Environmental Risk Assessment Handbook For Pesticide Registration in China

F.M. Peeters, Qu Mengmeng, Piao Xiuying, H. van der Valk and Tao Chuanjiang

ALTERRA
WAGENINGEN UR

Environmental Risk Assessment

Handbook for pesticide registration in China

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The work described in this report is done within the framework of the Sino-Dutch Pesticide Environmental Risk Assessment project (PERAP). PERAP is a cooperation platform between Chinese and Dutch governmental bodies and research institutes. The PERAP project is intended to assist China in the development of Chinese Environmental Risk Assessment (ERA) procedures for pesticide registration, including developing a series of relevant guidance documents.The underlying handbook is developed with the expertise provided by the project and therefore it is considered as one of the deliverables of the PERAP project. The handbook aims to increase the transparency and consistency in the ERA in the registration process. The handbook's major target readership includes Chinese regulatory authorities (ICAMA and the local Institutes for the Control of Agrochemicals (ICAs)), as well as other relevant research organizations and institutes and stakeholders in the context of pesticide registration.

The handbook focusses on 'environmental' and 'beneficial animals'. Aquatic ecosystems, birds, honeybees, silkworms and groundwater were selected as protection goals and for each of the protection the following three questions were answered : What do we want to protect? Where do we want to protect? How strict do we want to protect? For each protection goal risk assessment procedures are described. The risk characterization is expressed as a Risk Quotient (RQ) which is calculated by dividing the exposure concentration by the safe concentration (i.e. PEC/PNEC). If the value of RQ is below or equal to 1, i.e. the exposure is lower than the safe concentration, then the risk is acceptable. If the value of RQ is above 1, i.e. the exposure is higher than the safe concentration, it might be possible that the risk is not acceptable and higher tier risk assessment is needed. If higher tier assessment does not result in acceptable risk, mitigation measures or restrictions are given for every protection goal.

Keywords: pesticides, environment, risk assessment, tiered approach, protection goal, aquatic ecosystems, birds, honeybees, silkworm, groundwater

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Preface

The work described in this report is done within the framework of the Sino-Dutch Pesticide Environmental Risk Assessment project (PERAP). PERAP is a cooperation platform between Chinese and Dutch governmental bodies and research institutes.

The Institute for the Control of Agrochemicals, Ministry of Agriculture of the MoA (ICAMA) is responsible for the pesticide registration procedures in China. The following themes are considered to be of importance in the registration procedure:
1. Physical / chemical properties;
2. Analytical methods;
3. Human toxicology;
4. Residues;
5. Environment (behavior and fate of pesticides and ecotoxicology);
6. Efficacy.

The PERAP project is intended to assist China in the above mentioned theme "Environment" with the main goal to develop Chinese Environmental Risk Assessment (ERA) procedures for pesticide registration, including developing a series of relevant guidance documents. ICAMA and Alterra, Wageningen-UR, the Netherlands, the Chinese Agricultural Academy of Sciences (CAAS) and WILresearch, the Netherlands, have been working together towards this aim as the four major participants of the PERAP project. Some other institutions/organizations, such as Plant Research International, Wageningen UR, the Netherlands, Ctgb (Board for the Authorisation of Plant Protection Products and Biocides, the Netherlands), and others also made valuable contributions to this joint project.

The work was subdivided in 5 work packages and the main purposes of each work package is summarized below:
1. Project inception and formalization, overall project management, formalizing the continuation of the activities of the consortium partners after 2009;
2. Development of a risk assessment handbook, training of staff of four Contract Laboratories and ICAMA in the use of the handbook;
3. Development of guidelines and SOPs for standardized laboratory tests and working towards GLP certification of the ICAMA laboratories;
4. Development of capacity in working with environmental fate models and development of protective scenarios for China;
5. Develop, discuss and formal approval of the criteria for ERA.

The project aimed at the development of sound environmental risk assessment procedures, applicable in the Chinese context and acceptable as legal framework for the Chinese registration procedure. This entails development of (i) capacity to perform eco-toxicological and behavioural tests under GLP, (ii) methods to estimate exposure under normal agricultural use of pesticides and (iii) a risk assessment handbook.
This report is the end result of activity (iii). The work for this activity is mainly performed by Alterra (part of Wageningen UR), being the scientific partner on the Dutch side, and the Chinese regulatory authority ICAMA (Institute for the Control of Agro-chemical of the Ministry of Agriculture).

The basis of the work described is based on the extended and long-time experience of the Dutch partner Alterra with risk assessment development in the Netherlands and the European Union.

The underlying handbook is developed with the expertise provided by the project and therefore it is considered as one of the deliverables of the PERAP project. The handbook aims to increase the transparency and consistency in the ERA in the registration process. The handbook's major target readership includes Chinese regulatory authorities (ICAMA and the local Institutes for the Control of Agrochemicals (ICAs)), as well as other relevant research organizations and institutes and stakeholders in the context of pesticide registration.

Abbreviations

a.i.:	Active ingredient
ADI:	Acceptable Daily Intake
AR:	Application Rate
ARG:	Maximum Granule Application Rate
AV:	Avoidance factor
BCF:	Bio concentration Factor
$B_{loading}$:	Amount of the active ingredient on one Bait
bw:	body weight
C_0:	Initial Concentration after a single application (in Chapter 3)
cb:	Content of active ingredient in bait
cg:	Content of active ingredient in Granule
China-PEARL:	PEC calculation model
Ctgb:	Board for the Authorisation of Plant Protection Products and Biocides, the Netherlands
DDFI:	Daily Dry Food Intake of the indicator species
DDSI:	Daily Dry Soil Intake of the indicator species
DFI:	Daily Food Intake
DF_{phi} :	Degradation factor, when a pre-harvest interval between pesticide application and harvesting of mulberry leaves is applied
DGI:	Daily Grit Intake of birds
DT_{50}:	Time for 50% loss; half life due to dissipation
$DegT_{50}$:	Time for 50% degradation; half life due to degradation
EC_{50}:	Median effective concentration
EC_{rodent}:	Estimated rodenticide Concentration in the rodent (mg a.i./kg)
EC_i:	Estimated Concentration in rodent before a new meal on day n
EC_o:	Estimated Concentration in rodent immediately after one meal
EL:	Fraction of daily uptake eliminated
EPPO:	European and Mediterranean Plant Protection Organisation
ERA:	Environmental Risk Assessment
EU:	European Union
FIR:	Food Intake Rate
FIR/bw:	Food intake rate of indicator species per body weight per day
f_{twa}:	Time-Weighted-Average Factor
$G_{loading}$:	Amount of the active ingredient on one Granule
$G_{surface}$:	Number of Granules at soil surface
cr:	content of active ingredient in rodenticide
IDEFICS:	Spray drift simulation model
IGR:	Insect Growth Relator
Kd:	Soil parameter, sorption constant
K_f:	Freudlich adsorption coefficient
Koc:	Soil parameter, organic carbon sorption constant
Kom:	Soil parameter, organic matter sorption constant
Kow:	Partition coefficient between n-octanol and water
ICA:	(provincial) Institute for the Control of Agrochemicals, under the supervision of ICAMA
ICAMA:	Institute for the Control of Agrochemicals, Ministry of Agriculture
LC_{50}:	Median Lethal Concentration
LD_{50}:	Median Lethal Dose
LOAEL:	Lowest Observed Adverse Effect Level
LOEC:	Lowest Observed Effect Concentration
LOEL:	Lowest Observed Effect Level

MAF:	Multiple Application Factor
$MAF_{90\%}$:	Multiple Application Factor to be used with 90^{th} percentiles of residues
MAF_{mean}:	Multiple Application Factor to be used with arithmetic means of residues
M_M:	Molar mass of the relevant metabolite
MOA:	Ministry of Agriculture, P.R. China
M_p:	Molar mass of the parent substance
MRL:	Maximum Residue Limit
NOAEL:	No Observed Adverse Effect Level
NOEC:	No Observed Effect Concentration
NOEL:	No Observed Effect Level
NOEAEC:	No Observed Ecologically Adverse Effect Concentration
OBD:	One Bait Dose
OBW:	One Bait Weight
OECD:	Organization for Economic Cooperation and Development
OGW:	One Granule Weight
OSD:	One Seed Dose
OSW:	One Seed Weight
PaddyPearl:	PEC calculation model
PD:	Fraction of food type in Diet
PDF:	Pesticide Drift Factor
PEARL:	Pesticide Emission At Regional and Local scales (soft ware)
PEC:	Predicted Environmental Concentration
PEC_{gw}:	Predicted Environmental Concentration in groundwater
PEC_{ma}:	Predicted Environmental concentration on mulberry leaves for multiple application
PEC_{ma-fr} :	Predicted Environmental concentration on first row mulberry leaves for multiple application
PEC_{ma-sr}:	Predicted environmental concentration on second row mulberry leaves or multiple application
PEC_{max}:	Predicted Environmental Concentration, maximum
PEC_{twa}:	Predicted Environmental Concentration, time-weighted average
PEC_{syst} :	Predicted Environmental Concentration of systemic substance in pollen or nectar
PEC_{sa}:	Predicted Environmental concentration on mulberry leaves for single application
PEC_{sa-fr}:	Predicted Environmental Concentration on first row mulberry leaves for single application
PEC_{sa-sr}:	Predicted Environmental Concentration on second row mulberry leaves for single application
PDF_{fr}:	Pesticide Drift Factor for first row mulberry tree
PDF_{sr}:	Pesticide Drift factor for second row mulberry tree
PERAP:	(Sino-Dutch) Pesticide Environmental Risk Assessment Project
PHI:	Pre Harvest Interval
pKa:	log10 acid dissociation constant
PNEC:	Predicted No Effect Concentration
Pow:	the same as Kow
PT:	Fraction of diet obtained in Treated area
QSAR:	Quantitative Structure Activity Relationship
RIVM:	Rijks Instituut voor Volksgezondheid en Milieu, National Institute for Public Health and Environment, the Netherlands
$Residue_p$:	Residues in pollen or nectar of the relevant crop
RQ:	Risk Quotient
RUD:	Residue Unit Dose
$RUD_{90\%}$:	90^{th} percentile of Residue Unit Dose
RUD_{mean}:	Arithmetic means of Residue Unit Dose
RUD_{95} :	95^{th} percentile of the Residue Unit Dose
SETAC:	Society of environmental Toxicology And Chemistry
SFO:	Single First Order kinetics
$S_{loading}$:	Amount of the active ingredient on one Seed
$SP_{surface}$:	Number of Soil Particles at soil surface in the same size classes as granules

TWA:	Time-Weighted Average
TOXSWA:	TOXic substances in Surface Waters (soft ware)
TOP-rice:	Software interface
UF:	Uncertainty Factor
Wageningen-UR:	Wageningen University and Research Center, the Netherlands
WHO:	World Health Organization
%soil:	Percentage of dry soil in dry diet of indicator species

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1 Introduction

1.1 Legislation and policy background

The following regulations and rules should be considered as the legislation/policy background for this handbook:

- Regulation for Pesticide Administration (State Council Command No. 216, issued on May 8th, 1997 and revised on Nov. 29th, 2001);
- Implementation Approaches under the Regulation for Pesticide Administration (MOA Command No. 20, Jul 23rd, 1999 and revised on Jul 27th,2002, Jul 1st, 2004, Dec 8th, 2007));
- Dossier Requirements for Pesticide Registration (MOA Command No. 10, Jan 8th, 2008);
- National Food Safety Act (President Command No. 9, issued on Feb 28th,2009 and enforced on Jun 1st)- Implementation Regulation under the Context of National Food Safety Act (State Council Command No. 557, issued on Jul 20th, 2009);
- Drinking Water Management Act;
- Environmental Quality Standards for Surface Water (GB 3838-2002).

1.2 Contributions of ERA to environmental risk management

As mentioned in the 'Preface', one of the most important aspects to consider in the pesticide registration procedure is the impact of pesticides on the environment. ERA is used world-wide to examine the effects of an active ingredient (a.i.) or a formulated product on the environment, and it supports many types of management actions, including the regulation of pesticides. It provides information to risk managers about the effects on the environment of different management decisions. Attempts to eliminate risk associated with human activities in the face of uncertainties and potentially high costs present a challenge to risk managers. Although many considerations and sources of information are used by managers in the decision process, ERA is in particular adequate in providing a scientific evaluation of environmental risk.

The ERA process has several features that contribute to effective environmental decision-making:

- ERA can be used to predict changes in eco-toxicological effects as a function of changes in exposure to pesticide;
- ERA explicitly evaluates the uncertainty in the assessment. Uncertainty reflects the degree of confidence in the assessment and can help the risk manager to focus the research on those areas that will lead to the greatest reductions in uncertainty;
- ERA considers protection goals scientifically as well as politically in developing assessment endpoints and models. Such initial planning activities help ensure that results will be useful to risk managers.

1.3 ERA methodology

1.3.1 Protection goal

In '*Regulation for Pesticide Administration'* (State Council Command No. 216, issued on May 8th, 1997, revised on Nov. 29th, 2001), the following provision is given in terms of environmental protection:

'The use of any pesticide product should secure the protection of the environment, beneficial animals and endangered species.' (Item 28, Chapter 6).

This provision is generally the overall protection goal that the risk managers intend to achieve. However, in order to set up a pragmatic assessment approach and facilitate the communication between various groups with an interest, the provision should be elaborated in more detail, especially with regard to explicit definition of the terms 'environment', 'beneficial animals', and 'endangered species'. At this stage of development of ERA in China, the handbook focuses on 'environment' and 'beneficial animals'. 'Endangered species' should be taken into account in the future during the further development of ERA in China.

As a first step the following protection goals are selected in this handbook:
1. Aquatic ecosystem
2. Birds
3. Honeybees
4. Silkworms
5. Groundwater.

Additional environmental protection goals will be defined at later stages, representing other parts of the environment and other beneficial animals.

Each of the above protection goals will be elaborated upon in the section 'Detailed protection goals' in each chapter of this handbook.

The detailed protection goals will be addressed by answering the following three questions:
1. **What** do we want to protect?
   Which part of the environment, which species, etc.

2. **Where** do we want to protect?
   Which type of surface water, groundwater at which depth? On which specific geographical locations?

3. **How strict** do we want to protect?
   What are the criteria? Also related to the distinction between long term and short term effects.

1.3.2 The concept of ERA

The ERA approach outlined in this section attempts to address the concern for the potential impact of pesticides on the environment by examining both exposures resulting from pesticide emissions, as well as the effects of such emissions on the structure and function of the ecosystem.

The ERA approach is based on three basic assessment processes:
- Exposure analysis;
- Effect assessment;
- Risk characterization.

Figure 1.1 gives an overview of the approach of the ERA adopted in this handbook.

Possible risk should be characterized quantifiably, based on the comparison between the exposure parameters and the effect parameters. For those cases where a quantitative assessment of the exposure and/or effects is not possible a qualitative assessment can be performed.

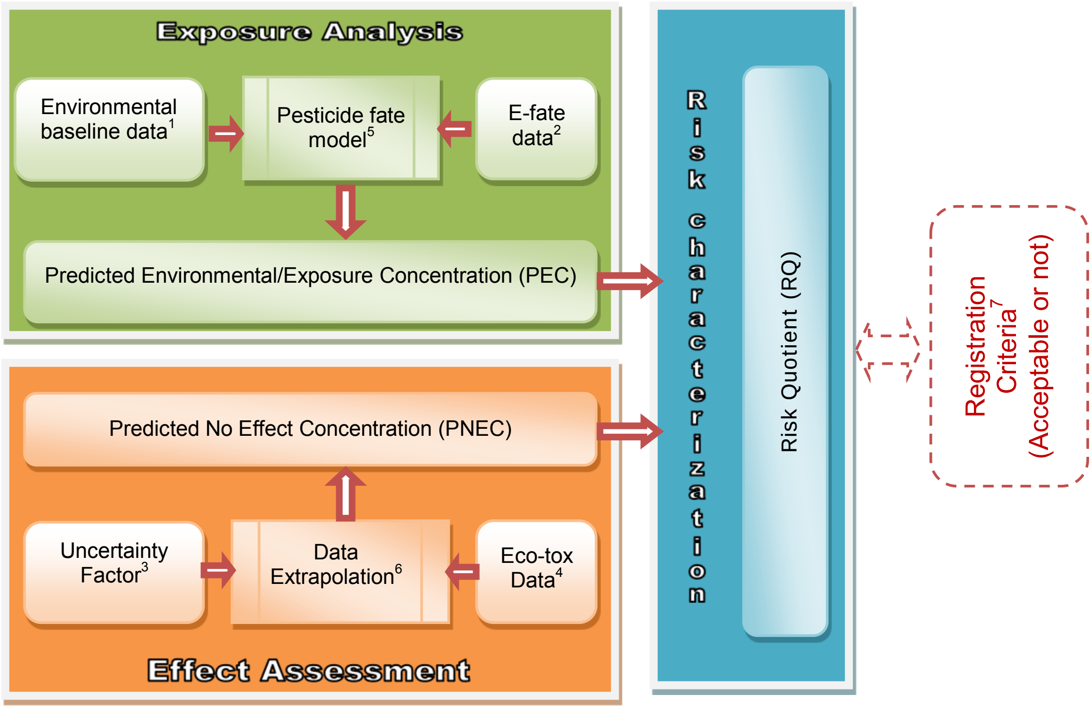

Figure 1.1 *Flowchart for the Environmental Risk Assessment approach adopted in this handbook.*

Explanation of notes in figure 1.1

1. Environmental baseline data: data used for establishing pesticide environmental fate model and scenario, including geographic data, meteorological information, crop category, etc.
2. E-fate data: data submitted in accordance with the Dossier Requirement for Pesticide Registration (*MOA Command No. 10, Jan. 8th, 2008*) and used as input parameters for pesticide environmental fate model, e.g. $DegT_{50}$ in soil, Koc.
3. Uncertainty factor: an expression of the degree of uncertainty in extrapolation from laboratory toxicity data on a limited number of species to the 'real' environment. See also 'Effect assessment' in this section.
4. Eco-tox data: data from ecotoxicological studies submitted in accordance with the Dossier Requirement for Pesticide Registration (*MOA Command No. 10, Jan. 8th, 2008*), e.g. acute toxicity to fish, etc.
5. Pesticide fate model: tools (i.e. computer program) used in exposure analysis for estimating the Predicted Environmental Concentration (PEC).
6. Data extrapolation: process of extrapolating from laboratory toxicity data on a limited number of species to the 'real' environment.
7. Registration criteria: the criteria based on management decision.

1.3.2.1 Effect assessment

A dose (concentration) – response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This concentration is known as the Predicted No Effect Concentration (PNEC).

The PNEC shall be based on the data from the eco-toxicological studies submitted in accordance with the Dossier Requirement for Pesticide Registration (*MOA Command No. 10, Jan. 8th, 2008*). The PNEC shall be extrapolated from the lowest values resulting from tests on organisms by applying a proper uncertainty factor. Usually results from single species laboratory tests are available, e.g. LD_{50} (median lethal dose), LC_{50} (median lethal concentration), EC_{50} (median effective concentration), or NOEL(C) (no-observed-effect level (concentration)). In several cases, established effect and/or no-effect concentrations from model ecosystem tests are available.

An uncertainty factor reflects the degree of uncertainty in extrapolation from single-species laboratory data to the multi-species ecosystem. Therefore, in general, as data is more extensive and tests are of longer duration, the degree of uncertainty will be smaller, and the uncertainty factor will also be smaller. For this reason long-term data are preferable over short-term data. The following aspects should be taken into account, if appropriate, when choosing the uncertainty factor:

- Intra- and inter-laboratory variation of toxicity data;
- Intra- and inter-species variation of toxicity data;
- Short-term to long-term/chronic toxicity extrapolation;
- Extrapolation of mono-species laboratory data to field impact on ecosystems.

1.3.2.2 Exposure analysis

The information on fate and behavior of pesticides in the environment is central to the assessment of the impact on non-target species. For each environmental compartment an exposure analysis shall be carried out in order to predict the concentration of the a.i. likely to be found. This concentration is known as the Predicted Environmental Concentration (PEC).

A PEC only needs to be determined for the environmental compartments to which emissions, discharges or distributions, including any relevant contribution from materials treated with formulated products (e.g. crop, etc.) are known or are reasonably foreseeable. The PEC shall be determined taking account of, in particular, and if appropriate:

- Adequately measured exposure data;
- The form in which the formulated product is marketed;
- The type of the formulated product;
- The application method and application rate;
- The physical-chemical properties of the pesticide;
- The relevant metabolites;
- Likely pathways to environmental compartments and potential for degradation and adsorption/desorption;
- The frequency and duration of exposure.

Where adequately measured and representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

1.3.2.3 Risk assessment

A risk assessment will be done for those environmental compartments that are exposed to the formulated product. The risk characterization will be expressed as a Risk Quotient (RQ) which is calculated by dividing the exposure concentration by the safe concentration (i.e. PEC/PNEC). If the value of RQ is below or equal to 1, i.e. the exposure is lower than the safe concentration, then the risk is acceptable. If the value of RQ is above 1, i.e. the exposure is higher than the safe concentration, it might be possible that the risk is not acceptable and higher tier risk assessment is needed. If higher tier assessment does not result in acceptable risk, mitigation measures or restrictions are needed (See also the sections below).

If it has not been possible to derive a RQ, the risk characterization shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure. (appropriate field studies and probabilistic methods may be applied case by case by expert judgment with a comprehensive description of the methodology and interpretation of the results.)

At present, an ERA methodology has been developed for each of the protection goals: aquatic ecosystems, birds, honeybees, silkworms and groundwater.

1.3.3 Tiered approach

In this handbook, the ERA for each protection goal follows a tiered approach in order to minimize costs and to encourage low risk products. Figure 1.2 shows the tiered approach for ERA described in this handbook.

Ideally, the less risk a product poses, the less cost will be necessary to pass the risk assessment. The first tier is based on model output with respect to exposure and laboratory data with respect to eco-toxicity. This is a general and simple conservative (worst-case) evaluation of the behavior and toxicity of the substance in the environment. Where the criteria of the first tier of the evaluation are not met, there is the possibility to submit supplementary data for conducting a refined risk assessment (higher tier). Higher tier data are more complex data that give a more realistic view (realistic-case).

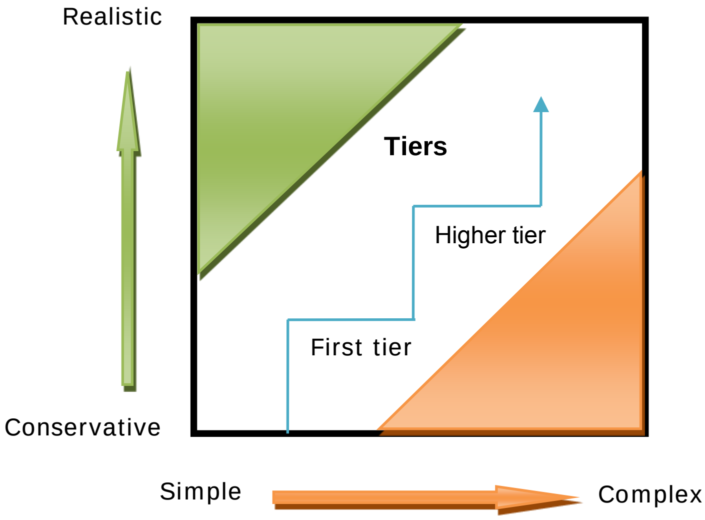

Figure 1.2 *Tiered approach for conducting ERA (redrafted after Solomon et al., 2008).*

The risk assessment can be refined by:
- Refining the exposure estimate (e.g. require measured pesticide residue data) and/or
- Refining the effect assessment (e.g. require data on more species).

In this handbook, the conceptual model of the risk assessment scheme was set up in such a way that any tiers for the effect assessments can be linked to any of the tiers for the exposure analysis, and vice versa by following the recommendations made by Boesten *et al.* (2007).
This so-called 'criss-cross' concept model allows optimal flexibility in the data that may be submitted by the applicant and in the assessment. Figure 1.3 shows the 'criss-cross' model. It should be noted that the exposure analysis and effect assessment for each protection goal contain different tiers but not necessarily three tiers and Figure 1.3 is intended to illustrate the possible combinations of exposure analysis and effect assessment.

However, the 1st tier risk assessment should be considered as a standard module and conducted as the first step of risk assessment for registration purposes. The methodology of the 1st tier assessment is explicitly elaborated upon in every relevant chapter, based on a combination of the 1st tier exposure analysis and 1st tier effect assessment. This is a general conservative evaluation of the behavior and toxicity of the substance in the environment. The uncertainty, generated from the assessment methodology, is quantified on the basis of scientific consensus and expert judgment.

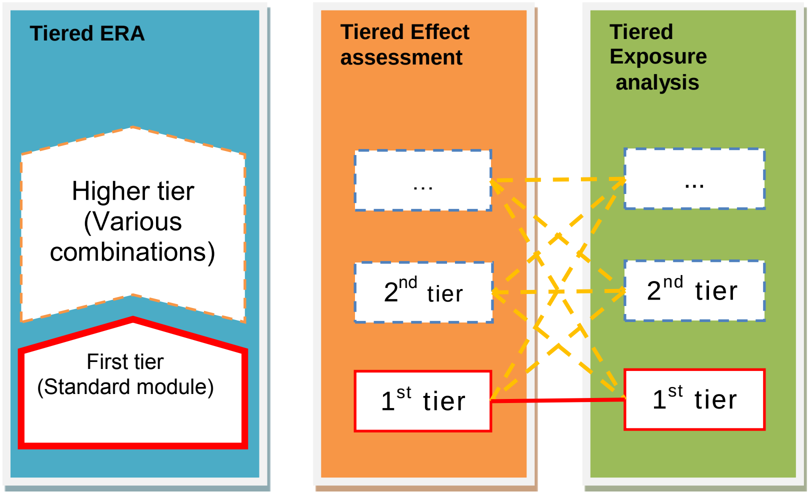

Figure 1.3 *The 'criss-cross' model allowing the flexibility in the tiered approach of ERA*

1.3.4 Environmental risk management suggestions based on ERA

The methodologies for ERA aim to identify whether the risk to the environment is acceptable or unacceptable. This identification provides the basis for the regulatory decision-making. If the risk is considered unacceptable, the risk assessment can be refined using the tiered approach (see also Section1.3.3). Independent of refinement according to the tiered approach, the risk can be re-assessed taking into account the estimated effect of a risk mitigation measure.

If the risk is considered acceptable after such refinement, there would be no impediment to registration of the pesticide with regard to the protection goal in question. Registration may be unconditional, or under the condition that risk mitigation measures be taken.

If, on the other hand, after refinement of the ERA the risk is still considered to be unacceptable, or refinement of the ERA was not possible, various options are available with respect to risk management of that pesticide:

- Refuse registration of the high risk use(s) of the pesticide;
- Refuse registration of all uses of the pesticide (e.g. if the risks of using the product are high, and the probability of it being used on other crops or in other use situations is high);
- Authorize the pesticide, with or without risk mitigation measures, but accepting a certain level of risk (e.g. for pesticides which are of great agronomic importance and for which no alternative products or pest management options are available).

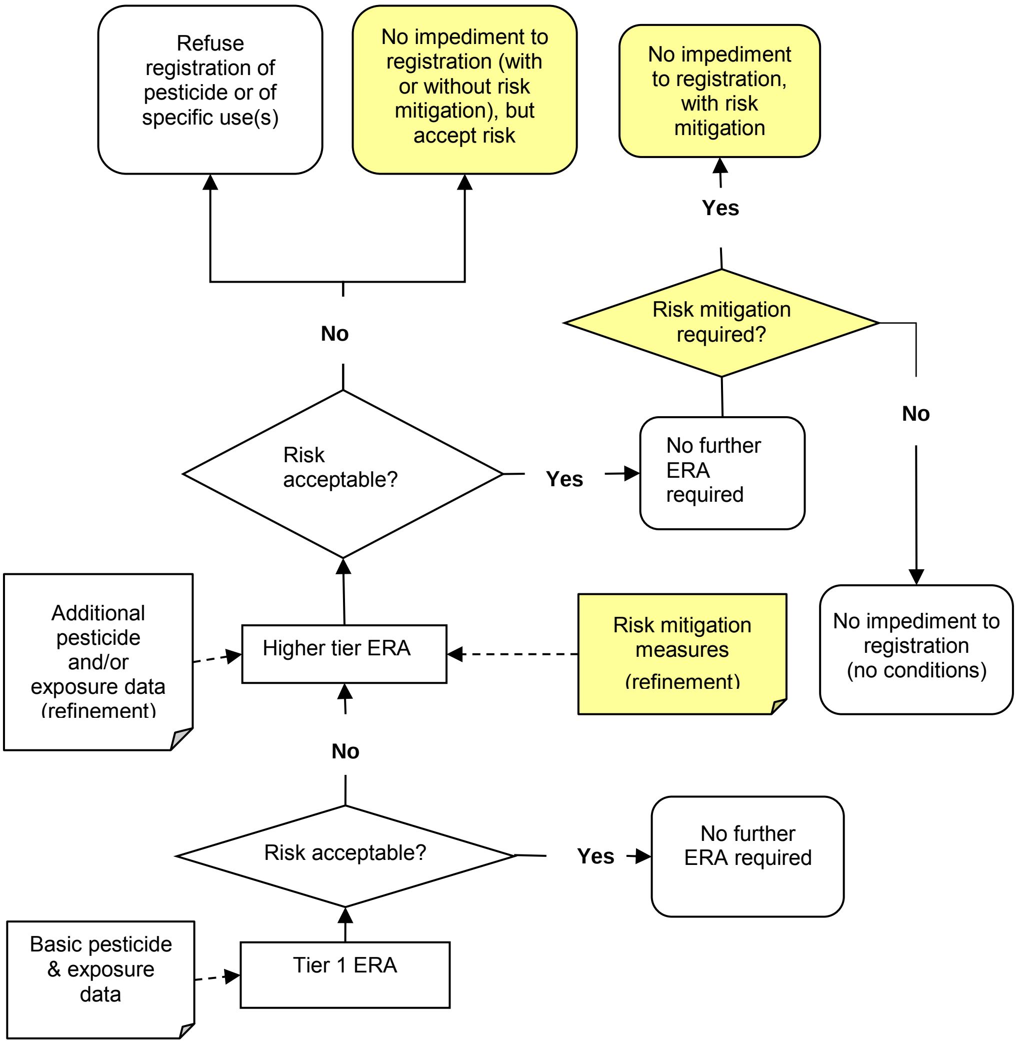

Figure 1.4 *The place of risk mitigation in ERA and decision-making process.*

Therefore, risk mitigation measures are first considered at the level of the environmental risk assessment. Subsequently, risk mitigation measures may become a condition for the authorization of the pesticide. In the latter case, specific restrictions apply or risk phrases are added to the label of the product. Hence, such information should be provided by the assessors to the risk managers to facilitate a 'scientifically-based' regulatory decision. Figure 1.4 schematically shows the link between risk mitigation, risk assessment and decision-making.

A section of 'Environmental Risk Management Suggestions' is included in each chapter of this handbook in order to provide the assessors with the guidance on how to derive management suggestions such as mitigation measures, precautionary notes for labeling, etc.

1.4 Data Requirements

ERA for pesticide registration is normally carried out on the basis of dossiers which are submitted by the applicants in line with the provisions of Dossier Requirements for Pesticide Registration (*MOA Command No. 10, Jan 8th, 2008*).

From a scientific point of view, the dossiers submitted should contain sufficient information to permit an assessment of the impact on every protection goal which is likely to be at risk from exposure to the active ingredient, its metabolites, degradation and reaction products possibly of toxicological significance.

Impact can result from a single, a prolonged or a repeated exposure and can be reversible or irreversible. In particular, the dossiers submitted should suffice to:
- Specify appropriate conditions or restrictions to be associated with any registration;
- Permit an evaluation of risks for the appropriate protection goals;
- Classify the pesticide product / active ingredient according to its hazard;
- Specify the precautions necessary for the protection of appropriate protection goals, to be mentioned on packaging (containers).

In each of the following chapters, detailed guidance is given which data are considered necessary to permit a risk assessment with regard to every protection goal discussed in this handbook.

1.5 Uniform structure of each chapter

In order to facilitate better communication with all groups with an interest, all the chapters are presented according to the uniform structure shown in Figure 1.5.

In the 'Environmental Risk Assessment' section of each chapter, flow charts of decision-making schemes are given to demonstrate the tiered risk assessment process for each of the protection goals considered. It should be noted that the uniform structure will be applied only if it is appropriate. In some special cases, the relevant chapters may be organized according to an alternative structure.

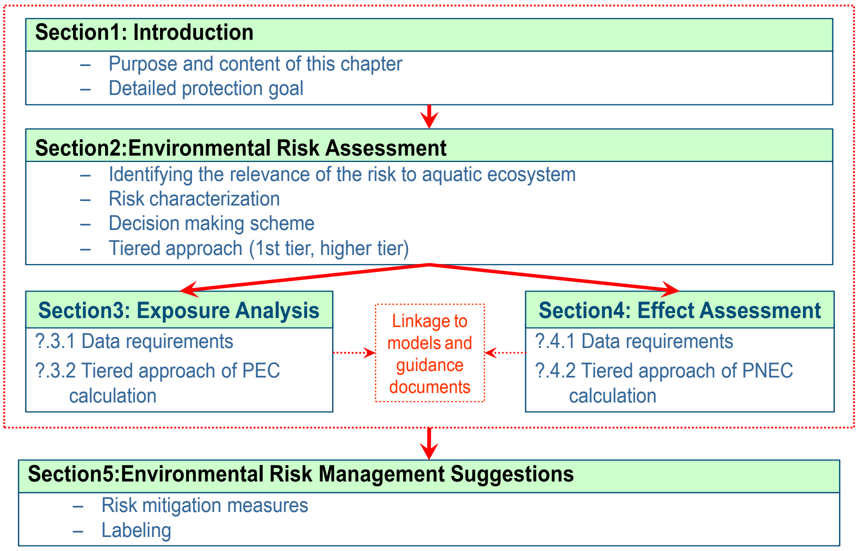

Figure 1.5 *The uniform structure of each chapter in this handbook.*

1.6 Future development

Research on the topic of environmental risk assessment is continuously being carried out, and tools and techniques progress rapidly. It should be noted that it can be difficult to fully take such progress into account in the dossiers and assessment reports during ongoing reviews. Therefore, depending on new developments in science and policy, the handbook should be updated periodically in order to make use of the best knowledge available. The following aspects have been recognized in the handbook as issues which at present cannot be addressed in this handbook and which need further attention in the future (the list is not exhaustive).

1.6.1 Evaluation of data submitted by the applicant

During the risk assessment it is very important to evaluate data with regard to their adequacy and completeness. Such an evaluation should be done in an impartial way using explicit and uniform standards. Hence it is necessary to develop a document to provide sufficient guidance on how to evaluate available data. This guidance document is not yet part of the manual but will be added at a later stage.

1.6.2 Metabolites

The a.i. of a formulated product may be transformed in the environment by either abiotic or biotic processes. Therefore, the potential risk of its metabolites, where they are of eco-toxicological relevance, should be assessed as well. In principle, the risk assessment process for metabolites will be similar to that for a.i.

The risk of metabolites is considered in this handbook for groundwater only. In the future, it is necessary to carry out some research so as to provide guidance on when and how to assess the risk of metabolites regarding the other protection goals.

1.6.3 ERA for a formulated product containing more than one a. i.

For a formulated product containing more than one active ingredient (a.i.), combination toxicity must be determined. This also applies to combinations of pesticide products for which a combination (tank mix) is recommended in the directions for use. There are some guidance documents available on this topic. Detailed guidance should be given after research is done on how to carry out a proper assessment for a formulated product containing more than one a.i.

1.6.4 Scenarios for surface water

In this handbook, the Predicted Environmental Concentrations (PECs) of active ingredients in surface water are calculated for the relevant exposure scenarios by using certain models. The exposure scenarios for China are established on the basis of discussions on the detailed protection goals and the vulnerability concept. Specifically, the following five types of water bodies are identified as protection goals:

1. Ecosystems in natural ponds in the scenario zones South China and Yangtze River basin;
2. All level 3 drainage channels in the scenario zones South China and Yangtze River basin;
3. Ecosystems in natural ponds in the three northern scenario zones;
4. All level 7 rivers in the three northern scenario zones;
5. Rivers in the valley of hilly catchments in the scenario zone Yangtze River basin.

In first instance, and based on expert judgment, the first of the five protection goals mentioned above, was considered to be the most vulnerable one and was therefore worked out in detail. However, an approximate calculation demonstrated that concentrations of pesticides in the level 3 drainage channels south of the Yangtze River might be similar to the concentrations in the water layer of the paddy rice field (see Annex A in Ter Horst et al., 2014). These concentrations might therefore be 10 – 20 times higher than the concentrations calculated for the natural pond south of the Yangtze River. The rest of the protection goals should also be worked out in more detail to complete the establishment of all the surface water scenarios.

1.7 Reference

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Development of scenarios for environmental risk assessment procedures of pesticides in China, Wageningen, Alterra Wageningen UR (University & Research centre), Alterra report 2559. 164 pp.; 49 fig.; 42 tab.; 74 ref.

2 Aquatic ecosystems

2.1 Introduction

2.1.1 Purpose and content of this chapter

This chapter gives guidance on how to assess the risk from the use of pesticides to aquatic ecosystems. The assessment process described in this chapter proceeds according to the methodology and concept of ERA as described in Chapter 1. After giving a general introduction, a tiered approach based on pragmatic decisions is described.

This chapter is divided into the following 5 sections:
2.1 Introduction (including detailed protection goals, etc.);
2.2 Environmental risk assessment (ERA);
2.3 Exposure analysis;
2.4 Effect assessment;
2.5 Environmental risk management suggestions.

The uniform structure described in the general introduction in Chapter 1 also applies to this chapter. For the overall process of decision-making, please see also flow charts 2.1 - 2.3. 'Decision-making scheme for aquatic ecosystems'.

2.1.2 Detailed protection goals

'Aquatic ecosystems' is identified as one of the protection goals in this handbook. For this protection goal, details of the protection goal are addressed by answering the following 3 questions:

Question 1: What do we want to protect?
Answer: The type of ecosystem that will be protected consists of ecosystems in surface water; surface water is not protected as a source for drinking water (for the time being).

Question 2: Where do we want to protect?
Answer: All natural or semi-natural water bodies, which can be channels, streams, rivers, ponds, lakes, marshland, etc. Specifically, five types of water bodies are identified as protection goals. Within the different types of water bodies scenario zones are selected. Since it is a large country with significant differences in climate, soil and terrain for agriculture, China is divided into six scenario zones based on precipitation and temperature. For each of the scenario zones individual scenarios are established to represent the realistic worst-cases for environmental risk of pesticide use. To learn more about protection goals, please see also Ter Horst et al., 2014.

The following five types of water bodies are identified as protection goals:
1. Aquatic ecosystems in natural ponds in the scenario zones South China and Yangtze River basin.
2. Aquatic ecosystems in all level 3 drainage channels in the scenario zones South China and Yangtze River basin. Level 3 drainage is based on the classical Chinese classification for irrigation and drainage systems.
3. Aquatic ecosystems in natural ponds in the three northern scenario zones.
4. Aquatic ecosystems in all level 7 rivers in the three northern scenario zones. Level 7 rivers is based on the Chinese River/channel classification.
5. Aquatic ecosystems in all rivers in the valley of hilly catchments in the scenario zone Yangtze River basin.

Question 3: How strict do we want to protect? What are the criteria? Relationship with long-term and short-term effects
Answer: The sustainability of the freshwater resources of the above aquatic ecosystem should be ensured. Therefore, survival and reproduction of the most sensitive aquatic organisms should not, or only briefly, be affected.

For the considerations and conclusions related to protection goal definition, please see Ter Horst et al., 2014 (report of Work package 4 of PERAP).

2.2 Environmental risk assessment (ERA)

2.2.1 Identifying the relevance of the risk to aquatic ecosystems

Section 2.2 gives guidance on the principles for the decision-making process of ERA for aquatic ecosystems. Readers should note that a preliminary phase is required, identifying the relevance of the risk of the pesticide to aquatic ecosystems. It is reasonable to trigger the assessment only if the exposure of aquatic ecosystems to the pesticide of concern cannot be excluded on the basis of its use pattern.

If a pesticide product is to be used indoors, e.g. within a glasshouse, domestic premises, factories, grain stores and other enclosed structures, the risk to non-target aquatic ecosystems is considered to be negligible. Certain pesticide products used outdoors may also pose a similar negligible risk (e.g. rodenticide baits, dipping of roots, seed treatment, treatment of plant/tree bases). In cases where the exposure or risk is considered negligible, an appropriate justification should be given.

When the exposure of aquatic ecosystems cannot be excluded, the exposure level in the aquatic ecosystem should be estimated. The exposure of aquatic ecosystems to pesticides depends on the amount of pesticide reaching the surface water. In this handbook, the Predicted Environmental Concentrations (PECs) of a.i. in the surface water are calculated for different time-windows in the relevant exposure scenarios by using certain models. The exposure scenarios for China are established based on discussion of the detailed protection goals and the vulnerability concept. Of the five protection goals mentioned in 2.1.2, the first two have been worked out in detail because they are, based on expert judgment, considered to be the most vulnerable ones. The other protection goals should be considered for future development (see also section 1.5). Exposure scenarios and models are established and used to estimate the exposure concentration in surface water according to the detailed definition of these two protection goals. See also Section 2.3 (exposure assessment) for more information.

The physical and chemical properties, environmental fate data of the a.i. and use patterns of the formulated products are of particular importance to the calculation of the PECs and for the choice of the time window considered relevant for the risk assessment.

2.2.2 Risk characterization

The risk characterization of aquatic ecosystems is expressed as a Risk Quotient (RQ, see also Chapter 1), which is calculated by dividing the exposure concentration by the safe concentration, according to the formula below.

$$\mathbf{RQ} = \frac{\mathbf{PEC}}{\mathbf{PNEC}} \quad \text{Formula 2.1}$$

RQ: Risk Quotient
PEC: Predicted Environmental Concentration, which is calculated by using certain computer models (see detailed calculations in Section 2.3)

PNEC: Predicted No Effect Concentration, which is calculated by using toxicity data and associated uncertainty factors (see detailed calculation in Section 2.4).

The risk of a particular pesticide product to relevant aquatic species representing different taxonomies (fish, arthropods and algae), should be addressed by calculating separate RQs for each of the various taxonomies.

2.2.3 Decision-making scheme

Flowcharts 2.1, 2.2 and 2.3 give step-wise guidance on the overall decision-making process of risk assessment for ecosystems. The Explanatory Notes give additional information to the flowcharts. Readers should refer to the decision-making schemes to assess the risk of a particular pesticide of concern. The final decision of the risk assessment should be made according to the criteria described below, i.e. based on RQ calculations for aquatic organisms and on the criterion with regard to bioconcentration. See also Section 2.2.4 for detailed explanation on the tiered approach used in the decision-making process.

2.2.3.1 Criterion based on RQ calculation

When effect level (PNEC) and exposure estimate (PEC) are put into Formula 2.1, both figures have to match with regard to time scale and their units to express concentrations.

If the value of RQ is below or equal to 1, i.e. the exposure is lower than the safe concentration, the risk shall be considered to be acceptable. If the value of RQ is above 1, i.e. the exposure is higher than the safe concentration, it indicates that the risk could be unacceptable. However, higher tier risk assessment can be used to refine the risk assessment, possibly resulting in a smaller RQ.

2.2.3.2 Bioconcentration criterion

Bioconcentration should also be considered for the pesticide of concern. The maximum Bioconcentration Factor (BCF) of the pesticide of concern should not be greater than 100, unless there are sufficient data to demonstrate that the pesticide of concern is readily biodegradable, in which case BCF should not be greater than 1000. Otherwise, the potential risk due to bioconcentration will be regarded as high.

However, higher tier risk assessment can be used to refine the risk assessment to show that under field conditions no unacceptable impact on the viability of exposed species (predators) occurs - directly or indirectly - after use of the formulated product according to the proposed conditions of use.

2.2.4 Tiered approach

2.2.4.1 Conceptual model

The conceptual model of the ERA scheme for aquatic ecosystems was set up in such a way that the tiers for the effect assessments can be linked to any of the tiers for the exposure analysis, and vice versa. This so-called 'criss-cross' model allows optimal flexibility in the data that may be submitted by the applicant and in the assessment. Figure 2.1 shows the 'criss-cross' model for the aquatic risk assessment of a pesticide, which has no insect growth regular (IGR) function or bioconcentration potential. A tiered approach shall then be used for ERA of aquatic ecosystem according to the conceptual model.

At 1st tier, the risk shall be assessed using effect data based on acute toxicity tests and exposure model output based on laboratory e-fate test data. When the risk characterization results in a RQ larger than 1, a higher tier assessment could be triggered to refine the risk assessment by refining either the effect assessment and/or the exposure analysis as demonstrated in the conceptual model in Figure 2.1. See also Flow chart 2.1, 2.2 for the stepwise guidance on decision-making.

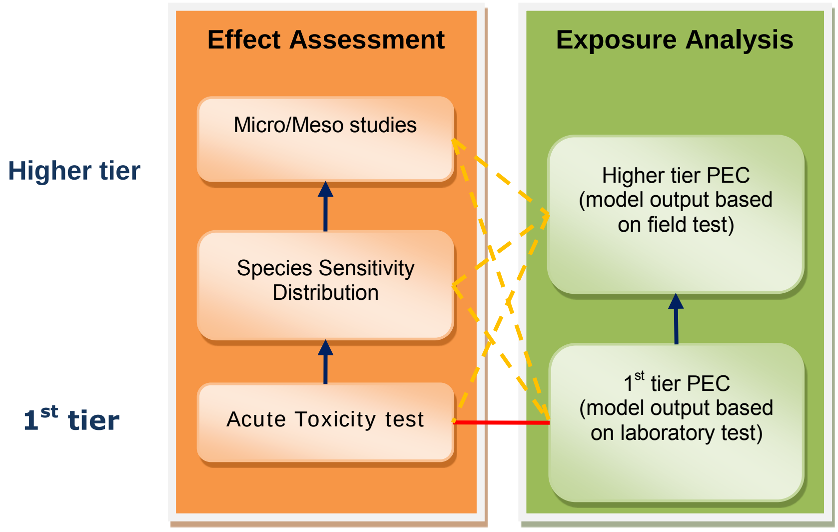


Figure 2.1 *The 'criss-cross 'model for the risk assessment of aquatic ecosystems.*

If the pesticide has an IGR mode of action or if there is any reason for special concerns regarding chronic effects, extra data are required (See also 'Data Requirement' in Section 2.4). Expert judgment is necessary to determine the time window for PEC calculation and the endpoint from chronic toxicity studies on a case-by-case basis (see flow chart 2.1).

If the pesticide has a potential for bioconcentration (logKow≥3), the bioconcentration effect of the pesticide to the aquatic ecosystem should also be assessed (see flow chart 2.1) and a bioconcentration study is required (See also 'Data Requirement' in Section 2.4) If the maximum BCF of the pesticide is larger than 100 (or, if the pesticide is demonstrated to be readily biodegradable and its BCF is larger than 1000), the pesticide is considered to be of high risk to the aquatic ecosystem, unless higher tier assessment can establish its safety. In case higher tier assessment is triggered, expert judgment is required to decide which kind of higher tier study should be carried out.

2.2.4.2 1st tier assessment of a pesticide which has no IGR function or bioconcentration potential

Table 2.1 summarizes PNECs and PECs used for risk characterization at the 1st tier. If a pesticide has no IGR function or bioconcentration potential, the 1st tier exposure analysis of aquatic ecosystems is based on model output data based on laboratory tests expressed as PEC. Section 2.3 gives detailed guidance on how to select input data and the time window to run the model.
The 1st tier effect assessment of aquatic ecosystems is based on acute toxicity data from standard species laboratory tests and associated uncertainty factors(UF). PNEC should be calculated for all 3 representative species (fish, arthropod and algae).

Table 2.1
PNECs and PEC used for risk characterization at 1st tier

	1st Tier	
Fish	PNEC	$PNEC_{fish}$
	PEC	PEC_{max}
Arthropods	PNEC	$PNEC_{arthropods}$
	PEC	PEC_{max}
Algae	PNEC	$PNEC_{algae}$
	PEC	PEC_{max}

PEC_{max}: the maximum value of PECs calculated by model (see also section 2.3)

2.2.4.3 Higher tier assessments of a pesticide which has no IGR function or bioconcentration potential

Possible higher tier approaches for exposure analysis include the supply of field studies. See section 2.3.1

Possible higher tier approaches for the effect assessment include Species Sensitivity Distribution (SSD) analysis (see 2.4.2.3.1), micro/mesocosm studies (see 2.4.2.3.2) or field studies and any other relevant scientific measures (case by case, using expert judgment).

The applicants are also welcome to supply their own risk assessment results as additional reference information, along with explicit interpretation on the scientific methodology, step-wise procedure and expert judgment, if applicable.

Once higher tier assessment is triggered, the applicants should provide sufficient data to ensure an integrated assessment for aquatic ecosystem on both acute risk and long term risk.

In this handbook, the Species Sensitivity Distribution (SSD) method is used as a possible refinement option for higher tier acute risk assessment. Based on the scientific research in the EU, when applying an extra uncertainty factor to the acute HC_5 (Hazardous Concentration for 5% of the species), an SSD analysis can also be used to address chronic risk using acute data. Therefore, SSD analysis is also used in this handbook for assessing chronic risk at a higher tier. If the chronic data are available from the applicants, then an appropriate evaluation and risk assessment should be done according to the guidance described in internationally recognized guidance documents, e.g. EU working document SANCO/3268/2001.

It should be noted that refinement reduces the uncertainty and produces a more precise characterization of the risk, but additional data do not necessarily result in a risk level which is lower than previously estimated.

Table 2.2

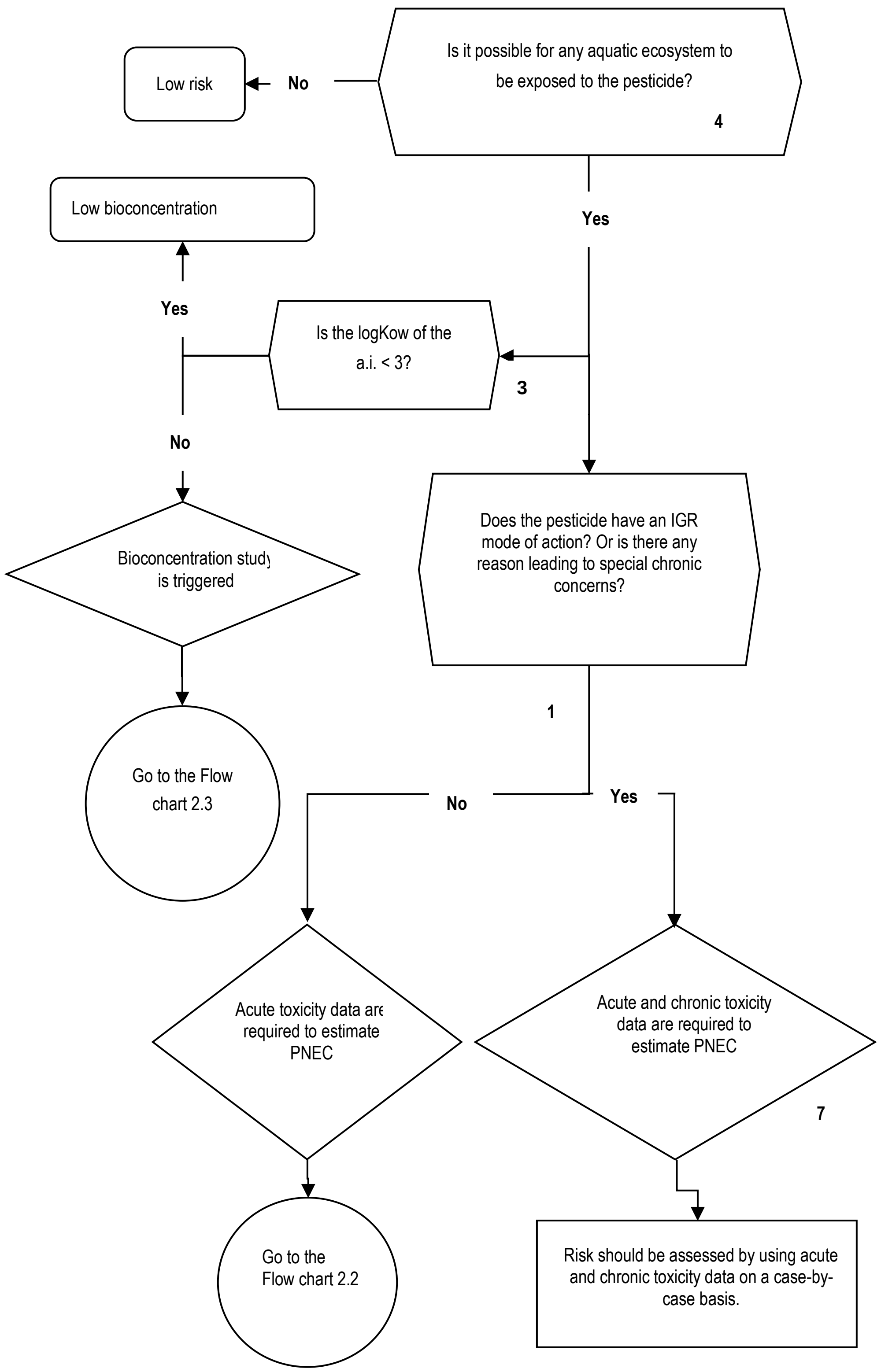
PNECs and PEC used for risk characterization at higher-tier assessments

	Higher Tier	
	SSD	Micro/Meso
PNEC	$PNEC_{SSD}$	$PNEC_{micro/meso}$
PEC	PEC_{max}	PEC_{max} **

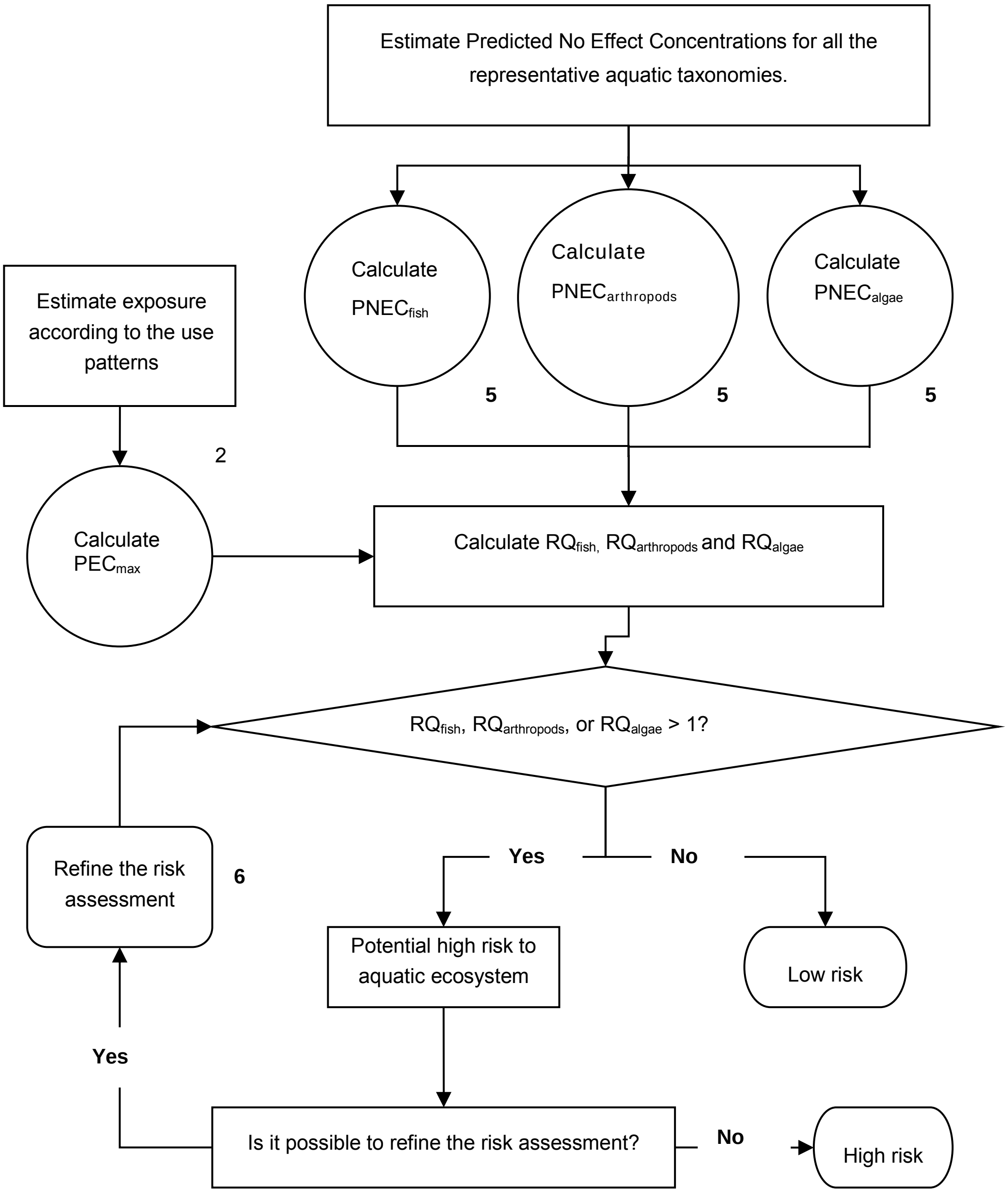
*** A PEC_{twa} should be used, only if the NOEC or NOEAEC is based on mean measured concentrations.*

2.2.4.4 Mitigation measures

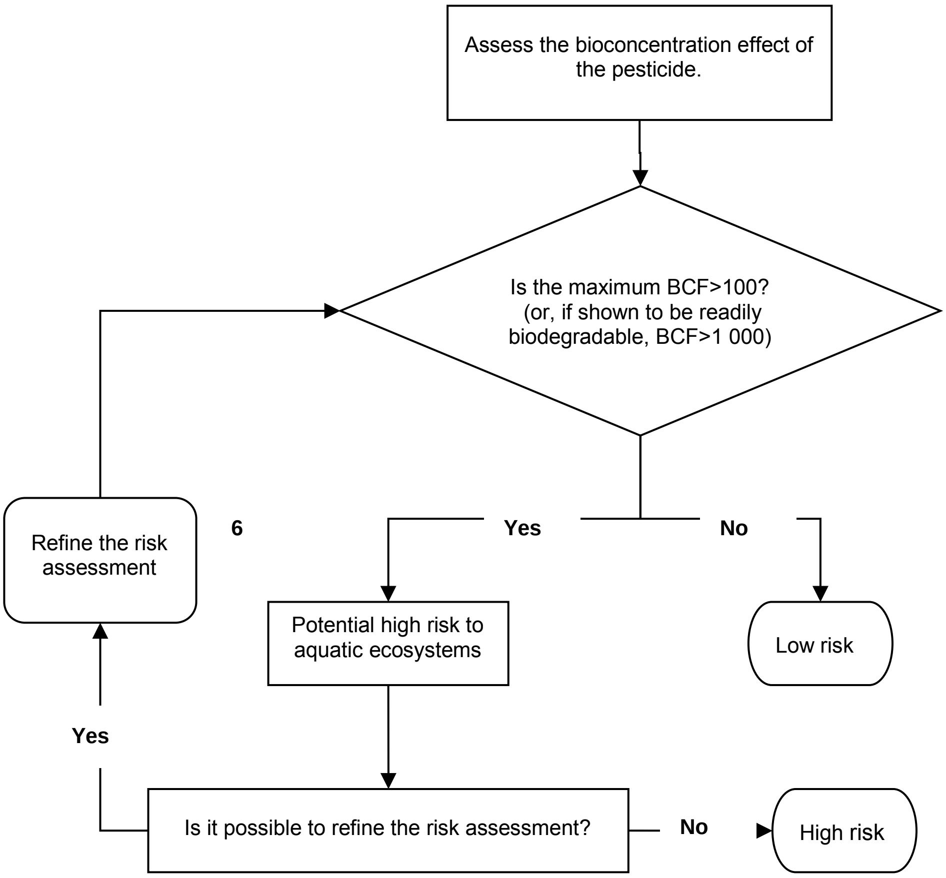
A standard risk assessment or even a higher-tier risk assessment may indicate that the risk to aquatic life may only be acceptable provided that risk mitigation measures are used. Necessary mitigation measures and other precaution notices shall then be clearly described on the label of the pesticide products. Detailed guidance is given in Section 2.5.



Flowchart 2.1 *Decision-making scheme for aquatic ecosystems: GENERAL.*



Flowchart 2.2 *Decision-making scheme for aquatic ecosystems: Sub-scheme A.*



Flowchart 2.3 *Decision-making scheme for aquatic ecosystems: Sub-scheme B.*

Explanatory Notes to Flowchart 2.1, 2.2 and 2.3

1. At the 1st tier assessment only acute toxicity studies are required because uncertainty due to extrapolation from acute data to long term effect is considered and covered by applying an uncertainty factor (UF). However, if the pesticide has a mode of action which may not manifest itself in an acute toxicity test (e.g. IGR), chronic toxicity test data should be submitted by the applicant for arthropods and/or fish and a different UF may be applied. See also section 2.2.4.1 and 2.4.2.1.
2. Both a PEC_{pond} and a $PEC_{channel}$ are calculated for relevant exposure scenarios using surface water exposure models. The highest value should be used in the calculation of RQ. Further information on the calculation of the PECs is given in Section 2.3.
3. Where the logKow of an a.i. is < 3, experimental research is not required.
4. See also Section 2.2.1 for the examples of unlikely exposure of aquatic ecosystems. Where the likelihood of exposure is not clear, the assessment should always be performed.
5. The acute toxicity tests must be carried out in accordance with standardized methods, with representatives of at least 3 different trophic levels, i.e. algae, aquatic arthropods and fish. See also section 2.4.1.
6. Possible refinement approaches include refining the effect assessment or/and the exposure analysis by carrying out extra studies. For details, see also Section 2.2.4.3
7. Presently, toxicity studies on shrimps and crab are required for IGR (Dossier Requirement for Pesticide Registration). However, such studies may not be sufficient for the assessment because they are usually acute toxicity studies. The applicants are advised to consult the registration authority about test design before carrying out studies on shrimp and crab to make sure that in particular the test duration is chosen appropriately.

2.3 Exposure analysis

2.3.1 Data requirements

2.3.1.1 Introduction

This section elaborates on the relevant parts of the '*Dossier Requirements for Pesticide Registration*' (MOA Command No. 10, Jan 8th, 2008) with regard to the environmental fate of pesticides in aquatic ecosystems, including circumstances in which the test is required, test conditions, test guidelines and test results for each data requirement.

Appendix 2-2 describes test conditions, guidelines and endpoints of the required studies.

2.3.1.2 Active ingredients

Hydrolysis as a function of pH

A. Circumstances in which required
The test is always required.

B. Test conditions:
The test should be performed at three different pH values (pH 4, 7 and 9) in sterile buffer solution.

C. Test guideline:
Chemical pesticide environment risk assessment test guideline' or internationally recognized guidelines, e.g. OECD 111.

D. Results:
$DegT_{50}$ of active ingredient in buffer solution (at pH 4, pH 7 and pH 9).

Anaerobic transformation in soil

A. Circumstances in which required
The test is required when the active ingredient will be applied to paddy fields.

B. Test conditions
The test should be performed for at least three types of soil. The soils used in the tests should be collected from paddy fields. The test system should be in an anaerobic condition.

C. Test guideline
'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 307.

D. Results
$DegT_{50}$ of active ingredient in soils.

Soil adsorption

A. Circumstances in which required
The test is always required.

B. Test conditions
The test should be performed for at least three types of soil. The Freundlich isotherm should be used to explain the adsorption processes of active ingredient in soil.

C. Test guideline
'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 106.

D. Results
K_{oc} or K_{om} of the active ingredient in soils.

2.3.1.3 Formulation products

Supplementary data for field studies could be carry out so as refine the exposure estimation where the pesticide cannot pass the lower-tier assessment. However, field studies are not included in the handbook at this moment, because sufficient methodology of design and evaluation for field studies are not available so far.

2.3.2 Tiered approach of PEC calculation

In this handbook, PEC_s of a.i. in surface water are calculated for the relevant exposure scenarios using the models PEARL and TOXSWA.

2.3.2.1 Surface water Scenarios and model

The exposure scenarios for China are established based on discussions on the detailed protection goals and the vulnerability concept. Among the five detailed protection goals mentioned in 2.1.2, the following one was worked out in more detail:

1. Aquatic ecosystems in natural ponds in the Scenario Zone South China and the Scenario Zone Yangtze River basin.

However, a rough calculation showed that concentration of pesticides in the level 3 drainage channels south of the Yangtze River might be similar to concentrations in the water layer of the paddy rice field. These concentrations might therefore be 10 – 20 times higher than the concentrations calculated for the natural pond south of the Yangtze River. To address this a conservative approach based on the scenarios for the protection goal 'Aquatic ecosystems in natural ponds in the Scenario Zone South China and the Scenario Zone Yangtze River basin' was worked out. The rest of the protection goals should be considered for future development (see also section 1.5).

Based on information such as soil properties, weather data and crop calendars, the following two realistic worst-case exposure scenarios have been defined for the protection goal. For more information on scenario establishment, please see also Ter Horst et al., 2014.

1. One scenario for natural ponds in the Scenario Zone South China;
2. One scenario for natural ponds in the Scenario Zone Yangtze River basin;

The PEARL model and the TOXSWA model are adapted to Chinese agricultural conditions and are coupled to calculate the PECs in surface water. An x^{th} percentile peak concentration of 20 years of simulation is used as input in the environmental risk assessment (x = 77 for Nanchang and 89 for Lianping). A user interface (TOP-rice) is provided for the two models to simplify their use. To learn more about TOP-rice for surface water PEC calculation, please see also Geng et al., 2010.

The two exposure scenarios mentioned above are parameterized and implemented in the TOP-rice software in such a way that the parameter values (e.g. soil, meteorology etc.) cannot be altered by the user. Therefore, users can easily run the models to generate the PEC of a pesticide in surface water for each scenario after inserting the application information of the pesticide and the pesticide properties.

The approach worked out for the protection goal 'Aquatic ecosystem in all level 3 drainage channels in the Scenario zone South China and Scenario Zone Yangtze River basin' is as follows:

1. Perform calculations for the target a.i. and its application scheme with the exposure scenarios for the natural pond using the TOPrice software tool.
2. Select from the summary report the x^{th} percentile (x = 77 for Nanchang and 89 for Lianping) of the 'Maximum runoff from water layer'.

This is a very conservative approach because it is assumed that the water in the level 3 drainage channel is completely replaced with paddy water during a runoff overflow event. The concentration of pesticide in the level 3 drainage channel is therefore considered to be equal to the concentration in the run-off overflow from the paddy field.

The exposure concentration in the natural pond is calculated by the PEARL-TOXSWA model chain. It should be noted that drift was not considered to be a driver for scenario selection. However, drift is taken into consideration as an entry route for the PEC calculations of surface water with the TOXSWA model. Table 2.3 presents the ground-deposited drift values simulated by the IDEFICS model. The detailed information on drift calculation is given in Franke et al., 2010.

For the natural pond scenario, spray drift deposition is calculated as a percentage of the application rate over 20 m width, assuming no buffer zones (pond dimensions are 20x33 m^2; assuming spray drift to occur perpendicular to the pond length of 33 m). These data are also shown in Table 2.3 in the 'pond' column.

For a first tier calculation the drift values given in Table 2.3 for ponds in a warm and humid climate, should be used in the surface water exposure calculation.

Table 2.3

Ground-deposited drift values simulated by the IDEFICS model (% of application rate)

Crop height, climate conditions	Distance from crop edge (m)						pond
	0.5	1.0	2.0	5.0	10.0	20.0	Integration 0-20 m
Crop height 5cm, warm and humid	42	23	5.3	1.3	0.6	0.2	3.73
Crop height 50cm, warm and humid	25	5.9	1.3	0.3	0.2	0.1	1.16
Crop height 5cm, cold and dry	45	28	8.2	2.3	1.2	0.6	4.78
Crop height 50cm, cold and dry	26	8.2	2.6	0.8	0.7	0.3	1.64

The drift curves in Franke et al. (2010) are not worst-case for situations where wind speed is above 3 $m\ s^{-1}$. Chinese policy makers therefore decided that farmers should not spray if wind speeds are above 3 Beaufort (3.4 – 5.4 $m\ s^{-1}$).

It should be noted that only paddy land is simulated in the scenarios. In most of the cases where the pesticide of concern is not intended to be used in paddy land, or not only in paddy land, these models and scenarios can be used to give worst-case PEC for 1st tier assessment if the user inputs the application information into the models by following the guidance given in Table 2.4.

The output of the models includes the x^{th} percentile of the annual maximum concentration (PEC_{max}) of 20 years of simulations (x = 77 for Nanchang and 89 for Lianping), which are used for different purposes (See also section 2.3.2.2 for detailed guidance).

Table 2.4

Guidance on dealing with the application information of different pesticides for surface water model input

Intended use of the pesticide	How to deal with the application information for model input
application in dry land crops only	Options: 1 application during the period mentioned on the label (i.e. early or late rice period) 2 applications, always during the early + late rice period, even if this does not correspond to the periods mentioned on the labels (e.g. even if label mentions apply during 22 Apr-15 Jul (first crop) and 15 Oct-Apr (third crop)) 3 applications, 1 in early rice + 1 in late rice + 1 in fallow soil (South-China; Lianping only) For early rice: application in early rice period (22 April – 10 July for Nanchang and 13 April – 15 July for Lianping) For late rice : application in late rice period (11 July – 20 October for Nanchang and 16 July – 23 October for Lianping) For dry land crops: application on fallow soil[1]
application in early rice (flooded rice paddies) only.	Application in early rice period only (22 April – 10 July for Nanchang and 13 April – 15 July for Lianping)
application in late rice (flooded rice paddies) only.	Application in late rice period only (11 July – 20 October for Nanchang and 16 July – 23 October for Lianping)
application in rice (both early rice and late rice / flooded rice paddies)	Application in early rice and late rice period (early: 22 April – 10 July for Nanchang and 13 April – 15 July for Lianping; late: 11 July – 20 October for Nanchang and 16 July – 23 October for Lianping)

1 PEARL does not simulate pesticide fluxes in surface runoff from drained paddy land. Therefore, the pond can only receive pesticide entries from spray drift in the period 21 Oct. – 21 Apr. for Nanchang and in the period 24 Oct. – 12 Apr. for Lianping (fallow soil).

Intended use of the pesticide	How to deal with the application information for model input
application in early rice (flooded rice paddies) and application in dry land crops	For early rice: application in early rice period (22 April – 10 July for Nanchang and 13 April – 15 July for Lianping) For dry land crops: application in late rice period (11 July – 20 October for Nanchang and 16 July – 23 October for Lianping)
application in late rice (flooded rice paddies) and application in dry land crops	For late rice : application in late rice period (11 July – 20 October for Nanchang and 16 July – 23 October for Lianping) For dry land crops: application on fallow soil[1]
application in rice (both early rice and late rice) (flooded rice paddies) and application in dry land crops	For early rice: application in early rice period (22 April – 10 July for Nanchang and 13 April – 15 July for Lianping) For late rice : application in late rice period (11 July – 20 October for Nanchang and 16 July – 23 October for Lianping) For dry land crops: application on fallow soil[1]

To learn more about scenario and models, see also Ter Horst et al., 2014

2.3.2.2 Establishment of PEC at 1st tier

Level 3 drainage channel

The PEC in the level 3 drainage channel is calculated by the PEARL model using the exposure scenarios for the natural pond. The input data and some explanations on the model are the same as those described in Section 6.3.2.3

It should be noted that the metabolites of the pesticide are NOT taken into consideration in the risk assessment for surface water, whilst PECs of the major metabolites are calculated in the risk assessment for groundwater.

The x^{th} percentile concentration in the run-off overflow from the paddy field (PEC_{max}) of 20 years of simulations (x = 77 for Nanchang and 89 for Lianping) is given as output and should be used in the 1^{st} tier risk assessment (selected from the section 'PEARL REPORT: Maximum runoff from water layer' in the summary file provided by the TOPrice software tool).

Natural pond

PECs in the pond are calculated by the PEARL-TOXSWA model chain using the TOPrice software tool. The x^{th} percentile peak concentration (PEC_{max}) of 20 years of simulations (x = 77 for Nanchang and 89 for Lianping) should be used in the 1^{st} tier risk assessment (selected from the section 'TOXSWA REPORT: Target percentiles water layer). The x^{th} percentile peak concentration (PEC_{max}) of 20 years of simulations (x = 77 for Nanchang and 89 for Lianping) should also be used for higher tier risk assessment, depending on the availability of different PNEC values. See Section 2.2.4 for detailed guidance on how to make use of different PECs. The input data and output data for the TOXSWA model (incorporated in the TOPrice software tool) are presented in Table 2.5 (note, however, that running the PEARL model, which is also incorporated in the TOPrice software, is also necessary to calculate the runoff overflow fluxes. Table 6.2 presents the input and output data of this model).

Table 2.5

Input data and output data for the TOXSWA model incorporated in the TOPrice software tool

Input data Parameters of substance	Output value
Molecular mass; Vapour pressure (with tested temperature); Solubility in water (with tested temperature); $DegT_{50}$ in water (with temperature of 20℃); K_{om} arithmetic mean of suspended solids (with tested temperature); Freundlich exponent Spray drift deposition	x^{th} percentile PEC_{max} (x = 77 for Nanchang and 89 for Lianping)

Some explanations concerning the relevant input data are given below.

DegT$_{50}$ in water

1 The highest DegT$_{50}$ values from hydrolysis test should be used.
2 If K_{om} in sediment and suspended solids is not available, K_{om} in soil can be used
3 DegT$_{50}$ values are converted to 20℃ using Formula 6.2.

$$DegT_{50}(20^0C) = DegT_{50}(T) \times e^{0.08\times(T-20)}$$ Formula 2.2

T = temperature at which the study was conducted (℃)

K_{om} can be calculated from Koc (see Formula 2.3)

$$Kom = \frac{Koc}{1.724}$$ Formula 2.3

Spray drift deposition

Spray drift values are listed in Table 2.3. For a first tier calculation the drift values in Table 2.3 for a pond in a warm and humid climate (spray drift deposition integrated over the width of the pond assuming no buffer zones) should be used in the calculation of the surface water exposure concentration. No buffer zones are assumed because crops are often grown very close to the water body in China.

2.3.2.3 Higher tier

Refinement of input parameters for surface water models, based on data from field studies, is one option for exposure analysis in a higher tier. However, field studies are not included in the handbook at this moment, because sufficient methodology of design and evaluation for field studies are not available so far.

2.4 Effect Assessment

2.4.1 Data requirement

2.4.1.1 Introduction

This section elaborates the relevant parts of '*Dossier Requirement for Pesticide Registration' (MOA Command No. 10, Jan 8th, 2008)* regarding aquatic toxicological studies, including test conditions, guidelines and endpoints.

Appendix 2-3 describes test conditions, guidelines and endpoints of the required studies.

2.4.1.2 Active ingredients

Toxicity to Fish

Acute toxicity to fish

Based on EU experience (Kwok et al. 2007), the cold water species are normally more sensitive than the warm water species. Therefore, studies with cold water species are always required, and studies using warm water species qualify as 'supplementary studies'. Modification of data requirements will probably be necessary by the end of the PERAP project.

A. Circumstances in which the test is required
The test should always be required.

B. Test conditions:
Test should be done for one warm water species (recommended species: Hydonio rerio). One extra cold water species must be tested if the test for warm water species results in 'highly toxic' (LC_{50}<1.0 mg/L).

C. Test guidelines:
'*Chemical pesticide environment risk assessment test guideline*'; or internationally recognized guidelines, e.g. OECD 203.

D. Results:
LC_{50}(mg/L).

Bioconcentration in fish

A. Circumstances in which the test is required

The test should be performed if the a.i. is likely to partition into fatty tissues (compounds with logKow > 3).

B. Test conditions:

The test should be performed using one of the following species: *Cyprinus carpio*, *Brachydanio rerio*, *Oryzias latipes* or *Xiphoporus helleri*.

C. Test guidelines:

'Chemical pesticide environment risk assessment test guideline'; or Internationally recognized guidelines, e.g. OECD 305.

D. Results:

BCF.

Acute toxicity to aquatic arthropods

Based on EU experience, an extra insect species should be tested for some pesticides because of their special application pattern, mode of action, etc. However, the EU testing guideline for extra species is not yet finalized at present. Therefore, it is better to wait for the EU testing guideline and modify data requirements accordingly.

A. Circumstances in which the test is required

The test is always required.

B. Test conditions:

The test should be performed for one species: *Daphnia magna.*

C. Test guidelines:

'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 202.

D. Results:

EC_{50}(mg/L) or LC_{50}(mg/L).

Effects on algae growth

Based on EU experience, an extra algae species or aquatic plant species should be tested for herbicides. At this stage of ERA development in China, this extra test is not included in the data requirements.

A. Circumstances in which the test is required

The test should always be required.

B. Test conditions:

The test should be performed using one of the following three species: *Chlorella vulgaris*, *Scenedesmus obliquus,* or *Selenastrum capricornutum.*

C. Test guidelines:

'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 201.

D. Results:

EC_{50} (mg/L), NOEC(mg/L).

Chronic toxicity to fish

Chronic toxicity data may only be supplementary data according to 'Dossier Requirement for Pesticide Registration (MOA Command No. 10, Jan 8th, 2008)'

A. Circumstances in which the test is required

The test is only required if the pesticide has a mode of action which may not show up in the acute toxicity test with fish.

B. Test conditions:

Expert judgment is required to decide which test has to be performed.

C. Test guidelines:

Internationally recognized guidelines, e.g. OECD

D. Results:

NOEC (mg/L)

Chronic toxicity to aquatic arthropods (Shrimp & Crab)

A. Circumstances in which the test is required

if the a.i has an IGR mode of action or if there is any reason for special chronic concerns.

B. Test conditions:

Expert judgment is required to decide which test has to be performed.
Presently, toxicity studies on shrimps and crab are required for IGR (Dossier Requirement for Pesticide Registration). However, such studies may not be sufficient for the assessment because they are usually acute toxicity studies. The applicants are advised to consult the registration authority about test design before carrying out such studies to make sure that the test duration, in particular, is appropriately chosen.

C. Test guidelines:

Internationally recognized guidelines, e.g. OECD.
A national guideline for testing chronic toxicity to aquatic arthropods is not yet available. Expert judgment is needed to determine the test duration and test species.

D. Results:

NOEC(mg/L).

2.4.1.3 Formulated products

Acute toxicity to fish, aquatic arthropods or effects on algae growth

If no information on the a.i. is available for any of the three taxonomic groups (fish, daphnia, algae), tests using the formulated product should be performed for all three groups. If information on the a.i. indicates that one of the groups is much more sensitive than others, tests using the formulated product only have to be performed using the most sensitive group. Otherwise, all three groups have to be tested.

Acute toxicity to fish

A. Circumstances in which the test is required:

The test should be performed if:

- the formulated product contains more than one a.i.;
- or the intended use includes direct application on water;
- or the a.i. is highly toxic to fish (LC_{50} from acute toxicity test of the a.i. < 1.0 mg/L);

B. Test conditions:

The test should be performed for a single species, i.e. the most sensitive one as concluded from the a.i. acute tests;

C. Test guidelines:

'*Chemical pesticide environment risk assessment test guideline*'; or internationally recognized guidelines, e.g. OECD 203.

D. Results:

LC_{50}(mg/L).

Acute toxicity to aquatic arthropods

A. Circumstances in which the test is required:

The test should be performed if:

- the formulated product contains more than one a.i.;
- or the intended use includes direct application on water;
- or the a.i. is highly toxic to *Daphnia* (EC_{50} from acute test of the a.i. < 1.0 mg/L).

B. Test conditions:

The test should be performed for one species: *Daphnia magna*.

C. Test guidelines:

'*Chemical pesticide environment risk assessment test guideline'*; or internationally recognized guidelines, e.g. OECD 202.

D. Results:

EC_{50}(mg/L).

Effects on algae growth

A. Circumstances in which the test is required:

The test should be performed if:

- the formulated product contains more than one a.i.;
- or the intended use includes direct application on water;
- or the a.i. is highly toxic to *algae* (EC_{50} from the test of the a.i. < 0.3 mg/L), or the formulated product contains more than one a.i.

B. Test conditions:

The test should be performed for one of the following three species: *Chlorella vulgaris,. Scenedesmus obliquus* or *Selenastrum capricornutum.*

C. Test guidelines:

'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 201.

D. Results:

EC_{50}(mg/L), NOEC (mg/L).

2.4.1.4 Additional tests for SSD

A. Circumstances in which the test is required:

If the pesticide cannot pass the 1st - tier risk assessment, additional tests for SSD can be carried out in order to refine the ERA.

B. Test conditions

For pesticides for which a specific group of organisms is known to be particularly sensitive, the species selected for further testing should be chosen from the relevant group. At least 5 species of fish or 8 species from other sensitive group should be tested.

In cases where pesticides do not appear to be selective to aquatic organisms (i.e., all standard tests organisms respond at, within an order of magnitude, similar concentrations), acute toxicity tests for at least 8 species from different taxonomic groups (i.e. fish, aquatic arthropods and primary producers) should be performed.

Tests can be performed with the a.i. or the formulated product.

Based on research performed in the EU (Maltby et al., 2005), arthropods are the most sensitive group for insecticides, and primary producers are the most sensitive group for herbicides (Brink et al., 2006). However, the 'most sensitive' group cannot be readily identified for fungicides. Therefore, in most cases dealing with fungicides, the test species for SSD should cover all 3 groups, arthropods, algae and vertebrates. Readers should note that research on this topic is still ongoing, and no final conclusions are available yet.

C. Test guidelines:

'*Chemical pesticide environment risk assessment test guideline*'; or internationally recognized guidelines, e.g. OECD 201, 202, 203.

D. Results:

$L(E)C_{50}$ for different test species.

2.4.1.5 Micro/mesocosm studies

A. Circumstances in which the test is required:

If the pesticide cannot pass the lower-tier risk assessment, using laboratory studies, micro/ mesocosm studies can be carried out in order to refine the ERA.
However, expert judgment is required to decide where and how the study should be performed.

B. Test conditions

The test material should be the formulated product.

C. Study design:

The term 'microcosm' can be used for small-scale studies, whereas the term 'mesocosm' generally refers to larger outdoor tests. Microcosm studies can be an effective compromise between standard laboratory tests and mesocosm studies. Mesocosm studies can examine effects of pesticides on communities of organisms under simulated field conditions.

The design of studies for higher-tier aquatic effects assessment should always be carefully considered on a case-by-case basis, and should take into account the findings of the standard risk assessment. The registration authority should be contacted before any microcosm or mesocosm study is carried out.

D. Results:

$NOEC_{community}$, $NOEC_{population}$ and NOEAEC

2.4.1.6 Field study and other supplementary studies

Higher tier studies, including field studies and other supplementary studies should be carried out if the pesticide cannot pass the lower-tier risk assessment.

However, since the trigger criterion for such a study has not yet been specified, expert judgment is required to decide on a case-by-case basis where and how the study should be performed. Also, the interpretation of the results should be justified explicitly.

2.4.2 Tiered approach of PNEC establishment for a pesticide with no IGR function or bioconcentration potential

For a pesticide which has no IGR mode of action nor bioconcentration potential, PNECs should be calculated according to the formula below by using endpoints from eco-toxicological studies and associated uncertainty factors:

$$\mathbf{PNEC} = \frac{\mathbf{EnP}}{\mathbf{UF}} \qquad \text{Formula 2.4}$$

PNEC = Predicted No Effect Concentration
EdP = Toxicity Endpoints.
UF = Uncertainty Factor.

2.4.2.1 Uncertainty factors

As explained in Chapter 1 an uncertainty factor should be taken into account to address the extrapolation from laboratory toxicity data on a limited number of species to the multi-species ecosystem. In general, the more extensive the data and the longer the duration of the tests, the smaller are the degree of uncertainty and the smaller the size of the assessment factor will be.

At the 1^{st} tier assessment, uncertainty due to extrapolation from acute data to long term effect is considered and covered by applying an uncertainty factor of 100 in the calculations of PNECs for fish and aquatic arthropods. However, if the pesticide has a mode of action which may not manifest itself in an acute toxicity test (e.g. IGR), chronic toxicity test data should be submitted by the applicant for arthropods and/or fish and a different value of the UF may be applied.

An uncertainty factor of 10 is used in derivation of PNEC of algae, since the life cycle of these species is comparably quite short and the toxicity endpoint is based on growth inhibition instead of immobilization or lethal effects.

The recommended uncertainty factors used for 1^{st} tier assessments are shown in Table 2.5.

It should be noted that the contribution of each of the different factors influencing the overall uncertainty cannot easily be quantified and may differ when dealing with acute and/or chronic testing. In rare cases where the acute to chronic ratio (A/C ratio) is low and the same PEC is used for acute and chronic risk assessment, the acute risk may appear to be higher than the chronic risk due to the greater uncertainty factor that is applied in the acute assessment. From a scientific point of view, this is not logical. In such cases, the real difference between acute and chronic toxicity is lower than was anticipated when setting general uncertainty factors. Under these circumstances, the use of a lower uncertainty factor than 100 in the acute risk assessment should be considered.

At higher tier assessments, the uncertainty factor in the derivation of PNEC from higher tier data can be reduced to a certain degree, e.g. when including results from SSD, micro/mesocosm studies, etc.

The testing of more species reduces the uncertainty of the risk assessment attributable to inter-species differences in sensitivity[2]. It therefore permits a reduction of the uncertainty factor that is applied to the lower-tier data. If a considerable number of additional species was tested in valid studies, then it is possible that the uncertainty factors that are applied to the lowest toxicity value could be lowered by up to an order of magnitude. However, the full order of magnitude reduction is likely only to apply to acute risk assessments, e.g. triggers for acute risk to fish and aquatic arthropods.
The recommended uncertainty factors used at higher tier assessments are shown in Table 2.6.

2.4.2.2 Establishment of PNEC in the 1st tier

For a pesticide which has no IGR function or bioconcentration potential, PNECs should be calculated for all the three representative species (fish, arthropods, and algae) according to Formula 2.4.

Toxicity endpoints (LC_{50}, EC_{50}, NOEC) from the following short-term ecotoxicity tests are necessary for establishing the 1st tier $PNEC_{fish}$, $PNEC_{arthropods}$ and $PNEC_{algae}$:

- fish acute test
- daphnia acute test
- algae toxicity test

Endpoints and Uncertainty Factors for establishing the 1st tier PNEC are given in Table 2.6.

Table 2.6
Endpoints and Uncertainty Factors for the 1st tier PNEC establishment

1st Tier		
$PNEC_{fish}$	EdP	LC_{50}
	UF	100
$PNEC_{arthropodarthropods}$	EdP	EC_{50}/ LC_{50}
	UF	100
$PNEC_{algae}$	EdP	EC_{50}
	UF	10
EdP = End Point UF = Uncertainty Factor		

When the toxicity data for both a.i. and its formulated product are available, especially for the 1st tier, the lowest toxicity value (e.g. LC_{50}, expressed in the concentration of the a.i.) for each representative species should be used in the PNEC calculation.

If the pesticide has an IGR mode of action or if there is any reason leading to special chronic concerns, the PNEC for the 1st tier assessment should be calculated using acute and chronic toxicity endpoints. The exact toxicity endpoint and the uncertainty factor should be determined through expert judgment.

At this stage of ERA development in China, chronic data are not required for 1st tier assessment. Uncertainty due to extrapolation from acute data to long-term effects is considered and covered in the UF used in the 1st tier assessment.

2.4.2.3 Establishment of PNEC in Higher tier

For higher tier assessments, PNEC can be calculated based on the results from SSD analysis, micro/mesocosm studies, or other supplementary studies. The uncertainty factor can be reduced to a certain degree by using such higher tier data. Endpoints and recommended uncertainty factors for different higher tier assessments are given in Table 2.7.

[2] Scientific opinion from PPP panel- to be added

Table 2.7
End points and Uncertain Factors for higher-tier assessments

	Higher Tier			
	$PNEC_{SSD}$			$PNEC_{Micro/Meso}$
	DT_{50} ≤ 10d and single exposure	DT_{50} > 10d or multiple exposure.		
EdP	$HC5_{acute-mean}$	$HC5_{acute-mean}$	$HC5_{Chron-mean}$	NOEC / NOEAEC
UF	1	10	1	3* if using NOEAEC

EdP = End Point
UF = Uncertainty Factor
* If the pesticide is highly persistent, a higher UF may be necessary.

Species Sensitivity Distribution (probabilistic method)
Based on the scientific research in EU by applying an uncertainty factor to acute HC_5, SSD also can be used to address the chronic risk using only acute data. Therefore, SSD is also used in this handbook for assessing chronic risk at higher tier.
If chronic data are available from the applicants, the relevant ERA could be conducted using these data according to the guidance described in internationally recognized guidance documents, e.g. EU working document SANCO/3268/2001.

A. Endpoints from SSD

One of the most straight-forward applications of probabilistic risk assessment (PRA) in aquatic risk assessment is the use of the 'species sensitivity distribution' (SSD). The SSD is a statistical distribution estimated from a sample of toxicity data and visualized as a cumulative distribution function (See Fig. 2.2).

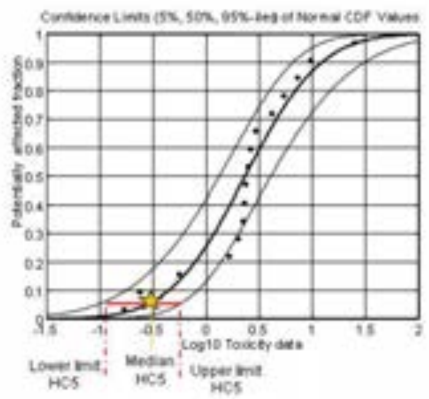


Figure 2.2 *Graphical presentation of the SSD curve, its 95% confidence interval, and the derivation of the lower limit and median hazardous concentration for 5% of the species (HC5).*

In this approach, toxicity data are fitted to a statistical model (e.g. ETX 2.0) in order to describe the distribution of sensitivities that would be expected in the 'universe' of species. The species sensitivity distribution can be defined, based on sufficient data of toxicity endpoints for as many test species as possible. The toxicity data used for this means have usually been obtained from so-called 'single species laboratory tests'. The number and type of additional species that should be tested depends on what is known about the mode of action or selectivity of the pesticide. See also Section 2.4.1.4 for data requirements.

Species sensitivity distributions are used to calculate the concentration, at which a specified proportion of species will be affected, referred to as the hazardous concentration (HC) for p (%) of species (HC_p). The most frequently estimated HCs are the HC5 and HC10. With the HC5 derived from a SSD of toxicity endpoint (e.g. LC_{50}, NOEC, etc.) values and an uncertainty factor, the PNEC for aquatic organisms can be calculated.

B. PNEC calculation using HC_5

If the pesticide tends to be not persistent (i.e. DT_{50} ≤ 10 days) and the use pattern of the pesticide requires only a single application, the mean value of HC_5 (HC_{5mean}) resulting from acute toxicity data (LC_{50}/EC_{50}), should be used to estimate the PNEC value. Based on the research done in EU, HC_{5mean} can provide sufficient safety margin for the protection of aquatic organisms, and therefore in this case HC_{5mean} with an uncertainty factor of 1 is used as PNEC (see also Table 2.2, 2.6).

If the pesticide tends to be persistent (i.e. DT_{50}>10 days) or the use pattern of the pesticide requires multiple applications, the mean value of HC_5 (HC_{5mean}) resulting from acute toxicity data (LC_{50}/EC_{50}), can be used to estimate the PNEC value, using an uncertainty factor of 10 (see also Table 2.2, 2.6). When there are sufficient chronic data available from the applicant, SSD based on chronic data could also be an option for ERA refinement and HC_{5mean}, based on chronic toxicity data (NOEC) can be used as PNEC, using an uncertainty factor of 1.

Mesocosm or microcosm

A. Endpoints from studies

The data from microcosm and mesocosm studies can be used to determine a number of endpoints which can be used in the risk assessment, e.g. to derive an PNEC. For the relevant taxonomic groups in the study, a no observed effect concentration at the community level ($NOEC_{community}$) should be derived using appropriate statistical techniques (e.g. Principal Response Curves). In addition, NOECs for populations of relevant organisms should be reported ($NOEC_{population}$). If there are effects at the community or population level, the time necessary for the occurrence of recovery should also be reported.

The $NOEC_{community}$, the $NOEC_{population}$ and the time necessary for recovery should then be used to determine a no observed ecologically adverse effect concentration (NOEAEC). The NOEAEC is defined as being the concentration at or below which no long-lasting adverse effects were observed in a particular higher-tier study (e.g. mesocosm).

B. PNEC calculation using NOEAEC

Nevertheless, indoor semi-realistic microcosm tests may be used to define an overall ecosystem effect level. It may be appropriate to compare a NOEAEC directly with the PEC, provided all the uncertainty has been satisfactorily accounted for. Otherwise, some uncertainty factor has to be applied to define the PNEC. The degree of uncertainty that is applied to these studies should be reduced in comparison to the uncertainty applied to the standard risk assessment but needs to be evaluated on a case-by-case basis and will depend on what other data are available in the risk assessment.

Field study and other supplementary data

The SSD method and micro/mesocosm studies are included in the concept model of ERA for aquatic organisms, and submission of these data should be considered as acceptable refinement options. However, if higher tier assessment is triggered, the applicant can choose to submit study and other supplementary data to refine the ERA so as to pass the assessment criterion, as long as the applicant can provide the assessors with sufficient information to justify the reasoning.

2.4.2.4 Bioconcentration risk in higher tiers

When 1st tier assessment shows that the pesticide may have a high potential to bioconcentrate, then higher tier risk assessment is appropriate. The following exposure routes could be considered:

1. Direct long-term effects in fish due to bioconcentration;
2. Secondary poisoning for birds and mammals; poisoning for birds and mammals;
3. Biomagnification in aquatic chains.

The specific evaluation and data requirements should be determined on a case-by-case basis.

2.5 Environmental risk management suggestions

2.5.1 Risk mitigation measures

When ERA for a certain pesticide indicates that the risk to aquatic ecosystems may only be acceptable providing that risk mitigation measures are used, such mitigation measures shall be taken into account for the risk managers to make a regulatory decision and explicit description on the label of the pesticide regarding the mitigation measures shall be ensured.

It should be noted that such mitigation measures should not weaken the efficacy of the pesticide. Moreover, it is important for the risk managers to assess the feasibility of such mitigation measures in terms of enforcement.

Table 2.8 provides the information on mitigation measures for surface water with good or limited feasibility in China.

Table 2.8
Relevant options for risk mitigation measures for aquatic organisms in China

Risk mitigation measure	Effectiveness of measure (relative reduction in exposure)	Conditions	Overall feasibility in China (good, limited, difficult)	Corresponding Label statement
Apply drift-reducing techniques [drift reduction]	25-99%, depending on specific technique	If cost increase for farmer is limited	Limited	LS.A.1 LS.A.5
Do not authorize aerial applications [drift reduction]	Variable	If ground applications can be used alternatively	Good	LS.A.1 LS.A.6
Restrict use to low- or no-emission applications (e.g. indoor applications, baiting, dipping, smearing or brushing, seed treatment) [all]	(almost) complete	If pest/disease/weed allows this measure If alternative pesticides or other pest management options are available against the target pest/disease/weed	Good/ Limited	LS.A.1
Reduce the application rate [all]	About linearly proportional to reduction in application rate	If efficacy of the pesticide is not affected.	Good	LS.A.1
Restrict use to formulation types that result in less drift/run-off/ drainflow (e.g. slow-release formulations, seed coatings, granules) [all]	Variable	If pest/disease/weed allows this measure	Good	LS.A.1
Refuse registration [all]	Complete	If alternative pesticides or other pest management options are available	Good	
Restrict use to paddy fields where no fish/shrimp/crab is raised.	Partial	Only relevant for paddy fields. If alternative pesticides or other pest management options are available	limited	LS.A.2 LS.A.1
no drainage of the paddy field immediately after spray.	Partial/variable	Only relevant for paddy fields Only when agricultural practice allows	good	LS.A.3 LS.A.1
Restrict use to the fields where no adjacent aquaculture area	Partial	If alternative pesticides or other pest management options are available	limited	LS.A.1 LS.A.4

If any risk mitigation measure is recommended, the risk assessor should re-evaluate the risk of the pesticide, taking into account the estimated effectiveness of the mitigation measure.

2.5.2 Labeling

There are two types of label statements:

A. General label statement which should be applied on all labels as a precautionary statement:

- LS.A.1: Do not clean the spray/application equipment in the river/stream/lake/pond.

B. Specific label statements linked to mitigation measures, which therefore should be used when a specific mitigation measure is required to reduce the risk to an acceptable level:

- LS.A.2 Do not apply the pesticide in the paddy field where fish/shrimp/crab is raised.
- LS.A.3 Do not drain the paddy field immediately after spraying.
- LS.A.4 Do not apply the pesticide adjacent to the aquaculture area.
- LS.A.5 Special drift-reducing techniques (specify the technique) should be used when the pesticide is applied.
- LS.A.6 Do not apply the pesticide by aerial applications.

2.6 Reference

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Appendix 2-1

Conditions, guidelines and endpoints of the required environmental fate tests

Data requirement	Conditions for a.i.	Conditions for formulations	Test Guideline	End point/Test results
Hydrolysis as a function of pH value	The test should be performed for three pH value of buffer solution.	-	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 111	DT_{50} a.i. in each pH value of buffer solution
Aerobic transformation in water-sediment system	The test should be performed for two types of water-sediment system under aerobic condition.	_	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 308	DT_{50} a.i. in water-sediment system (total system)
Anaerobic transformation in soil	The test should be performed for three types of soils at least when the a.i. will be applied to paddy field.	_	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 307	DT_{50} a.i. in soil
Soil adsorption	The test should be performed for three types of soil at least.	_	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 106	Koc or Kom a.i. in soil
Field study		Expert judgment is required to decide if field tests could provide useful information, case by case.		

Appendix 2-2

Conditions, guidelines and endpoints of the required aquatic toxicological tests

Data requirement	Conditions for a.i.	Conditions for formulated products	Test Guideline	End point/ Test results
Acute toxicity to Fish	**Test should be done** for one warm water species *(recommended species: BChydonio rerio*). One extra cold water species must be tested if the test of warm water species results in 'highly toxic'(LC_{50}<1.0 mg/L)	Required where* the a.i. is highly toxic to fish(LC_{50} from acute test of the a.i. < 1.0 mg/L) Or the formulated product contains more than one a.i.. **Test should be done** for one species: the most sensitive one, concluded from the a.i. acute tests;	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 203	LC_{50} mg/L
Bioconcen-tration	**Test should be done** for one of the following species: *Cyprinus carpio*; *Bhydanio rerio* *Oryzias latipes* *Xiphoporus helleri*	(not required for formulated product)	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 305	BCF
Acute toxicity to *Daphnia*	**Test should be done** for one species: *Daphnia magna*	Required where*: the a.i. is highly toxic to *Daphnia*(EC_{50} from acute test of the a.i. < 1.0 mg/L) Or the formulated product contains more than one a.i.. **Test should be done** for one species: *Daphnia magna*	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 202, part 1	EC_{50} mg/L
Toxicity to Algae	**Test should be done** for one of the following three: species *1. Chlorella vulgaris;* *2. Scenedesmus obliquus;* *3. Seonastrum capricornutum*	Required where the a.i. is highly toxic to Algae (EC_{50} from acute test of the a.i. < 0.3 mg/L) Or the formulated product contains more than one a.i.. **Test should be done** for one species of the following three: *1. Chlorella vulgaris;* *2. Scenedesmus obliquus;* *3. Seonastrum capricornutum*	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 201	EC_{50} (NOEC) mg/L
Toxicity to Shrimp & Crab	**Test should be done** for one species of shrimp and one species of crab. The recommended species are *Macrobhium nipponense* and *Eriocheir sinensi,* respectively..	(Not required for formulated product)	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines	EC_{50} (NOEC) mg/L
Further studies (field tests, etc.)	Where necessary a higher tiered study should be carried out case by case. Higher tiered study includes e.g. mesocosom study, monitoring study, etc.	Where necessary a higher tiered study should be carried out case by case. Higher tiered study includes e.g. mesocosom study, monitoring study, etc.		

* If from the data of acute tests of a.i. (fish, daphnia, algae), it can be concluded one of the three taxonomic groups is the most sensitive (100 times more sensitive), tests on only the most sensitive species of the relevant group have to be performed. Otherwise, all the three groups have to be tested.

3 Birds

3.1 Introduction

3.1.1 Purpose and content of this chapter

This chapter gives guidance on how to assess the risk of the use of pesticides to birds. The assessment process described in this chapter proceeds according to the methodology and concept of ERA described in Chapter 1. After giving a general introduction, a tiered approach based on pragmatic decisions is described.

This chapter is divided into the following 5 sections:
3.1 Introduction (including detailed protection goal, etc);
3.2 Environmental risk assessment;
3.3 Exposure analysis;
3.4 Effect assessment;
3.5 Environmental risk management suggestions.

The uniform structure described in the general introduction in Chapter 1 applies to this chapter with, however, some changes to several sections relating to exposure analysis. This is mainly because it is particularly difficult to quantify the exposure of birds to a pesticide, both spatially and temporally. In this chapter, risks of a particular pesticide to birds are assessed for all relevant exposure routes, which are carefully identified and established, based on preliminary considerations about potential exposures that may raise concerns.

3.1.2 Detailed protection goals

'Birds' is identified as one of the protection goals in this handbook. For this protection goal, details of the protection goal are addressed by answering to the following 3 questions:

Question 1: What do we want to protect?
Answer: All non-target wild birds need to be protected. Domestic birds will also be protected, as far as they may feed in treated crop fields.

Question 2: Where do we want to protect?
Answer: Birds will be protected in the treated crop fields, or other treated locations, i.e. the risk at the landscape scale is not considered.

Question 3: How strict do we want to protect? What are the criteria?
Answer: The greatest concern are effects at the population level. However, there is also strong public concern regarding the deaths of individual birds from the use of pesticide products, even though they may not have any significant effect on the population. Partly for that reason, and also because of the lack of agreed upon criteria for the acceptability of effects at the population level, only the risk to non-target individual birds (both mortality and reproduction effects) is assessed in this handbook.

No observed effect to any individual bird is accepted, at any time scale (acute, short-term and long-term; see section 3.2.1.1).

3.2 Environmental risk assessment

3.2.1 Identifying the relevance of the risk to birds

Section 3.2 gives guidance on the principles for the decision-making process of ERA for birds. Readers should note that a preliminary phase is required, identifying the relevance of the risk of the pesticide to birds. It is reasonable to trigger the assessment only if the exposure of birds to the pesticide of concern cannot be excluded according to its use pattern.

If a pesticide product is to be used indoors, e.g. within a glasshouse, domestic premises, factories, grain stores and other enclosed structures, then the risk to non-target birds is considered to be negligible. However, certain indoor uses of rodenticides may expose birds, and therefore they do require risk assessment. Certain pesticide products used outdoors may also pose a negligible risk. In cases where the exposure or risk is considered negligible, an appropriate justification should be given.

When the exposure of birds cannot be excluded, the formulation types and use patterns of a pesticide are of particular importance when considering which exposure routes could be regarded as relevant. Such considerations may hence greatly influence the estimation of the exposure dose.

There are 4 representative exposure routes which are identified and defined in this handbook (see Section 3.2.1.2). Readers should note that some potential exposure routes are not included in the handbook based on considerations with regard to the scope of the risk assessment.

3.2.1.1 Scope of the risk assessment

The scope of the risk assessment in this Chapter is: the determination of direct risk of a pesticide to non-target birds. The direct risk is defined as the risk from dietary exposure, i.e. from exposure to the product itself including exposure through treated or contaminated food. The dietary exposure could result from direct consumption of the pesticide product or the consumption of treated food (primary poisoning), and consumption of food that, although not directly treated, contains the active ingredients (secondary poisoning). However, secondary poisoning is at this stage only assessed for rodenticides in this handbook.

Exposure via non-dietary routes, e.g. dermal exposure and inhalation, is not considered because there is no generally accepted procedure for assessing them.

Moreover, the handbook does not include the risk to non-target birds from indirect effects, i.e. the removal of food sources due to the action of the plant protection products or alteration of habitat structure.

In determining the level of risk to birds, the following time scales are considered:
- Acute: minutes to hours, representing high level acute exposure, resulting in immediate effects.
- Short-term: hours to days, representing exposure routes with relatively high exposures over several days. Also appropriate for acutely toxic compounds with delayed effects (e.g. rodenticides).
- Long-term: days to weeks, representing long-term, low-level exposures, especially relevant to pesticides with bioaccumulative effects.

3.2.1.2 Representative Exposure Routes

Four representative exposure routes are defined in this handbook. Risks should be characterized for each relevant exposure route, if applicable. Based on EU experience, exposure via the drinking of surface water is known not to raise concerns, except in very rare cases, and is therefore not considered at this moment. Assessment of dermal and inhalation exposure is under development worldwide; no internationally accepted method for assessment is presently available.

Exposure Route 1: Exposure to sprayed crops, plants or insects.
In the case of spraying applications, intake via contaminated food is generally considered to be the most important exposure route.

Exposure Route 2: Exposure to treated seed
In the case of application as seed treatment, intake via contaminated food is generally considered to be the most important exposure route.

Exposure Route 3: Exposure to granules
For farmland birds, grit consumption, both for mineral content and for mastication, is an important constituent of dietary intake. For granularly formulated products, granules may be ingested accidentally when birds probe for, or peck at, food in or on treated soil, or they may be ingested intentionally by birds that mistake them for grit or food. It is not usual to assess all these routes in detail. The methods for assessing the potential risk for the two major routes, ingestion of granules when seeking grit and ingestion of soil when seeking food, are presented in this handbook.

Exposure Route 4: Exposure to rodenticides
For rodenticides primary poisoning by exposure to the rodenticide and secondary poisoning by exposure to contaminated rodents are the two main exposure routes considered in this handbook. However, secondary poisoning is considered to be relevant only for anticoagulants or rodenticides which have the potential for bioaccumulating and which have a 'slow acting' mode of action.

3.2.2 Risk characterization

The risk characterization of birds is expressed as a Risk Quotient (RQ, see also Chapter 1), which shall be calculated according to the formula below.

$$\mathbf{RQ} = \frac{\mathbf{PEC}}{\mathbf{PNEC}}$$ Formula 3.1

RQ: Risk Quotient
PEC: Predicted Exposure Concentration, which is calculated for each individual exposure route, if applicable (see detailed calculations in Section 3.3).
PEC is defined as Predicted Exposure Concentration and not as Predicted Environmental Concentration, since exposure is calculated on a body weight basis.
In US and EU, the phrase 'Estimated Theoretical Exposure' is sometimes used in bird risk assessment instead of 'PEC'. For the sake of consistency, PEC and PNEC are used in the handbook as the standard phrases referring to the exposure concentration (dose) and effect level
PNEC: Predicted No Effect Concentration, which is calculated by using toxicity data and associated uncertainty factors (see detailed calculation in Section 3.4).

The risk of a particular pesticide product to birds for different time scales, i.e. acute, short-term and long-term (see Section 3.1.2, Question 3), should be addressed by calculating separate RQs for each of the time scales.

3.2.3 Decision-making Scheme

Flowcharts 3.1, 3.2, 3.3 and 3.4 give step-wise guidance on the overall decision-making process of risk assessment for birds. The Explanatory Notes for the decision-making schemes give additional information to the flowcharts. Readers should refer to the decision-making schemes to assess the risk of a particular pesticide of concern. The final decision of the risk assessment should be made according to the criteria described in the following text, if appropriate, i.e. the criterion based on RQ calculation and the one seed/granule criterion.

3.2.3.1 Criterion based on RQ calculation
When toxicity data and exposure estimates are put into the formula, both numbers have to match with regard to time scale and their units to express concentrations; both should be expressed as either a daily dose or a concentration.

If the value of RQ is below or equal to 1, the risk is considered to be acceptable. If the value of RQ is above 1, it indicates that the risk could be unacceptable. However, higher tier risk assessment can be used to refine the risk assessment in order to lower the RQ. A tiered approach for ERA of birds is described in the following section.

3.2.3.2 One-seed/granule criterion

The one-seed dose or one-granule dose is the amount of the active ingredient per kg body weight that a bird will consume (be exposed to) when eating one seed or one granule. If birds are exposed and the amount of active ingredient in one granule or seed exceeds the LD50 the risk to birds will be considered as very high.

3.2.4 Tiered approach

3.2.4.1 Conceptual model

The conceptual model of the ERA scheme for birds was set up in such a way that the tiers for the effect assessments can be linked to any of the tiers for the exposure analysis, and vice versa. This so-called 'criss-cross' model allows optimal flexibility in the data that may be submitted by the applicant and in the assessment. Figure 3.1 shows the 'criss-cross' model for the risk assessment of birds.

A tiered approach shall then be used for ERA of birds according to the conceptual model. The conceptual model is applicable for each exposure route. At the 1st tier, the risk shall be assessed using effect data based on laboratory studies and the exposure doses based on realistic worst-case assumptions When the risk characterization results in a value of RQ above 1, a higher tier assessment can be used to refine the risk assessment by refining either the effect assessment and/or refining the exposure analysis as demonstrated in the model in Figure 3.1.

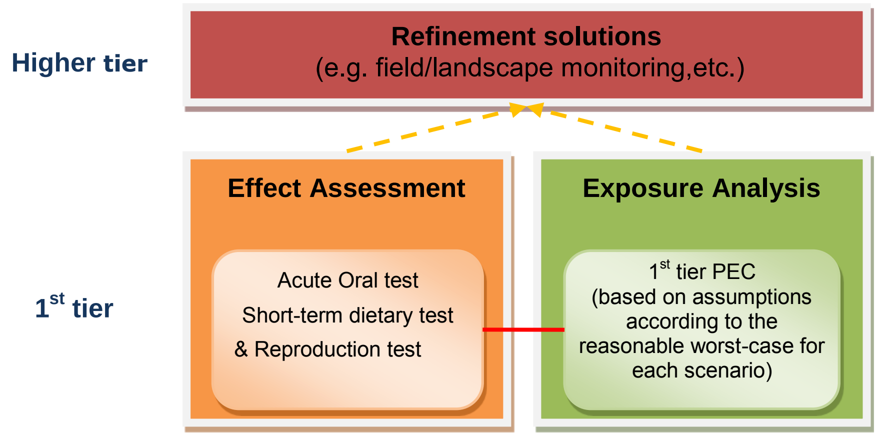


Figure 3.1 *The 'criss-cross 'model for the risk assessment of birds.*

3.2.4.2 1st tier

The 1st tier risk assessment of birds, which should be considered as a standard assessment module, is based on a combination of the 1st tier exposure analysis and the 1st tier effect assessment (see Figure 3.1). Table 3.1 summarizes the PNECs and PECs used for risk characterization at the 1st tier.
For the detailed guidance on 1st tier exposure analysis and explanation of associated abbreviations, please see Section 3.3.

For the detailed guidance on 1st tier effect assessment and explanation of associated abbreviations, please see Section 3.4.

Table 3.1

PNECs and PECs used for risk characterization at the 1st tier

Exposure route	Time scale	PNEC	PEC
Exposure Route 1: Exposure to sprayed crops, plants or insects	Acute	$PNEC_{acute}$	PEC_{acute}
	Short-term	$PNEC_{Short-term}$	$PEC_{short-term}$
	Long-term	$PNEC_{Long-term}$	$PEC_{long-term}$
Exposure Route 2: Exposure to treated seed	One seed criterion	NA(see section 3.4)	PEC_{OSD} or PEC_{OBD}
	Acute	$PNEC_{acute}$	PEC_{acute}
	Short-term	$PNEC_{Short-term}$	$PEC_{short-term}$
	Long-term	$PNEC_{Long-term}$	$PEC_{long-term}$
Exposure Route 3: Exposure to granules	One granule criterion	NA(see section 3.4)	PEC_{OGD}
	Acute	$PNEC_{acute}$	PEC_{acute}
	Short-term	$PNEC_{Short-term}$	$PEC_{short-term}$
	Long-term	$PNEC_{Long-term}$	$PEC_{long-term}$
Exposure Route 4: Exposure to rodenticides	Primary poisoning:acute	$PNEC_{acute}$	$PEC_{acute-p}$
	Primary poisoning:Short-term	$PNEC_{Short-term}$	$PEC_{short-term-p}$
	Primary poisoning:Long-term	$PNEC_{Long-term}$	$PEC_{long-term-p}$
	Secondary poisoning:acute	$PNEC_{acute}$	$PEC_{acute-s}$
	Secondary poisoning:Short-term	$PNEC_{Short-term}$	$PEC_{short-term-s}$
	Secondary poisoning:Long-term	$PNEC_{Long-term}$	$PEC_{long-term-s}$

3.2.4.3 Higher tier

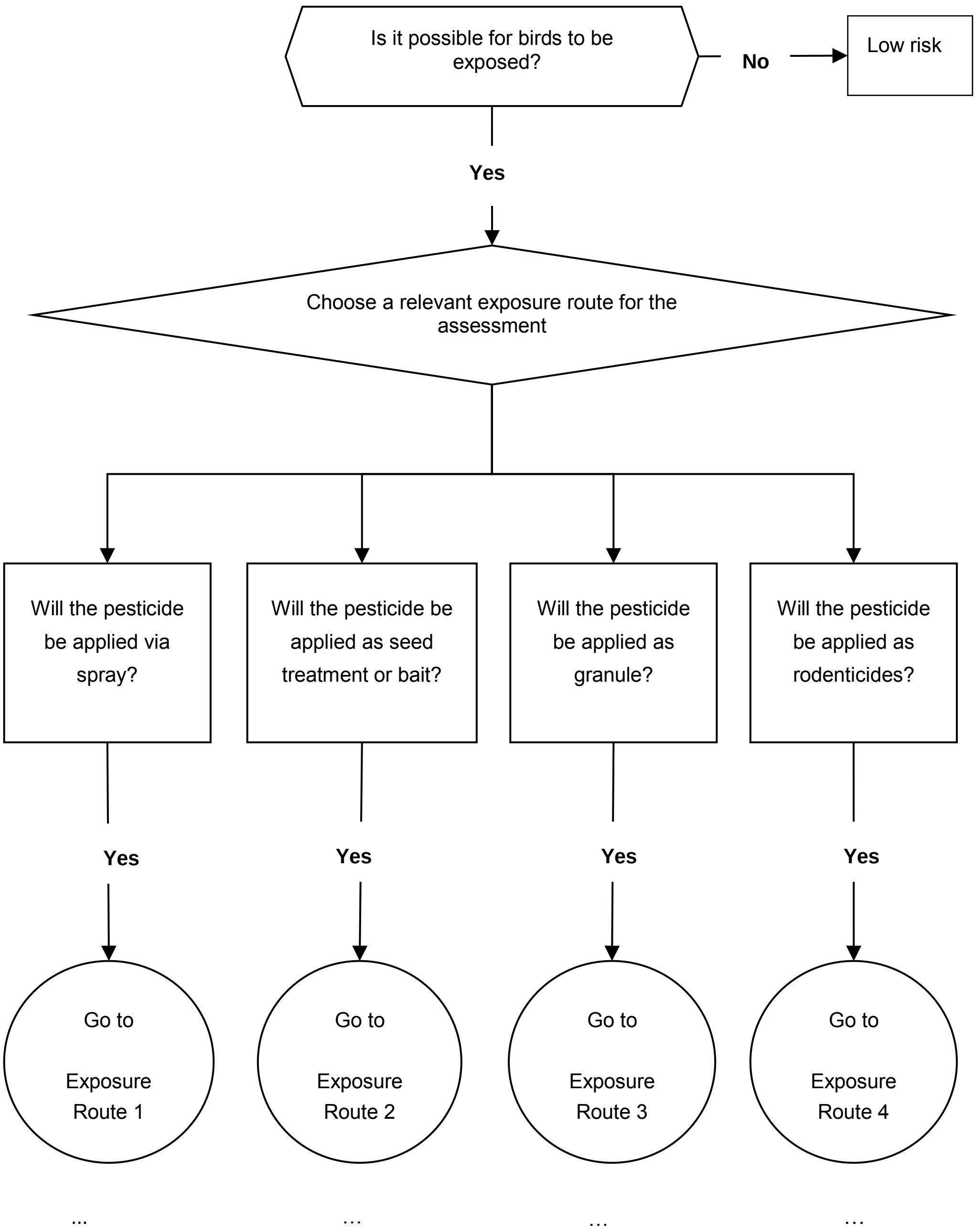
The refinement always needs additional data, either specific data on the product to be assessed or generic data. Some information may already be available in the dossier or can be produced through literature searches, other data have to be generated by performing new studies. As it is desirable to minimize animal testing, other options for refinement should be explored first, where possible. The assumptions and input data in the refinement steps should always be fully justified. It should be noted that refinement reduces the uncertainty and produces a more precise characterization of the risk, but additional data do not necessarily result in a risk level which is lower than previously estimated.

Feasible refinement recommended in this handbook is based on refining the exposure analysis, e.g. using residue trial data instead of default data in exposure estimation. For the detailed description of the recommended refining options, please see Section 3.3.

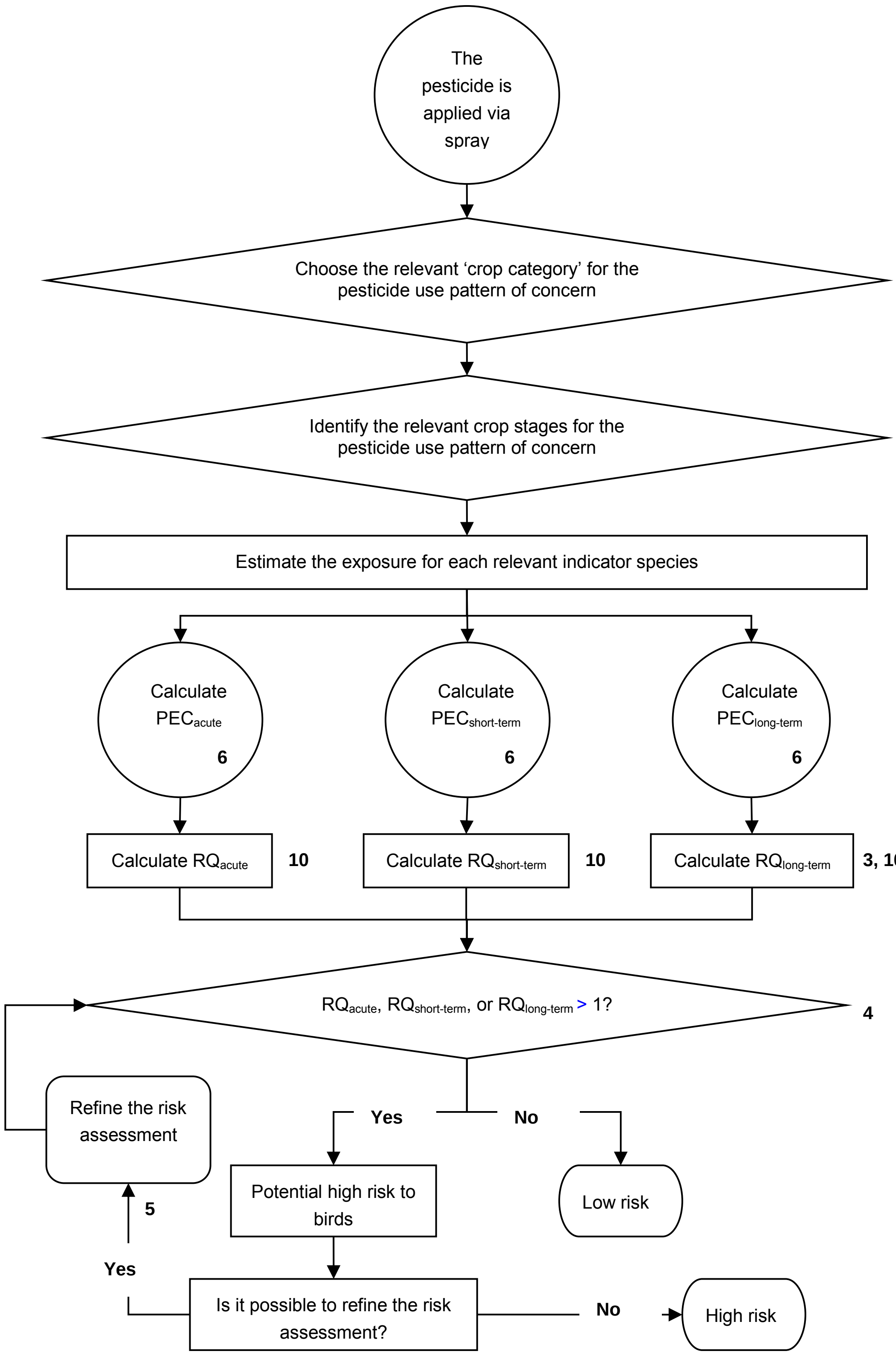
The applicants are also welcomed to supply their own risk assessment results as additional reference information, along with explicit interpretation on the scientific methodology, step-wise procedure and expert judgment, if applicable.

3.2.4.4 Mitigation measures

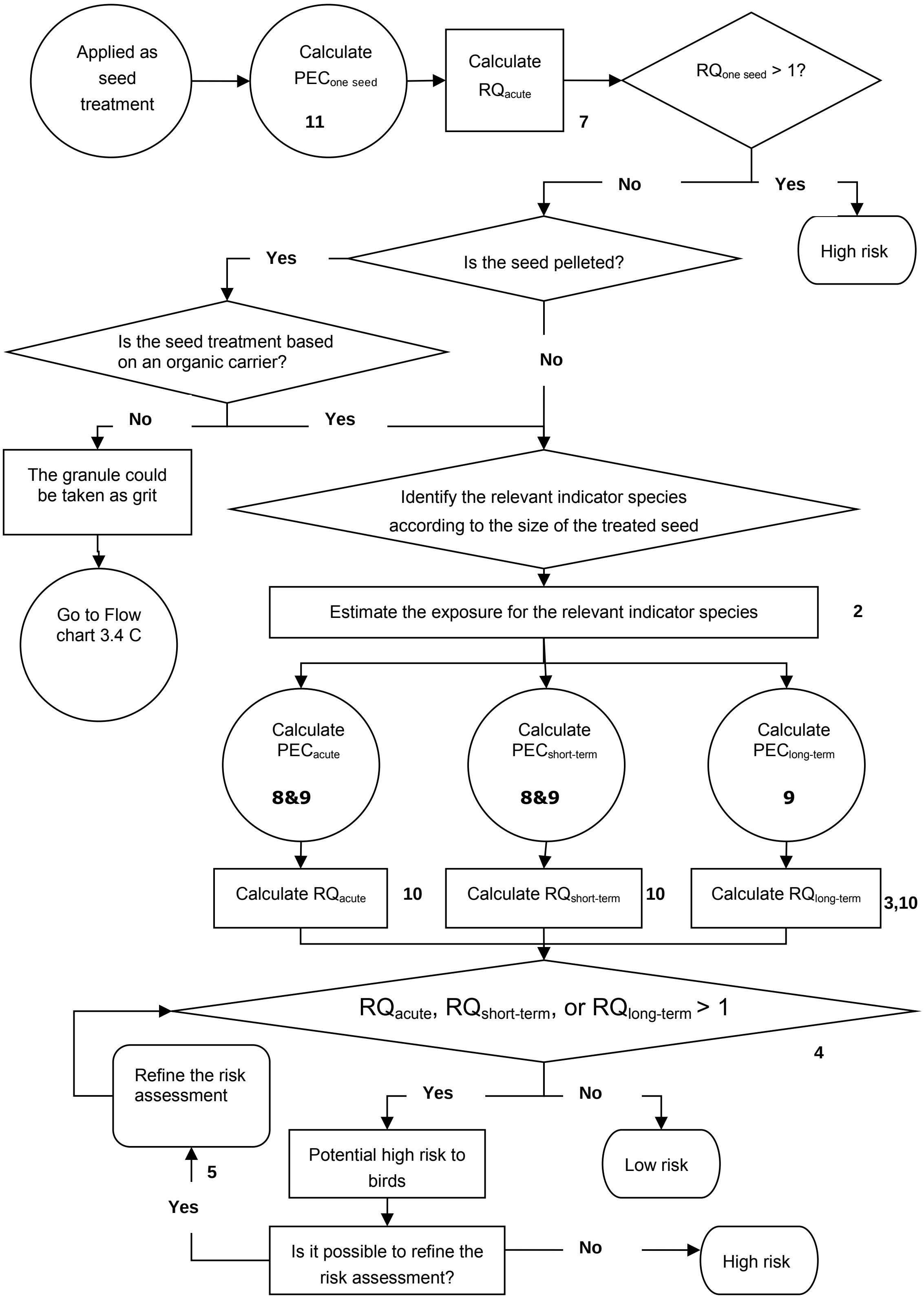
A standard risk assessment, or a higher-tier risk assessment, may indicate that the risk to birds may only be acceptable provided that risk mitigation measures are used. Necessary mitigation measures and other precautionary notices shall then be clearly described on the label of the pesticide products. Detailed guidance is given in Section 3.5.



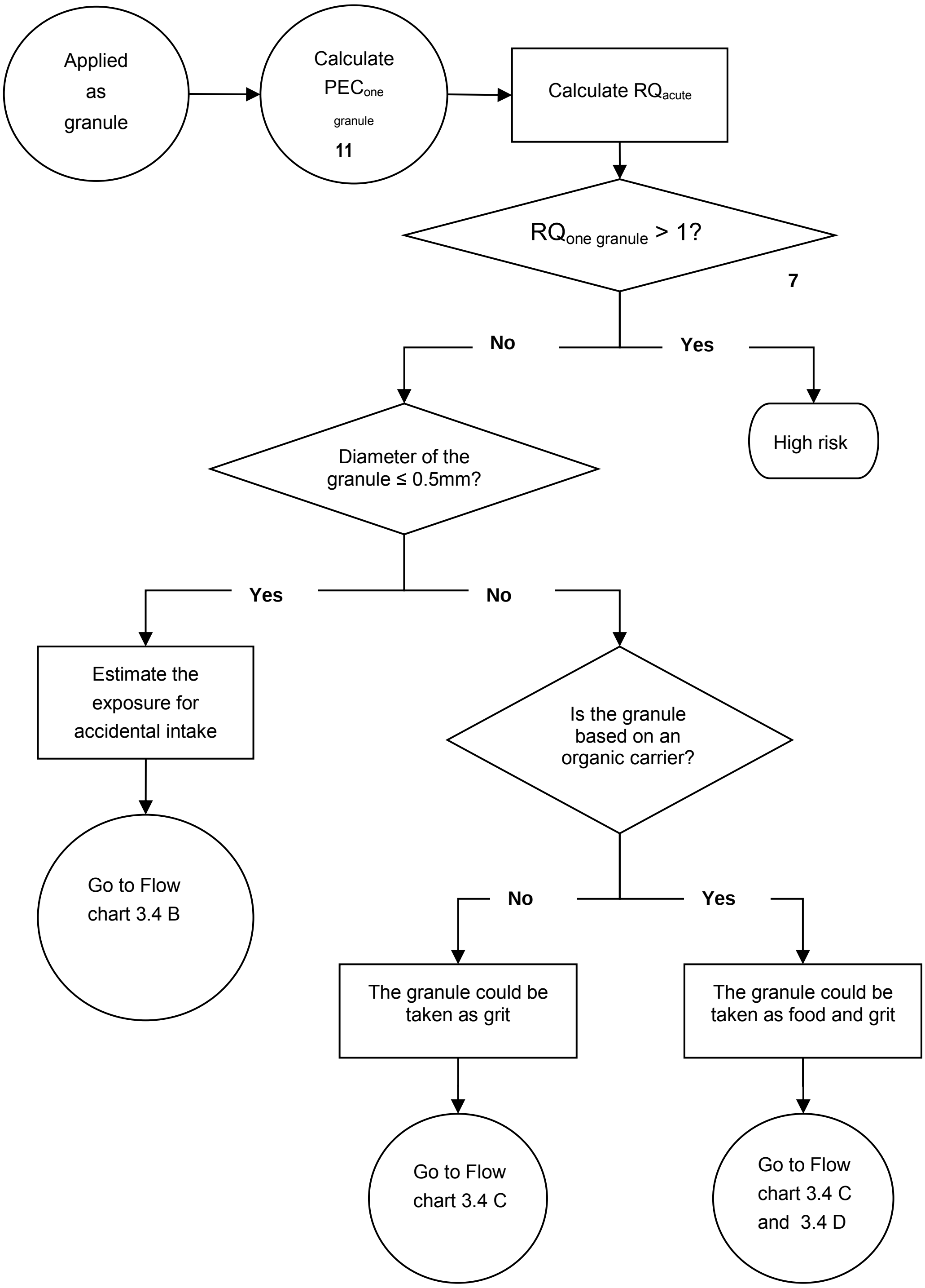
Flowchart 3.1 *Decision-making scheme for ERA of birds – GENERAL.*



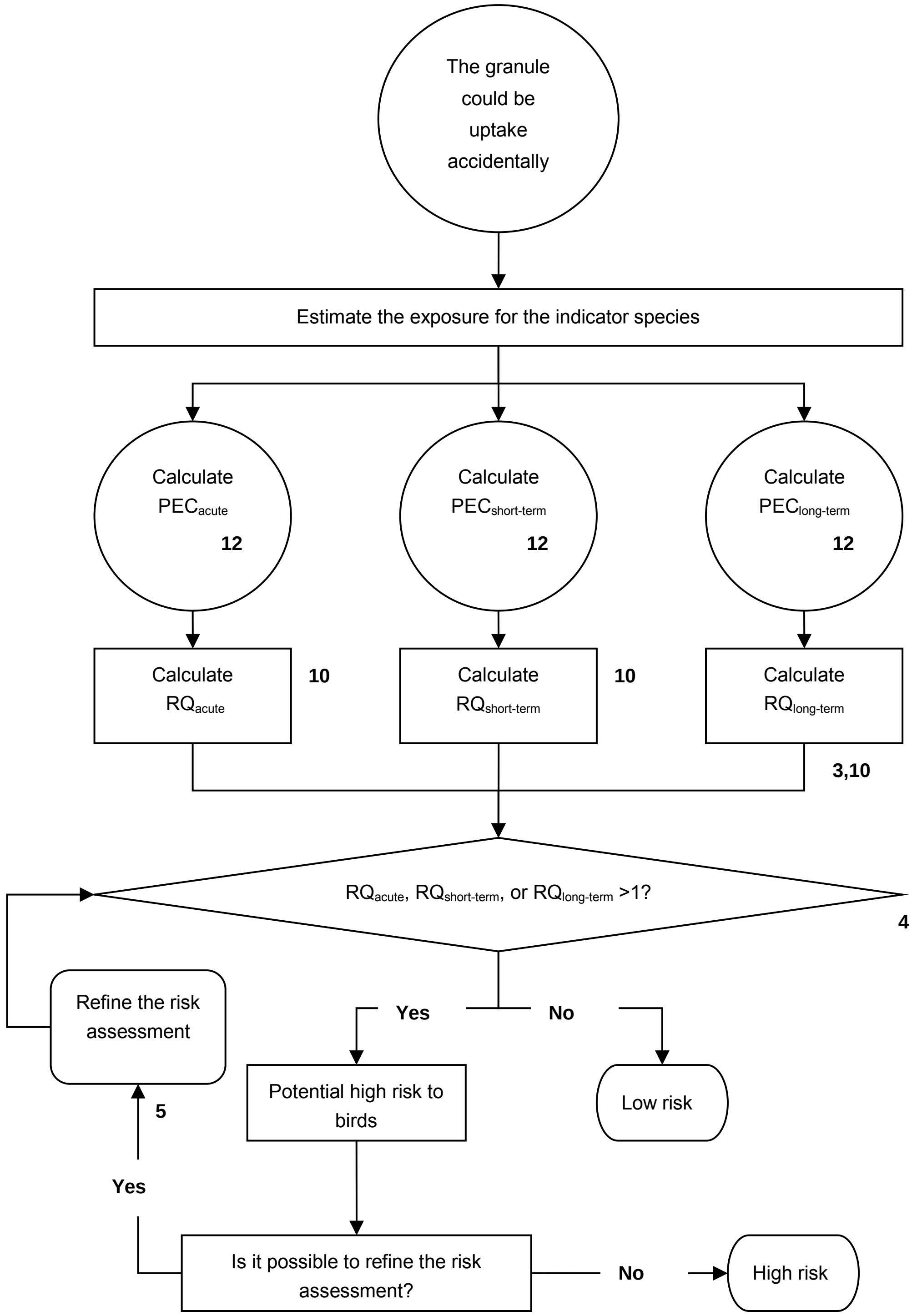
Flowchart 3.2 *Decision-making scheme for ERA of birds – Exposure Route 1:Sprayed crops, plans or insects.*



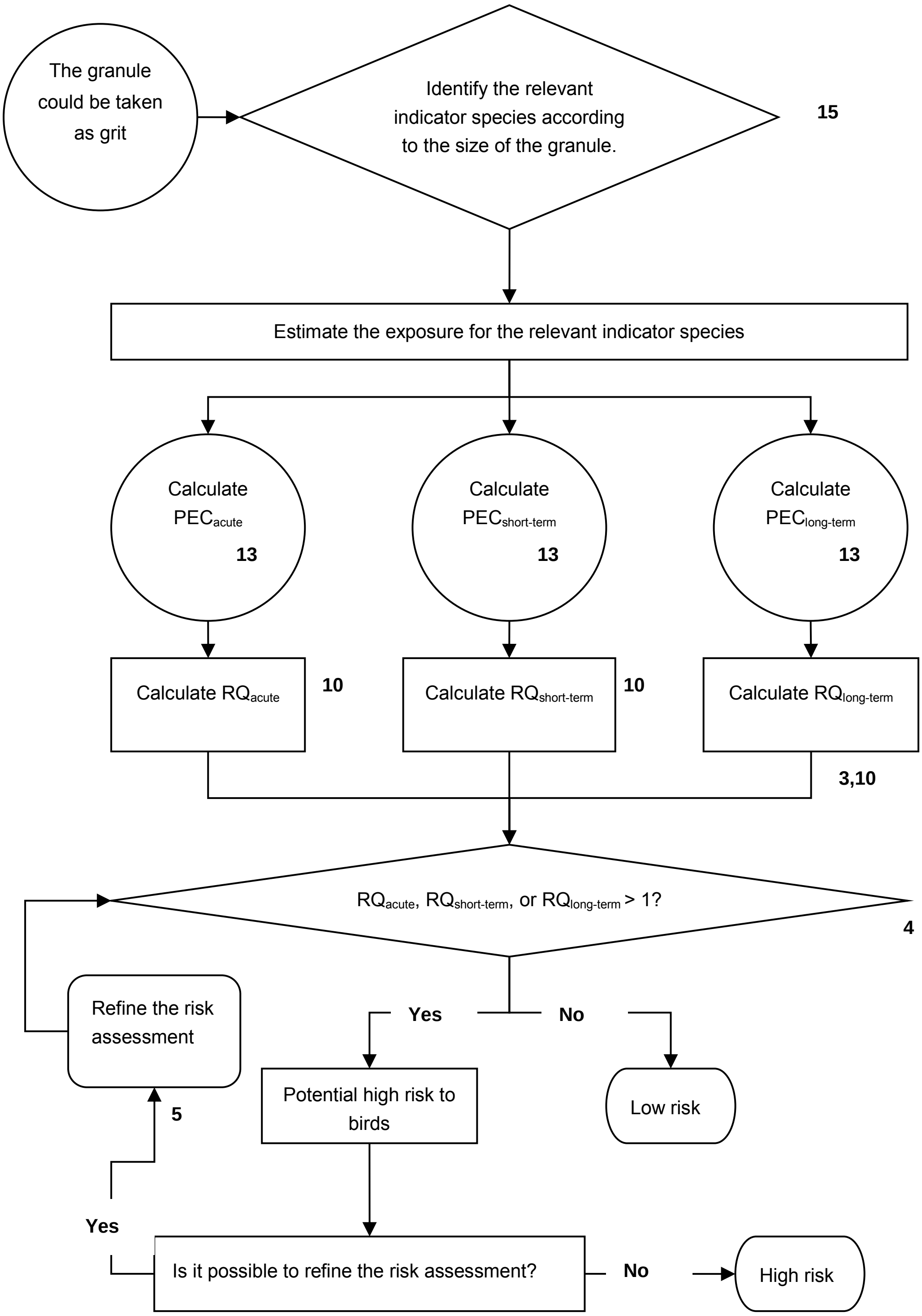
Flowchart 3.3 *Decision-making scheme for ERA of birds – Exposure Route 2: seed treatments.*



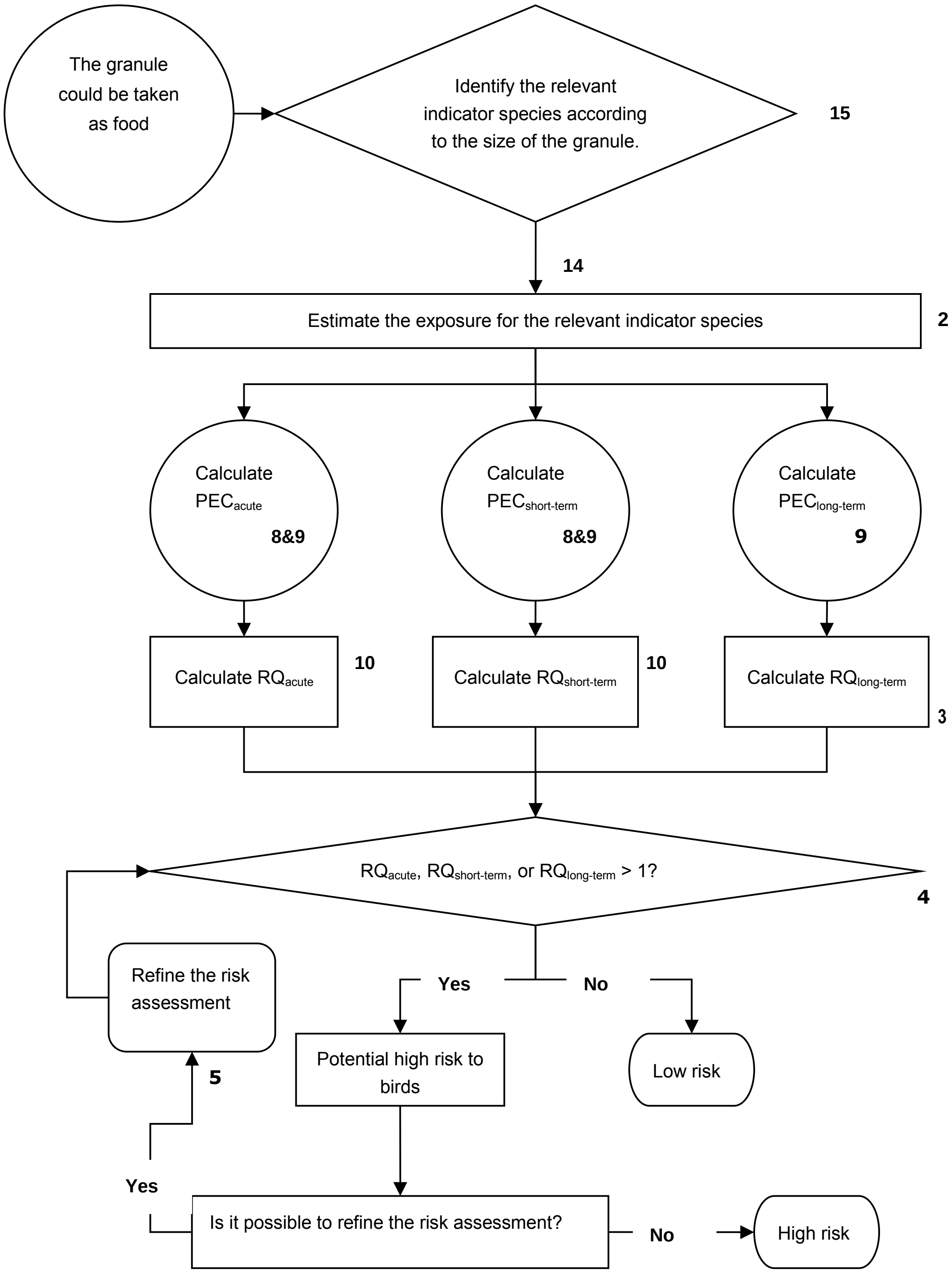
Flowchart 3.4A *Decision-making scheme for ERA of birds – Exposure Route 3 (general): Treatment with granules.*



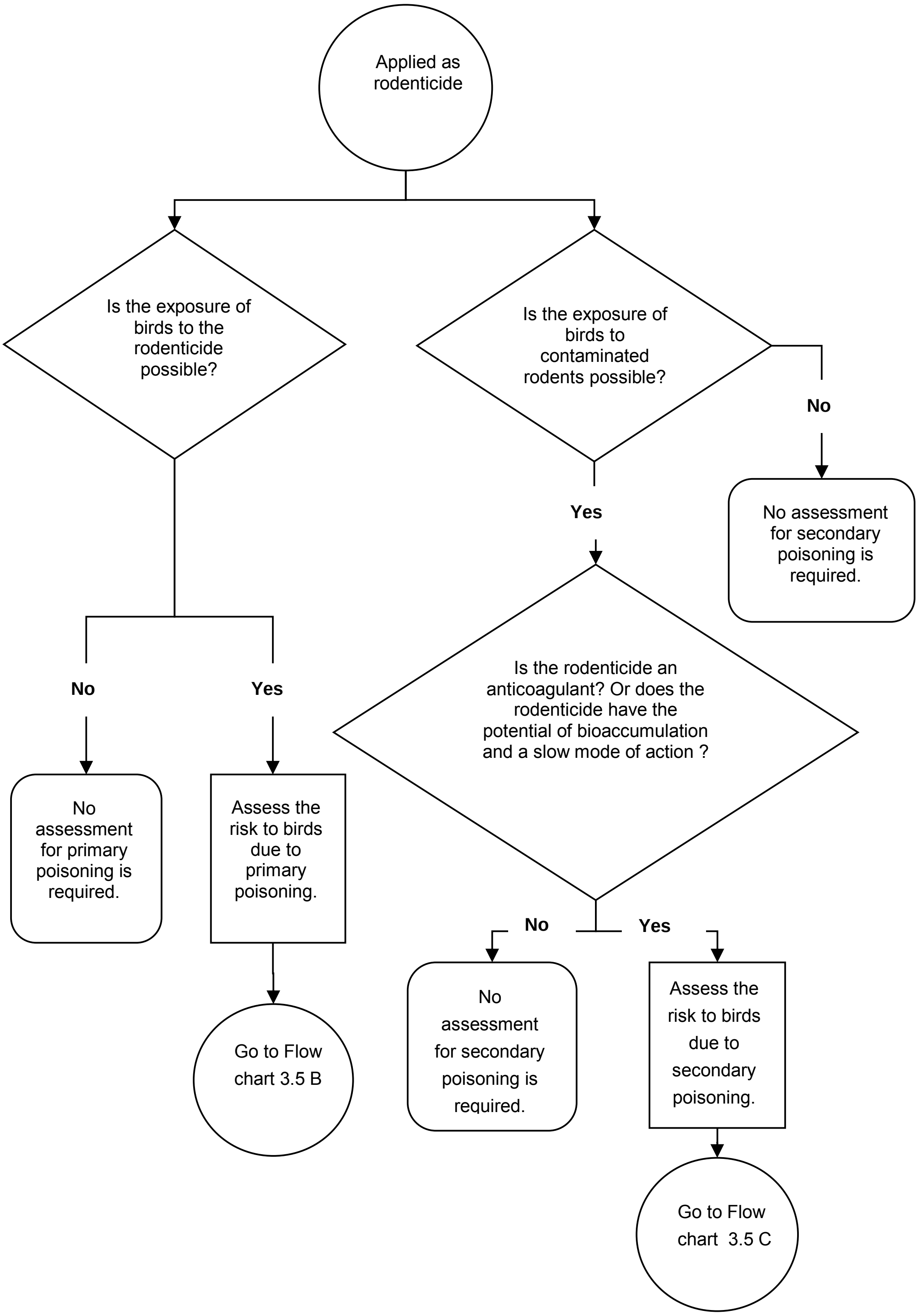
Flowchart 3.4B *Decision-making scheme for ERA of birds – Exposure Route 3:accidental uptake of granules.*



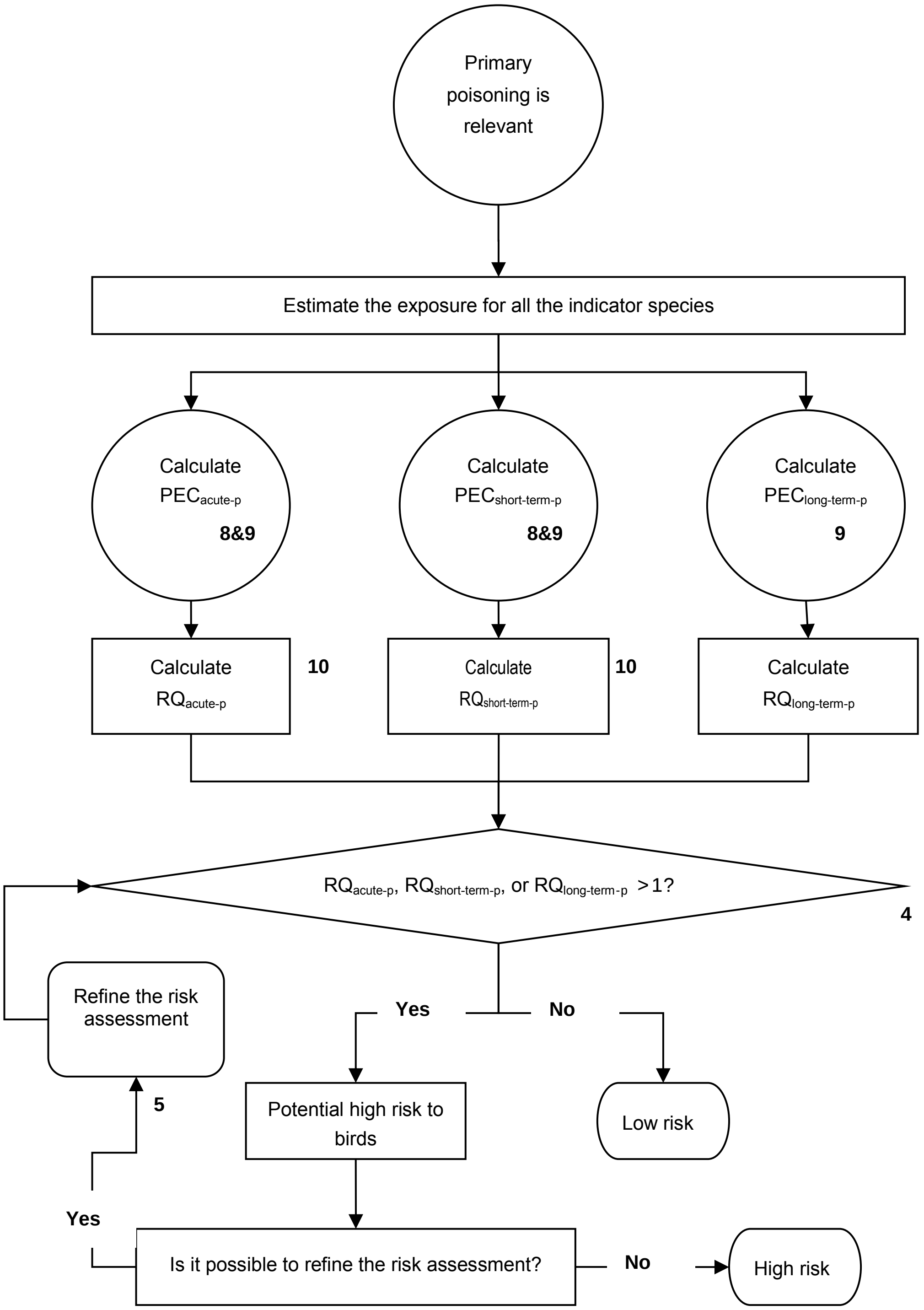
Flowchart 3.4C *Decision-making scheme for ERA of birds – Exposure Route 3: uptake of granules as grit.*



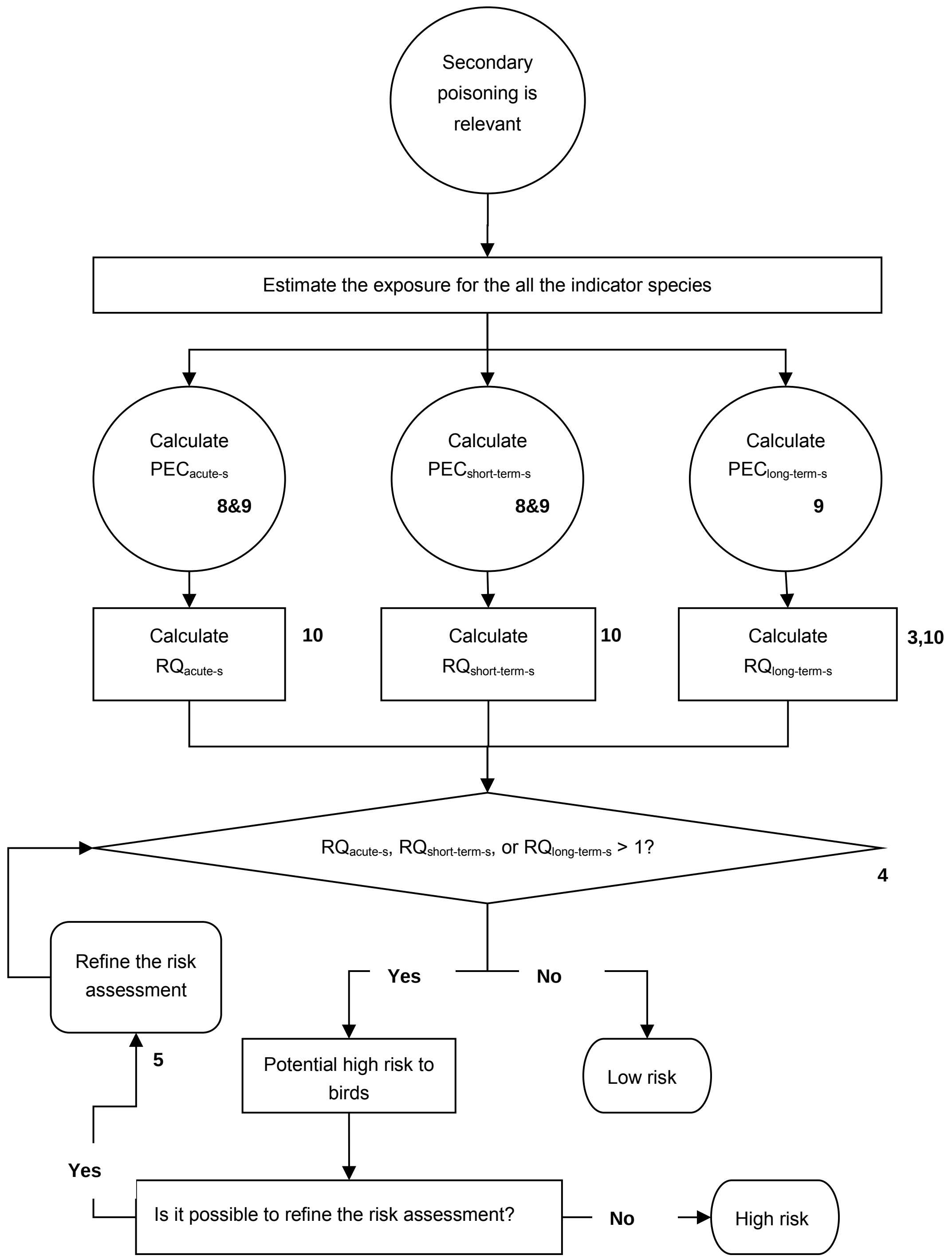
Flowchart 3.4D *Decision-making scheme for ERA of birds – Exposure Route 3: uptake of granules as food.*



Flowchart 3.5A *Decision-making scheme for ERA of birds – Exposure Route 4: Rodenticides.*



Flowchart 3.5B *Decision-making scheme for ERA of birds – Exposure Route 4: Rodenticides – primary poisoning.*



Flowchart 3.5C *Decision-making scheme for ERA of birds – Exposure Route 4: Rodenticides – secondary poisoning.*

Explanatory Notes to Flowchart 3.1, 3.2, 3.3, 3.4 (A, B, C, D), and 3.5 (A, B, C)

1. All relevant crops listed in the 'crop category' (Section 3.3.1, Table 3.2) should be assessed, unless there are sufficient data to indicate that only part of the crops are relevant to the pesticide use pattern of concern.
2. Exposure estimations should be done for all the relevant indicator species.
3. If acceptable chronic data for the pesticide of concern are available from the dossier submitted by the applicant, $RQ_{chronic}$ should be calculated by using the endpoints (NOED or NOEL) from the chronic data.
   If no acceptable chronic data are available from the dossier submitted by the applicant, an extra Uncertainty Factor of 10 could be applied so as to account for the extrapolation from acute toxicity endpoint to chronic endpoint (See Section 3.4). If the estimation suggests there would be

a high risk to birds, then the applicant would be required to submit the chronic studies for the pesticide of concern.

4. All three time windows should be assessed.
   If any of the three RQs is above 1, the pesticide of concern is considered to be of 'high risk' to birds for that particular time window, unless the refinement of risk assessment for that particular time window will result in a RQ below 1.
5. See Section 3.2.4.3 for possible higher tier solutions.
6. See Section 3.3.1 for the formulas (Formula 3.7, 3.8 and 3.10) used in this handbook to calculate PEC_{acute}, $PEC_{short\text{-}term}$ and $PEC_{long\text{-}term}$ in Exposure Route 1 - Spray
7. When a pesticide does not pass this criterion, theoretically, this indicates that for the use pattern assessed (at least) 50% percent of birds exposed to only one treated seed (or one granule) would die. Based on Dutch experience, the risk assessment for a pesticide with such a high potential risk tends to always result in the conclusion of 'unacceptable risk' to birds, despite incorporation of any refinements. Therefore, the criterion is set as a basic cut-off limit.
8. $PEC_{acute}=PEC_{short\text{-}term}$
   When a pesticide is applied as seed treatment, bait or as a granular product, the active ingredient is intended to be stable for a relatively long period of time in order to achieve the desired efficacy. Therefore, quick breakdown of the active ingredients in such use patterns is considered not relevant and no f_{twa} is considered for the 1st tier $PEC_{short\text{-}term}$ calculation.
9. See Section 3.3.1.2.2 for the formulas used in this handbook to calculate PEC_{acute}, $PEC_{short\text{-}term}$ and $PEC_{long\text{-}term}$ for bait and non-pelleted seed in Exposure Route 2.
   The same formulas are also used to calculate PEC_{acute}, $PEC_{short\text{-}term}$ and $PEC_{long\text{-}term}$ if the granules could be ingested intentionally by birds as food in Exposure Route 3. See the detailed explanation in Section 3.3.1.3.2.a
10. See Table 3.1 in Section 3.2.4.2 for the input values used in the calculations.
11. See Formula 3.11 used to calculate the PEC_{OSD} (Section 3.3.1.2.1) for estimation of the one seed dose used for the one seed criterion in Exposure route 2. See also Formula 3.18 used to calculate the PEC_{OGD} (Section 3.3.1.3.1) for estimation of the one granule dose used for the one granule criterion in Exposure route 3.
12. See Section 3.3.1.3.2 c for the formulas used in this handbook to calculate PEC_{acute}, $PEC_{short\text{-}term}$ and $PEC_{long\text{-}term}$ if the granules could be ingested accidentally as part of soil in Exposure Route 2.
13. See Section 3.3.1.3.2 b for the formulas used in this handbook to calculate PEC_{acute}, $PEC_{short\text{-}term}$ and $PEC_{long\text{-}term}$ if the granules could be ingested intentionally by birds as grit in Exposure Route 3.
14. When it is considered possible for the granule to be taken by birds as food, the exposure through the granule could be estimated by using the same scheme as used for seed treatment. The indicator species are hence identified according to the same criteria which are used for seed treatment.
15. For the estimation of the realistic worst-case for grit ingestion, it is assumed that small granules (size between 0.5 and 2 mm) are taken by small birds and that large granules (size between 2 and 6 mm) are taken by large birds.

3.3 Exposure analysis

3.3.1 1st tier

Exposure route 1 - Spray
In the 1st tier assessment realistic worst-case scenarios are considered, involving indicator species dependent upon crop category (see Table 3.2). These scenarios are designed for a general assessment of a substance, and are geared towards major crops or a range of crops on EU level, because scenarios specific to the situation in China have not yet been established.

The 'indicator species' given is not a real species but a hypothetical species which, by virtue of its size and feeding habits, is considered to be exposed to higher levels than other species occurring in a particular crop at a particular time. Rice is not included in this document because it will be addressed in the future.

At the start of an exposure analysis for birds, the most relevant exposure scenario for the crop and crop category under consideration should be selected. The information about the relevant crop category can be obtained from the pesticide label.

Table 3.2

Relevant indicator species according to crop (Source: EFSA 2010)

Crop category	Indicator species	Food intake rate (FIR) (g d^{-1})	Body weight (bw) (g)
Bare soils	Small granivorous bird (feeding on weed seeds)	4.3	15.3
Orchards and ornamentals /nursery	Small insectivorous bird	11.4	13.3
Grassland	Large herbivorous bird	740	2645
Vineyard	Small omnivorous bird (feeding on 25% crop leaves,25% weed seeds,50% ground arthropods)	14.8	28.5
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird (feeding on 25% crop leaves,25% weed seeds,50% ground arthropods)	14.8	28.5
Cotton	Small omnivorous bird (Weed seeds 50%,weed plant matter, 25%, animal matter 25%)	10.5	27.7

For all time scales the exposure should be expressed as a daily dose. Thus the equations for acute, short-term and long-term exposure estimates are similar, but the input parameters may be different. The estimated daily uptake of an active ingredient is given by the following formula 3.2:

$$\mathbf{PEC} = \frac{\mathbf{FIR}}{\mathbf{bw}} \times \mathbf{C} \times \mathbf{PT} \times \mathbf{PD}$$ Formula 3.2

In case of multiple applications and/or long-term considerations the concentration C may be expressed as:

$$\mathbf{C} = \mathbf{C_0} \times \mathbf{MAF} \times \mathbf{f_{twa}}$$ Formula 3.3

$$\mathbf{f_{twa}} = \frac{(\mathbf{1 - e^{kt}})}{\mathbf{kt}}$$ Formula 3.4

$$\mathbf{k} = \frac{\mathbf{ln2}}{\mathbf{DT_{50}}}$$ Formula 3.5

The concentration C_0 in the 1st tier assessment is calculated according to the formula below.

$$\mathbf{C_0} = \mathbf{RUD} \times \mathbf{AR}$$ Formula 3.6

with:

PEC: Predicted Exposure Concentration (mg/kg bw d^{-1})
FIR: Food intake rate of indicator species (g d^{-1})
Bw: Body weight (g)
C: Concentration of active ingredient in fresh diet (mg/kg)
PT: Fraction of diet obtained in treated area (number between 0 and 1)
PD: Fraction of food type in diet (number between 0 and 1)
C_0: Initial concentration after a single application (mg/kg)
MAF: Multiple application factor
f_{twa}: Time-weighted-average factor
DT_{50}: half-life of active ingredient in food (day)
K: degradation constant coefficient
T: Averaging time (day)

RUD: Residue unit dose (a.i.mg/kg fresh food which occur immediately after spraying of 1 kg of active ingredient per ha^{-1})

AR: Maximum application rate (a.i.kg/ha)

In the 1st tier it is assumed that the contaminated diet is not avoided, that birds satisfy their entire food demand within the treated area, and that birds feed on a single type of food. The factors PT and PD are therefore set to a value of 1.

Acute exposure

With regard to residues in vegetation and insects, 90th percentiles of the initial concentration ($RUD_{90\%}$) are used in the acute exposure analysis.

Multiple applications may cause build-up of residues and a multiple application factor (MAF) is calculated when more than one application is carried out during a growing season. MAF is a function of the number of applications, the application interval, and the DT_{50}. In the 1st tier, a default value of 10 days for DT_{50} on vegetation is used. $MAF_{90\%}$ values are shown in Table 3.3. Readers should note that in the case of insectivorous birds no MAF is applied. Table 3.4 shows standard residues normalized to an application rate of 1 kg/ha (RUD) for the various scenarios.

Calculation of PEC_{acute} in terms of daily dose (mg/kg bw) is performed according to formula 3.7, using the values presented in Table 3.3 and Table 3.4.

$$\mathbf{PEC_{acute}} = \frac{\mathbf{FIR}}{\mathbf{bw}} \times \mathbf{RUD_{90\%}} \times \mathbf{AR} \times \mathbf{MAF_{90\%}} \qquad \text{Formula 3.7}$$

PEC_{acute}: Predicted exposure concentration for acute exposure (mg/kg bw/d)

FIR/bw: Food intake rate of indicator species per body weight per day (g/g bw/d)

$RUD_{90\%}$: 90th percentile of residue unit dose (mg a.i./kg fresh food which occur immediately after spraying of 1 kg of active ingredient per ha^{-1})

AR: Maximum application rate (kg a.i./ha)

$MAF_{90\%}$: Multiple application factor to be used with 90th percentiles of residues

Table 3.3

Multiple application factors (MAF90%) to be used with 90th percentiles for residues based on DT_{50} of 10d for granivorous, herbivorous and omnivorous birds (Source: EFSA 2010)

Interval (d)	Number of applications								
	1	2	3	4	5	6	7	8	>8
7	1.0	1.4	1.6	1.8	1.9	1.9	1.9	2.0	2.0
10	1.0	1.3	1.5	1.5	1.6	1.6	1.6	1.6	1.6
14	1.0	1.2	1.3	1.3	1.4	1.4	1.4	1.4	1.4

Table 3.4

Spray scenarios for the acute exposure estimate (Source: EFSA 2010)

Crop category	Indicator species	FIR/bw	$RUD_{90\%}$	$MAF_{90\%}$
Bare soils	Small granivorous bird	0.28	87	Table 3.3
Orchards and ornamentals/ nursery	Small insectivorous bird	0.87	54	n.a.
Grassland	Large herbivorous bird	0.30	102	Table 3.3
Vineyard	Small omnivorous bird	0.52	46	Table 3.3
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	0.52	46	Table 3.3
Cotton	Small omnivorous bird	0.38	46	Table 3.3

Short-term exposure

Short-term exposure is assumed to last over a period of a few days. Therefore initial residues are more appropriate than time-weighted averages. However, in the course of some days birds will gather food in an area that is large compared to the spatial scale of residue variation. Therefore averaging of residues is expected to occur and arithmetic means are taken for residues in vegetation and insects. Multiple applications are again considered. However, as residue estimates are based on arithmetic means, standard MAF values can be applied here (Table 3.5). For other frequencies and intervals, MAF_{mean} can be calculated using Formula 3.9. Table 3.6 shows the standard residues, normalized to an application rate of 1 kg/ha (RUD) for the various scenarios.

Calculation of $PEC_{short\text{-}term}$ in terms of daily dose (mg/kg bw) is as follows:

$$\mathbf{PEC_{shor-term}} = \frac{\mathbf{FIR}}{\mathbf{bw}} \times \mathbf{RUD_{mean}} \times \mathbf{AR} \times \mathbf{MAF_{mean}} \qquad \text{Formula 3.8}$$

$$\mathbf{MAF_{mean}} = \frac{\left(1 - e^{(-0.69 \times n \times i)}\right)}{\left(1 - e^{(-0.69 \times i)}\right)} \qquad \text{Formula 3.9}$$

$PEC_{short\text{-}term}$: Predicted exposure concentration for short-term exposure (mg/kg bw/d)
FIR/bw: Food intake rate of indicator species per body weight per day (g/g bw/d)
RUD_{mean}: Arithmetic means of residue unit dose (mg a.i./kg fresh food which occur immediately after spraying of 1 kg of active ingredient per ha^{-1})
AR: Maximum application rate (kg a.i./ha)
MAF_{mean}: multiple application factor to be used with arithmetic means of residues
I: Interval of application (day)
n: Number of applications

Table 3.5

Standard Multiple Application Factors (MAFmean) to be used with mean residues, and based on a DT_{50} of 10d for granivorous, herbivorous and omnivorous birds (Source: EFSA 2010)

Interval (d)	Number of applications								
	1	2	3	4	5	6	7	8	>8
7	1.0	1.6	2.0	2.2	2.4	2.5	2.5	2.5	2.6
10	1.0	1.5	1.8	1.9	1.9	2.0	2.0	2.0	2.0
14	1.0	1.4	1.5	1.6	1.6	1.6	1.6	1.6	1.6

Table 3.6

Spray scenarios for the short-term exposure estimate (Source: EFSA 2010)

Crop category	Indicator species	FIR/bw	RUD_{mean}	MAF_{mean}
Bare soils	Small granivorous bird	0.28	40	Table 3.5
Orchards and ornamentals/ nursery	Small insectivorous bird	0.87	21	n.a.
Grassland	Large herbivorous bird	0.30	54	Table 3.5
Vineyard	Small omnivorous bird	0.52	21	Table 3.5
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	0.52	21	Table 3.5
Cotton	Small omnivorous bird	0.38	29	table 3.5

Long-term exposure

Long-term exposure analysis is very similar to the short-term assessment. Again, residue estimates are based on arithmetic means and for vegetation the same multiple application factors are employed (Table 3.5). In contrast to the short-term assessment, time-weighted-average (twa) residues are used as these better reflect long-term exposure. With regard to residues on vegetation a simple twa-factor is used in the 1st tier which is based on the following default values: a time window of 3 weeks, and a DT_{50} of 10 days. Using these assumptions f_{twa} is 0.53. Table 3.7 shows the standard residues, normalized to an application rate of 1kg/ha (RUD) for the various scenarios.

Calculation of $PEC_{long\text{-}term}$ in terms of daily dose (mg/kg bw) is as follows:

$$\mathbf{PEC_{long-term}} = \frac{\mathbf{FIR}}{\mathbf{bw}} \times \mathbf{RUD_{mean}} \times \mathbf{f_{twa}} \times \mathbf{AR} \times \mathbf{MAF_{mean}}$$ Formula 3.10

$PEC_{long\text{-}term}$: Predicted exposure concentration for long-term exposure (mg/kg bw/d)
FIR/bw: Food intake rate of indicator species per body weight per day (g/g bw/d)
RUD_{mean}: Arithmetic means of residue unit dose (mg a.i./kg fresh food which occur immediately after spraying of 1 kg of active ingredient per ha^{-1})
f_{twa}: Time-weighted-average factor
AR: Maximum application rate (kg a.i./ha)
MAF_{mean}: multiple application factor to be used with arithmetic means of residues

Table 3.7
Pray scenarios for the long-term exposure estimate (Source: EFSA 2010)

Crop category	Indicator species	FIR/bw	RUD_{mean}	MAF_{mean}	f_{twa}
Bare soils	Small granivorous bird	0.28	40	Table 3.5	0.53
Orchards and ornamentals/ nursery	Small insectivorous bird	0.87	21	n.a.	0.53
Grassland	Large herbivorous bird	0.30	54	Table 3.5	0.53
Vineyard	Small omnivorous bird	0.52	21	Table 3.5	0.53
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	0.52	21	Table 3.5	0.53
Cotton	Small omnivorous bird	0.38	29	Table 3.5	0.53

3.3.1.1 Exposure Route 2 - Seed treatment and bait

There are two steps in exposure analysis for seed treatment: i.e. a one seed dose for the one seed criterion and the PEC for assessment of the dietary exposure route. These are described in Sections 3.3.1.2.1 and 3.3.1.2.2 respectively.

Estimation of one seed dose for one seed criterion

In the first step, the exposure of a bird due to consuming one treated seed is estimated: the predicted environmental concentration after a one seed dose (PEC_{OSD})

A distinction is made between small birds and larger birds (seeds like maize, peas or beans are rarely swallowed whole by small birds).The body weight of a small bird is assumed to be 25 g for a seed size smaller than 3.5 mm, whereas that of a larger bird is taken to be 300g for seed sizes bigger than 3.5 mm. Because the endpoint of the toxicity test (LD_{50}) is expressed as mg a.i./kg bw, the one-seed or one-granule dose should be adjusted to a body weight of 1 kg. The PEC_{OSD} is calculated according to following formula 3.11 and 3.12, using values presented in Table 3.8 and 3.9.

For seed treatment:

$$\mathbf{PEC_{OSD}} = \frac{\mathbf{S_{loading}}}{\mathbf{bw}} \times \mathbf{10^3}$$ Formula 3.11

$$\mathbf{S_{loading}} = \mathbf{C} \times \mathbf{OSW} \times \mathbf{10^{-3}}$$ Formula 3.12

For bait:

$$\mathbf{PEC_{OBD}} = \frac{\mathbf{B_{loading}}}{\mathbf{bw}} \times \mathbf{10^3}$$ Formula 3.13

$$\mathbf{B_{loading}} = \mathbf{C} \times \mathbf{OBW} \times \mathbf{10^{-3}}$$ Formula 3.14

$$\mathbf{AR} = \mathbf{cb} \times \mathbf{10^4}$$ Formula 3.15

PEC_{OSD} :	Predicted exposure concentration for one seed dose (mg/kg bw)
$S_{loading}$:	Amount of the active ingredient on one seed (mg)
Bw:	Body weight (g)
C:	Concentration of active ingredient in seed or bait (mg a.i./kg seed or bait)
OSW:	One seed weight (g)
PEC_{OBD}:	Predicted exposure concentration for one bait dose (mg/kg bw)
$B_{loading}$:	Amount of the active ingredient on one bait (mg)
OBW:	One bait weight (g)
Cb:	Content of active ingredient in bait (%)

Table 3.8
Seed treatment scenarios for one seed criterion

Species	Size of seeds	Body weight(g)
Small birds	Small seeds(<3.5mm)	25
Large birds	Large seeds(≥3.5mm)	300

Table 3.9
Value of one seed weight (Source: Ctgb, Netherlands)

Crop group	Crop	One seed weight [g]
beets	Sugar beet	1.67E-02
	beets (z)	1.67E-02
	leaf beet (or chard)	1.67E-02
flower seeds	flower seeds	1.00E-03
kale	kale (or cow cabbage)	2.50E-03
	kale (or cow cabbage)	2.50E-03
	kale (or cow cabbage) (z)	2.50E-03
beans	runner bean	5.00E-01
	winged bean	4.55E-01
	snap bean (z)	3.33E-01
	stringbean (on stem)	3.33E-01
	stringbean (on pole)	3.33E-01
	french bean (on pole)	3.33E-01
	broad bean	1.00
	field bean	5.00E-01
	white bean	3.33E-01
broccoli	broccoli	1.00E-02
chicory	chicory	1.40E-03
peas	grey pea	3.33E-01
	green pea	2.00E-01
	green pea (z)	2.00E-01
yellow mustard	yellow mustard (z)	3.33E-03
barley	winter barleyt	4.00E-03
	spring barley	4.00E-02
oats	oats	3.03E-02
canary seed	canary seed (z)	6.67E-03
	canary seed (vo)	6.67E-03
caraway	caraway (z)	2.99E-03

Crop group	Crop	One seed weight [g]
turnip cabbage	turnip cabbage	2.99E-03
	turnip cabbage (z)	2.99E-03
kohlrabi	kohlrabi (v)	5.45E-03
	kohlrabi (i)	5.46E-03
cabbage	cabbage	2.00E-03
	cauliflower	2.50E-03
	chinese cabbage	2.50E-03
	Brussels sprout	2.50E-03
	pointed cabbage	2.50E-03
	white cabbage	2.50E-03
	red cabbage	2.50E-03
	savoy cabbage	2.50E-03
	"green leafy cabbage" (vo)	3.39E-03
oilseed rape	oilseed rape	5.00E-03
	spring oilseed raped (vo)	5.00E-03
beetroot	beetroot	1.67E-02
fodder radish	fodder radish (**)	1.11E-02
linseed (or flax seed)	fibre flax	5.56E-03
	oilseed flax	5.56E-03
lupin	lupin	1.67E-01
alfalfa	alfalfa (vo)	2.00E-03
maize	grain maize	2.50E-01
	forage maize	2.50E-01
	corncobmix	2.50E-01
	sweet corn	2.50E-01
paksoi	paksoi	4.00E-03
parsley	parsley	1.30E-03
purse lane	purselane (**)	5.00E-04
leek	leek	2.50E-03
radish	radish	1.00E-02
black (or spanish) radish	black (or spanish) radish	
rye	rye	2.86E-02
	spring rye (vo)	2.86E-02
	winter rye (vo)	2.86E-02
black salsify (or scorzonera)	black salsify	1.10E-03
celery	soup celery (or smallage)	1.11E-03
	blanching celery	1.11E-03
lettuce	head lettuce	1.20E-03
	iceberg lettuce	1.20E-03
spinach	spinach (z)	1.18E-02
	spinach (i)	1.18E-02
	spinach (v)	1.18E-02
wheat	winter wheat	4.35E-02
	spring wheat	4.35E-02
tomato	tomato	3.17E-03
triticale	triticale	4.00E-02
onion	seed onion	3.28E-03
	onion set	3.28E-03
	spring onion	3.28E-03
	pearl (or pickled) onion	3.28E-03
lamb's lettuce (or corn salad)	lamb's lettuce	1.20E-03
flax	flax	5.41E-03
bargeman's cabbage (or turnip)	bargeman's cabbage (vo)	2.50E-03
vetch	vetch	4.00E-02
white clover	white clover	6.99E-04
carrots	carrot (z)	1.03E-03
sunflower	sunflower (**)	6.67E-02

z: cultivation for seed
i: cultivation for industry
v: cultivation for the fresh food market
vo: cultivation for feed or fodder
** no data for seeds per m2, default 100

Estimation of exposure for dietary exposure

In the second step, the predicted exposure concentration (PEC) for dietary exposure resulting from seed treatment is assessed for three time scales, i.e. acute, short-term and long-term

A. Non-pelleted seeds

For non-pelleted seeds, the standard scenario for risk assessment is a bird feeding on freshly drilled seeds. At Tier 1, it can be assumed that seed-eating birds feed on treated seeds only (100 % diet). Furthermore, small birds that feed on small seeds and large birds that feed on large seeds such as maize, sugar beets and beans, are considered separately.

Acute exposure

Calculate the realistic worst-case predicted exposure concentration for acute exposure (PEC_{acute}) using the FIR/bw presented in Table 3.10.

$$\mathbf{PEC_{acute}} = \frac{\mathbf{FIR}}{\mathbf{bw}} \times \mathbf{C}$$ Formula 3.16

PEC_{acute}: Predicted exposure concentration for acute exposure (mg/kg bw d^{-1})
FIR/bw: Food intake rate of indicator species per body weight per day (g/g bw d^{-1})
C: Concentration of active ingredient of the formulated product (mg a.i./kg seed)

Table 3.10
Seed treatment scenarios for acute and short-term dietary exposure (Source: EFSA 2010)

Indicator species	size of seeds	FIR/bw
Small birds	small seeds (not maize, beans or peas)	0.3
Large birds	large seeds(maize/beans/peas)	0.1

Short-term exposure

Calculation of the predicted environmental concentration for short-term exposure ($PEC_{short-term}$) is performed in the same way as done for acute exposure (PEC_{acute}).

Long-term exposure

The time-weighted average factor of 0.53 is considered in the estimation of long-term exposure, which is based on the default values, assuming a time window of 3 weeks and a DT_{50} of 10 days. A time-weighted average factor is not applied for seed treatment in the EFSA guidance document (EFSA 2010), but it is used in the EPPO scheme (EPPO 2002). In this handbook the ftwa of 0.53 is used for long-term exposure of seed treatment. The predicted environmental concentration for long-term exposure ($PEC_{long-term}$) can be calculated using the parameters presented in Table 3.11.

$$\mathbf{PEC_{long-term}} = \frac{\mathbf{FIR}}{\mathbf{bw}} \times \mathbf{C} \times \mathbf{f_{twa}}$$ Formula 3.17

$PEC_{long-term}$: Predicted exposure concentration for long-term exposure (mg/kg bw d^{-1})
FIR/bw: Food intake rate of indicator species per body weight per day (g/g bw d^{-1})
C: Concentration of active ingredient in formulated product (mg a.i./kg seed)
f_{twa}: Time-weighted average factor

Table 3.11
Seed treatment scenarios for long-term dietary exposure (Source: EFSA 2010; EPPO 2002)

Indicator species	size of seeds	FIR/bw	f_{twa}
Small birds	small seeds(not maize, beans or peas)	0.3	0.53
Large birds	large seeds(maize, beans or peas)	0.1	0.53

B. Pelleted seeds

If the pelleted seed is based on an organic carrier (see 3.3.1.2.2), the estimation of exposure of birds through pelleted seeds is performed in the same way as done for the non-pelleted seeds taken as food. If the pelleted seed is based on an inorganic carrier (3.3.1.3.2.B) the exposure route for birds is assumed to be similar to the ingestion of granules when seeking grit.

3.3.1.2 Exposure Route 3 – granule

There are two steps in the exposure analysis for granular treatments: i.e. the one granule dose for the one granule criterion and the PEC for the dietary exposure route. These are described in Sections 3.3.1.3.1 and 3.3.1.3.2 respectively

Estimation of one granule dose for one granule criterion

The one granule criterion is similar to the one seed criterion expressed in 3.3.1.2.1. A distinction is made between small birds and larger birds (seeds like maize, peas or beans are rarely swallowed whole by small birds). The body weight of a small bird (granule sizes below 3.5 mm) is assumed to be 25 g, whereas that of a larger bird (granule sizes above 3.5 mm) is taken to be 300g. Because the endpoint of the toxicity test (LD_{50}) is expressed as mg a.i./kg bw, the one-seed or one-granule dose should be adjusted to a body weight of 1 kg. The predicted exposure concentration for a one granule dose (PEC_{OGD}) will be used in the exposure analysis and is calculated according to formula 3.18 and 3.19, using the values presented in Table 3.12.

$$\mathbf{PEC_{OGD}} = \frac{\mathbf{G_{loading}}}{\mathbf{bw}} \times \mathbf{10^3} \qquad \text{Formula 3.18}$$

$$\mathbf{G_{loading}} = \mathbf{cg} \times \mathbf{OGW} \times \mathbf{10} \qquad \text{Formula 3.19}$$

PEC_{OGD}:	Predicted exposure concentration for one granule dose (mg/kg bw)
$G_{loading}$:	Amount of the active ingredient on one granule (mg)
Bw:	Body weight (g)
cg:	Content of active ingredient in granule (%)
OGW:	One granule weight (g).

Table 3.12

Granule scenarios for one granule criterion

Species	Size of granules	Body weight(g)
Small birds	Small granules(<3.5mm)	25
Large birds	Large granules(≥3.5mm)	300

Estimation of exposure for dietary exposure route

Granules may be ingested intentionally by birds, mistaking them for food or grit, or they may be ingested accidentally when birds probe for, or peck at, food in or on treated soil, depending on the size of granule. It is assumed that birds take granules intentionally as food or grit if the size of a granule is above 0.5 mm, whereas they ingest granules accidentally as part of soil when the granule is smaller than 0.5 mm in size. The procedures for exposure analysis of birds are described below.

A. Ingestion of granules intentionally as food and as grit

If granules are based on an organic carrier (e.g. corncob) having a nutritional value, and the size of granule is above 0.5 mm, they may be taken by birds as food and grit. If a granule is taken by the bird as food, the exposure can be assessed in the same way as performed for non-pelleted seeds (see 3.3.1.2.2. A).
However, exposure to this type of granule should also be assessed using the procedure for grit given below (see 3.3.1.3.2.B).

These two estimates of exposure (for food and grit) are compared, and the largest of the two values is used in the risk assessment.

B. Ingestion of granules intentionally as grit

Granules with an inorganic base and a size of granules above 0.5 mm can be ingested intentionally when birds search for grit. For the estimation of a realistic worst-case for grit ingestion it is assumed that small granules (size between 0.5 and 2 mm) are taken by small birds and that large granules (size between 2 and 6 mm) are taken by large birds.

Acute exposure

The predicted environmental concentration for acute exposure (PEC_{acute}) for a representative typical species is calculated using the values presented in Table 3.12. The PEC_{acute} is calculated with the following Formulas 3.20 and 3.21.

$$\mathbf{PEC_{acute} = DGI \times \left[\frac{G_{surface}}{(SP_{surface}+G_{surface})}\right] \times G_{loading}}$$ Formula 3.20

$$\mathbf{G_{\mathit{surface}}} = \frac{\mathbf{\mathit{AR}\ x\ 10}}{\mathbf{\mathit{OGW}}}$$ Formula 3.21

$$\mathbf{G_{loading} = cg \times OGW \times 10}$$ Formula 3.22

PEC_{acute} :	Predicted exposure concentration for acute exposure (mg / kg bw / day)
DGI:	Daily grit intake of birds (number of grit / kg bw / day)
$G_{surface}$:	Number of granules at soil surface (number / m)
$SP_{surface}$:	Number of soil particles at soil surface in the same size classes as granules (number / m)
$G_{loading}$:	Amount of the active ingredient in one granule (mg a.i / granule)
ARG:	Maximum granule application rate (kg granules / ha)
OGW:	One granule weight (g / granule)
cg:	Content of active ingredient in granule (%)

Short-term exposure

Calculation of the predicted environmental concentration for short-term exposure ($PEC_{short-term}$) is performed in the same way as done for acute exposure (PEC_{acute}).

Long-term exposure

In the assessment of long-term exposure it is more appropriate to use time-weighted average residues rather than initial residues. When sufficient information is available, a time-weighted average correction for the number of granules and for the active ingredient should be applied. The time weighted average factor (f_{twa}) depends on the half-life of the compound or the half-life of the granules and is calculated using formulas 3.23 and 3.24.

$$\mathbf{f_{twa} = \frac{1-e^{-kt}}{kt}}$$ Formula 3.23

$$\mathbf{k = \frac{ln2}{DT_{50}}}$$ Formula 3.24

f_{twa}:	Time-weighted-average factor
DT_{50}:	Half-life of active ingredient in granule (d)
t:	Average time in days (d).

The predicted environmental concentration for an indicator species for assessment of the long-term exposure is calculated using the values presented in Table 3.13. The $PEC_{long-term}$ is calculated using formulas 3.25, 3.26 and 3.27.

$$\mathbf{PEC_{long-term} = DGI \times \left[\frac{G_{surface}}{(SP_{surface}+G_{surface})}\right] \times G_{loading} \times f_{twa}}..$$ Formula 3.25

$$G_{surface} = \frac{ARG\ x10}{OGW}$$ Formula 3.26

$$G_{loading} = cg \times OGW \times 10$$ Formula 3.27

$PEC_{long-term}$: Predicted exposure concentration for long-term exposure (mg / kg bw / d)
DGI: Daily grit intake of birds (number of grit / kg bw / day)
$G_{surface}$: Number of granules at soil surface (number / m)
$SP_{surface}$: Number of soil particles at soil surface in the same size classes as granules (number / m)
$G_{loading}$: Amount of the active ingredient in one granule (mg a.i / granule)
ARG: Maximum granule application rate (kg granules / ha)
OGW: One granule weight (g / granule)
cg: Content of active ingredient in granules (%)

Table 3.13

Granule scenarios for acute, short-term and long-term exposure for birds ingesting granules intentionally when seeking grit (Source: EFSA 2010)

Exposure duration	Size of birds	size of granules	DGI (no. of grit per day)	$SP_{surface}$ (no. of soil particles/m^2)	f_{twa}
Acute	large	2 mm ≤ size < 6mm	2450	70	n.a.
	small	0.5 mm ≤ size < 2mm	650	15200	n.a.
Short-term	large	2 mm ≤ size < 6mm	2450	70	n.a.
	small	0.5 mm ≤ size < 2mm	650	15200	n.a.
Long-term	large	2 mm ≤ size < 6mm	1300	70	Calculated by the formula 3.23 and 3.24 when sufficient information is available
	small	0.5 mm ≤ size < 2mm	390	15200	

C. Accidental ingestion of granules as part of the soil

The granules are assumed to be accidentally ingested by birds as a part of the soil if the size of the granule is below 0.5 mm.

The predicted exposure concentration for acute, short-term and long-term exposure (PEC) for a bird weighing 25 g is calculated according to Formula 3.28. In the realistic worst-case scenarios, it is assumed that the contaminated diet will not be avoided and that the birds will obtain their entire daily dietary dose from the treated area. The value of PT is therefore assumed to be 1.

The values for the residue unit dose (RUD) are based on an application rate of 1 kg active ingredient ha^{-1} and on the assumption that the formulation is broadcast. For the acute exposure assessment, it is assumed that the granule is mixed uniformly within a layer of 1 cm soil depth. For the short- and long-term exposure, it is assumed that the granule is mixed within a layer of 5 cm soil depth.

$$PEC = DDSI \times \frac{RUD}{1000} \times PD \times AR.$$ Formula 3.28

PEC: Predicted exposure concentration (mg/kg bw d^{-1})
AR: Maximum application rate (kg a.i./ha)
DDSI: Daily dry soil intake of the indicator species (g d^{-1})
RUD: Residue unit dose (concentration in soil as a result of an application rate of 1 kg active ingredient ha^{-1})
PD: Fraction of diet obtained in treated area.

Acute exposure

The PECacute for acute exposure is calculated using the values presented in Table 3.14, and using formulas 3.29 and 3.30.

$$\mathbf{PEC_{acute} = DDSI \times \frac{RUD}{1000} \times AR}$$ Formula 3.29

$$\mathbf{DDSI = \frac{DDFI \times \%soil}{100 - \%soil}}$$ Formula 3.30

PEC_{acute}:	Predicted exposure concentration for acute exposure (mg/kg bw d^{-1})
AR:	Maximum application rate (kg a.i./ha)
DDSI:	Daily dry soil intake of the indicator species (g kg^{-1} bw d^{-1})
RUD:	Residue unit dose (concentration in soil as a result of an application rate of 1 kg active ingredient ha^{-1}) (mg kg^{-1} dry soil)
DDFI:	Daily dry food intake of the indicator species (g dry weight kg^{-1} bw day^{-1})
%soil:	Percentage of dry soil in dry diet of indicator species (%)

Table 3.14

Granule scenarios for acute, short- and long-term exposure via contaminated soil (Source: EFSA 2010)

Exposure duration	DDFI (g kg^{-1} body weight day^{-1})	% soil (% of soil in diet)	DDSI (g kg^{-1} body weight day^{-1})	RUD (mg kg^{-1} dry soil)	f_{twa}
Acute	236	18	43	6.7	n.a.
Short-term	236	18	43	6.7	n.a.
Long-term	236	18	19	1.3	Calculated by the formula 3.33 and 3.34 when sufficient information is available

Short-term exposure

Calculation of the $PEC_{short\text{-}term}$ is performed in the same way as calculation of PEC_{acute} .

Long-term exposure

In the long-term exposure analysis it is appropriate to use time-weighted average residues rather than initial residues. When sufficient information is available, a time-weighted average correction for the number of granules and for the active ingredient is applied. The time weighted average factor (f_{twa}) depends on the half-life of the compound or the half-life of the granules and is calculated according to formulas 3.33 and 3.34.

The daily dry soil dose for long-term exposure ($PEC_{long\text{-}term}$) for a bird weighing 25 g is calculated using the values presented in Table 3.13 and using formulas 3.31, 3.32 and 3.33.

$$\mathbf{PEC_{long-term} = DDSI \times \frac{RUD}{1000} \times AR \times f_{twa}}$$ Formula 3.31

$$\mathbf{DDSI = \frac{DDFI \times \%soil}{100 - \%soil}}$$ Formula 3.32

$$\mathbf{f_{twa} = \frac{1 - e^{-kt}}{kt}}$$ Formula 3.33

$$\mathbf{k = \frac{\ln 2}{DT_{50}}}$$ Formula 3.34

$PEC_{long\text{-}term}$:	Predicted exposure concentration for long-term exposure (mg/kg bw d-1)
AR:	Maximum application rate (kg a.i./ha)
ftwa:	Time-weighted-average factor
DDSI:	Daily dry soil intake of the indicator species (g kg-1 bw d-1)
RUD:	Residue unit dose (mg/kg dry soil)
DDFI:	Daily dry food intake of the indicator species (g kg-1 bw day-1)

%soil: Percentage of dry soil in dry diet of indicator species (%)
DT_{50}: Half-life of active ingredient in granule (d)
k: Degradation constant coefficient.

3.3.1.3 Exposure route 4- rodenticide

Two types of exposure to rodenticides are assessed in the handbook: 1) direct exposure of the bird through consumption of the rodenticide bait (primary poisoning), and 2) indirect exposure of the bird through consumption of rodents that have eaten the rodenticide (secondary poisoning).

Primary poisoning
For primary poisoning by a rodenticide, the indicator species is a small bird with a body weight of 15 g. (see table 3.15)

Table 3.15
Indicator species for primary poisoning (source: Larsen, 2003)

Indicator species	FIR/bw
Small birds	0.3

The predicted exposure concentration (PEC) is assessed for dietary exposure to the rodenticide, and calculated using formula 3.35.

$$\mathbf{PEC = FIR/bw \times C \times AV \times PD \times PT}$$ Formula 3.35

PEC: Predicted exposure concentration (mg/kg bw d^{-1})
FIR/bw: Food intake rate of the indicator species per body weigh per day (g/g bw d^{-1})
C: Concentration of active ingredient in the rodenticide (mg/kg)
AV: Avoidance factor
PD: Fraction of diet obtained in the treated area
PT: Fraction of food type in diet

At Tier 1, it is assumed that rodenticide-eating birds feed on the rodenticide only (100 % diet). Therefore the values of AV, PD and PT are set to 1. No degradation of the rodenticide is considered in the 1^{st} tier for primary poisoning.

The predicted exposure concentration for primary poisoning is the same for non-anticoagulant and anticoagulant rodenticides, because the cumulative effect of anticoagulants is already considered to be covered in the toxicity studies.

The predicted exposure concentration is assessed for three time scales i.e. acute, short- and long-term.

Acute exposure
The predicted exposure concentration for acute primary poisoning ($PEC_{acute,p}$) is calculated according to formulas 3.36 and 3.37 and using the FIR/bw presented in Table 3.16.

$$\mathbf{PEC_{acute,p} = FIR/bw \times C.}$$ Formula 3.36

$$\mathbf{C = cr \times 10^4}$$ Formula 3.37

$PEC_{acute,p}$: Predicted exposure concentration for acute primary poisoning (mg a.i./kg bw d^{-1})
FIR/bw: Food intake rate of indicator species per body weigh per day (g food/g bw d^{-1})
C: Concentration active ingredient in the rodenticide (mg a.i./kg)
Cr: Content of active ingredient in rodenticide (%)

Short-term exposure

The calculation of the predicted exposure concentration for short-term primary poisoning ($PEC_{short-term,p}$) is performed in the same way as the calculation for acute exposure ($PEC_{acute,p}$).

Long-term exposure

The calculation of the predicted exposure concentration for long-term primary poisoning ($PEC_{long-term,p}$) is performed in the same way as the calculation for acute exposure ($PEC_{acute,p}$) .

Secondary poisoning

A sensitive species, having a high FIR/bw ratio, is used as indicator species for the risk assessment for secondary poisoning (i.e. the kestrel, (Larsen, 2003))

Table 3.16

Indicator species for secondary poisoning

Indicator species	body weight(g)	FIR/bw
Kestrel	209	0.38

The predicted exposure concentration for secondary poisoning of the indicator bird is calculated using formula 3.38.

$$\mathbf{PEC = FIR/bw \times EC_{rodent} \times AV_{bird} \times PD_{bird} \times PT_{bird}}$$ Formula 3.38

PEC: Predicted exposure concentration (mg/kg bw d-1)
FIR/bw: Food intake rate of indicator species per body weigh per day (g/g bw d-1)
EC_{rodent}: Estimated rodenticide concentration in the rodent (mg a.i./kg)
AV_{bird}: Avoidance factor for the indicator bird
PT_{bird}: Fraction of diet obtained in the treated area for bird
PD_{bird}: Fraction of food type in diet for bird.

At Tier 1, it is assumed that a predatory bird feeds on rodenticide exposed rodents only (100 % diet). Therefore the values of AV_{bird}, PD_{bird} and PT_{bird} are set to 1.

For many anti-coagulent rodenticides, rats tend to stop feeding on the rodenticide baits after about 5 days, and will die after about 7 days. Therefore it is assumed that the predatory bird eats the rodents which have fed on the rodenticide for 5 days continually. The EC_{rodent} is calculated using formula 3.39, 3.40 and 3.41.

$$\mathbf{EC_{rodent} = \sum_{i=1}^{n=4} EC_i + EC_0}$$ Formula 3.39

$$\mathbf{EC_i = EC_0 \times (1 - EL)^i}$$ Formula 3.40

$$\mathbf{EC_0 = FIR/bw_{rodent} \times C \times AV_{rodent} \times PT_{rodent} \times PD_{rodent}}$$ Formula 3.41

EC_{rodent}: Estimated concentration in rodent (mg a.i./kg bw)
EC_i: Estimated concentration in rodent before a new meal on day n
EC_o: Estimated concentration in rodent immediately after one meal (no elimination)
EL: Fraction of daily uptake eliminated (between 0 to1)
C: concentration of active ingredient in rodenticide (mg a.i./kg rodenticide)
FIR/bw_{rodent}: Food intake rate of rodent per body weigh per day (g/g bw d-1)
AV_{rodent}: Avoidance factor for rodent
PD_{rodent}: Fraction of diet obtained in the treated area for rodent
PT_{rodent}: Fraction of food type in diet for rodent
n: Number days of rodent to eat the rodenticide.

At Tier 1, it is assumed that a predator feeds on rodents which have been fed rodenticde only (100 % diet). Therefore the values of AV_{rodent}, PD_{rodent} and PT_{rodent} are set to 1. The default value for FIR/bw_{rodent} is 0.1, and the default value for EL is 0.3

The predicted exposure concentration is assessed for three time scales i.e. acute, short- and long-term for the dietary exposure route for secondary poisoning.

Acute exposure

For acute exposure the fraction of poisoned rodents in predator´s diet is assumed to be 1. The predicted environmental concentration for acute exposure ($PEC_{acute,s}$) for secondary poisoning is calculated according to formula 3.42, using the FIR/bw presented in Table 3.16.

$$\mathbf{PEC_{acute,s} = FIR/bw \times EC_{rodent}} \qquad \text{Formula 3.42}$$

$PEC_{long-terms}$:	Predicted exposure concentration for acute exposure by secondary poisoning (mg a.i./kg bw d^{-1})
FIR/bw_{bird}:	Food intake rate of indicator species per body weigh per day (g food/g bw d-1)
C:	Concentration of active ingredient in fresh rodenticide (mg a.i./kg)
cr:	Content of active ingredient in rodenticide (%)

Short-term exposure

Calculation of the predicted exposure concentration for short-term exposure ($PEC_{short-term,s}$) is performed in the same way as was done for acute exposure ($PEC_{acute,s}$) .

Long-term exposure

For long term exposure the fraction of poisoned rodents in the diet of the predator is assumed to be 0.5. The predicted environmental concentration for long-term exposure ($PEC_{long-term,s}$) for secondary poisoning is calculated according to formula 3.43, using the FIR/bw presented in Table 3.16.

$$\mathbf{PEC_{long-term,s} = FIR/bw \times EC_{rodent} \times 0.5} \qquad \text{Formula 3.43}$$

$PEC_{long-term,s}$:	Predicted exposure concentration for long-term exposure by secondary poisoning (mg a.i./kg bw d^{-1})
FIR/bw_{bird}:	Food intake rate of indicator species per body weigh per day (g food/g bw d^{-1})
C:	Concentration of active ingredient in fresh diet (mg/kg)
cr:	Content of active ingredient in rodenticide (%)

3.3.2 Higher tier

Exposure analysis can make use of several different options for refinement in higher tiers, e.g. the use of measured residues, the decline of residues in plants, avoidance, a refinement of PT and PD, etc. Risk mitigation options may also be taken into account in the estimation of exposure in higher tiers. In this section, the most pragmatic options are described, which are the use of measured residues and the decline of residue in plants. It is usually very difficult to obtain adequate data to refine AV, PT and PD, requiring a lot of time and high costs.

3.3.2.1 Measured residues

Refinement may be achieved either by making use of already available residue data, provided they were obtained under the conditions to be assessed, or by obtaining more data on the amount of residue on the food source.

With regard to the distribution and time-course of measured residues, usually the same considerations are applied as in the 1^{st} tier risk assessment:

a. For the acute exposure: take the 90^{th} percentile (or equivalent) of initial residues;
b. For the short-term exposure: take the arithmetic mean of initial residues;
c. For the long-term exposure: take the mean time-weighted-average residue (averaging may be done parametrically with an estimated DT_{50} or by considering the observed area-under-the-curve).

Note that deviations from these rules may be necessary depending on the number, quality and representativeness of data.

If residue trials involve repeated applications of the product and sampling starts at the last application, then buildup of residues is already included; such data are not subject to correction by using an additional multiple application factor.

If the main route of exposure is via the consumption of treated vegetation, data from the residues part of the dossier should be used first. For example, this part of the dossier may include information on day 0 residues as well as information on residue declines etc. These data may provide a more realistic residue level on vegetation, and possibly provide sufficient information for the generation of appropriate time-weighted average concentrations. However, the part of the plant which was analysed should correspond to the part which is expected to be eaten by birds. Moreover, the plant sample for analysis should be taken at the time when it is expected to be eaten by birds. It should be noted that if data from the dossier are used, then these should always be related to the proposed use and scenario being refined. If they are not, it may be necessary to request more appropriate data.

If the main route of exposure is through the consumption of treated insects, it may be beneficial to determine residue levels on appropriate insects etc. Insects should be collected through appropriate ways. The choice of collection technique will depend upon the risk highlighted and the insects likely to be consumed. It should be noted that collected insects should correspond to the insects consumed by birds. Samples from different collection techniques should not be pooled but should be kept separate and analyzed separately. Keeping samples separate will ensure a more accurate indication of the true level of exposure through that particular food source.

3.3.2.2 Residue decline in plants

Experience has shown that the disappearance of residues from plant material is fairly rapid even in cases where the substance is persistent in other environmental media. The assumption of first-order kinetics may be inappropriate when long time-frames are considered.

Refinement of time-weighted average factor

If DT_{50} is available, and differs from the tier 1 default value of 10 days, the f_{twa} should be recalculated. Assuming first-order kinetics:

$$\mathbf{f_{twa}} = \frac{\mathbf{1-e^{-kt}}}{\mathbf{kt}} \qquad \text{Formula 3.44}$$

$$\mathbf{k} = \frac{\mathbf{ln2}}{\mathbf{DT_{50}}} \qquad \text{Formula 3.45}$$

f_{twa}: Time-weighted average factor
k: Degradation constant coefficient
DT_{50}: Half-life of the active ingredient
t: Averaging time.

This equation is also used when an f_{twa} for an averaging time other than three weeks is needed. In the case of repeated applications the averaging time should not be longer than the interval.

For long term exposure, the disappearance of the granule should be taken into account.

Refinement of MAF

In the case of repeated applications residues will accumulate if at the end of an interval there are still remains from the previous application. In the 1st tier MAF is based on a default value for DT_{50} of 10 days. If data show that the disappearance rate differs from this default value, the MAF_{mean} should be recalculated for short-term and long-term exposure. Assuming first-order kinetics:

$$\mathbf{MAF_{mean}} = \frac{\mathbf{1-e^{-nki}}}{\mathbf{1-e^{-ki}}} \qquad \text{Formula 3.46}$$

$$\mathbf{k} = \frac{\mathbf{ln2}}{\mathbf{DT_{50}}}$$ Formula 3.47

MAF_{mean}: Mean multiple application factor
k: Degradation constant coefficient
n: Number of applications
i : Interval between applications (d)
DT_{50}: Half-life of the active ingredient (d).

3.4 Effect Assessment

3.4.1 Data requirement

3.4.1.1 Introduction

This section elaborates the relevant parts of "Dossier Requirement for Pesticide Registration" (MOA Command No. 10, Jan 8th, 2008) with special attention to the required bird toxicology studies.

The following sections elaborate on test conditions, guidelines and endpoints of the required studies. The studies described below are those which are scientifically necessary to allow the evaluation of risks to birds. For specific information about the circumstances in which these studies are required, please refer to the "Dossier Requirement for Pesticide Registration".

Appendix 3-1 describes test conditions, guidelines and endpoints of the required studies.

3.4.1.2 Active ingredients

Avian acute oral test
Circumstances in which the test is required:
The test is always required.

Test conditions:
The test should be performed using one recommended species: Japanese quail (Bobwhite is also acceptable). The highest dose used in tests need not exceed 1000 mg/kg bw.

Test guidelines:
"*Chemical pesticide environment risk assessment test guideline*"; or internationally recognized guidelines, e.g. OECD 223

Results
LD_{50}(mg/kg bw).

Avian short term dietary test
Circumstances in which the test is required:
The test is always required.

Test conditions:
The test should be performed using one recommended species: Japanese quail (Bobwhite is also acceptable). The highest dose used in tests need not exceed 2000 mg/kg food.

Test guidelines:
"*Chemical pesticide environment risk assessment test guideline*"; or internationally recognized guidelines, e.g. OECD 205.

Results
LD_{50}(mg/kg bw) and LC_{50}(mg/kg food).

Reproductive test

Circumstances in which the test is required

The reproductive toxicity of the active ingredient to birds must be investigated, unless it can be justified that exposure of adults or nest sites during the breeding season is unlikely to occur. There are plans for future development of a Chinese guideline and for capacity building for the performance of tests in Chinese contract laboratories through some domestic-funded projects over the next years. However, such studies are not currently required by 'Dossier Requirements for Pesticide Registration' (2008).

Test guidelines:

Internationally recognized guidelines, e.g. OECD 206.

Results:

NOED (mg/kg bw per day) and NOEC (mg/kg food).

3.4.1.3 Formulated products

Avian acute oral test

Circumstances in which the test is required

The test is always required unless the LD_{50} from an acute oral test of the a.i. is above 500 mg/kg bw.

Test conditions:

The test should be performed using one recommended species: Japanese quail (Bobwhite is also acceptable). The highest dose used in tests need not exceed 1000 mg/kg bw.

Test guidelines:

"Chemical pesticide environment risk assessment test guideline"; or internationally recognized guidelines.

Results**:**

LD_{50}(mg/kgbw).

3.4.2 Tiered approach of PNEC establishment

PNECs should be calculated according to the formula below by using endpoints from eco-toxicological studies and associated uncertainty factors:

$$\mathbf{PNEC} = \frac{\mathbf{EnP}}{\mathbf{UF}} \qquad \text{Formula 3.48}$$

PNEC: Predicted No Effect Concentration
EnP: Toxicity Endpoints
UF: Uncertainty Factor

3.4.2.1 Uncertainty factor

As explained in Chapter 1, an uncertainty factor (UF) should be taken into account to address the extrapolation from laboratory toxicity data on a limited number of species to all wild species of birds. In general, for more extensive data and longer test duration the degree of uncertainty will be smaller, and the needed uncertainty factor will also be smaller.

For 1st tier assessment, different UFs are used when assessing the risks to birds at different exposure time scales. Acute, short-term and long-term PNEC should be assessed by using data from acute, short-term and long-term toxicity studies, respectively.

The recommended uncertainty factors used for 1st tier assessments are shown in Table 3.17.

At higher tier assessments, the uncertainty factor can be reduced to a certain degree during the estimation of PNEC by using higher tier data. The use of uncertainty factors should be decided on a case by case basis using expert judgment.

3.4.2.2 Establishment of PNEC at 1st tier

Toxicity tests aim to assess the effects of potential exposure through various routes and over various time scales. The extent of the data required will depend on the nature of the active ingredient, the manner of use and the extent and scale of application. Generally, at the 1^{st} tier a standard data set will be necessary which will assess acute oral toxicity, short-term dietary toxicity and sometimes reproductive toxicity in avian species. The test species selected for these test protocols are regarded as surrogates for the species considered to be potentially at risk. However, due to the inherent variability in sensitivity between species and within species in their response to chemical toxicants, a degree of uncertainty may persist in the extrapolation of test findings to particular species of ecological concern. In addition, extrapolation of toxicity from laboratory tests to wild species should be done using appropriate extrapolation factors.

Readers should note that, especially for the 1^{st} tier, when the toxicity data for both active ingredient and its formulated product are available, the assessor should choose the lowest toxicity value (e.g. LC_{50}) to calculate the RQ.

The relevant toxicity endpoints and associated uncertainty factors regarding data extrapolation which are used in the 1^{st} tier RQ calculation are given in Table 3.17:

Table 3.17

Toxicity endpoints and uncertain factors used at the 1^{st} tier

PNEC	Endpoint	1^{st} tier Uncertainty factor
$PNEC_{oneseed/granule}$[1]	LD_{50} from acute oral test	1
$PNEC_{acute}$	LD_{50} from acute oral test	10
$PNEC_{Short\text{-}term}$	LD_{50} from short term dietary[2]	10
$PNEC_{Long\text{-}term}$	NOED from avian reproduction study[2]	5

1: $PNEC_{oneseed/granule}$
Scientifically, the effect level used for one seed/granule criterion calculation is not a 'no effect concentration'. However, in order to maintain consistency, the initial $PNEC_{oneseed/granule}$ is still used in this handbook.

2: $LD_{50short\text{-}term}$ and NOED
The standard endpoint from avian dietary studies is an LC_{50} with units of mg a. i./kg food. This value can be converted to LD_{50} short-term. Conversion from NOEC to NOED is also feasible. See 3.4.2.2.1 for detailed guidance.

Conversion of mg/kg food into mg/kg bw per day

The standard unit for avian dietary studies is mg a.i./kg food. If the mean body weight and the mean food consumption per day are known, this unit (mg/kg food) can be converted into the unit mg/kg bw per day

Assuming that the LC_{50} is 50 mg active ingredient kg^{-1} food, the mean body weight is 200 g and the mean food consumption is 29 g day^{-1}, then the DFI = 29 * 1000/200 = 145 g of food kg^{-1} body weight day^{-1} and the LD_{50} = $(50 \times 145)/1000$ = 7.25 mg kg^{-1} body weight day^{-1}. In the same way a NOEC can be converted into a NOED. It should be noted that data on body weight is not normally reported on a daily basis, but for the complete exposure period (e.g. 5 days for the Standard short term dietary test).

How to deal with Avoidance behavior

The outcome of standard dietary LC_{50} studies may not be the result of increased intake of chemical, but of decreased food consumption. This food avoidance behavior may be induced by repellent properties of the chemical, and it may be worthwhile to check whether relevant data are available. Because repellence dictates, sometimes to a high degree, the outcome of the LC_{50} value, these values should be used with caution in the risk characterization.

Extrapolated LD50 values from limit dose tests for birds

For pesticides which are not acutely toxic to birds, a limit test may be sufficient, using a single dose above the highest dose mentioned in 3.4.1.2. If there is no mortality, or a single mortality, at the limit dose in the acute test it is possible to calculate an extrapolated LD_{50} value.

The LD_{50} value is calculated according to formula 3.49:

$$\mathbf{LD_{50} = Limit\ Dose \times EF}$$ Formula 3.49

Limit dose: Dose used in the limit test of avian acute toxicity test (mg/kg bw), e.g. 2000 mg/kg bw.
EF: Extrapolation Factor.

Values for the proposed extrapolation factors are listed in Table 3.18.

Table 3.18
Extrapolation factors based on the number of individuals tested at a limit dose.

Number of animals tested at the limit dose	Extrapolation factor for no mortality at a limit dose	Extrapolation factor for a single mortality at a limit dose
5	1.61	1.23
10	1.89	1.52
15	2.05	1.70
20	2.17	1.80

Extrapolation of NOED from LC50

If the reproduction study is not available, the NOED could be extrapolated by using the LC50 derived from short term exposure. LC_{50} is first converted to $LD_{50short\text{-}tern}$, and the resulting $LD_{50short\text{-}term}$ is divided by a factor of 10 (see formula 3.50)

$$\mathbf{NOED = \frac{LD_{50\ short-term}}{10}}$$ Formula 3.50

How to deal with toxicity data from more than one species

For the acute assessment the geometric mean of toxicity values for all tested species should be used, except where the endpoint for the most sensitive tested species is more than a factor of 10 below the geometric mean for all tested species. In that case the toxicity data for the most sensitive species will be used for the risk assessment, but generally without applying any assessment factor (unless there are specific reasons to believe that this is not appropriate).

For reproductive studies, the endpoint from the most sensitive tested species should be used.

How to deal with more than one acute study on the same species

In cases where more than one acute study on the same species is available, it is proposed that the geometric mean of the endpoints for that species should be taken (including only those studies that are considered suitable for use in risk assessment). This endpoint is then used in the overall geometric mean. The studies should be equivalent in terms of guideline and in particular the vehicle/solvent used, since there may be a marked reduction in apparent toxicity when using an aqueous rather than an oil based vehicle (a effect known to occur e.g. for pyrethroids).

Higher tier

For higher tier assessment, it may be necessary to conduct more specific tests on species of, in the context of the proposed use, more ecological relevance. However, for welfare reasons preference should generally be given to refining the assessment without conducting additional animal studies where possible, e.g. by refining the exposure assessment.

When a higher tier study is considered necessary, requiring more birds being tested, the study should be carefully designed in consultation with the registration authority and relevant experts.

3.5 Environmental risk management suggestions

3.5.1 Risk mitigation measures

When ERA for a certain pesticide indicates that the risk to birds is only acceptable provided that risk mitigation measures are used, such mitigation measures shall be taken into account by the risk managers when taking a regulatory decision. Furthermore, mitigation measures should be explicitly described on the pesticide label. The possibilities of risk management very much depend on the type of product and its use patterns. Usually this is the final step, but often it may be useful to envisage risk mitigation measures before all possibilities of refinement are exhausted.
It should be noted that such mitigation measures should in principle not reduce the minimum required efficacy. Moreover, it is important that the risk managers assess the feasibility of such mitigation measures in terms of enforcement.

The table below provides the information on mitigation measures for birds with good or limited feasibility in China.

If any risk mitigation measure is recommended, the risk assessor should re-evaluate the risk of the pesticide, taking into account the estimated effectiveness of the mitigation measure

Table 3.19
Relevant options for risk mitigation measures for birds in China

Risk mitigation measure	Effectiveness of measure (relative reduction in exposure)	Conditions	Overall feasibility in China (good, limited, difficult)	Correspon ding Label statement
For all types of formulations				
Reduce the application rate	About linearly proportional to reduction in application rate	If efficacy of the pesticide is not affected.	Good	
Do not apply next to vulnerable habitats (e.g. nature reserves; bird sanctuaries)	Complete	If alternative pesticides or other pest management options are available	Good	LS.B.1
Refuse registration	Complete	If alternative pesticides or other pest management options are available	Limited	
For seed treatments				
Immediately remove any spills	Variable	none	Limited	LS.B.2
Seed to be drilled or incorporated into soil during/immediately after application	Variable	If germination allow this If equipment is available to farmers	Limited	LS.B.3
For granules				
Immediate removal of any spills	(almost) complete		Limited	LS.B.2
Granules to be drilled or incorporated into soil during/immediately after application	Variable	If equipment is available to farmers	Limited	LS.B.3
For rodenticides				
Use of burrow-baiting or bait stations, or boxes	Variable	If rodent species allows this	Limited	LS.B-R.2
Products shall contain an aversive agent and a dye.	Variable	If it does not affect efficacy	Good	
Restrict the use of the products with high concentration of a.i. to professionals	Variable		Good	LS.B-R.1:
Restrict the outdoor use of the product to professionals only	Variable	If alternative rodenticides are available to non-professionals	Good	LS.B-R.1:
Mark the treated areas	Variable		Limited	LS.B-R.3:

3.5.2 Labeling

The following specific label statements are linked to mitigation measures, which therefore should be used when a specific mitigation measure is required to reduce the risk to an acceptable level:

- LS.B.1: Do not apply in/around the nature reserve for birds
- LS.B.2: Remove any spills immediately.
- LS.B.3: Seeds/ granules must be drilled or incorporated into soil during/immediately after application
- LS.B-R.1: For professional use only.
- LS.B-R.2: Products can only be applied in bait boxes/ bait stations/ a burrow.
- LS.B-R.3: Mark the treated area in a proper way.

Hazard statements are not included in the handbook because the criteria have not been set for China.

3.6 References

EPPO (2002): Environmental risk assessment scheme for plant protection products. Chapter 11. Terrestrial vertebrates (sprayed products, seed treatment and granular formulations).

EC (2002): Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC. Working document SANCO/4145/2000, 25 September 2002. European Commission, Brussels

EFSA (2010) Risk assessment for birds and mammals. Guidance of EFSA, first published 17 December 2009, revised April 2010. European Food Safety Authority, Parma. EFSA Journal 7(12) 1438

Flether JS, Nellessen JE and Pfleeger TG (1994): Literature review and evaluation of the EPA food-chain from approved pesticides. Brighton Crop Protection Conference – Pests and Diseases, 793-798.

Larsen J (2003) Emission scenario document for biocides used as rodenticides. Supplement to the risk methodology for risk evaluation of biocodes. Report CA-Jun03-Doc.8.2-PT14. European Commission, Joint Research Centre, Institute for Health and Consumer Protection, Ispra, Italy.

OECD GUIDELINE FOR TESTING OF CHEMICALS, 205, 206.

OECD (2002): Working document SANCO/4145/2000: Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC.

Appendix 3-1

Conditions, guidelines and endpoints of the required toxicological tests

Data requirement	Conditions for active ingredient	Conditions for formulations	Test Guideline	End point/ Test results
Acute oral toxicity to Bird	Always required Test should be done: -for one species: Japanese quail (Bobwhite is acceptable) -the highest dose used in tests need not exceed 1 000 mg/kg* body weight.	Required where the a.i. is highly toxic to bird (LD_{50} from acute oral test of the a.i. < 50 mg/kg bw) or where results from mammal testing give evidence of a significantly higher toxicity of the formulation compared to the a.i. Test should be done: - for one species: Japanese quail (Bobwhite is acceptable) - the highest dose used in tests need not exceed 1 000 mg/kg* body weight.	OECD 223	LD_{50} mg/kg bw (NOEL)
Short-term Dietary toxicity to bird	Always required for one species: Japanese quail (Bobwhite is acceptable)	-	OECD 205	LC_{50} mg/kg bw·d or mg/kg food
Chronic toxicity to Bird	Always required, unless the exposure to birds during breeding season can be ruled out. for one species: Japanese quail (Bobwhite is acceptable)	-	OECD 206	NOEC mg/kg food or NOAEL mg/kg bw·d
Further studies (field tests, etc.)	Where necessary a higher tiered study should be carried out case by case.	Where necessary a higher tiered study should be carried out case by case.	NA	-

4 Honeybees

4.1 Introduction

4.1.1 Purpose and content of this chapter

This chapter gives guidance on how to assess the risk of the use of a pesticide to honeybees. The assessment process described in this chapter proceeds according to the methodology and concept of ERA described in Chapter 1. After giving a general introduction, a tiered approach based on pragmatic decisions is described.

This chapter is divided into the following 5 sections:
4.1 Introduction (including detailed protection goal, etc.);
4.2 Environmental risk assessment;
4.3 Exposure analysis;
4.4 Effect assessment;
4.5 Environmental risk management suggestions.

In this chapter, risks of a particular pesticide to bees are assessed for all relevant exposure routes, which are carefully identified and established, based on preliminary considerations about potential exposures that may raise concerns.

4.1.2 Detailed protection goals

Honeybees may be exposed to a pesticide when they forage on the flowering crops during or after pesticide application. 'Honeybees' are identified as one of the protection goals in this handbook (see also Chapter 1, Section 1.3.1). For this protection goal, details of the protection goal are addressed by answering the following 3 questions:

Question 1: What do we want to protect?
Answer: Although it is the worker bees that are exposed to pesticides while they are foraging away from their colonies, the greatest concern is at the population level, i.e. the survival of the honeybee colonies. The species of concern relevant to China includes *Apis mellifera* and the indigenous species *Apis cerana.*
Extrapolation to bumble bees and other pollinator species has not been verified and is not addressed in this handbook.

Question 2: Where do we want to protect?
Answer: Effects on colony survival are in principle assessed at the level of the bee hive. However, because honey bees can forage long distances away from their colonies (up to several kilometres), exposure to pesticides needs to be evaluated in any treated field or location. Furthermore, since apiculture occurs all over China, no geographical restrictions apply.

Question 3: How strict do we want to protect? What are the criteria?
Answer: No effect on the long-term survival of the honeybee colony.

4.2 Environmental Risk Assessment

4.2.1 Identifying the relevance of the risk to honeybees

Section 4.2 gives guidance on the decision-making process of the ERA for honeybees. Readers should note that a preliminary phase is required to identify the relevance of the risk of the pesticide to honeybees. It is reasonable to trigger the assessment only if the exposure of honeybees to the pesticide of concern cannot be excluded.

If a pesticide is to be used indoors, e.g. within a glasshouse (supposing that bees are not used for pollination), domestic premises, factories, grain stores and other enclosed structures, the risk to honeybees will generally be negligible. Certain pesticide products used outdoors may also pose a similar negligible risk, e.g. if used during winter when bees are not flying, pre-emergence use of herbicides, seed treatments and granules except when there is systemic activity, products for dipping bulbs, etc. In cases where the exposure is considered negligible, an appropriate justification should be given.

The most important route of exposure of honeybees to plant protection products is by direct contact with field sprays. In some cases, exposure of bees is not possible and there is no need for a detailed assessment of risks (see above). However, any crops in which there are flowering weeds, or which might be flown over by bees visiting other crops, may present a risk of exposure, even if the crops themselves are not attractive to bees. In such cases, it is prudent to regard exposure as a possibility and to proceed with the assessment.

When a pesticide product is applied through soil treatment or seed treatment, the mode of action of the active ingredients determines whether a risk to honeybees is relevant or not. If any active ingredient of the pesticide product has a systemic mode of action, this active ingredient may be transferred by the plant to pollen and nectar. Hence the honey bees may be exposed to the contaminated pollen or nectar during foraging or when the contaminated pollen is brought back to the hive.

4.2.1.1 The attractiveness of the cropped plant to honeybees

The attractiveness of the cropped plant to honeybees may be considered as an entry point for this risk assessment. In general, a crop can be considered non-attractive to bees if it is harvested before flowering. However, some plants not intrinsically attractive to bees may be visited due to extra-floral nectarines (e.g. in field beans) or due to honeydew produced by aphids. Similarly, the presence of bee-attracting flowering weeds or of "secondary" crops in a non-attractive crop may favor visits and result in some exposure. A description of agricultural attractiveness associated with the crop of concern may help in deciding whether visits and exposure may or may not be expected. At the moment no guidance is given on the attractiveness of different crops to honeybees.

4.2.1.2 Representative Exposure Scenarios

It is essential that the risk of a pesticide to the honeybees is assessed whenever there is a possibility that worker bees are exposed. Based on the description above, two representative exposure scenarios are identified and defined to assess the risk to honeybees:

Exposure Scenario 1: Sprayed pesticides.
The pesticide is sprayed in the crop field.

Exposure Scenario 2: Pesticides used for soil treatment or seed treatment.
The pesticide is applied to the field through soil treatment or seed treatment.

Risks due to direct exposure of hives to pesticides are not considered in this chapter.

4.2.2 Risk characterization

The risk characterization of honey bees is expressed as a Risk Quotient (RQ, see also Chapter 1), which is calculated according to Formula 4.1. The first tier RQ calculation for exposure scenario 1 (sprayed pesticides) does NOT use Formula 4.1, and section 4.2.4 gives more detailed guidance on how to calculate this RQ.

$$\mathbf{RQ} = \frac{\mathbf{PEC}}{\mathbf{PNEC}} \qquad \text{Formula.4.1}$$

RQ: Risk Quotient
PEC: Predicted Exposure Concentration, which are calculated for each exposure route, if applicable (see detailed calculations in Section 3.3)
PNEC: Predicted No Effect Concentration, which are calculated by using toxicity data and associated uncertainty factors (see detailed calculation in Section 3.4).

In the risk assessment for honey bees, PEC is defined as 'predicted exposure concentration' and not as 'predicted environmental concentration', because exposure is calculated on a body weight basis.

4.2.3 Decision-making scheme

Flowcharts 4-1, 4-2 and 4-3 give step-wise guidance on the overall decision-making process for risk assessment for honeybees. The Explanatory Notes for the decision-making schemes give additional information to the flowcharts. Readers should refer to the decision-making schemes to assess the risk of a particular pesticide of concern. The final decision of the risk assessment should be made on the basis of the RQ calculation as described below.

Criterion based on the RQ calculation:
If the value of RQ is below or equal to 1, the risk is considered to be acceptable. If the value of RQ is above 1, it indicates that the risk could be unacceptable. However, higher tier risk assessment can be used to refine the risk assessment in order to lower the RQ. A tiered approach for ERA of honeybees is described in the following section.

4.2.4 Tiered approach

4.2.4.1 Conceptual model

The conceptual model of the ERA scheme for honey bees was set up in such a way that the tiers for the effect assessments can be linked to any of the tiers for the exposure analysis, and vice versa. This so-called 'criss-cross' model allows optimal flexibility in the data that may be submitted by the applicant and in the assessment. Figure 4.1 shows the 'criss-cross' model for the risk assessment of honey bees.

A tiered approach shall then be used for ERA of honey bees according to the conceptual model. The conceptual model is applicable for each exposure route. At the 1st tier, the risk shall be assessed using effect data based on laboratory studies and the exposure doses based on realistic worst-case assumptions (not applicable for Exposure Scenario 1, see section 4.2.4.2.1). If the risk characterization results in a value of RQ above 1, a higher tier assessment can be used to refine the risk assessment, by refining the effect assessment and/or the exposure analysis as demonstrated in the model in Figure 4.1.

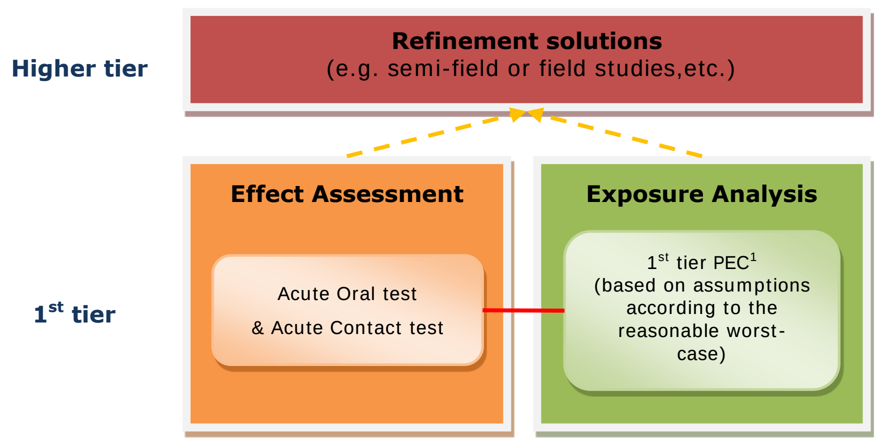


Figure 4.1 *The 'criss-cross 'model for the risk assessment of honey bees*

([1] not applicable for Exposure Scenario 1, see 4.2.4.2)

4.2.4.2 1st Tier assessment

Exposure scenario 1 – sprayed pesticides

For the assessment of risks arising from sprayed pesticides, the empirical Hazard Quotient method is used. This method has been validated using data collected under conditions which most resemble common practice (i.e. in field tests or by monitoring the product in use) (Aldridge and Hart, 1993; Mineau *et al.*, 2008). The 1st tier risk estimate is calculated according to Formula 4.2:

$$\mathbf{RQ_{sray}} = \frac{\mathbf{AR}}{\mathbf{LD_{50} \times 50}}$$ Formula 4.2

RQ_{spray} : Risk Quotient for Exposure Scenario 1 (sprayed pesticides)

AR: The highest application rate for the use pattern of concern as recommended in the label (kg a.i./ha)

LD_{50}: The lowest LD_{50} of the available oral and contact toxicity studies (ug a.i./bee).

Both the toxicity value (LD_{50}) and the application rate in the formula given above should always be expressed either on the basis of weight of active substance or on the basis of weight of the formulated product, but these should never be used together ('mixed') within a single evaluation. As the main route of hazardous exposure to acutely toxic compounds is through contact action, the contact LD_{50} is most important for insecticides. The oral LD_{50} is more relevant for the assessment of compounds not acutely toxic, such as herbicides. To achieve a good margin of safety, the risk assessment should be carried out selecting the lowest of the oral and contact LD_{50} values available.

Products containing mixtures of active substances should be evaluated by entering the toxicity and application rate of the formulated product only.

If the value of RQ_{spray} is below or equal to 1, the risk is considered to be acceptable, unless the pesticide acts as an insect growth regulator (IGR). If the pesticide is an IGR, additional assessments should be carried out according to Flowcharts 4-2 & 4-3 and Section 4.2.4.4 (Insect Growth Regulator).

If the value of RQ_{spray} is above 1, the risk could be unacceptable. However, higher tier risk assessment can be used to demonstrate that the risk is acceptable through the use of data from a more realistic study (see Section 4.2.4.3).

Exposure Scenario 2 – soil applied pesticides

The main route of exposure of honeybees to systemic pesticides applied to the soil or for seed treatment is oral exposure, through the consumption of contaminated pollen and nectar. Contact exposure to contaminated pollen and nectar cannot be excluded, but is not considered to be important and is not included in the risk assessment.

Exposure is assessed through estimation of the amount of residues that may be ingested by a bee in one day. However, residues in pollen or nectar are rarely quantified in residue studies available in the residue section of dossiers, since these studies are performed for other purposes (risk to consumers). In this handbook, estimates of the concentration in the aerial parts of the plant is considered as an estimate of residual concentration in nectar and pollen.

The 1st tier risk is estimated by calculating RQ according to Formula 4.3:

$$\mathbf{RQ_{syst}} = \frac{\mathbf{PEC_{syst}}}{\mathbf{PNEC_{syst}}}$$ Formula 4.3

RQ_{syst} : Risk Quotient for systemic pesticides
PEC_{syst}: Predicted Exposure Concentration for systemic pesticide (exposure of bees to pesticides in pollen or nectar)
$PNEC_{syst}$: Predicted No Effect Concentration for systemic pesticides.

An uncertainty factor (UF) of 10 is used for extrapolation from acute to chronic toxicity (EPPO, 2009).

If the value of RQ_{syst} is below or equal to 1, the risk is considered to be acceptable, unless the pesticide acts as an insect growth regulator (IGR). If the pesticide is an IGR, additional assessments should be carried out according to Flowcharts 4-2 & 4-3 and Section 4.2.3.3 Insect Growth Regulator.

If the value of RQ_{syst} is above 1, the risk could be unacceptable. However, higher tier risk assessment can be used to demonstrate that the risk is acceptable through the use of data from a more realistic study (see Section 4.2.4.3)

4.2.4.3 4Higher tier

The refinement always needs additional data, either specific data on the product to be assessed or generic data. Some information may already be available in the dossier or may be produced through literature searches, whereas other data may have to be generated through performing new studies. The assumptions and input data used in the refinement steps should be fully justified. It should be noted that refinement reduces the uncertainty and produces a more precise characterization of the risk, but additional data do not necessarily result in a risk level which is lower than previously estimated.

Feasible refinement recommended in this handbook for sprayed pesticide includes carrying out semi-field studies or field studies. Chinese test guidelines for these are not available, and they are not currently required according to '*Dossier Requirement for Pesticide Registration'.* Semi-field or field studies should be conducted under conditions representative of the uses to be assessed. This also allows for testing under specific use conditions (e.g. in relation to the moment of flowering) which are to be prescribed on the label for the purposes of risk management.

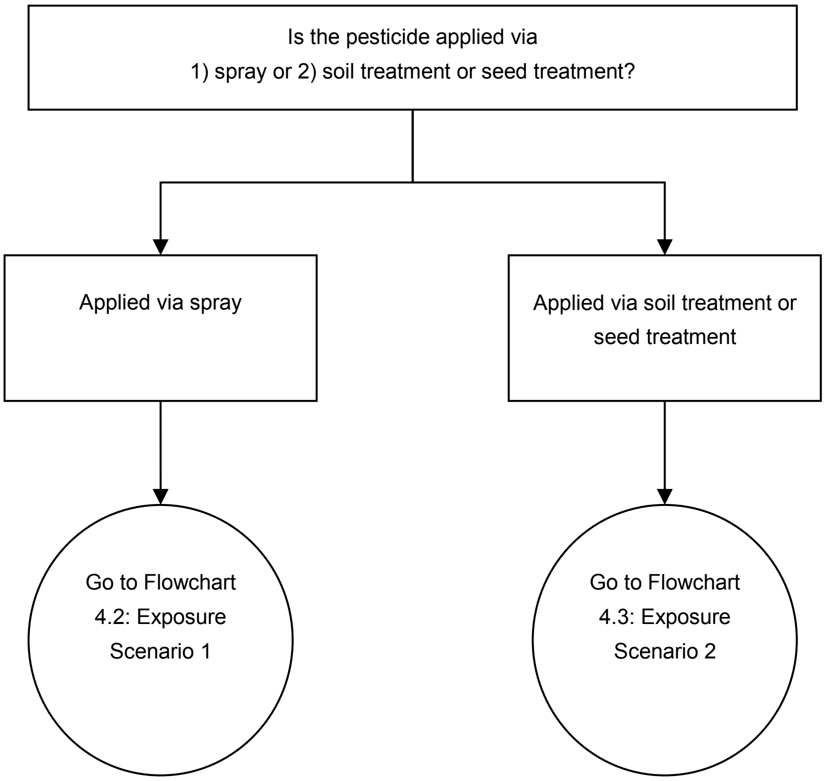
The applicants are also welcomed to supply their own risk assessment results as additional reference information, along with explicit interpretation on the scientific methodology, step-wise procedure and expert judgment, if applicable.

4.2.4.4 Insect Growth Regulator

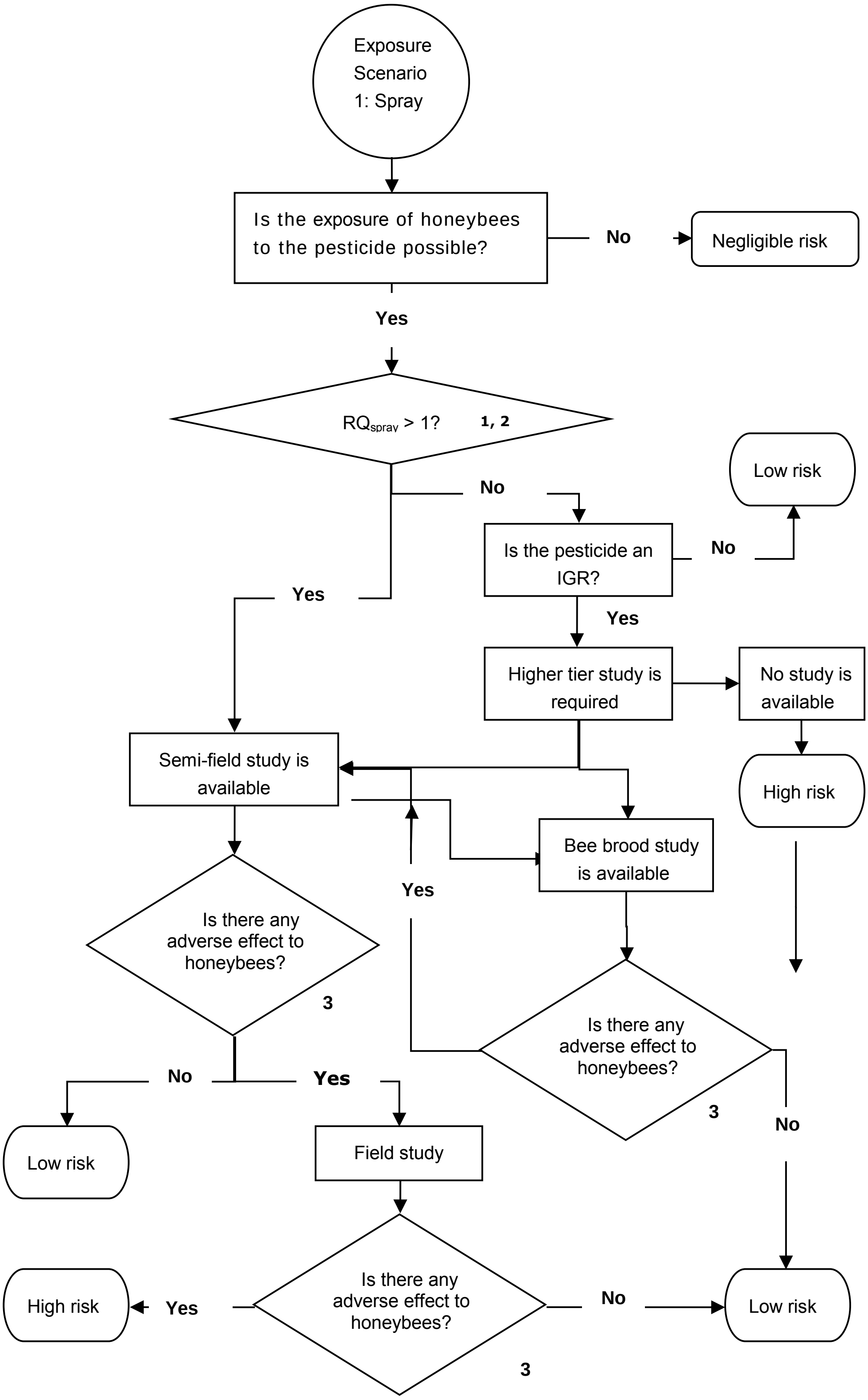
Preliminary screening of IGRs is performed through a bee brood feeding test. Chinese test guidelines for such bee brood tests are not available, and this test is not currently required according to '*Dossier Requirement for Pesticide Registration*'.There is too little data on exposure available to relate larval toxicity to field application rate and brood damage. Therefore, if any effects are detected in a feeding test, a cage test and/or field testing is necessary. A suitable method is described by Oomen et al. (1992). In these tests, possible effects on adult worker bees will be detected as well. This area of testing is the subject of ongoing development by the ICPBR Bee Protection Group. A bee brood test is not required when cage or field test data on brood effects are available.

4.2.4.5 Mitigation measures

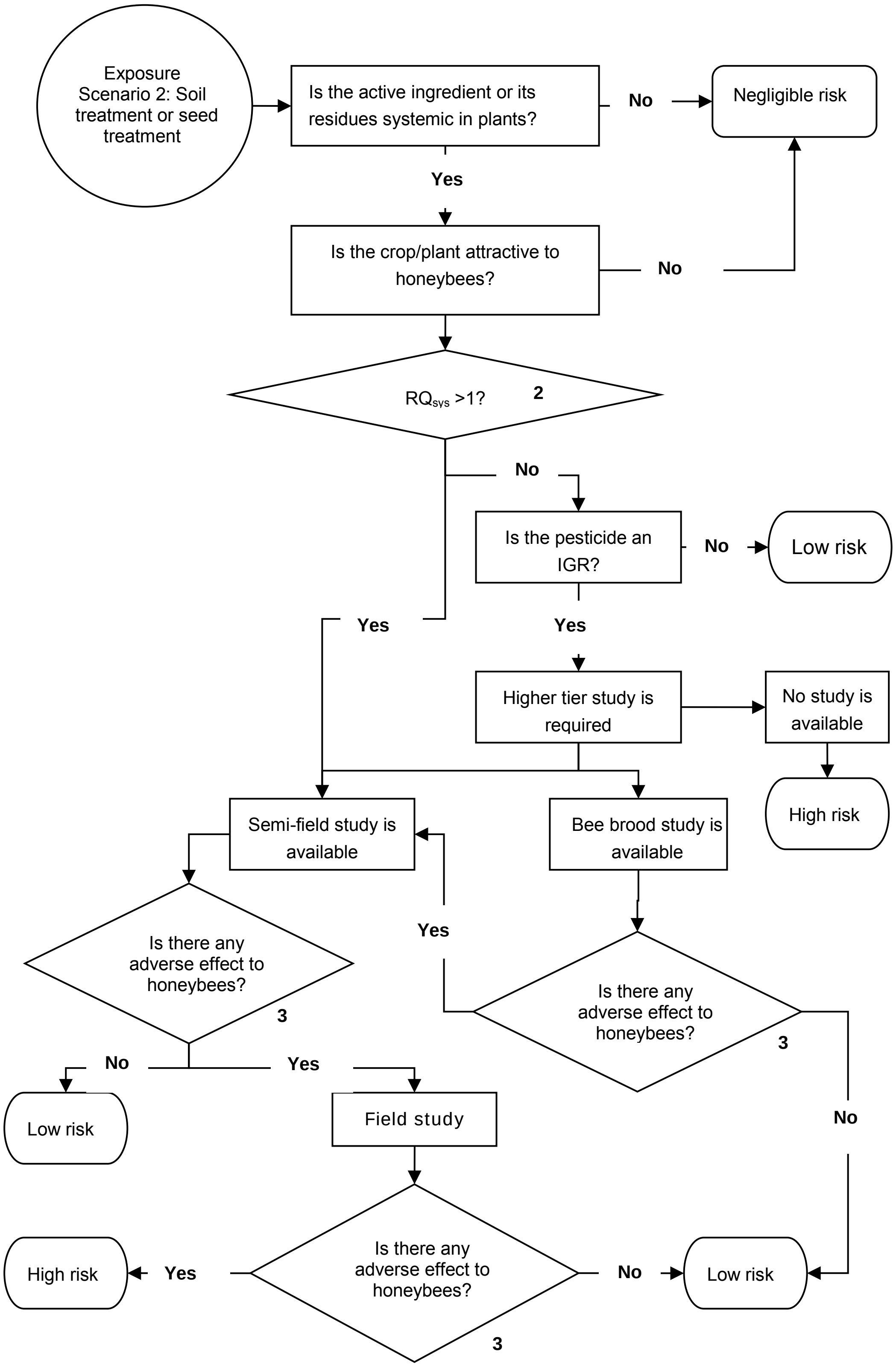
A standard risk assessment or even a higher-tier risk assessment may indicate that the risk to honeybees may only be acceptable provided that risk mitigation measures are used. Necessary mitigation measures and other precautions shall then be clearly described on the label of the pesticide products. Detailed guidance is given in Section 4.5.



Flowchart 4.1 *Decision-making scheme for ERA of honeybees- General.*



Flowchart 4.2 *Decision-making scheme for ERA of honeybees - Exposure Scenario 1*



Flowchart 4.3 *Decision-making scheme for ERA of Honeybees - Exposure Scenario 2.*

Explanatory Notes to Flowchart 4.1, 4.2 and 4.3

1. The lower value of LD50s from the oral and contact toxicity studies should be used. If more than one study is submitted, the lowest acceptable LD50 should be used.
2. Mitigation measures may be proposed by the applicant. If it can be shown that the risk is then acceptable, the risk manager will decide if the mitigation is feasible in China.
3. No adverse effect is acceptable if it is likely to result in a reduction in long-term colony survival.

4.3 Exposure analysis

4.3.1 Data requirements

This section elaborates the relevant parts of *'Dossier Requirements for Pesticide Registration'* (MOA Command No. 10, Jan 8th, 2008) regarding the environment fate of pesticide in plants (behavior and residues) where relevant for the honey bee risk assessment, including circumstances in which the test is required, test conditions, test guidelines and test results for each data requirement.

4.3.1.1 Exposure scenario 1 – sprayed pesticides

There are no specific data requirements on environmental fate for this scenario.

4.3.1.2 Exposure scenario 2 – systemic soil applied or seed treatment pesticides

A residue study is always required when treated crops are intended for human consumption.

Such studies should be available in the residue section of the dossier submitted by the applicants. However, these studies often will not fully meet the requirements for performing the risk assessment for honeybees. For the bee risk assessment, residue data in aerial parts of the plant, collected as close as possible to the flowering period are preferred, when available.

4.3.2 Establishment of PEC at 1st tier

4.3.2.1 Exposure scenario 1 – sprayed pesticides

No PEC is calculated in the 1st tier ERA for honey bees. The measure of exposure used in the assessment is the application rate.

The highest application rate as recommended on the label for the use pattern of concern is used. The application rate can be expressed as kg a.i./ha or as kg formulation/ha, provided it uses the same units as the LD_{50} value used in the calculation of the RQ.

4.3.2.2 Exposure scenario 2 – systemic pesticides applied to soil or as seed treatment

Exposure to systemic pesticide residues in pollen or nectar is assessed. The PEC of honey bees to a pesticide in pollen or nectar is a function of the estimated or measured residue level in pollen/nectar and the amount of pollen and/or nectar consumed.

$$\mathbf{PEC_{syst} = Residue_p \times MFI} \qquad \text{Formula 4.4}$$

PEC_{syst} Predicted Exposure Concentration (exposure of bees to pesticides in pollen or nectar,ug a.i./bee)

$Residue_p$: Residues in pollen or nectar of the relevant crop (mg a.i./kg)

MFI: The maximum daily food intake by a honey bee (g/bee).

Measured residue levels in pollen or nectar are preferred as input for the calculation of the PEC. However, these are often not available.

Alternatively, residue levels in aerial parts of the plant can be used, preferably measured as close to the period of flowering as possible. Residue levels in aerial parts of the plant are expected to be an overestimation of residue levels in pollen or nectar. The 90th percentile of the residue level for the relevant crop should be selected at this tier.

If residue data are not considered reliable or are not available, a generic worst-case value of 1 mg a.i./kg pollen or nectar should be used. This is expected to be an overestimation of residue levels in pollen or nectar.

For the maximum daily food intake by bees, a default value of 0.128 g/bee is used, unless more precise data are available (EPPO, 2009).

4.4 Effect assessment

4.4.1 Data requirements

4.4.1.1 Introduction

This section elaborates the relevant parts of *"Dossier Requirement for Pesticide Registration"* (MOA Command No. 10, Jan 8th, 2008) with special attention to the required honeybee toxicity studies.

The following sections provide test conditions, guidelines and endpoints of the required studies for each type of study. The studies described are scientifically necessary to allow the evaluation of risks to honeybees. For specific information related to the circumstances in which these studies are required, please refer to the "*Dossier Requirement for Pesticide Registration*".

4.4.1.2 Active ingredients

Oral and Contact Acute Toxicity study

Circumstances in which the test is required:
The test is always required.

Test conditions:
The test should be performed using one of the recommended species (*Apis mellifera* or *Apis cerana*).

Test guidelines:
"*Chemical pesticide environment risk assessment test guideline*"; OECD 213 and 214; or other internationally recognized guidelines.

Results:
$LD_{50\ oral}$ and $LD_{50\ contact}$ (ug a.i/bee).

4.4.1.3 Formulations

Oral and Contact Acute Toxicity study

Circumstances in which the test is required
The test is always required unless LD_{50} from an acute toxicity test of the a.i. is greater than 11 ug a.i./bee. The test is always required if the product contains more than one a.i.

Test conditions:
The test should be performed using one of the recommended species.

Test guidelines:
"*Chemical pesticide environment risk assessment test guideline*"; OECD 213 and 214; or other internationally recognized guidelines.

Results:
$LD_{50\ oral}$ and $LD_{50\ contact}$ (ug a.i/bee).

4.4.1.4 Additional data

Higher tier studies such as semi-field studies and field studies, and bee brood test are not required in the current 'Dossier Requirement for Pesticide Registration'.

A laboratory bee brood test may be performed according to Oomen *et al.* (1992). When a higher tier study or a bee brood test is used during the decision-making process for risk assessment of honeybees, expert judgment is required on how and where to carry out the study/test.

Effects resulting from the experimental treatment in semi-field or field studies may be difficult to interpret and it may be difficult to distinguish between treatment and other sources of mortality. Statistical analysis of the results should normally solve this problem. However, experience has shown that as a result of the required isolation and the scale of the experiments, studies with bees (particularly cage and field studies) do not readily lend themselves to this approach. In the case of semi-field or field studies, decisions on whether effects in such studies should be considered as 'significant' require expert judgment.

4.4.2 Establishment of 1st Tier PNEC

A PNEC is only calculated for scenario 2 (soil applied pesticides). For scenario 1 (sprayed pesticides) the LD_{50} is used directly in the RQ calculation

PNECsyst should be calculated according to the formula below by using endpoints from eco-toxicological studies and associated uncertainty factors:

$$\mathbf{PNEC_{syst}} = \frac{\mathbf{EnP}}{\mathbf{UF}} \quad \text{Formula 4.5}$$

PNEC: Predicted No Effect Concentration
EnP: Toxicity Endpoints (e.g. LD_{50}, ug a.i./bee)
UF: Uncertainty Factor.

4.4.2.1 Uncertainty factor

As explained in Chapter 1, to address the extrapolation from acute laboratory toxicity data on one species to chronic effects on the colonies of honeybees, an uncertainty factor (UF) should be taken into account. In general, more extensive data and longer test duration results in a smaller degree of uncertainty and also a smaller value for the uncertainty factor.
The recommended uncertainty factors used at 1st tier assessment are shown in Table 4.1.

At higher tier assessments, the uncertainty factor can be reduced to a certain degree. Which uncertainty factors should be used should be decided on a case by case basis using expert judgment.

4.4.2.2 Establishment of PNEC at 1st tier

Readers should note that especially for the 1st tier assessment, if toxicity data for both active ingredient and its formulated product are available, the lowest LD_{50} should be used to calculate the RQ.

The relevant toxicity endpoints used for 1st tier assessment are shown in Table 4-1.

Table 4.1
Toxicity endpoints and uncertain factors used at the 1st tier

PNEC	EdP	UF
$PNEC_{syst}$	LD_{50} [1]	10

1. LD_{50}
The lowest LD50 from the available oral and contact toxicity studies (ug a.i./bee) should be used during 1st tier assessment.

4.5 Environmental risk management suggestions

4.5.1 Risk mitigation measures

When ERA for a certain pesticide indicates that the risk to honeybee is only acceptable provided that risk mitigation measures are used, such mitigation measures shall be taken into account by the risk managers when taking a regulatory decision. Furthermore, mitigation measures should be explicitly described on the pesticide label. The possibilities of risk management very much depend on the type of product and its use patterns. Usually this is the final step, but often it may be useful to envisage risk mitigation measures before all possibilities of refinement are exhausted.

It should be noted that such mitigation measures should in principle not reduce the minimum required efficacy of the pesticide. Moreover, it is important that the risk managers assess the feasibility of such mitigation measures in terms of enforcement.

The table below provides the information on mitigation measures for honeybees with good or limited feasibility in China.

If any risk mitigation measure is recommended, the risk assessor should re-evaluate the risk of the pesticide, taking into account the estimated effectiveness of the mitigation measure.

Table 4.2
Relevant options for risk mitigation measures for honeybees in China

Risk mitigation measure	Effectiveness of measure (relative reduction in exposure)	Conditions	Overall feasibility in China (good, limited, difficult)	Corresponding Label statement
Reduce the application rate	About linearly proportional to reduction in application rate	If efficacy of the pesticide is not affected.	Good	
Restrict use to greenhouse crops	Complete	If no pollination in the greenhouse occurs	Limited	LS.H.3
Require protection or temporary closure of bee hives	Variable	If residual toxicity of the pesticide does not pose unacceptable risk	Limited	LS.H.4
Do not apply pesticide during flowering of crop	(almost) complete	If alternative pesticides or other pest management options are available during flowering	Difficult	LS.H.2[1]
Refuse registration	Complete	If alternative pesticides or other pest management options are available	Good	

[1]: While the feasibility of this measure may be difficult, the label statement is required for all sprayed pesticides that pose a high risk to bees.

4.5.2 Labeling

The following specific label statements are linked to mitigation measures, which therefore should be used when a specific mitigation measure is required to reduce the risk to an acceptable level:
- LS.H.2: Do not apply the pesticide during flowering.
- LS.H.3: For greenhouse use only.
- LS.H.4: Close hive during pesticide application and the following xxx hours.

4.6 References

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EC (2002) Guidance document on terrestrial ecotoxicology under Council Directive 91/4141/EEC. Document SANCO/10329/2002 rev 2 final. 17 October 2002. Health & Consumer Protection Directorate-General, European Commission, Brussels.

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Oomen P.A., de Ruijter A. and Van der Steen J. (1992) Method for honey bee brood feeding tests with insect growth-regulating insecticides. OEPP/EPPO Bulletin 22: 613-616.
Rortais A., Arnold G., Halm M.-P. and Touffet-Briens F. (2005) Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36: 71-83.

5 Silkworm

5.1 Introduction

5.1.1 Purpose and content of this chapter

This chapter gives guidance on how to assess the risk of the use of pesticides to the silkworm. The assessment process described in this chapter proceeds according to the methodology and concept of ERA described in Chapter 1. Following a general introduction, a tiered approach based on pragmatic decisions is described.

This chapter is divided into the following 5 sections:
5.1 Introduction (including detailed protection goal, etc.);
5.2 Environmental risk assessment;
5.3 Exposure analysis;
5.4 Effect assessment;
5.5 Environmental risk management suggestions.

In this chapter, risks of a particular pesticide to silkworms are assessed for all relevant exposure routes, which are carefully identified and established, based on preliminary considerations about potential exposures that may raise concerns.

5.1.2 Detailed protection goals

Silkworm larvae may be exposed to pesticide residues on the leaves of their food plant, the mulberry tree (*Morus spp.*), which are harvested for silkworm rearing. 'Silkworm' is identified as one of the protection goals in this handbook (see also Chapter 1, Section 1.3.1). For this protection goal, details of the protection goal are addressed by answering to the following 3 questions:

Question 1: What do we want to protect?
Answer: silkworm which are reared by Sericulturists for commercial purposes.

Question 2: Where do we want to protect?
Answer: Silkworm larvae may be exposed to pesticide residues on the leaves of their food plant, the mulberry tree (*Morus spp.*), which are harvested for silkworm rearing. The mulberry trees should be protected in the field so as to ensure the safety of silkworm.

Question 3: How strict do we want to protect? What are the criteria?
The silkworm (*Bombyx mori*) is of great economic importance in China. Mortality of silkworm due to exposure to pesticide is not acceptable for the Sericulturists. However, the ultimate concern is the effects on the silk productivity, both quantitative and qualitative. Therefore, the risk assessment should aim at protection at the chronic level to ensure that there will be no effects on the quality and quantity of silk production.

5.2 Environmental Risk Assessment

5.2.1 Identifying the relevance of the risk to silkworm

Section 5.2 gives guidance on the decision-making process of the ERA for silkworm. Readers should note that a preliminary phase is required to identify the relevance of the risk of the pesticide to silkworm. It is reasonable to trigger the assessment only if the exposure of silkworm to the pesticide of concern cannot be excluded according to its use patterns.

Pesticides can be applied to mulberry plantations to manage pests or diseases that affect the trees. Pesticide residues that remain on mulberry leaves may subsequently affect the silkworm, causing mortality or sub-lethal effects, which may result in silk production losses.

Alternatively, pesticides that are applied to crops that are situated close to mulberry plantations may drift onto the trees, and affect the silkworm larvae when leaves are harvested for feed.

It is essential that the risk of a pesticide to the silkworm is assessed whenever there is a possibility that mulberry leaves are exposed. Two representative exposure scenarios therefore are identified and defined in this handbook to assess the risk to silkworm (see Section 5.2.1.2)

If a pesticide product is to be used indoors, e.g. within a glasshouse, domestic premises, factories, grain stores and other enclosed structures, the risk to silkworm may be considered negligible. Certain pesticide products used outdoors may also pose a similar negligible risk. In cases where the exposure or risk is considered negligible, an appropriate justification should be given.

Pesticide products that are not applied through spraying are not covered in this handbook. However, readers should note that in some cases, exposure of silkworm to non-sprayed pesticide may be possible, in particular pesticides which have a systemic mode of action. A scenario for systemic pesticides applied to the mulberry tree may be developed at a later stage.

5.2.1.1 Scope of the risk assessment

Based on the sericulture practice in China, mulberry tree leaves are harvested and fed to silkworm larvae as their only forage until pupation.

During foraging on the mulberry tree leaves, silkworm are exposed to the pesticide both through ingestion of and contact with the residues that are present on/in mulberry leaves; ingestion is expected to be the main route.

5.2.1.2 Representative exposure scenarios

The mulberry trees, which are planted, cultivated and plucked by the sericulturists to provide feed to the silkworm, should be protected in the field so as to ensure the safety of silkworm. During and around the silkworm rearing seasons, pesticides may be applied to the mulberry trees directly and to the neighboring crop fields when there is a need for pest/disease/weed control. In both cases, pesticide residues may deposit on the mulberry leaves and hence pose a risk to silkworm. Accordingly, two representative exposure scenarios are defined in this handbook to address the exposure analysis in both cases. Risks should then be characterized using each relevant exposure scenario:

Exposure Scenario 1: Direct application

i.e. the pesticide is intended to be applied directly to mulberry trees.

When pesticide is applied directly to the mulberry trees, the pesticide will deposit on the mulberry leaves, which are used for sericulture, and hence may pose a risk to the silkworm. This scenario is established to address the above concern.

Exposure Scenario 2: Drift from neighboring crop fields

i.e. pesticide is intended to be applied to other crop fields which may result in drift to neighboring mulberry trees.

When a pesticide is applied to a neighboring field, the pesticide may drift onto the mulberry leaves. In practice, the 1st row of mulberry trees to the edge of the mulberry field is normally the last row being plucked for silkworm feed and could to some extent serve as the "buffer row" to protect the rest of the mulberry trees from the pesticide. In the handbook, pesticide residues on both the 1st and 2nd row are investigated to provide sufficient exposure information to the risk assessors.

If the pesticide will both be used on mulberry trees and in other cropping situations which may possibly result in drift onto neighboring mulberry trees, both risk assessment scenarios need to be evaluated.

5.2.2 Risk characterization

The risk characterization of silkworm is expressed as a Risk Quotient (RQ, see also Chapter 1), which is calculated according to the formula below.

$$\mathbf{RQ} = \frac{\mathbf{PEC}}{\mathbf{PNEC}}$$ Formula 5.1

RQ: Risk Quotient
PEC: Predicted Environmental Concentration (see detailed calculations in Section 5.3).
PNEC: Predicted No Effect Concentration (see detailed calculation in Section 5.4).

5.2.3 Decision-making Scheme

The Flowcharts 5.1, 5.2, 5.3 and 5.4 give step-wise guidance on the overall decision-making process of the risk assessment for silkworm. The Explanatory Notes for the decision-making schemes give additional information to the flowcharts. Readers may refer to the decision-making schemes to assess the risk of a particular pesticide of concern. The final decision of the risk assessment should be made according to the criterion based on RQ calculation.

5.2.3.1 Criterion based on RQ calculation

When toxicity data and exposure estimates are put into Formula 5.1, both numbers have to match with regard to time scale and their units to express concentrations.

If the value of RQ is below or equal to 1, the risk is considered to be acceptable. If the value of RQ is above 1, it indicates that the risk could be unacceptable. However, higher tier risk assessment can be used to refine the risk assessment in order to lower the RQ. A tiered approach for ERA of silkworm is described in the following section.

5.2.4 Tiered approach

5.2.4.1 Conceptual model

The risk assessment scheme for silkworm consists of three tiers, of which the first two have been worked out in detail. Following the recommendations made by Boesten *et al.* (2007), the conceptual model of the risk assessment scheme was set up in such a way that the tiers for the effect assessments can be linked to any of the tiers for the exposure assessments, and vice versa (Fig. 5.1).

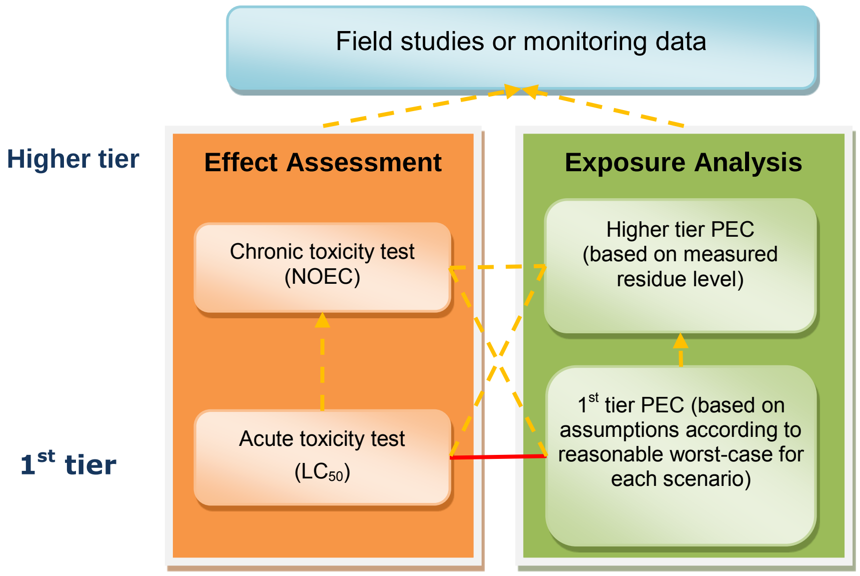


Figure 5.1 *The 'criss-cross 'model for the risk assessment of silkworm.*

The 1st tier risk assessment in Figure 5.1 is based on a comparison between the acute laboratory toxicity with estimated theoretical residue levels (No. 1 in the diagram). When the risk characterization results in a RQ greater than 1, a higher tier assessment could be triggered to refine the risk assessment by refining the effect assessment and/or the exposure analysis as demonstrated in the model in Figure 5.1. The 2nd and 3rd tiers are both considered to be higher tier assessments. The 2nd tier risk assessments can use three different approaches: a) a comparison between acute toxicity and measured residue levels; b) a comparison between chronic toxicity and estimated theoretical residue levels; and c) a comparison between chronic toxicity and measured residue levels. The 3rd tier risk assessment is based on field trials.

A standard protocol for the chronic dietary toxicity test of pesticides to Silkworm (Bombyx mori) is under development by ICAMA. The toxicity endpoints for the chronic toxicity test still need to be identified, in accordance with the further development of the chronic toxicity test.

5.2.4.2 1st tier

The 1st tier risk assessment for silkworm, which should be considered as a standard assessment module, is based on a combination of the 1st tier exposure analysis and the 1st tier effect assessment (see Figure 5.1). Table 5.1 summarizes PNECs and PECs used for risk characterization at the 1st tier.

For the 1st tier exposure analysis of silkworm, see Section 5.3. Exposure analysis should be done under relevant exposure scenarios as defined in this handbook.

For the 1st tier effect assessment of silkworm, see Section 5.4.

The requirements for dossiers differ for different registration types, according to '*Dossier Requirement for Pesticide Registration*'. Therefore, especially for the 1st tier, if the toxicity data for both active ingredient and the formulated product are available, the assessor should use the lowest toxicity value to calculate the RQ.

Table 5.1

PNECs and PECs for risk characterization at the 1st tier for silkworm

Exposure Scenario	Frequency of application	PNEC	PEC
Exposure Scenario 1: Direct application	Single	$PNEC_{acute\ dietary}$	PEC_{sa}
	Multiple		PEC_{ma}
Exposure Scenario 2: Drift from neighboring crop fields	Single		$PEC_{sa\text{-}fr}$ and $PEC_{sa\text{-}sr}$
	multiple		$PEC_{ma\text{-}fr}$ and $PEC_{ma\text{-}sr}$
fr = First row of mulberry trees sr = Second row of mulberry trees			

5.2.4.3 Higher tier

The refinement always needs additional data, either specific data on the product to be assessed or generic data. Some information may be available already in the dossier or can be produced through literature searches. Other data may have to be generated through performing new studies. In any case the assumptions and input data in the refinement steps should be fully justified. It should be noted that refinement reduces the uncertainty and produces a more precise characterization of the risk, but additional data do not necessarily result in a risk level which is lower than previously estimated.

Feasible refinement recommended in this handbook includes both refining the exposure analysis, e.g. using residue trial data instead of default residue unit dose in exposure estimation, and refining the effect assessment, e.g. using chronic toxicity data instead of acute toxicity data. For the detailed description of the recommended refining options, please see Sections 5.3 and 5.4.

Table 5.2 summarizes PNECs and PECs for risk characterization at higher tier.

The applicants are also welcomed to supply their own risk assessment results as additional reference information, along with explicit interpretation on the scientific methodology, step-wise procedure and expert judgment, if applicable.

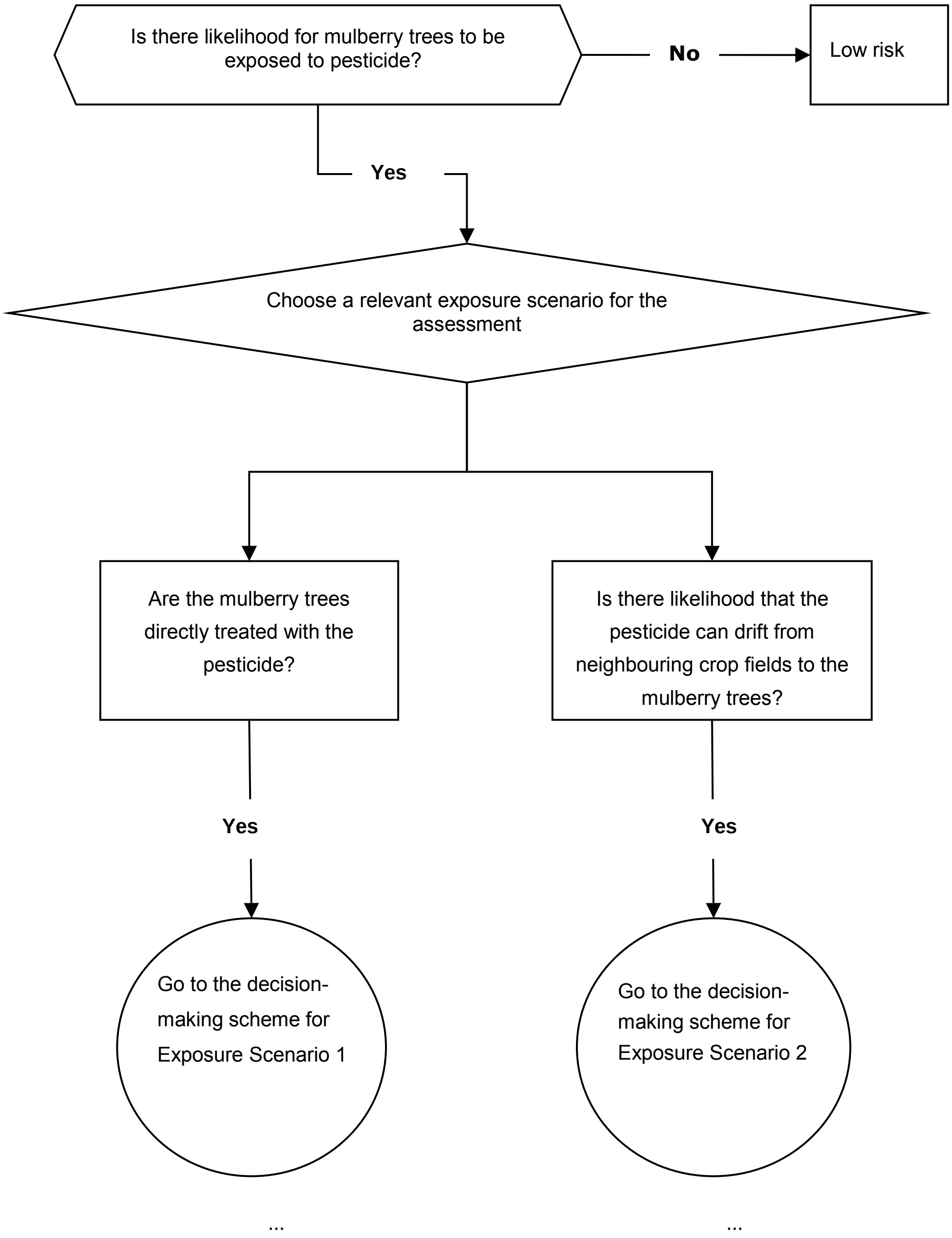
Table 5.2

PECs and PNECs for risk characterization at higher tiers for silkworm

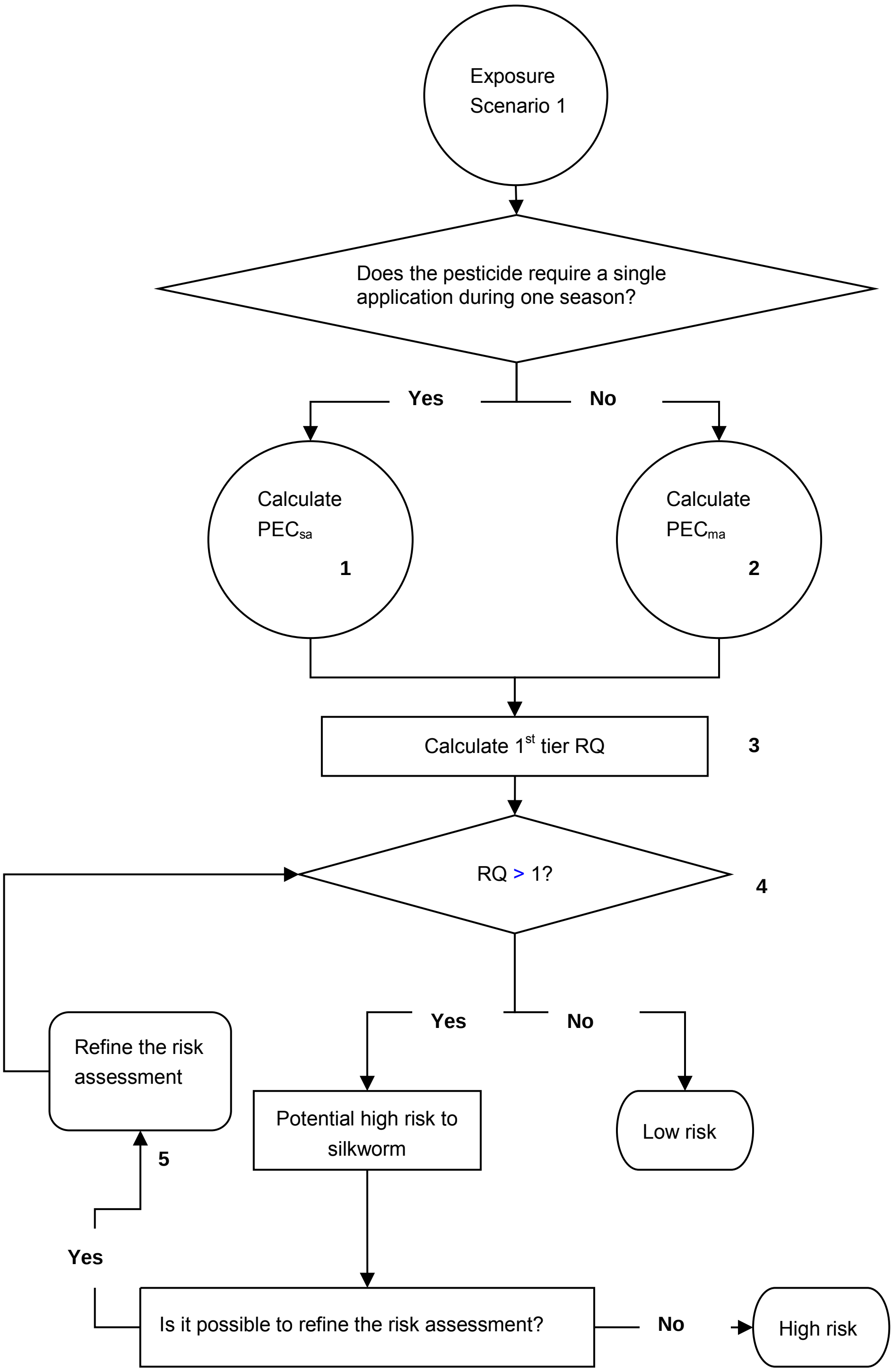
Exposure Scenario	Frequency of application	PNEC	UF	PEC
Exposure Scenario 1: Direct application	Single	$PNEC_{acute\ dietary}$	50	Measured residues
		$PNEC_{chronic\ dietary}$	5	Measured residues or PEC_{sa}
	Multiple	$PNEC_{acute\ dietary}$	50	Measured residues
		$PNEC_{chronic\ dietary}$	5	Measured residues or PEC_{ma}
Exposure Scenario 2: Drift from neighboring crop fields	Single	$PNEC_{acute\ dietary}$	50	Measured residues
		$PNEC_{chronic\ dietary}$	5	Measured residues
		$PNEC_{chronic\ dietary}$	5	$PEC_{sa\text{-}fr}$ and $PEC_{sa\text{-}sr}$
	multiple	$PNEC_{acute\ dietary}$	50	Measured residues
		$PNEC_{chronic\ dietary}$	5	Measured residues
		$PNEC_{chronic\ dietary}$	5	$PEC_{ma\text{-}fr}$ and $PEC_{ma\text{-}sr}$
NOTE: fr: First row of mulberry trees sr: Second row of mulberry trees				

5.2.5 Mitigation measures

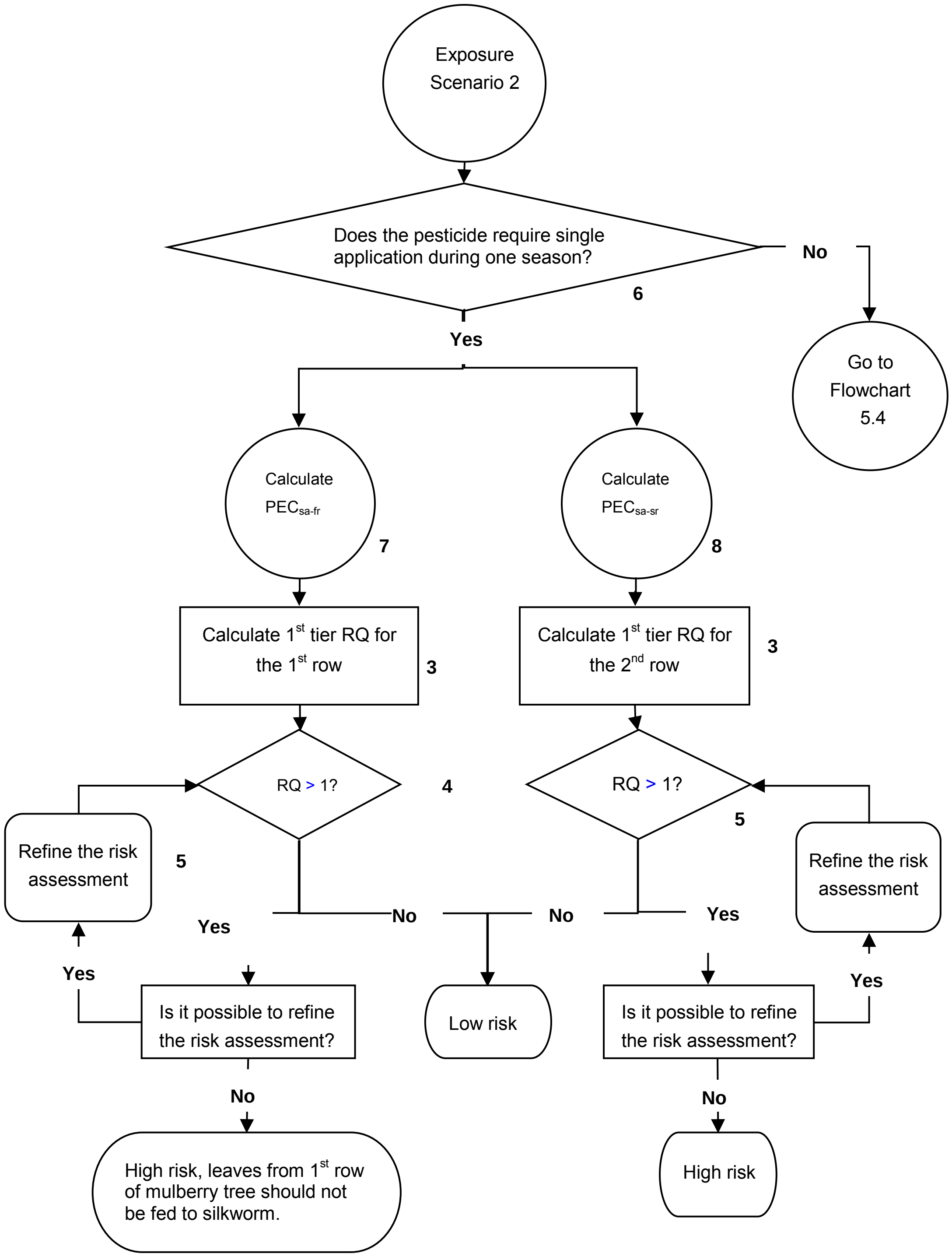
A standard risk assessment or even a higher-tier risk assessment may indicate that the risk to silkworm may only be acceptable providing that risk mitigation measures are used. Necessary mitigation measures and other precautionary notices shall then be clearly described on the label of the pesticide products. Detailed guidance is given in Section 5.5.



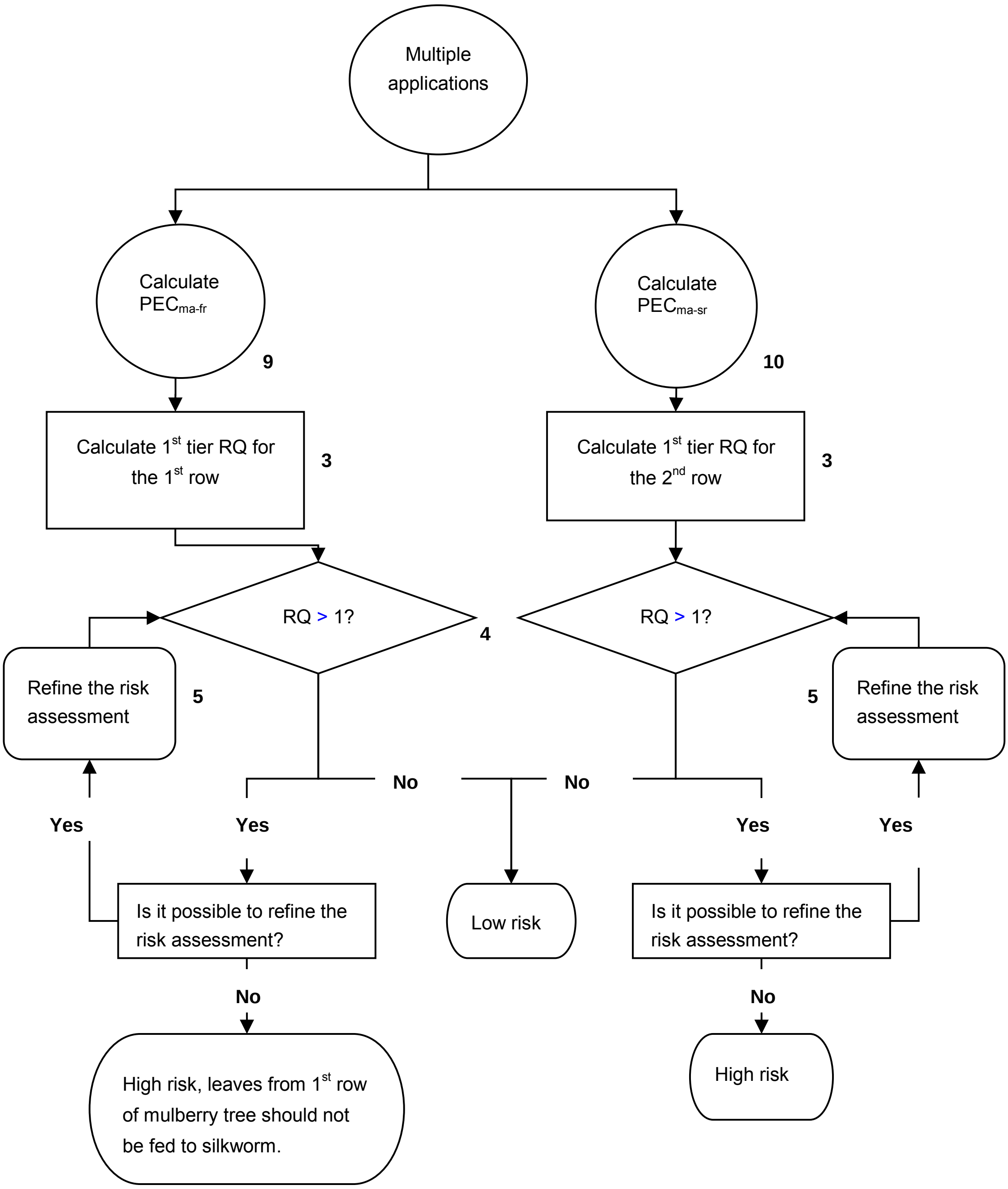
Flowchart 5.1 *Decision-making scheme for ERA of silkworm – General.*



Flowchart 5.2 *Decision-making scheme for ERA of silkworm - Exposure Scenario 1.*



Flowchart 5.3 *Decision-making scheme for ERA of silkworm - Exposure Scenario 2 (part 1).*



Flowchart 5.4 *Decision-making scheme for ERA of silkworm - Exposure Scenario 2 (part 2).*

Explanatory Notes to Flowchart 5.1, 5.2, 5.3 and 5.4

Note 1, 2: See Section 5.3.2.1 for the formulas to calculate the estimated theoretical exposure concentrations for single application situation (Formula 5.2), or for multiple application situations (Formula 5.4) in Exposure Scenario 1.

Note 3: Input values for calculating RQs at 1st tier assessment are summarized in Table 5.1 (Section 5.2.4.2 1st tier).

Note 4, 5: In case the relevant RQ is bigger than one at 1st tier assessment, it is possible to refine the risk assessment by triggering higher tier assessment. Possible higher tier assessment options are described in Section 5.2.4.3 and input values for calculating RQs at higher-tier assessment are summarized in Table 5.2 (Section 5.2.4.3).

Note 6: The "season" in this question refers to the silkworm breeding season. If more than one pesticide application is done during the silkworm breeding season, and about 1 month before, the multiple application exposure analysis should be carried out.

Note 7, 8: See Section 5.3.3.1 for the formulas to calculate the estimated theoretical exposure concentrations on the 1st row (Formula 5.7) and the 2nd row (Formula 5.8) of mulberry trees adjacent to the neighbouring crop field for single application situation in Exposure Scenario 2.

Note 9, 10: See Section 5.3.3.1 for the formulas to calculate the estimated theoretical exposure concentrations on the 1st row (Formula 5.9) and 2nd row (Formula 5.10) of mulberry trees adjacent to the neighbouring crop field for multiple application situations in Exposure Scenario 2.

5.3 Exposure Analysis

5.3.1 Data requirements

DT_{50} on vegetation
Circumstances in which required
The test is required for multiple applications and in case a PHI is recommended on the label.

Test conditions
Preferably a DT_{50} on mulberry should be provided. If the DT_{50} on mulberry is not available, a DT_{50} on a similar type of crop (leafy crop) may be used. These data are normally available in the residue dossier.

Test guideline
A national guideline is not available yet for mulberry, but for other crops national guidelines are available for residue trials.

Result
DT_{50} (d).

Residues on mulberry at the time of harvesting the leaves
Circumstances in which required
The test is required for higher tier exposure assessment.

Test conditions:
The test should be carried out on mulberry trees. The timing of application should be representative of the label recommendations for the pesticide.

Test guideline:
A national guideline is not available yet.

Results:
The concentration of a.i. in the mulberry leaves (mg/kg)

5.3.2 Exposure Scenario 1

5.3.2.1 1st tier

Initial residues on mulberry plants are based on an assessment of a large residue database (Baril *et al*. 2005). These authors assessed initial pesticide residue levels, measured within 24 hours after application, on a large variety of crops. On the basis of this assessment, an initial residue from a unit dose (RUD) (mg residue/kg fresh weight of vegetation per 1 kg a.i. of applied liquid pesticide) of 950 ppm/kg a.i. of applied pesticide was retained. This corresponds to the highest 95th percentile RUD for

mulberry-type plants (RUD_{95}), as calculated by Baril *et al*. (2005). This residue level represents a worst-case exposure situation.
A pre-harvest interval (PHI) between the moment of application and the moment of first harvest of mulberry leaves may be prescribed to ensure that pesticide residues do not pose an unacceptable risk to the silkworm. The fraction of pesticide residues that will degrade during the PHI, or degradation factor (DF_{phi}), can be estimated using Formula 5.3, which assumes first-order degradation kinetics.

If the pesticide is applied only once during the growing season, the estimated theoretical exposure after a single application (PEC_{sa}) is calculated using Formula 5.2.

$$\mathbf{PEC_{sa} = AR \times RUD_{95} \times DF_{phi}}$$ Formula 5.2

$$\mathbf{DF_{phi} = e^{\left(-\frac{0.693}{DT_{50}} \times PHI\right)}}$$ Formula 5.3

PEC_{sa}:	Predicted Environmental Concentration for single application (i.e. Pesticide residue level on mulberry leaves in mg a.i./kg fresh weight for single application)
AR:	Application rate of the pesticide (kg a.i./ha)
RUD_{95}:	95th percentile of the Residue Unit Dose for mulberry-type plants or trees. For the Tier 1 risk assessment, the RUD_{95} is set at 950 (mg residue/kg fresh weight of vegetation per kg a.i. of applied pesticide)
DF_{phi}:	Degradation factor, when a pre-harvest interval between pesticide application and harvesting of mulberry leaves is applied
DT_{50}:	Half-life of the pesticide on vegetation (days)
PHI:	Pre-harvest interval (days)

Multiple applications may cause a build-up of residue levels and must be taken into account in the exposure estimate. For the 1st tier risk assessment residue dynamics can be described by a multiple application factor (MAF). The MAF is a function of the number of applications, the application interval and the pesticide residue half-life (DT_{50}) on vegetation, assuming first order degradation kinetics. It can be calculated using Formula 5.5.

The estimated theoretical exposure after multiple applications PEC_{ma} is calculated using the following formula (Formula 5.4 and Formula 5.5).

$$\mathbf{PEC_{ma} = AR \times RUD_{95} \times MAF \times DF_{phi}.}$$ Formula 5.4

$$\mathbf{MAF = \frac{(1-e^{-nki})}{(1-e^{-ki})}}$$ Formula 5.5

PEC_{ma}:	Predicted Environmental Concentration for multiple application (i.e. Pesticide residue level on mulberry leaves in mg a.i./kg fresh weight for multiple application)
AR:	Application rate of the pesticide (kg active ingredient/ha)
RUD_{95}:	95th percentile of the Residue Unit Dose for mulberry-type plants or trees. For the Tier 1 risk assessment, the RUD_{95} is set at 950 (mg residue/kg fresh weight of vegetation per kg a.i. of applied pesticide)
MAF:	Multiple application factor
DF_{phi}:	Degradation factor when a pre-harvest interval between pesticide application and harvesting of mulberry leaves is applied
K:	$0.693/DT_{50}$ ($days^{-1}$)
DT_{50}:	Half-life of the pesticide on vegetation (days)
n:	Number of applications
i:	Application interval (days)

5.3.2.2 Higher tier

Exposure analysis can take different options for refinement in higher tiers, for instance measured residues may be used. Otherwise risk mitigation options can be taken into account for the estimation of exposure in higher tiers.

Measured residues

If they are representative and reliable, residue values of the pesticide on mulberry leaves can replace the estimated theoretical exposure. Residue values used for the risk assessment should be measured immediately prior to the start of the harvest of the mulberry leaves, and should be the result of applications at the dose rate and frequency for which registration is being sought.

5.3.3 Exposure Scenario 2

A pesticide drift factor (PDF) will be applied when calculating the PEC for environmental risk assessment to silkworm. The PDF is a function of the crop height, the distance between the crop field and the mulberry tree, the height of the mulberry tree and the climate conditions (i.e. temperature and humidity). It can be calculated using a drift model and detailed information is given in the appendix 5-1.

5.3.3.1 1st tier

In the 1st tier assessment the realistic worst-case scenario is considered in which a pesticide is applied by knapsack sprayer to a crop neighboring a mulberry plantation. The pesticide drifts onto the mulberry plantation and pesticide deposition is estimated on both the 1st and the 2nd row of mulberry trees adjacent to the sprayed field. One climate zone is selected which is representative for silkworm production but results in worst-case drift. The scenario is shown schematically in Figure 5.2. The pesticide drift factors (PDF) used for the first and second row of mulberry trees (PDF_{fr} and PDF_{sr}) are given in Table 5.3.

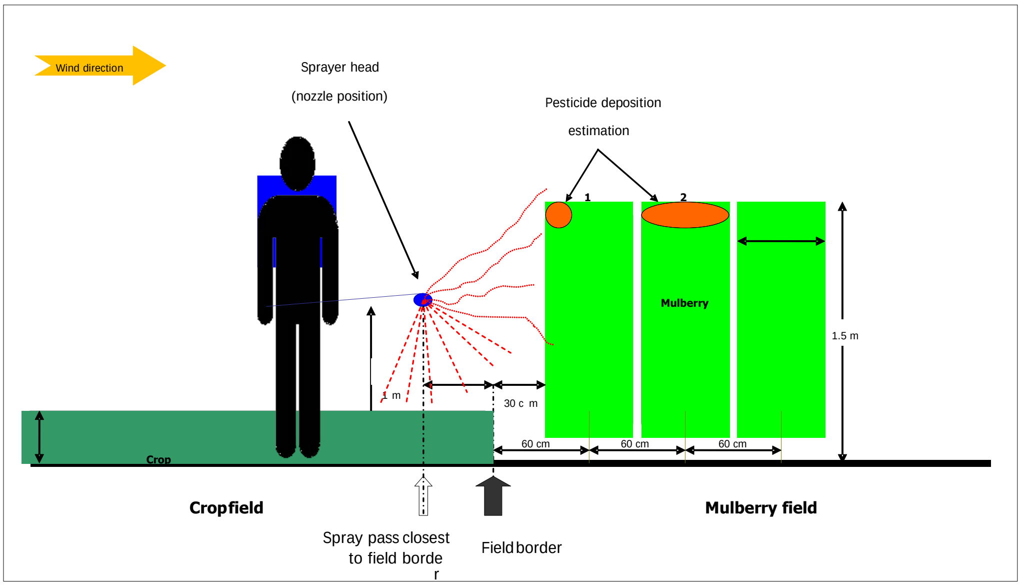


Figure 5.2 *Scenario description for Pesticides applied to crops drift onto neighbouring mulberry field.*

The estimated theoretical exposure after single applications PEC_{sa-fr} and PEC_{sa-sr} is calculated using Formulas 5.6 and 5.7.

$$\mathrm{PEC}_{sa-fr} = AR \times PDF_{fr} \times RUD_{95} \times DF_{phi}$$ Formula 5.6

$$\mathrm{PEC}_{sa-sr} = AR \times PDF_{sr} \times RUD_{95} \times DF_{phi}$$ Formula 5.7

PEC_{sa-fr}: Predicted Environmental Concentration on the first row for single application (i.e. pesticide residue level on first row mulberry leaves in mg a.i./kg fresh weight for single application)

$PEC_{sa\text{-}sr}$:	Predicted Environmental Concentration on the second row for single application (i.e. Pesticide residue level on second row mulberry leaves in mg a.i./kg fresh weight for single application)
AR:	Application rate of the pesticide (kg a.i./ha)
PDF_{fr}:	Drift factor for first row mulberry tree
PDF_{sr}:	Drift factor for second row mulberry tree
RUD_{95} :	95th percentile of the Residue Unit Dose for mulberry-type plants or trees. For the Tier 1 risk assessment, the RUD_{95} is set at 950 (mg residue/kg fresh weight of vegetation per kg a.i. of applied pesticide)
DF_{phi}:	Degradation factor, when a pre-harvest interval between pesticide application and harvesting of mulberry leaves is applied
DT_{50} :	Half-life of the pesticide on vegetation (days)
PHI:	Pre-harvest interval (days)

Table 5.3

Drift factors for realistic worst-case scenario

PDF_{fr}	PDF_{sr}
9.8%	0.6%

PDF_{fr} and PDF_{sr} are based on the 'worst-case' estimations calculated using the results of IDEFICS spray drift model simulations. For more information, please see also reference document '*spray drift estimation on mulberries adjacent to a sprayed field crop'*.

In case of multiple applications, multiple application factors are also applied in exposure scenario 2 in the same way as in exposure scenario 1.

The estimated theoretical exposure after multiple applications, $PEC_{ma\text{-}fr}$ and $PEC_{ma\text{-}sr}$ are calculated using Formula 5.8 and 5.9, using the values given in Tables 5.2 and 5.3.

$$PEC_{ma-fr} = AR \times PDF_{fr} \times RUD_{95} \times MAF \times DF_{phi}$$ Formula 5.8

$$PEC_{ma-sr} = AR \times PDF_{sr} \times RUD_{95} \times MAF \times DF_{phi}$$ Formula 5.9

$PEC_{ma\text{-}f}$:	Predicted Environmental Concentration on the first row for multiple application (i.e. Pesticide residue level on first row mulberry leaves in mg a.i./kg fresh weight for multiple application
$PEC_{ma\text{-}sr}$:	Predicted Environmental Concentration on the second row for multiple application (i.e. Pesticide residue level on second row mulberry leaves in mg a.i./kg fresh weight for multiple application)
AR :	Application rate of the pesticide (kg a.i./ha)
MAF:	Multiple application factor
RUD_{95}:	95th percentile of the Residue Unit Dose for mulberry-type plants or trees. For the Tier 1 risk assessment, the RUD_{95} is set at 950 (mg residue/kg fresh weight of vegetation per kg a.i. of applied pesticide)
PDF_{fr}:	Drift factor for first row mulberry tree
PDF_{sr}:	Drift factor for second row mulberry tree
DF_{phi}:	Degradation factor, when a pre-harvest interval between pesticide application and harvesting of mulberry leaves is applied
DT_{50}:	Half-life of the pesticide on vegetation (days)
PHI:	Pre-harvest interval (days)

5.3.3.2 Higher tier

Measured residues
If they are representative and reliable, residue values of the pesticide on mulberry leaves can replace the estimated theoretical exposure. However, residues due to drift from neighboring field are not usually tested. Expert judgment on how to construct the testing system is required before carrying out such residue studies.

5.4 Effect Assessment

This section elaborates on the relevant parts of "*Dossier Requirement for Pesticide Registration*" (*MOA Command No. 10, Jan 8th, 2008*) with special attention to the required silkworm toxicity studies.

The following sections provide test conditions, guidelines and endpoints of the required studies. The studies described are those which are scientifically necessary to allow the evaluation of risks to silkworm. For specific information related to the circumstances in which the following studies are required, please refer to the "*Dossier Requirement for Pesticide Registration*".

5.4.1 Data Requirement

5.4.1.1 Acute Toxicity study of Active Ingredient

Circumstances in which the test is required:
The test is always required.

Test conditions
The test should be performed using one of the recommended silkworm hybrids

Test guidelines
"*Chemical pesticide environment risk assessment test guideline*"; or Internationally recognized guidelines".

A standard protocol for the acute dietary toxicity test of pesticides to Silkworm (Bombyx mori) is provided by ICAMA (Sun et al. 2010). The laboratory test is based on exposure of silkworm larvae to pesticide-treated leaves of the mulberry tree (Morus spp.). Other testing protocols may be acceptable if it can be shown that the mode of exposure is similar to the ICAMA protocol and test results are comparable. The risk assessment has been developed based on this protocol, which is different from the method described in 'Chemical pesticide environment risk assessment test guideline'.

Results
LC_{50} (mg/kg mulberry leaf)

A 'dipping correction factor' should be applied to the toxicity endpoint resulting from the studies done according to '*Chemical pesticide environment risk assessment test guideline'*. The default DCF = 0.46 ml solution/g leaf (see Appendix 5-2).

5.4.1.2 Acute toxicity study of Formulation

Circumstances in which the test is required
The test is always required unless LC_{50} from acute toxicity test of the a.i. is above 200 mg/kg mulberry leaf.

Test conditions
The test should be performed using one of the recommended hybrids.

Test guidelines
"*Chemical pesticide environment risk assessment test guideline*"; or Internationally recognized guidelines

Results
LC_{50} (mg/kg mulberry leaf)

5.4.1.3 Chronic Toxicity
A standard test method for the chronic dietary toxicity test of pesticides to Silkworm (*Bombyx mori)* is under development by ICAMA. The toxicity endpoints for the chronic toxicity test still need to be identified, in accordance with further development of the chronic toxicity test.

The laboratory test is based on exposure of silkworm larvae to pesticide-treated leaves of the mulberry tree (*Morus spp.*). The toxicity endpoint used in the risk assessment is the lowest No Observed Effect Concentration (NOEC) for either relative silk production (mg silk produced/mg late instar larvae), the shell ratio (mg shell/mg cocoon), or the ISC cocoon quality class. Other testing protocols may be acceptable if it can be shown that the mode of exposure is similar to the standard testing method developed by ICAMA and test results are comparable.

5.4.1.4 Field Trial
Expert judgment is required to decide under which circumstances field trials will provide additional and useful information to assess the risk of the product. Applicants should contact ICAMA to discuss appropriate field trials protocols. Risk assessment is done on a case by case basis.

5.4.2 Tiered approach of PNEC establishment

PNECs should be calculated according to the formula below by using endpoints from eco-toxicological studies and associated uncertainty factors:

$$\mathbf{PNEC} = \frac{\mathbf{EnP}}{\mathbf{UF}}$$ Formula 5.10

PNEC: Predicted No Effect Concentration
EdP: Toxicity Endpoints (e.g. LC50, NOEC, etc. mg/kg leaf).
UF: Uncertainty Factor.

5.4.2.1 Uncertainty factors
Uncertainty Factors (UF) are used in this risk assessment to allow for two types of extrapolation:

An extrapolation is applied to allow for the difference between the acute dietary LC_{50} and the chronic No Observed Effect Concentration (NOEC). This extrapolation is needed because no mortality or sub-lethal effects on silk production and quality, in excess of natural variation, are acceptable in China. This extrapolation factor has been set to a value of 10. This is a default value based on similar extrapolations in honey bee, aquatic and bird risk assessment; it will need to be validated based on silkworm data.

A second extrapolation factor is applied to allow for differences between the standard silkworm *hybrid strain* used in the toxicity test (*B. mori* – Chun lei x Zhen zhu) and other silkworm hybrid strains that are being used in commercial silkworm production. This extrapolation factor has been set to a value of 5, based on a comparison of sensitivity of 6 commonly used hybrid strains to 4 insecticides with different modes of action (Sun *et al*.,2010).

5.4.2.2 Establishment of 1st Tier PNEC
PNEC at 1st tier should be calculated according to the formula 5.10 by using the endpoint from acute toxicity test to silkworm.

At the **1st tier,** the UF used in the risk assessments based on acute toxicity is the product of the two extrapolation factors mentioned in section 5.4.2.1. Endpoint and Uncertainty Factor for the 1st tier PNEC establishment are shown in table 5.3. See also Tables 5.1 and 5.2.

When the toxicity data for both a.i. and its formulated product are available, especially for the 1st tier, the lowest toxicity value (e.g. LC_{50}) for each representative species (all expressed in the concentration of a.i.) should be used in the PNEC calculation.

Table 5.3
Endpoint and Uncertainty Factor for the 1st tier PNEC establishment

1st tier PNEC	Toxicity Endpoint	Uncertainty Factor
$PNEC_{acute\ dietary}$	**LC_{50} (mg/kg leaf)**	**50**

5.4.2.3 Establishment of PNEC in Higher tier

At higher tier assessments, PNEC can be calculated based on the results from chronic toxicity test or field studies. If the chronic toxicity data are available to refine the risk assessment the UF for the risk assessment based on chronic toxicity is only the inter-hybrid extrapolation factor (UF = 5); if field or semi-field studies are available, expert judgment is required to choose the appropriate UF. Endpoints and recommended uncertainty factors for different higher tier assessments are given in Table 2.6. See also Tables 5.1 and 5.2.

Table 5.4
End points and Uncertain Factors for higher-tier assessments

Higher tierPNEC	Toxicity Endpoint	Uncertainty Factor
$PNEC_{chronic\ dietary}$	**NOEC** (mg/kg leaf)	**5**

5.5 Environmental risk management suggestions

5.5.1 Risk mitigation measures

When ERA for a certain pesticide indicates that the risk to silkworm is only acceptable provided that risk mitigation measures are used, such mitigation measures shall be taken into account by the risk managers when making a regulatory decision. Furthermore, mitigation measures should be explicitly described on the pesticide label. The possibilities of risk management very much depend on the type of product and its use patterns. Usually this is the final step, but often it may be useful to envisage risk mitigation measures before all possibilities of refinement are exhausted.

It should be noted that such mitigation measures should not reduce the minimum required efficacy of the pesticide. Moreover, it is important that the risk managers assess the feasibility of such mitigation measures in terms of enforcement.

The table below provides the information on mitigation measures for silkworm with good or limited feasibility in China. If any risk mitigation measure is recommended, the risk assessor should re-evaluate the risk of the pesticide, taking into account the estimated effectiveness of the mitigation measure.

Table 5.5
Relevant options for risk mitigation measures for silkworm in China

Risk mitigation measure	Effectiveness of measure (relative reduction in exposure)	Conditions	Overall feasibility in China (good, limited, difficult)	Corresponding Label statement
Pesticide application in mulberry plantation				
Reduce the application rate	About linearly proportional to reduction in application rate	If efficacy of the pesticide is not affected.	Good	
Reduce the application frequency	Less than linearly proportional to reduction in application frequency	If efficacy of the pesticide is not affected, or If alternate less hazardous product is available	Good	
Apply an effective pre-harvest interval	About exponentially proportional to size of the interval (assuming 1st order decline of residues)	If pest/disease/weed allows this measure	Good	LS.S.4
Limit application to periods when no silkworm rearing takes place (e.g. cold season)	(almost) complete	If efficacy is not affected Pesticide residues to degrade to non toxic concentrations before start of silkworm season	Good	LS.S.2
Refuse registration	Complete	If alternative pesticides or other pest management options are available	Good	
Pesticide application adjacent to mulberry plantation				
Do not authorize aerial applications [drift reduction]	Variable	If ground applications can be used alternatively	Good	LS.S.1
Do not harvest first row of mulberry trees (mulberry itself is "wind break")	Variable	If silkworm farmer has sufficient mulberry to feed the silkworm	Good (for mulberry farmers)	LS.S.3

5.5.2 Labeling

The following specific label statements are linked to mitigation measures, which therefore should be used when certain mitigation measures are required to reduce the risk to an acceptable level:

- LS.S.1: Do not apply the pesticide adjacent to the mulberry field/silk rearing rooms.
- LS.S.2: Do not apply the pesticide during the silkworm rearing seasons.
- LS.S.3: Inform neighboring silkworm farms when applying the pesticide./ Do not apply under highly windy conditions.
- LS.S.4: Do not harvest mulberry leaves within xxx days after application of the pesticide.

5.6 References

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Sun X, Jiang H, Zhang Y, Wang X and Van der Valk H. (2010) Development of an acute pesticide dietary toxicity test for the silkworm (*Bombyx mori* L.) – Activities in 2008 and 2009. Content Report No. 6. Sino/Dutch Pesticide Environmental Risk Assessment Project (PERAP), Institute for the Control of Agrochemicals of Ministry of Agriculture (ICAMA), Beijing. & Alterra – Wageningen University and Research Centre, Wageningen

Appendix 5-1

Drift model assumptions and results

1. Background

The IDEFICS spray drift model (v3.4) is developed by PRI, Wageningen-UR, the Netherlands. In PERAP, it is used to estimate the drift percentage in the neighboring crop field adjacent to mulberry fields resulting from spraying. Model simulations are performed using settings which are considered to be representative for realistic Chinese agricultural practice.

Drift under different climatic conditions is simulated with the IDEFICS spray drift model in order to find the reasonable worst-case drift percentage. In order to gather sufficient climatic information for IDEFICS spray drift model simulations, efforts have been made to identify representative climatic conditions in sericultural areas in China. The top five sericulture provinces in China, including Guangxi, Jiangsu, Sichuan, Zhengjiang, and Guangdong, account for approximately 70% of the total silk production in China. Climatic information in the sericulture areas of these five provinces was gathered at county level and then compiled into the input parameters for the IDEFICS spray drift model.

2. General settings for Simulations

The following settings are considered to be representative for realistic Chinese agricultural practice and are used in IDEFICS spray drift model simulations.

- nozzles XR11008 flat fan
- liquid pressure 300 kPa
- walking speed 0.70 m/s
- distance between walking paths: 1.00 m
- spray height above ground level: 1.00 m
- height of sprayed crop: 0.30 m
- outer nozzle position; 0.50 m upwind from crop edge
- wind speed: 3.0 m/s (measured 2.0 m above a grass plain)
- wind direction: perpendicular to crop edge
- atmospheric stability: neutral

The combination of nozzle type, liquid pressure, walking speed and distance between walking paths gives an applied dose of 750 l/ha (or 75 ml/m^2).

3. Different climatic conditions simulated using the IDEFICS spray drift model (v3.4).

Four climatic conditions were simulated:

1) temperature 20°C, relative humidity 40%
2) temperature 20°C, relative humidity 80%
3) temperature 32°C, relative humidity 60%
4) temperature 32°C, relative humidity 85%

Figure A5.1 shows an estimate of vertical distribution of spray drift, next to the sprayed field. In fact this corresponds to the deposits on the frontal side of the first mulberry tree.

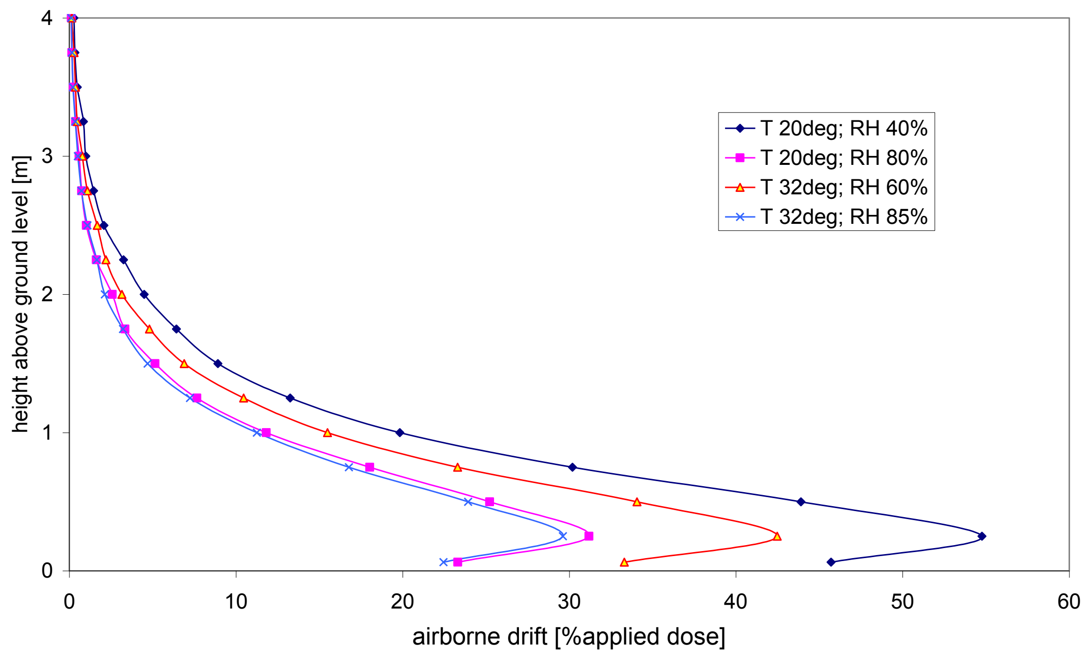


Figure A5.1 *Estimate of vertical distribution of airborne spray at the frontal side of the first mulberry tree.*

For the top 10 cm of the frontal side of the first mulberry tree, i.e. at height 1.4 - 1.5 m, the average deposits are given in Table A5-1. The part of the spray cloud distribution given in Figure 1 that is above the mulberry trees will flow further downwind, while spreading by diffusion. Due to this diffusion, the spray cloud will partially deposit onto the top of the mulberry trees. Estimates of these deposits for the first and second row of mulberries are also given in Table 1. Data are given as percentage of applied dose, and for a known dose of 75 ml/m^2, the deposits are shown as ml/m^2 as well.

Table A5-1
Estimated deposits (as % of applied dose) on mulberry trees adjacent to a sprayed crop field.

Location	Unit	Climatic conditions (T = temperature; RH = relative humidity)			
		T 20; RH 40	T 20; RH 80	T 32; RH60	T 32; RH 85
Frontal side	[%dose]	9.8	5.6	7.6	5.2
1.40-1.50m high	[ml/m^2]	7.3	4.2	5.7	3.9
Top side of first	[%dose]	1.82	1.07	1.46	1.08
mulberry	[ml/m^2]	1.36	0.80	1.09	0.81
Top side of second	[%dose]	0.61	0.35	0.48	0.35
mulberry	[ml/m^2]	0.46	0.26	0.36	0.26

4. Conclusions

The vertical frontal side of the first mulberry row is exposed to the highest level of spray drift. The top sides of both first and second mulberry row receive much less spray deposits. Typically, the top of the second row appears to receive about 1/3 of the spray deposited on the top of the first row, irrespective of the weather conditions.

Appendix 5-2

Dipping correction factor

The dietary toxicity test which is presently required uses an exposure method of dipping the mulberry leaf in various concentrations of the pesticide. The dose is then expressed as mg a.i./litre of dipping solution. An LC_{50} is subsequently calculated and the product is assigned to a hazard level. However, a direct comparison between the toxicity value (a concentration in a solution) and an (estimated) pesticide residue level on mulberry leaves in the field cannot be made. Thus the proper risk assessment is difficult, or even impossible, to carry out.

A dipping correction factor (DCF) was calculated as the volume of aqueous solution adhering to leaves, per gram of mulberry leaf. Figure A5-2 shows that the DCF ranges from about 0.4 to 3.1 over the range of leaf sizes that was assessed.

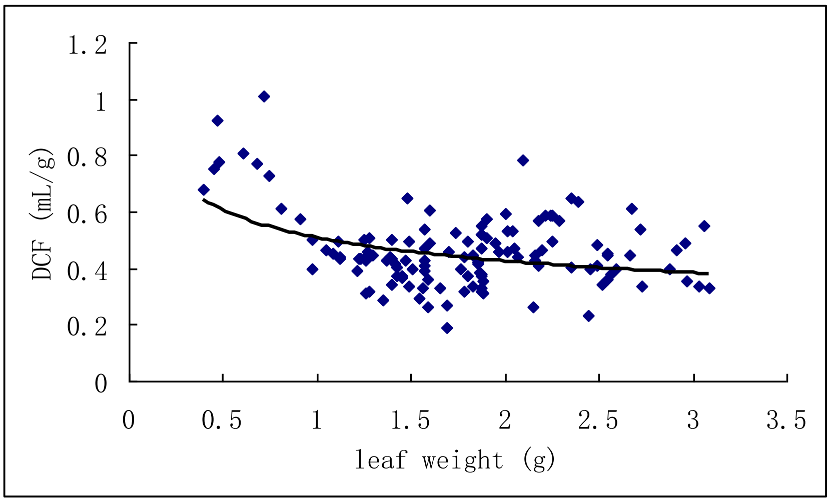


Figure A5-2 *Dipping correction factor (ml of aqueous solution/gram mulberry leaf) for a range of mulberry leaf weights. Regression line: DCF = 0.5077 * (leaf weight -0.2564); R2 = 0.146; n =127.*

The DCF as calculated above can be used to convert the LC_{50} obtained in the dipping test using the formula:

$$LC_{50[dipping]}\left(\frac{mg\ a.i}{L_{solution}}\right) \times DCF\left(\frac{ml_{solution}}{g_{leaf}}\right) = LC_{50\,[spraying]}\left(\frac{mg\ a.i}{kg_{leaf}}\right)$$

Formula A5-1

The DCF can be either standardized for an average leaf weight and applied for all toxicity tests, or actual leaf weights can be used (if available) in the regression equation. The default DCF used for a leaf weighing 1.5 grams is 0.46 ml solution/g leaf

It should be noted that when the variability in solution retention by mulberry leaves is high within the same laboratory, it will be even higher when the dipping test is carried out by different laboratories. Therefore, the DCF can only be considered as very approximate, and is not a precise conversion factor. This should be taken into account when using DCF for risk assessment [Based on Sun *et al.* 2010].

6 Groundwater

6.1 Introduction

6.1.1 Purpose and content of this chapter

This chapter gives guidance on how to assess the risk from the use of pesticides to groundwater. The assessment process described in this chapter proceeds according to the methodology and concept of ERA as described in Chapter 1. After giving a general introduction, a tiered approach based on pragmatic decisions is described.

This chapter is divided into the following 5 sections:
6.1 Introduction (including Detailed protection goal, etc.);
6.2 Environmental risk assessment (ERA);
6.3 Exposure analysis;
6.4 Effect assessment;
6.5 Environmental risk management suggestions.

The uniform structure described in the general introduction in Chapter 1 also applies to this chapter with some changes to several sections

6.1.2 Detailed protection goals

'Groundwater' is identified as one of the protection goals in this handbook (see also Introduction section 1.3.1). For this protection goal, details of the protection goal are addressed by answering the following 3 questions:

Question 1: What do we want to protect?
Answer: The groundwater is assessed as a resource for drinking water in this handbook, which implies that the ultimate protection goal is human health.

Question 2: Where do we want to protect?
Answer: All groundwater systems in China.

The relevant scenario zones for leaching to groundwater are selected and the target protection depths of the groundwater is defined:
1. Groundwater in drinking water wells at 10 m depth in the three northern scenario zones for land use dry land agriculture.
2. Groundwater at 2m depth in the scenario zones South China and Yangtze River basin for land use paddy rice.

The definition is provided by WP4 (Ter Horst et al., 2014). These two detailed protection goals are chosen for development by PERAP. Several other detailed protection goals are also identified but will not be developed by PERAP due to limited time and budget.

Question 3: How strict do we want to protect? This also relates to long term and short term effects.
Answer: The health of people who drink the groundwater should be ensured for a life-long time window. In this handbook, the Guideline Value (GV) for drinking water safety will be calculated on the basis of the most recently established ADI.

6.2 Environmental risk assessment (ERA)

6.2.1 Identifying the relevance of the risk to groundwater

Section 6.2 gives guidance on the principles for the decision-making process of the ERA for groundwater. Readers should note that a preliminary phase is required to identify the relevance of the risk of a pesticide to groundwater. It is reasonable to trigger the assessment only if the exposure of groundwater to the pesticide of concern cannot be excluded according to its use patterns. Appropriate justification should be given in case the exposure is considered negligible.

For outdoor use, soil will normally be exposed, except in certain specific situations, e.g. when precautions are taken to prevent contact with the soil (pots or containers are placed on sheeting), when the crop is not cultured in soil but on other substrates, or when some special application techniques are applied (e.g. wound treatment by smearing, injection of trees etc.). If treated seed or planting stock is transferred into the soil, it cannot be precluded that the pesticide gets into the soil.

When the pesticide is used in greenhouses without explicitly stating that substrate culture is used, it cannot be presumed that the product does not get into the soil and soil bound culture is assumed as a worst-case approach. When no transport of water into the soil can be expected (e.g. applications in closed storage rooms), leaching to groundwater could be considered negligible.

When the exposure of groundwater cannot be excluded, the exposure level of the active ingredient as well as its relevant metabolites in the groundwater should be estimated. In this handbook, the Predicted Environmental Concentrations in groundwater (PECgw) are calculated for both a.i and metabolites under the relevant exposure scenarios by using certain models. The exposure scenarios for China are established based on discussion of the detailed protection goals and the vulnerability concept. For more information on the models and associated exposure scenarios, please see Ter Horst et al., 2014.

The physical and chemical properties, environmental fate data of the a.i.'s and relevant metabolites, and the use patterns of the formulated products are of particular importance to the calculation of the PECgw.

6.2.2 Risk Characterization

The risk of leaching to groundwater is estimated by the calculation of a Risk Quotient (RQ, see also Chapter 1), which is calculated by dividing the exposure concentration by the safe concentration, according to the formula below.

$$RQ = \frac{PECgw}{\mathrm{PNEC}}$$

Formula 6.1

PECgw: Predicted Environmental Concentration in ground water
PNEC: Predicted No Effect Concentration

The PECgws should be calculated for the active ingredient and each of the relevant metabolites through the use of computer models and appropriate scenarios. For details of PECgw calculation, please see Section 6.3 Exposure analysis.

The PNECs should also be calculated for the active ingredient and each of the relevant metabolites according to 'Guidelines for Drinking-water Quality 3rd Edition' (World Health Organization, Geneva, 2008). For details of PECgw calculation, please see Section 6.4 Effect assessment.

When PECgw and PNEC's are combined in Formula 6.1, both numbers should use the same units and should be given for the same compound, i.e., either the active ingredient or one of the relevant metabolites.

6.2.3 Decision-making Scheme

Flowcharts 6.1 and 6.2 give step-wise guidance on the overall decision-making process of the risk assessment for groundwater. The Explanatory Notes give additional information to the flowcharts. Readers may refer to the decision-making schemes to assess the risk of a particular pesticide of concern. The decision should be made according to the result of RQ calculation as follows:

If the values of all the RQs (RQ for a.i and for all the relevant metabolites) are below or equal to 1, i.e. the exposure is lower than the safe concentration, the risk shall be considered to be acceptable.

If the value of any of the RQs is above 1, i.e. the exposure of at least one compound of concern is higher than the safe concentration, this indicates that the risk could be unacceptable. However, refinement options can be used to refine the risk assessment in order to lower the RQs. A tiered approach for ERA of groundwater is described in the following section.

6.2.4 Metabolites

Relevant metabolites should be assessed for groundwater using the same approach as used for the parent compound. The relevant metabolites are metabolites that account at any time for more than 10 % of the amount of active ingredient added, in at least two sequential measurements account for more than 5 % of the amount of active ingredient added if feasible, at the end of the study the maximum of formation is not yet reached but accounts for at least 5% of a.s. at the final measurement if feasible

6.2.5 Tiered approach

6.2.5.1 Conceptual model

The conceptual model of the ERA scheme for groundwater was set up in such a way that the tiers for the effect assessments can be linked to any of the tiers for the exposure analysis, and vice versa. This so-called 'criss-cross' model allows optimal flexibility in the data that may be submitted by the applicant and in the assessment. Figure 6.1 shows the 'criss-cross' model for the groundwater risk assessment of a pesticide. A tiered approach shall then be used for ERA of groundwater according to the conceptual model.

If the risk characterization results in a RQ above 1 for the 1st tier, a higher tier assessment could be triggered to refine the risk assessment, by refining the effect assessment and/or the exposure analysis as demonstrated in the conceptual model in Figure 6-1. See also Flow chart 6.1, 6.2 for the stepwise guidance on decision-making.

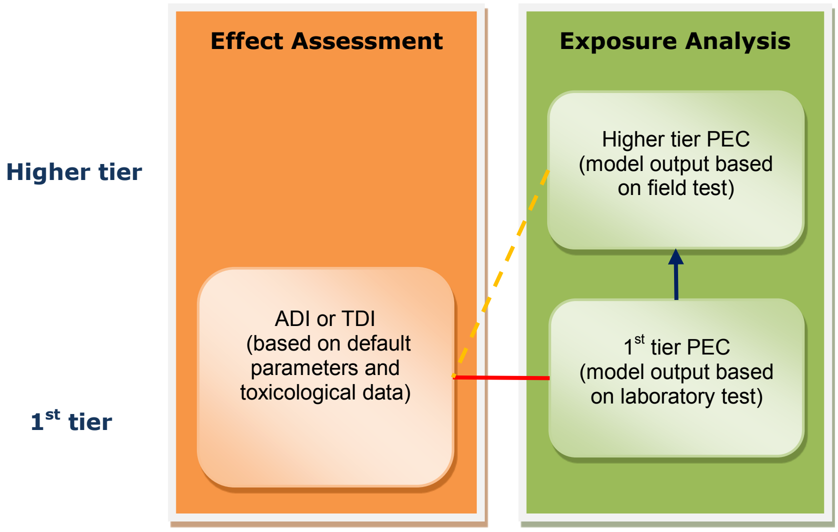


Figure 6.1 *The 'criss-cross 'model for the risk assessment of ground water.*

6.2.5.2 1st tier assessment

The 1st tier risk assessment of groundwater, which should be considered as a standard assessment module, is based on a combination of the 1st tier exposure analysis and the 1st tier effect assessment.

The 1st tier exposure analysis of groundwater is based on model output data expressed as PECgw, based on laboratory e-fate data submitted by the applicant according to 'Dossier Requirement for Pesticide Registration' (see also Section 6.3).

The 1st tier effect assessment of groundwater is establishment of PNEC according to the 'Guidelines for Drinking-water Quality 3rd Edition' (World Health Organization, Geneva, 2008) (see also Section 6.4).

6.2.5.3 Higher tier assessments

Once higher tier assessment is triggered, the applicants should provide sufficient data to ensure an integrated assessment for groundwater.

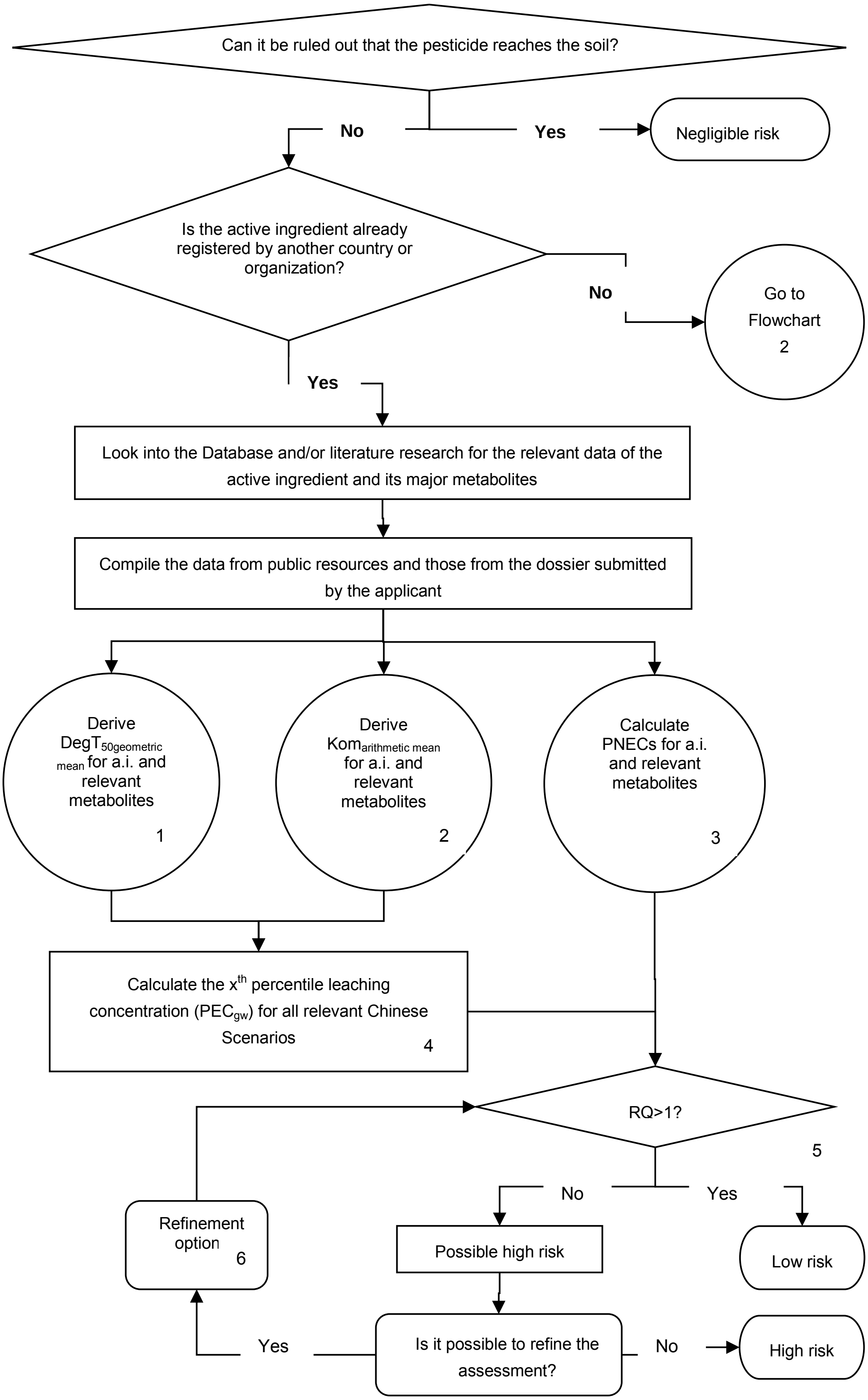
Possible refinement options include:
- Field dissipation studies
- Lysimeter and field leaching studies
- Monitoring studies of the upper groundwater
- Subsoil studies
- Monitoring at larger depth

Some of the above options may at present not be applicable in China. For options which are applicable in China recommendations are given in Section 2.3. with regard to data requirements and the use of the data.

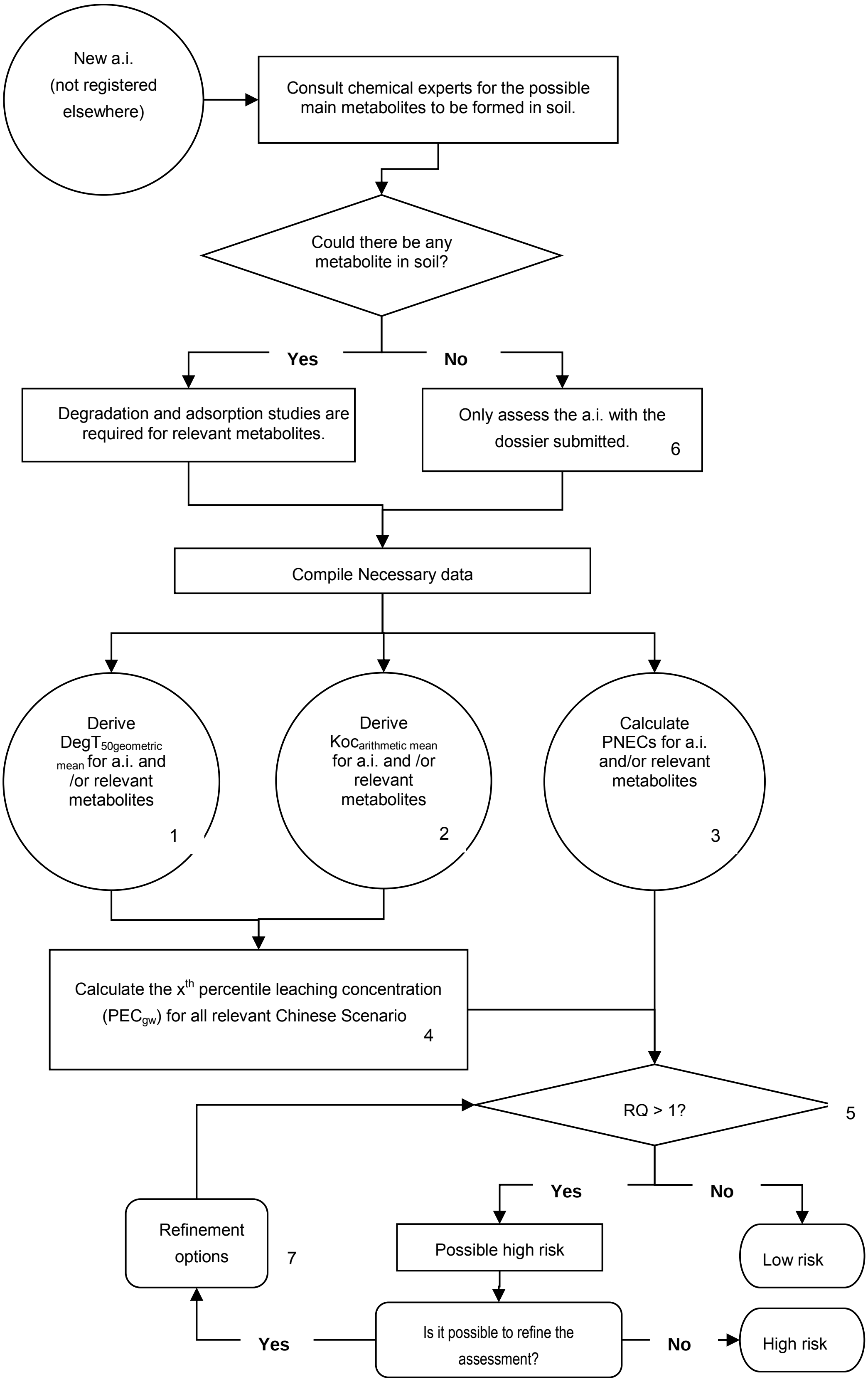
The applicants are also welcome to supply their own risk assessment results as additional reference information, along with explicit interpretation on the scientific methodology, step-wise procedure and expert judgment, if applicable.

6.2.5.4 Mitigation measures

A standard risk assessment or even a higher-tier risk assessment may indicate that the risk of leaching to groundwater may only be acceptable providing that risk mitigation measures are used. Necessary mitigation measures and other precautions shall then be clearly described in the label of the pesticide products. Detailed guidance is given in Section 6.5.



Flowchart 6.1 *Decision-making scheme for groundwater: GENERAL and Existing Chemicals.*



Flowchart 6.2 *Decision-making scheme for groundwater: New Chemicals.*

Explanatory Notes to Flowchart 6.1 and 6.2

1, 2, 3. See Section 6.3 Exposure analysis for the detailed requirements for input data to the Models.

4. For dry land north of the Yangtze River the overall 99th percentile leaching concentration is calculated with the ChinaPEARL model. For paddy land south of the Yangtze River the xth percentile leaching concentration (x = 77 for Nanchang, x = 89 for Lianping) is calculated with the TOPrice model. PECsgw for both a.i. and all the relevant metabolites should be calculated properly.

5. RQs should be calculated for the a.i as well as each of the relevant metabolites.

6. For existing pesticide whose metabolite(s) could not pass the 1st assessment by using the data from the database and/or public literatures, studies (e.g. degradation and adsorption) for the particular compound should be required.

   Besides, higher tier options and/ or possible mitigation measures could be incorporated in the assessing. See also section 6.5

7. Higher tier options and/ or possible mitigation measures could be incorporated in the assessing. See also section 6.5.

6.3 Exposure Analysis

Two different situations, i.e. dry land north of the Yangtze River and paddy land south of the Yangtze River, may be considered in exposure analysis for groundwater risk assessment, depending on which crop the use of the pesticide would be registered for. The exposure analyses for dry land north of the Yangtze River and paddy land south of the Yangtze River are described in the section 6.3.1 and 6.3.2 respectively.

6.3.1 Dry land north of the Yangtze River

6.3.1.1 Data requirements

This section elaborates on the relevant parts of '*Dossier Requirements for Pesticide Registration*' (MOA Command No. 10, Jan 8th, 2008) regarding the environmental fate of pesticides in groundwater, including circumstances in which test is required, test conditions, test guidelines and test results for each data requirement.

Appendix 6-1 describes test conditions, guidelines and endpoints of the required studies.

Soil adsorption

Circumstances in which required

The test is always required.

Test conditions

The test should be performed using four types of soil for the parent substance and at least three types of soil for the relevant metabolites.

Test guideline

'*Chemical pesticide environment risk assessment test guideline*'; or internationally recognized guidelines, e.g. OECD 106.

Results

Kom（Koc）or Kf of active ingredient and/or major metabolites

Aerobic transformation in soil

Circumstances in which required

The test is always required.

Test conditions

The test should be performed using four types of soil for the parent and at least three types of soil for the relevant metabolites. The relevant metabolites also involve the degradation products occurring in the soil photolysis test. The test should be performed under aerobic conditions.

Test guideline

'*Chemical pesticide environment risk assessment test guideline*'; or internationally recognized guidelines, e.g. OECD 307

Results

$DegT_{50}$ of the active ingredient and/or relevant metabolites in soil, degradation route

Soil photolysis

Circumstances in which required

A soil photolysis study must be reported unless it is rationalised that photolysis is not expected to contribute significantly to the degradation of the active substance in soil e.g. due to low light absorbance of the active substance.

Test conditions

The test should be performed for one type of soil. Both results of irrigation and dark test systems should be used.

Test guideline

OECD draft new guideline January 2002 or later revisions

Results

Transformation route and identification of the metabolites above 10% of initial amount parent.

6.3.1.2 Field studies

Field studies involve field dissipation tests, lysimeter, monitoring tests, and subsoil studies, etc.

Field dissipation test

Circumstances in which required

When the pesticide cannot pass the lower-tier risk assessment, the applicant can submit field dissipation tests to refine the exposure analysis.

Test conditions

The test should be performed using at least four types of soil.

Test guideline

OPPTS 835.6100 Terrestrial Field Dissipation, US EPA,2008.
EFSA (2010; note that this guideline was not yet available during the PERAP project)

Results

$DegT_{50}$ of the active ingredient and/or its relevant metabolites in soil, degradation route.

Lysimeter studies and field leaching studies

Lysimeter studies and field leaching studies are not an option in this handbook. For detailed information see section 6.3.1.3 (see 5.B).

Monitoring test

Circumstances in which required

When the pesticide cannot pass the lower-tier risk assessment, applicant can provide monitoring data so as refine the exposure analysis.

Test conditions
Monitoring of the deeper groundwater underneath a vulnerable soil type or a large number of fields with various soil types in China north of the Yangtze River.
Test guideline
No internationally recognized guideline is useful in its current form.

Results
Concentration of active ingredient and/or relevant metabolites in deeper groundwater, i.e. the groundwater present at 10 meter below the groundwater table underneath fields that have been treated with the pesticide.

Subsoil study
Subsoil study is not taken into account in this handbook. For detailed information see section 6.3.1.3. (see 5.A).

6.3.1.3 Tiered approach of PEC calculation

Groundwater Scenarios and ChinaPearl model
Six realistic worst-case groundwater scenarios have been defined for the purposes of a Tier 1 level assessment of the leaching potential of pesticides used on dry land north of the Yangtze River. Soil properties, weather data and crop information have been defined for each scenario. More details can be found in Ter Horst et al. (2014).

At present the ChinaPEARL model was developed to calculate the PEC_{gw} for dry land north of the Yangtze River.

A target depth of 1m is defined for the leaching scenarios, although the detailed protection goal mentions protection of groundwater at 10 m depth. The leaching concentration is assessed at 1 m depth because a number of factors make simulations of chemical transport in the subsoils difficult. Most important is the lack of information on subsoil properties. Moreover fractured rocks are not properly simulated by ChinaPEARL. However, in reality cracks may transport the pesticide quickly to the groundwater. Therefore, a conservative approach cannot be guaranteed if the leaching concentration would be assessed at deeper depth and when assuming the same properties for subsoil as used for the topsoil.

1st tier
The application data and substance properties are input into the ChinaPEARL model to calculate the PEC_{gw} in 1st tier exposure analysis for groundwater risk assessment. The input data and output values for the ChinaPEARL model are presented in Table 6.1.

Table 6.1
Input data and output value for China-Pearl model

Substance type	Input data				Output data
	General information of Substance	location	Application scheme	Parameters of substance	
Parent substance	Common name; substance type; formulation type; China Pearl substance name	Choose the location of scenario	Application absolute or relative; Crop event(emergence or harvest); Period +/- event; Application type; application date; Application dosage; Frequency of application; Application intervals; Fraction of interception	Molecular mass; Vapour pressure (with tested temperature); Solubility in water (with tested temperature); DegT 50 geometric mean (with tested temperature and soil moisture); K_{om} arithmetic mean(with tested temperature); Freundlich exponent; Reference concentration in liquid phase (default value=1mg/L) Option of pH dependent; If sorption is pH dependent: Koc soil (acid and base); pKa (Acid dissociation constant) The wash-off factor: default 0.1 mm-1 (EFSA, 2012) The uptake factor of pesticides by plants: 0.0 FOCUS (2000) The canopy process option: 'Lumped' The half-life at the crop surface: 10 days (EFSA, 2012).	Overall 99th percentile PEC_{gw}
metabolites	Common name; substance type; formulation type; China Pearl substance name	NA	NA	Molecular mass; Vapour pressure (with tested temperature); Solubility in water (with tested temperature); Fraction of transformed; DegT 50 geometric mean (with tested temperature and soil moisture); K_{om} arithmetic mean(with tested temperature); Freundlich exponent; Option of pH dependent; If sorption is pH dependent: K_{oc} soil (acid and base); pKa (Acid dissociation constant); The wash-off factor: default 0.1 mm-1 (EFSA, 2012) The uptake factor of pesticides by plants: 0.0 FOCUS (2000) The canopy process option: 'Lumped' The half-life at the crop surface: 10 days (EFSA, 2012).	Overall 99th percentile PECgw

The overall 99th percentile is found in the ChinaPEARL summary output file in the section 'PEARL report: Leaching'. Note that this report specifies this overall 99th percentile as the 'average concentration of a.i. closest to the 90th (temporal) percentile).

Some explanations about the relevant input data is described below.

1. Application scheme

<u>Application type</u>
In ChinaPEARL, a distinction is made between the following application types:
1. to the crop canopy, interception fraction specified by the model
   (The option 'to the crop canopy, interception fraction calculated by the model' is not used because the calculation of interception is not according to FOCUS groundwater).
2. to the soil surface, (e.g. bare soil application, pre-emergence application, and herbicide use in orchards, etc.)

3. incorporation (e.g. seed treatment: 5 cm incorporation for small seeds; 20 cm incorporation for bigger seeds or bulbs, e.g potato, etc)
4. injection

Application date
If the exact application date cannot be obtained from the label, select the 'relative application' option in ChinaPEARL and use the information on the label, for instance, 'apply pesticide before or after emergence (harvest)', or use expert judgment to specify the application date and use the option 'absolute applications' in ChinaPEARL.

For some permanent crop, e.g. apple, vine, etc., the emergence date is set to be Jan 1st and the harvest date is set Dec 31st. This should be considered when the relative application scheme is used.

Application dosage
The maximum application dosage on the label should be used.
Convert the unit of the application dosage to a.i. kg/ha.

Application interval
The minimum application interval on the label is used.

Interception factor by crop
The option "to the crop canopy, interception calculated by model" cannot be used. Instead the option 'to the crop canopy, interception fraction specified by the model' should be used, using interception values from the FOCUS interception table (Table 6.2).

Table 6.2
Spray interception (% of applied dosage) by crop type and growth stage (BBCH) (after Anonymous, 2011).

BBCH code*	00–09	10–19	20–29	30-39	40–89	90–99
Beans	0	25	40	40	70	80
Cabbage	0	25	40	40	70	90
Carrots	0	25	60	60	80	80
Cotton	0	30	60	60	75	90
Grass	0	40	60	60	90	90
Grass, established	90	90	90	90	90	90
Linseed	0	30	60	60	70	90
Maize	0	25	50	50	75	90
Oilseed rape	0	40	80	80	80	90
Onions	0	10	25	25	40	60
Peas	0	35	55	55	85	85
Potatoes	0	15	50	50	80	50
Soybean	0	35	55	55	85	65
Cereals	0	25	50	70	90	90
Strawberries	0	30	50	50	60	60
Sugar beets	0	20	70	70	90	90
Sunflower	0	20	50	50	75	90
Tobacco	0	50	70	70	90	90
Tomatoes	0	50	70	70	80	50

*) 00-09 is bare soil until emergence, 10-19 is leaf development, 20-29 is tillering, 30-39 is stem elongation, 40-89 is flowering and 90-99 is senescence to ripening.

2. Substance data

DegT50
The DegT50 values from laboratory studies are used in the 1st tier assessment, because the ChinaPEARL model needs a degradation half-life as input. Half-lives from field dissipation studies might also include other dissipation routes and might therefore not be true degradation half-lives, but rather dissipation half-lives.

DegT50 values are converted to 20℃ using Formula 6-2.

$$DegT_{50}(20^0C) = DegT_{50}(T) \times e^{0.08 \times (T-20)}$$ Formula 6.2

T: Temperature at which the study was conducted (℃)

Only Single First Order (SFO) DegT50 values are used

Single first-order kinetics : the rate of the change in pesticide concentration (dM/dt) is at any time directly proportional to the actual concentration remaining in the system. For SFO kinetics, the time for a decrease in the concentration by a certain percentage is constant throughout the experiment and independent of the initial concentration of the pesticide. First-order kinetics have also frequently been used to describe degradation in pesticide fate models.

For the metabolites, the information about the degradation path should be available. If the degradation path is unknown in the 1st screening we assume that all relevant metabolites are primary metabolites.

For photochemical metabolites, the maximum percentage of occurrence in the soil photolysis studies should be used. The geometric mean of all available DegT50 values is used as the input value in the China-PEARL model.

Kom (with tested temperature)
Based on overall available data, the arithmetic mean of K_{om} values is used as the input data in the model.

Calculate K_{om} using Formula 6-3 when K_{oc} values available.

$$Kom = \frac{Koc}{1.724}$$ Formula 6.3

Use a default value of 0.9 for the Freundich sorption exponent.

If the sorption is expected to be pH dependent because the substance has one or more pKa values in the range 2<pKa<6, sorption should be determined at pH 7-8 (3 soils). If the sorption of a substance or metabolite is pH dependent, the leaching for the relevant scenario(s) is calculated according to FOCUS procedures, using conservative estimates of K_{om} and DegT50. E.g the K_{om} can be taken at pH ($CaCl_2$) of 7.5 or, alternatively, the K_{om}, base may be used.

3. Crop

The scenarios for dry land north of the Yangtze River are parameterised for nine different crops only. In case registration is asked for use of a pesticide in a crop for which the scenarios are not parameterised, the following procedure should be used: i) Run the relevant scenarios in ChinaPEARL for all crops available and ii) select the worst-case (maximum 99th percentile PEC_{gw}) of the runs with all crops.

4. Irrigation

Weekly irrigation is assumed for all crops and scenarios north of the Yangtze River. ChinaPEARL calculates the irrigation amount in such a way that the required amount of water brings the soil water content in the root zone back to field capacity. However, irrigation is applied only if the amount required exceeds 15 mm. The ChinaPEARL user should select for all simulations the irrigation schedule: 'Northern China Irrigation'.

5. Start and stop dates of the simulations

In ChinaPEARL the start date of the simulation should be set to 01/01/1901 and the stop date should be set to 31/12/1926. ChinaPEARL performs 26 years of simulations of which the first six years are warm-up years. The overall 99th percentile leaching concentrations is selected from the last 20 years of simulations.

Higher tier

Exposure analysis can take several different options for refinement in higher tier, for instance, refinement of input parameters for PEC calculation model, lysimeter study, monitoring data, etc. It should be mentioned that special evaluation is required to decide if field tests could provide useful information on a case-by-case basis.

A. Refinement of input parameters

Field dissipation studies

There are two options for field dissipation studies in this handbook.

One option is not to include field dissipation studies, because at the time of the PERAP project there was no internationally recognized test guidance and an evaluation methodology of field dissipation studies was lacking.

The other option is to accept field dissipation studies. The DegT50 value that is to be entered may originate from field dissipation studies where the field experiment meets the requirements as given in EFSA (2010; note that this guidance was not available yet during the PERAP project). A key element of this guidance on the field test is that it should be clearly demonstrated that other dissipation routes can be excluded and that degradation is the only important dissipation process. This is only the case if a non-significant fraction of the dose disappeared via e.g. processes at the soil surface such as volatilization or photochemical transformation or can have leached out of the soil layers that were sampled.

Subsoil studies

Subsoil studies cannot be validated under China conditions. As a consequence subsoil studies are not accepted in this handbook at this moment.

B. Lysimeter and field leaching studies

Higher tier leaching evaluation is in the European framework based on lysimeter or field leaching studies. However, consensus about the exact evaluation methodology to arrive at Annex I inclusion has not yet been reached and the evaluation is based on expert judgment. It is unclear which concentration must be taken as starting point and how this could - where appropriate - be converted to other scenarios. There is no extrapolation and standardization in the European framework. Therefore lysimeter and field leaching studies are not an option in this handbook at this moment.

C. Monitoring data

The results of monitoring studies can be used in the evaluation process if the pesticide did not meet the criterion in the 1st tier. Depending on the protection goal the groundwater monitoring data from deep wells in areas with dry land agriculture north of the Yangtze river can be used in the higher tier.

The 99th percentile concentration in space of the long-term average concentration in groundwater at 10 m depth will be used. Important in the monitoring procedure is: (1) careful selection of the wells; (2) adequate sampling and analytical procedures; (3) large number of wells needed (in the order of 100); (4) filter depth at or below 10 m depth.

Monitoring results should demonstrate that there is no leaching of an active substance and/or its metabolite(s) above the legal criterion, under the suspicion that there is leaching. Since not very much monitoring data is available under Chinese conditions this will be a rare option.

6.3.2 Paddy land south of the Yangtze River

6.3.2.1 Data requirement

This section elaborates on the relevant parts of '*Dossier Requirements for Pesticide Registration'* (MOA Command No. 10, Jan 8th, 2008) with regard to the environmental fate of pesticide sin aquatic ecosystems, including circumstances in which required, test conditions, test guidelines and test results for each of the data requirements.

Appendix 6-2 describes test conditions, guidelines and endpoints of the required studies.

Aerobic transformation in water-sediment system

<u>Circumstances in which required</u>
The test is always required.

<u>Test conditions:</u>
The test should be performed using two different water-sediment systems. The test should be performed under aerobic conditions.

<u>Test guideline:</u>
'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 308

<u>Results:</u>
Identification of relevant metabolites in water-sediment system.

Soil adsorption

<u>Circumstances in which required</u>
The test is always required.

<u>Test conditions</u>
The test should be performed using four types of soil for the parent substance and three types of soil for relevant metabolites at least. The relevant metabolites include all metabolites occurring in the water-sediment system and the aerobic soil degradation and anaerobic paddy degradation study.

<u>Test guideline</u>
'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 106.

<u>Results</u>
K_{om} (K_{oc}) or K_f of active ingredient and/or major metabolites

Aerobic transformation in soil

<u>Circumstances in which required</u>
The test is always required.

<u>Test conditions</u>
The test should be performed using four types of soil for the parent and at least three types of soil for the relevant metabolites. The relevant metabolites also involve the degradation products occurring in the water-sediment system and in the aerobic soil degradation and the anaerobic paddy soil degradation study. The test should be performed under aerobic conditions.

Test guideline
’Chemical pesticide environment risk assessment test guideline’; or internationally recognized guidelines, e.g. OECD 307
Results
DegT50 of active ingredient and/or relevant metabolites in soil and degradation route

Anaerobic transformation in paddy soil
Circumstances in which required
The test is always required.

Test conditions
The test should be performed using four types of paddy soil for parent substance and at least three types of soil for the relevant metabolites. The relevant metabolites include all metabolites occurring in both the aerobic and anaerobic soil degradation studies and in the water-sediment system study. Test should be performed under anaerobic conditions.

Test guideline
’Chemical pesticide environment risk assessment test guideline’; or internationally recognized guidelines, e.g. OECD 307.

Results
DegT50 of active ingredient and/or major metabolites, transformation route in paddy soil.

6.3.2.2 Field studies
Field studies involve field dissipation tests**,** lysimeter, monitoring tests, and subsoil studies, etc.

Field dissipation test
Field dissipation tests are not taken account in this handbook, because an adequate test method for paddy land is not yet available.

Lysimeter studies and field leaching studies
Lysimeter studies and field leaching studies are not an option in this handbook. Detailed information is given in section 5B.

Monitoring test
Circumstances in which required
When pesticides cannot pass the lower-tier risk assessment, the applicant can provide monitoring data to refine the exposure analysis.

Test conditions
Monitoring of the upper groundwater underneath a restricted number of fields with a vulnerable soil type or a large number of fields with various soil types in China, south of the Yangtze River.

Test guideline
No internationally recognized guideline is available at the moment.

Results
Concentration of the active ingredient and/or its relevant metabolites in the upper groundwater, i.e., the groundwater present between 0 and 2 meter below the groundwater table underneath fields that have been treated with the pesticide.

Subsoil studies
Subsoil studies are not an option in this handbook. Detailed information is given in section 5A.

6.3.2.3 Tiered approach of PEC calculation

Groundwater scenarios and model

Two realistic worst-case groundwater scenarios have been defined for the purposes of a Tier 1 level assessment of the leaching potential of pesticides in paddy land. Soil properties, weather data and crop information have been defined for each scenarios. Detailed information can be found in ter Horst et al., 2014.

The TOPrice software tool was developed to calculate the PEC_{gw} for paddy land south of the Yangtze River. A target depth of 1m is defined in the TOP rice model to guarantee a conservative apporach (note that the detailed protection goals mentions protection of groundwater at 2 m depth in paddy land south of the Yangtze River in China.

1st tier

The application data and substance properties are input into the TOPrice software tool which is used to calculate the PEC_{gw} in 1st tier exposure analysis for the parent substance and its relevant metabolites. The input data and output data of the PEARL model, incorporated in the TOPrice software tool, are presented in Table 6.3.

At the moment TOPrice cannot handle the simulation of the behavior of the parent and its metabolites in the water layer of the paddy field in a single simulation. Therefore separate runs of the TOPrice software tool are needed for the parent substance and the relevant metabolites formed in the water layer on the paddy field.

Table 6.3

Input data and output data for the PEARL model incorporated in the TOPrice software tool

Substance type	Input data				Output data
	General information of Substance	location	Application scheme	Parameters of substance	
Parent substance	Common name; substance type; formulation type; China Pearl substance name	Choice the location of scenario	Application absolute or relative; Crop event(emergence or harvest); Period +/- event; Application type; application date; Application dosage; Frequency of application; Application intervals; Fraction of interception	Molecular mass; Vapour pressure (with tested temperature); Solubility in water (with tested temperature); DegT 50 geometric mean for aerobic transformation in soil (with tested temperature and soil moisture); DegT 50 geometric mean for anaerobic transformation in paddy soil (with tested temperature); K_{om} arithmetic mean (with tested temperature); Freundlich exponent; Reference concentration in liquid phase; Option of pH dependent; If sorption is pH dependent: K_{oc} soil (acid and base); pKa (Acid dissociation constant) The wash-off factor: default 0.1 mm-1 (EFSA, 2012) The uptake factor of pesticides by plants: 0.0 FOCUS (2000) The canopy process option: 'Lumped' The half-life at the crop surface: 10 days (EFSA, 2012)	x^{th} percentile PEC_{gw}
metabolites[3]	Common name; substance type; formulation type; China Pearl substance name	Choose the location of scenario	Application absolute or relative; Crop event(emergence or harvest); Period +/- event; Application type; application date; Application dosage of metabolite; Frequency of application; Application intervals; Fraction of interception	Molecular mass; Vapour pressure (with tested temperature); Solubility in water (with tested temperature); DegT 50 geometric mean for aerobic transformation in soil (with tested temperature and soil moisture); DegT 50 geometric mean for anaerobic transformation in paddy soil (with tested temperature); K_{om} arithmetic mean (with tested temperature); Freundlich exponent; Option of pH dependent; If sorption is pH dependent: K_{oc} soil (acid and base); pKa (Acid dissociation constant) Fraction of transformed; The wash-off factor: default 0.1 mm-1 (EFSA, 2012) The uptake factor of pesticides by plants: 0.0 FOCUS (2000) The canopy process option: 'Lumped' The half-life at the crop surface: 10 days (EFSA, 2012)	x^{th} percentile PEC_{gw}

[3] Metabolites presented in the table occurring water-sediment study.

The x^{th} percentile of leaching (x = 77 for Nanchang, x = 89 for Lianping) is found in the TOPrice summary output file in the section 'PEARL report: Leaching'. Note that this report specifies this x^{th} percentile as the 'average concentration of a.i. closest to the x^{th} percentile')

Some explanations about the relevant input data will be described in below.

1. Application scheme

<u>Application dose for metabolites</u>

$$\mathbf{Dose_M = f\left(\frac{M_M}{M_p}\right) Dose_p} \qquad \text{Formula 6.4}$$

$Dose_{M}$:	corrected pesticide dose for the relevant metabolite formed in the water layer on the paddy field, to be entered in the TOP rice model (kg/ha)
$Dose_{p}$:	pesticide dose of the parent substance, given on the label (kg/ha)
f:	formation fraction of the relevant metabolite formed in the water layer on the paddy field
M_{M}:	molar mass of the relevant metabolite formed in the water layer on the paddy field (g/mol)
M_p:	molar mass of the parent substance (g/mol)

It should be noted that only paddy land is simulated in the scenarios. In most of the cases where the pesticide of concern is not intended to be used in paddy land, or not only in paddy land, the above mentioned models and scenarios can be used to give worst-case PEC for 1^{st} tier assessment if the users input the application information to the models by following the guidance given in Table 2.4.

If calculations are performed with a pesticide label specifying application of the pesticide on the day of transplanting or one day after, it is advised to perform a second run applying the pesticide two days after application (for evaluation of risks of pesticide use in aquatic ecosystems in ponds) and use the highest PEC of the two runs (ter Horst et al., 2014 for reason).

2. Interception

Figures on spray interception in paddy rice were collected (see ter Horst et al., 2014) and put into the database of the TOPrice software tool. The correct figures are automatically selected by the TOPrice software tool.

Higher tier
The results of monitoring studies can be used in the evaluation process if the pesticide did not meet the criterion in 1st tier. Depending on the protection goal the groundwater monitoring data from shallow groundwater wells in paddy land in China, south of the Yangtze River can be used in a higher tier.

Two approaches are possible:
a. monitoring of the upper groundwater underneath a restricted number of fields with a vulnerable soil type, and
b. monitoring of the upper groundwater underneath a large number of fields with various soil types that are together representative of the total acreage of use of the substance

The 99th percentile concentration in space of the long-term average concentration in the shallow groundwater will be used.

Important in the monitoring procedure is: (1) monitoring of the top meter of groundwater at 8 – 10 fields; (2) fields have to be more vulnerable than the 99th percentile; (3) if possible, be sure that the weather is wet enough (or supplemented by irrigation).

Monitoring results should demonstrate that there is no leaching of an active substance and/or its metabolite(s) above the legal criterion, under the suspicion that there is leaching. As little monitoring data is available under Chinese conditions this will be a rare option.

6.4 Effect Assessment

6.4.1 Data requirement

Tolerable Daily Intake/ Acceptable Daily Intake for a.i. and the relevant metabolites should be obtained from the conclusion of the toxicological assessment. However, for an existing pesticide, Tolerable Daily Intake/ Acceptable Daily Intake in the database and/or public literature can also be used for the assessment of leaching to groundwater.

6.4.2 PNEC establishment

When determining the Regulatory Accepted Concentration of the pesticide (including a.i. and all the relevant metabolites) in groundwater, the following formula will be used to calculate the trigger value based on recommendations for deriving the WHO guideline values in groundwater for chemicals (‘Guidelines for Drinking-water Quality 3rd Edition’, World Health Organization, Geneva, 2008):

$$GV = \frac{TDI \times bw \times P}{C}$$

Formula 6.5

TDI: Tolerable daily intake (mg/kg bw·d)
Bw: Body weight (kg)
P: Fraction of the TDI allocated to drinking-water (%)
C: Daily drinking-water consumption (L)

This formula is especially applied for pesticides which have threshold toxic effects considering the policy that carcinogens could not be authorized in China.

For a compound that has been evaluated by WHO and therefore has Guideline Value (GV) listed in the ‘Guidelines for Drinking-water Quality 3rd Edition’ (World Health Organization, Geneva, 2008), the WHO GV will not be taken directly as PNEC because the GVs have not been reviewed for quite a long time, as recommended by WP5.

TDI is a compound-specific parameter (see also Section 6.4.2.1); default values could be set for bw, P and C according to the recommendation from 'Guidelines for Drinking-water Quality 3rd Edition' (World Health Organization, Geneva, 2008), if no specific data are available. The default values adopted in this handbook is given in Table 6.4. If different values are used, a sufficient justification should be submitted.

Table 6.4
Default values for PNEC calculation for groundwater

	Body weight (kg)	P (%)	C (L)
Default Value	60	20	2

6.4.3 Consideration for deriving the parameters for PNEC calculation

6.4.3.1 TDI estimation

The tolerable daily intake (TDI) is an estimate of the amount of a substance in food and drinking-water, expressed on a body weight basis (mg/kg or mg/kg of body weight), that can be ingested over a lifetime without appreciable health risk. For pesticides, TDI can be replaced by acceptable daily intakes (ADIs), which are established for pesticide residues that occur in food for plant protection reasons.

6.4.3.2 Allocation of intake (P)

As the primary sources of exposure to pesticide residues are possibly through both food and water, it is important to quantify the exposures from both sources. There are two ways to get the allocation of intake of drinking-water:

a. Where appropriate information on the exposure from food and water is available, the data will be used to estimate the proportion of the intake that comes from food and the proportion that comes from drinking water.
b. Where appropriate information on exposure from food and water is not available, allocation factors are applied that reflect the likely contribution of water to total daily intake. Normal allocation of the total daily intake to drinking-water is 20%. But this value may be changed. In the case of some pesticides, which are likely to be found as residues in food from which there will be significant exposure, the allocation for water may be as low as 1%.

6.4.3.3 Default assumptions of body weight and daily drinking-water consumption

The default assumption for consumption by an adult is 2 litres of water per day, while the default assumption for body weight is 60 kg. In some cases, when the guideline value is based on children, where they are considered to be particularly vulnerable to a particular substance, a default intake of 1 litre is assumed for a body weight of 10 kg; where the most vulnerable group is considered to be bottle-fed infants, an intake of 0.75 litre is assumed for a body weight of 5 kg.

6.4.3.4 Others factors needed to consider

The following factors are taken into account when calculating trigger values.
The UF used to establish the TDI/ADI

- Data quality
- Analytical aspects
- Treatment

6.5 Environmental Risk management suggestions

6.5.1 Risk mitigation measures

When ERA for a certain pesticide indicates that the risk to groundwater may only be acceptable providing that risk mitigation measures are used, such mitigation measures shall be taken into account by the risk managers to make a regulatory decision and explicit description on the label of the pesticide regarding the mitigation measures shall be ensured.

It should be noted that such mitigation measures should not weaken the efficacy of the pesticide. Moreover, it is important for the risk managers to assess the feasibility of such mitigation measures in terms of enforcement.

Table 6.5 below provides the information on mitigation measures for groundwater with good or limited feasibility in China.

If any risk mitigation measure is recommended, the risk assessor should re-evaluate the risk of the pesticide, taking into account the estimated effectiveness of the mitigation measure.

Table 6.5
Relevant options for risk mitigation measures for aquatic organisms in China

Risk mitigation measure	Effectiveness of measure (relative reduction in exposure)	Conditions	Overall feasibility in China (good, limited, difficult)	Corresponding Label statement
Reduction of application rate	About linearly proportional to reduction in application rate	If efficacy of the pesticide is not affected.	Good	
Restrict use to formulation types that result in less leaching (e.g. slow-release formulations, seed coatings)	Variable	If pest/disease/weed allows this measure	Good	
Restrict use to regions with deep groundwater level	Variable		Limited	**LS.G.1**
Refuse registration	Complete	If alternative pesticides or other pest management options are available	Good	

6.5.2 Labeling

The following specific label statements are linked to mitigation measures, which therefore should be used when certain mitigation measure is required to reduce the risk to acceptable level:
- LS.G.1: Do not apply in ［specify the area］.

6.6 Reference

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Appendix 6-1

Conditions, guidelines and endpoints of the required environmental fate tests for dry land

Data requirement	Conditions for active ingredient	Conditions for formulations	Test Guideline	Test results
Soil adsorption	The test should be performed for four types of soil for parent and three types of soil for relevant metabolites at least.	-	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 106	Kom of parent and/or relevant metabolites
Aerobic transformation in soil	The test should be performed for four types of soil for parent and three types of soil for relevant metabolites at least.	_	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 307	DegT50 of parent and/or relevant metabolites in soil, degradation route
Soil photolysis	The test should be performed for one type of soil at least.	_	OECD draft new guideline January 2002 or later revisions	Degradation route and identification of relevant metabolites
Field dissipation study	-	Expert judgment is required to decide if field tests could provide useful information, case by case.	OPPTS 835.6100 Terrestrial Field Dissipation, US EPA,2008	DegT50 of parent and/or relevant metabolites in soil, degradation route.
Monitoring data	--	-	-	Concentration of active ingredient and/or relevant metabolites in deeper groundwater, i.e., the groundwater present at 10 meter below the groundwater table underneath fields that have been treated with the pesticide.

Appendix 6-2

Conditions, guidelines and endpoints of the required environmental fate tests for paddy land

Data requirement	Conditions for active ingredient	Conditions for formulations	Test Guideline	Test results
Aerobic transformation in water-sediment system	The test should be performed for two types of water-sediment systems at least.		'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 308	Degradation route and identification of relevant metabolites
Soil adsorption	The test should be performed for four types of soil for parent and three types of soil for relevant metabolites at least.	-	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 106	Kom of parent and/or relevant metabolites
Aerobic transformation in soil	The test should be performed for four types of soil for parent and three types of soil for relevant metabolites at least.	_	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 307	DegT50 of parent and/or relevant metabolites in soil, degradation route
Anaerobic transformation in paddy	The test should be performed for four type of paddy soil at least .	_	OECD draft new guideline January 2002 or later revisions	Degradation route and identification of relevant metabolites
Monitoring data	-	-	-	Concentration of active ingredient and/or relevant metabolites in shallow groundwater, i.e., the groundwater present within 0 to 2 meter below the groundwater table underneath fields that have been treated with the pesticide.

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