be concluded that 6232 cases for comparative risk assessment may have to be considered. The number of 6232 cases is derived by multiplying the number of all PPPs containing a candidate of substitution with the average number of uses (18). In order to perform a comparative assessment of risks for these cases, alternative PPPs for the same intended uses must be available. Alternative PPPs without potential substitution candidates are available for 767 (41.2%) of the concerned 1863 authorised uses. On average, about three alternative PPPs are available for every intended use for which a PPP containing a potential substitution candidate is authorised. Thus, as many as 18479 comparative risk assessments of PPPs may become necessary in the future. For the combination of lawn as a culture and dicotyledonous weeds as pest organism a maximal number of 158 PPPs without candidates for substitution are available. For 13 intended uses more than 50 and for 178 more than ten alternative PPPs were authorised for use, respectively. However, for 220 intended uses only one alternative PPP was available in Germany in May 2013.

In contrast, for 1096 intended uses of PPPs containing potential substitution candidates there was no alternative PPP available in Germany at that date. Most often (40%), two PPPs containing potential substitution candidates are authorised for an intended use for which no alternative PPP is available. In 34.6% of the cases only one single PPP is authorised and no alternatives are available. Also, for 9.8% of the uses for which no alternative PPPs are available, more than two PPPs containing potential substitution candidates are authorised.

All 65 potential substitution candidates occurring in authorised PPPs in Germany are used in intended uses with no alternative PPP as well as in intended uses, for which potential alternative PPPs not containing any CFS are available. This means that all potential candidates for substitution may become subject of comparative assessments of PPPs.

5.6 Brief

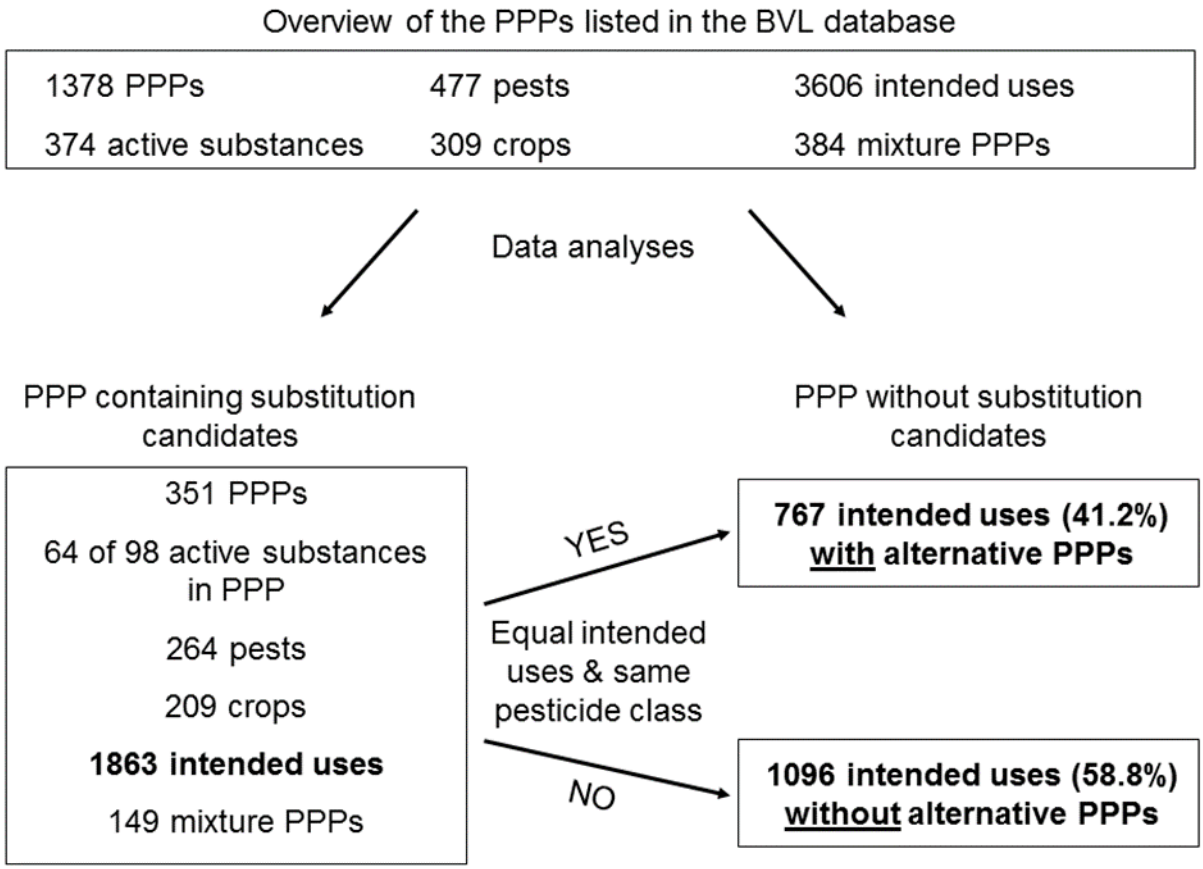
In this chapter, a strategy is developed to identify and describe the potential workload for comparative risk assessment in terms of the amount and cases for comparative risk assessment for PPPs. For this purpose, the PPP database of the Federal Office of Consumer Protection and Food Safety (BVL, 2013) was used to identify PPPs containing potential substitution candidates. Their distribution across crops, pests and authorised intended uses (combinations of crops and pests) was analysed. Additionally, the availability of potential alternative PPPs without potential substitution candidates was characterised for each of the relevant intended uses.

The analyses were performed for a set of the following 65 selected potential candidates for substitution: 1-Methylcyclopropen, Aclonifen, Carbendazim, Chlortoluron, Clodinafop, Cyproconazol, Cyprodinil, Difenacoum, Difenoconazol, Diflufenican, Dimethoat, Dimoxystrobin,

Epoxiconazol, Esfenvalerat, Etofenprox, Famoxadone, Fenpyroximat, Flazasulfuron, Fluazinam, Fludioxonil, Flufenacet, Flumioxazin, Fluopicolide, Fluquinconazol, Flurtamone, Flusilazol, Glufosinat, Haloxyfop-P (Haloxyfop-R), Imazamox, Isoproturon, Isopyrazam, Isoxaben,Copper hydroxid, Copper oxychloride, Copper sulfate (basic), lambda-Cyhalothrin, Metconazol, Metribuzin, Metsulfuron, Myclobutanil, Nicosulfuron, Paclobutrazol, Pencycuron, Pendimethalin, Pirimicarb, Prochloraz, Propiconazol, Propoxycarbazone, Prosulfocarb, Prosulfuron, Quinmerac, Quinoxyfen, Quizalofop-P, S-Metolachlor, Spinosad, Sulcotrion, Sulfosulfuron, Tebuconazol, Tebufenpyrad, Tepraloxydim, Terbuthylazin, Thiacloprid, Thifensulfuron, Triasulfuron, Triazoxid and Triflusulfuron. As the interpretation of criteria was not unambiguous at the time of performance of this analysis the final list of candidates for substitution may be different but the general pattern of findings will remain.

The aim was to get a well-founded idea about the number of PPPs that may become subject of a comparative risk assessment in the future and also about the number and the nature of different intended uses for which such comparative risk assessments may have to be conducted. An overview of the results gained by the analysis is shown in Figure 18.

Figure 18: Overview of the PPP analysis conducted with the BVL database (version May 2013).



From about 1378 PPPs authorised in Germany in May 2013, 351 PPPs contain one or more of the potential candidates for substitution. For 33 of the potential substitution candidates no PPP

is authorised for use in Germany. The 351 relevant PPPs are not equally distributed across all possible use categories, but they are mainly used as herbicides (37.3%), fungicides (36.2%) and insecticides (18.1%). The PPPs containing potential candidates of substitution are authorised for use against 164 out of a total of 477 different pests in 209 of a total of 309 different crops. In terms of affected crops, ornamentals and cereals are those for which the highest number of PPPs containing potential substitution candidates are authorised. In terms of target pests, annual dicotyledonous weeds are those for which the highest number of PPPs containing candidates for substitution are authorised; this applies to both products with and without potential candidates for substitution. PPPs containing potential substitution candidates are authorised for 1863 out of a total of 3606 different uses. Thus, even if only 25.5 % of all PPPs authorised in Germany may contain potential candidates for substitution, comparative risk assessment will have to be conducted for 51.7% of all intended uses.

For 58.8% of the PPPs containing potential substitution candidates no alternative PPP without potential substitution candidates is authorised in Germany. However, for 41.2% alternatives are available, which means that about 18479 comparative risk assessments of PPPs may become necessary when starting with the implementation of the comparative risk assessment under the current pesticide regulation.

6 Outline of an approach to comparative risk assessment

The aim of the work reported in this chapter was to outline a generic approach to the comparative environmental risk assessment of chemical plant protection products that relies on the data that are available to the competent Member State authority from the authorisation dossiers for individual products. The work included the following steps:

- examination of the legal aims and provisions for performing comparative environmental risk assessments; identification of resulting requirements for an appropriate approach, room for interpretation, and needs for operationalisation of key terms (section 6.1);
- examination of the available standard data basis and the assessment criteria routinely applied for PPP authorisation; identification of consequences for performing comparative assessment (section 6.2);
- review of the scientific literature on concepts of comparative risk assessment, approaches to the implementation of the substitution principle, ranking of PPPs by means of pesticide risk indicators, and methodologies for comparing pesticide risk profiles; identification of lessons to be learned for outlining an approach that may find consensual acceptance (section 6.3);
- review of the draft Commission guidance document on comparative assessment; identification of needs for advancement, refinement, and specification for the environmental part of comparative assessments (section 6.4); and
- derivation of a proposal for guiding principles of comparative environmental risk assessments of plant protection products (section 6.5), ready for testing of practical feasibility in subsequent case studies (Chapter 7).

All considerations in this chapter are

(i) entirely focussed on comparisons of environmental risks, and do not include any aspects of human health risk comparisons, and

(ii) strictly confined to comparisons of chemical PPPs; while comparisons with non-chemical alternatives were out of scope.

6.1 Legal aims and provisions

As already explained in the introduction, Article 50 of the PPP Regulation stipulates that Member states "*shall not authorise or shall restrict the use*" of a CFS containing PPP, where a comparative assessment demonstrates that an alternative exists which is

- "*significantly safer for human or animal health or the environment",*

in addition to a number of agronomic conditions for substitution that must be fulfilled. The assessment is limited to comparisons with already authorised alternative products or non-chemical methods. The comparative assessment must be performed by the Member States. Thus, the burden of proof is with the competent authority. In case of doubt, authorisation of the CFS containing candidate product cannot be refused. Hence, we conclude that an appropriate procedure must first of all provide clear, transparent, and agreeable rules for

distinction between unambiguous cases for substitution and cases where a significant increase in safety is either doubtful or not achievable.

Annex IV to the Regulation clarifies that "*significantly safer*" means

- *"significantly lower risk to health or the environment"*

and specifies that "*if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER)"* constitutes a *"significant difference in risk".*

Thus, substitution decisions must be clearly based on a comparison of risks, not just on a comparison of hazards. However, some room is left for the exact interpretation and the operationalisation of the term "*risk"*, and in particular the phrase "*risk to the environment"*. "*Risk to the environment"* is a multi-facetted concept comprising many different types of risk and various possible risk descriptors. Which of them should and could be included in a comparative assessment? Which are dispensable or inappropriate? The final decision on these questions is left to the expertise of the competent Member States authorities.

Ecotoxicological textbook knowledge says that "*risk"* is the "*probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent*" (Van Leeuwen and Vermeire 2007, p. 665). For regulatory purposes, however, data for quantifying chemical risks in such probabilistic terms are usually not available. As a way out of the dilemma, the so-called risk quotient (RQ) approach has been established across numerous pieces of chemicals legislation, not only in the EU but worldwide. Risk quotients measure risks in terms of the ratio between an exposure level (such as PEC) and a hazardous level (such as EC50) or a regulatory acceptable level (such as PNEC). In contrast to all other pieces of EU chemicals legislation, the PPP Regulation prescribes the use of inverse risk quotients (toxicity/exposure) for most but not all ecotoxicological endpoints; for bees, exposure/toxicity ratios are used but are denoted as hazard quotients (HQ)[6]. In comparison to probabilistic risk quantifications, the simple RQ approach has many limitations, but one well-recognised advantage is that it *"could be used for comparisons amongst alternative compounds (where comparable data are available)"* (ECOFRAM 1999, p. 5-11).

The PPP Regulation does not include any explicit definition of the terms "*risk*" and "*risk to the environment*". The Regulation says that PPPs must have

- "*no unacceptable effects on the environment*" (Article 4(3e) of the PPP Regulation).

The phrase *effects on the environment* includes but is not limited to adverse effects on non-target organisms for which risks can be characterised in terms of RQs. For example, contamination of groundwater above the EU drinking water standard (0.1 µg/l) is considered to be an *unacceptable effect on the environment* (Article 4 in conjunction with the specifications given in Commission Regulation 546/2011, Annex, Part I, Section C.2.5.1). Thus, the question arises whether comparative environmental risk assessments of PPPs should be confined to comparisons of RQs or whether other standard criteria for assessing *effects on the environment* should be included too. The TER-based significance criterion given in Annex IV of the Regulation may suggest focusing exclusively on RQ comparisons. The mentioning of "*risk to groundwater*" in the criteria for CFS identification (Table 1), however, may allow arguing for a

[6] The PPR Panel repeatedly called for a harmonization in terms of exposure/toxicity ratios (EFSA 2009). However, up to now, the inconsistent and confusing use of both toxicity/exposure and exposure/toxicity values within the same Regulation and across European chemicals legislation continues to be prescribed by the law.

broader approach. The resulting range of options is outlined in more detail in section 6.2.2 below.

The fact that PPPs have complex environmental risk profiles, comprising TER values and other indicators for a range of incomparable endpoints, means that a reduction of risks in one assessment area (such aquatic risks) may be counteracted by an increase in another area (such as risks to earthworms). For assessing the situation, it is therefore important to define significance levels for both risk increases and risk decreases. The problem is not explicitly addressed in the legal text, but Annex IV generally formulates that a tenfold or higher difference in TER values is a "*significant difference"*. Hence, we conclude that equivalent significance levels shall apply to the assessment of both increases and decreases of risks.

Recital 19 of the PPP Regulation explains that the comparative examination of CFS containing PPPs shall aim to replace them by

- "*plant protection products containing active substances which require less risk mitigation measures or by non-chemical control or prevention methods*".

Correspondingly, point 2 of Annex IV to the PPP Regulation requires that "*the stringency of imposed restrictions on use*" shall (*inter alia*) be considered in identifying "*a significant difference in risk*" "*on a case-by-case basis*".

Currently, there is no uniform system for defining risk mitigation measures or imposing restrictions on use. Member States follow their own rules and procedures. In Germany, risk mitigation measures for environmental protection are systematically derived from risk assessments. For the aquatic compartment for instance, TER values are routinely calculated for a range of exposure scenarios resulting from a variety of possible risk mitigation measures. On this basis, the least restrictive mitigation measure that ensures reduction of the risk to an acceptable level is identified and imposed with the authorisation. Thus, stringency of risk mitigation measures is a secondary reflection of risk assessment outcomes. Lower risk automatically leads to less risk mitigation. Under these conditions, we conclude that a procedure that focusses on quantitative comparisons of RQs (or other appropriate risk indicators) as the primary data source sufficiently serves the purpose of a comparative assessment. There is no necessity for separately comparing risk mitigation measures as a secondary information source. However, this does not exclude the possibility to use information on risk mitigation measures as a simple way of pre-selecting promising alternative products for starting the comparative assessment in cases where many potential alternatives are available.

As said, risk mitigation measures aim to reduce risks to an acceptable level. As a consequence, after enforcement of risk mitigation measures the remaining risk of a candidate product may not be higher than the risk of an alternative product without risk mitigation measures. With the aim for less risk mitigation measures expressed in Recital 19, however, it becomes clear that comparative risk assessments must refer to comparable conditions of use with either no risk mitigation measures or the same risk mitigation measures applied to both the candidate and the alternative product. Otherwise, the full risk reduction potential cannot be unveiled.

The aim of replacing CFS-containing products by "*products containing active substances which require less risk mitigation measures"*, as Recital 19 says, may be interpreted to indicate that CFS-containing products should be substituted by CFS-free products. However, the text is not explicit at this point. In fact, neither the main body of the legal text nor the Annexes exclude the possibility of a substitution of a candidate product by another candidate product, if a significant risk reduction would result. Thus, CFS-content is no criterion for the comparative assessment. However, substitution of a candidate product by another candidate product is no sustainable solution. Candidate products will be subject to reiterative comparative assessments

until an alternative becomes available that is both CFS-free and significantly safer. Hence, CFS-content may well be used as an important criterion for pre-selecting promising alternatives for inclusion in the comparative assessment (apart from risk mitigation measures).

6.2 Data requirements and assessment criteria

Detailed criteria for assessing the "*influence on the environment*" of individual chemical plant protection products have been set out in the Annex to Commission Regulation 546/2011 laying down Uniform Principles for PPP evaluation and authorisation, in the following shortly denoted as the *Uniform Principles*. Corresponding data requirements for products and active substances have been defined in Commission Regulations 284/2013 and 283/2013, respectively. The data must be provided by applicants.

6.2.1 Available data

For comparative assessments of different chemical plant protection products, no additional data requirements have been laid down in the new PPP Regulation. Hence, we conclude that data sets that the authority must consider to be sufficient for the authorisation of individual products should also be sufficient for performing comparative assessments of different products. Thus, an appropriate procedure should enable decision-making within the limitations of existing data from authorisation dossiers. Other information may be taken into consideration if available, but *de novo* generation of any further data cannot be a pre-requisite for completing a comparative risk assessment, since the pertinent Article 50 of the PPP Regulation does not define any additional data requirement that would go beyond the legal requirements for an authorisation dossier.

Data generation for the regulatory assessment of environmental risks of chemical plant protection products follows the principle of a tiered approach. Standard data requirements basically apply to every application for product authorisation (with exemptions). So-called higher tier testing or modelling is required only conditionally if standard data provide indications for unacceptable risks. As a consequence, comparative risk assessments may have to deal with asymmetric data situations where higher tier test data may be available for the more risky product only. Additional higher tier testing for the product with apparently lower risks cannot be required, for legal reasons, for economic reasons, and for ethical reasons of animal protection[7]. Hence, we conclude that an appropriate procedure must essentially be based on the comparison of risk estimates derived from standard test data. Comparisons of higher tier risk estimates should be included where possible, but cannot be an essential condition for decision making. Otherwise, the legislative aim would largely be rendered unenforceable.

The standard spectrum of data available for comparative environmental risk assessments of PPPs is defined by the acceptability criteria for the authorisation of PPPs on the basis of standard data sets, as laid down in the Uniform Principles, i.e. section C.2.5 of Part I of the Annex to the Commission Regulation (EU) No 546/2011. These criteria specify the requirements for PPPs which are considered to "*have no unacceptable effects on the environment*" according to Article 4(3e) of the PPP Regulation. They are structured into criteria on "*Fate and*

[7] This applies to requirements stipulated by the competent authorities. On their own initiative, applicants may always conduct such tests if they deem them appropriate, e.g. to achieve a product label with fewer or less severe mitigation requirements

distribution in the environment" and "*Impact on non-target species*", as summarised in Table 13 and Table 14, respectively. These criteria include a number of different data types: risk quotients such as TER and HQ, maximum adverse effect levels, bioconcentration factors, persistence times, and contamination levels in environmental compartments. This raises the question whether all these criteria for single product assessments should also be included in comparative product assessments, and if so, how this could be done properly. Alternatively it may be asked whether the exercise should be more focussed, in particular by comparing risk quotients. The answer depends on the exact interpretation of the requirement for a "*significantly lower risk to (...) the environment"* laid down in Annex IV of the PPP Regulation, in particular the understanding of the phrase *risk to the environment*, as detailed in the following.

Table 13: Requirements for PPP authorisation concerning Fate and distribution in the environment as laid down in the Uniform Principles, Commission Regulation 546/2011, Annex, Part I, Section C.2.5.1

Compartment	Criterion[1)]	Requirement
Soil	persistence (field)	DT90 ≤ 1 year and DT50 ≤ 3 months*
	non-extractable residues (lab)	≤ 70% of initial dose after 100 days with mineralisation ≥ 5%*
groundwater	concentration	≤ 0.1 µg/l or 10% of ADI (or equivalent toxicological limit value), whatever is lower
surface water	concentration	no unacceptable impact on non-target species
surface water used for drinking water abstraction	concentration	no compromise of drinking water quality standards
Air	airborne exposure concentration for operators, bystanders or workers	≤ AOEL (or equivalent limit value)

[1)] Criteria apply to active substances, including relevant metabolites and breakdown or reaction products as specified in the legal text

* unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues or unacceptable phytotoxic effects occur in succeeding crops or that there is an unacceptable impact on the environment

Table 14: Requirements for PPP authorisation concerning Impact on non-target species as laid down in the Uniform Principles, Commission Regulation 546/2011, Annex, Part I, Section C.2.5.2

Organism Group	Endpoint	Requirement
birds and other non-target terrestrial vertebrates	acute and short-term LD 50	TER ≥ 10*
	long-term	TER ≥ 5*
	BCF, related to fat tissue	BCF ≤ 1*
aquatic organisms	fish and Daphnia, acute	TER ≥ 100*
	fish and Daphnia, long-term	TER ≥ 10*
	algal growth inhibition	TER ≥ 10*
	BCF	BCF ≤ 1000*, if readily biodegradable
		BCF ≤ 100*, if not readily biodegradable
Honeybees	oral or contact	HQ ≤ 50 (1/HQ ≥ 0.02)*
other beneficial arthropods	lethal or sublethal lab tests at max. application rate	≤ 30 % of test organisms affected*
earthworms	acute	TER ≥ 10*
	long-term	TER ≥ 5*
non-target soil micro-organisms	N or C mineralisation after 100 days (lab)	affected by ≤ 25 %*

*unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the PPP in accordance with the proposed conditions of use

6.2.2 Applicable Criteria

As said before in section 6.1, the term *risk*, and in particular the phrase *risk to the environment*, is not explicitly defined, neither in the PPP Regulation nor in the Uniform Principles. Considering the context of its use in Annex IV and in other parts of the Regulation, the requirement for comparing *risks to the environment* may be interpreted in four different ways:

(i) Comparing *ecotoxicological* risks,
as defined in Section 10 of Part A of the Annex to Commission Regulation (EU) No 284/2013 on data requirements for PPPs;

(ii) Comparing risks for *impacts on non-target species*,
as specified in section C.2.5.1 of Part I of the Annex to the Uniform Principles in conjunction with Article 4(3e,ii) of the PPP Regulation;

(iii) Comparing risks for *effects on the environment*,
as listed in section C.2.5 of Part I of the Annex to the Uniform Principles in conjunction with Article 4(3e) of the PPP Regulation.

(iv) Comparing *ecotoxicological* risks (as defined for option *i*) and comparing risks for *groundwater* contamination (as defined as part of option *iii*), but not comparing *bioconcentration* and *persistence* (as defined for option *ii* and part of option *iii*) independently from resulting *ecotoxicological* risks, as further explained below.

Option (i) would be the narrowest interpretation. It would comply with the usual understanding of the term *risk* in the ecotoxicological literature and the corresponding definition in Commission Regulation 284/2013 on data requirements, which states:

- "*The ecotoxicological assessment shall be based on the risk that the proposed plant protection product poses to non-target organisms. In carrying out a risk assessment, toxicity shall be compared with exposure. The general term for the output from such a comparison is 'risk quotient' (RQ). RQ may be expressed in several ways, for example, toxicity:exposure ratio (TER) and as a hazard quotient (HQ)"* (Commission Regulation (EU) No 284/2013, Annex, Part A, Section 10, Point 8).

Option (ii) would be a slightly wider interpretation. It would consider the fact that the regulatory definition of unacceptable *impacts on non-target species* is not limited to risks for adverse effects, but includes bioconcentration factors as an independent assessment criterion (see Table 14). It would mean, that a significant reduction in bioconcentration potentials could be considered as a sufficient reasoning for substitution, not necessarily requiring positive evidence for a significant concurrent reduction of actual risks for adverse effects (of course provided that no other reasons argue against substitution).

Option (iii) would be the widest interpretation. It would consider the fact that the regulatory definition of unacceptable *effects on the environment* is not limited to *impacts on non-target species*, but includes *fate and distribution* as an independent assessment criterion, as established in terms of concentration limit values for environmental compartments laid down in the Uniform Principles (Table 13) and in terms of cut-off criteria for the approval of active substances that classify as POP or vPvB substances according to the criteria laid down in Annex II to the PPP Regulation 1107/2009. Option (iii) would mean, that a significant reduction in persistence and bioconcentration and/or in groundwater contamination potentials could also be considered as a sufficient reasoning for substitution, again not necessarily requiring positive evidence for a significant concurrent reduction of actual risks for adverse effects (and of course also provided that no other reasons argue against substitution).

Option (iv) would be a cross-cutting kind of interpretation, combining option (i) with part but not all elements of option (iii). It would consider the fact that the legal provisions are markedly different for groundwater contamination on the one hand and for bioconcentration and/or persistence parameters on the other hand. As a consequence, this option (iv) means that risks for groundwater contamination are considered to be subject of comparative assessments independent from and in addition to comparisons of ecotoxicological (and human) risks, while persistence and bioconcentration are not. Arguments in favour of such a differentiation can be based on the fact that acceptability criteria for persistence and bioconcentration (as laid down in the Uniform Principles) apply only conditionally, subject to so-called "*unless*" clauses (as given in the footnotes to Tables 13 and 14), while the upper limit value for acceptable groundwater concentrations (0.1 µg/L) applies unconditionally. The acceptability criteria for persistence and bioconcentration can be overruled by the results from (higher-tier) ecotoxicological risk assessments (provided POP, PBT or vPvB criteria are not fulfilled). In contrast, the acceptability criterion for groundwater contamination can only be lowered down further but it cannot be overruled by the results from (eco)toxicological risk assessments.

Deciding between these options is an affair of the competent Member States authorities. Clear opinions on the issue had not yet been officially formulated during the period for performance of this project, but the German UBA signalled to favour option (iv). We therefore conclude that an appropriate procedure for comparative environmental risk assessments must be based on comparisons of risk quotients, but should also be able to harbour comparisons of indicators for environmental contamination, in particular groundwater concentrations and optionally also other fate and distribution parameters such as bioconcentration and/or persistence.

The legal text defines a tenfold difference in TER values as a significant difference in risk, "*if relevant*". In the Uniform Principles, criteria for acceptable risks are not all defined in terms of TER values. Hence, definitions of equivalent significance levels are necessary for such assessment criteria, "*if relevant*". In agreement with Commission Regulation 284/2013, TER values may be considered just as a special form of risk quotients, as detailed above. Consequently, the legal significance criterion of a tenfold difference may be interpreted to apply to all RQs, not just to TERs.

Definition of equivalent significance criteria is less easy where acceptable levels have not been defined in terms of RQs but in terms of maximal effects of PPP use on target organisms, such as impact on beneficial arthropods other than honeybees or effects on non-target soil micro-organisms (see Table 14). With the aim to achieve full consistency, the best solution would be to revise testing requirements and acceptability criteria in a way that allows expressing acceptable impacts on non-target organisms uniformly in terms of RQs. Regarding beneficial arthropods, the German UBA has already done so and established a TER-based approach on a national level. Regarding soil microorganisms, a solution is not readily at hand. RQ calculations would require estimations of effect concentrations or doses. Derivation of such estimates from single point measurements of effects observed at a given application rate would require some kind of standard assumption about the slope of dose response curves. Working out such an approach or exploring other options for solving the problem was considered to be beyond the scope of this project.

If the requirement for the comparison of product *risks to the environment* is considered to be not limited to ecotoxicological risks in terms of RQs, but to include risks for environmental contamination beyond regulatory acceptable levels (options *ii*, *iii*, and *iv* above), it would be necessary to define a *significant difference in risk* for bioconcentration, persistence, or groundwater contamination (see Tables 13 and 14). Assuming that the (eco)toxicity of two products is not significantly different, it would be self-suggesting to consider a factor of at least

10 as a significant difference in bioconcentration, persistence, or groundwater contamination levels, in congruence to the legal definition of significant differences in TER values.

Independent from the option chosen for interpreting *risks to the environment*, the comparative assessment will have to deal with the fact that PPPs have complex risk profiles; just the number of endpoints for consideration will be somewhat higher or lower. For single product assessments, all the assessment criteria listed in the Uniform Principles (Tables 13 and 14) apply independently. There is no aggregation and no trade-off between incomparable endpoints, such as risks to bees, risks to earthworms, and risks of groundwater contamination. The PPP Regulation does not provide any clue that comparative product assessments may deviate from these principles.

Thus, it can be concluded that the task is to perform comparative overall assessments of risks, without any weighing or balancing of incomparable risks, and not excluding any endpoints *a priori*. On the other hand, however, it may be taken into consideration that comparative assessments under the PPP Regulation are applied only to such products that comply with the acceptability criteria defined in the Uniform Principles. The aim of the comparative assessment is not to ensure compliance with acceptable risk limits, but to explore possibilities for reducing risks further down to an unavoidable minimum. Under this presupposition, it may be argued that some kind of weighing or selecting different risks could be justifiable. In particular, it could be considered whether reduction of risks that are associated with the criteria for CFS identification should gain priority over other endpoints of lower regulatory concern.

The point is methodologically important, because justification for any kind of weighing may open the door for procedures that filter risks for comparative assessment or that aggregate incomparable risks into comparable indicators of overall risks. Many such approaches have been proposed, but for other purposes such as the calculation of sustainability indicators under Directive 2009/128/EC. Thus, the question arises whether adoption of such approaches could be an option for achieving consensually acceptable regulatory substitution decisions, and if not, whether other more appropriate methods for comparing complex risk profiles have already been suggested. To clarify the point, we reviewed the status of debate in the literature and we examined the development of a Commission guideline for comparative risk assessments, as detailed in the following sections.

6.3 Review of methods

Quantitative comparisons of plant protection product risks in terms of risk quotients for multiple endpoints and exposure situations is a novel and demanding regulatory task. Appropriate methodologies tailored for the requirements of the EU PPP Regulation are not readily available from the literature. This is the negative result from a search into the scientific literature on concepts of comparative risk assessment, approaches to the implementation of the substitution principle, ranking of PPPs by means of pesticide risk indicators, and methodologies for comparing pesticide risk profiles, as briefly summarised in the following. The positive outcomes of the exercise, however, are some lessons about possible pitfalls. An appropriate approach must get around them if not running the risk of being rejected for reasons of missing transparency or scientific validity.

6.3.1 Concepts of comparative risk assessment

There is a rich literature on "*comparative risk assessment*". In the widest context, the term denotes a structured approach to decision making and priority setting in environmental policies and environmental management. As a general framework for evaluating environmental problems and strategies for solution, comparative risk assessment was invented by the US EPA in the late 1980s, resulting in the first US national comparative risk report in 1987 (US EPA 1987). In subsequent years many US regions, states and localities undertook comparative risk projects for the purpose of guiding priority-setting decisions in environmental policies (Andrews, Apel, Linkov 2004). On an international level, the development and the application of the concept was reviewed in 2002 at a dedicated NATO Advanced Research Workshop. The outcome from the workshop was compiled in a book on "*Comparative risk assessment and environmental decision making*", edited by Linkov and Ramadan (2004), and subsequently developed further into a proposal for a framework that couples multi-criteria decision analysis with adaptive management methods (Linkov et al. 2006). Concerning goals and perspectives, the workshop introduced a distinction between two different types of comparative risk assessments: macro scale and micro scale applications. Macro scale studies consider multiple risks and different types of environmental problems on a state-wide, nation-wide or multi-national scale for different goals, such as political priority setting and societal consensus building. Micro scale applications have focused objectives within the general goal of comparing risks of alternatives in solving problems, for example different options for drinking water disinfection.

With this conceptual background, comparisons of risks of different chemicals used for a particular purpose can be classified as a special micro scale application of the general idea of comparative risk assessment. This special micro scale application is the key to the implementation of the substitution principle under European chemicals legislation. Unfortunately, however, the wider literature context of comparative risk assessment is scientifically and politically interesting, but practically almost useless for designing a regulatory procedure that efficiently meets the requirements of a specific piece of EU legislation, such as the PPP Regulation. Goals and approaches of macro scale comparative risk assessments are much too different from the requirements on the micro level; they do not provide principles or methodologies that could be easily adopted for comparative PPP risk assessments.

6.3.2 Implementing the substitution principle

The history, the meaning, and the implementation of the substitution principle as an element of chemicals legislation has been reviewed in a report prepared for the Swedish Chemicals Agency by Hansson and Ruden in 2007 (KEMI 2007), in revised form by Hansson, Molander, and Ruden in 2011, and most recently by Lofstedt in 2014, with extensive commenting provided by Abelkop (2014), Aven (2014), Dudley (2014), Olofsson (2014), Renn (2014), and the UK's Royal Society of Chemistry (RSC 2014). Lofstedt concludes that the substitution principle surprisingly is a woefully under-researched topic and that there is no consensus on how to best apply the principle.

Much of the debate circles around the question whether substitution decisions may only be taken on the basis of risk comparisons or whether comparisons of hazards may also provide a sufficient ground. Proponents of a hazard-based substitution argue that elimination of a hazard should always have priority over reducing the risk associated with a hazard by means of risk management measures. They consider the substitution principle as an application of the idea of "inherent safety", which is a guiding principle in chemical safety engineering (see Hansson

2010). It means that the desired functionality of a product or a production process is achieved by using the least hazardous materials possible. However, this approach presumes that the functionality and the toxicity of a chemical are different categories. It may work with chemical products for technical purposes, such as cooling, gluing, painting, lubricating, or degreasing, to name but a few examples. But it has obvious shortcomings for comparing plant protection products. PPPs are designed for killing or inhibiting target organisms. Being hazardous to organisms is the essential part of their functional features. Substitution of PPPs therefore may only aim (i) to eliminate certain hazardous properties (such as those defined by the legal CFS criteria) and (ii) to reduce risks to non-target organisms, but not to render PPPs biologically harmless.

The PPP Regulation prescribes a risk-based approach to comparative assessment. The literature controversy over hazard-based approaches is hence not further relevant for the task of designing an appropriate procedure. However, there are other important points of the general discussion about the implementation of the substitution principle that deserve consideration. Basically they all emerge from the fact that hazardous substances have complex risk profiles. This triggers a bundle of difficult questions:

- Which data sets are needed for completing a comparative risk assessment?
- How to deal with asymmetric data situations, where the spectrum of endpoints for which risk estimates are available are not perfectly identical for the two products that shall be compared?
- How to distinguish between significant and insignificant differences in risks for comparable endpoints, such as adverse effects on honeybees?
- How to weigh up crosscurrent changes in incomparable risks, for example if substitution reduces risks for reproductive toxicity in mammals, but raises risks for adverse effects on earthworms?
- How to aggregate complex profiles of incomparable risks into comparable indicators of overall risks?

At the current stage, conclusive and generally valid answers to all these questions cannot be derived from the debate in the literature. However, some advice can be deduced regarding the design of a procedure that may lead to consensually acceptable substitution decisions under the PPP Regulation, and not to an ever increasing number of court cases. As a simple strategy, such a procedure may avoid the most critical points for discussion by

- taking account of all available evidence
  about the full risk profiles of products, not disregarding any aspects of human and environmental risk assessment from the beginning;
- avoiding any risk/risk trade-offs
  between incomparable risks which would require societal valuation and judgement, unless a clear legal basis and an agreed regulatory methodology has been established for that purpose;
- providing full transparency
  about all rules and reasons for the decision.

6.3.3 Pesticide risk indicators

For the comparative assessment of chemicals in terms of their relative hazards and risks, numerous scoring and ranking systems have been proposed. In 1994, Davies, Swanson, and Jones already identified and evaluated 51 of such systems. In 2007, the KEMI report on the substitution principle stated that around 150 different chemical ranking and categorising schemes are available, and further ones have been developed since then. Apart from supporting substitution decisions by public or private actors, these scoring and ranking systems have been designed for a variety of purposes such as prioritising chemicals for further investigation or regulatory action, monitoring trends in environmental pollution, or assessing the life cycle impact of chemical products. Basically, all scoring and ranking systems aggregate hazard or risk profiles into a single or a composite index that allows a relative ranking. The index may by a numerical score or an assignment to a rank group such as high, low or medium risk. Scoring systems transform hazard or risk information for different endpoints into dimensionless scores and sum up or multiply the weighted scores. Results obtained with different scoring and ranking approaches may differ vastly and scientific consensus finding on the validity or invalidity of proposed methodologies is a slow and tedious process. It requires dedicated programs, as for example the joint UNEP–SETAC Life Cycle Initiative for harmonising so-called "characterisation factors" for human and environmental toxicity in life cycle impact analyses (LCIA) (see Rosenbaum et al. 2008).

A sub-set of the numerous scoring and ranking systems has been specifically developed for comparing pesticides risks. Collectively they are usually denoted as "pesticide risk indicators" (PRIs). Comparative evaluations of different PRIs have been presented by Labite, Butler, and Cummins (2011), by Feola, Rahn, and Binder (2011), and earlier by Reus et al. (2002).

Some PRIs are confined to human health risks, in particular occupational health risks, and hence out of the scope of this study. Examples are the operator exposure score proposed by Dosemeci et al. (2002), OHRI, the *Operational Health Risk Indicator* developed by Bergkvist (2004), and RRPDI, the *Ranking of the Risk of Pesticide Dietary Intake* suggested by Low et al. (2004).

A second group of PRIs aims at an overall risk ranking, including both human and environmental risks in a single indicator. Three popular examples are EIQ, the *Environmental Impact Quotient* (Kovach et al. 1992, Kromann et al. 2011), POCER, the *Pesticide Occupational and Environmental Risk Indicator* (Vercruysse and Steurbaut 2002), and EcoRR, the *Ecological Relative Risk* (Sánchez-Bayo et al. 2002). Ten further examples for such overall PRIs can be found in the review of Labite, Butler and Cummins (2011). We considered such total risk indicators to be inappropriate for the purpose of this project and did not examine them any further. The reason is not simply the a priori confinement of this study to environmental risks, but also the misalignment with the legal requirements. Under the PPP regulation, different protection goals, separate procedures, and independent assessment rules apply for human health risks and ecological risks, and hence they should also not be mixed up for regulatory comparisons of product risks.

The third group of PRIs focusses exclusively on environmental risks, and hence was of prior interest for this study. Concerning the input data, two types of such environmental PRIs may be distinguished: complex environmental PRIs which are based on risk quotients and simple PRIs which are not. Simple PRIs are designed for being workable with relatively low data requirements. They aggregate information on hazards, applied amounts, and environmental fate, but do not require risk quotient calculations. Two prominent examples are the *PestScreen* tool developed by Juraske et al. 2007, and PERI, the *Pesticide Environmental Risk Indicator* used

for monitoring pesticide impact in Sweden at national level as well as farm level (Berkvist 2004).

For the purpose of comparative risk assessments under the PPP Regulation, risk quotients are available and their use is legally prescribed. Thus, lower data demands are neither necessary nor legally appropriate. In addition, comparative evaluations have shown that simple PRIs are not predictive for complex risk-based PRIs (Feola, Rahn, and Binder 2011). For these reasons, we considered simple non-risk-based PRIs inappropriate for this project.

The literature search identified two PRIs that are both risk-based and fully confined to ecotoxicological endpoints. These are NERI, the *Norwegian Environmental Risk Indicator* (Stenrød et al. 2008), and SYNOPS, the *Synoptic Model for Plant Protection Agents* developed in Germany by Gutsche and Rossberg (1997) for comparing the environmental risk potentials of different pest management strategies. There are two other PRIs which are also largely focused on ecotoxicological risks but which have some overlap with human health risk assessment due to the inclusion of drinking water standards for assessing groundwater contamination levels. These are EPRIP, the *Environmental Potential Risk Indicator for Pesticides* invented by Padovani et al. (2004) and further improved by Trevisan et al. (2009), and PIRI, the *Pesticide Impact Rating Index* developed by Kookana et al. (2005).

Both NERI and SYNOPS have been adopted as tools for monitoring the effects of National Action Plans for reducing risks from the use of PPPs in Norway and Germany, respectively (Stenrød et al. 2008, BMI 2014a). Other countries use similar approaches such as those evaluated in the HAIR project (*Harmonized Environmental Indicators for Pesticides Risks*) (Kruijne et al. 2011, 2014). NERI sums up scores for product formulation, leaching potential, persistence, bioaccumulation, and risks to aquatic organisms, birds, earthworms, bees and other arthropods. SYNOPS is currently used to calculate two separate indicators for overall terrestrial and aquatic risks, based on risk quotients for bees and earthworms, and for algae, daphnids and fish, respectively (BMI 2014b).

Environmental PRIs such as NERI and SYNOPS are generally considered to be valuable tools for those purposes they have been designed for, but whether they could also be reasonably used for justifying regulatory decisions on product substitution under the PPP Regulation is rather questionable. One point is that the spectra of endpoints do not fully agree with the standard requirements for environmental risk assessment under the PPP Regulation. But this is only a minor technical problem which should be solvable by appropriate adaptations. In addition to that, however, there are two other points that are much more problematic, because they emerge from fundamental drawbacks of risk scoring and ranking systems. The advantage of such systems is to condense spectra of incomparable risks in a uniform index that allows relative ranking, but the main disadvantages are:

(i) Differences in product risks cannot be quantified on the level of aggregate overall risk indicators, neither in probabilistic terms nor in terms of differences between risk quotients. This is only possible on the level of single comparable endpoints.

(ii) Risk/risk trade-offs are hidden in the way risk quotients are transformed into scores, weighed and summed up. For example, the SYNOPS terrestrial risk indicator implies that an increase in the risk for bees can be compensated by a decrease in the risk for earthworms.

The UK's Royal Society of Chemicals considered the problem, not with regard to the PPP Regulation but in the context of substitution decisions under REACH, and came to conclude: "*Although various attempts to produce ranking scores have been made, none have been*

successfully adopted. This is because these systems have been trying to impose a technical process on what is properly a societal judgement" (RSC 2007).

In summary, we find that so-called pesticide risk indicators (i) do not facilitate the quantification of risk quotient differences as required by the PPP Regulation and (ii) do not comply with the requirements for consensually acceptable regulatory substitution decisions derived above from the debate about the implementation of the substitution principle, i.e. avoidance of risk/risk trade-offs, full transparency and best use of all available evidence.

6.3.4 Comparing pesticide risk profiles

An early attempt to develop a methodology for comparative analysis of complex ecotoxicological risk profiles of pesticides was made by a project team of the US EPA's Office of Pesticide Programs. The team's report was published in 1998 (US EPA 1998) and commented by a Scientific Advisory Panel (FIFRA SAP 1999). The report is interesting for this project because it includes a graphical approach which compares complex profiles of risk quotients without condensing data across incomparable endpoints. To this end, sets of risk quotients for specific uses of a range of alternative pesticide chemicals were displayed as a series of bar graph charts for direct visual comparison. The US EPA team explored that approach as one of two different basic approaches to aid decision-making. The other approach was a scoring method that ranks pesticides by means of a summary risk index, calculated as a weighted average of ratings for individual endpoints, basically similar to the pesticide risk indicators discussed above. The authors recommended concurrent and complementary use of both approaches.

The development of the dual methodology was brought forward by means of a case study. The case study was not designed to provide an exhaustive comparison of all ecological risks, but rather "*an illustrative example demonstrating how pesticides used as alternatives on the same site can be compared based on ecological risk and the results used to aid decision-making*" (US EPA 1998, p. 9). To this end, the authors selected 17 anonymised insecticide chemicals, four major crops (alfalfa, corn, cotton, peanuts), two different application techniques (granular, spray), and ten different endpoints characterised by risk quotients, including both acute and chronic risks for birds, fish and aquatic invertebrates. In addition to risk quotients, the analysis considered also information on the extent of use of the selected pesticides in the United States (% acres treated) as well as incidence reports on actual bird and fish kills.

From the graphical comparison of risk profiles, the authors concluded that for granular application one of the chemicals "*stands out as consistently presenting the greatest overall potential risks"* in all four crops (US EPA 1998, p. 85). The analysis did not include any criterion for distinguishing between significant and insignificant differences and a closer look at the figures may raise doubts whether the conclusion is really consistently valid for all individual endpoints. In principle, however, the example shows that such an approach may be useful for identifying PPPs that are clearly more or less risky than others which are used for the same purpose.

For spray application the picture was more complex with different chemicals representing the greatest risks for different organisms groups, crops, and application techniques.

The study had a different regulatory background and the aims went beyond a pairwise comparison of a candidate product with an alternative product as required under the EU PPP Regulation. The authors aimed to achieve a full ranking of the 17 chemicals. To this end,

(i) they did not compare absolute risk quotients but they transformed them into relative figures by expressing individual RQs as a percentage of the sum of the RQs of all

alternative chemicals for the same endpoint, crop, and application technique (only RQs exceeding regulatory levels of concern were included in the calculation);

(ii) they transformed these relative risk quotients into risk scores for summing them up in an overall risk index; and

(iii) they included incidence reports in the overall ranking procedure in addition to scores based on relative RQs.

The FIFRA Scientific Advisory Panel (FIFRA SAP 1999) considered all three steps being rather problematic, with the scientific validity being at least questionable if not missing at all. Graphical presentations were welcomed as an informative approach for clear and transparent communication of risk comparisons and corresponding decisions, but "*summing of risk quotients*" and "*comparisons of relative risk beyond comparisons of individual RQs*" was considered to be "*meaningless*", "*inappropriate*", or "*invalid*", due to the introduction of a number of ill-founded and mostly unstated assumptions.

The 1998 report was not the only attempt of the US EPA to develop an approach for the regulatory comparison of the ecological risks posed by different pesticides, but for the purposes of this project the others were less interesting. An earlier attempt, made already in 1992, did not consider complex risk profiles, but was confined to comparisons of acute avian risks from different granular pesticides (US EPA 1992). A later attempt compared risks of different rodenticides to birds and non-target mammals by means of a scoring approach, aggregating not only RQs but also other hazard and risk indicators for primary and secondary poisoning of the two different organism groups in a summary value.

6.4 Draft Commission guidance document

As a support for the Member States in carrying out the task of comparative risk assessments, the European Commission set out to prepare a guidance document on comparative assessment and substitution of PPPs. The development of the document started from a Swedish proposal made in November 2011 (KEMI 2011). Through several rounds of commenting by the other Member States, this was developed into a final Draft Commission Guidance Document until July 2014 (COM 2014). Until the end of this project (December 2014), the draft status of the paper did not change.

The paper provides a rough procedural scheme for the organisation of the whole process of comparative assessment in a stepwise fashion. In this process, the agronomical assessment of available alternatives is suggested to be performed and completed first. The comparative assessment of human health and environmental risks shall only be started, if one or more alternatives have passed a strong filter of the agronomic assessment. This implies that the assessment of the significance of potential economic or practical disadvantages, as required by Article 50 of the PPP Regulation, shall be based on isolated economic considerations. A possibility for weighing economic disadvantages with increases in safety for humans or the environment was included in earlier interim versions of the document, but disappeared from the final draft.

As clearly said in the document, "*the steps to follow in the comparative assessment for health and the environment (...) have not been elaborated in great detail*". The text does also not provide any further guidance to the interpretation and operationalisation of the requirement for a "*significant difference in risk*" beyond what is said in the legal text. The paper states that following recital 19 of the Regulation "*necessary risk mitigation needs to be taken into*

account" additionally. However, development of corresponding criteria is postponed to a medium term revision of the guidance.

The document acknowledges that PPPs have complex risk profiles, but fails to provide very clear and explicit rules for dealing with this accordingly. It simply says that "*it is not considered useful to propose guidance on what would characterise a significant difference in risk (...) for the comparison of risks in different areas of the assessment (e.g. risk for health vs. risk for the environment). Comparing risks in the same area of assessment may be easier (e.g. comparison of risk posed by different products to aquatic organisms)*". Additionally, the paper explains that comparisons of risk in different areas would require translation into a comparable measure such as a monetary value, but "*the risk assessments for plant protection products are considered to be too complex for such a procedure*".

Concerning quantitative comparisons of TER values, the document says that a factor of 10 should only be applied as a significance criterion "*when the authorisations of products are indeed compared based on conceptually equivalent TER-values"*. The exact meaning of the term "*conceptually equivalent TER-values"*, however, is left open. The paper also recognises that the criterion of tenfold difference in TER values "*only partly matches the general criteria for authorisation in the Uniform Principles*" but it does not provide any ideas on how to define equivalent criteria for other endpoints. The authors are also apparently aware of the problem of asymmetric data situations that may arise from the availability of higher tier studies for only one of two products that may have to be compared. They state: "*Where authorisations were granted based on higher tier studies this needs to be taken into account in when deciding on significant differences in environmental risk.*" Guidance on how this shall "*be taken into account*", however, is not given.

As a principle, the paper suggests conducting comparative risk assessments for human health and the environment in two main steps. In the first step, it shall be clarified "*whether a potential for substituting a candidate product actually exists*". To this end, a "*focussed assessment*" shall be conducted, which means that the candidate product shall be compared to alternatives only with respect to the criterion/criteria for CFS identification that was/were met by the active substance(s) in the candidate product. If this focussed assessment is able to demonstrate a significantly lower risk from the use of an alternative, the procedure shall continue to the second step. The second step then is a full comparison of the risk profiles of the candidate and the alternative product. The aim of the second step is to ensure that the potentials for significant risk reduction identified in step one for one assessment area are not counteracted by "*significant risks*" of the alternative product in other assessment areas or by "*extensive risk management measures necessary for the chemical or non-chemical alternative*". Otherwise "*the conclusion may be that substitution would not be the best tool for risk reduction*".

In the document, the proposed two-step procedure is considered to be "*the most straight-forward approach and is anticipated in most cases to reduce the workload*". If step one of the focussed assessment does not identify a significantly less risky alternative, then the assessment shall be stopped,

- "*unless available data or knowledge indicate a need for further evaluation in other areas of risk*".

However, no further specification or operationalisation of this "*unless*" clause is provided in the document. Without such detail, however, it is difficult to evaluate whether the expectation that the procedure can be stopped after step one in most cases may really materialise. On the contrary, there are good reasons to question this notion.

All data provided in the authorisation dossiers for individual products must be considered to be "*available*" to the competent authority, and hence must be taken into consideration. Typically, this will at least support comparative risk assessments for the spectrum of standard endpoints prescribed in the Uniform Principles, as explained in the sections above. The hazard-based criteria for CFS identification cover only a part of these endpoints for which risk assessments are conducted routinely. Furthermore, differences or indifferences for a single endpoint cannot be expected to be indicative for other very different hazards and exposure situations. For example, a candidate product may contain an active substance that has been identified for reason of a low ADI. The focussed first step assessment will consequently be confined to comparative human health risk assessments. If this leads to the conclusion that the available alternatives are not significantly safer for humans, this does not at all exclude the possibility that they are safer for the environment. Checking this possibility is not possible without conducting a comparative environmental risk assessment, at least at some kind of screening level for some pre-selected alternatives.

For the environmental part of the comparative risks assessments, there are further specific reasons to doubt whether the proposed two step procedure may indeed help to reduce the workload significantly. Our analyses have revealed that PBT criteria are by far most important for the number of comparative risk assessments that may have to be conducted (Faust et al 2014). In the Germany, 80% of the CFS in authorised products may be substances fulfilling two of the three PBT criteria. 70% do so because they have a high aquatic toxicity in combination with the P or B criterion (human toxicity criteria may apply additionally for a small fraction). These 70% of all CFS can be expected to account also for 70% of all candidate products. Thus, in the majority of cases, some kind of comparative environmental risk assessment will have to be conducted anyway. In these cases of CFS meeting two PBT criteria, the draft guidance documents suggests for the focussed first step assessment:

- *"Compare the risk for long-term effects on soil living organisms and on aquatic organisms using estimated cumulative exposure,*
- *Where relevant, compare the risk for bioconcentration, biomagnification and secondary poisoning of aquatic and terrestrial vertebrates, and*
- *Where relevant, compare also the potential for indirect exposure of humans."*

Subject to the exact interpretation of these tasks, such a focused first step assessment may already include a considerable part of the spectrum of endpoints for which a comparative assessment may be possible on the basis of standard data requirements laid down in the Uniform Principles. This is a consequence of the fact that the PBT assessment (as defined in the PPP Regulation)[8] is a composite criterion including persistence in water, sediment and soil, and bioaccumulation and toxicity in all kinds of aquatic organisms. Hence, it needs further clarification whether the workload for the proposed first step environmental risk comparison is really much lower than for the second step. If the first step leads to the identification of promising alternatives, the full comparison of risk profiles has to be conducted anyway. If not, the assessment shall be stopped unless the "*unless*" clause applies, as explained above. Again it may be argued that the spectrum of risks considered in the first step is not indicative for other types of environmental risk. A stop at stage one may therefore mean that for example an opportunity for significantly increasing the safety for bees is missed although it could be deducible from available data.

[8] Annex II, point 3.7.2 of Regulation (EC) No 1107/2009

6.5 Suggested principles

As a consequence of the considerations of the preceding sections, we suggest performing regulatory comparisons of environmental risks of PPPs on the basis of a set of generic principles. These principles aim to translate the legal provisions (section 6.1) into a practically feasible approach, simple and clear decision rules, and a fully transparent presentation of data and assessment criteria. They take account of the legal data requirements and the assessment criteria laid down under the PPP Regulation (section 6.2), as well as the debate about appropriate approaches and methodologies for comparative assessments in the scientific literature (section 6.3), and the status of guideline development on the Community level (section 6.4).

In considering all this information, particular attention was given to the fact that the burden of proof for demonstrating a significant risk reduction rests with the competent Member States authorities. Authorisation of the use of a candidate product may only be refused, if the proof for the existence of a significantly safer alternative is both scientifically robust and legally defendable, given the available data and methodologies.

A second important aspect for consideration was the fact that our analyses show that the competent authorities may indeed be confronted with the need to perform a rather high number of comparative assessments: around a quarter of all authorisation decisions may potentially be affected (Faust et al. 2014), unless CFS-containing products should be voluntarily withdrawn from the market or alternatives do not pass the filter of comparative agronomic assessment. This means that total reliance on a case by case handling of the task may be rather ineffective. Clear rules should be available that allows establishing a semi-automatic process for distinguishing between clear-cut cases and those that may require a detailed examination and case by case expert judgements.

The proposed principles comprise the following:

- comparative environmental assessments should be performed on the basis of full risk profiles, including all relevant endpoints for the regulatory risk assessment of PPPs for which comparable TER values or equivalent risk indicators are available to the authority at the time of decision making;
- quantitative comparisons of TER values or equivalent risk indicators should be performed separately for every comparable endpoint and exposure conditions; weighing, aggregating, and trade-offs across incomparable risks are inadvisable;
- tenfold differences in risk quotients should be applied as a uniform significance threshold for both risk reductions and risk increases that may be seen concurrently for different adverse effects on non-target organisms; where indicators for other types of regulatory relevant risks shall be included in the assessment, equivalent significance criteria should be defined *a priori*;
- as a standard decision rule, the use of an alternative product should be considered to be significantly safer, if the following two conditions apply concomitantly:

  (i) significant risk reduction for one or more endpoints

  AND

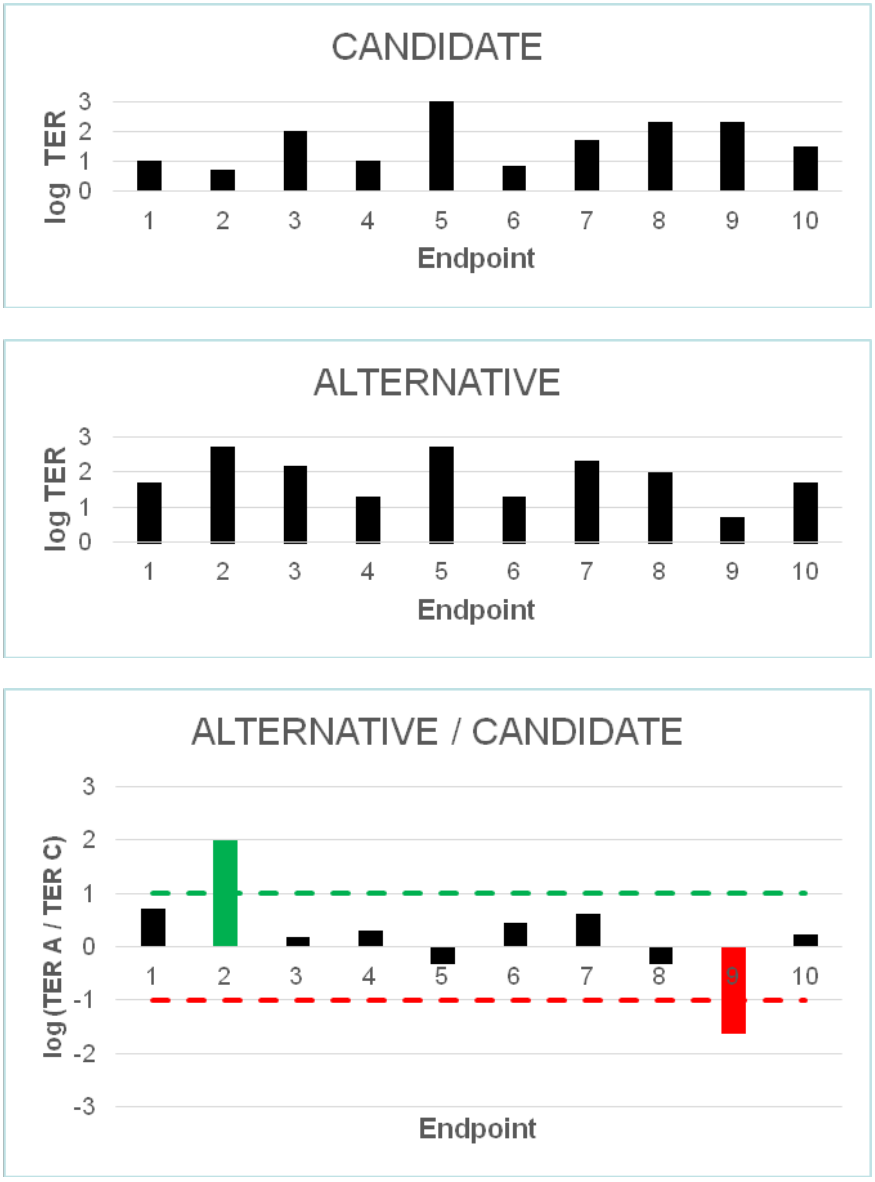
  (ii) no concurrent significant increase in risk for any other endpoint;

- exemptions from this rule may be granted on the basis of expert judgements for borderline cases or extreme situations; detailed conditions for such exemptions remain to be defined;
- in case of doubt, the comparative assessment should not claim a significant difference in risk.

The formulation of these principles has been focussed on the comparison of risk quotients for adverse effects on non-target organisms. As detailed in section 6.2.2, such risk quotients are the core of environmental risk profiling, but the competent authorities may decide to include other regulatory relevant types of risks to the environment, such as groundwater contamination in particular and optionally also bioconcentration and persistence. If so, thresholds for detecting significant differences would have to be defined. In correspondence to the explicit legal requirements for comparisons of risk quotients, it seems self-suggesting to apply the same significance criterion, i.e. a tenfold or higher difference between parameter values. However, the point of deriving such thresholds was beyond the scope of this project and may need further consideration. If included, persistence, bioconcentration, and groundwater contamination could each be compared on appropriate absolute scales or normalised to regulatory acceptable levels, such as the drinking water guideline value. When calculating quotients of the comparable values for a candidate and an alternative product, the result would be the same.

The application of the proposed principles is visualised in Figure 19 by means of a bar graph presentation of risk profiles for a theoretical example. It is assumed that comparable TER values for a common use of a candidate and an alternative PPP are available for a total of ten different endpoints. The resulting risk profiles are shown in the upper part of the figure. For the determination of the quantitative differences, the ratios between comparable TER values are calculated separately for every endpoint. The resulting spectrum of risk differences is shown in the lower part of the figure. By applying the legal significance threshold of a tenfold difference, the mere description of risk differences is turned into an assessment. The critical significance level is displayed in the figure by means of dashed lines, green for risk reductions and red for risk increases. By simple visual comparison of the risk difference bars with these critical levels, the assessment situation becomes immediately clear. In this arbitrary example, risk differences are insignificant for eight of the ten endpoints. For one endpoint, a significant risk reduction is seen (green bar). At the same time, however, this is counteracted by a significant increase of the risk for one other endpoint (red bar). Following the proposed decision rules, the outcome of the overall assessment is clear: it cannot be stated that use of the alternative is significantly safer; hence, authorisation of the candidate product cannot be refused.

Figure 19: Comparing TER-based risk profiles of two PPPs for a theoretical example



Dashed lines indicate the legal significance threshold (tenfold difference in TER values); red: significant risk increase; green: significant risk reduction

In this bar graph presentation, we choose to present differences in TER values in terms of the logarithm of the ratio of comparable TER values for the alternative and the candidate product. For the ease of understanding, this has the advantage that risk reductions and risk increases get positive and negative signs and are displayed in upward and downward direction, respectively. If exposure/toxicity ratios, such as HQ, or descriptors for persistence, bioconcentration or groundwater contamination shall be included in the differential risk profile, care must be taken to use reciprocal values (e.g. 1/HQ) in order to ensure that reductions and increases of risks all have all the same orientation in the assessment chart.

As a consequence of the proposed decision rule, four basic types of assessment situations can be distinguished. They are visualised in Figure 20 by means of bar graphs of risk differences for a spectrum of endpoints for which data may be available. The four possible assessment situations are the following:

(A) no significant risk differences for any assessment endpoint;

(B) significant increase of risk for one or more endpoints; insignificant risk differences for all other endpoints;

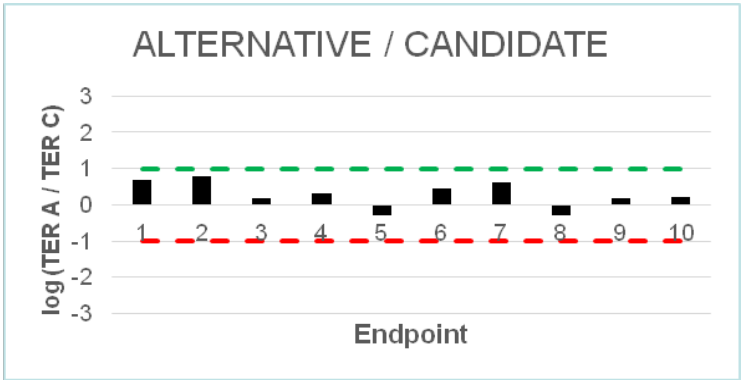
(C) both significant risk reductions and significant risk increases are observed in the spectrum of endpoints;

(D) significant risk reduction for one or more endpoints; risk differences for other endpoints are insignificant;

According to the proposed decision rule, the application for authorisation may only be rejected in the last situation D. In the first three situations A to C, the use of the alternative product cannot be said to be significantly safer than the candidate product.

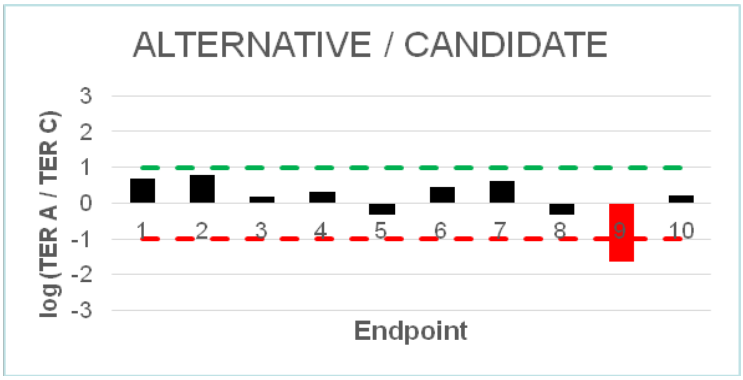
As with any principle, there may be borderline situations where rigid application of the proposed decision rules may be questionable, thus calling for a detailed examination of the special case and a corresponding expert judgement, which may overrule the generic principles, if considered appropriate. Two such possible situations are illustrated in Figure 21. In the first extreme case (upper part of the figure), risk reductions are seen as a consistent trend for all endpoints, but just do not reach the significant level for any individual endpoint. In the second extreme situation (lower part of the figure), significant risk reductions are seen for almost all endpoints, but unfortunately they are counteracted by a significant increase for one single endpoint. In both cases, the proposed decision rule would lead to the overall conclusion that the alternative is not significantly safer than the candidate product, and hence authorisation cannot be refused. Expert judgement on a case by case basis may come to a different decision due to an implicit or explicit weighing of risks and evidences. To work out detailed and transparent rules for such decision processes is a demanding task. Whether such work is really necessary and worth the effort, depends on the practical relevance of extreme situations such as those illustrated in Figure 21. As a consequence, we suggest postponing further considerations of this point until some experience has been gained about the typical problems that may result from the practical application of the proposed principles to a representative number of real cases for comparative assessment.

Figure 20: Assessment situations resulting from the comparison of TER-based risk profiles of two PPPs



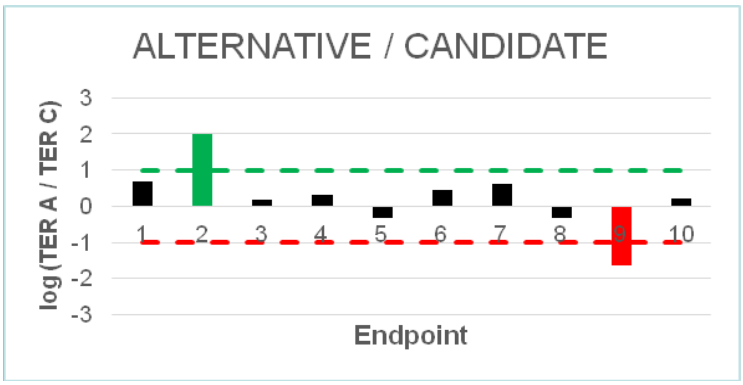
Situation A: No significant risk differences

Conclusion: Candidate product may be authorised



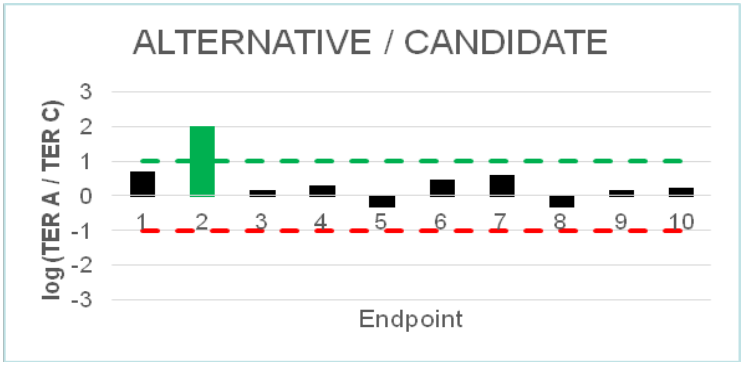
Situation B: The alternative shows significantly higher risk(s) for one or more endpoints and no significant risk reduction for any other endpoint

Conclusion: Candidate product may be authorised



Situation C: Significant risk reduction for one or more endpoints is counteracted by significant risk increases for one or more other endpoints

Conclusion: Candidate product may be authorised

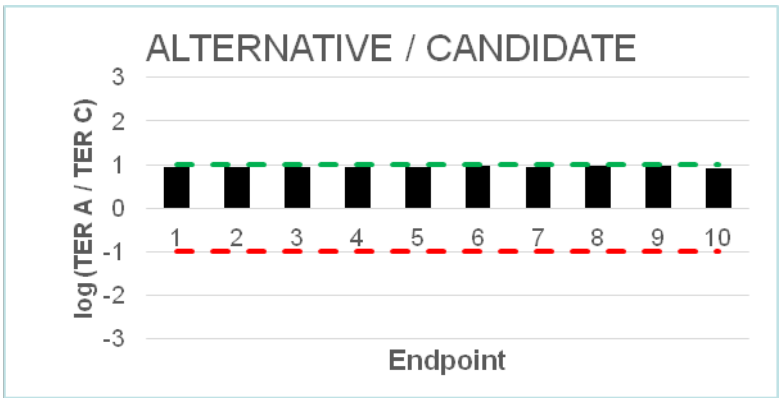


Situation D: Significant risk reduction for one or more endpoints and no significant risk increases for any other endpoints

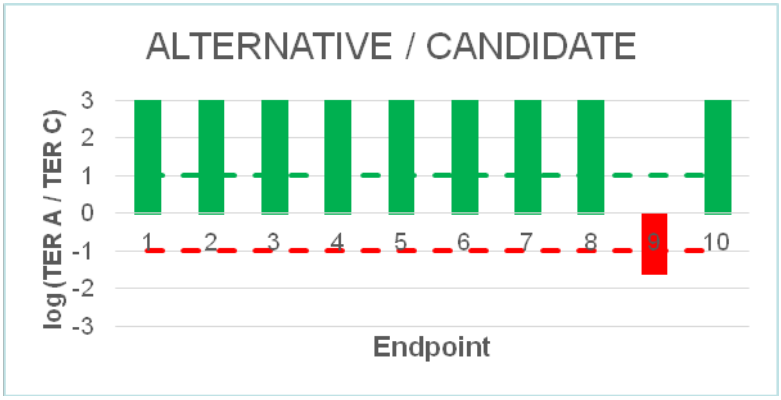
Conclusion: Authorisation of the candidate product may be refused

Dashed lines indicate the legal significance threshold (tenfold difference in TER values); red: significant risk increase; green: significant risk reduction

Figure 21: Borderline situations which may require expert decision



- Risk reductions are consistently seen for all endpoints but the legal significance threshold is just not reached for any of them



- Significant risk reductions are seen for almost all endpoints but counteracted by a significant increase for a single endpoint

Dashed lines indicate the legal significance threshold (tenfold difference in TER values); red: significant risk increase; green: significant risk reduction

7 Case studies

7.1 Aims and approach

Aims of the case studies were

(1) to explore the feasibility of a comparative assessment of environmental risk profiles of PPPs according to the principles proposed in the preceding chapter 6,

(2) to identify any practical problems requiring further refinement or operationalisation of the proposed principles, and

(3) to derive recommendations for further advancement of the proposed approach to a state ready for routine regulatory use.

It was not the aim of the case studies to provide exhaustive and conclusive risk comparisons for the selected products. The case studies did not include special quality assurance measures for regulatory decision making, such as independent double checking for any errors that may have occurred during data transfer and handling. In addition, the cases were selected with no official CFS list being available, but based on the projects' projections about future CFS as detailed in chapter 5. For all these reasons, names of products and active substances included in the case studies are anonymised throughout the public parts of this report in order to avoid any false discrimination. However, characterisations of the selected products and their active ingredients are provided in terms of use categories, chemical grouping, and MoA classifications.

Under the given time frame and with the available resources, the number of cases for practical examination was a priori limited to ten pairwise comparisons of potential CFS-containing candidate products with potential CFS-free alternatives, authorised for one or more common uses. In consultation with the UBA, these ten examples were selected to cover some major groups of crops, pests, modes of action, and reasons for CFS identification, as detailed in the following section 7.2.

As a result of the selection process, five different candidate products each were compared with two different alternative products, giving ten different cases in total. From the five candidate products two are used as herbicides, two as fungicides and one as an insecticide. The five candidate products contain a total of three different potential CFS. The two herbicidal products contain the same phenylurea compound, the two fungicidal candidate products both contain a triazole compound, and the insecticidal candidate product contains a potential CFS from the pyrethroid group. The alternatives comprised a total of six different products with six different active ingredients, two from each of the three main use categories, herbicides, fungicides, and insecticides, as detailed below.

For the eleven PPPs that were included in the ten comparative assessments, environmental risk profiles were generated on the basis of the information that is available from assessment reports prepared by the UBA for product authorisation. Any other information source was out of scope. Quantitative risk comparisons were confined to TER and HQ values. Other types of environmental assessment criteria laid down in the Uniform Principles may additionally be included in risk comparisons but would require further clarification or operationalisation first, as explained in the previous chapter 6 e. Hence, they were considered out of scope for this purpose.

For the purpose of the case studies, only TER and HQ values were used that are directly given in the assessment reports; we did not perform any additional calculations or re-calculations of such risk quotients from the hazard and exposure data documented in the reports. As a consequence, the risk profiles do not include the full spectrum of endpoints that have been tested but are confined to those endpoints that the authority considered to be critical for decision making in terms of granting authorisation and imposing risk mitigation measures. Other TER calculations are not included in the reports. Concerning aquatic organisms for instance, this means that a TER is typically calculated for the most sensitive test species and endpoint, and these of course may be different for different PPPs. Resulting comparisons of risks for non-target organisms in an environmental compartment hence refer to the test species that are most sensitive to each of two PPPs, but not necessarily to the same species or species group. Appropriateness or inappropriateness of such an approach remains subject to discussion.

The assessment reports typically include TER calculations for arrays of exposure scenarios that result from different possible risk mitigation measures. The aim is to identify the most appropriate risk mitigation measure, if necessary. Thus, restrictiveness of risk mitigation measures imposed with the authorisation decision is a direct reflection of the TER calculations. The UBA considers using differences in risk mitigation measures as an indicator for significant differences in risks. Such an indicator may be used for the purpose of pre-selecting alternative products for inclusion in a comparison with a candidate product, where many of such alternatives are available. To this end, a scoring system was developed by the authority for (re-)translating risk mitigation requirements into quantitatively comparable risk indicators, so-called “R-Scores” (Annex 4). To gain experience with this approach, calculation and comparison of such R-Scores was included in the case studies and the results were compared to a direct comparison of TER and HQ profiles.

7.2 Selection of cases

The selection of test cases started from the list of 33 potential CFS generated in this project (Table 9 in chapter 4). From this list, we initially selected all substances that are

a) used as herbicide, fungicide, or insecticide

AND which have been

b) consistently identified as a potential CFS by both (i) the work performed in this project (chapter 4) and (ii) the contract study performed for the European Commission by the Food Chain Evaluation Consortium (FCEC 2013), as summarised in section 4.8).

To narrow the selection of herbicides and fungicides further down, we chose to focus on substances that have been

c) identified as a potential CFS by both (i) human health criteria as well as (ii) environmental hazard criteria, as detailed in section 4.8.

This third selection criterion was not applicable to insecticides as it would have eliminated them all.

By these restrictive initial filter steps, we aimed to focus the exercise on (i) the three largest use groups (herbicides, fungicides, insecticides) and (ii) on examples that have a high chance to get real regulatory relevance in the foreseeable future. As a result, the list of 33 potential CFS was reduced to ten compounds which were initially considered for inclusion in the case studies.

Table 15 provides a characterisation of these 10 potential CFS in terms use categories, chemical classification, modes of action and relevant selection criteria. Where substances belong to the same group they are distinguished by numbering in brackets, such as pyrethroid (1), (2), (3).

Table 15: List of potential substitution candidates initially considered for case studies

Use category	Chemical class	Mode of action	PBT criteria fulfilled	CFS due to environ-mental hazards	CFS due to human health hazards	Listed in BVL	Authorised PPPs
Fungicide	Dicarboximide	Respiration inhibition	B, T	Yes	Yes	Yes	Yes
	Triazole (1)	Sterol biosynthesis inhibition	P, T	Yes	Yes	Yes	Yes
	Triazole (2)	Sterol biosynthesis inhibition	P, T	Yes	Yes	Yes	Yes
Herbicide	Unclassified	Inhibition of carotenoid biosynthesis	P, T	Yes	Yes	Yes	Yes
	Oxyacetamide	Inhibition of cell division	P, T	Yes	Yes	Yes	Yes
	Phenylurea	Inhibition of photosynthesis at PS II	P, T	Yes	Yes	Yes	Yes
Insecticide	Benzoylurea	Inhibitor of the chitin biosynthesis	P, B, T	Yes	No	No	Yes
	Pyrethroid (1)	Sodium channel modulator	P, B, T	Yes	No	Yes	Yes
	Pyrethroid (2)	Sodium channel modulator	P, T	Yes	No	Yes	No
	Pyrethroid (3)	Sodium channel modulator	B, T	Yes	No	Yes	Yes

In a second filter step, we considered the actual use of the 10 candidate substances as active ingredients of PPPs authorised for use in Germany and the availability of CFS-free alternative products. A priori, we chose to focus on products for spray application in a selection of major crops as an important sector of the PPP market. To avoid unnecessary complexity, we further decided to limit the exercise to comparisons of so-called mono-formulations, i.e. PPPs containing a single active ingredient, and to exclude so-called combination products with two or more active ingredients. Consequently, we excluded all potential CFS that did not meet any of the following additional criteria:

d) listed in the PPP database of the German Federal Office of Consumer Protection and Food Safety (BVL, version published in May 2013),

e) used as active ingredient of PPPs authorised in Germany,

f) used in mono-formulations,

g) used in spray agents,

h) used in PPPs for wheat, winter soft wheat, potato, sugar beet, or oilseed rape,

i) used for purposes for which CFS-free alternative products are available.

Limited data availability and missing actual use (criteria d and e) resulted in the exclusion of the benzoylurea insecticide and one of the pyrethroid insecticides (2), respectively. Criterion f (use in mono-formulations) was not fulfilled for the dicarboximide fungicide, one of the triazole fungicides (1), and the herbicide inhibiting carotenoid biosynthesis; these three substances were found to be currently used in Germany in combination products only. The other three criteria (g, h, i) turned out to be fulfilled for all remaining compounds.

As a result, the initial selection of ten potential CFS was cut down to a set of five substances fulfilling all criteria for possible inclusion in the case studies: a phenylurea and an oxyacetamide herbicide, one of the triazole fungicides (2) and two of the pyrethroid insecticides (1 and 3). From these five suitable compounds, we arbitrarily selected three, one from each of the three major use groups (Table 16): the phenylurea herbicide which is currently included in five authorised mono-formulations in Germany, the triazole (2) fungicide which is used as active ingredient of three authorised mono-formulations, and one of the pyrethroid insecticides (1) which is contained in a single authorised mono-formulation only.

Table 16: List of anonymised PPPs containing the selected potential substitution candidates, end of approval period and numbers of uses (crops and target pests)

Potential CFS selected for the case studies	PPPs containing the potential CFS selected for the case studies (mono-formulations only)	End of approval	Number of target pests	Number of crops	Code for PPPs selected for the case studies
Phenylurea herbicide	PPP 1 containing a phenylurea herbicide	31.12.2017	24	4	Not selected
	PPP 2 containing a phenylurea herbicide	31.12.2017	24	4	A
	PPP 3 containing a phenylurea herbicide	31.12.2018	10	2	Not selected
	PPP 4 containing a phenylurea herbicide	31.12.2018	10	2	B
	PPP 5 containing a phenylurea herbicide	31.12.2017	24	4	Not selected
Triazole fungicide (2)	PPP 6 containing a triazole fungicide	31.12.2021	14	4	C
	PPP 7 containing a triazole fungicide	31.12.2016	21	7	D
	PPP 8 containing a triazole fungicide	31.12.2021	2	2	Not selected
Pyrethroid insecticide (1)	PPP 9 containing a pyrethroid insecticide	31.12.2016	6	3	E

For each of the nine PPPs containing one of the three selected CFS, all authorised uses (combinations of crop and target pest) were identified, and for each of these uses all potential alternative PPPs were compiled. On the basis of this information, we arbitrarily chose (i) five out of the nine candidate PPPs (codified A to E as given in Table 16), (ii) three different uses of these candidate PPPs, one for each major use category as given in Table 17, and (iii) six different alternative PPPs (codified 1 to 6 as given in Table 17), two for each major use category. In selecting candidate PPPs and their uses, preference was given to products and uses for which a large number of potential alternatives are authorised. This increases the chance that the candidate PPPs may in fact become subject to comparative environmental risk assessments in the future, because the availability of a variety of alternatives decreases the probability that substitution of the candidate product is rejected already in an early assessment phase due to agronomic constraints. In selecting potential alternative products for the same use, we aimed to include representatives from major groups in terms of chemical classes and modes of action. As a result, the targeted number of ten pairwise comparisons was realised by the ten combinations of five potential candidate PPPs and six alternative PPPs given in Table 17 and codified A1 to E6.

Table 17: List of five candidate PPPs containing selected potential CFS, selected uses, and potential alternative PPPs (without CFS) selected for the case studies

Potential CFS selected for the case studies	Selected PPPs containing potential CFS	Use (crop * pest)	Total number of potential alternative PPPs without CFS	Potential alternative PPPs selected for the case studies	Case study code (CSC)
Phenylurea herbicide	A:PPP 2 containing a phenylurea herbicide	Winter soft wheat * annual dicotyledonous	39	1: Alternative PPP containing a pyridine (1)	A1
				2: Alternative PPP containing a sulfonylurea	A2
	B:PPP 4 containing a phenylurea herbicide	Winter soft wheat * annual dicotyledonous	39	1: Alternative PPP containing a pyridine (1)	B1
				2: Alternative PPP containing a sulfonylurea	B2
Triazole fungicide (2)	C:PPP 6 containing a triazole fungicide	Wheat * mildew	32	3: Alternative PPP containing a pyrazole	C3
				4: Alternative PPP containing a strobilurin	C4
	D:PPP 7 containing a triazole fungicide	Wheat * mildew	32	3: Alternative PPP containing a pyrazole	D3
				4: Alternative PPP containing a strobilurin	D4
Pyrethroid insecticide (1)	E:PPP 9 containing a pyrethroid	Potatoes * aphids	4	5: Alternative PPP containing a neonicotinoid	E5

Potential CFS selected for the case studies	Selected PPPs containing potential CFS	Use (crop * pest)	Total number of potential alternative PPPs without CFS	Potential alternative PPPs selected for the case studies	Case study code (CSC)
	insecticide			6: Alternative PPP containing a pyridine	E6

7.3 Data retrieval

For the five potential candidate products and the six alternatives, environmental risk assessment reports were provided by the UBA, including but not necessarily limited to the intended uses selected for this case studies (Table 17). The assessment reports were provided as text files written in Word® format. For the purpose of generating and comparing risk profiles, all relevant information had to be manually extracted and transferred into spreadsheet software. To this end, a uniform data mask was outlined (Annex 3 to this report) and technically established in form of an Excel® spreadsheet. The spreadsheet was designed to enable semi-automatic generation of graphical presentations of risk profiles and their quantitative comparison in terms of differences between risk quotients. In addition to risk quotients, a range of supporting information was also extracted from the assessment reports and included in the spreadsheets, as detailed below.

Structure, content, and layout of the spreadsheet are described in this section, but for the confidentiality reasons explained in section 7.1 above, neither the completed sheets nor the original assessment reports are included in this public report. Assessment reports are written in German and therefore the German notation was also maintained for all information compiled in the spreadsheets in order to avoid any possible confusion that may result from different translations. English expressions used in the following have been chosen by the authors of this report and do not claim to represent official terminology of the contracting authority.

7.3.1 Data mask structure and spreadsheet design

The spreadsheet was designed for a pairwise comparison of a candidate product with an alternative product. For every such comparison, a separate sheet must be used. In order to present a product comparison as clear as possible, the spreadsheet includes the data mask in duplicate: one for the candidate and one for the alternative product. They are organised side by side, providing every bit of comparable information in parallel in the same line.

All compiled information on risks refers either to the active substance (AS) or to the whole product (PPP) as indicated in the data mask. For the purpose of this case study, the formation of any metabolites was considered to represent degradation in the sense of the persistence criterion and hence information on possible risks of metabolites was excluded from the data compilation. Also, isomers of an AS were not considered separately, where applicable.

Risk assessment reports are structured into five main sections:

I. General information on the PPP

II. Fate and distribution in the environment

III. Ecotoxicological investigations

IV. Risk analysis and risk management

V. Required risk management measures

This basic structure was fully retained in the data mask. In addition, all headlines for sub-sections were fully adapted to the extracted data wherever applicable. In this way, full traceability of all extracted information back to the original assessment reports was ensured.

In the data mask, information is organised in four columns. The first column defines the parameter, test, or organism. The content is pre-defined and not subject to changes or additions. The second and the third column are for corresponding data entries. The second column is the primary place for data entries. In section IV of the mask (risk analysis), the risk quotients are entered in this second column. The third column is only used in special sections of the mask, where additional specifications of values or parameters are required on a case by case basis. The fourth column includes all data that are selected from the data entries for actual use in risk profiling and risk comparison. Primarily, these are TER and HQ values; P and B data may be included optionally. However, this option was not realised for the purpose of the case studies as explained in the preceding sections. A further option is to include R-Scores, secondarily derived from risk mitigation measure as described in Annex 4 to this report, not as an additional endpoint but as an alternative approach for pre-selections of products for comparisons, as explained above. Where any information in the data mask was not directly taken from the original assessment report but secondarily derived, such as R-Scores, these data were clearly marked by printing in red.

The spreadsheet was designed to generate the values for risk comparisons given in the fourth column automatically from the manual data entries in the second or third column. However, manual processing of the data was necessary in cases where the TER or HQ values were not exactly defined in the assessment reports but provided only in terms of being smaller (TER <x) or larger (HQ >x) than a given value, respectively. The handling of such data in risk profiling, risk comparison, and comparative risk assessment is detailed in the corresponding sections 7.4, 7.5, and 7.6 below.

The spreadsheet files were each structured into five sub-sheets. The first-sheet includes the data masks for the candidate product and the alternative as described above. The other four sub-sheets are generated automatically from the information in the first sub-sheet. Three sub-sheets provide the graphical presentations of risk profiles and risk comparisons as well as the underlying data separately for the three assessment areas: birds and mammals, aquatic ecotoxicology, and terrestrial ecotoxicology. The fifth sub-sheet provides a summary of the quantitative risk differences for all endpoints for which comparable risk quotients are available as a basis for significance assessment and decision-making according to the rules proposed in section 6.5 above.

For generating all the risk profiles and comparisons, the underlying risk quotients in the fourth column of the data mask (see above) were divided into two categories: a standard set of endpoints which is automatically included in all profiles and comparisons, and a set of additional endpoints which require manual selection to be included in graphs and quantitative comparisons. For these additional endpoints, comparable data were found to be only occasionally available and hence it would be pointless to include them in every standard graph that is generated automatically. In the fourth column of the data mask, the two categories are clearly highlighted by a colour code: green for standard endpoints, and orange for additional endpoints that need manual selection.

7.3.2 Content entered into the data mask

In the first section of the data mask, "*General information on the PPP*", the PPP is characterised by the authorisation number, the trade name of the PPP, the type of formulation, the common name of the active substance, the content of the technical and the pure active substance, and any existing authorisations prior to the preparation of the assessment report from which the data were taken. All intended uses for which authorisation was granted on the basis of the assessment report are listed in terms of crops and target pests. The active substance is characterised in terms of a chemical classification. Data on water solubility and partition coefficient (log P_{OW}) are included as these are determinants for certain testing requirements.

In the second section on "*Fate and distribution in the environment*", data for persistence assessment are listed, such as degradation in soil, water and water/sediment systems. For degradation in soils, only results from aerobic lab studies at 20°C were entered into the data mask. Priority was given to studies at a soil water potential pF = 2. Field studies were not considered. In case, the assessment report contained several degradation rates (DT50) meeting these requirements, all the data were entered in the data mask and the geometric mean was calculated, unless a geometric mean value had already been calculated in the assessment report which could be directly used. For reasons explained in Chapter 6, comparisons of persistence data were not actually included in this case study exercise, but the work was confined to comparisons of risk quotients. Thus, design and content of this part of the data mask had only preparatory character: if wanted, inclusion into the risk profiles and comparisons would be immediately possible.

From the contents of the third section of assessment reports on "*Ecotoxicological investigations*", only bioconcentration factors (BCF) for the PPP and the active substance were transferred into the data mask, if available. As for persistence data, also the recording of BCF data had only preparatory character. Comparisons of BCF data were not actually included in the case studies, but it would immediately be possible to do so. Eco-toxicity data were not transferred from the assessment reports into to the data mask. As explained above, the case studies were confined to the comparison of risk quotients that had already been calculated in the original assessment reports, not including any re-calculations or additional calculations for further endpoints. Hence, transfer of the original eco-toxicity data was not needed for the purpose of these case studies. Whether it may be needed for an advanced procedure remains subject to further considerations.

The fourth section of assessment reports, "*Risk analysis and risk management*", provides a range of risk quotients which may be grouped into three major assessment areas: (i) risks for birds and mammals, (ii) risk for aquatic organisms, and (iii) risks for terrestrial organisms (other than birds and mammals). The third assessment area (terrestrial organisms), includes risk quotients for honey bees, (other) arthropods, earthworms, other soil macro-organisms, and terrestrial plants. All these data were completely entered into the data mask, including any relevant specifications of units, test conditions or exposure scenarios. Risks for soil micro-organisms are currently not assessed in terms of risk quotients (see section 6.2.2) and were hence out of the scope of the case studies and not included in the data mask. In assessment reports prepared from 2009 onwards, section IV additionally includes a sub-section summarising the assessment of PBT properties. Where available, these data were recorded in the data mask for informative purposes, but not used for risk profiling and comparison.

In the first assessment area, birds and mammals, risk assessment reports provide risk quotients separately for birds and for mammals, and within these groups separately for (direct poisoning of) insectivore, herbivore, and omnivore species, as well as for secondary poisoning of predators

via earthworms and via fish. For each of these types of organisms and exposure routes, risk quotients are provided in the risk assessment reports separately for acute, short-term (birds only), and long-term toxicity, separately for results from standard assessments and from refined assessments (direct poisoning only), and separately for the active ingredient and the formulated PPP (standard assessments only). Available TERs from refined assessments may be additionally differentiated by season (spring or autumn application).

In some cases, a standard and a refined assessment had been conducted for the same group of birds or mammals, the same exposure route and the same exposure season, based on the same toxicity data and using the same exposure model, only differing by adjustments of default parameter values to values considered to be more realistic under the foreseeable conditions of use of a PPP, such as lowering a PT factor[9] from 1.0 to 0.5. Under such conditions, TER values from standard and refined assessments were considered to be no incomparable categories but to be quantitatively comparable for the purpose of a comparative assessment. As a consequence, all available values were documented in the data sheets, but only the refined TER values were used for the comparative assessment. In the spreadsheets, both types of data were distinguished by white and grey highlighting of entry fields, respectively. The decision for aggregating standard and refined TER values in this way under specific restrictive conditions was taken during the data compilation as an ad hoc approach to removing minor obstacles for the purpose of the case studies. The refined TER values are usually higher than the standard values. Hence the decision followed the suggested principle that in case of doubt risk differences should not be considered significant. In addition, it may be considered that accepted refinements in current regulatory practice rarely lead to an increase of TER values by a factor of 10 or more. Hence, it is unlikely that any opportunities for significant risk reductions will be masked by the approach taken here. Nevertheless, 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 and for aggregating (or non-aggregating) sub-ordinated assessment endpoints, as further discussed in section 8.2.

In the second assessment area, aquatic organisms, all TER values provided in an assessment report typically refer to the same species and toxicity parameter (e.g. EC50 or NOEC), the one that the authority considered to be critical for decision making, i.e. usually the one that was shown to be most sensitive to the particular active substance or PPP. However, a wide array of different TER values is usually calculated for a variety of exposure scenarios resulting from different exposure routes and different possible risk mitigation measures. For spray applications (to which the case studies were confined) three different exposure routes are assessed separately: spray drift, run-off, and drainage. In the evaluated assessment reports, TERs for spray drift scenarios had been separately calculated for possible combinations of drift reduction technologies (0%, 50%, 75%, 90%) with non-spray buffer zones (0m, 1m, 3m, 5m, 10m, 15m, 20m), TERs for run-off scenarios had been separately calculated for different possible vegetated buffer strips (0m, 5m, 10m, 20m), and TERs for drainage scenarios had been separately calculated for spring/summer or autumn/winter applications.

In the third assessment area, terrestrial organisms, separate hazard quotients were available in the assessment reports for oral exposure and for contact exposure of honeybees to either the formulated PPP or to the active substance. For (other) arthropods in non-target areas, TERs for the critical species and toxicity parameter refer either to the active ingredient or to the complete PPP and had been separately calculated for a range of scenarios resulting from

[9] PT = proportion of an animal's daily diet obtained in habitat treated with pesticide

possible combinations of spray drift reduction (0%, 50%, 75%, 90%) with non-spray buffer zones (1m, 5m). For earthworms, assessment reports distinguish between TERs for acute and chronic exposure to either the active substance or to the PPP. For other soil macro-organisms, TERs are separately provided for toxicity to collembola and for impacts on the degradation of plant materials by either the active substance or the PPP. For terrestrial plants in non-target areas, TERs refer to the critical species and toxicity parameter, separately for the PPP and for the active ingredient and separately for the same range of exposure scenarios as for arthropods.

In the last section of the data mask, "*Required risk management measures*", all risk mitigation requirements are listed with respect to the protection of groundwater (NG), terrestrial non-target areas (NT) and aquatic ecosystems (NW), as codified by the authority (see Annex 4). Risk mitigation requirements for groundwater protection (NG) were recorded for informative purposes only, because comparisons of risks for groundwater contamination were out of the scope of the case studies, as explained above and in the preceding chapter 6. Risk mitigation requirements for terrestrial non-target areas (NT) and for aquatic ecosystems (NW) were transformed into corresponding "R-Scores" by applying the methodology proposed by the contracting authority (Annex 4).

7.4 C haracterisation of risk profiles

Ecotoxicological risk profiles were generated for the five candidate and the six alternative products included in the case studies (Table 17). As an illustration, three examples are described and graphically presented in the following. The examples are all potential candidate products, one of each of the three majors use categories: a phenylurea herbicide (product "B"), a pyrethroid insecticide (product "E"), and a triazole fungicide (product "C").

Graphical presentations of the risk profiles for these three products (Figures. 22, 23, and 24) are each separated into the three major assessment areas: birds and mammals, aquatic ecotoxicology, and terrestrial ecotoxicology. For each assessment area, all available TER and HQ values are presented as bar charts. Risk mitigation requirements and corresponding R-Scores are included in the charts for informative and comparative purposes. Within the major assessment areas, risk indicators are grouped by endpoints and exposure scenarios in accordance with the structure of the assessment reports, as described in the preceding section. TERac, TERs, and TERl denote risk quotients for acute, short-term, and long-term toxicity, respectively. Within each group, endpoints are specified in terms of tiered assessment levels, exposure scenarios, and exposure to the active ingredient or the PPP, as indicated by different colours and explained in the corresponding legends.

As risk quotients may differ by several orders of magnitude, logarithmic scaling is used in all charts. TER values are directly displayed, this means that higher values represent lower risks. To get the same kind of inverse relationship in case of risk assessments for bees, HQ values are not directly displayed, but the reciprocal values 1/HQ are used. Where TER or 1/HQ values were not exactly defined in the assessment reports but only in terms of being larger than a given limit value (>x), the limit value is shown in the bar graphs and marked with the sign ">" in bold red.

For including risk mitigation codes in the same bar graph presentations, a simple binary score is used: "0" for non-applicable mitigation requirements, and "1" for applicable requirements. In contrast to TER and 1/HQ values, this is for informative purposes only and not usable for subsequent quantitative risk comparisons. If risk mitigation measures apply, corresponding R-Scores are also directly displayed in the graphs. If no risk mitigation measures apply, R-Scores do not become zero but take constant low values as defined in Annex 4 (0.9 for aquatic and 5.6

for terrestrial scores. However, these base values were omitted from the charts. When comparing R-Scores with TER values, care must be taken. The scaling is different and they are inversely related to TER values, i.e. the higher the value, the higher the risk.

The combined graphical presentation of risk quotients, risk mitigation requirements, and R-scores provides a complete picture of all information compiled. Therefore, this way of data visualisation was chosen for the purposes of this report. The different scalings, however, are a clear disadvantage. Without the detailed explanations given here, the score level presentations for mitigation requirements and R-scores are not immediately understandable. For future use of graphical risk profiling as a tool for comparative assessments, separate presentation of risk quotients from any other types of risk indicators is therefore recommended. However, even if the bar graph presentation is confined to risk quotients, careful interpretation is still required, as explained in the following.

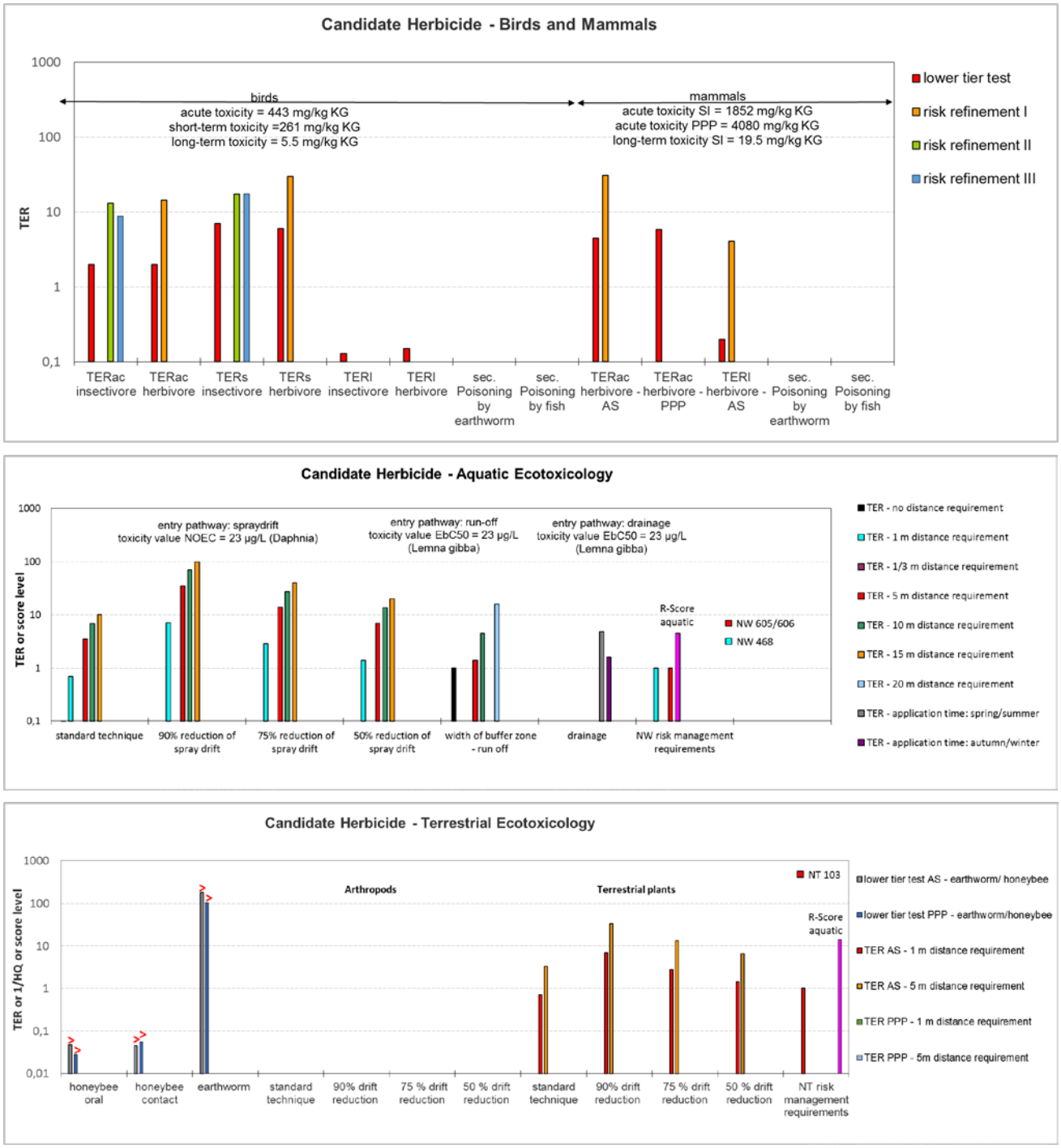
When looking at the individual graphical presentations of risk profiles, it must be taken into consideration that they were designed to allow direct comparisons of two products “vertically” endpoint by endpoint, but they were not optimised for “horizontal” comparisons of risks for different endpoints from the same product. Such horizontal comparisons require careful interpretation. It must be taken into account that different acceptability criteria apply to TER values for different endpoints. For standard endpoints they vary between one hundred and five (Table 14), and for higher tier assessments competent authorities may occasionally lower them even further down to a minimum of one. The problem becomes even more severe when comparing TER values with HQ values or the reverse 1/HQ. Unfortunately, they are numerically incomparable to TER values. This results from the different definitions of both types of risk quotients under the PPP directive. TER values are dimensionless, because numerator (toxicity) and denominator (exposure) must always be expressed in uniform metrics. HQ values in contrast have a dimension: gram active substance per hectare divided by the LD50 in microgram per bee. As a standard acceptability criterion, these HQ values must not exceed a value of 50 (Table 14). This means that 1/HQ values depicted in the bar graphs must be equal to or higher than 0.02 to be assessed as acceptable and hence equivalent to numerically much higher TER values. Avoidance of these confusing incomparabilities would require a consistent and harmonised risk-quotient-based assessment system.

7.4.1 Ecotoxicological risk profile of a phenylurea herbicide (candidate product “B”)

Figure 22 displays the risk profile of the selected CFS-containing phenylurea herbicide, split into three bar charts for the three areas of consideration: birds and mammals, aquatic ecotoxicology, and terrestrial ecotoxicology.

For birds and mammals, acute (TERac) and short-term (TERs) values derived from first-tier modelling all fell below the trigger value of 10 (see Table 14). Consequently, values derived from refined risk assessments were additionally available in the assessment report: two refinement levels for insectivore birds, and one refinement level for herbivore birds and mammals. Concerning the TERac for mammals, lower tier values were available for both the active substance (AS) and the formulated PPP, while the refined assessment was confined to the AS. Long-term values (TERl) from standard testing also all fell below the relevant trigger value, which is five (Table 14). Corresponding results from refined assessments, however, were only available for mammals, but not for birds. Due to a log Pow <3, significant bioaccumulation of the active substance is not expected, and consequently TER values for secondary poisoning of fish or earthworm feeding predators were not available from the assessment report.

Figure 22: Risk profile of a phenylurea herbicide (candidate product "B")



Concerning aquatic ecotoxicology, TER values for exposure via spray-drift were given in the assessment report for the long-term toxicity (NOEC) to *Daphnia magna* as the critical toxicity endpoint, while TER values for exposure via run-off or drainage referred to an EC50 for *Lemna gibba* as the critical toxicity value. As explained in section 7.3.2 above, TER values were available for a range of exposure scenarios resulting from possible measures for the reduction of spray drift and run-off, and from the effect of seasonal application on drainage. On this basis, the authority had chosen the appropriate exposure reduction measures that are necessary to reduce the risk from spray drift to acceptable levels (NW 605/606) and to prevent

any disposal of the original PPP or spraying tank dilutions into water bodies (NW 468). As detailed in Annex 4, the requirements for spray drift reduction translate into an aquatic R-Score of 7.41.

Concerning terrestrial ecotoxicology, HQ values for honeybees and TER values for earthworms were available from the assessment reports in terms of maximal (HQ <x) and minimal values (TER >x), respectively. In addition, exact TER values were available for terrestrial plants. TER values for arthropods were not included in the reports as they are less sensitive than plants and hence not critical for decision making. The inverse hazard quotients (1/HQ) for oral and contact exposure of honeybees to the AS and the PPP all exceeded the trigger value of 0.02. Hence, higher-tier assessments had not been performed for honeybees. The TER values for earthworms exposed to the AS or the PPP also clearly exceeded the relevant trigger value of 10 by a factor of ten or larger, thus not requiring any higher tier assessments. For terrestrial plants in non-target areas, the assessment report provides TER values between 1 and 10, depending on the application of possible risk reduction measures. To achieve an acceptable level of five, the authority decided to require risk mitigation measures codified as NT 103, which corresponds to a terrestrial R-Score of 14.3 (Annex 4).

7.4.2 Ecotoxicological risk profile of a pyrethroid insecticide (candidate product "E")

Figure 23 displays the risk profile of the selected CFS-containing pyrethroid insecticide. The bar graphs are structured as before for the phenylurea herbicide (Figure 22).

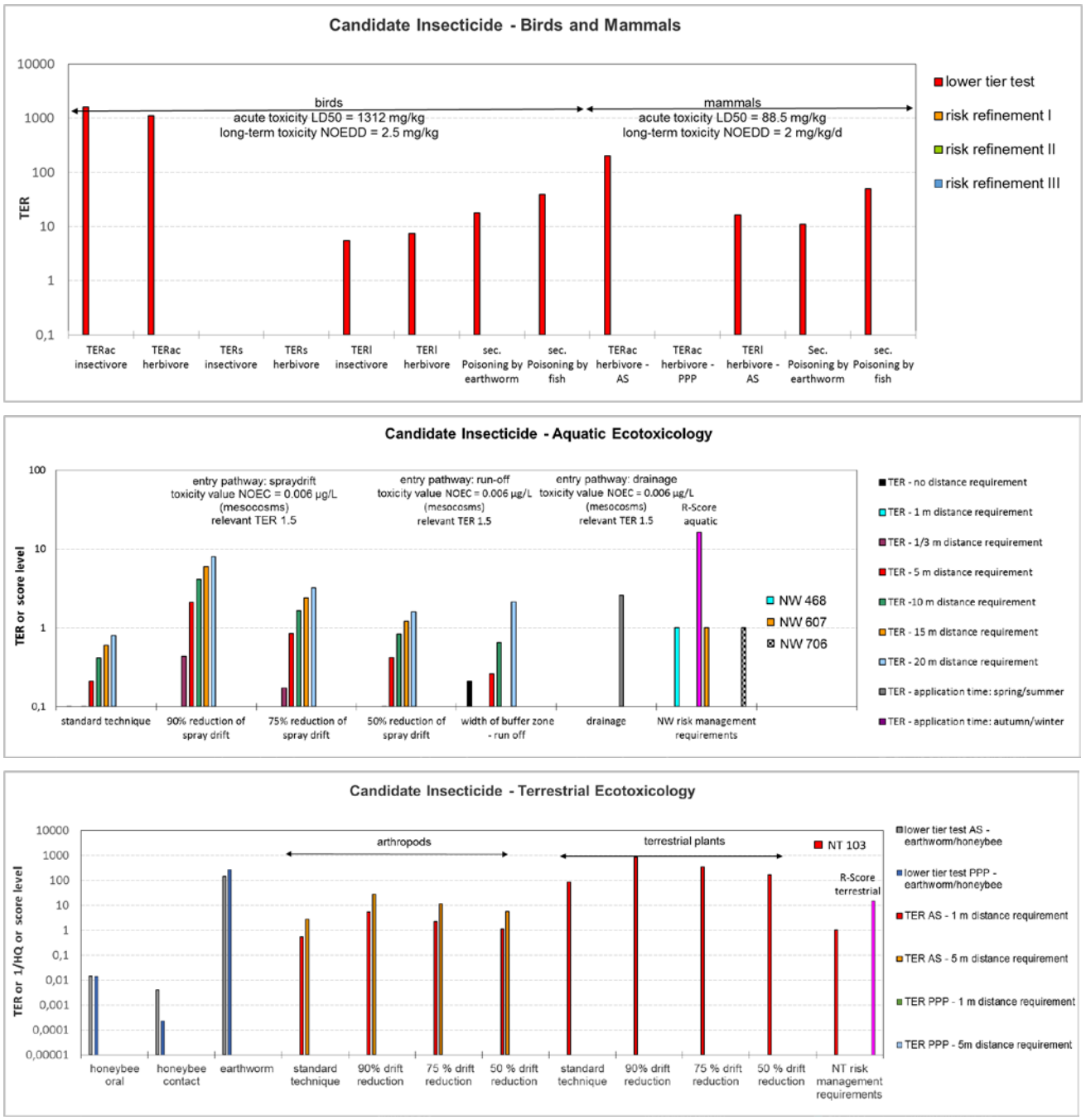
For birds and mammals (upper bar graph), the risk assessment report included TER values for 10 out of a total of 13 endpoints that were included in the data mask as a standard (see section 7.3 above). Concerning birds, TER values were not given for short-term exposure (TERs) but for acute (TERac) and long-term exposure (TERl) of both, insectivore and herbivore species. They well exceeded the threshold values of 10 and 5, respectively; consequently refined assessments had not been conducted. Concerning mammals, no TER values were given for exposure to the formulated PPP, but for both acute (TERac) and long-term exposure (TERl) of herbivore species to the AS, and additionally for secondary poisoning of predators via both earthworms and fish. Acceptability criteria for acute (TER ≥10) and long-term exposures (TER ≥10) were all met.

Concerning risks to the aquatic environment (second bar graph), all TER values given in the assessment report referred to a NOEC from a mesocosm study as the most relevant toxicity value for the authorisation decision. For this higher tier endpoint, the authority considered TER values equal to or higher than 1.5 as an acceptable risk level. Nine out of a total of 18 TER values that were calculated for spray-drift under a variety of possible risk mitigation regimes exceeded the acceptability criterion of 1.5. To ensure such conditions of use, the authority imposed the risk management requirement NW 607, which corresponds to an aquatic R-Score of 16.41. For the run-off exposure scenario, one out of four TER values calculated for different possible mitigation requirements exceeded the threshold value of 1.5. This acceptable level was found to be achievable if a vegetated buffer strip of 20 m width is kept. For exposure via drainage, acceptable TER values above 1.5 were found for spring/summer application; autumn/winter application was not considered relevant. For limiting the risk resulting from run-off, the authority imposed the risk mitigation requirement NW 468. In addition, mitigation requirement NW 468 was imposed to prevent any disposal of the product or diluted spraying solutions into water bodies.

Concerning honeybees (third bar graph) the inverse of the HQ (1/HQ) was reported to be smaller than 0.02 and hence unacceptable, independent from the exposure route (oral or contact) and for both the AS and the formulated PPP. A need for refined and more detailed risk

assessment by the competent authority was concluded. Concerning earthworms, TER values were estimated to be 10-fold higher than the threshold value of 10, for both exposure to the AS and the formulated PPP. Concerning arthropods (other than honeybees), four out of a total of eight TER values calculated for different risk mitigation scenarios exceeded the applicable threshold value of 5. To ensure such acceptable exposure situations, the authority imposed the risk mitigation requirement NT 103 which corresponds to a terrestrial R-Score of 14.3. Concerning terrestrial plants in non-target areas, TER values were calculated in the report for exposure situations resulting from a standard minimum non-spray buffer zone of 1 m in combination with four different possible degrees of drift reduction. In all four scenarios, TER values were higher than the applicable threshold value of 10 and hence considered acceptable.

Figure 23: Risk profile of a pyrethroid insecticide (candidate product "E")



7.4.3 Ecotoxicological risk profile of a triazole fungicide (candidate product "C")

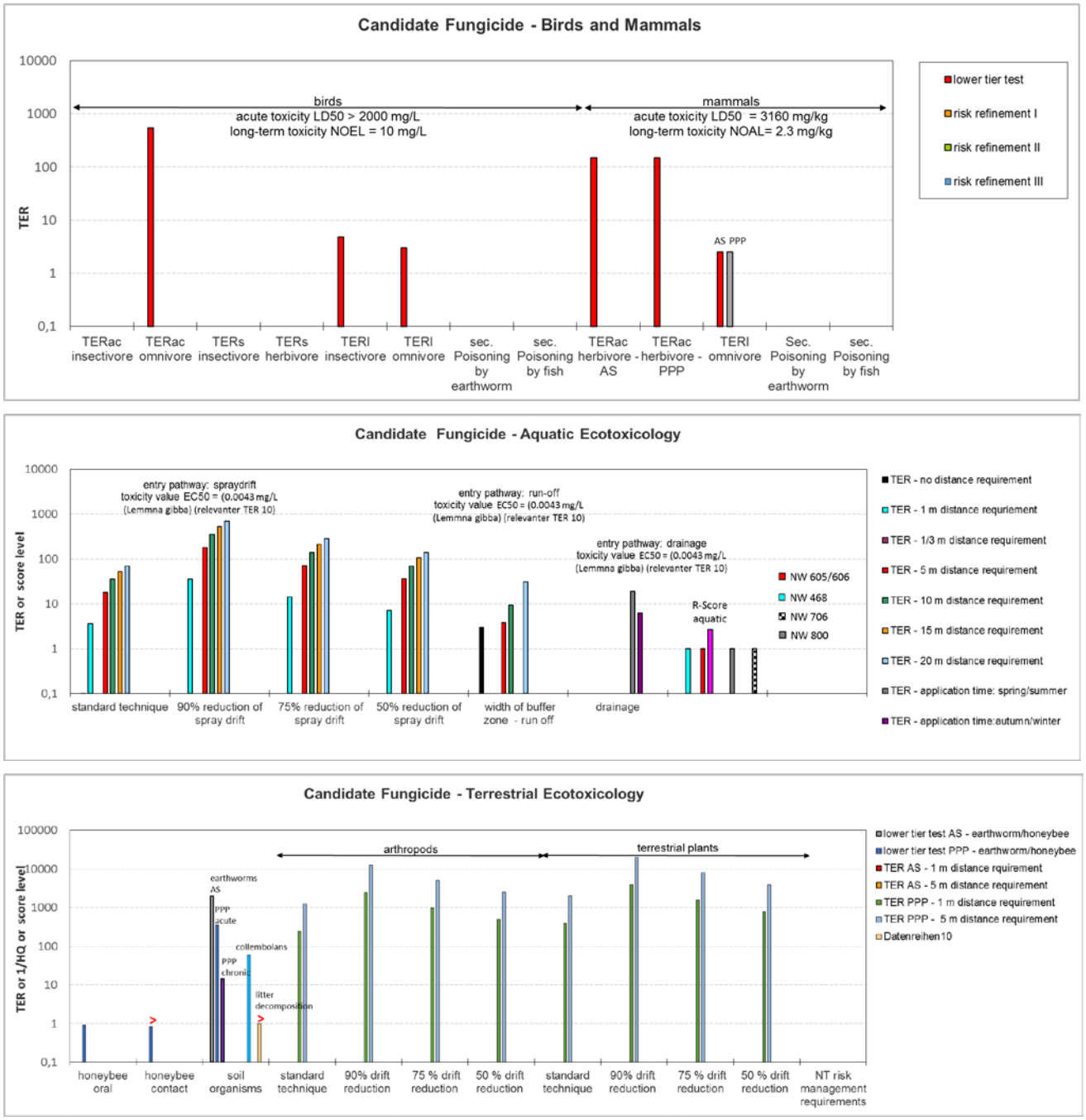
For the selected CFS-containing triazole fungicide, the ecotoxicological risk profile is shown in Figure 24, with bar graphs structured as before for the phenylurea herbicide and the pyrethroid insecticide (Figures 22 and 23).

Concerning the risk assessment for birds and mammals, seven relevant TER values were included in the assessment report. Risks for acute effects on birds (TERac based on LD50) were assessed for omnivore species only, while long-term risks (TERl based on NOEL) were separately assessed for insectivore and omnivore species. The TERac value exceeded the threshold value of ten, and consequently refined assessments were not conducted. The long-term TERl for insectivore birds was calculated to be higher than the applicable threshold of five, and hence acceptable. For omnivore birds, the reported TER is slightly below the standard acceptability limit, but refined assessments were not performed. For herbivore mammals exposed to the AS or the formulated PPP, acute risks were found to comply with the standard acceptability criterion (TER ≥10). Long-term TER values for omnivore mammals were reported to be 2.5, both for the AS and the formulated PPP. By way of derogation from standard requirements, the authority considered a TER value of two or higher to be acceptable in this case. This condition was fulfilled. The potential for biomagnification was considered to be low; consequently calculations of TER values for secondary poisoning of predatory mammals were not included in the assessment report.

Risk assessments for the aquatic environment were uniformly based on EC50 values for *Lemna gibba* as the critical toxicity endpoint for the authorisation decision. For the spray-drift exposure pathway, TER values were reported for a matrix of 20 different combinations of non-spray buffer zones (distance requirements) with drift reduction techniques. On this basis, the authority considered an acceptable risk level to be achievable by imposing the risk mitigation requirement NW 606/605, corresponding to an aquatic R-Score of 2.68. For assessing risks resulting from run-off, TER values were calculated for four different sizes of vegetated buffer strips. The risk was found to be acceptable (TER ≥10), if the distance between application area and surface water does not fall short of 20 m. Considering drainage, TER values were reported to be acceptable for spring/summer application, but not for autumn/winter. For mitigation of risk from run-off and drainage, the requirements NW 706 and 800 were imposed with the authorisation of the product. To prevent any disposal of the diluted or undiluted PPP into water bodies, mitigation requirement NW 468 applies additionally.

For assessing the risks to terrestrial species (other than birds and mammals), HQ values for honeybees and TER values for earthworms, collembolans, impact on litter decomposition, other non-target arthropods and terrestrial plants in non-target areas were calculated in the assessment report, including a standard range of possible risk mitigation scenarios for arthropods and plants. All values were found to be acceptable, not requiring any dedicated risk mitigation measures.

Figure 24: Risk profile of a triazole fungicide (candidate product "C")



7.5 Comparison of risk profiles

Pairwise comparisons of risk profiles were performed for the ten cases listed in Table 17. Three examples are described and graphically presented in detail in this section 7.5. All other cases are included in a summary assessment of significant risk differences in the subsequent section 7.6. The three examples include the three candidate products for which risk profiles have been described in the preceding section 7.4. Each of them is compared to one selected potential alternative, comprising the test cases B2, E5, and C3 as defined in Table 17. For the first example (case B2), the graphical comparison is given in full detail, including the full risk

profiles of both products individually as well as the differential profile of resulting risk differences (Figures 25 A-C). For the other two examples, the graphical illustration is confined to the presentation of risk differences (Figures 26, 27). Graphical presentations of risk differences are confined to risk quotients (TER and 1/HQ); the alternative comparison of R-scores is separately addressed in the subsequent section 7.6.

For the purpose of the case studies, we considered TERs or HQs for different PPPs to be comparable, if they referred to exactly the same category as defined in the assessment report, i.e. the same species group, toxicity parameter, exposure scenario, and concentration or dose metrics for the active ingredient or the formulated PPP. If not falling into exactly the same category, they were considered to be incomparable, such as TER values based on active ingredients vs TER values based on whole PPPs. No attempt was made to aggregate such categories any further. Such attempts may be subject to further refinements of the proposed approach. With the same rationale we also did not split up TER values that aggregate various species or species groups. Instead, in view of the regulatory purposes, TER values for the aquatic system that may originate from different types of species for different types of products were considered to be comparable.

Bar chart presentations of risk differences were prepared as outlined in section 6.5 above: the logarithms of the ratios of comparable TER values or 1/HQ values for the alternative and the candidate product are shown as bars. Risk reductions and risk increases have positive and negative values and are displayed in upward and downward direction, respectively. Values equal to or larger than +1 correspond to tenfold or larger risk reductions; values equal to or smaller than -1 correspond to tenfold or larger risk increases.

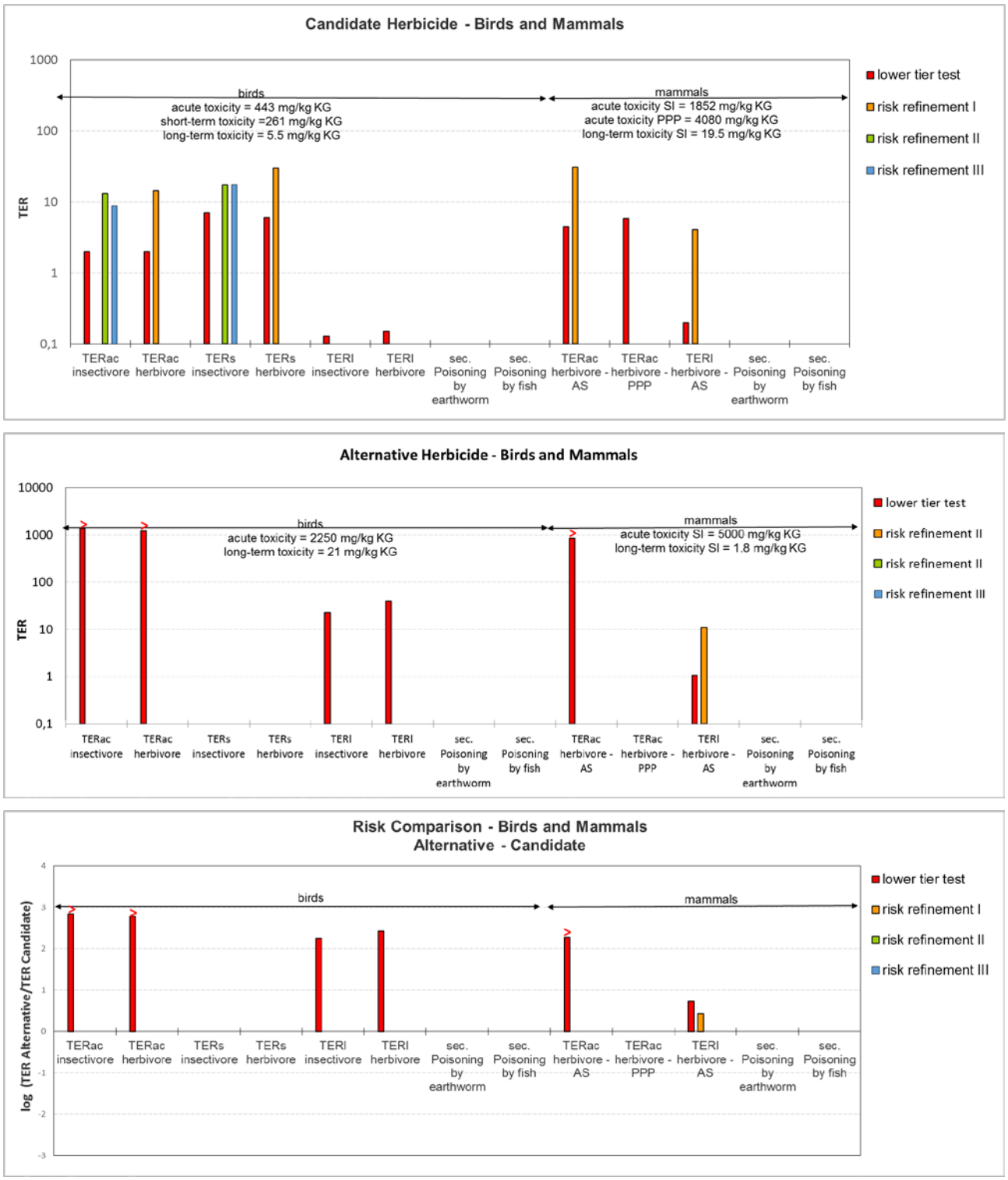
Where asymmetric data situations did not provide comparable TERs or HQs as defined above, no bars were depicted. The same applies to situations where the TER or 1/HQ for both the alternative and the candidate product were only defined in terms of being larger than a limit value (>x). In this situation, the ratio between the risk quotients for the two products cannot be determined, but any value is mathematically possible. The consequences of this issue is discussed in more detail below and in chapter 8.

Where the risk quotient (TER or 1/HQ) for either the alternative or the candidate product was defined in terms of an inequality (>x), but not for both products, the resulting ratio between both values is also an inequality, denoting the risk difference to be larger or smaller than a limit value, respectively. In these cases, the limit value is depicted in the graphical presentations and signed by “>” or “<” as appropriate. As detailed in section 6.7 below, such data situations may provide inconclusive evidence regarding the significance or insignificance of risk differences. Where this means that the possibility of a significant risk increases cannot be ruled out, the bars are marked with a red question mark.

7.5.1 Risk comparison between a candidate phenylurea herbicide and an alternative sulfonylurea herbicide (Case B2)

The risk profile resulting from spray application of the selected candidate phenylurea herbicide against annual dicotyledonous weeds in winter soft wheat was compared to an authorised sulfonylurea product as a potential CFS-free alternative (Case B2 in Table 17). In Figures 25 A, B, and C, the risk comparison is shown graphically for birds and mammals, aquatic organisms, and (other) terrestrial organisms, respectively. In these three figures, the upper parts are a repetition of the risk profile of the candidate product shown already in Figure 22 above, the middle parts show the corresponding risk profile of the potential alternative, and the lower parts provide the resulting quantitative differences.

Figure 25A: Risk comparison between a candidate phenylurea herbicide and an alternative sulfonylurea herbicide (Case B2). Part A: Risk to birds and mammals



Concerning birds (Figure 25A, left part), comparable lower-tier TER values were available for both acute and long-term risks to both insectivore and herbivore species. For all four endpoints, TER values for the alternative were more than 100-fold higher than for the candidate product, thereby indicating a potential for a significant risk reduction. No comparable TER values were

available for short-term toxicity to birds, which had additionally been tested for the candidate but not for the alternative product. Furthermore, refined acute and short-term risk assessments had been conducted for the candidate product, but not for the alternative as it had passed the standard assessment criteria. Risks of secondary poisoning of predatory birds had not been assessed for both products.

Concerning mammals (Figure 25A, right part), comparable TER values were available for the lower tier assessment of risks for acute toxicity of the AS and for both lower-tier and tier-I assessments of long-term risks of the AS. For acute effects, the comparison shows a potential for significant risk reduction, as the TERac value for the alternative is more than 100-fold higher than for the candidate product. For long-term effects, the comparison shows only slight and insignificant potentials for risk reduction, both on the basis of lower-tier assessments and refined tier-I assessments. No comparable TER values were available for acute effects of the formulated product, which had been additionally assessed for the candidate product, but not for the alternative. In addition, a refined assessment of risks for acute effects of the AS had been conducted for the candidate product, but not for the alternative as it fulfilled the standard assessment criteria. Risks of secondary poisoning of predatory mammals had not been assessed for both products.

Concerning pelagic organisms in the aquatic environment (Figure 25B), comparable TER values were available for all three relevant exposure pathways: spray-drift, run-off, and drainage. For the candidate product, TER values for exposure via spray-drift referred to a NOEC for daphnids, while TER values for run-off and drainage referred to an EC50 for *Lemna* as the critical toxicity endpoint. For the alternative product, all values referred to the EC50 in *Lemna*. For exposure via spray-drift, the TER calculations for the two products had been conducted for different arrays of potential risk mitigation scenarios. However, comparable values were available for four common scenarios: 5m distance requirement in combination with 0%, 50%, 75%, and 90% drift reduction technique, respectively. In all these four scenarios, TER values for the alternative were more than 10-fold higher than for the candidate product, thereby indicating a significant potential for risk reduction. For exposure via run-off, TER values for both the candidate product and the alternative referred to the same set of four different risk mitigation scenarios: 0, 5, 10, and 20 m vegetated buffer strip. For all these four scenarios, the comparison consistently shows some potential for risk reduction, but all ratios remain clearly below the significance level of a 10-fold reduction. For exposure via drainage, comparable TER values were available for both spring/summer and autumn/winter scenarios. As for run-off, risks of the alternative were consistently lower than for the candidate, but not reaching the significance level of a 10-fold reduction.

Concerning risks to honeybees (Figure 25C, left part), 1/HQ values for oral exposure to the AS were available in terms of minimal values (1/HQ >x) for both the alternative and the candidate product. Hence, the actual risk difference cannot be quantified and no bar is shown in the figure. The difference between the minimum values was insignificant. An additional HQ value for oral exposure to the formulated PPP was available for the candidate, but not for the alternative product. The same applies to HQ values for contact exposure to both the AS and the formulated PPP. Risk assessments for other beneficial arthropods had not been conducted, neither for the candidate nor for the alternative product.

Concerning earthworms, comparable TER values were available for risks from exposure to the AS. The TER value for the candidate had been reported to be greater than 178 and hence well meeting the acceptability criterion of ≥10. The corresponding TER value for the alternative was also found to meet the acceptability criterion, but a very high exact value of 16,667 was reported. As a consequence, the ratio between the values calculates to be a value smaller than

two orders of magnitude ((16,667/>178) ≤ 93.64). Thus, it is possible that substitution may indeed lead to further reduction of the risk to earthworms from a relatively low to a very low level. However, it is also possible that the difference is actually insignificant, and even the possibility of a significant risk increase cannot be excluded with certainty. No comparable TER values were available for the risk to earthworms from exposure to the formulated PPP. This had been assessed for the candidate product, but not for the alternative.

Figure 25B: Risk comparison between a candidate phenylurea herbicide and an alternative sulfonylurea herbicide (Case B2). Part B: Aquatic Ecotoxicology

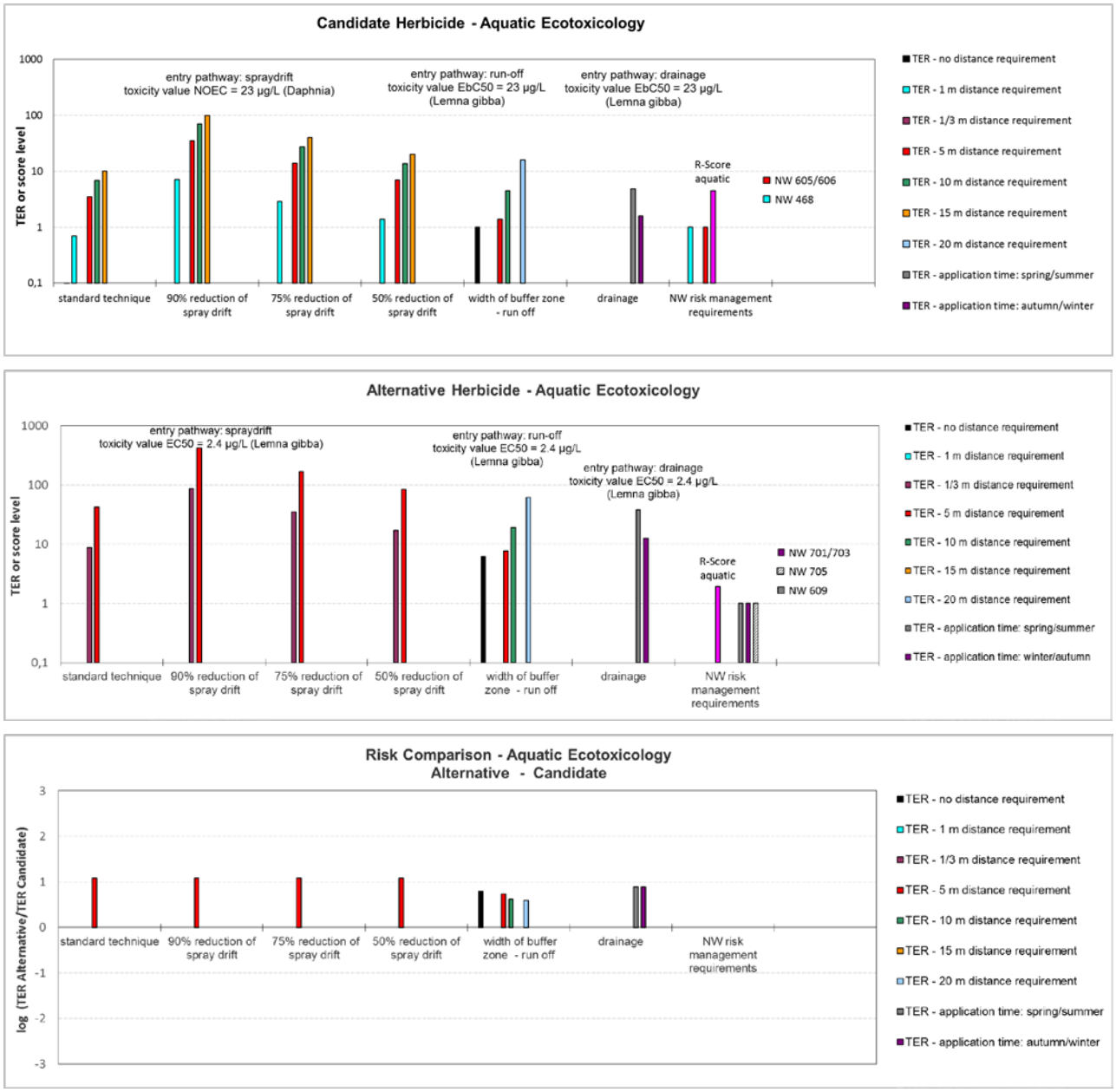
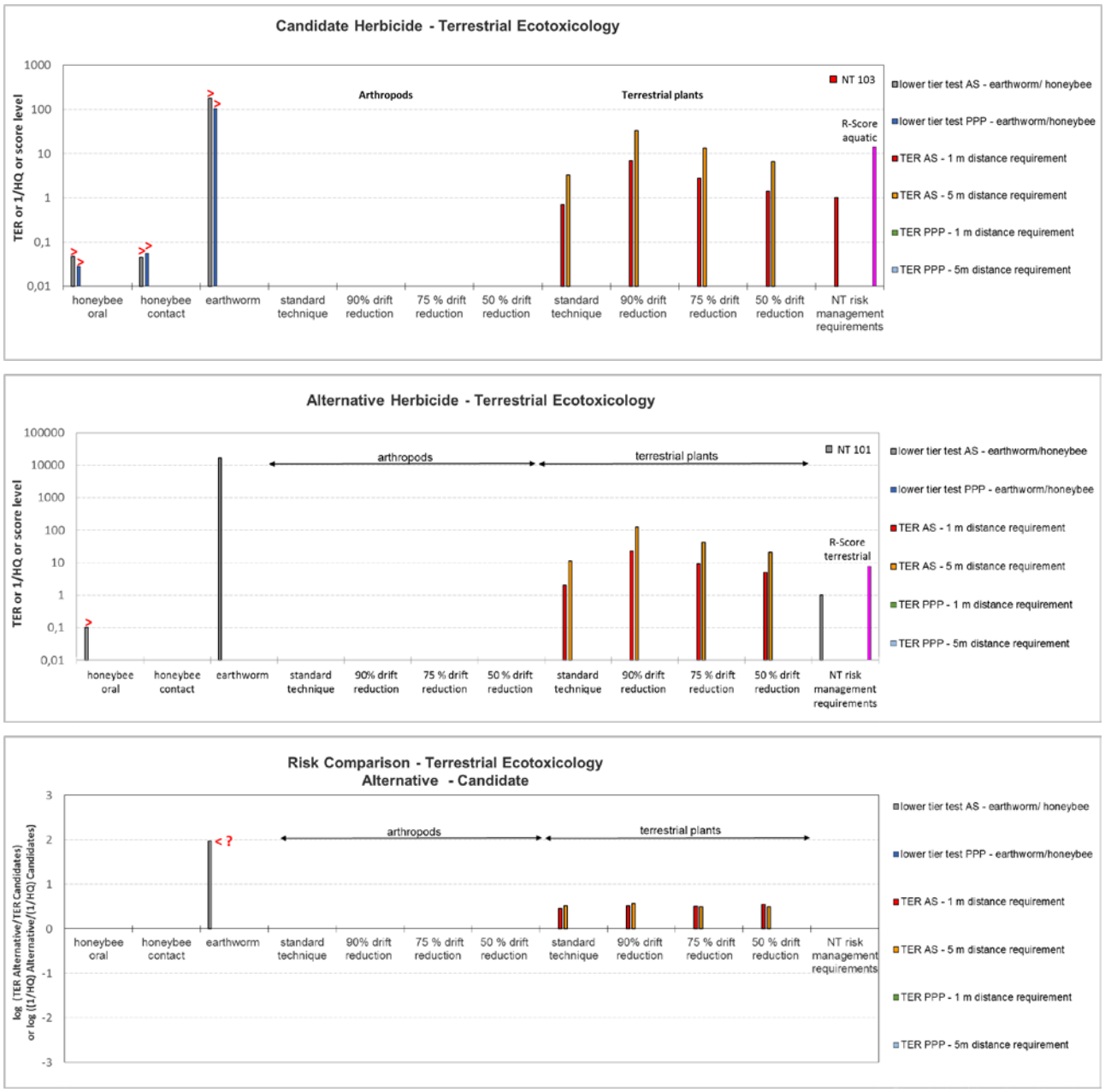


Figure 25C: Risk comparison between a candidate phenylurea herbicide and an alternative sulfonylurea herbicide (Case B2). Part C: Terrestrial Ecotoxicology



Concerning terrestrial plants in non-target-areas, comparable TER values were available for a common array of eight different exposure scenarios resulting from a variety of different possible risk mitigation measures: 1 m or 5 m non-spray buffer zone, each in combination with 0%, 50%, 75%, or 90% drift reduction. Consistently, the risks of the alternative product were lower than those of the candidate product in all eight scenarios, however, the differences in TER values were always smaller than one order of magnitude and hence judged to be insignificant.

In summary, comparable risk quotients were available for a total of 27 different risk assessment endpoints, including ten different toxicological endpoints in seven different species groups on the numerator side of the quotients, and a variety of exposure scenarios for different routes,

mitigation measures, and application seasons on the denominator side. For two of the endpoints, risk differences were either not quantifiable (honeybees) or inconclusive (earthworms) due to definition by inequalities. The remaining 25 TER values were consistently found to be higher for the alternative than for the candidate product. In 10 out of the 25 cases, the potential risk reduction exceeded the legally defined significance threshold of a tenfold difference in TER values. Following the decision rules suggested in section 6.5, this example would therefore clearly qualify as a case for substitution, provided (i) that the absence of risk increases for bees and earthworms can be confirmed and (ii) that considerations about human toxicology and agronomic aspects do not argue against this ecotoxicological conclusion.

7.5.2 Risk comparison between a candidate pyrethroid insecticide and an alternative neonicotinoid insecticide (Case E5)

As a second example, the comparison of risk profiles is explored in this section for case E5 (see Table 17), i.e. the comparison of ecotoxicological risks resulting from spray application of a pyrethroid insecticide against aphids in potato cultures with the corresponding risks of a neonicotinoid product which has been authorised for the same use as a potential alternative. As a shortcut, however, the graphical comparison is confined to the quantitative differences in comparable risk quotients (Figure 26), not again showing the original individual risk profiles of both products and not describing the qualitative commonalities and differences to the same level of detail as in the previous example.

Concerning risks to birds (Figure 26, upper left part), comparable lower-tier TER values were available for both acute and long-term risks to both insectivore and herbivore species. Substitution of the candidate product by the alternative product would reduce risks for long-term effects, but increase risks for acute effects. However, all these risk differences are smaller than a factor of ten and hence insignificant according to the legal provisions.

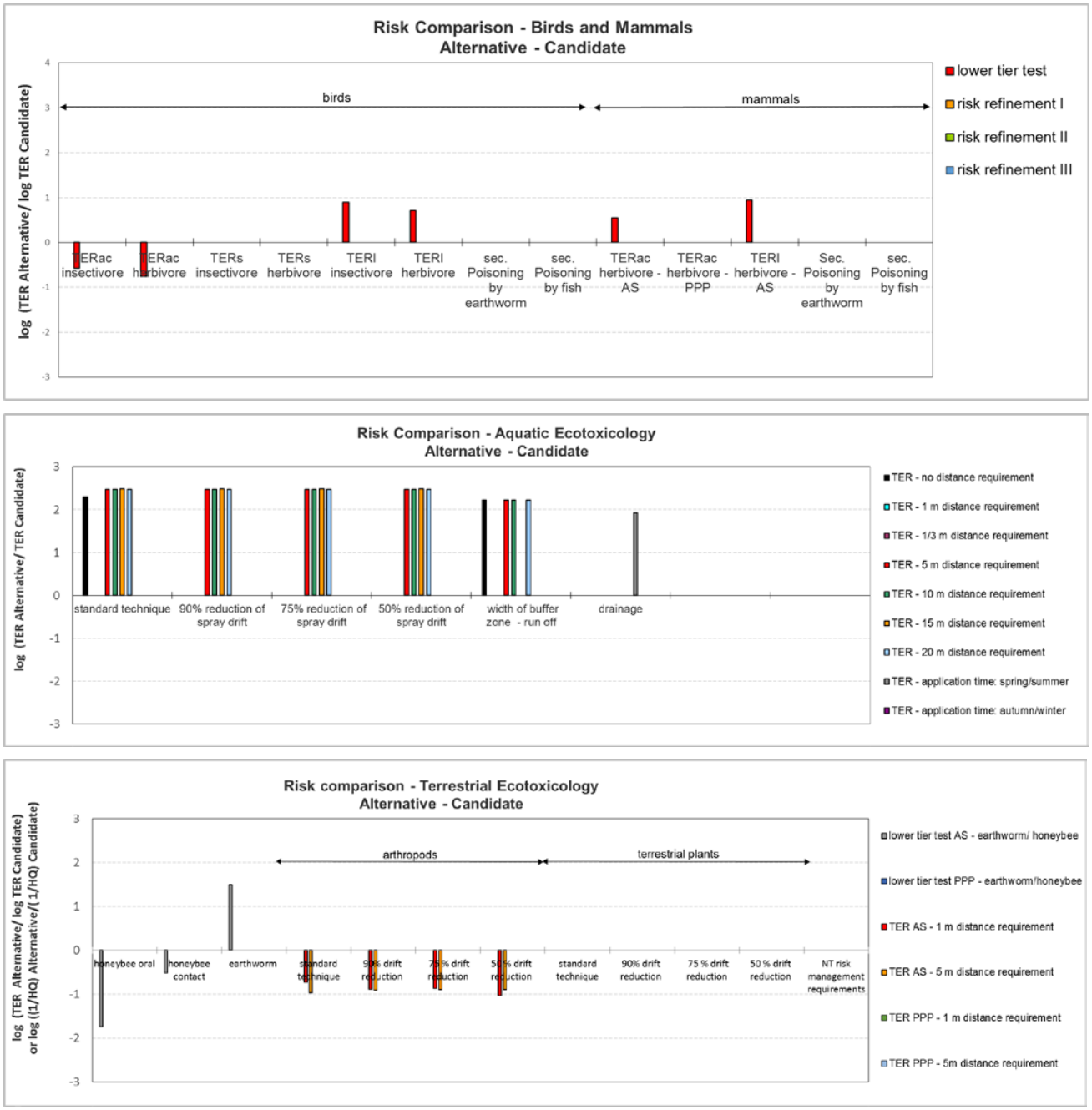
Concerning mammals (Figure 26, upper right part), comparable TER values were available for acute and for long-term risks from exposure of herbivore species to the AS. In contrast to birds, substitution would not only reduce long-term risks, but also short-term-risks. As for birds, however, the risk differences are smaller than tenfold and hence insignificant.

Risks for secondary poisoning of both birds and mammals had been assessed for the candidate product but not for the alternative product, and hence no comparable TER values were available for assessing corresponding risk differences. Such asymmetric data situations results from conditional testing schemes, where the assessment of secondary poisoning is triggered by indications for a high bioaccumulation potential. Since the equations for assessing secondary poisoning are targeted at substances that bioaccumulate via lipophilic mechanisms, it can safely be assumed that this exposure pathway is less relevant and the resulting specific risk lower for less lipophilic than for more lipophilic substances, but the difference in risk cannot be quantified. Moreover, no statement is currently possible for substances that could bioaccumulate via non-lipophilic mechanisms.

Concerning aquatic organisms (Figure 26, middle part), comparable TER values were available for exposure via spray-drift, run-off, and drainage. TER values for the candidate product were all based on a NOEC determined in a higher tier mesocosm study. In contrast, TER values for the alternative were based on an HC5 value derived from a distribution of EC50 values for invertebrates. For spray-drift exposure, comparable TER values included a total of 17 different risk mitigation scenarios. In all these scenarios, substitution of the candidate product by the alternative product would result in significant risk reductions, as TER values differ consistently by more than two orders of magnitude. The same applies to risks from exposure via run-off,

where comparable TER values were available for a range of four different risk mitigation scenarios. A slightly smaller but still clearly significant potential for risk reduction is also given for exposure via drainage, where comparable TER values were only available for spring/summer application, not for an autumn/winter scenario.

Figure 26: Risk comparison between a candidate pyrethroid insecticide and an alternative neonicotinoid insecticide (Case E5)



Concerning risks to honeybees (Figure 26, lower left part), comparable HQ values were available for both oral and contact exposure. Both products bear a high risk for bees, with the risks of the alternative being even higher than those of the candidate product. As a

consequence, substitution would result in an increase of risks for bees. The risk differences are insignificant for contact exposure, but highly significant for oral exposure with 1/HQ decreasing by clearly more than an order of magnitude. Also for other beneficial arthropods, substitution would increase risks. In seven out of eight risk mitigation scenarios, the corresponding differences in TER values did just not reach the significant level of an order of magnitude; in one of the scenarios it was just exceeded.

For earthworms, the situation is exactly the opposite as for bees and other arthropods. Substitution would raise the TER value by more than 10-fold and hence represent a significant risk reduction. For terrestrial plants, risk assessments had only been performed for the alternative but not for the candidate product. Hence a comparison is impossible for that type of endpoint.

In summary, the comparison of risk profiles reveals that substitution of the candidate product by the alternative product would result in significant risk reductions for earthworms and aquatic organisms on the one hand, and in significant risk increases for honeybees on the other hand. For other types of endpoints, risk differences are insignificant. Following the decision rules suggested in section 6.5, this is an example for a situation where substitution would not be clearly advantageous for the environment; it would entail a trade-off between incomparable risks, such as those for honeybees and for aquatic organisms. As a consequence, authorisation of the candidate product could not be rejected, unless there would be special reasons for an expert decision that would overrule the suggested principles in the specific case.

7.5.3 Risk comparison between a candidate triazole fungicide and an alternative pyrazole fungicide (Case C3)

The third example is a comparison of the ecotoxicological risk profiles of two fungicides (case C3 in Table 17). The candidate product contains a triazole which is a potential candidate for substitution. The alternative is a pyrazole product. Both have been authorised for spray application against mildew in wheat. As for the previous example, the graphical presentation is confined to the differences in comparable risk quotients (Figure 27).

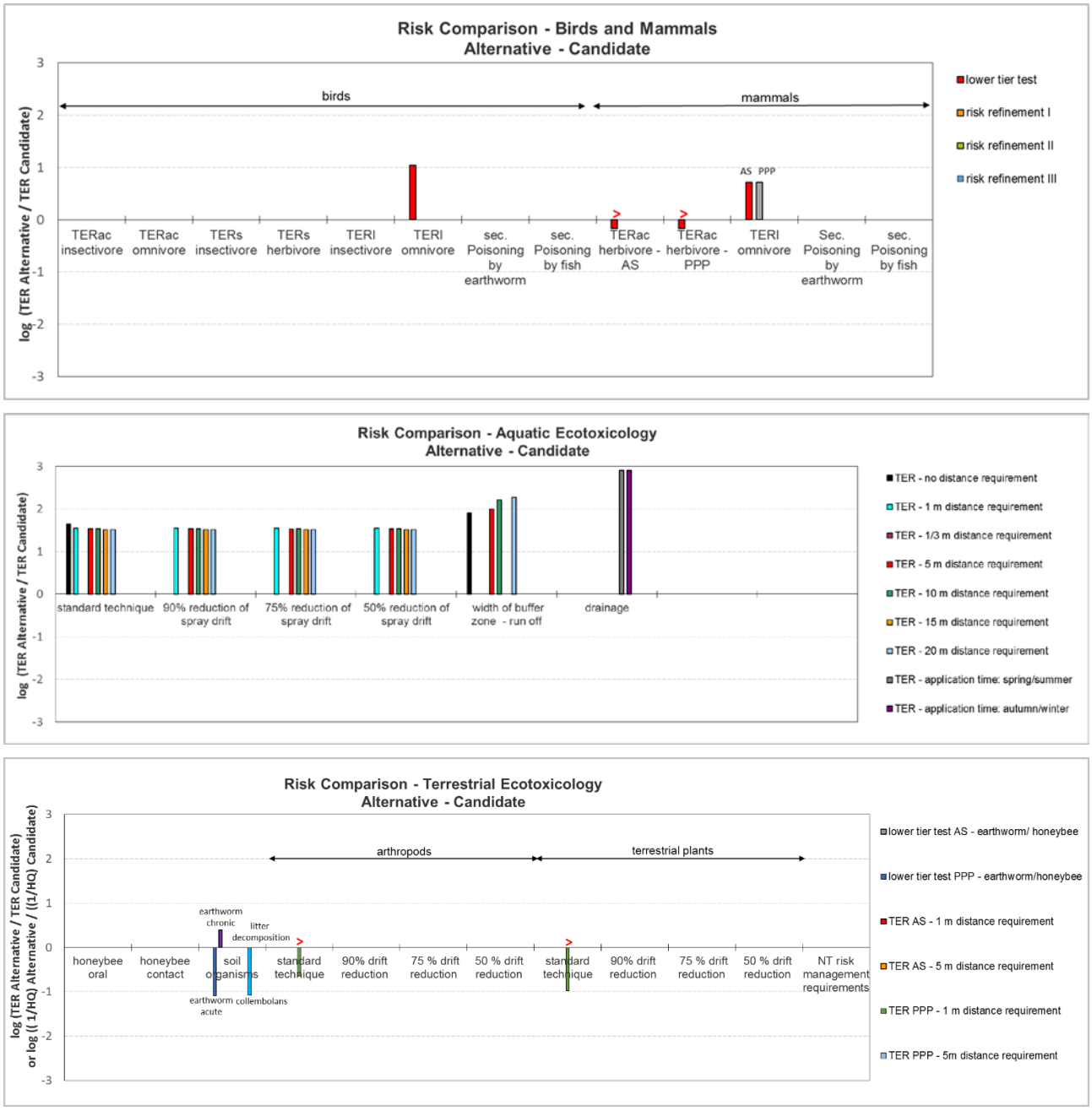
As a basis for quantitative comparisons of the risks to birds, TER values for long-term effects in omnivore species were available from the assessment reports for both products (Figure 27, upper left part). The values differed by slightly more than a factor of ten, with the alternative product being significantly safer for birds than the candidate product. For risks of acute toxicity in omnivore birds, TER values of the alternative and the candidate product had both been reported to be smaller than 549. Hence the actual risk difference was not calculable. TER values for acute effects in insectivore species were only available for the candidate product, not for the alternative.

For mammals, comparable TER values were available for acute effects of both the AS and the PPPs for herbivore species, and for long-term effects of the AS and the PPPs for omnivore species (Figure 27, upper right part). The TER value for acute effects of the alternative product had only been determined to be larger than a value of 103, while the TER value for the candidate was given as a definite value of 150. As a consequence, there is no positive evidence for a significant risk reduction, but the possibility of a significant risk increase (by a factor of ten or more) can be safely excluded. For long-term effects on mammals, the alternative product was shown to bear lower risks than the candidate product, but the risk differences were below the legal significance criterion and hence do also not provide an argument for substitution.

For aquatic organisms, comparable TER values were available for all three relevant exposure pathways: spray-drift, run-off, and drainage (Figure 27, middle part). TER values for the

candidate product were all based on an EC50 for *Lemna gibba*, while TER values for the alternative all referred to an EC50 value for *Cyprinus carpio* as the critical toxicity level. For spray-drift exposure, comparable TER values included a total of 21 different risk mitigation scenarios. For all these scenarios, risk differences were almost identical, consistently indicating that a significant reduction of risks to aquatic organisms would be achievable by substitution of the candidate product by the alternative. For exposure via run-off, comparable TER values included four different risk mitigation scenarios. In all four scenarios, substitution would result in significant risk reductions. The risk differences slightly increase with an increase of the width of the vegetated buffer strip between treated areas and surface waters. For exposure via drainage, comparable TER values were available for both spring/summer and autumn/winter scenarios. In both scenarios, substitution would reduce aquatic risks drastically, with TER values of the alternative being almost three orders of magnitude higher than for the candidate product.

Figure 27: Risk comparison between a candidate triazole fungicide and an alternative pyrazole fungicide (Case C3)



For honeybees (Figure 27, lower left part), directly comparable HQ values were not available. Risks from both oral and contact exposure had been assessed for both products, however, HQ values for the candidate product referred to the formulated PPP, while HQ values for the alternative product referred to the pure AS. This asymmetry in the data situation causes a considerable gap in the differential risk profile. The development of an appropriate procedure for closing such gaps was beyond the scope of this exploratory exercise, but it is clearly needed for advancing the proposed methodology towards a routinely applicable tool.

For earthworms (Figure 27, lower left part), the comparison of TER values indicates opposite effects of a substitution on risks for acute and for chronic effects: the risk for acute toxic effects would be increased, while the chronic risk would be reduced. However, according to the legal

criterion, the risk increase for acute effects is significant, while the reduction of risks for chronic effects is not. Thus in all, the comparison of risks for earthworms provides a clear argument against substitution[10].

For comparing the risks to other soil macro-organisms (Figure 27, lower left part), TER values for toxic effects on collembolans and for effects on litter decomposition were available for both products. As for earthworms, the risk of the alternative product for collembolans turned out to be significantly higher than the risk of the candidate product. For effects on litter decomposition, the risk difference was not quantifiable, because the TER values for both products had only been reported to exceed a value of one each.

Concerning risks to beneficial arthropods (other than bees) and to terrestrial plants in non-target areas (Figure 27, lower middle and right part), comparable TER values were available for standard application techniques and standard distance requirements. For the alternative product, these values were only defined in terms of exceedance of certain values (>x). As a consequence, it is not clear from the data whether the risk differences are insignificant or whether significant risk reductions may occur, but the possibility of a significant risk increase (by a factor of ten or more) can be excluded with certainty. Arrays of TER values resulting from a range of different risk mitigation scenarios had been calculated for the candidate product, but not for the alternative, and were hence not comparable and do not provide any further evidence.

In summary, the comparison of risk profiles reveals that substitution of the candidate fungicide by the alternative product would result in significant risk reductions for birds and for aquatic organisms, but also in significant risk increases for earthworms (acute effects) and other soil macro-organisms. For other endpoints, risk differences are insignificant according to the legal assessment criterion. Following the proposed assessment principles (section 6.5), the situation is similar to the previous example for insecticides: substitution would not be generally advantageous for the environment. As a consequence, authorisation of the candidate product could not be rejected, unless special reasons would argue for an exemption from the rules.

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[10] This conclusion is reached by considering acute and chronic TER values as independent descriptors of different types of risks for earthworms, strictly following the separate acceptability criteria laid down in the Uniform Principles (see Table 14). Alternatively, it could be argued that comparisons of chronic risks provide evidence that may be considered to override comparisons of acute risks. This could lead to a more straightforward conclusions. In support of this argument, reference could be made to the general principles for decision-making laid down in the Uniform Principles, which require Member States "*to ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species*" (Section C.1.5. of Part I of the Annex to the Uniform Principles). It may be argued that achievement of this goal automatically includes adequate protection from acute risks. Following this line of thinking, the requirement for acute toxicity studies in earthworms has already been dropped in the new Commission Regulation No 284/2013 on data requirements for PPPs, now exclusively focussing on tests for sub-lethal effects and field studies. Hence, contradictory conclusions about risk differences for acute and chronic effects in earthworms, as observed in this case study, will no longer occur in comparisons of products tested under the new Commission Regulation No 284/2013.

7.6 Summary assessment of risk differences

7.6.1 Compilation and inspection of all available data

In addition to the three illustrative examples shown in the previous section 7.5, pairwise comparisons of risk profiles were performed in the same way also for the other seven cases listed in Table 17. For all the ten test cases, a complete documentation of the availability of comparable risk quotients and the resulting risk differences is provided in Table. 18. The table includes the full list of endpoints for which risk quotients (RQ), defined in terms of TER or 1/HQ values, were compiled from the UBA assessment reports and entered into the data mask (Annex 3 to this report).

Table 18: Availability of comparable risk quotients and resulting risk differences in the ten case studies

Endpoint (numbering refers to the data mask given in Annex 3)	RQ	log (RQ Alternative / RQ Candidate)									
		Case study Code (see Table 17)									
		A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
3. Risks for birds and mammals											
3.1a Birds, acute toxicity											
A) Active substance											
Insectivore species	TER	>1.58	>2.47	>1.95	>2.84	no data	A only	C only	0.28	-0.58	-0.51
Herbivore species	TER	C only	>2.00	C only	>2.78	A only	no data	(>/>)	C only	-0.75	C only
Omnivore species	TER	no data	no data	no data	no data	(>/>)	C only	A only	no data	no data	A only
B) Product											
Insectivore species	TER	>1.12	C only	A only	no data	no data	no data	no data	no data	no data	no data
Herbivore species	TER	C only	C only	no data	no data	no data	no data	no data	no data	no data	no data
Omnivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
C) Refined risk assessment											
Insectivore species											
Autumn/spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	C only	C only	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	C only	C only	no data	no data	no data	no data	no data	no data
Herbivore species											
Autumn/spring	TER	no data	no data	C only	C only	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
3.1b Birds, short-term toxicity											
A) Active substance											
Insectivore species	TER	>1.14	C only	>1.30	C only	no data	A only	C only	-0.20	no data	no data
Herbivore species	TER	>1.1	C only	>1.3	C only	no data	no data	C only	C only	no data	no data

		5		2							
Omnivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
B) Product											
Insectivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Herbivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Omnivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
C) Refined risk assessment											
Insectivore species											
Autumn/spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	C only	C only	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	C only	C only	no data	no data	no data	no data	no data	no data
Herbivore species											
Autumn/spring	TER	no data	no data	C only	C only	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data

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Table 18 continued

Endpoint (numbering refers to the data mask given in Annex 3)	RQ	log (RQ Alternative / RQ Candidate)									
		Case study Code (see Table 17)									
		A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
3.1c Birds, long-term toxicity											
A) Active substance											
Insectivore species	TER	0.03	0.52	1.76	2.25	C only	0.10	C only	1.78	0.90	0.47
Herbivore species	TER	0.23	0.73	1.92	2.43	A only	no data	1.81	C only	0.71	C only
Omnivore species	TER	no data	no data	no data	no data	1.04	C only	A only	no data	no data	A only
B) Product											
Insectivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Herbivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Omnivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
C) Refined risk assessment											
Insectivore species											
Autumn/spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	no data	no data	no data	no data	C only	C only	no data	no data
Spring	TER	no data	no data	no data	no data	no data	no data	C only	C only	no data	no data
Herbivore species											
Autumn/spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	no data	no data	no data	no data	C only	C only	no data	no data
3.1d Birds, secondary poisoning											
Earthworm-eating birds	TER	no data	no data	no data	no data	no data	no data	C only	C only	C only	C only
Fish-eating birds	TER	no data	no data	no data	no data	no data	no data	C only	C only	C only	C only
3.2a Mammals, acute toxicity											
A) Active substance											
Omnivore species	TER	no data	no data	no data	no data	C only	C only	no data	no data	no data	no data
Insectivore species	TER	A only	no data	A only	no data	no data	no data	C only	C only	no data	no data
Herbivore species	TER	>0.21	>1.55	>0.94	>2.27	> -0.16	1.21	> -0.02	1.36	0.55	0.18
Medium-size herbivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
B) Product											
Omnivore species	TER	no data	no data	no data	no data	C only	C only	no data	no data	no data	no data
Insectivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Herbivore species	TER	no data	no data	C only	C only	> -0.16	C only	A only	no data	no data	no data
Medium-size herbivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
C) Refined risk											

assessment											
Insectivore species											
Autumn/spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data

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Table 18 continued

Endpoint (numbering refers to the data mask given in Annex 3)	RQ	log (RQ Alternative / RQ Candidate)									
		Case study Code (see Table 17)									
		A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
Herbivore species											
Autumn/spring	TER	no data	no data	C only	C only	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
3.2b Mammals, long-term toxicity											
A) Active substance											
Insectivore species	TER	A only	no data	A only	no data	A only	no data	0.85	C only	no data	A only
Omnivore species	TER	no data	no data	no data	no data	0.72	C only	A only	no data	no data	no data
Herbivore species	TER	0.11	-0.86	1.69	0.73	A only	A only	0.02	0.13	0.94	C only
Medium-size herbivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
B) Product											
Insectivore species	TER	no data	no data	no data	no data	A only	no data	A only	no data	no data	no data
Omnivore species	TER	no data	no data	no data	no data	0.72	C only	A only	no data	no data	no data
Herbivore species	TER	no data	no data	no data	no data	A only	no data	A only	no data	no data	no data
Medium-size herbivore species	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
C) Refined risk assessment											
Insectivore species											
Autumn/spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Herbivore species											
Autumn/spring	TER	no data	no data	C only	0.43	no data	no data	no data	no data	no data	no data
Autumn	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
Spring	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
3.2c Mammals, secondary poisoning											
Earthworm-eating mammals	TER	no data	no data	no data	no data	no data	no data	C only	C only	C only	C only
Fish-eating mammals	TER	no data	no data	no data	no data	no data	no data	C only	C only	C only	C only
4. Risks for aquatic organisms											
4.1a Exposure route: spray drift and evaporation/deposition											
Standard technique											
0m distance	TER	-0.22	C only	0.00	C only	1.64	0.10	0.64	-0.90	2.30	no data

1m distance	TER	-0.19	C only	0.04	C only	1.54	-0.26	0.57	-1.23	A only	A only
1/3m distance	TER	no data	A only	no data	A only	no data	no data	no data	no data	C only	C only
5m distance	TER	-0.19	0.86	0.02	1.08	1.53	-0.35	0.55	-1.33	2.47	2.66
10m distance	TER	-0.19	C only	0.02	C only	1.53	-0.34	A only	A only	2.48	2.66
15m distance	TER	A only	no data	0.03	C only	1.52	-0.36	A only	A only	2.48	2.68
20m distance	TER	no data	no data	no data	no data	1.52	-0.36	A only	A only	2.47	2.68

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Table 18 continued

Endpoint (numbering refers to the data mask given in Annex 3)	RQ	log (RQ Alternative / RQ Candidate)									
		Case study Code (see Table 17)									
		A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
90% Reduction											
0m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
1m distance	TER	-0.19	C only	0.03	C only	1.55	-0.32	0.57	-1.30	A only	A only
1/3m distance	TER	no data	A only	no data	A only	no data	no data	no data	no data	C only	C only
5m distance	TER	-0.19	0.86	0.03	1.08	1.53	-0.34	A only	A only	2.47	1.96
10m distance	TER	-0.19	C only	0.02	C only	1.53	-0.34	A only	A only	2.48	1.96
15m distance	TER	no data	no data	C only	C only	1.52	C only	A only	no data	2.48	1.98
20m distance	TER	no data	no data	no data	no data	1.52	C only	A only	no data	2.47	1.98
75% Reduction											
0m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
1m distance	TER	-0.18	C only	0.03	C only	1.55	-0.31	0.57	-1.29	A only	A only
1/3m distance	TER	no data	A only	no data	A only	no data	no data	no data	no data	C only	C only
5m distance	TER	-0.19	0.86	0.03	1.08	1.53	-0.34	A only	A only	2.47	2.66
10m distance	TER	-0.19	C only	0.03	C only	1.53	-0.34	A only	A only	2.48	2.66
15m distance	TER	no data	no data	C only	C only	1.52	-0.36	A only	A only	2.48	2.68
20m distance	TER	no data	no data	no data	no data	1.52	C only	A only	no data	2.47	2.68
50% Reduction											
0m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
1m distance	TER	-0.20	C only	0.03	C only	1.55	-0.37	0.57	-1.35	A only	A only
1/3m distance	TER	no data	A only	no data	A only	no data	no data	no data	no data	C only	C only
5m distance	TER	-0.19	0.86	0.02	1.08	1.53	-0.35	0.55	-1.33	2.47	3.36
10m distance	TER	-0.19	C only	0.02	C only	1.53	-0.34	A only	A only	2.48	3.36
15m distance	TER	no data	no data	C only	C only	1.52	-0.35	A only	A only	2.48	3.37
20m distance	TER	no data	no data	no data	no data	1.52	-0.36	A only	A only	2.47	3.37
4.1b Exposure route: run-off and drainage											
Run-off											
0m vegetated buffer zone	TER	3.69	0.89	3.60	0.79	1.90	C only	0.67	C only	2.22	2.26
5m vegetated buffer zone	TER	C only	0.84	C only	0.73	2.00	C only	0.79	C only	2.22	2.23
10m vegetated buffer zone	TER	C only	0.73	C only	0.63	2.20	C only	0.99	C only	2.22	1.97

20m vegetated buffer zone	TER	C only	0.70	C only	0.59	2.27	C only	A only	no data	2.22	1.62
Drainage											
Spring/Summer	TER	>>0.42	1.00	>>0.31	0.89	2.91	C only	1.70	C only	1.92	1.50
Autumn/Winter	TER	>>0.92	1.01	>>0.80	0.89	2.90	C only	1.69	C only	no data	no data
5. Risks for honeybees											
5.1 Acute toxicity											
A) Active substance											
oral	1/HQ	<-0.4 !	(>/>)	<0.6 !	(>/>)	A only	A only	<0.3 !	(>/>)	-1.75	C only
contact	1/HQ	(>/>)	C only	(>/>)	C only	A only	A only	<-0.5 !	(>/>)	-0.52	C only

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Table 18 continued

Endpoint (numbering refers to the data mask given in Annex 3)	RQ	log (RQ Alternative / RQ Candidate)									
		Case study Code (see Table 17)									
		A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
B) Product											
oral	1/HQ	no data	no data	C only	C only	C only	> -0.74	no data	A only	C only	C only
contact	1/HQ	no data	no data	C only	C only	C only	C only	no data	no data	C only	C only
6. Risks for arthropods											
A) Active substance											
Standard technique											
0m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
1m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	-0.74	1.52
5m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	-0.97	1.51
90% Reduction											
1m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	-0.90	0.82
5m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	-0.92	0.81
75% Reduction											
1m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	-0.87	1.52
5m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	-0.91	1.51
50% Reduction											
1m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	-1.04	2.22
5m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	-0.91	2.21
B) Product											
Standard technique											
0m distance	TER	no data	no data	no data	no data	no data	A only	no data	A only	no data	no data
1m distance	TER	no data	no data	no data	no data	> -0.64	-1.47	A only	A only	no data	no data
5m distance	TER	no data	no data	no data	no data	C only	-1.49	no data	A only	no data	no data
90% Reduction											
1m distance	TER	no data	no data	no data	no data	C only	-1.47	no data	A only	no data	no data
5m distance	TER	no data	no data	no data	no data	C only	C only	no data	no data	no data	no data
75% Reduction											
1m distance	TER	no data	no data	no data	no data	C only	-1.46	no data	A only	no data	no data
5m distance	TER	no data	no data	no data	no data	C only	C only	no data	no data	no data	no data
50% Reduction											
1m distance	TER	no data	no data	no data	no data	C only	-1.46	no data	A only	no data	no data
5m distance	TER	no data	no data	no data	no data	C only	C only	no data	no	no data	no data

									data		
7. Risks for soil macro-organisms											
7.2 Earthworms											
A) Active substance											
acute	TER	(>/>)	<1.67 !	(>/>)	<1.97 !	C only	<-0.4 !	C only	<-0.6 !	>1.50	1.46
chronic	TER	no data	no data	no data	no data	no data	no data	C only	C only	no data	no data

Table continued on the next page

Table 18 continued

Endpoint (numbering refers to the data mask given in Annex 3)	RQ	log (RQ Alternative / RQ Candidate)									
		Case study Code (see Table 17)									
		A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
B) Product											
acute	TER	(>/>)	C only	(>/>)	C only	-1.09	-0.03	A only	A only	C only	C only
chronic	TER	A only	no data	no data	no data	0.40	-0.30	A only	A only	no data	no data
7.2 Other soil macro-organisms											
A) Active substance											
Collembolans	TER	no data	no data	no data	no data	no data	no data	C only	C only	no data	A only
Impact on litter decomposition	TER	no data	no data	no data	no data	no data	no data	C only	C only	no data	no data
B) Product											
Collembolans	TER	no data	no data	no data	no data	-1.08	C only	A only	no data	no data	no data
Impact on litter decomposition	TER	no data	no data	no data	no data	(>/>)	C only	A only	no data	no data	no data
9. Risks for terrestrial plants											
A) Active substance											
Standard technique											
0m distance	TER	no data	no data	no data	no data	no data	no data	no data	no data	no data	no data
1m distance	TER	1.08	0.46	1.08	0.46	A only	no data	A only	no data	C only	C only
5m distance	TER	C only	0.58	C only	0.52	no data	no data	no data	no data	no data	no data
90% Reduction											
1m distance	TER	1.09	0.52	1.09	0.52	no data	no data	no data	no data	C only	C only
5m distance	TER	C only	0.57	C only	0.57	no data	no data	no data	no data	no data	no data
75% Reduction											
1m distance	TER	1.08	0.51	1.08	0.51	no data	no data	no data	no data	C only	C only
5m distance	TER	C only	0.50	C only	0.50	no data	no data	no data	no data	no data	no data
50% Reduction											
1m distance	TER	1.08	0.55	1.08	0.55	no data	no data	no data	no data	C only	C only
5m distance	TER	C only	0.50	C only	0.50	no data	no data	no data	no data	no data	no data
B) Product											
Standard technique											
0m distance	TER	no data	no data	no data	no data	no data	A only	A only	A only	no data	no data
1m distance	TER	no data	no data	no data	no data	> -0.97	> -1.3 !	A only	A only	no data	no data
5m distance	TER	no data	no data	no data	no data	C only	> -1.3 !	A only	A only	no data	no data
90% Reduction											
1m distance	TER	no data	no data	no data	no data	C only	C only	no data	no data	no data	no data

5m distance	TER	no data	no data	no data	no data	C only	> - 2.0 !	A only	A only	no data	no data
75% Reduction											
1m distance	TER	no data	no data	no data	no data	C only	C only	no data	no data	no data	no data
5m distance	TER	no data	no data	no data	no data	C only	> - 2.0 !	A only	A only	no data	no data
50% Reduction											
1m distance	TER	no data	no data	no data	no data	C only	C only	no data	no data	no data	no data
5m distance	TER	no data	no data	no data	no data	C only	> - 2.0 !	A only	A only	no data	no data

Where risk quotients where neither available for the alternative nor for the candidate product, "*no data*" was entered into the table. Where a risk quotient was either available for the alternative (A) or for the candidate product (C) but not for both, this is indicated in the table by the entries "*A only*" and "*C only*", respectively. Where risk quotients where available for both the alternative and the candidate product, the resulting risk difference is given in terms of the decadic logarithm of the ratio between the RQ values of the alternative and the candidate product. Log values of +1 and -1 correspond to 10fold risk reductions and risk increases, respectively. They represent the legal threshold for significant risk differences. Where substitution would result in significant risk reductions (log values ≥1), values are printed in green. Significant risk increases (log values ≤1) are indicated by red figures. Insignificant risk differences are printed in black. Where the data provide conclusive evidence for either significant risk reduction or significant increase or insignificant risk differences, the values are printed in bold green, bold red, or bold black, respectively. Where the evidence is inconclusive, values are not printed in bold, and where this means that the possibility of a significant risk increase cannot be ruled out, the data are flagged with a red exclamation mark. The reasons for such inconclusive data situations are explained in the following.

Unfortunately, TER or 1/HQ values from the assessment reports were not always defined in terms of exact values (= x) but partly in terms of inequalities only, denoting exceedance of a certain value (>x). Where this applied to both the value for the alternative ($>x_A$) and the candidate product ($>x_C$), the resulting ratio ($>x_A/>x_C$) is not solvable but may take any value. As a consequence, the risk difference cannot be quantified. In Table 18 these cases are denoted by the symbol ">/>" in brackets. Where only one of the two compared risk quotients is defined by an inequality of the type ">x" while the other one is an exact value, the resulting ratio is also an inequality, either denoting exceedance of a minimal value ($>x_A/x_C$) or lower deviation from a maximum value ($x_A/>x_C = <(x_A/x_C)$). Depending on the actual figures, this may lead to inconclusive data situations where the significance of risk differences cannot be assessed with certainty. This is shown in Table 19 below, which defines six possible data constellations. In two of these constellations conclusive evidence is given, either for a significant risk reduction or a significant increase. In one constellation there is no conclusive evidence for a significant risk reduction but the opposite possibility of a significant risk increase can be excluded with certainty. The other three possible data constellations imply that the possibility for a significant risk increase cannot be ruled out with confidence. These are the cases flagged with a red exclamation mark in Table 18. According to the proposed decision rules (section 6.5), they are critical for decision making if significant risk reductions and no significant risk increases can be seen for any other endpoints. Then the substitution decision depends on a confirmation or falsification of the evidence from the inconclusive data.

Table 18 includes a total 250 different categories of comparable TER or 1/HQ values. For 174 of these endpoints, quantitative assessments of risk differences were possible in one or more of the

ten test cases. For the remaining 76 endpoints, comparable data were in all cases missing for both or either products, or they were insufficient for a quantitative comparison due to definition by an inequality for both the alternative and the candidate product. These 76 endpoints, for which quantitative comparisons were generally not possible, include:

- all assessments of secondary poisoning of birds and mammals (4 endpoints),
- refined risk assessments for birds and mammals in all but one case (29 of 30 endpoints of refined assessments),
- a large part of assessments of formulated product risks (in contrast to risks from the AS) (24 of 41 endpoints for whole PPP assessments),
- assessments of risks of the AS to omnivorous birds (in contrast to insectivore and herbivore species) (3 endpoints),
- assessments of risks for acute toxicity to mammals other than small herbivore species (3 endpoints referring to insectivore, omnivore, and medium-size herbivore species),
- assessments of risks for long-term toxicity to medium-size herbivore mammals (in contrast to insectivore, omnivore, and small herbivore species) (1 endpoint),
- minor parts of the spectra of risk mitigation measures routinely investigated for the protection of aquatic species, arthropods, and terrestrial plants in adjacent fields and surface waters from effects of the AS (9 endpoints),
- the risk for chronic effects of the AS to earthworms (in contrast to chronic effects of the formulated PPP and acute effects of both the AS and the PPP (1 endpoint), and
- risks of the AS for other soil-macro-organisms (in contrast to effects of the formulated PPP) (2 endpoints).

The fact that risk differences were generally not assessable for 76 of the 250 endpoints, for which information was collected from the assessment reports, means a reduction of the level of differentiation that could be possible for a comparative assessment of risks to different sub-groups of species (e.g. herbivore vs. omnivore mammals), and different exposure conditions (e.g. different buffer zone or buffer strip widths). Fortunately, however, it does not mean that any of the major endpoints for regulatory standard assessment of pesticide risks (see Table 14) would have to be totally excluded from the comparative assessment due to missing or insufficient data in all test cases. For one or more sub-categories of those main endpoints, comparable data remained available in one or more of the test cases.

Where risk differences for the same species group and exposure route were calculable for a range of different risk mitigation scenarios (aquatic species, arthropods, and terrestrial plants), the results were in all cases consistent in the sense that they would not lead to any conflicting conclusions for the same species group. Depending on the actual risk mitigation measures, risk differences between two comparable products were sometimes significant and sometimes insignificant, but implausible changes from a significant risk reduction to a significant increase or vice versa did not occur.

Table 19: Assessment situations resulting from risk quotients (RQ) defined by inequalities (> x)

RQ_A	RQ_C	RQ_A / RQ_B	(x_A /x_B)	Significant risk reduction?	Insignificant risk differences?	Significant risk increase?
> x_A	= x_C	> (x_A/x_B)	≥ 10	YES	NO	NO
			> 0.1, < 10	possible	possible	NO
			≤ 0.1	possible	possible	possible
= x_A	> x_C	< (x_A/x_B)	≥ 10	possible	possible	possible
			> 0.1, < 10	NO	possible	possible
			≤ 0.1	NO	NO	YES

* RQ values are TER or 1/HQ values; suffixes A and C denote the alternative and the candidate product, respectively.

7.6.2 Data aggregation and assessment of risk differences

Given the findings from the initial general inspection of the full data set, we focussed the further data evaluation on the resulting evidence about quantitative risk differences and the consequences for regulatory decision making. To this end, we processed the data in a stepwise fashion, as detailed in the following.

As a first step, we reduced the complexity of the data presentation to obtain a more comprehensible overview. For this purpose, we transformed the full data presentation from Table 18 into a condensed version given in Table 20. In this condensed version

- all 76 endpoints with completely missing or insufficient data are eliminated,
- data matrices for arrays of exposure scenarios resulting from a variety of possible risk mitigation measures for the same products, exposure routes, and affected species groups (aquatic species, terrestrial arthropods, and terrestrial plants) are each reduced to three key figures:
    - o the risk difference seen without any risk mitigation measures,
    - o the minimum risk difference seen with any possible risk mitigation measure, and
    - o the maximum risk difference that may occur with any possible risk mitigation measure,
- all fields with missing or insufficient data for quantitative risk comparisons are left blank, and
- the hierarchical sub-structuring of main endpoints is slightly changed: primary differentiation for species groups (birds and mammals), exposure routes (honeybees), or exposure regimes (earthworms), and secondary differentiation by data applying to AS or PPP and data from standard assessments or refined assessments, where applicable.

As a result of this first step, the information is reduced from 250 to 43 endpoints for which quantitatively comparable risk quotients were available in one to ten of the ten test cases. As a general pattern, it can be seen from the table that the data situation for birds, mammals, and aquatic organisms is more favourable than for the other major species groups, i.e. honeybees and other arthropods, earthworms and other soil macro-organisms, and terrestrial plants. For birds, mammals, and aquatic species, conclusive quantitative data are available in all ten cases for at least one or more of the subordinated endpoints. For each of the other major groups,

there are one or more test cases where quantitative data are either completely missing or provide inconclusive evidence only (flagged by exclamation marks).

As a second step, we transformed the continuous data into discrete data by classifying them in accordance with the legal significance criterion for risk differences. Basically we distinguished between significant risk reduction, significant risk increase, and insignificant risk differences. Insignificant risk differences were further sub-divided into insignificant risk reductions, insignificant risk increases and constant risks. For visual presentation, these five risk classes were symbolised by signs and colour codes as defined in Table 21. Where inconclusive data did not allow assigning values to a single class, all possible classes were indicated by the corresponding symbols given in brackets as also shown in Table 21.

Table 20: Risk differences observed in the ten case studies (condensed presentation of all quantitative data from Table 18)

Endpoint	RQ	log (RQ Alternative / RQ Candidate)									
		Case study Code (see Table 17)									
		A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
Birds, acute toxicity											
insectivore species											
AS	TER	>1.58	>2.47	>1.95	>2.84				0.28	-0.58	-0.51
PPP	TER	>1.12									
herbivore species, AS	TER		>2.00		>2.78					-0.75	
Birds, short-term toxicity, AS											
insectivore species	TER	>1.14		>1.30					-0.20		
herbivore species	TER	>1.15		>1.32							
Birds, long-term toxicity, AS											
insectivore species	TER	0.03	0.52	1.76	2.25		0.10		1.78	0.90	0.47
herbivore species	TER	0.23	0.73	1.92	2.43			1.81		0.71	
omnivore species	TER					1.04					
Mammals, acute toxicity, herbivore species											
AS	TER	>0.21	>1.55	>0.94	>2.27	> -0.16	1.21	> -0.02	1.36	0.55	0.18
PPP	TER					> -0.16					
Mammals, long-term toxicity											
insectivore species, AS	TER							0.85			
herbivore species, AS											
standard assessment	TER	0.11	-0.86	1.69	0.73			0.02	0.13	0.94	
refined assessment	TER				0.43						
omnivore species											
AS	TER					0.72					
PPP	TER					0.72					
Aquatic organisms, exposure via spray drift and evaporation/deposition											
without risk mitigation	TER	-0.22		0.00		1.64	0.10	0.64	-0.90	2.30	
with risk mitigation											
min	TER	-0.20	0.86	0.02	1.08	1.52	-0.37	0.55	-1.35	2.47	1.96
max	TER	-0.18	0.86	0.04	1.08	1.55	-0.26	0.57	-1.23	2.48	3.37
Aquatic organisms, exposure via run-off											
without risk mitigation	TER	3.69	0.89	3.60	0.79	1.90		0.67		2.22	2.26
with risk mitigation											
min	TER		0.70		0.59	2.00		0.79		1.92	1.50
max	TER		1.01		0.89	2.91		1.70		2.22	2.23
Aquatic organisms, exposure via drainage											
spring/summer	TER	>>0.42	1.00	>>0.31	0.89	2.91		1.70		1.92	1.50
autumn/winter	TER	>>0.92	1.01	>>0.80	0.89	2.90		1.69			
Honeybees, acute toxicity											
oral											
AS	1/H	<-0.4 !		<0.6 !				<0.3 !		-	

Endpoint	RQ	log (RQ Alternative / RQ Candidate)									
		Case study Code (see Table 17)									
		A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
	Q									1.75	
PPP	1/HQ						> -0.74				
contact, AS	1/HQ							<-0.5 !		-0.52	
Arthropods (other than honeybees)											
without risk mitigation											
AS	TER									-0.74	1.52
PPP	TER					> -0.64	-1.47				
with risk mitigation											
AS, min	TER									-1.04	0.81
AS, max	TER									-0.87	2.22
PPP, min	TER						-1.49				
PPP, max	TER						-1.46				
Earthworms											
acute											
AS	TER		<1.67 !		<1.97 !		<-0.4 !		<-0.6 !	>1.50	1.46
PPP	TER					-1.09	-0.03				
chronic, PPP	TER					0.40	-0.30				
Other soil macro-organisms											
collembolans, PPP	TER					-1.08					
Terrestrial plants											
without risk mitigation											
AS	TER	1.08	0.46	1.08	0.46						
PPP	TER					> -0.97	> -1.3 !				
with risk mitigation											
AS, min	TER	1.08	0.50	1.08	0.50						
AS, max	TER	1.09	0.58	1.09	0.57						
PPP, min	TER						> -2.0 !				
PPP, max	TER						> -1.3 !				

As a third step, we aggregated subordinated endpoints wherever the classified data provided the same evidence. For example, the classified risk differences for acute toxicity to birds did not differ within each case study when they had been determined either for both insectivore and herbivore species, or for both the AS and the formulated PPP. Hence, we skipped these differentiations and kept only the aggregated information for the main endpoint (acute toxicity to birds). As a result of such aggregations, the list of endpoints was further reduced to only 22 different categories.

As a result of the combined steps 3 and 4, we obtained the picture shown in Table 22. The picture immediately shows that significant risk reductions are possible in all 10 cases for one or more endpoints, partly counter-acted by significant risk increases for one or more other endpoints in some of the cases.

The decision criteria proposed in section 6.5 only require a distinction between significant and insignificant changes in risk quotients, no sub-differentiation of insignificant changes into insignificant risk reductions, insignificant risk increases, and constant risks. However, such differentiations may be helpful in borderline cases such as those illustrated in Figure 21 of chapter 6, for example if risk reductions are consistently seen for all endpoints but the legal significance criterion is just not reached for any of them. However, inspection of all ten profiles of classified risk differences given in Table 22 revealed that no such extreme situation is given in any of the ten cases examined.

Table 21: Classification of risk differences according to the legal significance criterion

log (RQ_A / RQ_B)*	y	Classification	Symbol in Table 22	Symbol in Table 23
= y	≥ 1	significant risk reduction	↑	
	> 0, < 1	insignificant risk reduction	↗	→
	0	constant risk	=	
	> -1, < 0	insignificant risk increase	↘	
	≤ -1	significant risk increase	↓	
> y	≥ 1	significant risk reduction	↑	
	≥ 0, < 1	insignificant risk reduction OR significant risk reduction	(↑↗)	(↑→)
	≥ -1, < 0	no significant risk increase, any other class is possible	(↑↗=↘)	
	< -1	any class is possible	(↑↗=↘↓)	(↑→↓)
< y	> 1	any class is possible	(↑↗=↘↓)	
	> 0, ≤ 1	no significant risk reduction, any other class is possible	(↗=↘↓)	(→↓)
	> -1, ≤ 0	insignificant risk increase OR significant risk increase	(↘↓)	
	≤ -1	significant risk increase	↓	

* RQ values are TER or 1/HQ values; suffixes A and C denote the alternative and the candidate product, respectively.

As a consequence, the presentation of results can be further simplified by skipping the sub-differentiation of insignificant risk differences and indicating them all by a common symbol as defined in Table 21 and realised in Table 23.

In this simplified presentation of classified risk differences in the ten case studies, we additionally condensed the presentation of risk differences for different risk mitigation scenarios in a single cell each. In some cases, significance or insignificance of risk differences was dependent on the mitigation measures actually applied. In all these cases, however, the direction of changes was fully consistent, i.e. there were either partly significant and partly

insignificant risk reductions, or there were partly significant and partly insignificant risk increases. But in no case did different risk mitigation measures result in opposing risk differences, i.e. increases and decreases were not seen in the same case for the same endpoint.

Table 22: Classified and aggregated risk differences in the ten case studies

Endpoint	Classified risk difference (symbols as defined in Table 21)									
	Case study Code (see Table 17)									
	A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
Birds, acute toxicity	↑	↑	↑	↑				↗	↘	↘
Birds, short-term toxicity	↑		↑					↘		
Birds, long-term toxicity	↗	↗	↑	↑	↑	↗	↑	↑	↗	↗
Mammals, acute toxicity	(↑↗)	↑	(↑↗)	↑	(↑↗ =↘)	↑	(↑↗= ↘)	↑	↗	↗
Mammals, long-term toxicity	↗	↘	↑	↗	↗		↗	↗	↗	
Aquatic organisms, exposure via spray drift and evaporation/deposition										
without risk mitigation	↘		=		↑	↗	↗	↘	↑	
with risk mitigation	↘	↗	↗	↑	↑	↘	↗	↓	↑	↑
Aquatic organisms, exposure via run-off										
without risk mitigation	↑	↗	↑	↗	↑		↗		↑	↑
with risk mitigation										
min		↗		↗	↑		↗		↑	↑
max		↑		↗	↑		↑		↑	↑
Aquatic organisms, exposure via drainage	(↑↗)	↑	(↑↗)	↗	↑		↑		↑	↑
Honeybees, acute toxicity										
oral	(↘↓)		(↗=↘ ↓)			(↑↗= ↘)	(↗=↘ ↓)		↓	
contact							(↘↓)		↘	
Arthropods (other than honeybees)										
without risk mitigation					(↑↗ =↘)	↓			↘	↑
with risk mitigation										
min						↓			↓	↗
max						↓			↘	↑
Earthworms, acute toxicity										
AS		(↑↗= ↘↓)		(↑↗= ↘↓)		(↘↓)		(↘↓)	↑	↑
PPP					↓	↘				
Earthworms, chronic toxicity					↗	↘				
Other soil macro-organisms, collembolans					↓					
Terrestrial plants										
without risk mitigation	↑	↗	↑	↗	(↑↗ =↘)	(↑↗= ↘↓)				
with risk mitigation	↑	↗	↑	↗		(↑↗= ↘↓)				

Table 23: Simplified presentation of classified risk differences in the ten case studies

Endpoint	Classified risk difference (symbols as defined in Table 21)									
	Case study Code (see Table 17)									
	A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
Birds, acute toxicity	↑	↑	↑	↑				→	→	→
Birds, short-term toxicity	↑		↑					→		
Birds, long-term toxicity	→	→	↑	↑	↑	→	↑	↑	→	→
Mammals, acute toxicity	(↑→)	↑	(↑→)	↑	(↑→)	↑	(↑→)	↑	→	→
Mammals, long-term toxicity	→	→	↑	→	→		→	→	→	
Aquatic organisms, exposure via spray drift and evaporation/deposition										
without risk mitigation	→		→		↑	→	→	→	↑	
with risk mitigation	→	→	→	↑	↑	→	→	↓	↑	↑
Aquatic organisms, exposure via run-off										
without risk mitigation	↑	→	↑	→	↑		→		↑	↑
with risk mitigation		→↑*		→	↑		→↑*			
Aquatic organisms, exposure via drainage	(↑→)	↑	(↑→)	→	↑		↑		↑	↑
Honeybees, acute toxicity										
oral	(→↓)		(→↓)			(↑→)	(→↓)		↓	
contact							(→↓)		→	
Arthropods (other than honeybees)										
without risk mitigation					(↑→)	↓			→	↑
with risk mitigation						↓			→↓*	→↑*
Earthworms, acute toxicity										
AS		(↑→↓)		(↑→↓)		(→↓)		(→↓)	↑	↑
PPP					↓	→				
Earthworms, chronic toxicity					→	→				
Other soil macro-organisms, collembolans					↓					
Terrestrial plants										
without risk mitigation	↑	→	↑	→	(↑→)	(↑→↓)				
with risk mitigation	↑	→	↑	→		(↑→↓)				

* depending on the actual mitigation scenario

As a final outcome, the simplified presentation of classified risk differences in the ten case studies (Table 23) reveals results that are summarised in Table 24 and which can be formulated as follows:

- In all ten cases, substitution would lead to significant risk reductions for one or more endpoints. This necessary but insufficient requirement is always fulfilled.
- In three cases (C3, C4, E5) both significant risk reductions and significant risk increases are observed in the spectrum of endpoints. In these three cases, it is clear that the use of the alternative product cannot be said to be significantly safer than the candidate

product. The comparative assessment can be stopped on the basis of the available evidence. An application for authorisation of the candidate product could not be rejected.

- In six cases (A1, A2, B1, B2, D3, E6), significant risk reductions are seen for one or more endpoints and no conclusive evidence for any significant increases is given for any other endpoint. These are potential cases for substitution, but unfortunately a final conclusion cannot be drawn on the basis of the information that has been collected from the assessment report. In each of these six cases, evidence is either missing or inconclusive for one or more legal standard endpoints. For these endpoints, comparable risk quotients were either not calculated in the reports for one or both products, or they were only given in terms of inequalities (>x or <x) which resulted in inconclusive assessment situations. For clarifying whether these gaps could be closed, it would be necessary to check all available exposure and toxicity data and to re-calculate risk quotients wherever possible and necessary.
- In one case (D4), an additional problem pops up: a significant increase of the risk for aquatic organisms is seen, but only if risk mitigation measures are assumed to be applied, not in a scenario without risk mitigation measures.

  As can be seen from Table 18, in case D4 the ratio between TER values calculated for standard application techniques and no distance requirements is just below the significance level (log value -0.9, corresponding to a factor of 8), while the differences between values calculated for one or five meter distance requirements in combination with different levels of spray drift reduction are slightly above the significance threshold (log values between -1.23 and -1.35, corresponding to factors between 16 and 23). For the purpose of this case study, no attempt was made to explore the detailed differences in exposure and risk modelling for the two products that cause these minor variations in risk differences for different exposure scenarios. In general, however, occurrence of such variations is not much surprising. Constant TER ratios would only be expectable, if aquatic exposure modelling would have been performed in the same way for both products and if the exposure model ensures a constant proportionality between exposure estimates for two different products across the matrix of possible combinations of distance requirements with drift reduction levels (apart from the necessary provision that toxicity estimates are kept constant).

  Minor variations in risk differences with different aquatic exposure scenarios were observed in most of the ten cases, but only in case D4 does this lead to an assessment dilemma because the estimates are spread around the threshold value of a tenfold risk difference. Thus the question arises how such conflicting results should be weighted and assessed. To this end, a refinement of the proposed decision rules is needed. The point is further addressed in the discussion in chapter 8.

Table 24: Summary assessment of risk differences in the ten case studies

Criterion	Case study Code (see Table 17)									
	A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
Conclusive evidence for a **significant risk reduction** for one or more endpoints?	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Conclusive evidence for a **significant risk increase** for one or more endpoints?	NO	NO	NO	NO	YES	YES	NO	(YES) *	YES	NO
Inconclusive evidence or missing data for one or more legal standard endpoints?	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

* only for risk mitigation scenarios

7.6.3 Comparison of R-Score-based assessments with TER-based assessments of risk differences

As a possible approach for pre-selecting alternative products that may be included in a comparative assessment in cases where many of such potential alternatives are available, the use of R-Scores derived from German risk mitigation requirements was explored. R-Scores were calculable for aquatic organism exposed via spray-drift and for terrestrial organisms in off-field habitats, based on data for arthropods and terrestrial plants. In Table 25, the resulting values and assessments are compared to corresponding TER-based assessments for the same endpoints and also for the spectrum of endpoints not covered by R-Scores.

As explained in Annex 4, differences in R-Scores of a factor of ten or larger allow safely to expect a significant risk difference in terms of the legal TER-based criterion. This is confirmed by the data for aquatic risks in two cases: E5 and E6.

Table 25: Comparison of R-Score-based assessments with TER-based assessments of risk differences

(R-Score-based assessments according to criteria specified in Annex 4; symbols for TER-based assessments as defined in Table 21)

Criterion	Case study Code (see Table 17)									
	A1	A2	B1	B2	C3	C4	D3	D4	E5	E6
Aquatic organisms, exposure via spray drift										
R-Score-based assessment										
R-Score Candidate / R-Score Alternative	0.6	2.3	1.0	2.3	3.0	0.6	3.0	0.6	18.2	18.2
Significant risk difference?	unlikely	unlikely	unlikely	unlikely	unlikely	unlikely	unlikely	unlikely	significant reduction expected	significant reduction expected
TER-based assessment										
without risk mitigation	→		→		↑	→	→	→	↑	
with risk mitigation	→	→	→	↑	↑	→	→	↓	↑	↑
Arthropods and terrestrial plants in off-field habitats										
R-Score-based assessment										
R-Score Candidate / R-Score Alternative	2.6	1.9	2.6	1.9	1.0	1.0	1.0	1.0	0.2	1.4
Significant risk difference?	unlikely	unlikely	unlikely	unlikely	unlikely	unlikely	unlikely	unlikely	unlikely	unlikely
TER-based assessment										
Arthropods (other than honeybees)										
without risk mitigation					(↑→)	↓			→	↑
with risk mitigation						↓			→↓*	→↑*
Terrestrial plants										
without risk mitigation	↑	→	↑	→	(↑→)	(↑→↓)				
with risk mitigation	↑	→	↑	→		(↑→↓)				
Other endpoints (TER-based assessment)										
Conclusive evidence for a significant **risk reduction** for one or more OTHER endpoints?	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Conclusive evidence for a significant **risk increase** for one or more OTHER endpoints?	NO	NO	NO	NO	YES	NO	NO	NO	YES	NO

* depending on the actual mitigation scenario

If the differences in R-Scores are smaller than ten, significant risk differences in terms of TER values are assessed to be “possible” or “unlikely”, with the boundaries of these classes being

slightly differently defined for aquatic and terrestrial R-Scores. For the cases examined, the classification “unlikely” always applied (except for the two cases of expectable significant risk differences mentioned before). However, although considered to be “unlikely”, significant differences in TER values were in fact observed in a relatively large part of the cases assessed: significant risk reductions for aquatic organisms in cases B2 and C3 and for terrestrial organisms in cases A1, B1, and E6; significant risk increases for terrestrial organisms in case C4 and for aquatic organisms in risk mitigation scenarios for case D4. Pending a detailed case-by-case examination of the reasons, these observations indicate that the use of R-Scores for pre-selecting products for comparisons may indeed only be advantageous if large differences exceeding a factor of ten are observed. In addition, it must be taken in consideration that for one or more of those endpoints that are not covered by the R-Scores, significant risk reductions were seen in all ten test cases and significant risk increases in two of them. Thus, from the cases studied, there is no indication that assessments based on R-Scores are in anyway representative for ecotoxicological endpoints that were not included in their derivation.

8 Discussion

The following discussion builds on the considerations in Chapter 6 about an appropriate approach for the comparative ecotoxicological risk assessment of PPPs. We reflect those theoretical considerations in light of the practical experience gained in the case studies described in Chapter 7. Firstly, we summarise and discuss the lessons learned from the case studies (section 8.1), secondly we identify needs and outline options for the refinement of the principles of comparative ecotoxicological PPP assessments proposed in Chapter 6 (section 8.2), and finally we condense the project results into a set of five main recommendations (section 8.3).

8.1 Lessons learned from the case studies

The case studies explored the feasibility of a comparative assessment of environmental risk profiles of PPPs according to the principles proposed in section 6.5. The experience gained may be summarised in two main points:

(1) The suggested principles work. Clear, transparent, and unambiguous assessment results can be obtained from comparisons of risk profiles, provided that risk quotients for a spectrum of relevant endpoints are available. Immediate needs for a further refinement of decision rules became evident in one out of ten cases only: the use (or non-use) of evidence on risk differences under risk mitigation scenarios requires further clarification.

(2) In UBA assessment reports, the routine calculation of risk quotients is insufficient to support conclusive comparative assessments. In each of the ten test cases, there were one or more basic assessment endpoints for which the immediately available evidence on quantitative risk differences was inconclusive or where risk quotients had not been calculated at all. Efficient closing of these gaps is the critical step for successful routine application of the proposed approach.

The information gaps essentially arise from the different requirements of an efficient “compliance assessment” for a single PPP and a conclusive “comparative assessment” for two or more PPPs. The term “compliance assessment” is meant to denote the process of checking the compliance of a proposed use of a single PPP with legal acceptability criteria for resulting environmental risks, such as those summarised in Tables 13 and 14. The performance of such compliance checks has been (and continues to be) the core of the authorisation procedure, and the development of all corresponding rules and guidelines has been geared towards managing this task both effectively (in terms of protection goals) and efficiently (in terms of the use of resources). Now, the legislator introduced the comparative assessment of two or more products as an additional task. The environmental risks and the eco-toxicological assessment endpoints concerned are the same, and the corresponding data requirements for applicants remained unchanged. But unfortunately, the procedural requirements for the evaluation and the assessment of data are different. Three features of established procedures for single product assessment do not fit well with the concept of comparative product assessment:

(1) Compliance assessments for single PPPs focus on critical endpoints. In contrast, comparative assessments of different PPPs require symmetric data matrices for a full set of endpoints.

In case study A1 for example, the quantitative determination of TER values for arthropods in off-field habitats was waived in view of the much stronger effects of the

herbicidal products on terrestrial plants. On the basis of the resulting data situation, the comparative product assessment is now able to demonstrate the opportunity for a significant risk reduction for terrestrial plants, but unfortunately the possibility of a counteracting increase of risks for arthropods cannot be ruled out with certainty due to missing data.

(2) Compliance assessments for single PPPs focus on the exceedance of TER trigger values (or the lower deviation from HQ trigger values). If this is ensured, the exact quantification can be waived and the estimation in terms of an inequality (TER > x, or HQ < z) is sufficient. Comparative assessments, in contrast, require exact risk quotients, in some situations for only one of two compared products, but usually for both. Otherwise risk differences are indeterminable or inconclusive as detailed in section 7.6.1.

In six out of ten case studies, inexact determinations of risk quotients are a major obstacle to a final substitution decision. In case study A2 for example, the TER values for acute effects on earthworms were reported to be 16,667 for the alternative and > 357 for the candidate product. Hence the ratio calculates to be < 47, which is totally inconclusive. May be, there is indeed a significant risk reduction because the exact factor is ten or something between ten and 47. But unfortunately, an insignificant risk difference not exceeding a factor of ten, or even a significant risk increase due to an actual factor smaller than 0.1 cannot be excluded. To avoid such decision dilemmas, it is absolutely important to ensure that risk quotients are estimated as precisely as possible. Other practice would foil the legislators' intent to identify opportunities for significant risk reductions wherever possible.

(3) Compliance assessments for single PPPs make use of tiered ad hoc deviations from standard assumptions if standard assumptions yield unacceptable risk quotients in a specific case. The focus is on absolute risk quotients under assumed real field conditions, and the aim is to see whether they become acceptable when assumptions are shifted from conservative standard scenarios to field scenarios that are considered to be more realistic. Comparative product assessments, in contrast, are focused on relative risk differences. The absolute risk level is less important as it is presumed to be acceptable for both products anyway. Strict comparability of conditions for exposure and effect assessment is hence more important than the assumed degree of realism. Where such comparability is not given or unsure, risk differences cannot be assessed with certainty.

In case study C4 for example, an initial scenario for chronic risks of the alternative product to earthworms had resulted in an unacceptable TER value smaller than five. By changing the scenario parameters to values considered to be still sufficiently protective under field conditions, the TER had been raised above the trigger value of five. For the candidate product, only a single calculation of a chronic earthworm TER had been performed in the assessment report, the exposure assumptions, however, were different from both scenarios examined for the alternative. Thus, the question arises, which of the values should best be used for a risk comparison? In this particular case, the answer fortunately turned out to be non-critical, because the risk differences for chronic effects on earthworms were insignificant, no matter which of the available values were chosen for the calculation (the minimal difference was recorded in Table 18), and moreover, significant risk increases were seen for another endpoint (arthropods), thus rendering substitution inappropriate anyway. In other cases, however, the question of comparability or incomparability of risk quotients may become crucial for a conclusive

assessment and hence deserves further considerations and the development of clear consented rules.

Summarising these observations, we may conclude that standard format and content of risk assessment reports need advancement if they shall efficiently support both compliance assessments of single products and comparative assessments of different products. In an interim period, closing of critical information gaps for conclusive comparative assessments will inevitably require additional calculations or re-calculations of risk quotients for endpoints or assessment conditions that are deemed uncritical for a single product assessment but which may become crucial for a comparative product assessment.

Such re-calculations or de novo calculations of risk quotients were beyond the scope of the case studies. Hence, no experience has been gained concerning the question whether critical gaps could indeed in all cases be closed on the basis of the information that is available to the authority. Presumably many but not all missing risk quotients may be determinable with sufficient precision from the information that has been provided by the applicant in the past. The data requirements imposed on the applicant and the assessment rules followed by the authority are governed by secondary legislation and administrative implementation guidelines. As the development of all these pieces has been focused on compliance assessments in the past, it is well possible that they include data requirements and assessment rules that do not well support the new task of comparative assessments. To clarify the point and to identify possible needs for harmonisation, a dedicated analysis of all relevant guidelines and implementation regulations should be performed.

As it is conceivable that complete closure of all gaps in a comparative matrix of risk quotients may be rather resource demanding or even be impossible, alternative options must be considered also. Figuratively speaking, the alternative to closing a gap is bridging a gap. The risk quotient matrices seen in the case studies seem to provide ample opportunities for such bridging approaches. For example, risk quotients for birds, mammals and all other terrestrial organisms are always sub-differentiated into values referring to the formulated PPP and values referring to the active substance (AS). This often leads to asymmetric data situations. In case study D3 for example, available TER values for collembolans refer to the AS in case of the candidate product and to the PPP in case of the alternative product. For the purpose of the case study no attempt was made to bridge this gap and the values were treated as being incomparable. However, it is more than self-suggesting to solve the problem by defining rules for extrapolations from AS-based values to PPP-based values and vice versa.

The definition of such bridging rules and principles may be considered as part of the wider task of refining the proposed principles which is discussed in the following.

8.2 Needs and options for the refinement of suggested principles for comparative assessments

In the following, we briefly re-consider the proposed principles in light of the experience gained through the case studies. The considerations are structured along a line of five basic questions that need further clarification. These relate to (i) the set of risks to be included in the assessment, (ii) the distinction between comparable and incomparable risks, (iii) the definition of significance criteria for risk comparisons, (iv) the problem of asymmetric data situations, and (v) the relevance of risk differences observed under risk mitigation scenarios.

Which risks should be included in the comparative eco-toxicological assessment?

The implementation of the proposed approach to comparative assessment requires a distinction to be made between a core set of mandatory risk assessment endpoints and any other facultative endpoints. The distinction is important for enforcing the principle that substitution should not lead to any significant risk increases, without rendering substitution practically impossible. As the number of possible endpoints is infinite, an unconditional requirement for positive evidence on the absence of any significant risk increases for any possible endpoint could block any final conclusion.

For mandatory endpoints, such positive evidence must be available that allows to exclude the possibility of a significant risk increase, in addition to the requirement for the demonstration of a significant risk reduction for one or more endpoints of concern. Hence, if data for mandatory endpoints are missing or insufficient for reaching conclusive evidence, these data gaps must be closed or bridged. Facultative endpoints, in contrast, are to be included in the comparison of risk profiles only if comparable data are available to the authority. Otherwise the consideration of facultative endpoints may be skipped and the negative finding of the absence of any evidence on significant risk differences should be considered as sufficient information. This applies to all refined assessments and higher tier assessments. They are performed on a case by case basis and hence quantitatively comparable risk quotients may only occasionally be available for two different products.

Following the considerations in Chapter 6, the core set of mandatory endpoints should comprise the spectrum of risks for which acceptability criteria have been laid down in Commission Regulation 546/2011 on *Uniform Principles* (see Tables 13 and 14). This definition of the core set provides a legally well-founded frame but still requires some clarification of details. Predominantly, these needs for clarification relate to (i) risks for persistence, bioconcentration and groundwater contamination, and (ii) adaptations of standard criteria to technical and scientific progress, as outlined in the following.

- *Persistence, bioconcentration and groundwater contamination*

  As detailed in section 6.2.2, the legal requirement for comparing *risks to the environment* leaves some room interpretation. For the purposes of the case studies we used a restrictive interpretation, confining the assessment to eco-toxicological risks that are quantifiable in terms of risk quotients. A wider interpretation, in contrast, would allow including comparisons of risks of persistence, bioconcentration and groundwater contamination (all or in part), independent from direct evidence on potentially resulting adverse effects on environmental organisms. This is a normative decision that needs to be taken by the competent authorities.

  The general argument in favour of including persistence (P) and bioconcentration (B) and/or groundwater contamination in comparative assessments is that the law considers such features of substances to be inacceptable risks on their own, if exceeding defined limits such as the drinking water limit value or the criteria for classifying substances as vPvB. As a consequence, it may be argued that substitution should aim to reduce such features further down to a necessary minimum, may be focussed on groundwater only or including other environmental compartments too.

  The opposing view is that these are indicators of exposure only, needing to be set in relation to eco-toxicological properties in order to define a comparable risk. As a consequence of this view, particular attention would have to be given to the risks of adverse long-term effects that may result from substances that persist in the environment, accumulate in biota, and/or migrate into groundwater. In order to decide

whether substitution would result in a significant reduction of such risks, however, some practical obstacles have to be accounted for:

- The assessment of risks from secondary poisoning of birds and mammals by substances accumulating in their food is performed only conditionally for substances which have a high log P_{OW} and for which a BCF has consequently been determined experimentally. For substances not fulfilling the "B"-criterion, the risk for secondary poisoning is assumed to be acceptably low and corresponding risk quotients are usually not determined. As a consequence, the significance of a risk reduction that may be achievable by substitution of a CFS that meets the "B"-criterion may remain indeterminable due to the asymmetry in available risk information. The dilemma is well demonstrable by our case studies. In four out of the ten cases, BCF values and risk quotients for secondary poisoning were available (D3, D4, E5, E6), but in any case only for the candidate product, not for the alternative. Hence, the quantification of risk differences is not possible in these cases. Estimates of risk quotients for secondary poisoning on the basis of log P_{OW} values may be considered as a possible solution to the problem. However, no established procedure exists for this purpose and hence such an approach may go beyond performing comparative assessments on the basis of information available from the authorisation of individual products.
- Criteria for assessing the risks of adverse effects resulting from groundwater contamination are established for human health effects but not for ecotoxicological effects. Assessment of risks for groundwater communities is an issue under scientific debate but an established regulatory procedure does not exist[11]. There seems to be no scope for inclusion of this aspect in comparative assessments in the short-term.

Due to these practical obstacles, quantitative comparisons of risks from secondary poisoning of birds and mammals as well as risks for adverse effects on groundwater communities cannot be mandatory elements of a procedure for making a substitution decision. For a routine procedure, assessments of the quantitative differences in persistence and bioconcentration data and/or predicted groundwater concentrations are the only options. For reasons explained in section 6.2.2, there appear to be quite strong regulatory arguments to accept a significant difference in expectable groundwater concentrations as a sufficient reasoning for a substitution decision (provided that no other reasons argue against substitution). Significant differences in persistence and bioconcentration data, in contrast, may have a lower chance of finding consensual acceptance as a sufficient reasoning. An exhaustive consideration of all pros and cons goes beyond the scope of this discussion and basically every Member State is free in taking this normative decision at its own discretion. However, if Member States take different positions in this debate, the consequences may undermine the idea of zonal

[11] In specific cases (insecticides with a relatively high leaching potential) risk assessments for groundwater communities have been performed in Germany (personal information from the UBA). The assessments were focused on crustaceans and based on the reasoned assumption that groundwater crustaceans would be similarly sensitive as surface water crustaceans. Due to favourable outcomes, no restrictions resulted from these assessments. As such studies are performed on a case by case basis only, there is no scope for including risks for groundwater communities in a list of mandatory endpoints for comparative assessments.

authorisation. Initiatives for consensus finding on the point, at least within the same authorisation zone, are hence a self-suggesting follow-up action from this project.

- *Adaptation of standard criteria to technical and scientific progress*

  The assessment criteria laid down in the *Uniform Principles* (Tables 13 and 14) essentially reflect the state of regulatory debate at and before 1996. Since then, adaptations to technical and scientific progress have been brought forward. They have not yet been laid down in a revised legislation on Uniform Principles, but they have been established in terms of European and national guidelines for conducting risking assessments under the PPP Regulation or in terms of revised data requirements for PPPs that have been set in new Commission Regulation No 284/2013. As a consequence, the list of endpoints and criteria that are routinely listed and examined in UBA assessment reports, and which were consequently included in the case studies, deviates from the *Uniform Principles* already now and can be expected to be subject to further adaptations in the future. Risks for terrestrial plants in adjacent off-field areas are an example for new criteria that have already been included in the UBA assessments as an additional standard endpoint. Risks for acute effects of PPPs on earthworms are an example for criteria that may have no more relevance for comparative assessments in the future because they have been dropped as a standard data requirement in favour of a focus on data for sub-lethal effects and field studies in the new Commission Regulation No 284/2013.

  When fixing a core set of mandatory endpoints which must be included in a comparative risk assessment, such adaptations should of course be acknowledged. However, the timeframe during which such adaptations were introduced must be taken into consideration. For comparative assessments it may become necessary to draw on assessment reports that have been generated a decade ago and which may hence not necessarily comply with the current standards. Exploring the issue in full detail was out of the scope of this study and may require further efforts.

How to distinguish between comparable and incomparable risks?

From a strict scientific point of view, risk quotients may be considered to be comparable only if they refer to exactly the same effect in the same species under the same test and exposure conditions. For regulatory purposes, however, it is common practice to aggregate data across different species in the same environmental compartment, if common exposure estimates apply. This practice is based on the concept of *representative species* and the concept of the *most sensitive species,* i.e. individual test species are considered as representatives of species groups only, and the whole ecosystem is assumed to be protected if the most sensitive species is protected (which may be different for different chemicals). Based on this rationale, the whole array of all taxa of aquatic organisms is aggregated into a single risk quotient which is considered to indicate the risk for the aquatic community as a whole.

For the purpose of performing comparative product assessments in the case studies, we adopted all regulatory definitions of endpoints as they are used in the assessment reports without any revision or modification. We consider this defendable as a pragmatic solution that is in line with all established procedures. However, for the sake of transparency it should be clearly pointed out what aggregations across species may mean for risk comparisons. If the most sensitive species and the rank order of sensitivities for the remaining species are different for two different PPPs, a significant risk reduction means that the distance between the predicted exposure concentration and the lowest toxic concentration for the most sensitive

species is increased by at least an order of magnitude, but it does not mean that risks are necessarily also decreased for every single species or group of species. On the contrary, it may well happen that for some less sensitive species the risk is actually increased, but of course in no case to a level higher than for the most sensitive species. If this consequence should not be consensually acceptable, then it would be necessary to disintegrate the various species groups such as fish, daphnids and algae in a risk profile and to calculate the risk differences separately. This is possible and the decision rules would remain same, but the workload would of course be raised. Whether the resulting conclusions would actually be different in a relevant number of cases remains subject to further analyses.

What is a significant risk difference?

As detailed in section 6.1, the legal text stipulates that a deviation between risk quotients by a factor of at least ten constitutes a significant difference in risk. This provides a clear decision rule, but three details need further clarification: (i) the consideration (or non-consideration) of differing risk levels, (ii) the assessment of risk differences for standard endpoints that are not assessed in terms of risk quotients, and (iii) the establishment of significance criteria for comparisons of chemical PPPs with non-chemical methods, as outlined in the following.

- *Consideration of risk levels*

  The legal text defines significant risk differences independently from the risk level on which the change takes place. Whether a high risk is shifted towards a lower risk or whether a very low risk is further reduced to an ultra-low risk does not play a role. As an example, shifting a TER from 1 to 10 or from 1,000 to 10,000 is equally assessed as a tenfold and hence significant risk reduction, but the gain in environmental safety is obviously much higher in the first than in the second situation.

  The substitution principle aims at providing incentives for continuous improvements of environmental safety beyond compliance with fixed acceptability thresholds. With this in mind, it may be argued that any risk reduction by a factor of ten or more is a desirable progress, independent from the level on which it takes place. However, disregarding risk levels may become critical when it comes to the problem of weighing risk increases and risk reductions for different endpoints.

  As a principle, we suggested not to apply weighing of incomparable risks and assessing increases and decreases of risks both in the same way, thus rejecting cases for substitution where substitution would lead to a significant increase for any endpoint. However, at least theoretically, there may be situations where rigid application of this principle may lead to unreasonable or at least non-optimal decisions.

  Such a theoretical example would be a situation where substitution would raise the TER for one endpoint from 2 to 200, while for another endpoint it would be decreased from 10,000 to 1,000. In this situation, a removal of a strong reason for concern would contrast with a risk increase on a level that is usually considered to be negligible. It is self-evident that such an extreme situation would call for expert judgement in order to decide on a possible deviation from the suggested standard decision rule for the particular case. To this end, the development of more sophisticated decision rules may be considered necessary. However, whether there is really a strong need for bringing this forward cannot be said on the basis of the experience gained in the ten case studies. No such extreme situations were observed. All risk differences between products were

seen on levels relevant for usual assessments of compliance with acceptability criteria, not on extra-ordinary low levels.

- *Standard endpoints that are not assessed in terms of risk quotients*

  As explained in section 6.2.2, there are two standard assessment endpoints for which acceptable levels have not been defined in the *Uniform Principles* in terms of RQs but in terms of maximal effects of PPPs, i.e. impact on beneficial arthropods other than honeybees and effects on non-target soil micro-organisms (see Table 14). Thus the question has to be answered, how significance criteria for changes in these risks can be defined that are equivalent to a change in risk quotients by a factor of ten or more?

  Fortunately, adaptations to technical and scientific progress have already eliminated the problem regarding risk assessments for beneficial arthropods: a TER-based approach is now in use, and additionally the scope of the assessment has been broadened to include not only beneficial arthropods but all non-target arthropods in off-field areas. Regarding soil microorganisms, however, the problem continues to exist and a solution is not readily at hand. As it is a legally defined standard assessment endpoint, in cannot be ignored in a comparative risk assessment, but a reasonable approach to address it must be developed. This is a clear follow-up requirement from this study.

- *Comparisons of chemical PPPs with non-chemical methods*

  As explained in section 6.1., the legal requirement for comparative assessments is not confined to comparisons of CFS-containing chemical PPPs with other chemical products but explicitly includes comparisons with non-chemical control or prevention methods where such methods are available for the same purpose. The basic assessment criterion is the same as for comparisons of two chemical products: authorisation of the candidate PPP may be refused or withdrawn if the alternative non-chemical product or method can be demonstrated to show a “significantly lower risk”. The operationalisation of the significance criterion in terms of a tenfold difference in TER values or other risk quotients, however, is not applicable for non-chemical PPPs.

  This project was deliberately focussed on the development of an approach for comparative environmental risk assessments of chemical PPPs, as stated in the introduction (Chapter 3.3). The establishment of procedures and significance criteria for comparisons of chemical risk with non-chemical risks was beyond the scope and hence remains an open task for follow-up studies. To our knowledge, guidance on the issue is totally missing so far.

How to deal with asymmetric data situations resulting from sub-differentiations of major endpoints?

In assessment reports, some major endpoints, for which acceptability criteria have been legally defined, are minutely sub-differentiated by a matrix of parameters, including but not limited to:

- differentiations between AS-based values and PPP-based values for all endpoints except risks for aquatic organisms,
- differentiations between trophic groups of birds and mammals, such as insectivore, herbivore, and omnivore species, partly further distinguished by species size groups,

- seasonal differentiation between scenarios for the exposure of aquatic organisms via drainage (spring/summer vs autumn/winter), and
- differentiation between oral and contact exposure of honeybees.

For comparative assessments, such differentiations create problems due to resulting asymmetric data situations. For differentiations between AS-based and PPP-based risk quotients the practical problem was already illustrated in the preceding section 8.1. For other differentiations between sub-ordinated endpoints the problem is essentially the same. In case study C4 for example, available risk quotients for long-term mammalian toxicity referred to omnivore species in case of the candidate product and to herbivore species in case of the alternative product. As a consequence, the risk difference for long-term effects in mammalians was not quantifiable. Thus, the development of rules and procedures for closing such gaps, either by recalculation of missing RQs or by endpoint to endpoint extrapolations is a crucial next step that follows from this study.

For the necessary differentiation between mandatory and facultative endpoints (see above) it is important to notice that an assessment of main endpoints, such as long-term mammalian toxicity, is mandatory while the sub-categories are facultative endpoints. For assessing the main endpoint, comparable risk quotients must be available for at least one of the sub-categories but not necessarily for all. More detailed rules may need to be worked out for the different main endpoints separately.

How to consider evidence on risk differences observed under risk mitigation scenarios?

Recital 19 of the PPP Regulation explains that the comparative examination of CFS containing PPPs shall aim to replace them by products "*which require less risk mitigation measures*". As a consequence, we may conclude that risk comparisons should refer to exposure situations resulting from the use of products without any risk mitigation measures beyond legal standard requirements that may apply to all products. This would also be in line with the approach used for the calculation of pesticide risk indicators for monitoring the effects of the National Action Plan for reducing risks from the use of PPPs in Germany (BMI 2014b).

In case study D4 we have seen a situation where risk differences were insignificant for aquatic organisms if no risk mitigation measures are applied, but they became consistently significant when risk mitigation scenarios were assumed (see section 7.6.2). Basically, these differences may reflect the uncertainties in the risk quotient calculations. Where risk differences are at the borderline between significance and insignificance, slight variations in exposure scenarios may result in different conclusions.

Basically, this situation leaves two options for decision making. Either absolute preference is given to the difference observed with no risk mitigation measure assumed, based on the principal argument raised above. Alternatively, the differences observed under risk mitigation scenarios are considered to cast doubt on the validity of the conclusion drawn from the differences seen without risk mitigation measures. According to the proposed principles, the authorisation of a candidate product cannot be refused if evidence exists that does not allow ruling out the possibility of a significant risk increase with confidence. The rule could be considered to be applicable in the situation of case study D4, if preference to the values seen without risk mitigation measures should be no consensually acceptable rule.

8.3 Recommendations

Five recommendations for setting up a process for comparative environmental risk assessment of plant protection products can be provided based on the results of the project:

- First of all, a consensus on the principles for comparative risk assessment is needed in order to devise a coherent process scheme of how to perform comparative assessments. The needs for exemptions and special cases, by contrast, are expected to emerge from first practical experience, for which the general principle of allowing expert judgement for borderline cases would suffice at the beginning.
- Secondly, as identified during the case study investigations, it would be highly advisable to plan a process whereby data access would be simplified. This relates to necessary risk information which is generated during the ongoing authorisation of plant protection products. Two issues can be raised here. The ease of product comparison would substantially improve if the risk assessment report provided a more coherent reporting structure. Moreover, an electronic data base and retrieval of risk measures such as TER or HQ values could render risk comparisons a semi-automated and thus effort-optimised process.
- Thirdly, in view of the zonal authorisation that is called for in the current plant protection regulation and in response to already raised business concerns about unfair product discrimination we advise to seek harmonisation of approaches for comparative PPP assessment at least within the same authorisation zone.
- Fourth, acknowledging that comparative risk assessment is also called for under the biocides directive as well as for REACH compounds that require authorisation this seems an opportunity to save future resources and ensure coherent regulatory strategies by devising consistent principles and possibly even similar approaches across chemical risk assessment under different regulations.
- Fifth, it may prove a substantial simplification for the process of comparing products to plan and establish reference cases for major indications. As there are many PPPs available for major pests and crops one may else be faced with repetitive binary product comparisons.

From the project efforts it emerges that comparative environmental risk assessment of plant protection products may become a novel cornerstone of regulatory activities that helps to improve the environmental quality by leading to substitution of less viable products.

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10 Annexes

Annex 1 – Potential CFS in the BVL database

Annex 2 - Plant protection products (PPPs) in the BVL database containing potential candidates for substitution (CFS)

Annex 3 - Data mask used for the retrieval of data from assessment reports of the UBA

Annex 4 – Calculation of R-Scores

Annex 1

Potential CFS in the BVL database

No	German name for a.i.	CFS-Indication
1	Aclonifen	E
2	Cyprodinil	E
3	Difenacoum	E
4	Difenoconazol	E
5	Diflufenican	E
6	Esfenvalerat	E
7	Etofenprox	E
8	Fenpyroximat	E
9	Flazasulfuron	E
10	Fludioxonil	E
11	Fluopicolide	E
12	Imazamox	E
13	Imazosulfuron	E
14	Isoproturon	E
15	Isopyrazam	E
16	Isoxaben	E
17a	Kupferhydroxid	E
17b	Kupferoxychlorid	E
17c	Kupfersulfat, basisch	E
18	lambda-Cyhalothrin	E
19	Metribuzin	E
20	Metsulfuron	E
21	Nicosulfuron	E
22	Paclobutrazol	E
23	Pencycuron	E

24	Pendimethalin	E
25	Pirimicarb	E
26	Prochloraz	E
27	Propiconazol	E
28	Propoxycarbazone	E
29	Prosulfocarb	E
30	Prosulfuron	E
31	Quinmerac	E
32	Quinoxyfen	E
33	S-Metolachlor	E
34	Spinosad	E
35	Sulfosulfuron	E
36	Tebufenpyrad	E
37	Thifensulfuron	E
38	Triasulfuron	E
39	Triflusulfuron	E
1	Chlortoluron	EH
2	Cyproconazol	EH
3	Dimoxystrobin	EH
4	Epoxiconazol	EH
5	Famoxadone	EH
6	Fluazinam	EH
7	Flufenacet	EH
8	Flumioxazin	EH
9	Fluquinconazol	EH
10	Flurtamone	EH
11	Haloxyfop-P (Haloxyfop-R)	EH
12	Metconazol	EH
13	Triazoxid	EH

1	1-Methylcyclopropen	H
2	Carbendazim	H
3	Clodinafop	H
4	Dimethoat	H
5	Flusilazol	H
6	Glufosinat	H
7	Myclobutanil	H
8	Quizalofop-P	H
9	Sulcotrion	H
10	Tebuconazol	H
11	Tepraloxydim	H
12	Terbuthylazin	H
13	Thiacloprid	H

Indication as CFS through criteria for:
E – Environment
EH – Environment + Human
H - Human

Annex 2

Plant protection products (PPPs) in the BVL database containing potential candidates for substitution (CFS)

PPP (MITTELNAME)	Candidate for substitution	Additional active substance
Aagrano UW 2000	Carbendazim	Imazalil
ABSOLUTE M	Diflufenican	Flupyrsulfuron
ACANTO Prima	Cyprodinil	Picoxystrobin
ACCENT	Nicosulfuron	
ACCURATE	Metsulfuron	
Achat	Propiconazol	
Activus	Pendimethalin	
ACTIVUS SC	Pendimethalin	
Acupro	Diflufenican Metsulfuron	
ADDITION	Diflufenican Pendimethalin	
Adexar	Epoxiconazol	Fluxapyroxad
AGENT	Propiconazol	Fenpropidin
Alister	Diflufenican	Iodosulfuron Mesosulfuron
Alliance	Diflufenican Metsulfuron	
Alto 240 EC	Cyproconazol	
Ampera	Prochloraz Tebuconazol	
Aramo	Tepraloxydim	Tepraloxydim
Arelon Flüssig	Isoproturon	
Arelon TOP	Isoproturon	
Arena C	Fludioxonil Tebuconazol	
ARIGO	Nicosulfuron	Mesotrione Rimsulfuron

Artett	Terbuthylazin	Bentazon
Artist	Flufenacet Metribuzin	
ARTUS	Metsulfuron	Carfentrazone
ASKON	Difenoconazol	Azoxystrobin
Aspect	Flufenacet Terbuthylazin	
Attribut	Propoxycarbazone	
AZUR	Diflufenican Isoproturon	Ioxynil
Bacara	Diflufenican Flurtamone	
Bacara FORTE	Diflufenican Flufenacet Flurtamone	
Bandur	Aclonifen	
BANJO	Fluazinam	
BANJO FORTE	Fluazinam	Dimethomorph
BANNER MAXX	Propiconazol	
Basta	Glufosinat	
Bayer Garten Gartenspray Calypso Perfekt	Thiacloprid	
Bayer Garten Gemüse-Pilzfrei Infinito	Fluopicolide	Propamocarb
Bayer Garten Gießmittel gegen Schädlinge	Thiacloprid	
Bayer Garten Gießmittel gegen Schädlinge Calypso	Thiacloprid	
Bayer Garten Kombi-Rosen-Schädlingsfrei	Thiacloprid	
Bayer Garten Kombi-Schädlingsfrei	Thiacloprid	
Bayer Garten Kupferkalk	Kupferoxychlorid	
BAYER GARTEN LANGZEIT-UNKRAUTFREI PERMACLEAN	Flufenacet	Glyphosat Metosulam
Bayer Garten Langzeit-Unkrautfrei Permaclean AF	Flufenacet	Glyphosat Metosulam
Bayer Garten Orchideen Schädlingsfrei Lizetan AF	Thiacloprid	
Bayer Garten Rosen-Pilzfrei Baymat	Tebuconazol	

Bayer Garten Rosen-Pilzfrei Baymat Plus AF	Tebuconazol	Trifloxystrobin
Bayer Garten Rosen-Pilzfrei Folicur	Tebuconazol	
Bayer Garten Rosen-Pilzfrei Spray	Tebuconazol	
Bayer Garten Rosen-Pilzfrei Spray Baymat	Tebuconazol	
Bayer Garten Rosen-Pilzfrei Spray Baymat Plus	Tebuconazol	Trifloxystrobin
Bayer Garten Rosen-Pilzfrei Spray Folicur	Tebuconazol	
Bayer Garten Rosen-Pilzschutz M	Myclobutanil	
Bayer Garten Rosen-Schädlingsfrei Calypso	Thiacloprid	
Bayer Garten Schädlingsfrei Calypso	Thiacloprid	
Bayer Garten Schädlingsfrei Calypso Perfekt AF	Thiacloprid	
Bayer Garten Spinnmilbenspray Plus	Thiacloprid	Methiocarb
Bayer Garten Universal Rasenunkrautfrei Loredo	Diflufenican	Mecoprop-P
Bayer Garten Universal-Pilzfrei Baycor M	Myclobutanil	
Bayer Garten Universal-Pilzfrei M	Myclobutanil	
Bayer Garten Zierpflanzenspray Lizetan Plus	Thiacloprid	Methiocarb
Bi 58	Dimethoat	
Bi 58 Combi-Stäbchen	Dimethoat	
Bi 58 Insektenvernichter	Dimethoat	
Bi 58 Spray	Dimethoat	
Biscaya	Thiacloprid	
Blattlaus-frei Spiess-Urania	Dimethoat	
Blattlaus-Spray Dimeton	Dimethoat	
BONTIMA	Cyprodinil	
Boxer	Isopyrazam Prosulfocarb	
Brazzos	Imazosulfuron	
Bromoterb	Terbuthylazin	Bromoxynil

Butisan Gold	Quinmerac	Dimethenamid-P Metazachlor
Butisan Top	Quinmerac	Metazachlor
Cadou SC	Flufenacet	
Calaris	Terbuthylazin	Mesotrione
Caliban Duo	Propoxycarbazone	Iodosulfuron
Caliban Top	Propoxycarbazone	Amidosulfuron Iodosulfuron
Calypso	Thiacloprid	
Cantus Gold	Dimoxystrobin	Boscalid
Capalo	Epoxiconazol	Fenpropimorph Metrafenone
CAPITAN	Flusilazol	
CARAMBA	Metconazol	
Carax	Metconazol	Mepiquat
Carmina 640	Chlortoluron Diflufenican	
Casper	Prosulfuron	Dicamba
Celaflor Pilzfrei Saprol	Myclobutanil	
Celaflor Rosen-Pilzfrei Saprol Spray	Myclobutanil	
CELEST	Fludioxonil	
CHA1270	Diflufenican Metsulfuron	
CHAC	Terbuthylazin	
Champion	Epoxiconazol	Boscalid
CHARISMA	Famoxadone Flusilazol	
CHIKARA	Flazasulfuron	
CHORUS	Cyprodinil	
Chrysal Blattläuse STOP	Dimethoat	
CHRYSAL Rosen-Pilze STOP	Myclobutanil	

CHRYSAL Zierpflanzenspray D+	Dimethoat	
CIRAL	Metsulfuron	Flupyrsulfuron
Cirkon	Prochloraz Propiconazol	
CIRONTIL	Nicosulfuron	Dicamba Rimsulfuron
CLAYTON SPARTA	lambda-Cyhalothrin	
Clearfield-Vantiga	Imazamox	Metazachlor
CLICK	Quinmerac Terbuthylazin	
COM-11701-I-0-ME	Pirimicarb	
Combi-Stäbchen Hortex D	Dimethoat	
Combi-Sticks Insektan	Dimethoat	
COMPO Duaxo Universal Pilz-frei AF	Difenoconazol	
COMPO Schildlaus-Spray	Dimethoat	
COMPO Zierpflanzen-Spray Bi 58	Dimethoat	
COMPO Zierpflanzen-Spray D	Dimethoat	
CONCERT SX	Metsulfuron Thifensulfuron	
CONSERVE	Spinosad	
CRUISER OSR	Fludioxonil	Metalaxyl-M Thiamethoxam
CTU 700	Chlortoluron	
Cuproxat	Kupfersulfat, basisch	
Cuprozin Flüssig	Kupferhydroxid	
Cuprozin progress	Kupferhydroxid	
Cuprozin WP	Kupferhydroxid	
Custodia	Tebuconazol	Azoxystrobin
CYCLONE	lambda-Cyhalothrin	
Danadim Progress	Dimethoat	
DEBUT	Triflusulfuron	

Dehner Zierpflanzenspray	Dimethoat	
DELU Zier- und Zimmerpflanzen-Spray	Dimethoat	
Desmel	Propiconazol	
Detia Insekten-Spritzmittel	Dimethoat	
Detia Pflanzenschutz-Spray	Dimethoat	
Detia Pflanzenschutz-Stäbchen Neu	Dimethoat	
Detia Rosen- und Zierpflanzen-Spray Pilzfrei NEU	Myclobutanil	
Diamant	Epoxiconazol	Fenpropimorph Pyraclostrobin
DIFLANIL 500 SC	Diflufenican	
Dinagam	Quizalofop-P	
DIRIGENT SX	Metsulfuron	Tribenuron
Dual Gold	S-Metolachlor	
Duaxo Rosen Pilz-frei	Difenoconazol	
Duaxo Rosen-Pilz Spray	Difenoconazol	
Duaxo Universal Pilz-frei	Difenoconazol	
Duaxo Universal Pilzspritzmittel	Difenoconazol	
Duett Ultra	Epoxiconazol	Thiophanat-methyl
DYNALI	Difenoconazol	Cyflufenamid
Eclat	Prosulfuron	Bromoxynil
EfA	Tebuconazol Triazoxid	Fluoxastrobin Prothioconazol
EfA Spezial	Tebuconazol	Fluoxastrobin Prothioconazol
EfA Universal	Tebuconazol	Fluopyram Fluoxastrobin Prothioconazol
Efilor	Metconazol	Boscalid
Elumis	Nicosulfuron	Mesotrione
EPOK	Fluazinam	Metalaxyl-M

EPOXION	Epoxiconazol	
Epoxion Top	Epoxiconazol	Fenpropidin
EQUATION PRO	Famoxadone	Cymoxanil
Erdbeerspritzmittel Botrysan	Cyprodinil Fludioxonil	
Etisso Blattlaus-Sticks	Dimethoat	
Etisso Combi-Sticks	Dimethoat	
Exemptor	Thiacloprid	
FALKON	Diflufenican	Penoxsulam
FENIKAN	Diflufenican Isoproturon	
Fezan	Tebuconazol	
Filon	Prosulfocarb	
Finy	Metsulfuron	
Flamenco FS	Fluquinconazol Prochloraz	
FLEXIDOR	Isoxaben	
Florissa Schädlings - Spray	Dimethoat	
Folicur	Tebuconazol	
FORTRESS	Quinoxyfen	
FORTRESS 250	Quinoxyfen	
Fuego Top	Quinmerac	Metazachlor
Funguran	Kupferoxychlorid	
Funguran progress	Kupferhydroxid	
Fussa	Diflufenican Metsulfuron	
Gabi Pflanzenspray	Dimethoat	
GALACTICO	Famoxadone	Cymoxanil Folpet
GALLANT SUPER	Haloxyfop-P (Haloxyfop-R)	

Gardenline Combi-Sticks	Dimethoat	
Gardenline Schädlingsspray	Dimethoat	
Gardo Gold	S-Metolachlor Terbuthylazin	
Gardobuc	Terbuthylazin	Bromoxynil
Gladio	Propiconazol Tebuconazol	Fenpropidin
GOLTIX TITAN	Quinmerac	Metamitron
GROPPER SX	Metsulfuron	
HARMONY MILLENIUM	Thifensulfuron	Flupyrsulfuron
HARMONY SX	Thifensulfuron	
HARVESAN	Carbendazim Flusilazol	
Herbaflex	Isoproturon	Beflubutamid
Herold	Diflufenican Flufenacet	
Herold SC	Diflufenican Flufenacet	
Horizon	Tebuconazol	
HYGANEX-flüssig	Glufosinat	
HYGANEX-Perfekt	Flumioxazin	
Infinito	Fluopicolide	Propamocarb
InnoProtect Bromoterb	Terbuthylazin	Bromoxynil
Innoprotect Dual Gold	S-Metolachlor	
Innoprotect Elumis	Nicosulfuron	Mesotrione
InnoProtect Epoxion Top	Epoxiconazol	Fenpropidin
InnoProtect Isofox	Isoproturon	Bifenox
InnoProtect Pendi 400 SC	Pendimethalin	
InnoProtect Seguris	Epoxiconazol Isopyrazam	
Insekten Spritzmittel Roxion D	Dimethoat	
Insekten-Spritzmittel Roxion	Dimethoat	

Isofox	Isoproturon	Bifenox
Juwel	Epoxiconazol	Kresoxim-methyl
JUWEL FORTE	Epoxiconazol Quinoxyfen	Fenpropimorph
Juwel Top	Epoxiconazol	Fenpropimorph Kresoxim-methyl
Kaiso Sorbie	lambda-Cyhalothrin	
KARATE FORST flüssig	lambda-Cyhalothrin	
Karate Zeon	lambda-Cyhalothrin	
Katamaran Plus	Quinmerac	Dimethenamid-P Metazachlor
KATANA	Flazasulfuron	
Kayak	Cyprodinil	
KELVIN	Nicosulfuron	
KELVIN OD	Nicosulfuron	
Kiron	Fenpyroximat	
Klick&GO Pilzfrei Saprol	Myclobutanil	
KUPFERSPRITZMITTEL	Kupferoxychlorid	
Lambda WG	lambda-Cyhalothrin	
LANDOR CT	Difenoconazol Fludioxonil Tebuconazol	
Legend power	Myclobutanil Quinoxyfen	
Lentipur 700	Chlortoluron	
Lido SC	Terbuthylazin	Pyridat
Locstar	Epoxiconazol	Fenpropimorph Kresoxim-methyl
Loredo	Diflufenican	Mecoprop-P
Luna Experience	Tebuconazol	Fluopyram
Lynx	Tebuconazol	
Malibu	Flufenacet	

	Pendimethalin	
MASAI	Tebufenpyrad	
Matador	Tebuconazol	Triadimenol
Matador Super	Tebuconazol	Spiroxamine
MAXIM XL	Fludioxonil	Triadimenol Metalaxyl-M
Methiocarb 0,05+Thiacloprid 0,025 AE	Thiacloprid	Methiocarb
Mikado	Sulcotrion	
Milagro 6 OD	Nicosulfuron	
MILAGRO forte	Nicosulfuron	
Mirage 45 EC	Prochloraz	
Mistral	Metribuzin	
Monceren G	Pencycuron	Imidacloprid
Monceren Pro	Pencycuron	Prothioconazol
Monitor	Sulfosulfuron	
Motivell Extra 6 OD	Nicosulfuron	
Motivell Forte	Nicosulfuron	
Nando 500 SC	Fluazinam	
NICOGAN	Nicosulfuron	
NISSHIN	Nicosulfuron	
NISSHIN EXTRA 6 OD	Nicosulfuron	
Nozomi	Flumioxazin	
Ohayo	Fluazinam	
Olando	Sulfosulfuron	Pyraclostrobin
Opera	Epoxiconazol	
Optimo	Epoxiconazol	Kresoxim-methyl
Opus	Epoxiconazol	Pyraclostrobin

Opus EC	Epoxiconazol	
Opus Top	Epoxiconazol	Fenpropimorph
Orius	Tebuconazol	
ORIUS TOP	Prochloraz Tebuconazol	Fenpropidin
Orius Universal	Prochloraz Tebuconazol	
Osiris	Epoxiconazol Metconazol	
Panarex	Quizalofop-P	
Peak	Prosulfuron	
PERFEKTHION	Dimethoat	
Perfekthion Insektenvernichter	Dimethoat	
Pflanzenschutz-Zäpfchen	Dimethoat	
Picona	Pendimethalin	Picolinafen
Pilzfrei Ectivo	Myclobutanil	
Pilzfrei Saprol Neu AF	Myclobutanil	
PIRIMAX	Pirimicarb	
Pirimor Granulat	Pirimicarb	
Pixie	Diflufenican	Mecoprop-P
POTACUR SX	Thifensulfuron	Tribenuron
Primagram Gold	S-Metolachlor Terbuthylazin	
PRINCIPAL	Nicosulfuron	Rimsulfuron
Priori Xtra	Cyproconazol	Azoxystrobin
PROFI CTU	Chlortoluron	
Profi Metribuzin	Metribuzin	
Profiler	Fluopicolide	Fosetyl
Pronic	Nicosulfuron	
Pronto Plus	Tebuconazol	Spiroxamine

Prosaro	Tebuconazol	Prothioconazol
Protugan	Isoproturon	
RA-200-flüssig	Glufosinat	
RA-50	Flumioxazin	
RADIUS	Cyproconazol Cyprodinil	
Rebell	Quinmerac	Chloridazon
Rebell Ultra	Quinmerac	Chloridazon
REFINE EXTRA SX	Thifensulfuron	Tribenuron
REVUS TOP	Difenoconazol	Mandipropamid
Ricorso	Metsulfuron	
ROGOR 40 L	Dimethoat	
Rogor 40 LC	Dimethoat	
Rosen Pilz-Frei Rosal AF	Myclobutanil	
Rosenpflaster Doctor Plant	Dimethoat	
Rubin TT	Prochloraz	Pyrimethanil Triticonazol
SAFARI	Triflusulfuron	
Samson 4SC	Nicosulfuron	Nicosulfuron
SAMSON EXTRA 6 OD	Nicosulfuron	
Savvy	Metsulfuron	
Schädlings-Sticks Insektan	Dimethoat	
SCORE	Difenoconazol	
SEGURIS	Epoxiconazol Isopyrazam	
Sencor Liquid	Metribuzin	
Sencor WG	Metribuzin	
Shirlan	Fluazinam	
Shock DOWN	lambda-Cyhalothrin	

Skyway Xpro	Tebuconazol	Bixafen Prothioconazol
Smart Fresh	1-Methylcyclopropen	
Solar	Isoproturon	Bromoxynil
Spectrum Gold	Terbuthylazin	Dimethenamid-P
Sphere 267,5	Cyproconazol	Trifloxystrobin
SpinTor	Spinosad	
Sportak 45 EW	Prochloraz	
SPYRALE	Difenoconazol	Fenpropidin
Stomp Aqua	Pendimethalin	
Stomp Raps	Pendimethalin	
Stratego	Propiconazol	Trifloxystrobin
Successor T	Terbuthylazin	Pethoxamid
SULCOGAN	Sulcotrion	
Sumicidin Alpha EC	Esfenvalerat	
Sumimax	Flumioxazin	
Swing Gold	Dimoxystrobin Epoxiconazol	
SWITCH	Cyprodinil Fludioxonil	
SYD 41110 F	Difenoconazol Fludioxonil	
SYMPARA	Tebuconazol	Prothioconazol
Systhane 20 EW	Myclobutanil	
Tabularaza	Difenacoum	
TANOS	Famoxadone	Cymoxanil
TARGA SUPER	Quizalofop-P	
Taspa	Difenoconazol Propiconazol	Metosulam
Terano	Flufenacet Flufenacet	Metosulam

Terano flüssig	Flufenacet	Metosulam
Terbuthylazin 500	Terbuthylazin	
Terminus	Fluazinam	
terrex Universalinsektizid	Dimethoat	
Thiacloprid Low-Flow-Aerosol	Thiacloprid	
Tilmor	Tebuconazol	Prothioconazol
Tilt 250 EC	Propiconazol	
TOLKAN FLO	Isoproturon	
Toluron 700 SC	Chlortoluron	
TOPIK 100	Clodinafop	
Toprex	Difenoconazol Paclobutrazol	
TRAFO WG	lambda-Cyhalothrin	
Traxos	Clodinafop	Pinoxaden
Trebon 30 EC	Etofenprox	
Trinity	Chlortoluron Pendimethalin Diflufenican	
Ultima Käfer- und Raupenfrei	Spinosad	
UNIVERSAL PILZ-FREI KUPFER KONZ. 45	Kupferoxychlorid	
UNIX	Cyprodinil	
UP CTU	Chlortoluron	
Vento power	Myclobutanil Quinoxyfen	
Vorox F	Flumioxazin	
ZARDEX G	Cyproconazol	Imazalil
ZEAGRAN	Terbuthylazin	
Zeagran ultimate	Terbuthylazin	Bromoxynil
Zoom	Triasulfuron	Dicamba

Annex 3

Data mask used for the retrieval of data from assessment reports of the UBA (explanation in section 7.3)

Section or criterion in the assessment report	Candidate PPP			Alternative PPP			Inclusion in graphical comparisons of risk profiles
	Data from the assessment report	Supplementary data from the assessment report	Data used for risk comparison	Data from the assessment report	Supplementary data from the assessment report	Data used for risk comparison	
I. Allgemeine Angaben zum Antrag							-
1. Allgemeine Angaben							-
Kennnummer							-
Pflanzenschutzmittel							-
Formulierung							-
Wirkstoff							-
techn. Wirkstoffgehalt im Mittel [g/L]							-
reiner Wirkstoffgehalt im Mittel [g/L]							-
bestehende Zulassungen							-
							-
2. Anwendungsgebiete (die zu bearbeitende Indikation ist mit * zur markieren)							-
	Schad-Organismus/ -erreger	**Kultur**	**Gruppierung**	**Schad-Organismus/ -erreger**	**Kultur**	**Gruppierung**	-
00-001							-
00-002							-
00-003							-
00-004							-
00-005							-
00-006							-
00-007							-
00-008							-
00-009							-
00-010							-
00-011							-
00-012							-
00-013							-
00-014							-
00-015							-
00-016							-
00-017							-
00-018							-
00-019							-
00-020							-
00-021							-
00-022							-
00-023							-
00-024							-
01-002							
							-
3. Informationen zum Wirkstoff							-
3.1 Identität *(alte ZB 2.1)*							-
Wirkstoff							-
Wirkstofftyp							-
Wirkstoffgruppe							-
							-
3.2 physikalische und chemische Eigenschaften *(alte ZB 2.2)*							-
Wasserlöslichkeit							-
Verteilungskoeffizient log POW							-
							-

Table continued on the next page

Annex 3 continued

II. Verhalten und Verbleib in der Umwelt							-
1.1 Verhalten und Verblein in der Umwelt des Wirkstoffes							-
1.1a Abbau im Boden *(alte ZB 3.1a)*							-
Abbaugeschwindigkeit des Wirkstoffes (DT50) Laborstudien aerob, bei 20°C, kein Freiland, vorrangig pF2 [d]							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
							-
geometrisches Mittel [d]		#ZAHL!	#ZAHL!		#ZAHL!	#ZAHL!	
Feldstudie erforderlich [Ja/Nein]							-
							-
1.2a Abiotischer und biotischer Abbau in Wasser *(alte ZB 3.2a)*							-
Leicht biologisch abbaubar [Ja/Nein]							-
							-
1.2b Abbau des Wirkstoffes im Wasser/Sediment System *(alte ZB 3.2a)*							-
DT50 Gesamtsystem (pond & river) [d]							-
							-
							-
							-
geometrisches Mittel		#ZAHL!	#ZAHL!		#ZAHL!	#ZAHL!	
DT50 Wasser (pond & river) [d]							-
							-
							-
							-
geometrisches Mittel		#ZAHL!	#ZAHL!		#ZAHL!	#ZAHL!	
DT50 Sediment (pond & river) [d]							-
							-
							-
							-
geometrisches Mittel		#ZAHL!	#ZAHL!		#ZAHL!	#ZAHL!	
							-
III. Ökotoxikologische Untersuchungen							-
5. Studien zur Biokonzentration von Wirkstoff und Präparat in Fischen (alte ZB 4.3)							-
Biokonzentrationsfaktor (BCF) Wirkstoff							-
Biokonzentrationsfaktor (BCF) Präparat							-
							-
IV. Risikoanalyse und Risikomanagement							-
1. Beurteilung der PBT Eigenschaften (nicht in alten ZB)							-
Persistenz ($DT50_{Wasser}$ > 40d oder $DT50_{Boden}$ > 120d oder $DT50_{Sediment}$ > 120d) [Ja/Nein]							-
Bioakkumulierbarkeit (BCF > 2000) [Ja/Nein]							-
Toxizität (NOEC < 0.01 mg/L) [Ja/Nein]							-
							-

Table continued on the next page

Annex 3 continued

3. Risiko für Vögel und Säuger							-
3.1a Akute Toxizität Vögel							-
A) Wirkstoff							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER Insektivor			0			0	birds&mammals
TER Herbivor			0			0	birds&mammals
TER omnivore Art			0			0	
							-
B) Präparat/Mittel							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER Insektivor			0			0	
TER Herbivor			0			0	
TER omnivore Art			0			0	
							-
C) verfeinerte Risikobewertung							-
relevanter TER (akut):							-
TER Insektivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			0			0	birds&mammals
Herbst			0			0	birds&mammals
Frühjahr			0			0	birds&mammals
TER Herbivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			0			0	birds&mammals
Herbst			0			0	birds&mammals
Frühjahr			0			0	birds&mammals
							-
3.1b Kurzzeittoxizität Vögel							-
A) Wirkstoff							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER Insektivor			0			0	birds&mammals
TER Herbivor			0			0	birds&mammals
TER omnivore Art			0			0	
							-
B) Präparat/Mittel							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER Insektivor			0			0	
TER Herbivor			0			0	
TER omnivore Art			0			0	
							-
C) verfeinerte Risikobewertung							-
relevanter TER (short term):							-
TER Insektivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			0			0	birds&mammals
Herbst			0			0	birds&mammals
Frühjahr			0			0	birds&mammals

Table continued on the next page

Annex 3 continued

TER Herbivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			0			0	birds&mammals
Herbst			0			0	birds&mammals
Frühjahr			0			0	birds&mammals
							-
3.1c Langzeittoxizität Vogel							-
A) Wirkstoff							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER Insektivor			0			0	birds&mammals
TER Herbivor			0			0	birds&mammals
TER omnivore Art			0			0	
							-
B) Präparat/Mittel							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER Insektivor			0			0	
TER Herbivor			0			0	
TER omnivore Art			0			0	
							-
C) verfeinerte Risikobewertung							-
relevanter TER (long term):							-
TER Insektivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			0			0	birds&mammals
Herbst			0			0	birds&mammals
Frühjahr			0			0	birds&mammals
TER Herbivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			0			0	birds&mammals
Herbst			0			0	birds&mammals
Frühjahr			0			0	birds&mammals
							-
3.1d Anreicherung Nahrungskette "sekundäre Vergiftung" Vögel							-
Regenwurm fressende Vögel							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			0			0	birds&mammals
Fisch fressende Vögel							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			0			0	birds&mammals
							-
3.2a Akute Toxizität Säuger							-
A) Wirkstoff							-
Omnivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			0			0	

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Annex 3 continued

Insektivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
Herbivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	birds&mammals
Mittlerer herbivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
B) Präparat/Mittel							-
Omnivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
Insektivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
Herbivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	birds&mammals
Mittlerer herbivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
							-
C) verfeinerte Risikobewertung							-
relevanter TER (long term):							-
TER Insektivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			**0**			**0**	
Herbst			**0**			**0**	
Frühjahr			**0**			**0**	
TER Herbivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			**0**			**0**	birds&mammals
Herbst			**0**			**0**	birds&mammals
Frühjahr			**0**			**0**	birds&mammals
							-

Table continued on the next page

Annex 3 continued

3.2b Langzeittoxizität Säuger							-
A) Wirkstoff							-
Insektivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
Omnivorer Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
Herbivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	birds&mammals
Mittlerer herbivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
							-
							-
B) Präparat/Mittel							-
Insektivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
Omnivorer Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
Herbivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
Mittlerer herbivore Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER			**0**			**0**	
							-
C) verfeinerte Risikobewertung							-
relevanter TER (long term):							-
TER Insektivor	**TER**	**AWM [kg a.i./ha]**		**TER**	**AWM [kg a.i./ha]**		-
Herbst/Frühjahr			**0**			**0**	
Herbst			**0**			**0**	
Frühjahr			**0**			**0**	

Table continued on the next page

Annex 3 continued

TER Herbivor	TER	AWM [kg a.i./ha]		TER	AWM [kg a.i./ha]		-
Herbst/Frühjahr			0			0	birds&mammals
Herbst			0			0	birds&mammals
Frühjahr			0			0	birds&mammals
							-
3.2c Anreicherung in der Nahrungskette "sekundäre Vergiftung" Säuger							-
Regenwurm fressende Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER_{lt}			0			0	birds&mammals
Fisch fressende Säuger							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
TER_{lt}			0			0	birds&mammals
							-
4. Risiko für aquatische Organismen (Bewertung gem. Anhang VI, Teil C 2 Entscheidungsverfahren – Spezielle Grundsätze, Punkt 2.5.2.2)							-
4.1a Eintragspfad Spraydrift und Verflüchtigung/Deposition							-
Indikation/Gruppe							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
konv. T.	TER			TER			-
0m Abstand			0			0	aquatic ecotox.
1m Abstand			0			0	aquatic ecotox.
1/3m Abstand			0			0	aquatic ecotox.
5m Abstand			0			0	aquatic ecotox.
10m Abstand			0			0	aquatic ecotox.
15m Abstand			0			0	aquatic ecotox.
20m Abstand			0			0	aquatic ecotox.
90% Red.	TER			TER			-
0m Abstand			0			0	aquatic ecotox.
1m Abstand			0			0	aquatic ecotox.
1/3m Abstand			0			0	aquatic ecotox.
5m Abstand			0			0	aquatic ecotox.
10m Abstand			0			0	aquatic ecotox.
15m Abstand			0			0	aquatic ecotox.
20m Abstand			0			0	aquatic ecotox.
75% Red.	TER			TER			-
0m Abstand			0			0	aquatic ecotox.
1m Abstand			0			0	aquatic ecotox.
1/3m Abstand			0			0	aquatic ecotox.
5m Abstand			0			0	aquatic ecotox.
10m Abstand			0			0	aquatic ecotox.
15m Abstand			0			0	aquatic ecotox.
20m Abstand			0			0	aquatic ecotox.
50% Red.	TER			TER			-
0m Abstand			0			0	aquatic ecotox.
1m Abstand			0			0	aquatic ecotox.
1/3m Abstand			0			0	aquatic ecotox.
5m Abstand			0			0	aquatic ecotox.
10m Abstand			0			0	aquatic ecotox.
15m Abstand			0			0	aquatic ecotox.
20m Abstand			0			0	aquatic ecotox.
AWB erforderlich [Ja/Nein, NWxxx]							-
							-

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Annex 3 continued

4.1b Eintragspfade Run-off und Drainage							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
Eintragspfad Run-off	**TER**			**TER**			-
0m bew. Randstreifen			**0**			**0**	aquatic ecotox.
5m bew. Randstreifen			**0**			**0**	aquatic ecotox.
10m bew. Randstreifen			**0**			**0**	aquatic ecotox.
20m bew. Randstreifen			**0**			**0**	aquatic ecotox.
Eintragspfad Drainage	**TER**			**TER**			-
Frühjahr/Sommer			**0**			**0**	aquatic ecotox.
Herbst/Winter			**0**			**0**	aquatic ecotox.
AWB erforderlich [Ja/Nein, NWxxx]							-
							-
5. Risiko für Honigbienen (Bewertung gem. Anhang VI, Teil C 2 Entscheidungsverfahren – Spezielle Grundsätze, Punkt 2.5.2.3)							-
5.1 akute Auswirkungen							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
LD/C50 [ug/Biene]							-
A) Wirkstoff							-
oral							-
Kontakt							-
B) Präparat/Mittel							-
oral							-
Kontakt							-
Gefährdungsquotient (QHA/QHC)							-
A) Wirkstoff							-
oral			**0**			**0**	terrestrial ecotox.
Kontakt			**0**			**0**	terrestrial ecotox.
B) Präparat/Mittel							-
oral			**0**			**0**	terrestrial ecotox.
Kontakt			**0**			**0**	terrestrial ecotox.
Bienenschutz							-
							-
6. Risiko für Arthropoden (Bewertung gem. Anhang VI, Teil C 2 Entscheidungsverfahren – Spezielle Grundsätze, Punkt 2.5.2.4 i.V.m. UBA-Bewertungskonzept/TER-Ansatz)							-
A) Wirkstoff							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
konv. T.	**TER**			**TER**			-
0m Abstand			**0**			**0**	
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
90% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.

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Annex 3 continued

75% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
50% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
AWB erforderlich [Ja/Nein, NTxxx]							-
B) Präparat/Mittel							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
konv. T.	**TER**			**TER**			-
0m Abstand			**0**			**0**	
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
90% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
75% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
50% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
AWB erforderlich [Ja/Nein, NTxxx]							-
							-
7. Risiko für Bodenmakroorganismen (Bewertung gem. Anhang VI, Teil C 2 Entscheidungsverfahren – Spezielle Grundsätze, Punkt 2.5.2.5)							-
7.2 TER-Berechnung für Regenwürmer							-
A) Wirkstoff							-
Akut							
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
berechneter TER			**0**			**0**	terrestrial ecotox.
Chronisch							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
berechneter TER			**0**			**0**	

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Annex 3 continued

B) Präparat/Mittel							-
Akut							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
berechneter TER			**0**			**0**	terrestrial ecotox.
Chronisch							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
berechneter TER			**0**			**0**	
							-
7.2 TER-Berechnung für andere Boden-Makroorganismen							-
A) Wirkstoff							-
Collembolen/Springschwänze							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
berechneter TER			**0**			**0**	
Ausw. auf Streuabbau							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
berechneter TER			**0**			**0**	
B) Präparat/Mittel							-
Collembolen/Springschwänze							
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
berechneter TER			**0**			**0**	
Ausw. auf Streuabbau							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
berechneter TER			**0**			**0**	
							-
9. Risiko für terrestrische Pflanzen (Bewertung gem. UBA-Konzept /TER-Ansatz)							-
A) Wirkstoff							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
konv. T.	**TER**			**TER**			-
0m Abstand			**0**			**0**	
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
90% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.

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Annex 3 continued

75% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
50% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
AWB erforderlich [Ja/Nein, NTxxx]							-
B) Präparat/Mittel							-
Indikation							-
Aufwandmenge/-häufigkeit							-
relevante Toxizität							-
relevanter TER							-
konv. T.	**TER**			**TER**			-
0m Abstand			**0**			**0**	
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
90% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
75% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
50% Red.	**TER**			**TER**			-
1m Abstand			**0**			**0**	terrestrial ecotox.
5m Abstand			**0**			**0**	terrestrial ecotox.
AWB erforderlich [Ja/Nein, NTxxx]							-
							-
VI. Festzusetzende Risikomanagement-Maßnahmen wenn Anwendungsbestimmungen vergeben = x für alle Indikationen aufnehmen							-
Grundwasserschutz							-
NG 402			**0**			**0**	aquatic ecotox.
NG 404	x		**0**			**0**	aquatic ecotox.
NG 405	x		**0**			**0**	aquatic ecotox.
NG 408			**0**			**0**	aquatic ecotox.
NG 410			**0**			**0**	aquatic ecotox.
NG 411			**0**			**0**	aquatic ecotox.
Terrestrik							-
NT 101			**0**			**0**	terrestrial ecotox.
NT 102			**0**			**0**	terrestrial ecotox.
NT 103	x		**0**			**0**	terrestrial ecotox.
NT 104			**0**			**0**	terrestrial ecotox.
NT 105			**0**			**0**	terrestrial ecotox.
NT 106			**0**			**0**	terrestrial ecotox.

Table continued on the next page

Annex 3 continued

NT 107			0			0	terrestrial ecotox.
NT 108			0			0	terrestrial ecotox.
NT 109			0			0	terrestrial ecotox.
R-Score Terrestrik*			0			0	terrestrial ecotox.
Aquatik							-
NW 467			0			0	aquatic ecotox.
NW 468	x		0	x		0	aquatic ecotox.
NW 469			0			0	aquatic ecotox.
NW 605/606	x		0	x		0	aquatic ecotox.
							-
NW 607			0			0	aquatic ecotox.
NW 608			0			0	aquatic ecotox.
NW 609			0			0	aquatic ecotox.
NW 701/703			0			0	aquatic ecotox.
NW 705			0			0	aquatic ecotox.
NW 706			0			0	aquatic ecotox.
NW 800							-
R-Score Aquatik*			0			0	aquatic ecotox.

Annex 4 – Calculation of R-Scores

Calculation of a risk score from imposed use restrictions as a measure for relative risk levels from contamination of off-field habitats by plant protection products via spray drift

Prepared by Dr. Andreas Hoellrigl-Rosta, German Federal Environment Agency (UBA)

a) Surface water bodies

In the risk assessment for surface water bodies with regard to their possible contamination by plant protection products via spray drift, TER values are calculated. These are based on a matrix of PEC values that reflect modelled spray drift entries depending on buffer zones kept and drift-reducing nozzles used during the application. The ecotoxicity of a compound is described by a relevant effect value (EC_{50}, NOEC, ...) in combination with an adjusted assessment/safety factor. Hence, a matrix of TER values is produced, which the relative risk levels depending on buffer zones and nozzle category. If, for the simplest case of a single application of a plant protection product, the parameters are chosen to achieve a TER value of 100 for the maximum acceptable drift mitigation (20 m buffer zone in combination with 90 % drift reduction), a generic TER matrix is produced, here for the arable-crop scenario (as an example), in which the single TER values can be considered to also represent relative risk levels.

drift red.	0 %	50 %	75 %	90 %
buffer zone				
* m	0.5	1.1	2.2	5.4
5 m	2.6	5.3	10.5	26.3
10 m	5.2	10.3	20.7	51.7
15 m	7.5	15	30	75
20 m	10	20	40	100

* minimum distance to water bodies as imposed by Federal State laws; in the risk assessment for authorisation purposes, a distance of 1 m (application in arable crops) or 3 m (application in high crops) is assumed

Where use restrictions (official German term: Anwendungsbestimmungen, abbreviated as AWB) are necessary for an authorisation of a plant protection product in a certain use, their type and extent are deduced from the actual level of risk in this use. Hence, sorting of the values from the generic TER matrix according to increasing relative risk levels results in a sequence of progressively restrictive use restrictions, which are characterised by a specific combination of buffer zones to be kept and drift-reducing nozzles to be used during the application.

risk level	use restr.	0%	50%	75%	90%
0.5	none	0	0	0	0
1.1	NW 609	5	0	0	0
2.2	NW 605/606	5	5	0	0
2.6	NW 605/606	5	5	5	0
5.2	NW 605/606	10	5	5	0
5.3	NW 605/606	15	5	5	0
5.4	NW 605/606	15	10	5	0
7.5	NW 605/606	15	10	5	5
10	NW 605/606	20	10	5	5
10.3	NW 607	not possible	10	5	5
10.5	NW 607	not possible	15	5	5
15	NW 607	not possible	15	10	5
20	NW 607	not possible	20	10	5
20.7	NW 607	not possible	not possible	10	5
26.3	NW 607	not possible	not possible	15	5
30	NW 607	not possible	not possible	15	10
40	NW 607	not possible	not possible	20	10
51.7	NW 607	not possible	not possible	not possible	10
75	NW 607	not possible	not possible	not possible	15
100	NW 607	not possible	not possible	not possible	20

Insofar, the use restrictions imposed for a certain use represent the regulatory decision with regard to the exposure and ecotoxicity parameters to be considered as well as the relative level of risk (for aquatic organisms) arising from that use. As a consequence, the use restrictions may be employed for a computer-based automated sorting of plant protection products authorised for a certain use according to their risk for aquatic ecosystems or even for the whole environment (presuming that the risk level for the entirety of aquatic organisms will also be representative for other environmental compartments and organism groups).

To derive a value for the relative risk level of a plant protection product in a given use from the respective imposed restriction, first, an index (I_{AWB}) is calculated. This index makes use of the concept that a use restriction required for granting an authorisation is unequivocally defined by four pairs of values for drift-reducing nozzle technique (D_1 = 0 %, D_2 = 50 %, D_3 = 75 %, and D_4 = 90 % drift reduction) and buffer zone ($B_{1...4}$ = 5…20 m, or not possible when a buffer zone > 20 m would be required to achieve an acceptable risk for granting the authorisation). Basically, the index is calculated as follows:

$$I_{AWB} = \sum_{n} \left(1 - D_n\right) \times 0{,}5^{B_n / 5}$$

The two factors in the term after the summation sign reflect drift mitigation due to drift-reducing nozzles and buffer zones, which also have a multiplying impact in reality. A simplified approach has been selected for the impact of buffer zones, where it is assumed that spray drift entries are halved per each 5 m additional distance. For values of *n* where a buffer zone of 20 m in combination with the drift reduction D_n is not sufficient to achieve an acceptable risk, the expression $B_n/5$ is undefined. Hence the whole term to be summed up is set to 0 for these values of *n*.

In the resulting index I_{AWB}, larger figures (up to the maximum possible value of 1.85 for a use that can be authorised without a need for buffer zones and drift-reducing nozzles) correspond to less

restrictive measures linked to an authorisation and thus to a lower level of risk. In contrast, smaller figures (down to the minimum possible value of 0.00625 for the combination of 20 m buffer zone and 90 % drift reduction) depict a higher level of risk. Where no authorisation is possible, I_{AWB} thus becomes 0.

When the reciprocal values for I_{AWB} are plotted against the values for relative risk levels, they follow the shape of a parabolic curve quite well. Therefore, the following transformation is made to ease subsequent calculations:

$$I'_{AWB} = \sqrt{\frac{1}{I_{AWB}}}$$

Using linear regression, the following relationships are obtained between the relative risk level (here termed R) and the transformed index I'_{AWB}:

Drift scenario arable crops	$I'_{AWB} = 0.1151 \times R + 0.63$
Drift scenario vines	$I'_{AWB} = 0.1205 \times R + 0.93$
Drift scenario orchards early	$I'_{AWB} = 0.1269 \times R + 0.94$
Drift scenario orchards late	$I'_{AWB} = 0.1231 \times R + 0.94$
Drift scenario hops	$I'_{AWB} = 0.1279 \times R + 0.89$
Drift scenarios averaged	$I'_{AWB} = 0.1227 \times R + 0.87$

Via the inverse function $R_{Score} = 8.1502 \times I'_{AWB} – 7.05$ of the linear function for the averaged drift scenarios, the transformed index I'_{AWB} can thus be converted into a risk score (R_{Score}), which basically depicts the level of risk that had to be taken into account for imposing the respective use restriction for the given use. To avoid negative values of R_{Score} (the lowest possible I'_{AWB} value of 0.7 would be converted into an R_{Score} of -1.1), the straight line of the inverse function is shifted upwards by addition of 1.96. As a consequence, the lowest possible I'_{AWB} value of 0.7 is then converted to an R_{Score} of 0.9, which corresponds to the highest risk level for an authorised use without drift mitigation in the most critical scenarios orchards early and hops. The resulting equation for R_{Score} is thus $R_{Score} = 8.1502 \times I'_{AWB} – 5.09$. The quality of the correlation between risk level and R_{Score} as expressed by the coefficient of determination r^2 ranges from 0.9645 to 0.9971 for the 5 most important drift scenarios. This is deemed sufficient for the intended function of the risk score as a sorting criterion for the first step of a comparative assessment and as a tool for identifying obviously inadequate alternatives for the candidate product.

Drift scenario arable crops	$r^2 = 0,9957$
Drift scenario vines	$r^2 = 0,9971$
Drift scenario orchards early	$r^2 = 0,9694$
Drift scenario orchards late	$r^2 = 0,9920$
Drift scenario hops	$r^2 = 0,9654$

A detailed comparison of values for the drift scenario arable crops as an example case demonstrates that the R_{Score} slightly overestimates the risk levels in the range of lower risks (less restrictive measures needed for granting an authorisation). The “significantly lower risk” according to Annex IV Point 2 of Regulation 1107/2009 of an authorised use without use restrictions (relative risk level 0.5) as compared to an authorised use with the use restriction NW 605/606, 0 %/10 m, 50 %/5 m, 75 %/5 m, 90 %/* m (relative level of risk 5.2 – factor 10.4) would thus not be detected via the score (R_{Score} without use restriction: 2,0; with NW 605/606 5.5 – factor 2.75). In the opposite

direction, it can be safely assumed that a factor ≥ 10 between two R_{Score} values will indeed describe a "significantly lower risk" according to the Regulation.

rel. risk level	use restr.	0%	50%	75%	90%	I_{AWB}	I'_{AWB}	R_{Score}
0.5	none	0	0	0	0	1.85	0.7	0.90
1.1	NW 609	5	0	0	0	1.35	0.9	1.92
2.2	NW 605/606	5	5	0	0	1.1	1.0	2.68
2.6	NW 605/606	5	5	5	0	0.975	1.0	3.16
5.2	NW 605/606	10	5	5	0	0.725	1.2	4.48
5.3	NW 605/606	15	5	5	0	0.6	1.3	5.43
5.4	NW 605/606	15	10	5	0	0.475	1.5	6.74
7.5	NW 605/606	15	10	5	5	0.425	1.5	7.41
10.0	NW 605/606	20	10	5	5	0.3625	1.7	8.45
10.3	NW 607		10	5	5	0.3	1.8	9.79
10.5	NW 607		15	5	5	0.2375	2.1	11.63
15.0	NW 607		15	10	5	0.175	2.4	14.39
20.0	NW 607		20	10	5	0.14375	2.6	16.41
20.7	NW 607			10	5	0.1125	3.0	19.21
26.3	NW 607			15	5	0.08125	3.5	23.50
30.0	NW 607			15	10	0.05625	4.2	29.27
40.0	NW 607			20	10	0.040625	5.0	35.35
51.7	NW 607				10	0.025	6.3	46.46
75.0	NW 607				15	0.0125	8.9	67.81
100.0	NW 607				20	0.00625	12.6	98.00

b) terrestrial off-field habitats

Analogous to the risk assessment for surface water bodies, TER values are calculated for spray drift entries of plant protection products in terrestrial off-field habitats that are based on a matrix of PEC values depending on buffer zones kept and drift-reducing nozzles used during the application. Again, the ecotoxicity of a compound is described by a relevant effect value (LR_{50}, ER_{50}, ...) in combination with an adjusted assessment/safety factor. Different from the assessment for surface water bodies, only buffer zones up to 5 m can be considered; therefore, a comparatively smaller matrix of generic TER values or relative risk levels is produced, as demonstrated for the drift scenario arable crops.

drift red.	0 %	50 %	75 %	90 %
buffer zone				
* m	2,1	4,1	8,2	20,6
5 m	10	20	40	100

* for authorisation purposes, a distance of 1 m (application in arable crops) or 3 m (application in high crops) is assumed

As described above, the use restrictions that are necessary for granting an authorisation of the plant protection product in a given use reflect actual risk levels. Deviating from the approach for surface water bodies, mitigation of spray drift entries to terrestrial off-field habitats must in first instance be achieved by drift-reducing nozzles and then only in second instance by buffer zones. A specific use restriction is assigned to each of the 6 possible combinations of buffer zone and nozzle technique. These restrictions are coded with figures increasing from 101 to 109, and may therefore in principle be used for calculating an index I_{AWB} = [use restriction code] – 100.

rel. risk level	use restr.	I_{AWB}
2.1	none	0
4.1	NT 101	1
8.2	NT 102	2
10	NT 103	3
20	NT 103	
20.6	NT 103	
40	NT 108	8
100	NT 109	9

Like the use restrictions for the protection of aquatic ecosystems, also those for the protection of terrestrial ecosystems may be employed for a computer-based automated sorting of plant protection products authorised for a certain use according to their risk for terrestrial arthropods or plants in off-field habitats. Owing to the lower discriminatory power of the system with max. 6 risk levels, and also due to the different exposure conditions in the pertinent ecotoxicity test systems, extrapolation from specific plant or arthropod risk estimates to the entire environment is clearly not meaningful.

Different from the index based on use restrictions for the protection of aquatic ecosystems, the I_{AWB} derived from use restrictions to protect terrestrial ecosystems is not founded on realistic quantitative drift-reduction estimates, but on the numbering of (not equidistant) risk levels. Nevertheless, it can be demonstrated by plotting the I_{AWB} against the values of the corresponding risk levels (here termed as R) that the index can be considered in a good approximation as being proportional to the logarithmic risk levels. For the drift scenario arable crops, the following functional equation can be derived:

$I_{AWB} = 2.5737 \times \ln R - 2.5382$
with a coefficient of determination $r^2 = 0.9654$

When transferring this concept to the use restrictions as they can be imposed for high crops, it must be taken into account that the use restrictions for the combination of default distance and drift-reducing nozzles have other codes (NT 104…106) than those for arable crops (NT 101…103), whereas the use restrictions for the combination of a 5-m buffer zone and drift-reducing nozzles share the same coding in both cases (NT 107…109). However, the relative impact of the 5-m buffer zone on risk levels as compared tot he respective standard distance is similar for arable and high crops; hence, the use restriction codes NT 104…106 for high crops should be replaced by the corresponding use restriction codes NT 101…103 for arable crops when the I_{AWB} is calculated.

I_{AWB} = [use restriction code] – 100 for NT 101…103
I_{AWB} = ([use restriction code] – 3) – 100 for NT 104…106
I_{AWB} = [use restriction code] – 100 for NT 107…109

Using linear regression, the following relationships are obtained between the logarithmic relative risk level and the index I_{AWB}:

Drift scenario arable crops	$I_{AWB} = 2.5737 \times \ln R - 2.54$
Drift scenario vines	$I_{AWB} = 3.2208 \times \ln R - 5.46$
Drift scenario orchards early	$I_{AWB} = 3.4825 \times \ln R - 6.99$
Drift scenario orchards late	$I_{AWB} = 3.3289 \times \ln R - 6.11$
Drift scenario hops	$I_{AWB} = 3.4167 \times \ln R - 6.57$
Drift scenario averaged	$I_{AWB} = 3.2047 \times \ln R - 5.54$

Via the inverse function $\ln R_{Score} = 0.3120 \times I_{AWB} + 1.73$ of the linear function for the averaged drift scenarios, the index I_{AWB} can also here be converted into a risk score (R_{Score}), which basically depicts the level of risk that had to be taken into account for imposing the respective use restriction for the given use. The goodness of fit as expressed by the coefficient of determination r^2 ranges from 0.9071 to 0.9956 for the 5 most important drift scenarios and is thus slightly lower than for the R_{Score} based on use restrictions to protect aquatic ecosystems. Nevertheless, the values are still deemed to be of sufficient quality for the intended function of the risk score.

Drift scenario arable crops	$r^2 = 0.9071$
Drift scenario vines	$r^2 = 0.9200$
Drift scenario orchards early	$r^2 = 0.9956$
Drift scenario orchards late	$r^2 = 0.9578$
Drift scenario hops	$r^2 = 0.9798$

Again, the detailed comparison of values for the drift scenario arable crops as an example case demonstrates that the R_{Score} based on use restrictions to protect terrestrial organisms might not capture each individual case of a “significantly lower risk” according to the Regulation. It can, however, be safely assumed that a factor ≥ 10 between two R_{Score} values will describe such “significantly lower risk” with high certainty.

R	ln R	I_{AWB}	R_{Score}
2.1	0.7419	0	5.6
4.1	1.4110	1	7.7
8.2	2.1041	2	10.5
10	2.3026	3	14.4
40	3.6889	8	68.5
100	4.6052	9	93.5

Summary

a) R_{Score} Aquatic

1. Derivation of the I_{AWB} from the imposed use restriction NW 60x with the relevant data with regard to nozzle technique and buffer zone

$$I_{AWB} = \sum_{n} (1 - D_n) \times 0{,}5^{B_n / 5}$$

D_n: nozzle technique (D_1 = 0 %, D_2 = 50 %, D_3 = 75 % and D_4 = 90 % drift reduction)
B_n: buffer zone to be kept to achieve an acceptable risk ($A_{1\ldots4}$ = 5…20 m); where a buffer zone of 20 m is not sufficient, the term to be summed is zet to 0..

2. Transformation

$$I'_{AWB} = \sqrt{\frac{1}{I_{AWB}}}$$

3. Calculation of the R_{Score}

$R_{Score} = 8.1502 \times I'_{AWB} - 5.09$

4. Assessment criteria

$R_{Score} / R'_{Score} \geq 10$	significant difference in risk can be expected
$10 > R_{Score} / R'_{Score} \geq 5$	significant difference in risk is possible
$R_{Score} / R'_{Score} < 5$	significant difference in risk is unlikely

b) R_{Score} Terrestrial

1. Derivation of the I_{AWB} from the imposed use restriction NT 10x

I_{AWB} = [use restriction code] – 100	for NT 101…103
I_{AWB} = ([use restriction code] – 3) – 100	for NT 104…106
I_{AWB} = [use restriction code] – 100	for NT 107…109

2. Calculation of the R_{Score}

$\ln R_{Score} = 0.3120 \times I_{AWB} + 1.73$

3. Assessment criteria

$R_{Score} / R'_{Score} \geq 10$	significant difference in risk can be expected
$10 > R_{Score} / R'_{Score} \geq 8$	significant difference in risk is possible
$R_{Score} / R'_{Score} < 8$	significant difference in risk is unlikely