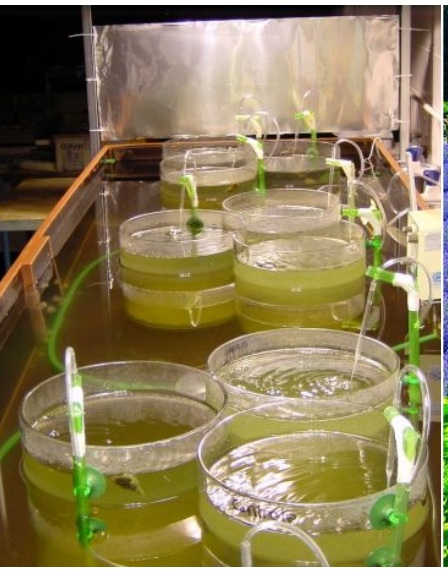
Content Report 4



Environmental Risk Assessment Handbook

Draft 2

20 July 2009

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1 Introduction

The risk assessment handbook (as part of the overall PERAP project) will be used in the regular dossier evaluation in the pesticide registration procedure in China. Dossier evaluation will be done by ICAMA and by staff of the provincial contract laboratories of ICAMA. Therefore ICAMA will need master trainers to train the staff of the contract laboratories. In this result the development of the handbook and the training of the master trainers are combined. The handbook will be developed by at least 2 ICAMA staff who will become the trainers for the contract labs.

During the development of the handbook, in depth training will be provided by Alterra to ICAMA staff on the various topics. In this way, two regular ICAMA staff will be trained as risk assessment master trainer who can train contract laboratory staff.

2 Environmental Risk Assessment Handbook: Draft 2

The handbook will be developed by ICAMA and Alterra and will have an introduction chapter and a chapter for each protection goal.

Two workshops were already given in 2007:
- The first workshop focused on the general approach of an environmental risk assessment with special attention to aquatic organisms.
- The second workshop focused on the risk assessment of aquatic organisms in more detail and also the chapter of the handbook was worked out in more detail (political decisions related to this topic can be added later).

One workshop was given in 2008. The goal of the third workshop is to finalize the draft of chapter 1 (introduction) and chapter 2(aquatic organisms), and to get trained on the risk assessment of birds.

After the above workshop, a draft of the handbook (chapter1 and chapter2) was circulated for comments from experts at Alterra and Ctgb. At the same time, WP2 worked on Chapter 3 birds and sent 1st draft of that chapter and associated quesitons to Ctgb for comments.

The goals of this workshop (July, 2009) are to make a new draft of chapter 3 based on the comments, to finalize chapter 1 and chapter 2 based on comments from circulation, and to receive training on environmental risk assessments for rodenticide and honeybees.

Metabolites in the context of Leaching to groundwater were discussed among WP2, WP4, WP5 and expert from Ctgb. The conclusion is demonstrated in Fig.1

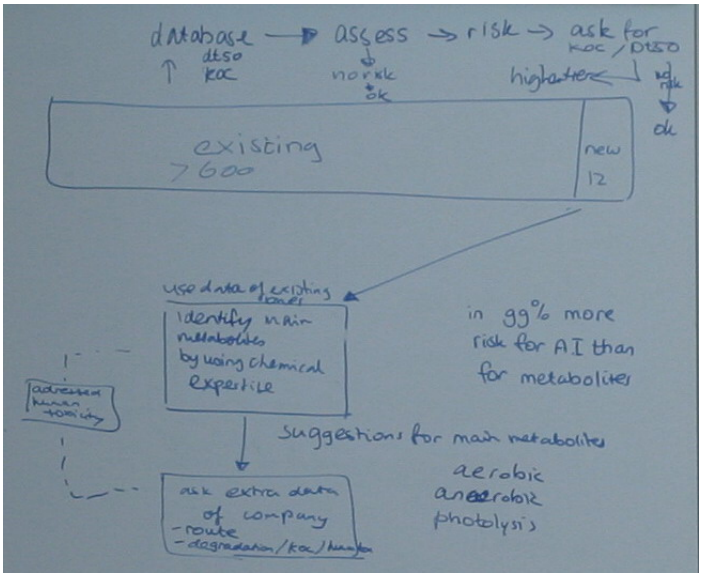

Fig. 1 the conclusion about metabolites in context of leaching to groundwater

A new draft of the handbook (See **Annex1 Environmental Risk Assessment Handbook for Pesticide Registration**) has been achieved according to the following conclusions made during this workshop:

1) Chapter 1 Introduction and Chapter 2 Aquatic ecosystems have been circulated among PERAP experts for comments since last November. During this workshop, WP2 discussed the comments from Peter, Paul and Harold. Based on the discussion, the following conclusions have been made and taken into consideration in Chapter 1 and 2:
- A section about "identifying the relevance of the risk to aquatic ecosystems' has been added.
- A section about "identifying the relevance of the risk' will also be added to Chapter 1 introduction

- A new version will be finished by September according to the comments. This version is considered to be pre-final draft and will be updated after input from WP4 is available.

2) **A draft of Chapter 3 Birds and associated list of questions were sent to Jacoba (Ctgb) for comments. During this workshop, WP2 visited Ctgb and RIVM (Robert Luttick) for discussion on ERA for birds. The following conclusions have been made and taken into consideration in Chapter 3**
   - **New EU Guidance Document**: A new EU guidance document on ERA of birds is going to be finalized in December 2009. Based on the information from Ctgb and Robert Luttik, the major 'scientific content' in the current draft will be adopted by EU. In order to adopt the most up-to-date sciences, WP2 decided to adopt the default values in the new EU guidance document (e.g. RUD, etc), if applicable.
   - **Relevant exposure routes**: Different exposure routes have been prioritized according to their potential of causing risk in reality (based on EU experience) and data availability. 4 representative exposure routes are identified to be taken into account in the handbook, including: exposure via spray, exposure to granule, exposure to treated seed and exposure to rodenticides. Secondary poisoning is considered only in the case of rodenticides exposure.
   - **Chronic data**: Reproduction toxicity data are not mandatorily required in 'Dossier Requirements for Pesticide Registration' at this moment. In the case when such data are not available, chronic risk could be addressed by using acute date with an additional extrapolation factor. A factor of 10 is used in the handbook based on expert judgement. Adjusting could be made based on WP5's outcome.
   - **'One seed/granule criterion'**: The 'one-seed/granule-criterion' (EPPO scheme) is adopted in the handbook as a 'cut-off' criterion.
   - **Rodenticide**: Rodenticide is regulated as biocide in EU. In the handbook, rodenticide exposure will be written based on the biocide risk assessment Guidance Document.

3) **Chapter 4 (bees) will be developed based on the training.**

4) **Assessment of Metabolites will be taken into account for leaching to groundwater.**

5) **Editing:** WP2 decided to start to look for a translator to check the language and then translate the English version to Chinese.

3 List of Consulted Experts

The following experts are consulted during the workshop:

Harold van der Valk **(harold.vandervalk@wxs.nl)**

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Appendix 1 Environment Risk Assessment Handbook for Pesitcide Registration

List of Contents

Abbreviations

BCF:	Bioconcentration factor
EC_{50}:	median effective concentration
ERA:	Environmental Risk Assessment
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 dosage.
NOEL(C):	No observed effect level (concentration), i. e. the maximum treatment level(concentration) used in a test which produces no adverse effect.
PEC:	Predicted Environmental Concentration
PERAP:	(Sino-Dutch) Pesticide Environmental Risk Assessment Project
RAC:	Regulatory Acceptable Concentration
RQ:	Risk Quotient

Preface

The Institute for the Control of Agrochemicals, Ministry of Agriculture of P.R. China(ICAMA) is responsible for the pesticide registration procedures in China. The following parts are considered to be of importance in the registration procedure:

- Physical / chemical properties;
- Analytical methods;
- Human toxicology;
- Residues;
- Environment (behavior and fate of pesticides and ecotoxicology);
- Efficacy.

The Pesticide Environmental Risk Assessment Project (PERAP) is an international collaboration project between China and the Netherlands. PERAP project is intended to assist China to develop Chinese Environmental Risk Assessment (ERA) procedure for pesticide registration purpose, including developing a series of relevant guidance documents. ICAMA and Alterra, Wageningen UR , the Netherlands, have been working together towards this aim as two leading participants of PERAP project.

The underlying handbook is developed with the expertise provided by the project and therefore is considered as one of the deliveries 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 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. [1]

[1] Tools and techniques in environmental risk assessment progress rapidly. It is noted that it can be difficult to take such progress fully into account in the dossiers and assessment reports during ongoing reviews. To provide a reliable framework for the review process and to avoid undue delays, the validity date of the handbook should be specified, preferably before the end of PERAP project so that the use of the handbook for pesticide registration procedures will be ensured.

1 Introduction

1.1 Legislation/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 in May 8th, 1997, revised in Nov. 29th, 2001)
- Implementation Approaches under the Regulation for Pesticide Administration' (MOA Command No. 20, Jul 23rd, 1999)
- Dossier Requirements for Pesticide Registration' (MOA Command No. 10, Jan 8th, 2008)
- Stockholm Convention'(ratified by China)

Environmental quality standards for surface water' (GB 3838-2002);
(to be added)

As given in section 1.1 one important aspect to consider in the pesticide registration procedure is the impact of pesticides on the environment. Protection of the environment from the potential adverse effects of pesticides is based on an ERA.

1.2 Contributions of Environmental Risk Assessment (ERA) to Environmental risk management

ERA is used world-wide to examine the effects of an active ingredient (a.i.) or a formulation 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 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 ecotoxicological 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 the Chinese 'Regulation for Pesticide Administration' (State Council Command No. 216, issued in May 8th, 1997, revised in 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 are intended to achieve; however, in order to set up a pragmatic assessment approach and facilitate the communication between different interested groups, the provision should be further elaborated, especially in terms of explicit definition of the terms 'environment ', 'beneficial animals', and 'endangered species'. At this stage of development of ERA in China, this

handbook will only focus on ‘environment’ and ‘beneficial animals’. ‘Endangered species’ will be taken into account in the future, if appropriate.

Therefore, the following protection gaols are selected in this hand book and together they represent the ‘environment’ and ‘beneficial animals’:

1. Aquatic ecosystem.
2. Birds.
3. Honey bees.
4. Silkworms.
5. Groundwater.

Each of the above protection goals will be elaborated in the section of ‘detailed protection goals’ in each chapter of this hand book. 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 specific geographical locations?

3. How strict do we want to protect?

- What are the criteria? Also relates to long term effects 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 pesticides and the effects of such emissions on the structure and function of the ecosystem.

The ERA approach is based on three basic assessing processes:

- Exposure analysis;
- Effect assessment;
- Risk assessment.

Fig. 1-1 gives an overview of the approach of the ERA adopted in this handbook. Possible risk should be quantifiably characterized, 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 done.

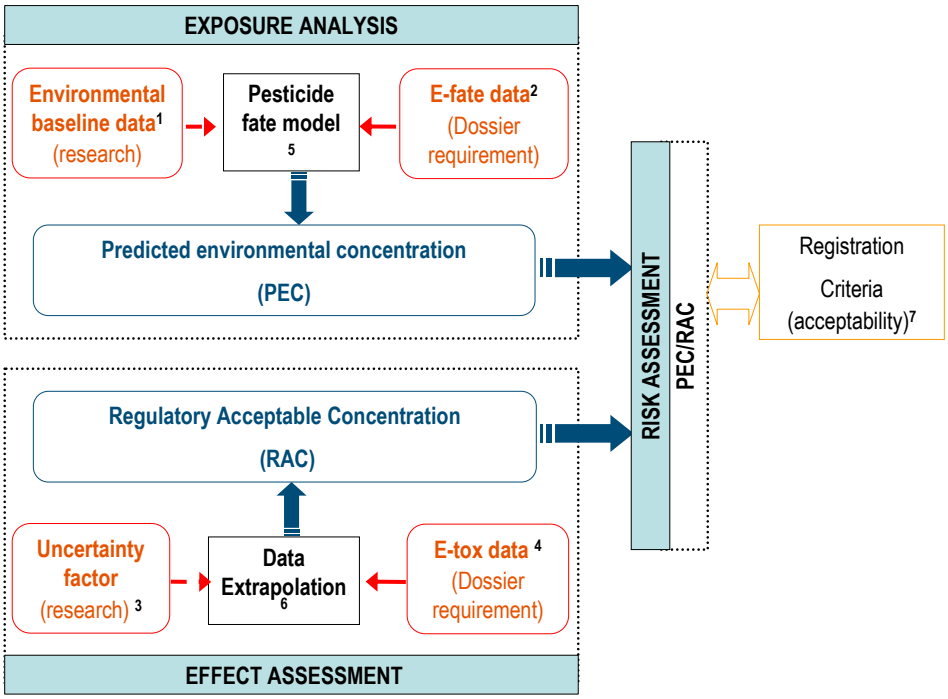


Fig. 1-1: Flow chart for the Environmental Risk Assessment approach adopted in this handbook

Explanatory Notes for Fig.1-1:
1. Environmental baseline data: the data used for establishing pesticide environmental fate model and scenario, including geographic data, meteorological information, crop category, etc.
2. E-fate data: the data submitted in accordance with the ·'Dossier Requirement for Pesticide Registration' (MOA Command No. 10, Jan. 8th, 2008) and used as the input parameters for pesticide environmental fate model, e.g. DT_{50} in soil, Koc, etc.
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. E-tox data: the data from the 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: the tools (i.e. computer models) used in exposure analysis for estimating the predicted environmental concentration (PEC). Readers should notice that for some protection goals (e.g. bees, etc.) the exposure analysis may be done with methods other than pesticide fate models. (awaiting input from Work Package 4)
6. Data extrapolation: the process of extrapolating from laboratory toxicity data on a limited number of species to the 'real' environment.
7. Registration criteria: the political decision for the acceptability of the risk of a particular pesticide. (awaiting decision from Work Package 5)

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 Regulatory Acceptable Concentration (RAC). ¶The RAC shall be based on the data from the ecotoxicological studies submitted in accordance with the ·'Dossier Requirement for Pesticide Registration' (MOA Command No. 10, Jan. 8th, 2008) The RAC shall be calculated by applying an uncertainty factor to the lowest values resulting from tests on organisms. 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 is an

expression of the degree of uncertainty in extrapolation from single-species laboratory data to the multi-species ecosystem. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the uncertainty factor. For this reason long-term data are preferred to short-term data. The following has to be taken into account when choosing the appropriate 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

Exposure analysis: The information on fate and behaviour of pesticide in the environment is central to the assessment of 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. present in the formulation product likely to be found. This concentration is known as the Predicted Environmental Concentration (PEC).

A PEC, or where necessary a qualitative estimate of exposure[2], need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material (e.g. crop, etc.) treated with formulation products are known or are reasonably foreseeable. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:

- adequately measured exposure data,
- the form in which the formulation product is marketed,
- the type of the formulation product,
- the application method and application rate,
- the physical-chemical properties,
- the relevant metabolites[3],
- likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
- the frequency and duration of exposure.

Where adequately measured, 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.

Risk assessment: A risk assessment will be done for those environmental compartments that are exposed to the formulation product. The risk characterization will be expressed as Risk Quotient (RQ) which is calculated by dividing the exposure concentration by the safe concentration (i. e. PEC/RAC). If the RQ is smaller than 1, i.e. the exposure is lower than the safe concentration, the risk is acceptable. If the RQ is bigger than 1, i.e. the exposure is higher than the safe concentration, it might be possible that the risk is not acceptable. Higher tier risk assessment is needed. If higher tier doesn't help mitigation measures or restrictions are needed.

If it has not been possible to derive a RQ (i.e. PEC/RAC), 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. (Whereas appropriate field studies and probabilistic methods may be applied case by case by expert judgement with a comprehensive description of the methodology and interpretation of the results.)

At present, an ERA methodology has been developed for each protection goal: aquatic ecosystem, groundwater, honey bees, silkworms and birds.

[2] At this stage of ERA development in China, the handbook only focused on the quantitative exposure analysis. The qualitative estimate of exposure will be addressed case by case based on expert judgement.
[3] At this stage of ERA development in China, ERA of metabolites is not taken into account in this handbook. See also Section 1.6.2.

1.4 Environmental risk management suggestions based on ERA

The methodologies for ERsA aim at the identification of acceptable or unacceptable risks. This identification provides the basis for the regulatory decisions, which follow from the ERA. Therefore, the environmental risk management suggestions should be provide by the assessors to the risk managers to facilitate a 'scientifically-based' regulatory decision. 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 such suggestions as mitigation measures, precaution notes for labelling, etc..

1.5 General procedures of ERA for pesticide registration

1.5.1 Tiered approach:

In this hand book, the ERA for each protection goal follows a tiered approach in order to minimize the cost and to encourage environment-friendly products. Fig. 1-2 shows the tiered approach for ERA described in this handbook.

Ideally, the less hazardous a product is, the less cost it will need to pass the risk assessment. The first tier is based on model output as regards exposure and on laboratory data as regards 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).

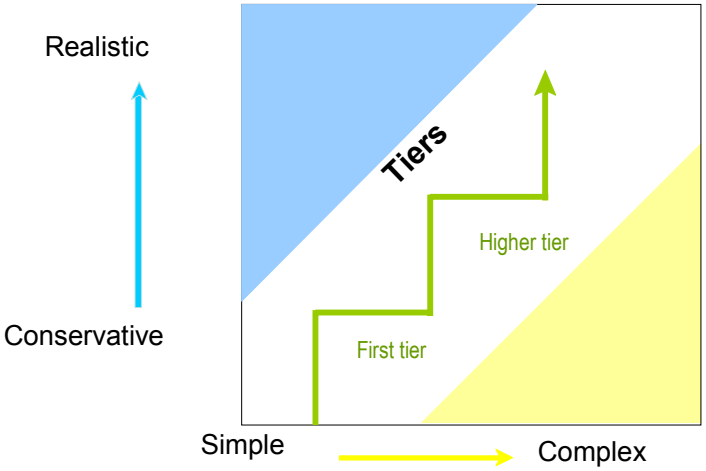


Fig. 1-2: Tiered approach for conducting ERA

1.5.2 General concept:

Following a tiered approach(Fig. 1-2), 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 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. Fig. 1-3 shows the 'criss-cross' model.

However, the 1st tier risk assessment should be considered as a standard assessment module and conducted as the first step of risk assessment for registration purpose. The approaches of 1st tier assessment are explicitly elaborated 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 behaviour and toxicity of the substance in the

environment. The uncertainty, generated from the assessment approaches, is quantified on the basis of scientific consensus and expert judgement.

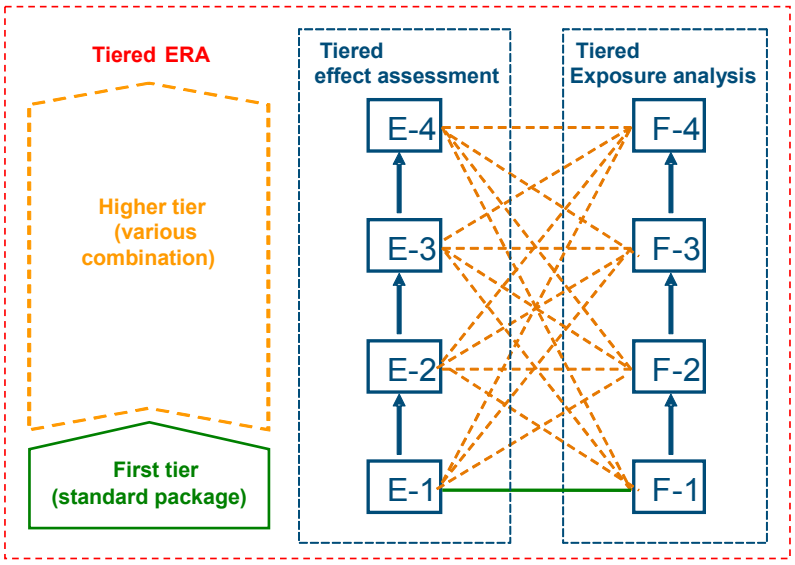


Fig. 1-3: 'criss-cross' model, allowing the flexibility in the tiered approach of ERA

1.6 Uniform structure of each chapter

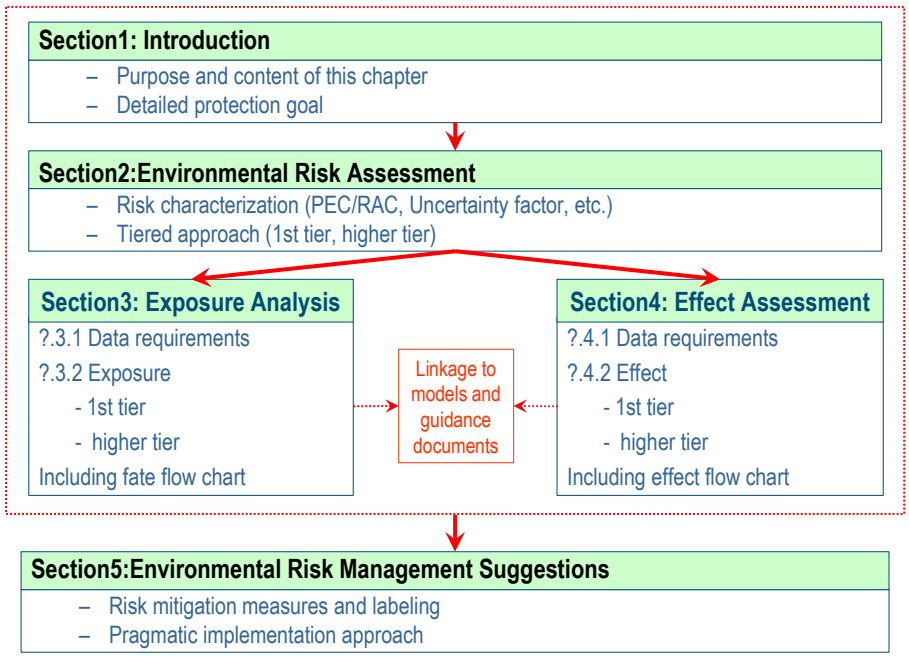


Fig. 1-4: the uniform structure of each chapter in this handbook

In order to facilitate better communication with all the interested groups, all the chapters are intended to be presented as in the uniform structure as demonstrated in the Fig. 1-4 below:Readers should notice that the uniform structure will be applied only if it is appropriate. In some special cases, the relevant chapters may be laid out in an alternative structure (e.g. chapters for silkworm and groundwater, etc.)

1.7 Future Development

1.7.1 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. For general guidelines on the evaluation of available data, please see the reference document ……4

Any supplementary study submitted by the applicant, where there is no appropriate Chinese national test guideline available for such study at present, shall be done according to the relevant internationally recognized test guidelines, e.g. OECD guidelines.

1.8 Metabolites

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

[4] awaiting discussion with Rik and Tao; proposing to have a separated working manual

2 Aquatic ecosystems

2.1 Introduction

2.1.1 Purpose and content of this chapter

This chapter is intended to give guidance on how to assess the risk from the use of pesticides to aquatic ecosystems. The assessment process described in this chapter follows the same methodology and concept of ERA as laid out in the general introduction section before. According to the general introduction, a tiered approach is set out for pragmatic purpose. This chapter is divided into the following 5 sections:

2.1 Introduction (including Detailed protection goal, 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 also applies to this chapter. For the overall process of decision making, please see also Appendix 2-1 'Decision making chart for the ERA of aquatic ecosystems'.

2.1.2 Detailed protection goals

'Aquatic ecosystems' is identified as one of the protection goals in this handbook.(see also Introduction section 1.3.1). For this protection goal, the detailed protection goals are addressed by answering the following 3 questions:

Question 1:What do we want to protect?
Answer:
Type of ecosystem that will be protected are ecosystems in the 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 waters, which can be small streams, ponds, marshland, etc., down stream of so-called 'channels'. Definition of a 'channel', so far, is a channel which is man-made; used for irrigation and/or drainage; not-permanent water body; max. 2 m wide and max. 1 m depth. [5]

Question 3: How strict do we want to protect? What are the criteria? Also relates to long term effects and short term effects
Answer:
Awaiting decision from WP5.

2.2 Environmental risk assessment (ERA)

2.2.1 Identifying the relevance of the risk to aquatic ecosystem

Section 2.2 gives guidance on the principles for decision making process of the ERA for aquatic ecosystems. Readers should notice that a preliminary phase is required upfront to identify the relevance of the risk of a pesticide to aquatic ecosystems, because it is

[5] As defined by the experts at the workshop 2007 (Workshop on ERA Criteria and Scenario Selection, Beijing), the freshwater system up to the main drainage canal should be protected from any unacceptable adverse effects (see also Introduction). The sustainability of the freshwater resources of the above aquatic ecosystem should be ensured.

reasonable to trigger the assessment only when the exposure of aquatic ecosystems to the pesticide of concern can not be excluded according to its use patterns.
If a pesticide product is to be used indoors, e.g. glasshouse, domestic premises, factories, grain stores and other enclosed structures, then the risk to non-target aquatic ecosystems is considered to be 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.

When the exposure of aquatic ecosystems can not be excluded, the exposure level in the aquatic ecosystem should be estimated. The exposure of aquatic ecosystems to pesticides depends on the loading to the surface water, In this handbook, the Predicted Environmental Concentrations (PECs) of a.i.s in the surface water are calculated for different time-windows under the relevant exposure scenarios by using certain models. The exposure scenarios are established for China based on discussion on the detailed protection goals and the vulnerability concept. For the more information on the models and associated exposure scenarios, please see 'User Manuel …….' t6

The physical and chemical properties, environmental fate data of the a.i.s and use patterns of the formulation products are of particular importance to the calculation of the PECs and to the consideration on which time window could be regarded as relevant in the risk assessment.

2.2.2 Risk characterization

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

$$RQ = \frac{PEC}{RAC}$$

Formula.2.1

PEC = Predicted Environmental Concentration

RAC = Regulatory Accepted Concentration

The risk of a particular pesticide product to all the relevant aquatic species representing different taxonomies(fish, invertebrates and algae), should be addressed by calculating RQs respectively.
Readers should notice that the risks should be characterized for different time scales as well. However, due to the unavailabilities of the chronic ecotoxicological data, the RQ for long term risk may not be calculated (see also section 2.4).[7]

2.2.3 Decision-making Scheme[8]

The following Flow chart 2.1, 2.2, 2.3 and 2.4 give step-wise guidance on the overall decision-making process of risk assessment for ecosystems. The Explanatory Notes give additional information to the flow charts. Readers could 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 Bioconcentration criterion.

2.2.3.1 Criterion based on RQ calculation

When toxicity figures and exposure estimates are put into Formula 2.1, both figures have to match with regard to time scale and have the same unit.

[6] Awaiting input from WP4.
[7] Considering the Chinese database, decision on whether taking chronic data into account or not is still not final yet. Awaiting input from WP5.
[8] Discussion with Rik and Tao requested: how to put this in the legislation?

If the RQ is smaller than 1, i.e. the exposure is lower than the safe concentration, the risk shall be considered to be acceptable.
If the RQ is bigger than 1, i.e. the exposure is higher than the safe concentration, it indicates that the risk could be unacceptable. However, higher tier risk assessment then can be triggered to refine the risk assessment so as to lower the RQ. Therefore, a tiered approach for ERA of aquatic ecosystem is described in the following section.

2.2.3.2 Bioconcentration Criterion

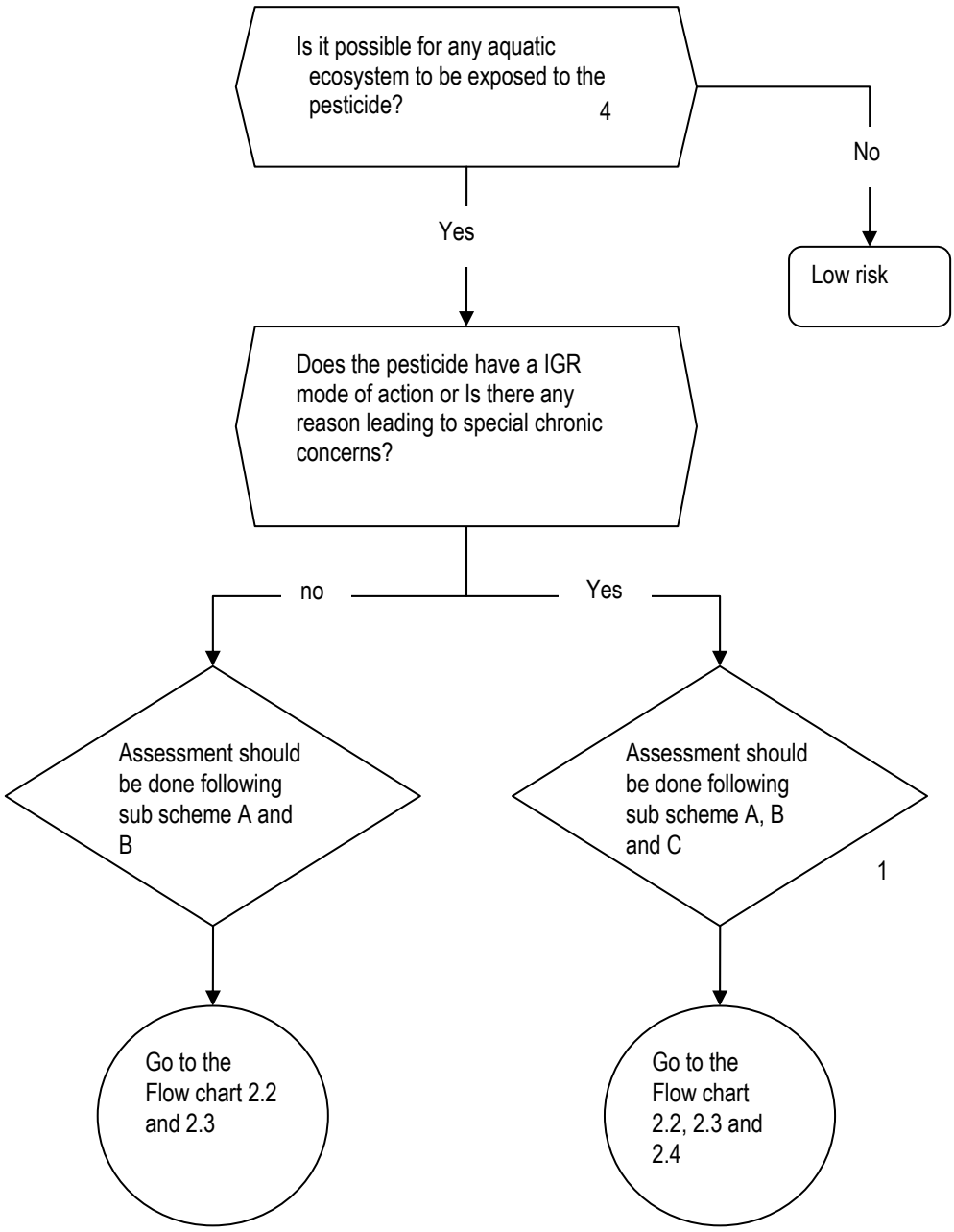
Bioconcentration effect should also be considered for the pesticide of concern.The maximum Bioconcentration Factor (BCF) of the pesticide of concern should not be greater than 100, unless there are sufficient data to justify that the pesticide of concern is readily biodegradable, where the maximum BCF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

However, higher tier risk assessment then can be triggered to refine the risk assessment so as to under field conditions no unacceptable impact on the viability of exposed species (predators) occurs - directly or indirectly - after use of the formulation product according to the proposed conditions of use

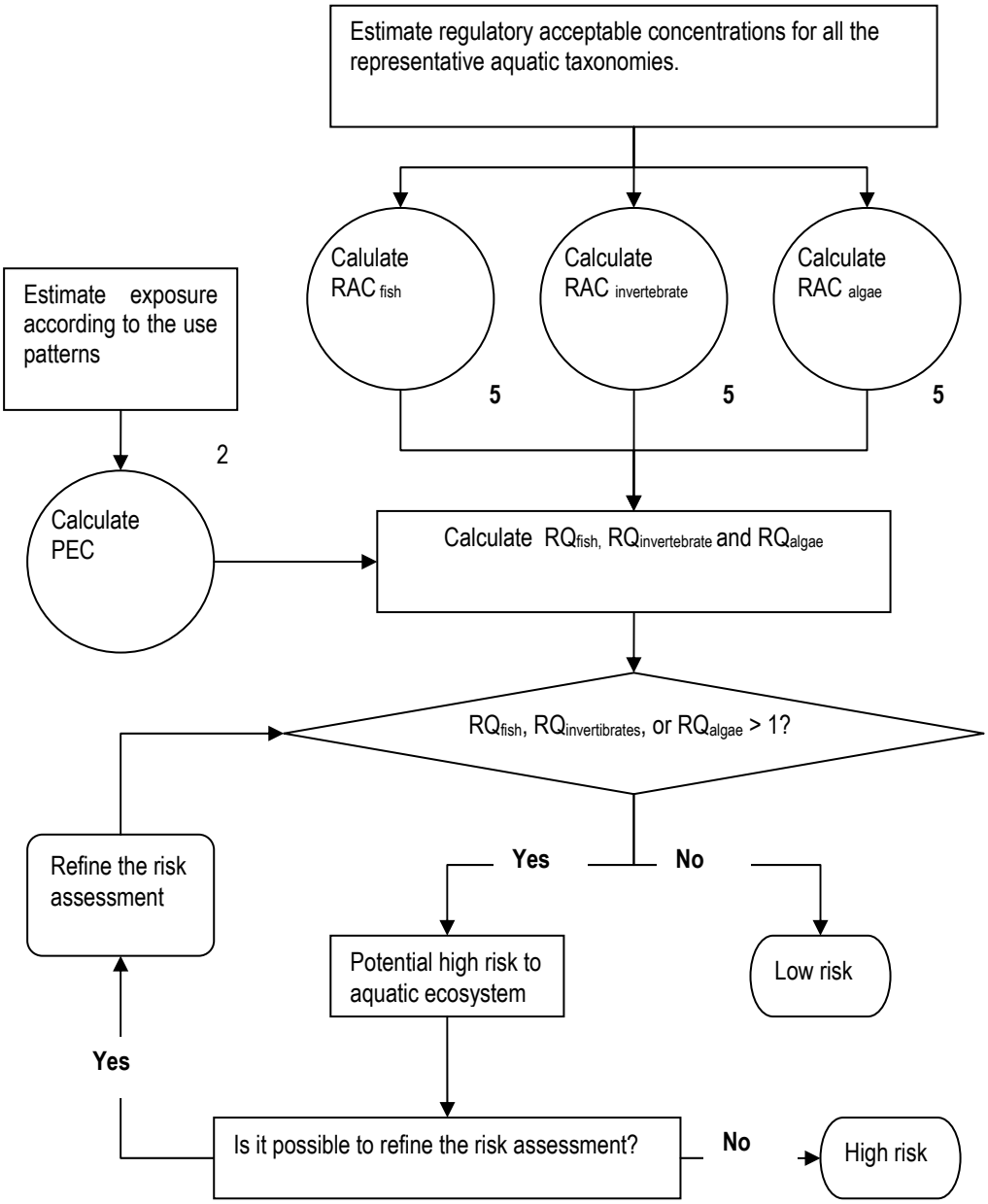
2.2.3.3 Mitigation measure

A standard risk assessment or even a higher-tier risk assessment may indicate that the risk to aquatic life may only be acceptable providing that risk mitigation measures are used (see also Section 2.5). Necessary mitigation measures and other precaution notices shall then be clearly described in the label of the pesticide products. The precaution sentences for labeling in Appendix 1-1 shall be followed, if appropriate[9]

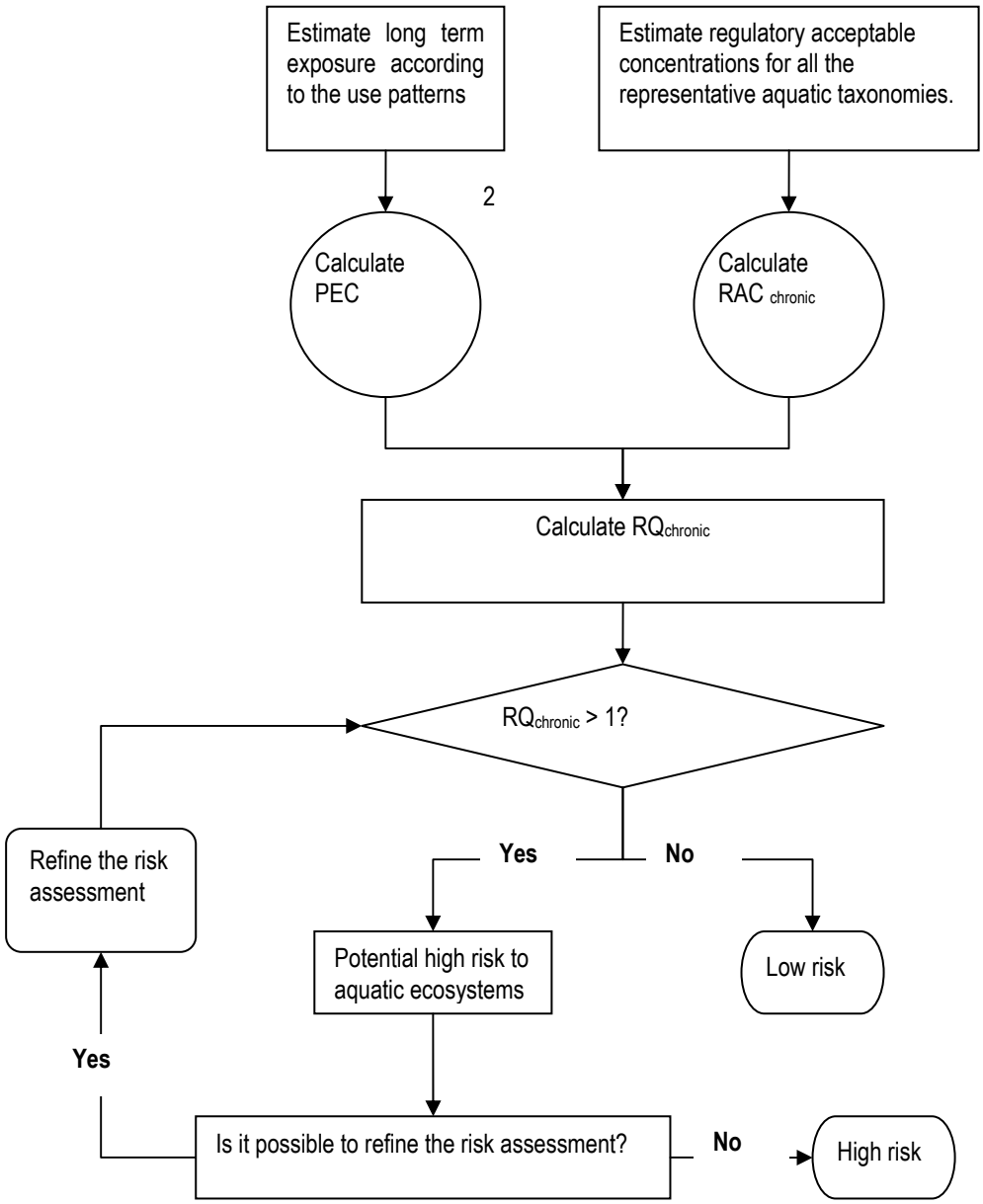
[9] (Discussion with Floor next week (*To be finalized pending the project, must be in line with Labelling regulation!!*).



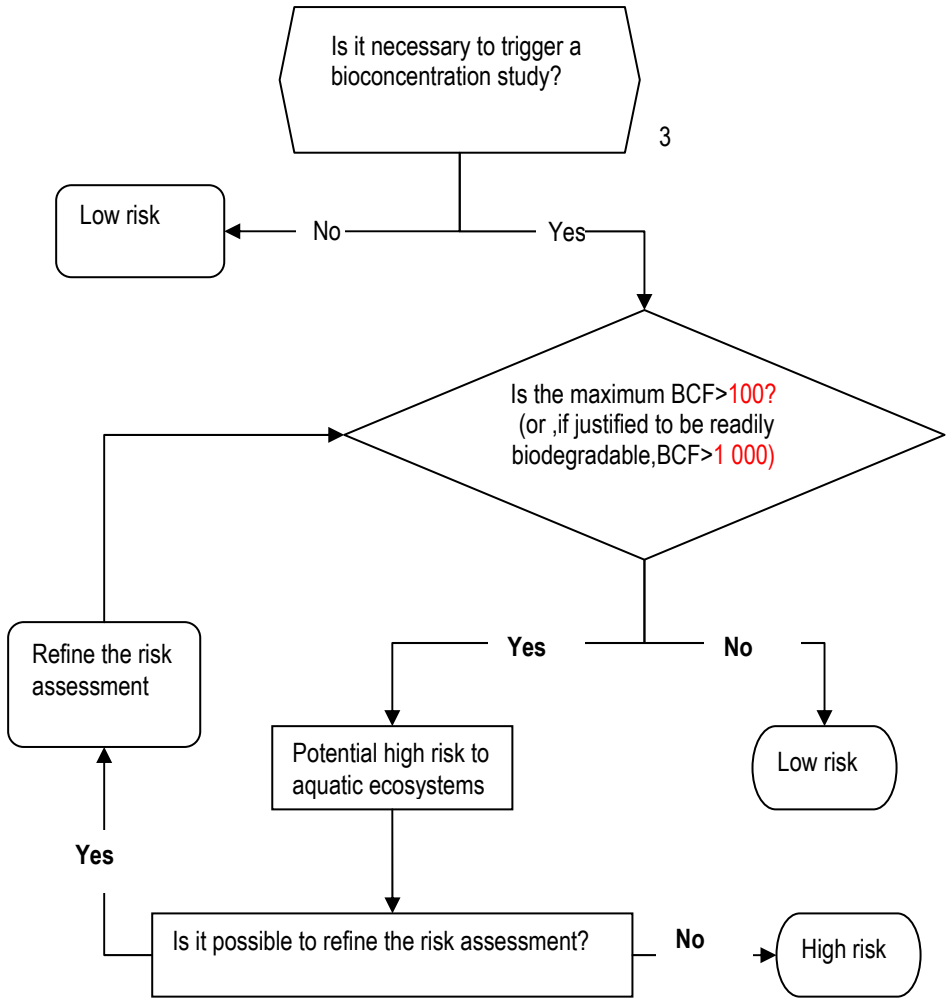
Flow chart 2.1: Decision-making scheme for aquatic ecosystems: GENERAL



Flow chart 2.2: Decision-making scheme for aquatic ecosystems: Sub-scheme A



Flow chart 2.3:Decision-making scheme for aquatic ecosystems: Sub-scheme B



Flow chart 2.4:Decision-making scheme for aquatic ecosystems: Subscheme C

Explanatory Notes for Flow chart 2.1,2.2,2.3 and2.4

1. Chronic study of the pesticide of concern is required so as to provide suffitient chronic effect data.

2. PEC is calculated for relevant exposure scenarios with adequate surface water exposure models**.** Further information on the calculation and determination of the PEC is given in Chapter 2, Section 2.3.

3. Where the logKow of a a.i. < 3, experimental research is not required.

4. For each active ingredient, information concerning toxicity to aquatic organisms must be provided, unless it can be demonstrated that it can be ruled out that the pesticide reaches surface water during agricultural use of the formulation product. For the purposes of labelling, data concerning acute toxicity of the active ingredient to algae, daphnia and fish must always be provided.

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 invertebrates and fish.

6. refer to the section of refinement measures' (Section No…..)

2.2.4 Tiered approach

2.2.1.1 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. Fig. 2-1 shows the 'criss-cross' model for the risk assessment of aquatic ecosystems.

A tiered approach shall then be followed 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 the PEC model output based on laboratory e-fate test data When the risk characterization results in a RQ bigger than 1, then a higher tier assessment could be triggered to refine the risk assessment, by refining the effect assessment and/or exposure analysis as demonstrated in the conceptual model in Fig. 2-1.

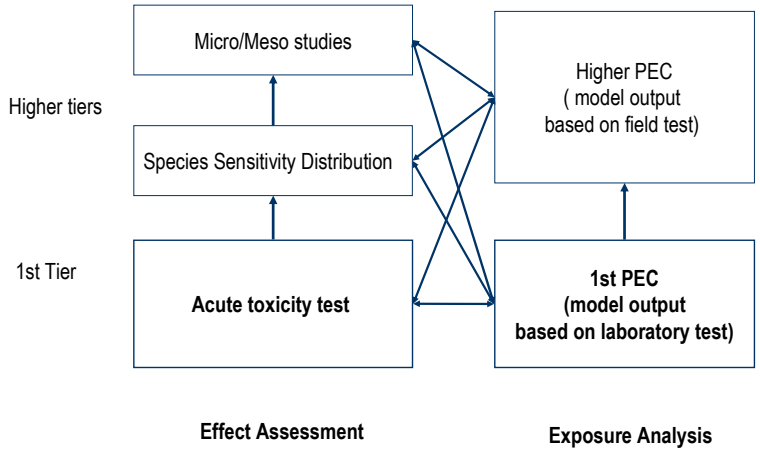


Fig. 2-1: the 'criss-cross 'model for the risk assessment of aquatic ecosystems

2.2.4.1 1st tier assessment:

The 1st tier risk assessment of aquatic ecosystems, which should be considered as a standard assessment module, is based on a combination of the 1st tier exposure analysis and 1st effect assessment (see Fig. 2-1). Table 2-1 gives recommendations on the choice of appropriate parameters for risk characterization at 1st tier

The 1st tier exposure analysis of aquatic ecosystems is based on model output data expressed as PEC, based on laboratory e-fate data submitted by the applicant according to 'Dossier Requirement for Pesticide Registration'. (see also Section 2.3)

The 1st tier effect assessment of aquatic ecosystems is based on acute toxicity data from standard species laboratory tests submitted by the applicant according to 'Dossier Requirement for Pesticide Registration '(see also Section 2.4) RAC should be calculated for all the 3 representative species (fish, invertebrate and algae).

NOTE:
The requirements for dossiers differ for different registration types, according to 'Dossier Requirement for Pesticide Registration'. Therefore, especially for the 1st tier, when the toxicity data for both a.i. and its formulation product are available, the assessor should choose the lowest toxicity value(e.g. LC_{50} for fish) for each representative species(all expressed in the concentration of a.i) .

Table 2-1: End points, PECs and Uncertainty Factors for 1st tier assessment

1st Tier[10]		
Fish	**EdP**	LC50
	PEC	PECmax
	UF	100
Arthropods	**EdP**	EC50/ LC50
	PEC	PECmax
	UF	100
Algae	**EdP**	EC50
	PEC	PECmax
	UF	10

EdP = End Point
PEC = Predicted Environmental Concentration
UF = Uncertainty Factor

2.2.4.2 Higher tier assessments:

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

Possible higher tier approaches for the effect assessment include SSD analysis (see 2.4.2.3.1), micro/mesocosm studies (see2.4.2.3.2) or field studies and any other relevant scientific measures(case by case with expert judgement).

Table 2-2 gives recommendations on the choice of appropriate data for each factor at higher tier assessments

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 judgement, if applicable.

From a scientific point of view, the acute and chronic risks should both be assessed at each tier, respectively. However, when it is justified that long tem exposure is unlikely to occur according to the use pattern of the pesticide of concern, its chronic risk can be regarded as not relevant.

However, for a pragmatic purpose, only acute toxicity should be considered for the 1st tier assessment at present (as indicated in Fig. 2-1), since the chronic toxicity data may only be supplementary data according to 'Dossier Requirement for Pesticide Registration (MOA Command No. 10, Jan 8th, 2008)'; therefore may not be available for a certain period of time. 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.

Uncertainty due to extrapolation from acute data to long term effect is considered and covered in the UF used in the 1st tier assessment.

In this handbook, Species Sensitivity Distribution(SSD) method is used as a possible refinement option for higher tier acute risk assessment. Based on the scientific research in EU, by applying an uncertainty factor to the acute HC_5, SSD also can be used to address the chronic risk with acute data. Therefore, SSD is also used in this handbook for assessing chronic risk at 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

[10] 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 effect is considered and covered in the UF used in the 1st tier assessment.

described in internationally recognized guidance documents, e.g. EU working document SANCO/3268/2001 [11]

Table 2-2: End points, PECs and Uncertainty Factors for higher-tier assessments

Higher Tier				
	SSD			Micro/Meso
	DT50≤10d & single exposure	DT50>10d or multiple exposure		
EdP	$HC5_{acute\text{-}mean}$	$HC5_{acute\text{-}mean}$	$HC5_{Chron\text{-}mean}$	NOEC /NOEAEC
PEC	PEC_{max}	PEC_{max}		PEC_{max} **
UF	1	10	1	3***, if using NOEAEC

DT50 = DT50 for the whole system from water-sediment study
EdP = End Point
PEC = Predicted Environmental Concentration
UF = Uncertainty Factor
** A PECtwa should be possible, only if the NOEC or NOEAEC is based on mean measured concentrations.
*** If the pesticide is highly persistent, a higher UF should be necessary

2.2.5 ERA for a formulation product containing more than 1 a. i.

In order to address the ERA for a formulation product containing more than 1 a.i., combination toxicity must be determined for such kind of formulation products (as well as for combinations of pesticide products of which the combination (tank mix) is recommended in the directions for use). See also Appendix 1-2 for the ERA for 'combination formulation product'.

[11] To avoid 2 decision making procedures and to make it work based on available data at present, based on the discussion with Paul, WP2 proposes not to require chronic data at the 1st tier and to use SSD method and acute data to assess chronic risk.

2.3 Exposure analysis

2.3.1 Data requirements

2.3.1.1 Introduction

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 aquatic ecosystem, including circumstances in which required, test condition, test guideline and test result for each data requirement.

Appendix 2-1 describes test conditions, guidelines and endpoints of the required studies.

2.3.1.2 Active ingredients

2.3.1.2.1 Hydrolysis as a function of pH

A. Circumstances in which required
The test must always be required.

B. Test conditions:
Test should be done for three different pH values (pH4, 7 and 9) of sterile buffer solution.

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

D. Results:
DT50 of active ingredient in buffer solution

2.3.1.2.2 Aerobic transformation in water-sediment system

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

B. Test conditions:
Test should be done for two different water-sediment systems. The test system should be aerobic condition.

C. Test guideline:
'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 308

D. Results:
DT50 of active ingredient in water-sediment system

2.3.1.2.3 Anaerobic transformation in soil (awaiting result of WP4)

A. Circumstances in which required
the test must be required when the active ingredient will be applied to paddy field.

B. Test conditions
Test should be done for three types of soil at least. The soil used in the test should be collected from paddy field. The test system should be anaerobic condition.

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

D. Results
DT50 of active ingredient in soil

2.3.1.2.4 Soil adsorption

A. Circumstances in which required
the test must always be required.

B. Test conditions
Test should be done for three types of soil at least. 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
Koc or Kom of active ingredient in soil

2.3.1.3 Formulation products

2.3.1.3.1 Field studies[12]

Where the pesticide can not pass the lower-tier risk assessment, supplementary data for field studies could be carry out so as refine the exposure analysis. However, expert judgment is required to decide if field tests could provide useful information on a case-by-case basis.

2.3.2 Tiered approach of PEC calculation[13]

2.3.2.1 Development of Scenario and PEC model in China

1. General description about the relationship between exposure analysis and scenario/PEC model for surface water
2. Give the general information about tiered approach of scenario/PEC model if it is available.

2.3.2.2 PECs (PECmax, PECtwa)

PEC_{max}: is the maximum concentration in surface water after last application.
PEC_{twa}: is time weighted average concentration in surface water at intervals of some days (e.g. 1, 7, 14, 21, 28days) after application. The intervals is never being longer test period.

2.3.2.3 1st tier

2.3.2.3.1 Exposure module 1: fish pond

1. Describe what kind of data (input) will be used in PEC model.
Input parameters: end point of E-fate study, application pattern, physic-chemical properties.
2. output of PEC model calculation

2.3.2.3.2 Exposure module 2: down-stream of 'channel'

2.3.2.3.3 Exposure module 3: paddy field]

[12] Field studies: It need discuss that whether field study can be used in exposure analysis for aquatic ecosystem, and how to use the result of field study.
[13] Tiered approach of PEC calculation: At this stage, only the general outline of this part has been written. The content of the section awaiting result from WP4.

2.3.2.4 Higher tier

Refinement of input parameters[14]

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

2.4.1.2 Active ingredients

2.4.1.2.1 Toxicity to Fish

A. Acute toxicity to fish

a) Circumstances in which required
The test should always be required

b) Test conditions:
Test should be done for one warm water species *(recommended sepecies: Brachydonio 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)[15]

c) Test guidelines:
'Chemical pesticide environment risk assessment test guideline'; or Internationally recognized guidelines, e.g. OECD 203

d) Results:
LC_{50}(mg/L)

B. Bioconcentration in fish

a) Circumstances in which required
The test should be performed where the a.i. is likely to partition into fatty tissues (such as log pow ≥ 3).

b) Test conditions:
Test should be done for one of the following species: *Cyprinus carpio*; *Brachydanio rerio, Oryzias latipes,* or *Xiphoporus helleri.*

c) Test guidelines:'

[14] Refinement of input parameters: in this stage, we don't know how to refine the input parameters of PEC model. So, the higher tier of PEC calculation will need to discuss.
[15] Based on EU experience, the cold water species are normally more sensitive than the warm water species, therefore, it should be more relevant to require for studies with cold water species as 'always required' and studies for warm water species as 'supplementary studies'. Modification of data requirements will probably be necessary by the end of PERAP project.

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

d) Results:
BCF

2.4.1.2.2 Acute toxicity to aquatic invertebrates[16]

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

B. Test conditions:
Test should be done 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)

2.4.1.2.3 Effects on algae growth[17]

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

B. Test conditions:
Test should be done 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 (mg/L), NOEC.

2.4.1.3 Formulation products:

2.4.1.3.1 Acute toxicity to fish, aquatic invertebrates or effects on algae growth
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 relevant group have to be performed, otherwise, all the three groups have to be tested.

A. Acute toxicity to fish

a) Circumstances in which required:
The test should be performed where:
- the formulation product contains more than one a.i.;

[16] Based on EU experience, an extra insect species should be tested for some pesticide because of their special application patterns, mode of actions, etc. However, the EU testing guideline for extra species is not yet finalized at present. Therefore, it would be better to wait for the EU testing guideline and then consider modification of data requirements.
[17] Based on EU experience, an extra algae species or aquatic plant species should be tested for herbicide. At this stage of ERA development in China, this extra test is not included in the data requirements. Modification of data requirements will probably be necessary by the end of PERAP project, if further discussion concludes this is necessary for herbicide ERA.

- 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. <1.0mg/L);

b) Test conditions:
Test should be done for one species: the more sensitive one, 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)

B. Acute toxicity to aquatic invertebrates

a) Circumstances in which required:
The test should be performed where:
- the formulation 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. <1.0mg/L).

b) Test conditions:
Test should be done 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)

C. Effects on algae growth

a) Circumstances in which required:
The test should be performed where:
- the formulation 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. < 0.3mg/L), or the formulation product contains more than one a.i..

b) Test conditions:
Test should be done for one species of the following three: *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

2.4.1.4.1 Circumstances in which required:

Where the pesticide can not pass the 1st -tier risk assessment, additional tests for SSD could be carried out so as to refine the ERA.

2.4.1.4.2 Test conditions:

For pesticides which are known that a specific group of organisms is particularly sensitive, then 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. (see also Section 2.4.2.3.1, point c.)

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

NOTE: *Base on the research done in EU, arthropod is the most sensitive group for insecticides, and primary producer is the most sensitive group for herbicides. For fungicides it has to be decided case by case which group is the most sensitive group; while in most of cases, there is no 'most sensitive species'.*[18]

Test could be done with the a.i. or the formulation product.

2.4.1.4.3 Test guidelines:

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

2.4.1.4.4 Results:

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

2.4.1.5 Micro/mesocosm studies

2.4.1.5.1 Circumstances in which required:

Where the pesticide can not pass the lower-tier risk assessment where lab study data are used, Micro/ mesocosm study could be carried out so as to refine the ERA.

However, expert judgment is required to decide where and how the study should be performed

2.4.1.5.2 Test conditions:

The test material should be the formulation product..

2.4.1.5.3 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.

[18] Based on the research in EU so far, the 'most sensitive' group can hardly be identified for fungicides. Therefore, in most cases (fungicide), the test species for SSD should cover all 3 groups, invertebrates, algae and vertebrates. However, readers should note the research on this topic is still going on, so the conclusion hasn't been finalized yet.

2.4.1.5.4 Results:

NOECcommunity, NOECpopulation and NOEAEC

2.4.1.6 Field study and other supplementary studies

2.4.1.6.1 Circumstances in which required:

Higher tier studies, including field studies and other supplementary studies should be carried out where the pesticide can not pass the lower-tier risk assessment

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

2.4.2 Tiered approach of RAC establishment

2.4.2.1 Uncertainty factors

As explained in 'Chapter 1' (*See also in Table 2-1, 2-2 and Terms of Reference*), 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 is the degree of uncertainty and the size of the assessment factor.
At the 1st tier assessment, the uncertainty factor of 100 is therefore in general necessary to cover the uncertainty resulting from the use of short term endpoint from the single species test in RAC establishment. However, an uncertainty factor of 10 should be used in case of algae, since the life circle of such species is comparably quite short and the toxicity endpoint is based on growth inhibition instead of immobilization or lethal effect . The recommended uncertainty factors used at 1st tier assessment are shown in Table 2-3.

NOTE:
It should be noted that the contribution of each of the different factors influencing the overall uncertainty can not easily be quantified and may differ in the field of acute and 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 to 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 can be reduced to a certain degree in RAC establishment by using higher tier data, including result from SSD, micro/mesocosm studies, etc. The recommended uncertainty factors used at higher tier assessments are shown in Table 2-4.

NOTE:
The testing of more species reduces the uncertainty of the risk assessment attributable to inter-species differences in sensitivity[19]. 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. trigger for acute risk to fish and aquatic invertebrates.

2.4.2.2 Establishment of RAC in the 1st tier

Data submitted on the toxicity for aquatic organisms (LC_{50}, EC_{50}, NOEC) form the basis for establishing a RACacute by application an uncertainty factor. End points from the following short-term ecotoxicity tests are necessary to calculate a RAC (according to formula x) for each of the aquatic organism.
- fish acute test
- daphnia acute test
- algae toxicity test

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

The most sensitive RAC of the three RACs available will be used as input RACacute for the risk assessment, as calculated according to the formula below:

$$RAC = \frac{EdP}{UF}$$

Formula 2.2

RAC = Regulatory Acceptable Concentration
EdP = Toxicity Endpoints, e.g. LC50, EC50,etc.
UF =Uncertainty Factor.

Endpoints and Uncertainty Factors for the 1st tier RAC establishment are given in Table 2-3 (also in Table 2-1)

Table 2-3: Endpoints and Uncertainty Factors for the 1st tier RAC establishment

1st Tier[20]		
Fish	**EdP**	LC50
	UF	100
Arthropods	**EdP**	EC50/ LC50
	UF	100
Algae	**EdP**	EC50
	UF	10

EdP = End Point
PEC = Predicted Environmental Concentration
UF = Uncertainty Factor

2.4.2.3 Establishment of RAC in Higher tier

At higher tier assessments, RAC can be calculated based on the results from SSD analysis, micro/mesocosm study, 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 2-4 (also in Table 2-2).

Table 2-4: End points Uncertain Factors for higher-tier assessments

Higher Tier				
	SSD			**Micro/Meso**
	DT50≤10d & single exposure	**DT50>10d or multiple exposure.**		
EdP	$HC5_{acute\text{-}mean}$	$HC5_{acute\text{-}mean}$	$HC5_{Chron\text{-}mean}$	NOEC /NOEAEC
UF	1	10	1	3***, if using NOEAEC

EdP = End Point
PEC = Predicted Environmental Concentration
UF = Uncertainty Factor
*** If the pesticide is highly persistent, a higher UF should be necessary.

2.4.2.3.1 Species Sensitivity Distribution (probabilistic method)[21]

[20] 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 effect is considered and covered in the UF used in the 1st tier assessment.

A. Methodology

Probabilistic risk assessment (PRA) is an emerging approach to ERA, although it has been applied for many years in other scientific disciplines.

In aquatic risk assessment, PRA can be applied in a variety of ways, at various levels of sophistication and complexity, covering both the effects and exposure aspects of the risk assessment. The advantages of using probabilistic approaches are:

- More of the available data are used than in a simple quotient approach;
- By determining the shape of the sensitivity distribution, uncertainty associated with the linear extrapolations associated with standard lower-tier assessments is removed;
- The generation of additional data is encouraged, because generally more data provide a better definition of the distribution and a less conservative risk assessment.

One of the most straight-forward applications of PRA 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).

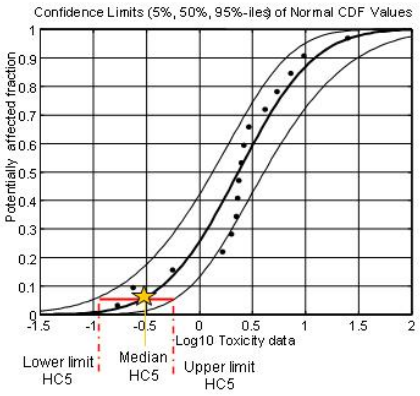


Fig. 2-2 Graphical presentation of the species sensitivity distribution curve, its 95% confidence interval, and the derivation of the lower limit and median hazardous concentration for 5% of the species (HC5).

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 as possible test species. The normally used toxicity data have been obtained from so-called 'single species lab tests'.

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 (HCp) . 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 a certain uncertainty factor, the RAC for aquatic organisms can be calculated.

B. 'Sensitive taxonomic group'

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. In general, for compounds which do not appear to be selective to aquatic organisms (i.e., all

[21] 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 with 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.

standard tests organisms respond at similar - within an order of magnitude - concentrations), it is suggested that 8 species could be used as a minimum to describe the distribution of sensitivities of aquatic organisms. Lower numbers may be appropriate for groups of organisms like fish (5 species) which show a lower variability like for example algae.(see also section 2.4.1.4 for data requirement)

However, in cases where it is known that a specific group of organisms is particularly sensitive, then the species selected for further testing should be chosen from the relevant group. For insecticides, arthropods is the most sensitive group and for herbicides, primary producers is the most sensitive group. For fungicides it has to be decided case by case which group is the most sensitive group.[22]

C. RAC 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 single application, the mean value of HC_5 (HC_{5mean}), resulted from acute toxicity data(LC_{50}/EC_{50}), should be used to estimate the RAC value. Based on the research done in EU, HC_{5mean} can provide sufficient safety margin for the protection of aquatic organisms, therefore, in this case, HC_{5mean} with an uncertainty factor of 1 is used as RAC (see also Table 2-2, 2-4).

If the pesticide tends to be persistent (i.e. DT_{50} 10 days) or the use pattern of the pesticide requires multiple application, the mean value of HC_5 (HC_{5mean}), resulted from acute toxicity data (LC_{50}/EC_{50}), could be used to estimate the RAC value with an uncertainty factor of 10. (see also Table 2-2, 2-4). When there are sufficient chronic data available from the applicant, SSD based on chronic could also be the option of ERA refinement and HC_{5mean}, based on chronic toxicity data (NOEC) can be used as RAC with an uncertainty factor of 1.

2.4.2.3.2 Mesocosm or microcosm[23]

A. Define the endpoints of the studies(to be finalized pending the following workshop):
the data from microcosm and mesocosm studies should be used to determine a number of endpoints which can then be used further in the risk assessment (e.g. to derive an RAC). For the relevant taxonomic groups in the study, a no observed effect concentration at the community level (NOECcommunity) should be derived using appropriate statistical techniques (e.g. Principal Response Curves). In addition, NOECs for populations of relevant organisms should be reported (NOECpopulation). Where there are effects at the community or population level, the time taken for recovery to occur should also be reported.

The NOECcommunity, the NOECpopulation and the time taken 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). No long-lasting effects are defined as those effects on individuals that have no or only transient effects on populations and communities and are considered of minor ecological relevance (e.g., effects that are not shown to have long-term effects on population growth, taking into account the life-history characteristics of the organisms concerned). Different recovery rates may therefore be acceptable for different types of organisms. The NOEAEC can therefore be higher than the NOECcommunity or NOECpopulation. Thus, if at a single test concentration effects were determined but

[22] Based on the research in EU so far, the 'most sensitive' group can hardly be identified for fungicide. Therefore, in most cases (fungicide), the test species for SSD should cover all 3 groups, invertebrates, primary producers and vertebrates. However, readers should note the research on this topic is still going, so the conclusion hasn't been finalized yet.

[23] It could be very difficult to evaluate and summarize a higher tier study, in particular micro/mesocosm study, in a consistent way. Therefore, based on EU experience, establishing a separate manual for evaluating and summarizing such study is recommended. The proposal has been raised by WP2, awaiting WP1's conclusion.

recovery occurs and the effect is considered of no concern for the ecosystem sustainability, that concentration should be used as NOEAEC. Different NOEAECs may be derived from a study depending on the protection aim (e.g. in-crop versus off-crop area).

B. Use the data:

As an intermediate test, indoor semi-realistic microcosms may serve to highlight issues which need to be addressed in a future outdoor mesocosm test. Due to the generally smaller species diversity in indoor microcosms, pesticide-stress may lead to more or less exaggerated indirect effects, since in these less complex systems not all feedback mechanisms will take place that may dampen pesticide-stress in the field. In addition, more pronounced responses of sensitive populations may occur in indoor microcosm tests due to a slower dissipation of the pesticide from the water phase (eg, because of less-pronounced photodegradation) and the lower potential for natural recolonisation of eliminated populations. Nevertheless, indoor semi-realistic microcosm tests may be used to define an overall ecosystem effect level. There is, however, a need to define a NOEAEC and the subsequent RAC using expert judgement, as is the case for field studies.

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 RAC. 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.

2.4.2.3.3 Field study and other supplementary data

SSD method and micro/mesocosm studies are included in the concept model of ERA for aquatic organisms, and submission of those 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.

2.5 Environmental Risk management suggestions24

2.5.1 Risk mitigation measures and labeling

When ERA for a certain pesticide indicates that the risk to aquatic ecosystem 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 measure 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.

2.5.2 Pragmatic Implementation approaches

At this stage of ERA development in China, pragmatic aspects in terms of implementation of the tiered ERA approaches (See also section 2.2)should also be taken into consideration by the risk managers.

In the case of ERA for aquatic ecosystem, different 1st tier RQs, e.g. 1000, 10, and 1.5 may indicate different levels of concerns. Therefore, for the implementation purpose, different 1st tier RQs could result in different management decisions. Table 2-5 gives suggestions on management decisions that may be practically feasible, regarding different RQs generated from ERA.[25]

Table 2-5 Management decision with different 1st tier RQs

1st RQ	Management decision	
	Risk acceptability	Implementation approaches
RQ < 1	Acceptable	Authorization
1≤RQ<100	unacceptable, but might be refined	Provisional authorization, higher tier data are required at registration renewal.
RQ≥100	unacceptable	No authorization,

[24] This section is not finalized. Based on the comments from Harold and Peter and discussion within WP2, the conclusion is to keep the scientific assessing part separated from the 'final decision making' part, because the latter should be an integrated decisions based on both political considerations and the results from risk assessment for all the protection goals.Relevant text will be provided by WP5.

[25] WP2 proposes to use a 'management safety factor' (e.g. 100) to screen the real 'worst' pesticide, and apply certain management measures. Comments from Harold, Tao and Rik are highly appreciated.

Appendix 1-1 Specific safety precautions for Labeling

1: To protect groundwater/soil organisms do not apply this or any other product containing (identify a.i. or class of substances, as appropriate) more than (time period or frequency to be specified).

The phrase shall be assigned to plant-protection products for which an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures are necessary to avoid accumulation in soil, effects on earthworms or other soil-dwelling organisms or soil microflora and/or contamination of groundwater.

2: To protect groundwater/effects on aquatic ecosystems do not apply to (soil type or situation to be specified) soils.

The phrase may be assigned as a risk-mitigation measure to avoid any potential contamination of groundwater or surface water under vulnerable conditions (e.g. associated to soil type, topography or for drained soils), if an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures are necessary to avoid unacceptable effects.

3: To protect aquatic ecosystems/non-target plants/non-target arthropods/insects respect an unsprayed buffer zone of (distance to be specified) to non-agricultural land/surface water bodies.

The phrase shall be assigned to protect non-target plants, non-target arthropods and/or aquatic organisms, if an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures are necessary to avoid unacceptable effects.

4: To protect aquatic organisms/non-target plants do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks and other situations with a high risk of run-off.

Depending on the use pattern of the plant-protection product, Member States may assign the phrase to mitigate the risk of run-off in order to protect aquatic organisms or non-target plants.

5: To protect birds/wild mammals the formulation product must be entirely incorporated in the soil; ensure that the formulation product is also fully incorporated at the end of rows.

The phrase shall be assigned to plant-protection products, such as granules or pellets, which must be incorporated to protect birds or wild mammals.

6: To protect birds/wild mammals remove spillages. The phrase shall be assigned to plant-protection products, such as granules or pellets, to avoid uptake by birds or wild mammals.

It is recommended for all solid formulation products, which are used undiluted.

7: Do not apply during bird breeding period.

The phrase shall be assigned when an evaluation according to the uniform principles shows that for one or more of the labelled uses such a mitigation measure is necessary.

8: Dangerous to bees/To protect bees and pollinating insects do not apply to crop plants when in flower/Do not use where bees are actively foraging/ Remove or cover beehives

during application and for (state time) after treatment/Do not apply when flowering weeds are present/Remove weeds before flowering/Do not apply before (state time)

The phrase shall be assigned to plant-protection products for which an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures must be applied to protect bees or other pollinating insects. Depending on the use pattern of the plant-protection product, and other relevant national regulatory provisions, Member States may select the appropriate phrasing to mitigate the risk to bees and other pollinating insects and their brood.

For rodenticides

1: The baits must be securely deposited in a way so as to minimise the risk of consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents.
To ensure compliance of operators the phrase should appear prominently on the label, so that misuse is excluded as far as possible.

2: Treatment area must be marked during the treatment period. The danger frombeing poisoned (primary or secondary) by the anticoagulant and the antidote against it should be mentioned.
The phrase should appear prominently on the label, so that accidental poisoning is excluded as far as possible.

3: Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips.
To avoid secondary poisoning of animals the phrase shall be assigned to all rodenticides containing anticoagulants as a.i.s.

Reference

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2. Kwok, K.W.H., K.M.Y. Leung, V.K.H. Chu, P.K.S. Lam, D. Morritt, L. Maltby, T.C.M. Brock, P.J. Van den Brink, M.St.J. Warne and M. Crane. (2007). Comparison of tropical and temperate freshwater species sensitivities to chemicals: implications for deriving safe extrapolation factors. Integrated Environmental Assessment and Management 3: 49-67.
3. Van den Brink, P.J., N. Blake, T. C.M. Brock and L. Maltby (2006). Predictive value of Species Sensitivity Distributions for effects of herbicides in freshwater ecosystems. Journal of Human and Ecological Risk Assessment 12: 645-674.
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5. Chemical pesticide environment risk assessment test guideline, (draft, 2008)
6. Dossier Requirements for Pesticide Registration, Minister of Agriculture, China, 2008.
7. Regulation for Pesticide Administration, State Concil Command No. 216, issued in May 8th, 1999, revised in Nov. 29th, 2001
8. Implement of Regulation for Pesticide Administration, MOA Command No. 20, Jul 23rd, 1999
9. Dossier Requirement for Pesticide Registration, MOA Command No. 10, Jan 8th, 2008

Environmental quality standards for surface water, *GB 3838-2002*

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 done** for three pH value of buffer solution.	**-**	'Chemical pesticide environment risk assessment test guideline'; or internationally recognized guidelines, e.g. OECD 111	DT50 a.i. in each pH value of buffer solution
Aerobic transformation in water-sediment system	The test **should be done** 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	DT50 a.i. in water-sediment system (total system)
Anaerobic transformation in soil	The test **should be done** 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	DT50 a.i. in soil
Soil adsorption	The test **should be done** 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 formulation products	Test Guideline	End point/ Test results
Acute toxicity to Fish	**Test should be done** for one warm water species *(recommended sepecies: Brachydonio 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 ai <1.0mg/L) -Or the formulation product contains more than one a.i.. **Test should be done** for one species: the most sensitive one, concluded from the ai acute tests;	'Chemical pesticide environment risk assessment test guideline'; or Internationally recognized guidelines, e.g. OECD 203	LC_{50} mg/L
Bioconcentration	**Test should be done** for one of the following species: 1 *Cyprinus carpio*; 2 *Brachydanio rerio* 3 *Oryzias latipes* 4 *Xiphoporus helleri*	(not required for formulation 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 ai <1.0mg/L) - Or the formulation 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	Required where	'Chemical pesticide	EC_{50}

	three: species *1. Chlorella vulgaris;* *2. Scenedesmus obliquus;* *3.Seonastrum capricornutum*	-the a.i. is highly toxic to Algae (EC_{50} from acute test of the ai < 0.3mg/L) -Or the formulation 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*	environment risk assessment test guideline'e; or Internationally recognized guidelines, e.g. OECD 201	(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 *Macrobrachium nipponense* and *Eriocheir sinensi,* respectively..	(not required for formulation 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.				

Appendix 2-3: Insect growth regulator (to be developed)

1. **IGR is a special group of pesticide, which may have adverse effect on non-target aquatic crustaceans, in particular on ecdysis process.**

Therefore, submitted data for the registration of a.i. with function of IGR, should provide enough information to assess its risk to aquatic organisms. As stated in 'Dossier Requirement for Pesticide Registration', besides data requirements listed in Chapter 2, applicant should provide the following data concerning toxicity to aquatic crustaceans:

Effects on shrimps and crab

Circumstances in which required

The test is required for those a.i.s which function as insect growth regulators.

Test conditions:

Test should be done for one species of shrimp and one species of crab. The recommended species are *Macrobrachium nipponense* and *Eriocheir sinensi*, respectively.

Test guidelines:

'Chemical pesticide environment risk assessment test guideline'; or Internationally recognized guidelines

Results:

LC_{50} (mg/L).

2. Risk assessment

What we are aware of at present:

a. long term effect is crucial in ERA of IGR.

b. Toxicity data for Shrimp and Crab are required for IGR at present, which might not be of high relevance, because they are acute data in most cases.

3 Bird

3.1 Introduction:

3.1.1 Purpose and content of this chapter

This chapter is intended to give guidance on how to assess the risk of the use of pesticide to birds. The assessment process described in this chapter follows the same methodology and concept of ERA which are laid out in general introduction in Chapter 1. According to the general introduction, a tiered approach is set out for pragmatic purposes.

This chapter is divided into the following 5 sections:

2.1 Introduction (including detailed protection goal, etc.);
2.2 Environmental risk assessment;
2.3 Exposure analysis;
2.4 Effect assessment.
2.5 Environmental risk management suggestions.

The uniform structure described in the general introduction applies in this chapter with some change to several sections which relate to exposure analysis. This is mostly 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 respectively under all the relevant Exposure Routes, which are identified and established carefully, 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.(see also Introduction section 3.1). For this protection goal, the detailed protection goals are addressed by answering to the following 3 questions:

Question 1:What do we want to protect?

Answer:

The greatest concern is effects at the population level. However, there is also strong public concern regarding the deaths of individual birds from the use of pesticide products although they may not have any significant effect on the population. Partly for that reason, and because of the lack of agreed criteria for the acceptability of effects at the population level, only the risk to non-target individual bird is discussed in this handbook.

Question 2: Where do we want to protect?

Answer:

The treated crop field which non-target birds frequent, i.e. No consideration is made of the risk at the landscape scale.

Question 3: How strict do we want to protect? What are the criteria?

Answer:[26]

In determining the level of risk to birds, the following time scales are considered[27]:

[26] awaiting decision from WP5. no effect(mortality and/or chronic effect) on individual?

[27] see: *Environmental risk assessment scheme for plant protection products*, Chapter 11: Terrestrial vertebrates EPPO, 2002

•acute: minutes to hours, representing gorging behaviour, diurnal peaks in feeding (e.g. dawn and dusk) and products which depurate or dissipate very rapidly.
•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.
No observed effect to any individual bird is accepted at each time scale.

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 decision making process of the ERA for birds. Readers should notice that a preliminary phase is required upfront to identify the relevance of the risk of a pesticide to birds, because it is reasonable to trigger the assessment only when the exposure of birds to the pesticide of concern can not be excluded according to its use patterns.

If a pesticide product is to be used indoors, e.g. glasshouse, domestic premises, factories, grain stores and other enclosed structures, then the risk to non-target birds is considered to be 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.

When the exposure of birds can not be excluded, the formulation types and use patterns of a pesticide are of particular importance to the consideration of which exposure routes could be regarded as relevant, and such consideration hence would have great influences on the estimation of exposure dose.

There're 4 representative exposure routes which are identified and defined in this handbook(see section 3.2.1.2). Readers should notice that some potential exposure routes are not included in the handbook based on the consideration on the scope of the risk assessment.

3.2.1.1 Consideration on the 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 the product itself including exposure via treated or contaminated food, .The dietary exposure could come from direct consumption of product or of treated food, and consumption of food that, although not directly treated, contains the active ingrediences (e.g.bioaccumulation in fish). However, only direct consumption of product or of treated food is considered in this handbook for pragmatic purposes, because the data regarding the exposure from 'non-directly-treated food' are often not available, while at the same time, the potential risks due to such exposure are generally low based on EU experiences.[28]
Exposure via non-dietary routes, e.g. dermal exposure and inhalation, is not considered because there is no generally accepted approach to 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.

3.2.1.2 Representative Exposure Routes

4 representative Exposure Routes are defined in this handbook as following. Risks should be characterized under each relevant Exposure Route, if applicable[29]:

[28] Based on discussion with Ctgb.
[29] Based on EU experience, exposure via drinking water is known as raising no concern except in very rare cases and hence not considered at this moment. Dermal and inhalation exposures are in development world wide; no internationally accepted assessing method is available at present

Exposure Route 1: Exposure to sprayed crops/plants/(insects)
In case of spray application, intake via contaminated feed is generally considered to be the most important exposure route.

Exposure Route 2: Exposure to granules
In case of granule formulation products, grit consumption by farmland birds is an important constituent of dietary intake for both mineral content and mastication. 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. A method for assessing the potential risk for the two major routes, ingestion of granules when seeking grit and ingestion of soil when seeking food, is presented in this handbook

Exposure Route 3:, Exposure to treated seed
In case of application as treated seed, intake via contaminated feed is generally considered to be the most important exposure route.

Expousre Route4: Exposure to rodenticides
In some cases, where a use of rodenticides may result in exposure of non-target birds or mammals. In these cases, the potential risk of secondary poisoning should be considered (see section 3.3.5 also).

3.2.2 Risk characterization

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

$$RQ = \frac{ETE}{EdP/UF} \qquad \text{Formula.3.1}$$

RQ = Risk Quotient

ETE = Estimated Theoretical Exposure, which are calculated under each Exposure Route, if applicable(see detailed calculations in section 3.3).

UF = Uncertainty factor;(see section 3.4)

EdP = ToxicityEndponts, e.g. LC50,LD50 or NOEL (see section 3.4).

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

3.2.3 Decision-making Scheme

The following Flow chart 3.1, 3.2, 3.3 and 3-4 to 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 flow charts. Readers could 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 figures and exposure estimates are put into the formula, both figures have to match with regard to time scale and have the same unit, either daily dose or concentration. If the RQ is smaller than 1, the risk shall be considered to be acceptable.

If the RQ is bigger than 1, it indicates that the risk could be unacceptable. However, higher tier risk assessment then can be triggered to refine the risk assessment so as to lower the RQ. Therefore, a tiered approach for ERA of birds is described in the following section

3.2.3.2 One-seed /granule criterion[30]

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. Where birds are exposed and the amount of active ingredient in 1 granule/seed /LD50 (target species)) >1, no authorization may be granted unless the risk to birds can be removed by mitigation measures.

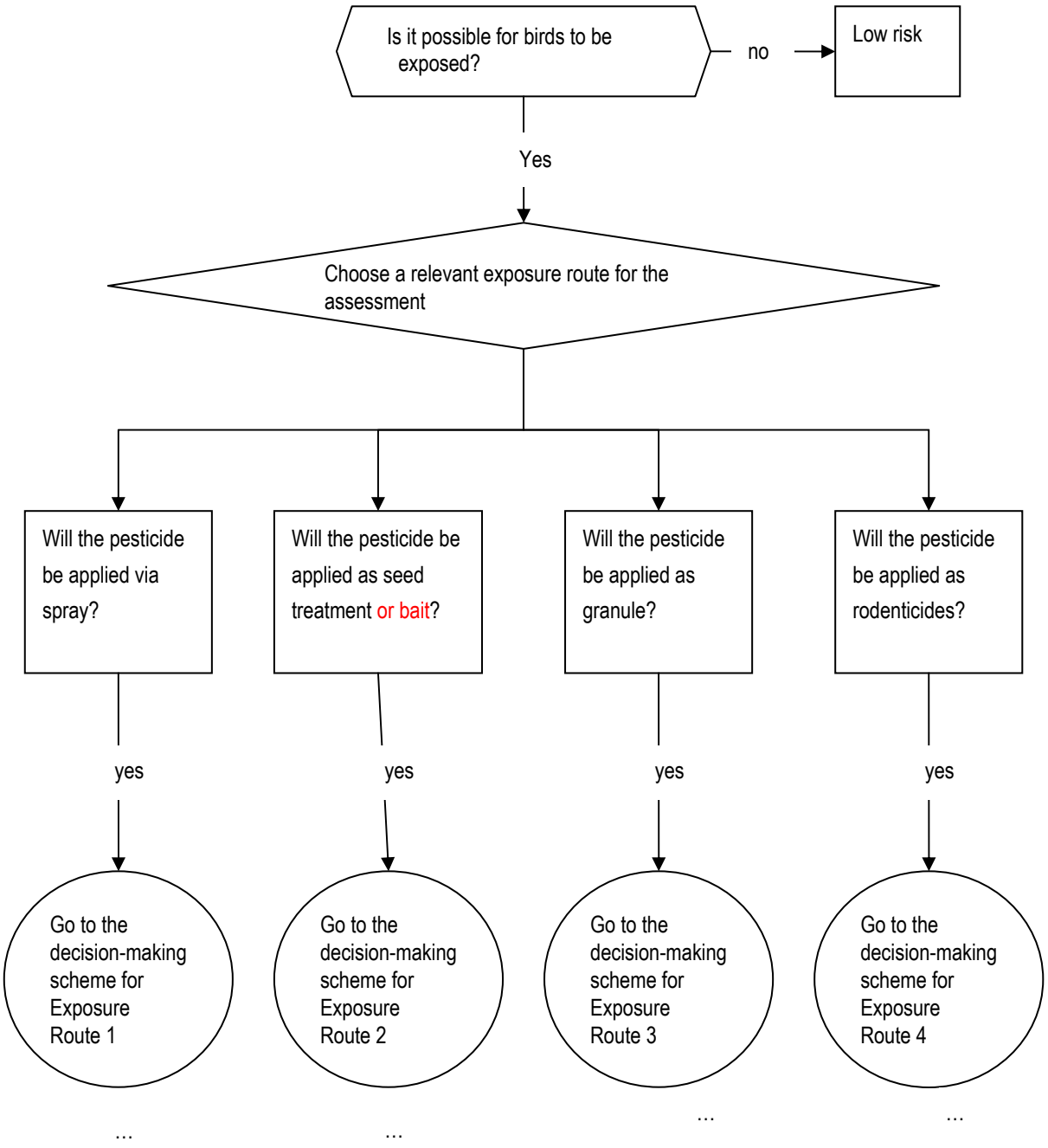
For birds, a differentiation is made between small birds (seeds like maize, peas or beans are rarely swallowed whole by small birds) and larger birds. The body weight of a small bird is assumed to be 25 g, whereas that of a larger bird is taken to be 300 g. No differentiation between species is made for the accidental or intentional consumption of granules. Because the end-point of the toxicity test (LD50) 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 detailed calculation please see section 3.3.

3.2.3.3 Mitigation measure

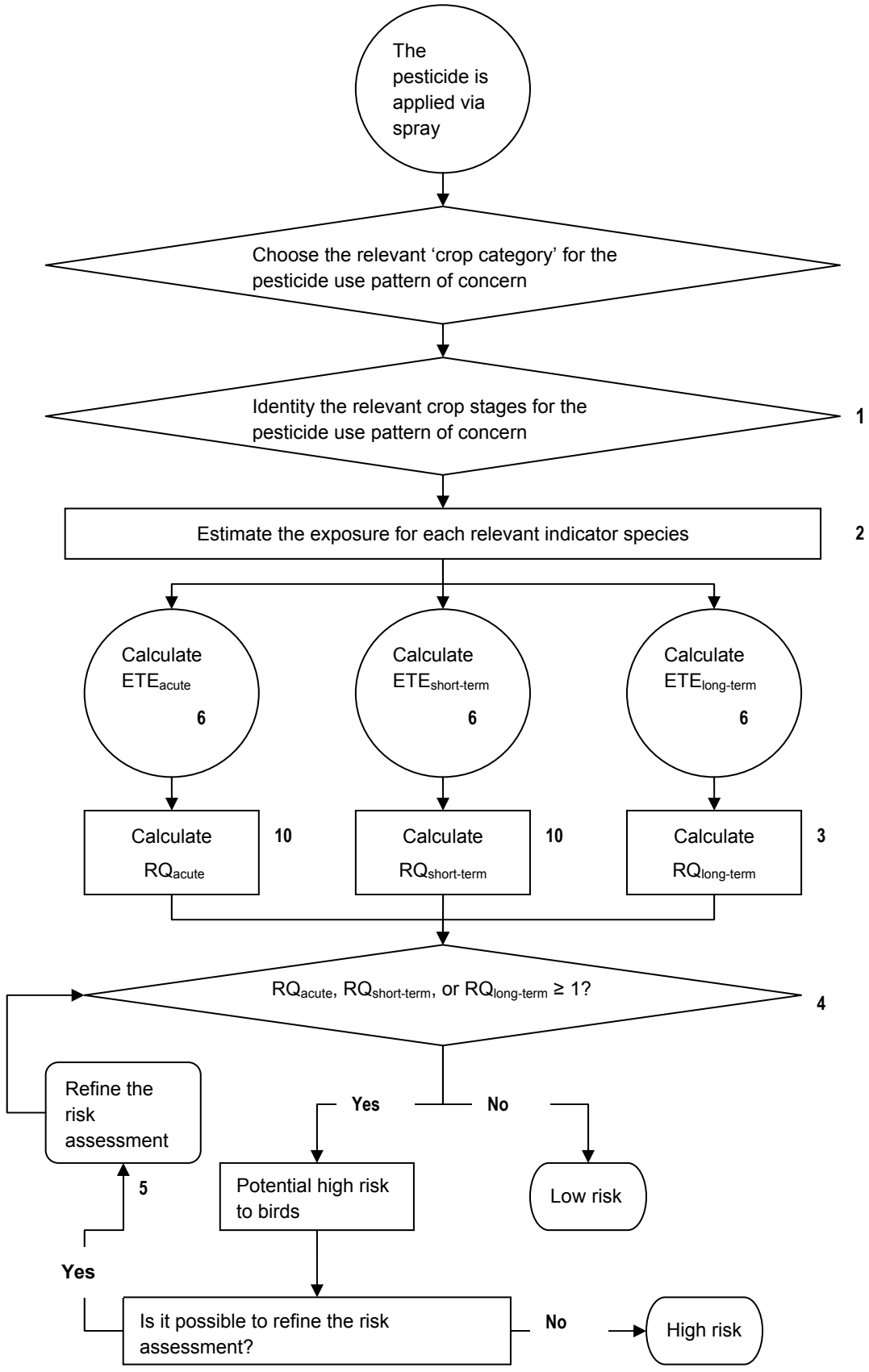
A standard risk assessment or even a higher-tier risk assessment may indicate that the risk to birds may only be acceptable providing that risk mitigation measures are used (see also Section 3.5). Necessary mitigation measures and other precaution notices shall then be clearly described in the label of the pesticide products. The precaution sentences for labeling in Appendix 1-1 shall be followed, if appropriate[31]

[30] To be discussed with WP5

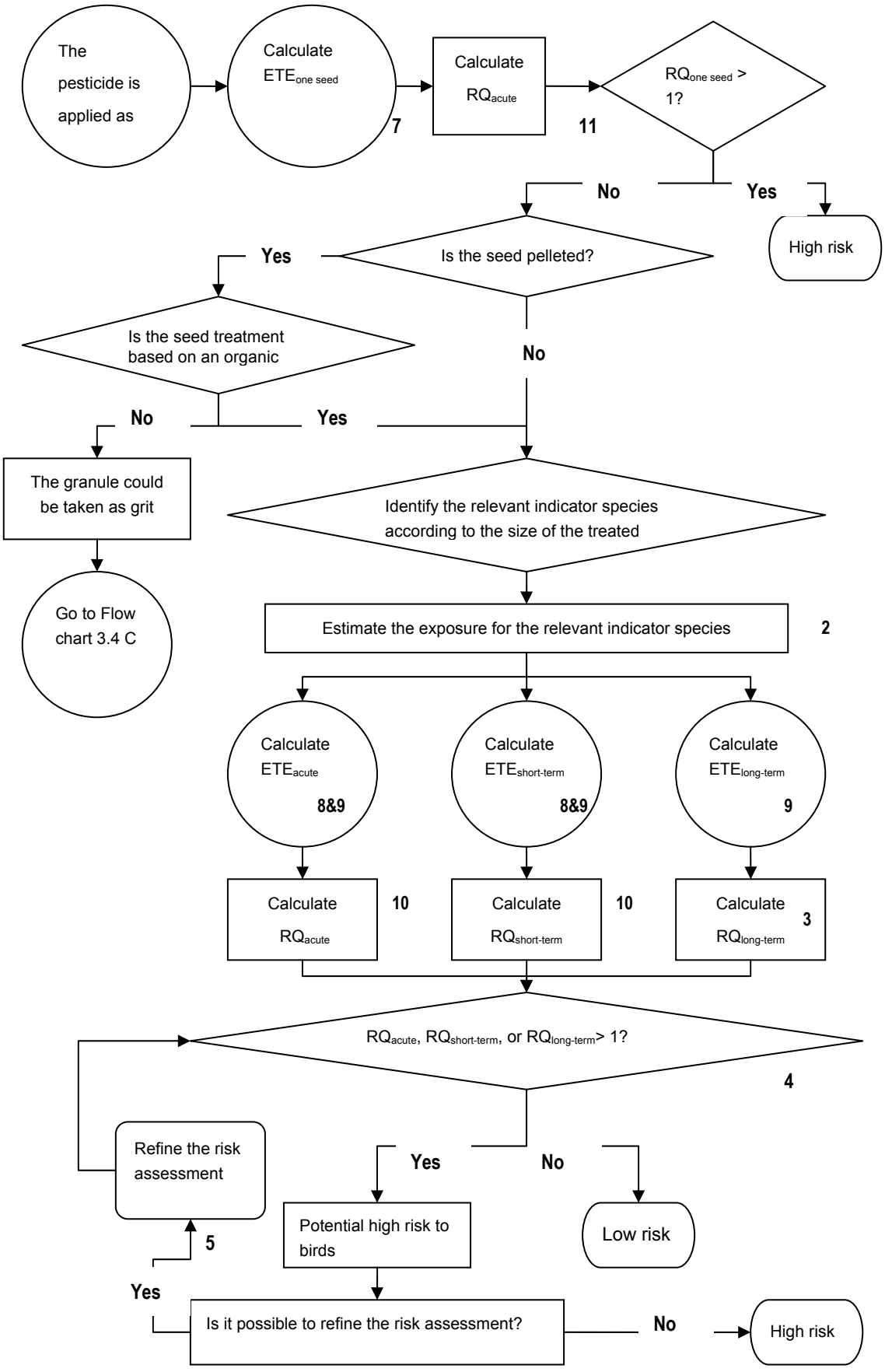
[31] *To be finalized pending the project, must be in line with Labelling regulation!!*).



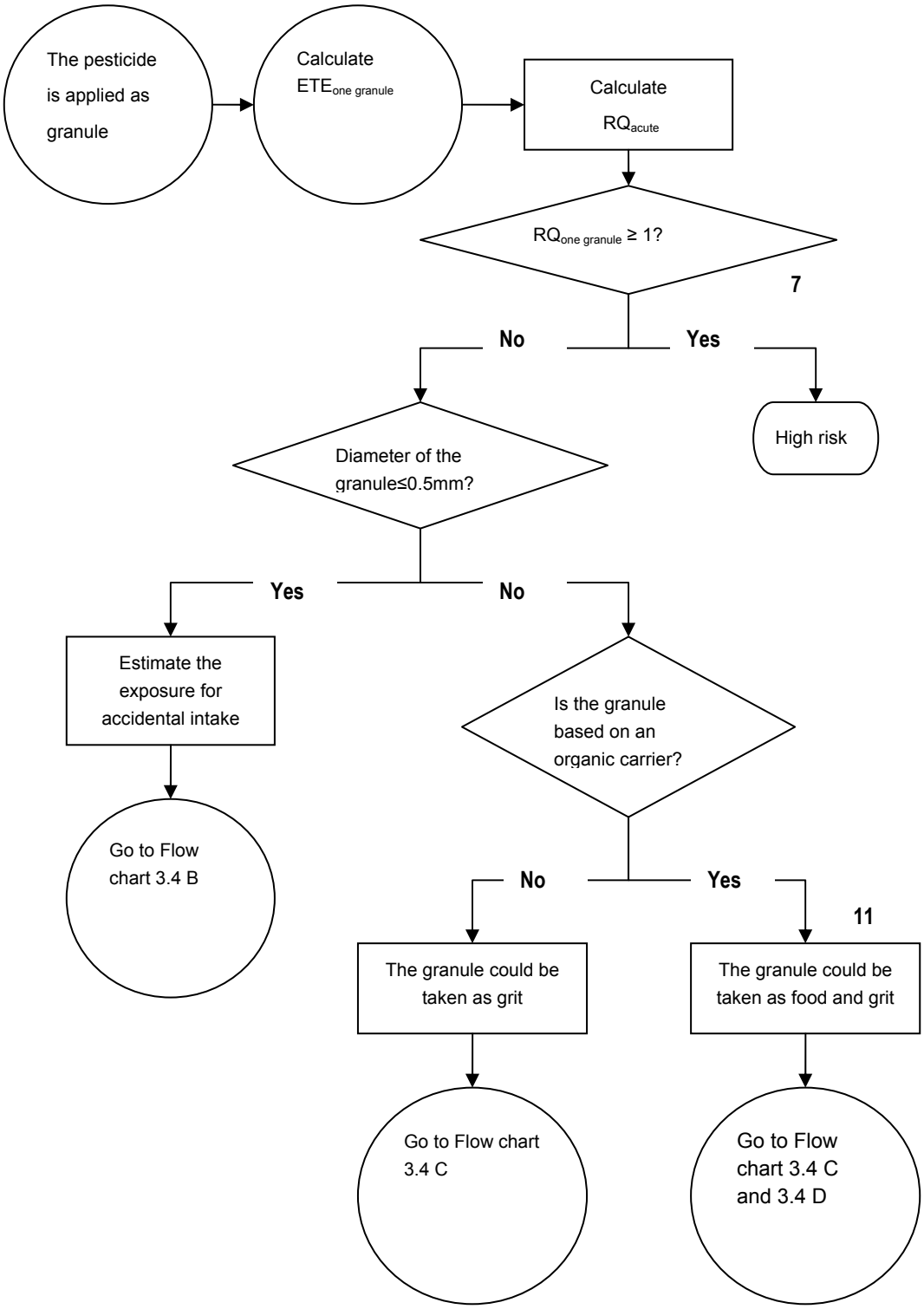
Flow chart 3.1:Decision-making scheme for ERA of birds - GENERAL



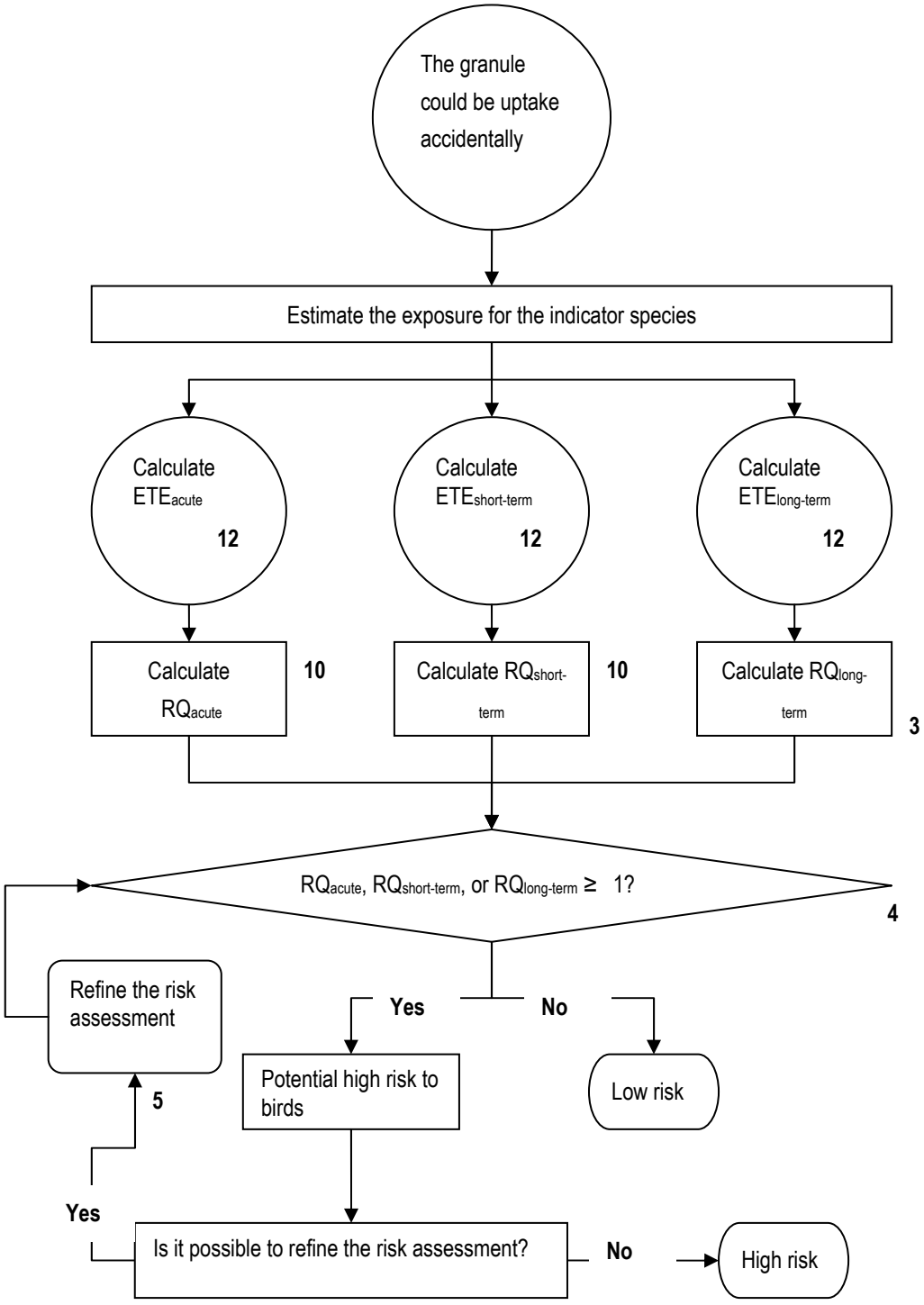
Flow chart 3.2:Decision-making scheme for ERA of birds - Exposure Route 1



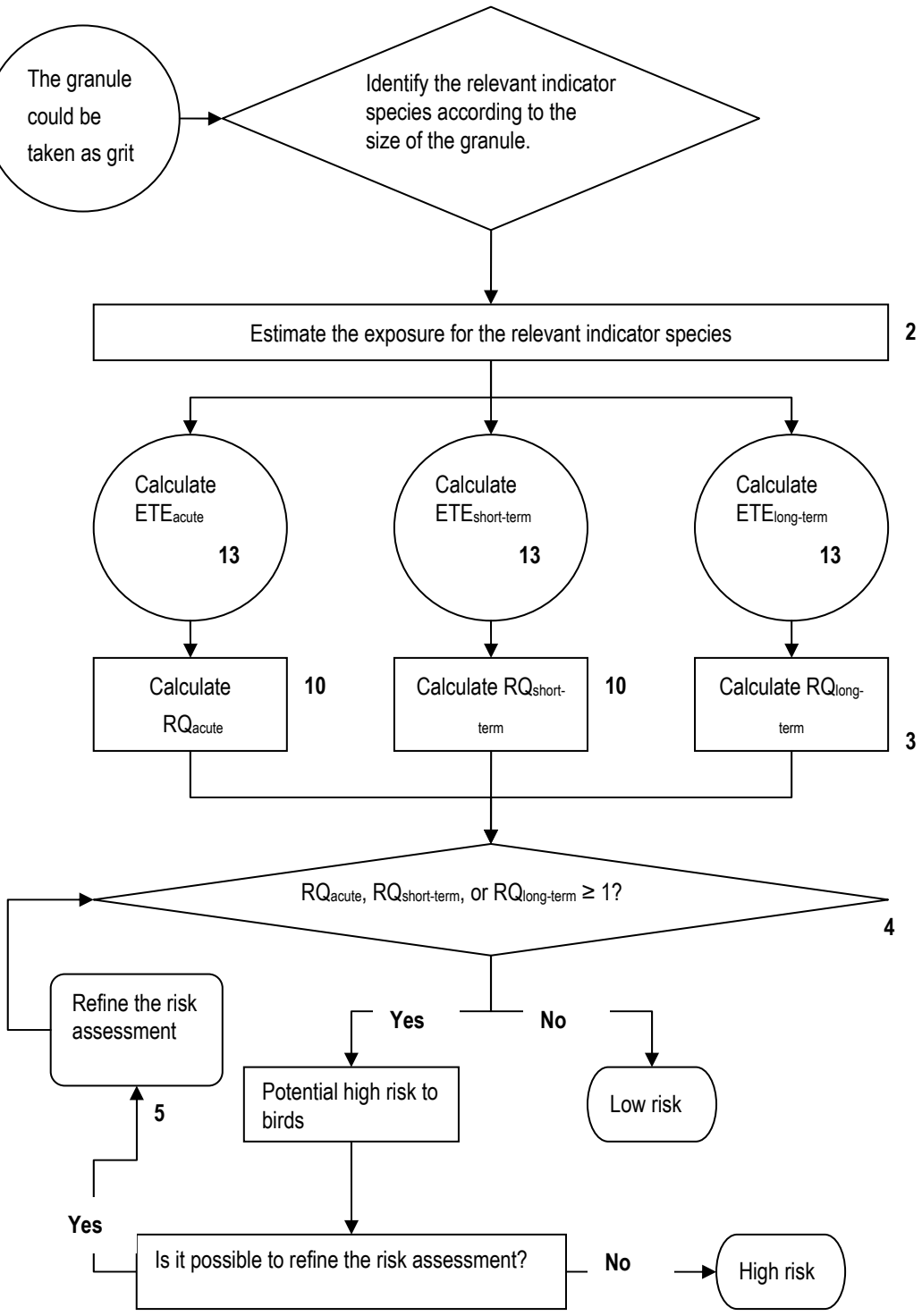
Flow chart 3.3:Decision-making scheme for ERA of birds - Exposure Route 2



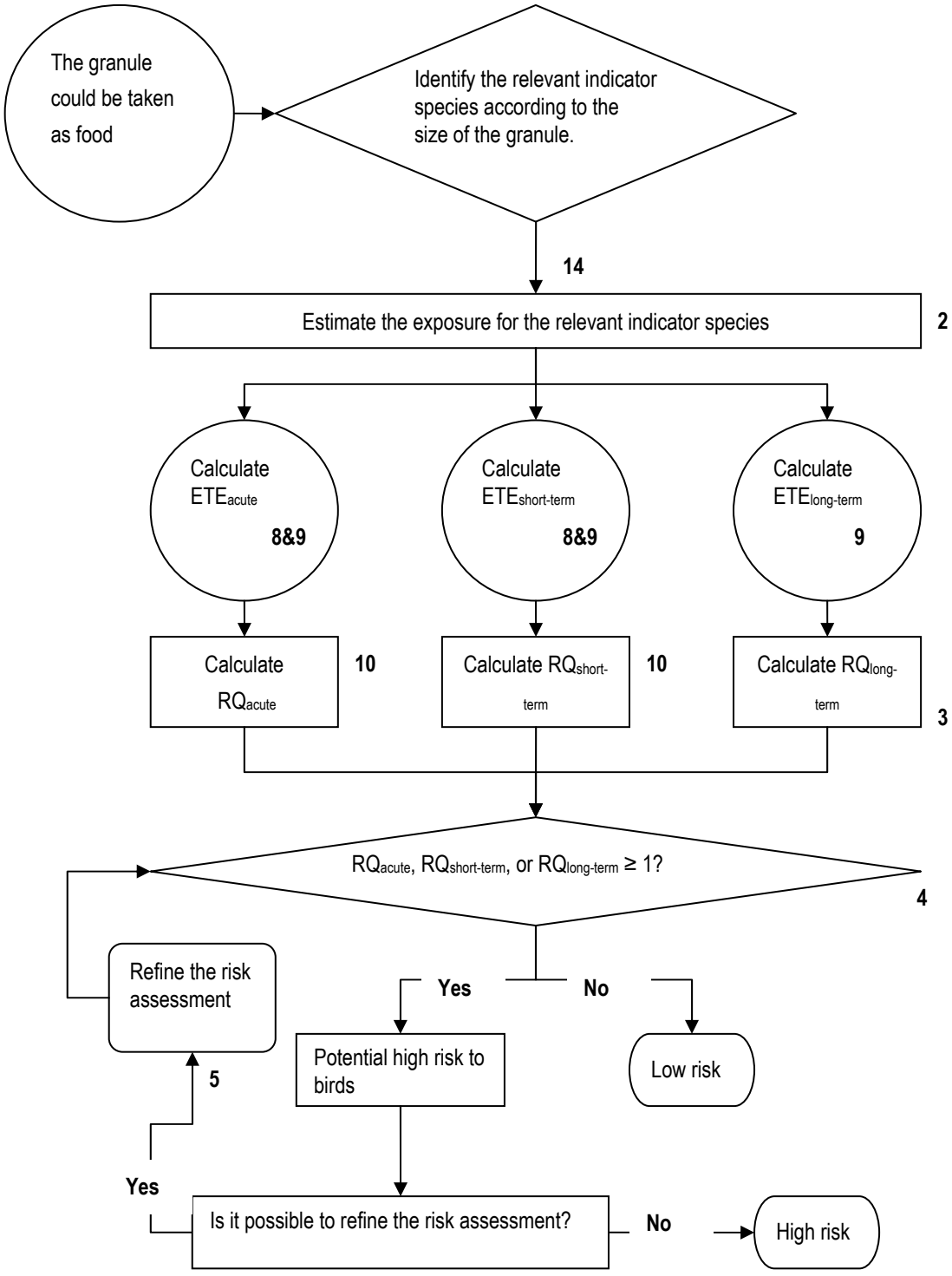
Flow chart 3.4A:Decision-making scheme for ERA of birds - Exposure Route 3(general)



Flow chart 3.4B:Decision-making scheme for ERA of birds - Exposure Route 3(accidental uptake)



Flow chart 3.4C:Decision-making scheme for ERA of birds - Exposure Route 3 (uptake as grit)



Flow chart 3.4D:Decision-making scheme for ERA of birds - Exposure Route 3 (uptake as food)

Explanatory Notes to the Flow chart 3.1, 3.2, 3.3 and 3.4(A, B, C, D):

1, All the development stages of the relevant crop listed in the 'crop category' (reference no…..) should be assessed, unless there are sufficient data to indicate that only part of the stages 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, $RQ_{chronic}$ will then 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, two possible approached could be considered so as to assess the long term risk of the pesticide of concern to bird, i.e. 1. In the case where no historical data or open literature data regarding the pesticide's chronic toxicity are available (e.g. new chemical), an extra Uncertainty Factor could be applied so as to account for the extrapolation from acute toxicity endpoint to chronic endpoint; 2. In the case where historical data or open literature data regarding the pesticide's chronic toxicity are available (e.g. from the database for over 400 existing compounds in China, which is currently in development at CAU), an estimation of the long term risk could be made according to those chronic data. 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 the 3 time windows should be assessed.

If any of the 3 RQ is bigger than 1, the pesticide of concern is consider to be of 'high risk' to birds under that particular time window, unless the refinement of risk assessment for that particular time window will result in a RQ lower than 1.

5, refer to the section of refinement measures' (Section No…..)

6, refer to the equations in the section of exposure route 1- spray

7, When pesticide does not pass this criterion, theoretically, it indicates that 50% percent of birds exposed to only one treated seed (or one granule) would die according to the assessed use pattern. Based on the EU experience, risk assessment for any pesticide with such a high potential risk tends to always result in the conclusion of 'unacceptable risk' to birds despite of incorporation of any refinement solutions. Therefore, the criterion is set as a basic cut-off limit.

8, ETEacute=ETEshort-term

When pesticide is applied as seed treatment, bait or as granule products, the active ingredients are intended to be stable for a relatively longer period of time so as to achieve the desirable efficacy. Therefore, a quick breakdown of the active ingredients in such use patterns is considered to be not relevant and no ftwa is considered for the 1st tier $ETE_{short\text{-}term}$ calculation.

9, refer to the equations in section of exposure route 2- seed treatment and bait

10, refer to the appropriate toxicity data for each calculation listed in the section of effect assessment

11 refer to the equations in the section of exposure route 2- section ?.?.? one-seed criterion

12 refer to the equations in the section of exposure route 3- section ?.?.? accidental uptake

13 refer to the equations in the section of exposure route 3- section ?.?.? uptake as grit

14 When it is considered to be possible for the granule to be taken by birds as food, the exposure of the granule could be estimated by following the same scheme as for seed treatment. The indicator species are hence identified according to the same criteria which are applied for seed treatment.

3.2.4 Tiered approach

3.2.4.1 Conceptual model

The conceptual model of the ERA scheme for bird 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 followed for ERA of bird according to the conceptual mode. The conceptual model is applicable for each Exposure Routes. At 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 RQ bigger than 1, then a higher tier assessment could be triggered to refine the risk assessment, by refining the effect assessment and/or exposure analysis as demonstrated in the model in Figure 3-1.

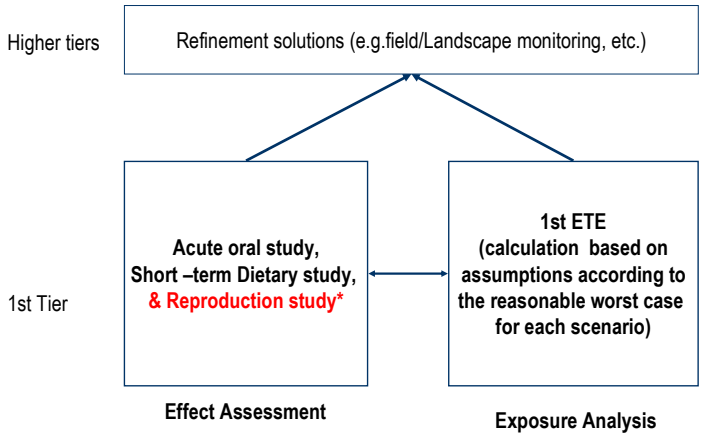


Fig. 3-1 the 'criss-cross 'model for the risk assessment of birds

NOTE:

***:** *When it is justified that the pesticide has very low toxicity to birds or long tem exposure is unlikely to occur according to the use pattern of the pesticide of concern, its long-term risk can be regarded as not relevant. However, based on the EU experience, It is known that in most cases, regarding birds exposure to pesticides, long-term effects can not be pre-excluded, therefore, data from relevant chronic studies, of which reproduction study is the one generally accepted world wide, are necessary for many pesticide products to fulfil a chronic assessment..*

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

therefore may not be available for a certain period of time. It is known that acute or short term exposure may result in long term effects, especially for pesticides applied during breeding seasons of birds. Therefore, it is very difficult to rule out the possibility of long term effects resulted from pesticide application. Expert judgement is hence required to set forth when the chronic data should be a necessity to the comprehensive assessment for a particular pesticide product. [32]

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 1st effect assessment (see Figure 3-1). Table 3-1 gives recommendations on the choice of appropriate parameters for risk characterization at 1st tier

Table 3-1 *parameters for risk characterization at 1st tier*

Exposure route	Time scale	Toxicity Endpoint	Uncertainty factor	Exposure Dose[33]
1	Acute	LD_{50} from acute oral test	10	ETE_{acute}
	Short-term	LC_{50} from short term dietary	10	$ETE_{short\text{-}term}$
	Long-term	NOED * from avian reproduction study	5	$ETEl_{ong\text{-}term}$
2	One seed criterion			ETE_{OSD}
	Acute	LD_{50} from acute oral test	10	ETE_{acute}
	Short-term	LC_{50} from short term dietary	10	$ETE_{short\text{-}term}$
	Long-term	NOED * from avian reproduction study	5	$ETE_{long\text{-}term}$
3	One granule criterion			ETE_{OGD}
	Acute	LD_{50} from acute oral test	10	ETE_{acute}

[32] To be discussed with Dutch experts and WP 5

[33] DGD_{acute}, $DGD_{short\text{-}term}$, $DGD_{long\text{-}term}$ are applied in case of the Ingestion of granules intentionally as part of grit ingestion. $DDSD_{acute}$, $DDSD_{short\text{-}term}$, $DDSD_{long\text{-}term}$ are applied in case of in Ingestion of granules accidentally as part of soil ingestion.

	Short-term	LC_{50} from short term dietary	10	$ETE_{short\text{-}term}$
	Long-term	NOED * from avian reproduction study	5	$ETE_{long\text{-}term}$
				$DDSD_{long\text{-}term}$

The 1st tier exposure analysis of birds see also Section 3.3

The 1st tier effect assessment of birds see also Section 3.4.

NOTE:
The requirements for dossiers differ for different registration types, according to 'Dossier Requirement for Pesticide Registration'. Therefore, especially for the 1st tier, when the toxicity data for both active ingredient and its formulation product are available, the assessor should choose the lowest toxicity value to calculate the RQ(e.g. LC_{50} for bird).

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 be available already in the dossier or can be produced by literature searches, other data have to be generated by new studies. As it is desirable to minimise animal testing other options for refinement should be explored first, where possible. 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 expected.

Feasible refinement recommended in this handbook are 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 judgement, if applicable.

3.2.5 ERA for metabolites [34]

3.2.6 ERA for a formulation product containing more than 1 a. i.. [35]

3.2.7 ERA for rodenticides (rodenticidal baits)[36]

[34] At this stage of ERA development in China, the ERA for metabolites is not addressed in this handbook, but the consequences of this omission have been discussed and evaluated with Ctgb and Alterra. If possible, the metabolites will be taken into account in the future.

[35] Not discussed in details until now.

[36] The decision making scheme has not been worked out yet.

3.3 Exposure analysis

3.3.1 1st tier

3.3.1.1 Exposure route 1 - Spray

In the 1st tier assessment the realistic worst-case scenarios are considered which involve indicator species designed according to crop category[37] (see Table 3-2). This 'indicator species' is not a real species but, by virtue of its size and feeding habits is considered to have higher exposure than other species that occur in a particular crop at a particular time. Rice is not included in this document because it will be addressed in future.

Table 3-2: Relevant indicator species according to crop

Crop category	Indicator species	FIR (g/d)	Body weigh (g)
Bare soils	Small granivorous bird	4.35	15.3
Orchards and ornamentals/nursery	Small insectivorous bird	11.5	13.3
Grassland	Large herbivorous bird	1301.22	2645
Vinyard	Small omnivorous bird	64.37	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	64.37	28.5
Cotton	Small omnivorous bird	63.14	27.7

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

$$ETE = \frac{FIR}{bw} \times C \times PT \times PD (mg / kg \cdot bw / d)$$

Formula 3.2

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

$$C = C_0 \times MAF \times f_{twa}$$

Formula 3.3

[37] These scenarios are designed for a generalized assessment of a substance intended for major crops or a broad spectrum of crops on EU level, because the scenarios fitted in China situation have not established so far.

$$f_{twa} = \frac{(1 - e^{kt})}{kt} \quad \text{……..……..} \qquad \text{Formula 3.4}$$

$$k = \frac{\ln 2}{DT_{50}} \text{ K=ln2/DT50……} \qquad \text{Formula 3.5}$$

Otherwise it is assumed in the 1st tier that the contaminated diet is not avoided and birds satisfy their entire food demand in the treated area and birds feed on a single food type. Thus the factors PT and PD become 1.So the concentration C_0 in the 1st tier assessment is calculated according to the formula below.

$$C_0 = RUD \times AR \text{ ……..} \qquad \text{Formula 3.6}$$

ETE = Estimated theoretical exposure (mg/kg bw d^{-1})
FIR = Food intake rate of indicator species (g d^{-1})
Bw = Body weight (g)
C = Concentration of compound 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

t = Averaging time
RUD = residue unit dose (RUD is the residue levels in mg/kg fresh food which occur immediately after spraying of 1 kg of active ingredient ha^{-1})
AR = maximum application rate (kg/ha)

We should be select the most relevant exposure scenario according to crop category when beginning the exposure analysis for bird. The information about crop category can obtain from the label of formulated product.

3.3.1.1.1 Acute exposure

With regard to residues in vegetation and insects 90th percentiles of the initial concentration are used in acute exposure analysis.

Multiple applications may cause sum-up of residues and therefore need considerations. MAF is a function of the number of applications, interval, and DT50. In the 1st tier a default value of 10 days for DT50 on vegetation is used. However, ordinary MAF-values cannot be applied to upper percentiles because it is unlikely that each time the upper percentile is exceeded. Therefore special $MAF_{90\%}$ factors have been calculated in order to predict the true 90th percentile of the peak after n applications based on the log distribution of the residue data

(Table 3-3). Note in the case of insects and granules no MAF is applied. Table 3-4 shows standard residues (normalised to an application rate of 1kg/ha) for the various scenarios.

Calculation of ETE_{acute} in terms of daily (mg/kg bw) is as follows formula 3.7 using the values presented in Table 3-3 and Table 3-4.

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

ETE_{acute} = Estimated theoretical exposure for acute exposure (mg/kg bw/d)
FIR/bw = Food intake rate of indicator species per body weigh per day (g/ g bw/d)
$RUD_{90\%}$ = 90th percentile of residue unit dose
AR = maximum application rate (kg/ha)
$MAF_{90\%}$ = Multiple application factor to be used in concentration with 90th percentiles for residues

Table 3-3: Multiple applications factors ($MAF_{90\%}$) to be used in concentration with 90th percentiles for residues for herbivorous birds and omnivorous birds

Interval (d)	Number of applications								
	1	2	3	4	5	6	7	8	∞
7	1.0	1.4	1.7	1.8	1.9	1.9	1.9	2.0	2.0
10	1.0	1.3	1.5	1.6	1.6	1.6	1.6	1.6	1.6
14	1.0	1.2	1.3	1.4	1.4	1.4	1.4	1.4	1.4

Table 3-4: spray scenarios for the acute exposure estimate

1	2	3	4	5
Crop category	Indicator species	FIR/bw	$RUD_{90\%}$	$MAF_{90\%}$
Bare soils	Small granivorous bird	0.284	87.0	n.a.
Orchards and ornamentals/nursery	Small insectivorous bird	0.865	54.1	n.a.
Grassland	Large herbivorous bird	0.492	102.3	See table 3-3
Vinyard	Small omnivorous bird	2.26	70.3	See 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	2.26	70.3	See table 3-3
Cotton	Small omnivorous bird	2.28	70.3	See table 3-3

3.3.1.1.2 Short-term exposure

Short-term exposure aims at a time frame of a few days. Therefore initial residues are more appropriate than time-weighted average. However in the course of some days they will gather

food in an area that is large compared to the spatial scale of residue variation. So averaging of residues is expected to occur and therefore 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 with the formula 3.9. Table 3-6 shows the standard residues (normalised to an application rate of 1 kg/ha) for the various scenarios.

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

$$ETE_{short-term} = \frac{FIR}{bw} \times RUD_{mean} \times AR \times MAF_{mean} \ldots$$ Formula 3.8

$$MAF_{mean} = \frac{(1 - e^{-0.069ni})}{(1 - e^{-0.069i})}$$ Formula 3.9

$ETE_{short\text{-}term}$ = Estimated theoretical exposure for short-term exposure (mg/kg bw/d)
FIR/bw = Food intake rate of indicator species per body weigh per day (g/ g bw/d)
RUD_{mean} = arithmetic means of residue unit dose
AR = maximum application rate (kg/ha)
MAF_{mean} = arithmetic means of multiple application factor
I = interval of application
N = number of applications

Table 3-5: standard Multiple Applications Factors (MAF_{mean}) for residues based on a DT50 of 10 days for herbivorous bird and omnivorous birds

Interval (d)	Number of applications								
	1	2	3	4	5	6	7	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

1	2	3	4	5
Crop category	Indicator species	FIR/bw	RUD_{mean}	MAF_{mean}
Bare soils	Small granivorous bird	0.284	40.2	n.a.
Orchards and ornamentals/nursery	Small insectivorous bird	0.865	21.0	n.a.
Grassland	Large herbivorous bird	0.492	54.2	See table 3-5
Vinyard	Small omnivorous bird	2.26	28.7	See 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	2.26	28.7	See table 3-5
Cotton	Small omnivorous bird	2.28	28.7	See table 3-5

3.3.1.1.3 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 (Table 3-5) are employed. In contrast to the short-term assessment time-weighted-average (twa) residue are used here 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 which are 3 weeks of time window and 10days of DT50. With these assumptions f_{twa} is 0.53[38][39]. Table 3-7 shows the standard residues (normalized to an application rate of 1kg/'ha) for the various scenarios.
Calculation of $ETE_{long\text{-}term}$ in terms of daily dose (mg/kg bw) is as follows:

$$ETE_{long-term} = \frac{FIR}{bw} \times RUD_{mean} \times f_{twa} \times AR \times MAF_{mean} . \qquad \text{Formula 3.10}$$

$ETE_{long\text{-}term}$ = Estimated theoretical exposure for long-term exposure (mg/kg bw/d)
FIR/bw = Food intake rate of indicator species per body weigh per day (g/ g bw/d)
RUD_{mean} = arithmetic means of residue unit dose
f_{twa} = time-weighted-average factor
AR = maximum application rate (kg/ha)
MAF_{mean} = arithmetic means of multiple application factor

[38] In case of repeated applications the maximum f_{twa} may be underestimated when the interval is shorter than the time window. However the reasonable procedure what dealing with such case has not developed so far.

[39] f_{twa} for 1 to 3days of time window be used If short-term exposure lead to reproductive effect. For 1 days the f_{twa} is 1; for 2 days 0.93 and for 3 days 0.90. However, normally f_{twa} of 0.53 is used for the long-term exposure analysis based on EU experience.

Table 3-7: spray scenarios for the long-term exposure estimate

1	2	3	4	5	6
Crop category	Indicator species	FIR/bw	RUD_{mean}	MAF_{mean}	f_{twa}
Bare soils	Small granivorous bird	0.284	40.2	n.a.	0.53
Orchards and ornamentals/nursery	Small insectivorous bird	0.865	21.0	n.a.	0.53
Grassland	Large herbivorous bird	0.492	54.2	See table 3-5	0.53
Vinyard	Small omnivorous bird	2.26	28.7	See 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	2.26	28.7	See table 3-5	0.53
Cotton	Small omnivorous bird	2.28	28.7	See table 3-5	0.53

3.3.1.2 Exposure Route 2 - Seed treatment and bait

There are two steps in exposure analysis for seed treatment i.e. one seed dose for one seed criterion and the theoretical exposure (daily dietary dose) for dietary exposure route, which are described 3.3.1.2.1 and 3.3.1.2.2 respectively.

3.3.1.2.1 Estimation of one seed dose for one seed criterion

One seed criterion can be considered as a precautionary warning system for potential high-risk application for birds. The body weight of a small bird is assumed to be 25g for seed size smaller than 3.5 cm , whereas that of a larger bird is taken to be 300g for seed size bigger than 3.5cm. Estimated theoretically exposure (ETE_{osd}) will be applied in exposure analysis for risk assessment which calculated according to following formula 3.11 and 3.12 using values presented in Table 3-8.

For seed treatment:

$$ETE_{OSD} = \frac{S_{loading}}{bw} \times 10^3 \qquad \text{Formula 3.11}$$

$$S_{loading} = AR \times OSW \times 10^3 \qquad \text{Formula 3.12}$$

For bait:

$$ETE_{ObD} = \frac{B_{loading}}{bw} \times 10^3 \qquad \text{Formula 3.13}$$

$$B_{loading} = AR \times OBW \times 10^3$$ Formula 3.14

$$AR = cb \times 10^6$$ Formula 3.15

ETE_{OSD} = Estimated theoretically exposure (One seed dose) (mg/kg bw)
$S_{loading}$ = amount of the active ingredient on one seed (mg)bw=body weight (g)
AR =maximum seed treatment rate (mg/kg)OSW=one seed weight (g)
ETE_{ObD} = Estimated theoretically exposure (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 production

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

3.3.1.2.2 Estimation of exposure for dietary exposure

The estimated theoretical exposure is assessed for three time scales i.e. acute, short- and long-term in dietary exposure route for seed treatment.

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). Both body weight of a small bird is assumed to be 15g and that of a larger bird is taken to be 300g should be taken into account[40].

a1. Acute exposure (minutes to hours)

Calculate the realistic worst case estimated theoretical exposure (ETE_{acute}) for each relevant species using the FIR/bw presented in Table 3-9.

$$ETE_{acute} = \frac{FIR}{bw} \times AR$$ Formula 3.16

For bait:

$$AR = cb \times 10^6$$ Formula 3.17

ETE_{acute} = estimated theoretical exposure for acute exposure (mg/kg bw d^{-1})
FIR/bw = Food intake rate of indicator species per body weigh per day (g/g bw d^{-1})
AR = maximum seed treatment rate (mg/kg)
Cb = content of active ingredient in bait production

[40] The guidance document on risk assessment for birds and mammals (SANCO/4145/2000) consider one indicator species i.e. small bird. Two indicator species i.e. small bird and big bird are taken into account in new guidance document and EPPO scheme.

Table 3-9: seed treatment scenarios for acute dietary exposure

Indicator species	body weight(g)	FIR/bw[41]
Small birds	15	0.3
Large birds	300	0.1

a2. Short-term exposure (days to weeks)

Calculate the realistic worst case estimated theoretical exposure ($ETE_{short\text{-}term}$) for each relevant species using the FIR/bw values had already presented in Table 3-9.

$$ETE_{short-term} = \frac{FIR}{bw} \times AR \qquad \text{Formula 3.18}$$

For bait:

$$AR = cb \times 10^6 \qquad \text{Formula 3.19}$$

$ETE_{short\text{-}term}$ = realistic worst case estimated theoretical exposure for short-term exposure (mg/kg bw d^{-1})
FIR/bw = Food intake rate of indicator species per body weigh per day (g/g bw d^{-1})
AR = maximum seed treatment rate (mg/kg)
Cb = content of active ingredient in bait production

a3 Long-term exposure (weeks to months)

The time-weighted average factor of 0.53 is considered in the estimation of exposure for the long-term which are based on the following default values which are 3 weeks of time window and 10days of DT50[42]. Calculate the realistic worst case estimated theoretical exposure ($ETE_{long\text{-}term}$) for each typical species using the parameters presented in Table 3-10.

$$ETE_{long-term} = \frac{FIR}{bw} \times AR \times f_{twa} \qquad \text{Formula 3.20}$$

For bait:

$$AR = cb \times 10^6 . \qquad \text{Formula 3.21}$$

$ETE_{long\text{-}term}$ = realistic worst case estimated theoretical exposure for long-term exposure (mg/kg bw d^{-1})
FIR/bw = Food intake rate of indicator species per body weigh per day (g/g bw d^{-1})
AR = maximum seed treatment rate (g/kg)
f_{twa} = time-weighted-average factor
cb = content of active ingredient in bait production

41 The value of FIR/bw came from new guidance document (Scientific Opinion of the Panel on Plant protection products and their Residues (PPR) on the Science behind the Guidance Document on Risk Assessment for birds and mammals).

42 Time-weighted average factor is not applied for seed treatment in EU guidance document (SANCO/4145/2000), but that used in EPPO scheme. The f_{twa} of 0.53 is applicable for long-term exposure of treatment seed in this handbook.

Table 3-10: seed treatment scenarios for short- and long-term dietary exposure

Indicator species	Body weight (g)	FIR/bw	f_{twa}
Small birds	15	0.3	0.53
Large birds	300	0.1	0.53

b. pelleted seeds

The estimation of exposure of pelleted seeds for bird is same as the non-pelleted seeds are taken by bird as food if the pelleted seed based on organic carrier (see 3.3.1.2.2). Whereas the exposure route of pelleted seeds for birds is similar to the ingestion of granule as seeking grit if the pelleted seed based on anorganic carrier (3.3.1.3.2 b).

3.3.1.3 Exposure Route 3 – granule

The estimation of one granule dose for one granule criterion and the analysis of estimated theoretical exposure (daily dietary dose) for dietary exposure route for granule, which are described 3.3.1.3.1 and 3.3.1.3.2 respectively.

3.3.1.3.1 Estimation of one granule dose for one granule criterion

One granule criterion is similar to one seed criterion expressed in 3.3.1.2.1. The body weight of a small bird is assumed to be 25g for granule size smaller than 3.5 cm, whereas that of a larger bird is taken to be 300g for granule size bigger than 3.5cm. Estimated theoretically exposure (ETE_{ogd}) will be applied in the exposure analysis for risk assessment which is calculated according to the formula 3.22 and 3.23 using values presented in Table 3-11.

$$ETE_{ogd}=G_{loading}/bw*10^{3} \qquad \text{formula 3.22}$$

$$G_{loading}=cg*OGW*10^{-3} \qquad \text{formula 3.23}$$

ETE_{ogd} = Estimated theoretically exposure (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 production
OGW = one granule weight (g)

Table 3-11: 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

3.3.1.3.2 Estimation of exposure for dietary exposure route

Granules may be ingested intentionally by birds that mistake them for food or grit, or they may be ingested accidentally when birds probe for or peck at food in or on treated soil according to the size of granule. Birds take granules intentionally as food or grit if the size of granule is bigger than 0.5mm, whereas they ingest granule accidentally as part of soil. The procedures of exposure analysis to bird are described in below.

a) Ingestion of granules intentionally as food

If granules are based on an organic carrier (e.g. corncob) having a nutritional value and the size of granule is bigger than 0.5mm then they may be taken by birds as food or as grit.

The exposure could be assessed in a same way as for non-pelleted seeds if granule be taken by bird as food (see 3.3.1.2.2 a). Note should recalculate the maximum application rate (AR) according to the formula in below if the unit of application dose expressed as kg/ha.

$AR=cg*10^6$ formula 3.24
AR=maximum application rate (mg/kg)
cg=content of active ingredient in granule production

If granule be ingested by bird as grit the exposure could be assessed in the same procedure as grit (see 3.3.1.3.2 b).

Compare two results from estimation of exposure expressed in above then take the bigger value to the risk assessment.

b) Ingestion of granules intentionally as grit

Granules with an anorganic base and the size of granule is bigger than 0.5mm could be ingested intentionally when birds search for grit

b.1 Acute exposure

It is assumed in the assessment 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 bird for the estimation of realistic worst-case for grit ingestion.

Calculate the realistic worst-case estimated theoretical exposure (ETE_{acute}) for a representative typical species for acute exposure using the values presented in Table 3-12. The ETE_{acute} be calculated with the following formula 3.25 and 3.26.

$$ETE_{acute}=DGI_{rwc}*(G_{surface}/SP_{surface}+G_{surface}))* G_{loading}$$ formula 3.25

$$G_{surface}=(AR*10)/(cg* OGW)$$ formula 3.26

ETE_{acute} = realistic worst-case estimated theoretical exposure for acute exposure (mg/kg bw d^{-1})
DGI_{rwc} = daily grit intake of birds (kg^{-1} bw day^{-1})
$G_{surface}$ = number of granules at soil surface (1 m^2)
$SP_{surface}$ = number of soil particles at soil surface in the same size classes as granules (1 m^2)
$G_{loading}$ = the amount of the active ingredient in one granule (mg)
AR = maximum application rate (kg/ha)
OGW = one granule weight (g)
Cg = content of active ingredient in granule production

b.2 Short-term exposure

Calculate the reasonable worst-case estimated theoretical exposure ($ETE_{short-term}$) for a representative typical species for short-term exposure using the values presented in Table 3 - 12. The $ETE_{short-term}$ be calculated with the following formula 3.27 and 3.28.

$$ETE_{short-term} = DGI_{rwc} *(G_{surface}/SP_{surface}+G_{surface}))* G_{loading}$$ formula 3.27

$$G_{surface}=AR/(cg* OGW*10)$$ formula 3.28

$ETE_{short-term}$ = realistic worst-case estimated theoretical exposure for short-term exposure (mg/kg bw d^{-1})
DGI_{rwc} = daily grit intake of birds (kg^{-1} bw day^{-1})
$G_{surface}$ = number of granules at soil surface (1 m^2)

$SP_{surface}$ = number of soil particles at soil surface in the same size classes as granules (1 m^2)
$G_{loading}$ = the amount of the active ingredient in one granule (mg)
AR = maximum application rate (kg/ha)
OGW = one granule weight (g)
Cg = content of active ingredient in granule production

b.3 Long-term exposure

Time-weighted average residues are used in the long-term exposure analysis. With the length of the time window (average time) fixed at 21days, the time-weighted-average factor depends only on the half-life of the compound. The f_{twa} of 0.53 is considered for the long-term exposure analysis based on the following 10days of DT50. If data shows that the DT50 is shorter than 10days, then the f_{twa} should be recalculated using the formula 3.31 and 3.32.

Calculate the reasonable worst-case estimated theoretical exposure for an indicator species for long-term exposure using the values presented in Table 3-12. The $ETE_{long\text{-}term}$ be calculated with the following formula 3.29 and 3.30.

$$ETE_{long\text{-}term}=DGI*(G_{surface}/SP_{surface}+G_{surface}))* G_{loading}*f_{twa} \quad \text{formula 3.29}$$
$$G_{surface}=AR/(cg* OGW*10) \quad \text{formula 3.30}$$
$$f_{twa}=(1-e^{-kt})/kt \quad \text{formula 3.31}$$
$$(k=ln2/DT50 \quad \text{formula 3.32}$$

$ETE_{long\text{-}term}$ = realistic worst-case estimated theoretical exposure for long-term exposure (mg/kg bw d^{-1})
DGI_{rwc} = daily grit intake of birds (kg^{-1} bw day^{-1})
$G_{surface}$ = number of granules at soil surface (1 m^2)
$SP_{surface}$ = number of soil particles at soil surface in the same size classes as granules (1 m^2)
$G_{loading}$ = the amount of the active ingredient in one granule (mg)
AR = maximum application rate (kg/ha)
OGW = one granule weight (g)
Cg = content of active ingredient in granule production
T = average time in days

Table 3-12: granule scenarios for acute, short- and long-term exposure for birds ingesting granules intentionally when seeking grit

Exposure duration	Size of birds	Body weight (g)	DGI (No. of grit per day)	$SP_{surface}$ (No. of soil particles/m^2)	f_{twa}
Acute	large	400	2453	71	n.a.
	small	15	651	15200	n.a.
Short-term	large	400	2453	71	n.a.
	small	15	651	15200	n.a.
Long-term	large	400	2453	71	0.53
	small	15	651	15200	0.53

c) Ingestion of granules accidentally as part of soil

The granules are ingested by bird accidentally as part of soil if the size of granule is smaller than 0.5mm.

Calculate the realistic worst-case estimated theoretical exposure (ETE) for a 25g bird for acute, short- and long-term exposure according to the formular***. 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 treated area. So PT is 1.

The values for the residue unit dose (RUD) are based on an application rate of 1kg 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 equally mixed in a layer of 1cm soil.

For the short- and long-term exposure, it is assumed that the granule is mixed over a layer of 5 cm. If other incorporation depths are preferred, the RUD values should be recalculated using the formula 3.34.

ETE = DDSI*RUD/1000*PT *AR formula 3.33
RUD= formula 3.34

ETE = realistic worst-case estimated theoretical exposure for acute exposure (mg/kg bw d^{-1})
AR = maximum application rate (kg/ha)
DDSI = daily dry soil intake of the indicator species (g d^{-1})
RUD = esidue unit dose (concentration in soil as a result of an application rate of 1 kg active ingredient ha^{-1})
PT = fraction of diet obtained in treated area

c.1 Acute exposure(minutes to hours)

Calculate the ETE_{acute} for acute exposure using these values presented in Table 3-13 with the following formula 3.35 and 3.36.

ETE_{acute} = DDSI*RUD/1000 *AR formula 3.35
DDSI=DDFI/(100-%soil)*%soil formula 3.36

ETE_{acute} = realistic worst-case estimated theoretical exposure for acute exposure (mg/kg bw d^{-1})
AR = maximum application rate (kg/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})
DDFI = daily dry food intake of the indicator species (g dry weight day^{-1})
%soi = percentage of dry soil in dry diet of indicator species

Table 3-13: granule scenarios for acute, short- and long-term exposure via contaminated soil

Exposure duration	Body weight (g)	DDFI (g kg^{-1} body weight day^{-1})	% of soil in diet (% soil)	DDSI (g kg^{-1} body weight day^{-1})	RUD (mg kg^{-1} day soil)	f_{twa}
Acute	25	323	18	70.9	6.667	n.a.
Short-term	25	323	18	70.9	1.333	n.a.
Long-term	25	323	18	70.9	1.333	0.53

c.2 short-term exposure(days to weeks)

Calculate the $ETE_{short-term}$ for a 25g bird for short-term exposure using these values presented in Table 3-13 following the formula 3.37 and 3.38.

$ETE_{short-term}$ = DDSI*RUD/1000*AR formula 3.37
DDSI=DDFI/(100-%soil)*%soil formula 3.38

$ETE_{short-term}$ = realistic worst-case estimated theoretical exposure for short-term exposure (mg/kg bw d^{-1})
AR = maximum application rate (kg/ha)
DDSI = daily dry soil intake of the indicator species (g d^{-1})
RUD = residue unit dose
DDFI = daily dry food intake of the indicator species (g dry weight day^{-1})
%soil = percentage of dry soil in dry diet of indicator species

c.3 Long-term exposure (weeks to months)

In the long-term exposure analysis time-weighted average residues are used. The f_{twa} of 0.53 is considered for the long-term exposure analysis based on the following 10days of DT50 and 21days of length of time window. If data shows that the DT50 is shorter than 10days, then the f_{twa} should be recalculated using the formula 3.41 and 3.42.

Calculate the daily dry soil dose ($ETE_{long\text{-}term}$) for a 25g bird for long-term exposure using short-cut value presented in Table 3-13 with the following formula 3.39 and 3.40.

$ETE_{long\text{-}term} = DDSI*RUD/1000*AR*f_{twa}$ formula 3.39

$DDSI=DDFI/(100-\%soil)*\%soil$ formula 3.40

$f_{twa} = (1-e^{-kt})/kt$ formula 3.41

$k= ln2/DT50$ formula 3.4

$DDSD_{long\text{-}term}$ = realistic worst-case estimated theoretical exposure for long-term exposure (mg/kg bw d^{-1})
AR = maximum application rate (kg/ha)
f_{twa} = time-weighted-average factor
DDSI = daily dry soil intake of the indicator species (g d^{-1})
RUD = residue unit dose
DDFI = daily dry food intake of the indicator species (g dry weight day^{-1})
%soil = percentage of dry soil in dry diet of indicator species

3.3.1.4 Exposure route 4 – rodenticide

3.3.1.4.1 Primary poisoning

3.3.1.4.2 Secondary poisoning

3.3.2 Higher tier

Exposure analysis can take several different options for refinement in higher tier, for instance, measured residues, residue decline in plants, avoidance and refine PT and PD, etc. Otherwise risk mitigation options can be taken into account for the estimation of exposure in higher tier. In this section pragmatic options are described which are measured residues and residue decline in plants because it is very difficult that obtain adequate data to refine PT and PD for which are consuming a lot of time and costs.

3.3.2.1 Measured residues

Refinement may be possible by making use of available residue data for the substance 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 generally the same considerations are applied as in the risk assessment:

a. For the acute exposure: take 90th percentile (or equivalent) of initial residues.
b. For the short-term exposure: take arithmetic means of initial residues.
c. For the long-term exposure: take mean time-weighted-average residues (averaging may be done parametrically with an estimated DT50 or by considering the observed area-under-curve).

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

If residue trials involve repeated applications of the product and sampling starts at the last application then sum up of residues is included and these data are not subject to an additional multiple application factor.

If the main route of exposure is via the consumption of treated vegetation, then 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 give a more realistic level on vegetation as well as providing sufficient information to enable appropriate time-weight average concentrations to be generated. However, it has to be observed whether the part of the plant which was analysed matches what 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 it is not then it may be necessary to request more appropriate data.

If the main route of exposure is via the consumption of treated insects, then, it may be beneficial to determine residue levels on appropriate insects etc. Insects should be collected via 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 insects collected should be those that birds may be consuming. Samples from different collection techniques should not be pooled but should be kept separate and analysed separately. Keeping samples separate will ensure a more accurate indication of the true level of exposure via 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 the case the substance is persistent in other environmental media. So the assumption of first-order kinetics may be inappropriate when long time-frames are considered.

3.3.2.2.1 Refinement of time-weighted average factor

If data show that the DT50 is shorter than 10 days which is used as a default value in tier 1 then f_{twa} should be recalculated. Assuming first-order kinetics it is:

$$f_{twa} = (1-e^{-kt})/kt \qquad \text{formula 3.}$$

$$k = \ln 2/DT50 \qquad \text{formula 3.}$$

T =Averaging time

This equation is also used when an f_{twa} for an averaging time other than 3 weeks is needed. In case of repeated applications the averaging time should not be longer than the interval.

3.3.2.2.2 Refinement of MAF

In 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 DT50 of 10 days. If data show that the disappearance is faster then the MAF_{mean} should be recalculated for short-term and long-term exposure. Assuming first-order kinetics it is:

$$MAF_{mean} = (1-e^{-nki})/(1-e^{-ki}) \qquad \text{formula 3.}$$

$$K=\ln 2/DT50 \qquad \text{formula 3.}$$

N =Number of applications
i =Interval between applications (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 aquatic toxicological studies.

The dossiers submitted must be sufficient to permit an assessment of the impact on birds, likely to be at risk from exposure to the active ingredient, its metabolites, degradation and reaction products, where they are of environmental significance[43].

Impact can result from single, prolonged or repeated exposure and can be reversible or irreversible. In particular, the dossiers submitted should be sufficient to:

- specify appropriate conditions or restrictions to be associated with any registration;
- permit an evaluation of risks for non-target species like birds, populations, communities, and processes - as appropriate,
- classify the pesticide product / active ingredient as to hazard,
- specify the precautions necessary for the protection of non-target species like birds, to be mentioned on packaging(containers)

The following sections, in line with ”Dossier Requirement for Pesticide Registration”, elaborate test conditions, guidelines and endpoints of the required studies for each required study. The studies described below are those which are scientifically necessary to allow the evaluation of risks to birds. For specific information related to the circumstances in which the following studies are required, please refer to the” Dossier Requirement for Pesticide Registration”.

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

[43] At this stage of ERA development in China, the ERA for metabolites is not addressed in this handbook, but the consequences of this omission will be discussed and evaluated with Ctgb and Alterra. If possible, the metabolites will be taken into account in the future.

3.4.1.2 Active ingredients :

3.4.1.2.1 Avian acute oral test

Circumstances in which required:
Test should always required.

Test conditions:
Test should be done for one recommended species: Japanese quail (Bobwhite is also acceptable) and the highest dose used in tests need not exceed 1 000 mg/kg bw

Test guidelines:
“Chemical pesticide environment risk assessment test guideline”; or Internationally recognized guidelines

Results
LD 50(mg/kg bw)

3.4.1.2.2 Avian short term dietary test

Circumstances in which required:
Test should always required.

Test conditions:
Test should be done for one recommended species: Japanese quail (Bobwhite is also acceptable) and the highest dose used in tests need not exceed 2 000 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)

3.4.1.2.3 Reproductive test

Circumstances in which required
The reproductive toxicity of the active ingredient to birds must be investigated, unless it can be justified that continued or repeated exposure of adults or exposure of nest sites during the breeding season is unlikely to occur. ??

Test guidelines:
Internationally recognized guidelines, e.g. OECD 206

Results:
NOED (mg/kg bw per day) NOEC (mg/kg food)

3.4.1.3 Formulation products :

3.4.1.3.1 Avian acute oral test

Circumstances in which required

The test should always be required unless LD50 from acute oral test of the ai is bigger than 500 mg/kg bw

Test conditions:
Test should be done for one recommended species: Japanese quai(Bobwhite is also acceptable) and the highest dose used in tests need not exceed 1 000 mg/kg bw

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

Results:
LD50(mg/kgbw)

3.4.2 Tiered approach

3.4.2.1 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 be contingent on the nature of the active ingredient, the manner of use and the extent and scale of application. Generally, at 1st tier, a standard data set will be necessary which will assess acute oral toxicity, short-term dietary toxicity and reproductive toxicity in avian species. The test species selected for these test protocols are regarded as surrogates for the ecological 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.

The relevant toxicity endpoints and associated uncertainty factors regarding data extrapolation which are used in 1st tier RQ calculation are as follows:

Table 3-???: toxicity endpoints and uncertain factors used at 1st tier

Time scale	**Endpoint**	**Uncertain factor applied at 1st tier**[44]
Acute	LD_{50} from acute oral test	10
Short term	LC_{50} from short term dietary	10
Long term	NOED * from avian reproduction study	5

*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`
On the assumption that the LC50 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 LD50 = 50 * 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). The outcome of standard dietary LC50 studies may often not result from increased intake of chemical, but from decreased food consumption. This food avoidance behaviour can be induced by repellent properties of the chemical(if relevant data are available). Because repellence dictates, sometimes to a high degree, the outcome of the LC50 value, these values should be used with caution in the risk characterization.

[44] To be discussed with WP5

3.4.2.2 Higher tier

For higher tier assessment, it may be necessary to conduct more specific tests on species of more ecological relevance in the context of the proposed use. 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 higher tier study requiring more testing birds are considered necessary, the study should be carefully design with the consultation to the registration authority and relevant experts.

3.5 Environmental Risk management suggestions[45]

3.5.1 Risk mitigation measures and labeling

When ERA for a certain pesticide indicates that the risk to bird 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. 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 measure 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.

3.5.2 Pragmatic Implementation approaches[46]

[45] This section is not finalized. Based on the comments from Harold and Peter and discussion within WP2, the conclusion is to keep the scientific assessing part separated from the 'final decision making' part, because the latter should be an integrated decisions based on both political considerations and the results from risk assessment for all the protection goals.Relevant text will be provided by WP5.
[46] To be discussed with CTgb and experts in Alterra

References:

1. EPPO(2002): Environmental risk assessment scheme for plant protection products. Chapter 11. Terrestrial vertebrates (sprayed products, seed treatment and granular formulations).
2. OECD(2002): Working document SANCO/4145/2000: Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC.
3. 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.

Appendix 3-2: 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 (LD50 from acute oral test of the ai <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 401 or SETAC**	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	??	**-**	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	-

Chapter 4 Honey bee

Chapter 5 Silkworm

Chapter 6 Groundwater