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## Setting environmental criteria for risk assessment

Evaluation of Chinese environmental risk assessment procedures

Harold van der Valk, Tao Chuanjiang, Geng Yue, Ma Jing, Zhou Ruize, Jia Ran, Liu Yunfei, Li Chongjiu, Li Wenjuan, Lin Yan, Ma Xiaodong, Qu Mengmeng, Piao Xiuying, Mechteld ter Horst and Werner Pol







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Harold van der Valk<sup>1</sup>, Tao Chuanjiang<sup>2</sup>, Geng Yue<sup>4</sup>, Ma Jing<sup>4</sup>, Zhou Ruize<sup>4</sup>, Jia Ran<sup>4</sup>, Liu Yunfei<sup>4</sup>, Li Chongjiu<sup>4</sup>, Li Wenjuan<sup>3</sup>, Lin Yan<sup>4</sup>, Ma Xiaodong<sup>4</sup>, Qu Mengmeng<sup>2</sup>, Piao Xiuying<sup>2</sup>, Mechteld ter Horst<sup>1</sup>, Werner Pol<sup>5</sup>

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#### Abstract

A study was conducted to assess the impact of applying newly developed risk assessment procedures and acceptability criteria on the number and type of pesticides registered in China. Risks of the 100 most used pesticides, representing about 93% of the total volume of pesticides applied in China in the period 2005 – 2008, were assessed for representative and/or realistic worst case use patterns (i.e. crops, dose rates, application frequencies and intervals).

The risk assessment procedure for groundwater in dry land agriculture in China is based on the criterion that the overall 99th percentile leaching concentration in groundwater at 10 m depth should not exceed the drinking water guidance value established according to WHO guidelines. Only limited exceedance of this criterion was found in the study and it was therefore considered appropriate.

The risk assessment procedure for honey bees is based on the criterion that no effect should occur on the long-term survival of the honeybee colony. It was found that the risk quotients as applied in the European Union are also appropriate in China. However, an upper trigger for the risk quotient may be considered by ICAMA to limit the requirement for certain second tier studies.

The risk assessment procedure for silkworm is based on the principle that pesticide application in mulberry fields or neighbouring crop fields should not affect long-term survival of silkworm larvae. The study showed that the developed risk assessment procedure and criteria are appropriate for the Chinese situation, even though a considerable number of insecticides resulted in unacceptable risk. Better data in particular on toxicity, initial residues on mulberry and pesticide half-lives on plant foliage would be required to further refine the risk assessment procedure.

**Keywords:** pesticide, risk assessment, registration criteria, China, honey bee, groundwater, silkworm, PERAP.

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# Preface

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

The Institute for the Control of Agrochemicals of the Ministry of Agriculture (ICAMA) is responsible for pesticide registration in China. The main aim of PERAP was to contribute to the development and strengthening of Chinese environmental risk assessment (ERA) procedures for pesticide registration. ICAMA, Alterra – WageningenUR (The Netherlands), the Chinese Academy of Agricultural Sciences (CAAS), China Agricultural University (CAU), and WILresearch (The Netherlands) have been collaborating towards this aim as major partners in PERAP. Various other institution, such as Plant Research International – WageningenUR (the Netherlands), the Ctgb – Dutch Board for the Authorisation of Plant Protection Products and Biocides, also made valuable contributions to this joint project.

The project was subdivided in 5 work packages and the main purpose of each work package is summarized below:

- WP1: Project inception and management; formalization of the continuation of the activities of the consortium partners after 2009.
- WP2: Development of an ERA handbook; training of staff of ICAMA and four Chinese contract laboratories in the use of the handbook.
- WP3: Development of guidelines and standard operating procedures laboratory tests; implementation of good laboratory practice (GLP) procedures in the ICAMA laboratories.
- WP4: Development of capacity in working with environmental fate models; development of protective environmental fate scenarios for China.
- WP5: Development and discussion of the acceptability criteria for ERA.

The project aimed at establishing sound environmental risk assessment procedures, applicable to the Chinese context and acceptable as legal framework for the Chinese registration procedure. This entailed the development of (i) capacity to perform eco-toxicological and environmental fate tests under GLP, (ii) methods to estimate exposure under normal agricultural use of pesticides, and (iii) an environmental risk assessment handbook.

This report contributed to activity (iii) and focusses on acceptability criteria for environmental risk assessment in China. The various ERA procedures developed under PERAP applied preliminary acceptability criteria to decide whether a pesticide can be accepted for registration. These criteria were based on approaches taken by other established registration authorities, such the European Union and the US Environmental Protection Agency.

However, the impact that setting these criteria may have on the number of pesticide products that will continue to be registered in China was not known. This study therefore aims to evaluate the consequences of setting different registration criteria on the number and type of pesticides that may be registered, or require risk mitigation, in China. The study should provide a basis for ICAMA to set environmental registration criteria which are both economically realistic and environmentally sound. This report covers the assessments that have been conducted for the following protection goals: (i) groundwater in Northern China, (ii) honey bees and (iii) silkworm.

The study was by team consisting of researchers from China Agricultural University, the Chinese Academy of Agricultural Sciences, ICAMA, Ctgb and Alterra.





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# 1 Introduction

## 1.1 Objective of the study

The Sino-Dutch Pesticide Environmental Risk Assessment Project has developed environmental risk assessment (ERA) procedures for several priority protection goals identified by ICAMA. For each of these ERA procedures, preliminary acceptability criteria were set to decide if a pesticide can be accepted for registration, if it requires additional risk assessment, or if its registration should be refused in China. The preliminary registration criteria were based on approaches taken by other established registration authorities, such the European Union and the US Environmental Protection Agency.

However, the impact that setting these criteria may have on the number of pesticide products that will continue to be registered in China is not known. If criteria are very strict, many pesticides that are presently registered or newly proposed will not be acceptable. This could greatly reduce the number of pesticides available to farmers. If the criteria are weak, there is a risk that pesticides which pose an unacceptable risk to the environment will be accepted for registration in China.

Therefore, this study aims to evaluate the consequences of setting different registration criteria on the number and type of pesticides that may be registered, or require risk mitigation, in China. Furthermore, the results of the study should provide a basis for ICAMA to set environmental registration criteria which are both economically realistic and environmentally sound.

The study will be carried out for the protection goals that have been identified as a priority under the project:

1. groundwater (as drinking water)
2. honey bees
3. silkworm
4. birds
5. aquatic organisms in surface water

This report covers the assessments that have been done for groundwater in Northern China, honey bees and silkworm.

## 1.2 General methodology

The basic principle of the study methodology is that every ERA scheme was run for a representative subset of the pesticides that are presently registered for use in China. The consequences of setting specific environmental registration criteria on the number and type of pesticides that is acceptable for registration will then be evaluated.

### 1.2.1 Pesticides included in the study

ICAMA identified the 100 most used pesticides in China, by volume, based on use estimates made by the National Agro-Tech Extension and Service Centre of the Ministry of Agriculture for 2005, 2006 and 2008. These use estimates were based on pesticide industry sales data, pesticide consumption statistics over previous years, and expected cropping areas, among others.

The resulting list of 100 active ingredients consists of 45 insecticides, 20 herbicides, 23 fungicides, 6 acaricides, 2 rodenticides and 4 plant growth regulators (Annex 1). The listed pesticides represent approximately 93% of the total volume of pesticides used in China during the mentioned period.

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In addition to the active ingredients, all metabolites as they are listed in the Footprint Pesticide Properties Database (Footprint, undated) were also compiled. This resulted in an additional 49 compounds.

For each of the active ingredients, the Department of Applied Chemistry of China Agricultural University (DAC/CAU) identified all commercial formulations registered in China, as well as related use pattern data (crops, dose rates, application frequencies and intervals). The principal data sources for these data were the official pesticide labels as they are approved by ICAMA. This resulted in a data set with a total number of about 17 400 cases (commercial product and use pattern combinations). It should be noted that the pesticide application data used in the assessments were those available in 2010. Registered crops, dose rates, application frequencies and intervals for the studied pesticides may have changed since then.

### 1.2.2 Collection of pesticide property data

For each of the compounds, relevant pesticide property data were collected by DAC/CAU. All physico-chemical data, environmental fate parameters and human and ecotoxicity endpoints needed to run the ERA procedures were compiled. Data were collected for the active ingredients as well as for metabolites as far as the latter were available. The pesticide property data and their principle sources are listed in Annex 2.

Pesticide property data were compiled in an MS Excel database.

### 1.2.3 Risk assessment procedures

The environmental risk assessment procedures that were applied were those defined in the ICAMA Environmental Risk Assessment Handbook, draft version of 13 August 2010 (ICAMA, 2010). The handbook describes procedures for the risk assessment of five protection goals: groundwater (as drinking water), honey bees, silkworm, birds and aquatic organisms. In this version of the report, the ERA procedures for the first 4 protection goals will be assessed.

### 1.2.4 Statistics

All statistical comparisons were carried out using XLSTAT version 2011.1.01 (Addinsoft™).

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## 2 Groundwater in dry land agriculture

### 2.1 Principle of the risk assessment procedure

#### 2.1.1 General

The risk to human health of pesticides that have leached into groundwater is assessed by the ERA procedure developed for pesticide registration in China (ICAMA 2010). Groundwater is thus used as a drinking water resource, which makes the ultimate protection goal human health (and not environmental health).

The principle of the risk assessment procedure is that a predicted environmental concentration ( $PEC_{gw}$ ) of the pesticide active ingredient and its relevant metabolites (if applicable) are estimated in groundwater using the China-PEARL leaching model (Alterra 2009). Residues are then compared with a drinking water guidance value ( $GV_{dw}$ ) calculated according the method described by WHO (2008). Risk for human health is characterized by a risk quotient (RQ):

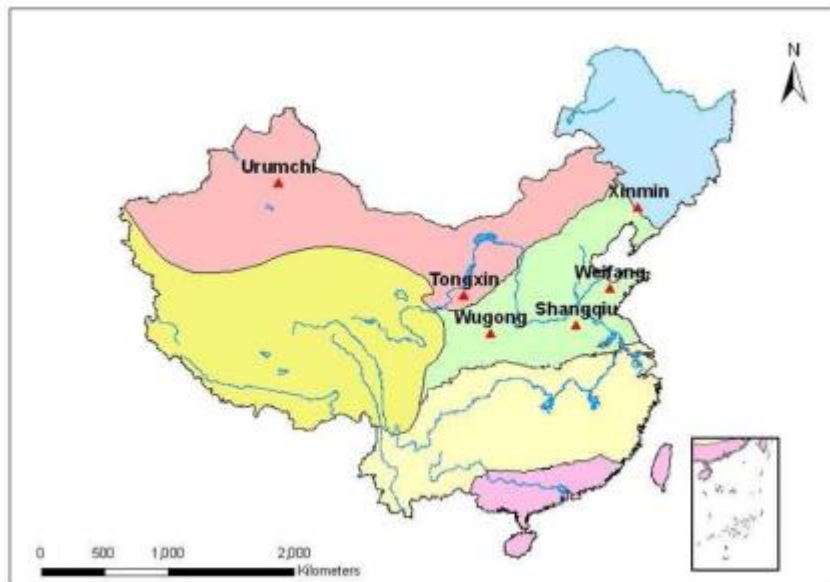
$$RQ = \frac{PEC_{gw}}{GV_{dw}}$$

If  $RQ > 1$ , then the risk to human health of the pesticide leaching to groundwater is considered unacceptable. As a result, higher tier risk assessments are triggered, risk mitigation measures are required, or the pesticide will not be registered.

#### 2.1.2 Predicted environmental concentration

The China-PEARL pesticide leaching model calculates the leaching concentration (PEC) at 1 m soil depth for each of the defined scenarios, based on yearly application(s) of the pesticide for a period of 20 years. The leaching concentration at 1 m depth can be considered a conservative estimate for the 10 m depth leaching concentration identified as protection goal.

For dry land agriculture in China pesticide leaching scenarios were defined for six locations in three geographical zones in Northern China, and for 12 crops (Table 2.1 and Figure 2.1). Details about the selection of these scenarios and the environmental and crop parameters used in each of the scenarios are provided by Ter Horst *et al.* (2014).



**Figure 2.1** Locations for the groundwater scenarios in dry land agriculture used in the China-PEARL pesticide leaching model (Ter Horst et al., 2014).

The scenario locations and the final leaching concentration were selected in such a way that they describe an overall vulnerability approximating the 99<sup>th</sup> percentile of all possible situations in dry land agriculture in China. In other words, in 99% or more of all situations of pesticides applied in dry land agriculture in China to the crops listed in Table 2.1, will pesticide concentrations in groundwater at 10 m depth be less than the PEC calculated by China-PEARL. This is considered a realistic worst case assessment.

**Table 2.1**

*Locations for the groundwater scenarios in dry land agriculture used in the China-PEARL pesticide leaching model, and associated crops (ter Horst et al., 2014).*

Scenario zone	Scenario location	Province	Average annual rainfall	annual temperature	soil organic matter content	Crop
Northeast China	Xinmin	Liaoning	572 mm	8.7 °C	1 – 2 %	Spring wheat Spring maize Soybean Sugar beet
Northwest China	Urumqi	Xinjiang	252 mm	6.7 °C	0.6 – 1 %	Spring wheat Spring maize Potatoes Cotton Alfalfa
	Tongxin	Ningxia	270 mm	8.9 °C	0.6 – 1 %	Spring wheat Spring maize Potatoes
North China	Weifang	Shandong	599 mm	12.4	0.6 – 1 %	Winter wheat Summer maize Cotton Soybean Apple
	Shangqiu	Henan	655 mm	14.1	0.6 – 1 %	Winter wheat Summer maize Cotton Soybean Tobacco
	Wugong	Shaanxi	590 mm	13.2	0.6 – 1 %	Winter wheat Summer maize Cotton Soybean Vine

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### 2.1.3 Drinking water guidance value

The drinking water guidance value (GV) used in the risk assessment was calculated according to the *WHO guidelines for drinking water quality* (WHO, 2008). The guidance value is calculated based on the Acceptable Daily Intake (ADI) of the pesticide and the water consumption of a “standard person” (60 kg body weight; 2 litres of water consumption/day; fraction of total daily intake of pesticide through drinking water is 20%).

The WHO guidelines assume that life-long consumption of drinking water with a pesticide concentration equal to the GV will not result in adverse health effects, both chronic and acute.

## 2.2 Methodology

### 2.2.1 Input data used for the calculations

All input parameters required for the dry land groundwater risk assessment are listed in Annex 3. This annex also defines the way in which each of the input parameters were chosen and used for the risk assessment. Some important parameters choices are described below.

#### **Pesticide properties**

Mandatory physico-chemical properties for both the parent and the metabolite were the aerobic degradation half-life (DegT<sub>50</sub>) in soil as well as the sorption coefficient K<sub>om</sub> (or K<sub>oc</sub>). If either the DegT<sub>50</sub> or the K<sub>om</sub> (or K<sub>oc</sub>) were not available for the compound in question, the China-PEARL model was not run, and the risk assessment could therefore not be carried out. In addition, for metabolites, the estimated formation fraction should be available. No default values were accepted for these three parameters.

Similarly, if no Acceptable Daily Intake (ADI) was available for a parent pesticide compound, the risk assessment would not be carried out. In cases where no ADI was available for a metabolite, a risk assessment was carried out however.

For a number of physico-chemical properties, default values for were used, generally the same as those applied in the European PEARL models. If more than one value for a given pesticide parameter was available in the CAU database, depending on the parameter either the geometric or arithmetic mean was used or the most conservative value. This is described in Annex 3 for each of the parameters.

#### **Application schemes**

China-PEARL was only run for the pesticide/crop combinations for which an application rate (=dosage) had been defined on the label; all uses without a defined application rate were excluded from the calculations.

For each pesticide/crop combination, the highest application rate and/or highest application frequency mentioned on the label were assessed.

Dosages expressed on the label as quantity of a.i. per ha (or per mu) were always used as priority. However, sometimes dosages were only expressed as a dilution ratio of the product, which cannot be directly converted to an area dose rate. In such cases, standard conversion factors were applied, based on general agricultural practice in China as defined by ICAMA (Annex 4).

The timing of pesticide application used for the calculations is, in principle, the one mentioned on the pesticide label. However, in many cases the label did not provide absolute or relative (to emergence or harvest) timing of application. Similarly, the interval between pesticide applications is the one mentioned on the pesticide label. However, in many cases the label did indicate more than one application, but did not provide application intervals. For these cases where application information on



the label was insufficient, default application schemes were prepared, based on information obtained by ICAMA from the regional Plant Protection Stations and/or the regional ICAs. These application schemes are detailed in Annex 5.

## Scenarios

The risk assessment for a given pesticide/crop combination was carried out for all scenario locations that included that crop.

### 2.2.2 Selection of compounds

The original list of pesticides consisted of 100 parents and 49 metabolites (Section 1.2.1). Not all of these compounds could be evaluated in the dry land groundwater risk assessment, for various reasons. These were biopesticides or rodenticides, types of pesticides for which the China-PEARL model cannot presently calculate leaching concentrations; pesticides which are only applied in rice or cabbage, for which no scenarios have been developed in China-PEARL; the absence of application details or sufficient physico-chemical data to be able to run the model; a metabolite which was only formed under anaerobic conditions; a minor non relevant metabolite; and mixtures (Table 2.2).

As a result, 67 parent compounds and 43 metabolites could be included in the analysis, which is 74% of the original set.

Table 2.2

*Reasons for non-inclusion of certain pesticides (parents and metabolites) in the dry land groundwater risk assessment. For more details see Annex 6.*

Data set	Reason for non-inclusion	Number of compounds
Total parents		100
Total metabolites		49
	Biological pesticides	1
	Rodenticides	2
	Pesticides only applied on rice ( <i>with or without sufficient physico-chemical data</i> )	12
	Pesticide only applied on cabbage or rice <i>with or without sufficient physico-chemical data</i> )	1
	Compounds with insufficient physico-chemical data	9
	Pesticides with no or incomplete application details ( <i>with or without sufficient physico-chemical data</i> )	5
	Inappropriate metabolite	1
	Metabolite is minor fraction, not relevant	1
	Mixture of active ingredients	7
	<b>Total compounds not included</b>	<b>39</b>
Total parents included		67
Total metabolites included		43

### 2.2.3 Model version

The China-PEARL model, versions 1.1.1 beta 5 of December 2009 was used for these calculations (Alterra, 2009)<sup>1</sup>.

### 2.2.4 Risk assessment

All guidance values (GV) were calculated on the basis of recent ADIs, even if this resulted in a different value from those listed in the *WHO guidelines* for the same pesticide. This approach was chosen since many WHO drinking water guidance values for pesticides are relatively old, and may not have used the latest internationally agreed ADIs.

<sup>1</sup> The beta 5 and beta 6 versions of China-PEARL have some slight differences, but this was found not to cause significant changes in predicted leaching concentrations (ter Horst, *pers. comm.*).

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Risk quotients (RQ) for parent compounds were always calculated as defined in section 2.1.1, i.e. the ratio between the leaching concentration and the drinking water guidance value (GV).

However, only for a few metabolites could a GV be calculated, because for many metabolites no ADI has been defined. In those cases, the following approach was taken:

- Leaching concentrations for all metabolites that were considered not relevant and for which no ADI had been established, were compared with the threshold of toxicological concern (TTC). The TTC is the concentration of a toxicologically non-relevant metabolite in drinking water which is expected not to have any long-term effects on human health. It was set by the EU at 0.75 µg/L (SANCO 2003). A metabolite is toxicologically considered non-relevant if it has lower biological activity than its parent, is not genotoxic and is not defined as toxic. Metabolites were identified as non-relevant according to the Footprint database (Footprint, undated).
- The risk of all metabolites that were considered relevant but for which no ADI had been established was not assessed individually, since no acceptability criteria could be defined. The only exceptions were metabolites with calculated leaching concentrations of 0 µg/L, which were considered to pose a negligible risk.
- However, for relevant metabolites without an ADI, a comparison was also made between the guidance value of the parent compound and total residues (parent & all metabolites) in the groundwater. This basically assumes that the metabolites are as toxic as the parent compound, which is likely an overestimation of risk.

For the purpose of this study, all cases which had an  $RQ > 1$  were considered to pose an unacceptable risk. All cases with an  $RQ \leq 1$  were considered not to pose unacceptable risk, though compounds with  $0.5 < RQ \leq 1$  were labelled as “possibly raising concern”.

## 2.3 Results

### 2.3.1 Data set

In total, 1182 cases of pesticides leaching to groundwater in dry land agriculture were evaluated (a case being a combination of a pesticide compound (parent or metabolite) with a scenario location and a crop). Of these, 726 cases referred to parent compounds and 456 to metabolites (Annex 7).

A summary of the results is provided in Table 2.3; more details are provided in Annex 7 and in the groundwater spreadsheet accompanying this report.

### 2.3.2 Pesticides exceeding the risk quotient

Of the 67 parent compounds, 66 had established ADIs, while for one pesticide (fenaminosulf) no ADI was available. Of the 43 metabolites, seven had established ADIs and risk for drinking water consumption could be assessed using the standard risk quotient (Section 2.2.4). Of the remaining 36 metabolites, 5 were considered not toxicologically relevant and were assessed against the threshold of toxicological concern (TTC). The risk of the other 31 (relevant) metabolites could not be evaluated individually. Leaching concentrations for these metabolites were summed and added to the parent compound, to obtain total residues in groundwater, and assessed against the GV of the parent compound.

Table 2.3 shows that in 13 cases the RQ was greater than 1, and risk to groundwater was therefore considered unacceptable in the first tier assessment. This represents 1.1% of all cases evaluated. A total of 960 cases, or 83% of all assessments, did not pose an unacceptable risk for groundwater contamination, although 20 cases were identified as being of concern. In 648 cases, the model did not calculate any pesticide residue in groundwater ( $PEC = 0$ ). No individual RQ could be calculated for 186 cases (16% of total). These were mostly metabolites for which no ADI was available. However, about 20% of this unevaluated data set had an  $RQ > 1$  when total residues were assessed.

The assessment for six pesticides out of 67 evaluated (5.5%) showed one or more cases where  $RQ > 1$ ; only for 1 pesticide were all  $RQs > 1$  (Table 2.4). For five pesticides, the parent compound was encountered at leaching concentrations exceeding the  $RQ$ ; for one pesticide it was a metabolite.

All applications of the herbicide **fomesafen** resulted in exceedance of the  $RQ$ , irrespective of the scenario location (Table 2.4). This herbicide was only assessed on soybean because it is not registered on another crop in China.

Table 2.3

*Results of the evaluation of the risk assessment for groundwater in dry land agriculture in China. Further details are provided in Annex 7.*

	Number	Percentage	
<b>Summary statistics</b>			
Number of parent compounds assessed; of which:	67	61%	
with ADI established	66		
without ADI established	1		
Number of metabolites assessed; of which:	43	39%	
relevant, with ADI established	7		
relevant, but no ADI established	31		
not relevant, with ADI established	0		
not relevant, and no ADI established	5		
Total number of compounds assessed	110		
Number of cases assessed for parent compounds	726		
Number of cases assessed for metabolites	433		
Total number of cases assessed	1159		
<b>Summary evaluation</b>			
<b>All compounds</b>			
Number of cases with $RQ > 1$ (unacceptable)	13	1.1%	of cases
Number of cases with $RQ \leq 1$ (acceptable); of which:	960	82.8%	of cases
number of cases with $0.5 < RQ \leq 1$ (concern)	20	1.7%	of cases
number of cases with $RQ \leq 0.5$	940	81.1%	of cases
Number of cases for which $RQ$ could not be calculated	186	16.0%	of cases
Number of cases with $PEC = 0$	648	55.9%	of cases
Number of compounds for which at least 1 case is $RQ > 1$ (unacceptable)	6	5.5%	of parents
Number of compounds for which all cases are $RQ > 1$ (unacceptable)	1	0.9%	of parents
Number of cases with total residues $RQ > 1$	37	3.2%	of cases
<b>Parent compounds</b>			
Number of cases (parents) with $RQ > 1$ (unacceptable)	12	1.7%	of parents
Number of cases (parents) with $RQ \leq 1$ (acceptable); of which:	697	96.0%	of parents
number of cases (parents) with $0.5 < RQ \leq 1$ (concern)	10	1.4%	of parents
number of cases (parents) with $RQ \leq 0.5$	687	94.6%	of parents
Number of cases (parents) for which $RQ$ could not be calculated	17	2.3%	of parents
<b>Metabolites</b>			
Number of cases (metabolites) with $RQ > 1$ (unacceptable)	1	0.2%	of metabolites
Number of cases (metabolites) with $RQ \leq 1$ (acceptable); of which:	282	61.8%	of metabolites
Number of cases (metabolites) with $0.5 < RQ \leq 1$	10	2.3%	of metabolites
Number of cases (metabolites) with $RQ \leq 0.5$	253	58.4%	of metabolites
Number of cases (metabolites) for which $RQ$ could not be calculated	169	39.0%	of metabolites

Two out of eight applications of **atrazine**, both in spring maize, exceeded the acceptable  $RQ$  (in Urumqi and Tongxin) (Table 4). The third application in spring maize, in Xinmin, did not exceed the  $RQ$ , although it attained a leaching concentration of concern. The lower leaching concentration in Xinmin may possibly be explained because of the higher organic matter contents in that location compared to the two first locations (ter Horst *et al.*, 2014). Applications of atrazine in summer maize, apple and vines did not exceed the acceptable  $RQ$ . However, this herbicide merits further attention since total residues exceeded the acceptable  $RQ$  for the parent in 7 out of 8 evaluated cases.

Table 2.4

Summary of cases where the risk quotient for groundwater in dry land agriculture was greater than 1 (considered unacceptable risk).

Pesticide	Compound	Number of cases with RQ>1	Scenario location(s)	Crop(s)	Exceedance of GV	Remarks <sup>1, 2</sup>
Atrazine	Parent	2 out of 8	Tongxin	Spring maize	1.2 x	Also, 4 additional cases of concern, <sup>1</sup> and 7 RQ total residues > 1
			Urumqi	Spring maize	1.5 x	
Carbendazim	Parent	2 out of 17	Weifang	Apple	5.1 x	Two dose rates and application frequencies
			Weifang	Apple	4.8 x	
Carbofuran	Parent	3 out of 15	Urumqi	Cotton	2.4 x	Also, 3 additional cases of concern, <sup>1</sup> and 3 RQ total residues > 1
			Weifang	Cotton	1.9 x	
Fomesafen	Parent	4 out of 4	Xinmin	Soybean	1.3 x	
			Shangqiu	Soybean	1.5 x	
			Weifang	Soybean	1.7 x	
			Wugong	Soybean	1.3 x	
Omethoate	Parent	2 out of 10	Urumqi	Cotton	2.2 x	Also, 1 additional case of concern
			Weifang	Cotton	2.3 x	
Thiophanate-methyl	Metabolite: carbendazim	1 out of 16	Weifang	Apple	1.4 x	Also, 2 additional cases of concern

<sup>1</sup> "Case of concern" is defined as  $0.5 < RQ \leq 1$

<sup>2</sup> RQ total residues is based on comparison of the sum of the leaching concentrations of all metabolites and the parent compound with the GV of the parent compound.

Applications of the fungicide **carbendazim** exceeded the acceptable leaching concentration only in apple (2 out of 17 evaluated cases) (Table 2.4). The RQ was exceeded by about a factor 5. In all other evaluated scenarios/crops (spring wheat, winter wheat, sugar beet, soybean and cotton) no particular concern for groundwater was identified. The high level of exceedance of the RQ in apple is probably the result of the relatively high application rate and frequency (3 – 8 applications/season) in apple compared to the other crops.

Two cases of applications of the insecticide **carbofuran** in cotton led to an exceedance of the RQ for groundwater, in Urumqi and Weifang, with a factor 1.9 to 2.4 (Table 2.4). Both cases were furrow treatments. Similar applications in Shangqiu and Wugong did not lead to exceedance of the acceptable groundwater RQ, although in Shangqiu they pose concern. Since the application rates and frequencies in cotton were the same for all scenario locations, and organic matter content and annual rainfall were similar (ter Horst et al., 2014), the difference in leaching concentrations is likely caused by the difference in cropping calendars (and thus application timing) or irrigation amounts. When carbofuran was applied as a seed dressing rather than as furrow treatment, leaching concentrations more than halved. Applications of carbofuran in sugar beet, spring maize and summer maize did not exceed the acceptable RQ.

Two cases of spray applications of the insecticide **omethoate** in cotton led to an exceedance (with about a factor 2) of the RQ for groundwater, in Urumqi and Weifang (Table 2.4). Similar applications in Shangqiu and Wugong did not lead to exceedance of acceptable leaching concentrations, although in Shangqiu they pose concern. The reason for the observed difference among scenario locations is probably similar to carbofuran. Applications of omethoate in spring wheat and winter wheat did not lead to an exceedance of the acceptable RQ.

Finally, applications in apple (Weifang) with the fungicide **thiophanate-methyl** lead to an exceedance of the acceptable RQ (Table 2.4). For this fungicide, the metabolite carbendazim (a fungicide in itself; see above), and not the parent compound exceeded the acceptable leaching concentration. The high application frequency in apple (6 sprays per season) probably explains why the RQ was exceeded. The two applications evaluated for potato (Tongxin and Urumqi) resulted in leaching concentration posing

concern. The application rate on potato was the highest of all crops. The other scenarios (vines, spring wheat, winter wheat, tobacco and sugar beet) did not exceed the acceptable groundwater RQ.

**Table 2.5**

*Summary of cases meriting attention with respect to the risk for groundwater contamination in dry land agriculture (other than those listed in Table 2.4).*

Pesticide	Compound(s) concerned	Number of cases with $0.5 < RQ \leq 1$ <sup>1</sup>	Number of cases with $RQ_{\text{total residues}} > 1$ <sup>2</sup>	Number of cases with $PEC > TTC$ <sup>3</sup>
Acetochlor	Parent & metabolites	--	16 out of 16	--
Aldicarb	Metabolite	3 out of 5	3 out of 5	--
Chlorothalonil	Metabolites	1 out of 13	8 out of 13	--
Chlorpyrifos	Metabolite	--	--	8 out of 21
Chlortoluron	Parent & metabolites	1 out of 12	--	12 out of 12
Dimethoate	Metabolite	1 out of 12	--	--
Procymidone	Parent	1 out of 2	--	--
Trichlorfon	Metabolite	3 out of 15	--	--

<sup>1</sup>  $0.5 < RQ \leq 1$  is defined as "case of concern"

<sup>2</sup>  $RQ_{\text{total residues}}$  is based on comparison of the sum of the leaching concentrations of all metabolites and the parent compound with the GV of the parent compound. This is only calculated for relevant metabolites without ADIs

<sup>3</sup> Only calculated for non relevant metabolites

### 2.3.3 Pesticides meriting attention

In addition to the six pesticides discussed above, eight other pesticides merit further attention. This is either because for one of more cases the RQ was between 0.5 and 1, or because the  $RQ_{\text{total residues}}$  exceeded 1, or because the PEC of non relevant metabolites exceeded the threshold of toxicological concern (TTC) (Table 2.5).

The TTC of 0.75 µg/L was exceeded for the non relevant metabolite of the herbicide chlortoluron in all evaluated scenarios (winter wheat, spring wheat, spring maize, summer maize). The same was true for the metabolite of the insecticide chlorpyrifos, in 8 out of 21 evaluated situations (apple, winter wheat, spring wheat, spring maize, summer maize). However, exceedance of the TTC does not necessarily imply unacceptable risk to groundwater, but it does suggest that further toxicological assessments of these metabolites would be useful.

For three pesticides, the herbicide acetochlor, the insecticide/nematicide aldicarb and the fungicide chlorothalonil, did total residues of relevant metabolites and parent compounds exceed the guidance value for the parent compound. This occurred in the majority of scenarios for all three pesticides. Again, exceedance of the parent RQ does not necessarily imply that leaching concentrations of individual metabolites are unacceptably high. However, due to the lack of metabolite-specific ADIs, this cannot be evaluated. The total residue approach can be considered a worst case risk estimate, because it assumes that toxicities of metabolites are similar to the parent compounds, which is not often the case. Again, further toxicological assessments of these metabolites would be useful to ascertain risk.

For six pesticides was the RQ for either parent or metabolite between 0.5 and 1, which though not unacceptable we interpret in this study as posing concern. The insecticide/metabolite aldicarb leads to a leaching concentration of concern for one of its metabolites, aldoxycarb, in both cotton and tobacco. The insecticide dimethoate resulted in a leaching concentration of concern of its metabolite omethoate in apple. The herbicide chlortoluron led to a concern in one application in spring maize. The fungicide chlorothalonil applied in vines resulted in a leaching concentration of concern of its metabolite



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2-amido-3,5,6-trichlo-4-cyanobenzenesulphonic acid. The fungicide procymidone similarly led to a leaching concentration of concern after application in vines. And finally, application of the fungicide trichlorfon in soybean and tobacco lead to leaching concentrations of concern for its metabolite dichlorvos. For all these pesticides, limited mitigation measures might be considered.

### 2.3.4 Effect of scenario location and crop

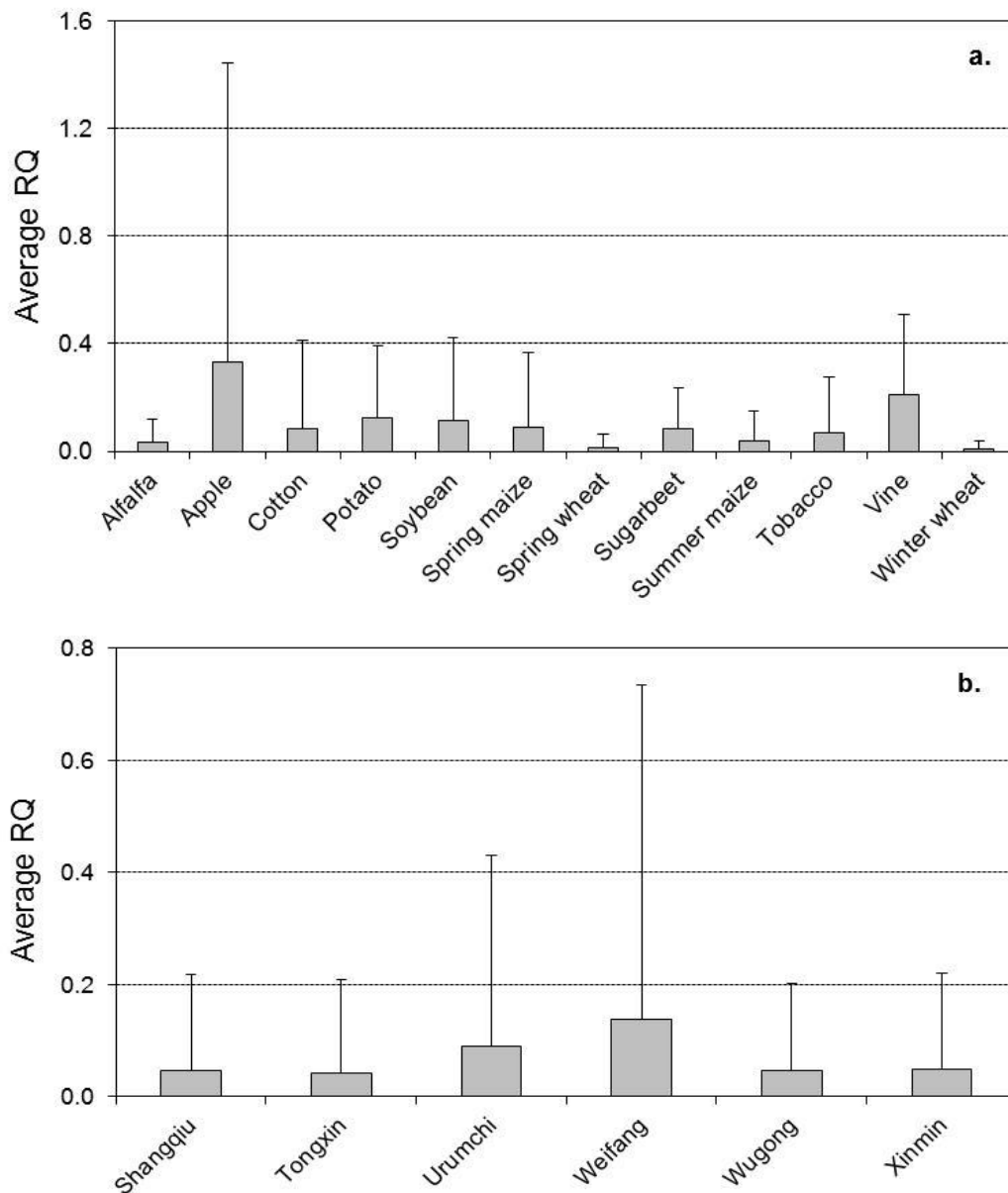
It was also assessed whether any specific crop, scenario location or combination of these two resulted in systematically higher risk quotients. This assessment was only carried out for cases for which a RQ could be calculated, i.e. parents and metabolites with an ADI.

Table 2.6 lists the average RQ values for all location-crop combinations. Figure 2.2 shows the average RQ values for groundwater contamination by crop (all locations combined) and by location (all crops combined).

A two-way ANOVA was performed with RQ values as dependent variable, and location and crop as explanatory variables. The goodness of fit statistics of the model showed that the RQs were very variable, with only a small fraction of the variability being explained by these two variables ( $R^2 = 0.05$ ;  $df = 777$ ). However, the ANOVA was statistically significant, indicating that the variables did have an effect on the RQ ( $F = 2.55$ ;  $P < 0.001$ ;  $df = 16$ ). Pairwise comparisons using Fisher's LSD test indicated that there were no significant differences in RQ values between locations, but there were differences between crops ( $P < 0.05$ ) (Table 2.6). Pesticide applications in apple has a significantly higher RQ than any in other crop. The risk to groundwater of pesticide applications in winter wheat, spring wheat and alfalfa were significantly lower than in all other crops.

The crop with the highest average RQ is apple (Figure 2.2a). Pesticide leaching to groundwater for this crop is only modelled in Weifang (Table 2.6). The high risk to groundwater for this crop-location combination is likely due to the relatively high pesticide application rates and frequencies in this crop, combined with the high annual rainfall and low soil organic matter content of the scenario location (ter Horst *et al.*, 2014).

Figure 2.2a furthermore shows the generally low risk for groundwater of pesticide applications in alfalfa, spring wheat and winter wheat. Leaching in spring or winter wheat was modelled in all three locations each and showed low average RQ values in all those six locations (Table 2.6), suggesting that the low risk is due to the crop (calendar) and the type of pesticides used.



**Figure 2.2** Average risk quotients for groundwater (a) by crop – all scenario locations combined) and (b) by location (all scenario crops combined). For statistical comparisons see Table 2.6.

Figure 2.2b shows that the RQ in Weifang, averaged over all crops, was the highest of all scenario locations. The high RQ values in apple are partly responsible for this, but in most cases where leaching in the same crop was modelled in different locations, Weifang showed the highest risk. As indicated earlier, the relatively high annual rainfall in this location (average annual precipitation of 599 mm; the highest but one) may be (partly) responsible for the high leaching potential.

Risk to groundwater were also relatively higher for the Urumqi scenario location, in spite of the low annual rainfall. It is not entirely clear why this was the case, but it may be a combination of cropping calendar, low temperature and irrigation amounts.

However, neither of these two locations were significantly different from the other from a statistical point of view (Table 2.6).

Table 2.6

Average risk quotients for groundwater, for all evaluated crops and scenario locations. Averages followed by the same letter are not significantly different (Fisher's LSD test,  $P < 0.05$ ).

Crop	ocation hangqiu	Tongxin	lrumqi	Weifang	Vugong	Kinmin	Crop average	
Alfalfa			0.034				0.034	C
Apple				0.329			0.329	A
Cotton	0.048		0.136	0.126	0.032		0.085	BC
Potato		0.111	0.139				0.125	BC
Soybean	0.110			0.141	0.087	0.111	0.112	B
Spring maize		0.096	0.127			0.048	0.090	BC
Spring wheat		0.012	0.022			0.011	0.015	C
Sugarbeet						0.084	0.084	BC
Summer maize	0.031			0.055	0.022		0.036	BC
Tobacco	0.070						0.070	BC
Vine					0.211		0.211	AB
Winter wheat	0.005			0.009	0.004		0.006	C
<b>Location average</b>	<b>0.046 a</b>	<b>0.043 a</b>	<b>0.091 a</b>	<b>0.137 a</b>	<b>0.046 a</b>	<b>0.048 a</b>	<b>0.074</b>	

Certain crops were grown in more than two scenario locations (Table 6). A notable similarity in average RQ values occurs for soybean, grown across 4 locations. Apparently, risk of pesticide leaching to groundwater in soybean is relatively independent from location. Large differences in risk to groundwater were observed, however, in cotton, with average RQ values ranging a factor 3-4 among locations. Interestingly, the average RQ for cotton in Shangqiu is relatively low, even though annual rainfall in that location (average of 655 mm) is the highest of all six scenarios.

## 2.4 Discussion

### 2.4.1 Data set

The assessment of the risk of pesticides to groundwater in dry land agriculture in China could be carried out with a large data set. Overall, risk quotients could be calculated with the procedures described in the environmental risk assessment handbook (ICAMA 2010) for 67 out of 68 parent compounds and 7 out of 48 metabolites. For an additional six metabolites, the TTC approach could be applied. This corresponded with 992 individual cases, or 84% of the total number of cases assessed. This data set can be considered sufficiently large to allow a sound evaluation of the risk assessment method and the acceptability criteria.

Data which are needed to be able to carry out the risk assessment, but which were often not available, were the ADI for relevant metabolites, the DegT<sub>50</sub> and K<sub>oc</sub> (or K<sub>om</sub>) in soil, and basic pesticide application details (dosage per surface area, application frequency, application timing).

The availability of ADIs of metabolites was mainly checked against Footprint pesticide properties database, which provides up-to-date information on information made available through European Union pesticide registration system and other reliable sources. It is not very likely that many additional national ADIs for metabolites would be available. However, the absence of ADIs for many metabolites poses a problem for groundwater risk assessment in China, since these are an essential element in the calculation of the drinking water guidance value.

Whenever chronic toxicity data are available for metabolites, these might be used to calculate an ADI. It is not realistic, however, to require pesticide companies to generate new chronic toxicity data for many metabolites. For toxicologically non relevant metabolites, the threshold of toxicological concern is a scientifically sound alternative. For relevant metabolites without an ADI we calculated total residues and compared these to the GV of the parent compound. This is likely to be, in most cases, an

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overestimate of risk. It would therefore be a good first tier approach to assess the risk for this group of metabolites.

In some cases, essential physico-chemical parameters needed to run the China-PEARL model were not available: the aerobic DegT<sub>50</sub> in soil, the K<sub>oc</sub> or K<sub>om</sub> and the formation fraction in soil (in the case of metabolites). In this study, no risk assessment was carried out for compounds that lacked these parameters. Both the DegT<sub>50</sub> and K<sub>oc</sub> are presently mandatory data requirements for registration in China, and therefore such data should in future not be lacking for new pesticides being proposed for registration.

Basic pesticide application data (dosage per surface area, application frequency, application timing) were also sometimes missing on the pesticide label, which was used as the main data source for these parameters in this study. This does not necessarily mean that such information was not provided in the pesticide registration dossier, but those were not accessed. It is strongly recommended, however, that basic pesticide application parameters are listed on the pesticide label, as they also form the basis for good agricultural practice.

## 2.4.2 First tier risk assessment

Table 3 shows that in 13 cases the RQ was greater than 1, and risk to groundwater was therefore considered unacceptable in the first tier assessment. This represents only 1.1% of all cases evaluated. A total of 979 cases, or 83% of all assessments, did not pose an unacceptable risk for groundwater contamination. Therefore, overall only a very limited fraction of the pesticides did not pass the first tier acceptability criterium.

It should be underlined that this is probably an underestimate of the number of pesticides not passing the groundwater acceptability criterium, because in 190 cases (16% of total) no RQ could be calculated, principally because no ADIs were available for metabolites. It is likely that some of these cases would have resulted in unacceptable risk.

## 2.4.3 Risk mitigation measures

If the risk quotient is greater than one, various risk mitigation options can be considered to reduce the risk of groundwater contamination to an acceptable level. Based on a review of risk mitigation options (Tao and Van der Valk, 2011), the following risk mitigation measures were considered to be the most realistic and feasible under Chinese agronomic conditions:

- reduction of application rate (dosage)
- reduction of application frequency
- restriction to specific formulations that result in less leaching\
- refusal of registration

Risk mitigation options will therefore be assessed for the 13 cases of exceedance of the acceptable RQ listed in section 2.3.2. A summary of this assessment is provided in Table 2.7.

Leaching concentration after two out of eight applications of the herbicide **atrazine**, both in spring maize, exceeded the acceptable RQ (in Urumqi and Tongxin) (Table 2.4) and a third case in this crop resulted in a level of concern. Atrazine was applied once at 2.88 kg a.i./ha, 7 days pre-emergence, to the soil surface. A reduction of application frequency is thus not feasible. Atrazine in spring maize is not recommended on the label at lower dosages than the one modelled, however, in summer maize a maximum application rate of 2.25 kg a.i./ha is listed (a 22% reduction compared to spring maize). When China-PEARL was rerun with this lower application rate in spring maize, the RQ ranged from 0.9 to 1.1. Other formulations of this herbicide, less prone to leaching, are probably not commercially available. In view of the above, the risk of atrazine applied in spring maize reaching unacceptable concentrations in groundwater remains high. Refusal of registration of atrazine in spring maize may be possible because, within the top-100 list of pesticides in China used for this study, another five herbicides are listed for pre-emergence use in spring maize.

Applications of the fungicide **carbendazim** exceeded the acceptable leaching concentration in apple, in 2 out of 17 evaluated cases (Table 2.4). Carbendazim was applied to the crop canopy, either at a dose rate of 1.5 kg a.i./ha (8 times during the season) or 2.25 kg a.i./ha (3 times during the season). The RQ was exceeded by about a factor 5 in both cases. Given the high degree of exceedance of the RQ, it is unlikely that a reduction in dose rate and/or application frequency would lead to acceptable concentrations in groundwater. Similarly, a change in formulation type (for canopy sprays) would quite certainly not lead to a sufficient reduction in risk. Refusal of registration of the use carbendazim on apple would be an option. At least one other fungicide was available in the top-100 list of pesticides in China recommended against the same disease for which carbendazim was recommended<sup>2</sup>.

Two cases of applications of the insecticide **carbofuran** in cotton led to an exceedance of the RQ for groundwater, in Urumqi and Weifang, with a factor 1.9 to 2.4 (Table 2.4). Both cases were furrow treatments at 0.9 kg a.i./ha, twice in the growing season. Similar applications in Shangqiu and Wugong did not lead to exceedance of the acceptable groundwater RQ, although in Shangqiu they posed concern. When the insecticide **carbofuran** was applied as a seed dressing rather than as furrow treatment, once at the same dose rate as the furrow treatment, leaching concentrations more than halved and did not exceed the acceptable RQ. Therefore, a change of formulation, application type and frequency would be feasible risk reduction methods for this insecticide.

Application of the herbicide **fomesafen** in soybean, sprayed once, 14 days after emergence at 0.56 kg a.i./ha, resulted in an exceedance of the guidance value in all four scenario locations where soybean is grown (Table 2.4). The GV was exceeded by a factor 1.3 to 1.7, depending on location. There is no information available as a basis for a reduction in application rate, while a reduction in application frequency is not possible. Similarly, a change in formulation is not likely to reduce leaching concentrations sufficiently. The only option available would be a refusal of registration of this herbicide in soybean. Two other post-emergence herbicides are listed in the top-100 pesticides in China which might be used as alternative to fomesafen.

Two cases of spray applications of the insecticide **omethoate** in cotton, at a dose rate of 0.6 kg a.i./ha, sprayed twice in the growing season against aphids, led to an exceedance (with about a factor 2) of the RQ for groundwater, in Urumqi and Weifang (Table 2.4). Similar applications in Shangqiu and Wugong did not lead to exceedance of acceptable leaching concentrations, although in Shangqiu they pose concern. There was no information available to justify a reduction in dose rate or application frequency, as a means to reduce risk. It is possible that a change in formulation might lead to a sufficient reduction in leaching concentrations, although it is not likely to reduce risk sufficiently and no information was available to test this. The registration of omethoate could be refused in cotton, because at least eight other insecticides are available in the top-100 list against aphids which did not lead to exceedance of the acceptable RQ.

Applications in apple (Weifang) with the fungicide **thiophanate-methyl**, at a dose rate of 1.3 kg a.i./ha, six times in the growing season, lead to an exceedance of the acceptable RQ (Table 4). For this fungicide, the metabolite carbendazim (a fungicide in itself; see above), and not the parent compound exceeded the acceptable leaching concentration, with a factor 1.4. There was no information available to justify a reduction in dose rate or application frequency, as a means to reduce risk, although this might possible without a reduction in efficacy. Modelling application of thiophanate-methyl 1.0 kg a.i./ha – 6 times in the season, or 1.3 kg a.i./ha – 4 times in the season, both resulted in RQ values of 1.1, which still indicates risk. A change in formulation might lead to a sufficient reduction in leaching concentrations, although it is not likely to reduce risk sufficiently and no information was available to test this.

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<sup>2</sup> During this study, the aerobic DT<sub>50</sub> in soil cited in the Footprint database was amended downwards from 260 days to 34 days. The calculations discussed above were still done with the higher value. When the lower DT<sub>50</sub> value is used, no cases did exceed the acceptable RQ for groundwater anymore.



Table 2.7

*Summary of the possibilities to apply risk mitigation measures to reduce the risk of groundwater contamination to acceptable levels.*

Compound	Mitigation measure Reduce application rate	Reduce application frequency	Restrict to formulations with less leaching	Refuse registration for use on crop in question
Atrazine	22% reduction did not result in clearly acceptable leaching concentrations	Not possible	Not possible	Possible (alternatives available)
Carbendazim	Not likely to reduce risk sufficiently	Not likely to reduce risk sufficiently	Not likely to reduce risk sufficiently	Possible (alternatives available)
Carbofuran	Not possible	Possible	Possible (seed dressing)	Possible, but may not be needed
Fomesafen	Not possible	Not possible	Not likely to reduce risk sufficiently	Possible (alternatives available)
Omethoate	Not possible	Not possible	Not likely to reduce risk sufficiently	Possible (alternatives available)
Thiophanate-methyl	Not likely to reduce risk sufficiently	Not likely to reduce risk sufficiently	Not likely to reduce risk sufficiently	Possible (but alternatives available?)

In all the above cases where the acceptable RQ has been exceeded, higher tier risk assessment could also be applied to further assess the level and acceptability of any risk of groundwater contamination. The present options available for higher tier assessments of groundwater leaching risk in China are relatively limited (ICAMA 2010). However, several methods for higher tier risk assessment for groundwater have been developed in Europe (Focus, 2009) and these merit further attention in the future for China as well.

## 2.5 Acceptability criteria

The principle of the risk assessment for pesticides in groundwater in dry land agriculture in China is that the overall 99<sup>th</sup> percentile leaching concentration in groundwater at 10 m depth should not exceed the drinking water guidance value established according to WHO guidelines.

The WHO guidelines for drinking water quality (WHO 2008), which describe the method to establish guidance values (GV), are presently the only international standards for pesticides in drinking water (van Eck, 2004). The WHO GV is a toxicologically derived maximum residue limit (MRL), using the no-observed-adverse-effect-level (NOAEL) obtained from chronic mammalian toxicity tests as a basis.

The US-EPA applies a so-called drinking water limit of comparison (DWLOC) as a maximum acceptable groundwater concentration in the first tier(s) of its risk assessment. Like the WHO GV, the DWLOC is a toxicologically based standard calculated on the basis of acute and/or chronic mammalian toxicity test data.

The European Community established about 30 years ago a generic MRL for pesticide residues in drinking water at what was effectively a zero concentration level (i.e. 0.1 µg/L). This was a political choice and not one based upon toxicological considerations. It still applies presently as the groundwater standard for the registration of pesticides. This European MRL is generally considerably stricter than the GV proposed for China. On the other hand, in the European system, the overall 90<sup>th</sup> percentile leaching concentration is used for comparison with the standard, which is less strict than the scenarios developed for China. Overall, however, the European risk assessment procedure for pesticides in groundwater is likely to be stricter than the one proposed for China or applied in the USA.

The present study indicated that only a limited fraction of the evaluated groundwater leaching cases exceeded the acceptable RQ. It was also shown that for several of these cases realistic risk mitigation measures might be taken to reduce the risk for groundwater contamination to an acceptable level. Furthermore, there is presently no convincing scientific justification to deviate from the proposed leaching scenarios and guidance values.

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Therefore, in conclusion, on the basis of the study described in this chapter, there does not seem to be a reason to amend the risk assessment procedure for dry land agriculture proposed in the ICAMA ERA Handbook (ICAMA 2010), nor the proposed acceptability criteria for groundwater risk.



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## 3 Honeybees

### 3.1 Principle of the risk assessment procedure

#### 3.1.1 General

The risk of pesticides to honey bees is assessed by the ERA procedure developed for pesticide registration in China (ICAMA, 2010). Risk to honeybees is evaluated for two scenarios: i. sprayed pesticides (both systemic and non-systemic products) and ii. systemic pesticides applied as soil treatment or seed treatment. For sprayed and systemic pesticides, both scenarios are evaluated.

The principle of the risk assessment procedure is that risk for honey bees is characterized by a risk quotient (RQ):

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

with PEC being the predicted exposure concentration and PNEC the predicted no effect concentration. If  $RQ > 1$ , then the risk of the pesticide to honey bees is considered unacceptable. As a result, higher tier risk assessments are triggered, risk mitigation measures are required, or the pesticide will not be registered.

#### 3.1.2 Predicted exposure concentration

The predicted exposure concentration (PEC) used for sprayed pesticides is the application rate of the pesticide (in g a.i./ha) divided by an extrapolation factor of 50. This approach is based on empirical evidence from field observations of bee mortality incidents in Europe (EPPO, 2010).

The predicted exposure concentration (PEC) for systemic pesticides is an estimate of pesticide residues in pollen or nectar.

#### 3.1.3 Predicted no effect concentration

The predicted no effect concentration (PNEC) used for sprayed, non-systemic, pesticides is the acute contact or oral  $LD_{50}$  established for the honeybee.

The predicted no effect concentration (PNEC) used for systemic pesticides is the acute oral  $LD_{50}$  established for the honeybee, divided by an uncertainty factor of 10 to allow for extrapolation from acute to chronic effects.

#### 3.1.4 Protection goal

The above risk assessment procedure aims to ensure that no effect will occur on the long-term survival of the honeybee colony. Both European and Asian honeybees are expected to be protected by this approach.

However, this procedure does not cover the possible impact of insect growth regulators, or pesticides with similar modes of action, which may have a specific effect on development of bee brood. Such effects are covered by higher tier assessments in the ICAMA ERA handbook.

More details on the exact calculations carried out for the risk assessments are provided in the handbook (ICAMA, 2010).

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## 3.2 Methodology

### 3.2.1 Input data used for the calculations

All input parameters required for the honeybee risk assessment are listed in Annex 8. This annex also defines the way in which each of the input parameters were chosen and used for the risk assessment. Some important parameter choices are described below.

#### **Crops, dose rates and application frequencies**

Given the large number of crops and associated application schemes in China where honeybees may be exposed to pesticides, for this study a selection was made based on the following criteria: The crops selected from the CAU database were those having the highest application rate (dosage) and the highest application frequency and, in case more dosages were recommended, also the lowest application rate with the lowest frequency. In this manner, the full range of exposure to the pesticide was expected to have been covered, including worst case situations.

Within the ICAMA ERA handbook, the application frequency is not used for the RQ calculations. However, application frequency was used in the interpretation of the results. In particular, RQ values approaching 1 were considered meriting particular attention when application frequency was high and the application interval narrow.

Only pesticides applied as sprays (both systemic and non-systemic), or systemic pesticides applied otherwise (generally to the soil or the seed), were assessed.

#### **Exposure probability**

For the purpose of this study, it was assumed that honeybees could be exposed to pesticides in all selected crops as defined in the paragraph above. No distinction in crop attractiveness and period of flowering and pesticide application was made for the first tier assessment. Therefore, this should be considered as worst case. As a second step, the potential crop attractiveness to honeybees was included in the assessment, however.

#### **Toxicity data**

Acute oral and contact LD<sub>50</sub> values were generally collected from the EU Footprint database (Footprint, undated) and the Pesticide Manual (Tomlin, 2010). Results from all acute tests (24h, 48h, 72h and 96h) were used interchangeably. When more LD<sub>50</sub> values were available for the same type of test, the lowest value was used in the assessment. For the scenario representing sprayed pesticides, the risk assessment was carried out selecting the lowest of the oral or contact LD<sub>50</sub> values. For the scenario representing systemic pesticides, only oral LD<sub>50</sub> values were used.

#### **Residue data**

For the scenario representing systemic pesticides, a default residue value of 1 mg a.i./kg pollen or nectar was always used, although it is recognized that this is a worst case residue concentration (ICAMA, 2010; EPPO, 2010). However, measured residues in pollen or nectar are rarely available.

### 3.2.2 Selection of compounds

The risk of only parent pesticide compounds was assessed; no risk assessment for metabolites was carried out, as this is not general practice in Europe (EPPO, 2010), nor recommended in the ICAMA ERA handbook (ICAMA, 2010). The original list of pesticides consisted of 100 parents compounds (Section 1.2.1). Not all of these compounds could be evaluated for various reasons. These were: rodenticides, which normally do not expose honeybees; pesticides for which no honeybee acute toxicity data were available; pesticide mixtures; and pesticides for which no appropriate application scheme was defined (Table 3.1).

In total, 82 parent compounds could therefore be included in the analysis.



Table 3.1

*Reasons for non-inclusion of certain pesticides in the honey bee risk assessment. For more details see Annex 10.*

Data set	Reason for non-inclusion	Number of compounds
Total compounds		100
	Biological pesticides	1
	Rodenticides	2
	Mixtures of active ingredients	4
	No LD <sub>50</sub> values available (with or without application schemes)	6
	No appropriate application schemes available	3
	Non-systemic pesticides applied to soil	2
	<b>Total compounds not included</b>	<b>18</b>
Total compounds included		82

## 3.3 Results

### 3.3.1 Data set

A total of 82 pesticides were included in the evaluation of the honeybee risk assessment procedure. Of these, 39 (48%) were insecticides, 18 (22%) were herbicides, 17 (21%) were fungicides, 5 (6%) were acaricides and 3 (4%) were plant growth regulators (Table 3.2).

Only 2 compounds were insect growth regulators (both insecticides), while 46 compounds were systemic (i.e. the pesticide being absorbed and translocated in the plant tissue). Seventy-nine pesticides were sprayed to the crop canopy and thus evaluated through the spray scenario. Two systemic herbicides and one systemic insecticide were only applied to the soil in the data set and therefore only evaluated through the systemic pesticide scenario. For eight systemic pesticides (17% of all systemics) no oral LD<sub>50</sub> values were available, and these could therefore only be assessed through the sprayed pesticide scenario.

In total, 215 cases of pesticide risk to honeybees were evaluated (a case being a combination of a pesticide with dose rate and a crop).

A summary of the results is provided in Table 3.2; more details are provided in Annex 11 and in the honeybee spreadsheet accompanying this report.

### 3.3.2 Pesticides exceeding the risk quotient

The assessments of 34 pesticides (41% of the total) resulted in all RQ<sub>spray</sub> values being greater than 1. This means that even at the lowest dose rate, the risk of these pesticides to honeybees was not acceptable (Table 3.2). Not surprisingly, most of these compounds were insecticides; for 84% of insecticides, all RQ<sub>spray</sub> values exceeded the acceptable limit. The other groups of pesticides showed considerably less risk, with at most 20% of acaricides showing all RQ<sub>spray</sub> values > 1.

For 57% of the pesticides, the RQ<sub>spray</sub> and/or the RQ<sub>syst</sub> exceeded the acceptable level in at least one case per pesticide. Again, this was in particular so for insecticides, where 95% of pesticides had at least 1 case exceeding the acceptable RQ<sub>spray</sub>. Other groups of pesticides showed less risk, but exceedance of at least one RQ<sub>spray</sub> still occurred for 17 to 33% of the compounds (Table 3.2).

Table 3.2

Results of the evaluation of the risk assessment for honeybees in China. Further details are provided in Annex 11. If  $RQ > 1$ , the risk is considered not acceptable.

	Number (percentage) of which:					
	All pesticides	insecticides	herbicides	fungicides	acaricides	PGRs
<b>Summary statistics</b>						
Total compounds assessed (percentage of all)	82	39 (48%)	18 (22%)	17 (21%)	5 (6%)	3 (4%)
of which:						
insect growth regulators	2	2	0	0	0	0
pesticides sprayed to crop canopy	79	38	16	17	5	3
systemic pesticides	46	17	16	10	0	3
pesticides applied on at least 1 crop attractive to bees	57	31	8	11	5	2
Total cases assessed	215					
<b>Summary evaluation</b>						
<i>All crops</i>						
Total cases with $RQ_{\text{spray}} > 1$	112					
Pesticides with at least 1 $RQ_{\text{spray}} > 1$ and/or $RQ_{\text{syst}} > 1$ (percentage of total compounds)	47 (57%)	37 (95%)	3 (17%)	5 (29%)	1 (20%)	1 (33%)
of which:						
pesticides with at least 1 $RQ_{\text{spray}} > 1$	46	36	3	5	1	1
pesticides with all $RQ_{\text{spray}} > 1$	34	31	1	1	1	0
pesticides with $RQ_{\text{syst}} > 1$	12	12	0	0	0	0
Pesticides with all $RQ_{\text{spray}} \leq 1$ and $RQ_{\text{syst}} \leq 1$ (percentage of total compounds)	33 (40%)	2 (5%)	15 (83%)	12 (71%)	4 (80%)	2 (67%)
<i>Crops attractive to bees</i>						
Total cases with $RQ_{\text{spray}} > 1$	48					
Pesticides with at least 1 $RQ_{\text{spray}} > 1$ and/or $RQ_{\text{syst}} > 1$ (percentage of total compounds on attractive crops)	35 (61%)	30 (98%)	1 (13%)	3 (27%)	1 (20%)	0 (0%)
of which:						
pesticides with at least 1 $RQ_{\text{spray}} > 1$	34	29	1	3	1	0
pesticides with all $RQ_{\text{spray}} > 1$	4	3	0	0	1	0
pesticides with $RQ_{\text{syst}} > 1$	8	8	0	0	0	0
Pesticides with all $RQ_{\text{spray}} \leq 1$ and $RQ_{\text{syst}} \leq 1$ (percentage of total compounds on attractive crops)	22 (39%)	1 (2%)	7 (87%)	8 (73%)	4 (80%)	2 (100%)

Forty-six of the evaluated compounds (56% of the total) were systemic. This included insecticides, herbicides, fungicides and plant growth regulators. Of these systemic pesticides, about a quarter exceeded the acceptable  $RQ_{\text{syst}}$ , all being insecticides. So even though quite a few herbicides and fungicides were systemic, their risk to honeybees was always acceptable.

In all cases where it could be compared, both the  $RQ_{\text{syst}}$  and the  $RQ_{\text{spray}}$  were  $> 1$ . This means that the scenario for sprayed pesticides was also protective for systemic pesticides.

Two pesticides evaluated were insect growth regulators (IGRs) (buprofezin and chlorbenzuron). According to the ICAMA ERA handbook, a higher tier evaluation is immediately triggered for pesticides with this mode of action. In one of the two cases, the  $RQ_{\text{spray}}$  would have been considered acceptable, and no higher tier testing evaluation have been triggered. The  $RQ_{\text{spray}}$  is therefore not necessarily sufficiently protective for this group of pesticides, and the need for specific testing/evaluation for IGRs, as indicated in the handbook, is supported.

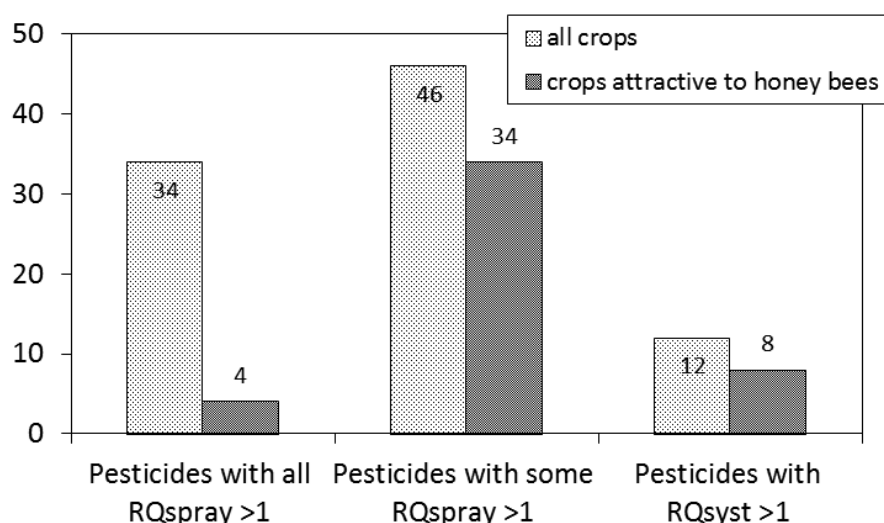
### 3.3.3 Refinement evaluations

#### Attractiveness of the crop to honeybees

In the risk assessment presented above, it was considered that all the crops were attractive to honeybees, but this is not necessarily the case. Crops are generally attractive to honeybees as a source of pollen or nectar. However, some plants that are intrinsically not attractive to bees may be visited due to extra-floral nectaries, e.g. in field beans, or due to honeydew produced by aphids on crops otherwise not attractive to bees (EPPO, 2010).

Annex 9 list crops that are known to be visited by honey bees, based on the compilation made by Klein *et al.* (2007). This was a global assessment, and as such also relevant for China. However, the list has not yet been updated with any specific Chinese data. The list does not take into account situations where an intrinsically unattractive crop grows together with weeds that are attractive to honeybees. If the list in Annex 9 is applied to the 215 cases evaluated in this study, 101 cases (47%) concerned crops that are attractive to honeybees.

Table 3.2 and Figure 3.1 shows the number of pesticides exceeding the acceptable RQ if the risk assessments are only done for crops which are attractive to honeybees. Risk was considered absent for crops which are not normally visited by honeybees.



**Figure 3.** Effect of including crop attractiveness to bees in the risk assessment. Compared are the number of compounds with  $RQ > 1$  when risk assessment is done for all crops with the those when risk assessment is only done for crops that are attractive to honeybees.  $RQ_{\text{spray}}$  = risk quotient for sprayed pesticides;  $RQ_{\text{syst}}$  = risk quotient for systemic pesticides. (More details are provided in Table 3.2 and Annex 11).

The number of compounds with all  $RQ_{\text{spray}} > 1$  drops from 34 to 4 (an 88% reduction); the number of compounds with at least 1  $RQ > 1$  drops from 46 to 34 (a 26% reduction); and the number of compounds with  $RQ_{\text{syst}} > 1$  drops from 12 to 8 (a 33% reduction). Therefore, taking into account the attractiveness of crops to honeybees reduces the number of pesticides/cases exceeding the acceptable RQ very considerably. It should be noted though that for this study a limited number of cases was selected, and that the reduction of exceedance of the RQ is indicative and may be somewhat different if a larger data set is assessed.

### Timing of application

The timing of application in relation to the time of flowering of the crop is another parameter which can be used to refine the risk assessment. In this study, it was assumed that pesticide application occurred during flowering and thus when honeybees would be present in the crop. This may not always be the case. However, detailed information to confirm whether flowering and application would coincide was not available for this study.

## 3.4 Discussion

### 3.4.1 Data set

The assessment of the risk of pesticides to honeybees in China was carried out with a considerable data set. Overall, risk quotients could be calculated with the procedures described in the environmental risk assessment handbook (ICAMA 2010) for 82 pesticides. This corresponded with 215

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individual cases. This data set can be considered sufficiently large to allow a good evaluation of the risk assessment method and the acceptability criteria. It is not expected that an assessment of a larger data set would lead to fundamentally different conclusions.

Data which are needed to be able to carry out the risk assessment, but which were often not available, were the acute LD<sub>50</sub> values. In 39% or 46% of the cases, either the contact or the oral LD<sub>50</sub> respectively, were not available; in 7% of cases, neither was available (Annex 11 and Table 3.1).

Furthermore, basic pesticide application data (dosage per surface area, application frequency, application timing) were also sometimes missing on the pesticide label, which was used as the main data source for these parameters in this study. This does not necessarily mean that such information was not provided in the pesticide registration dossier, but those were not accessed. It is strongly recommended that basic pesticide application parameters are listed on the pesticide label, as they also form the basis for good agricultural practice.

### 3.4.2 First tier risk assessment

The evaluation carried out in chapter 3.3 indicates that a relatively large fraction of pesticides would pose an unacceptable risk for some or all of the crops on which it is submitted for registration. This is in particular the case for insecticides. If crop attractiveness is taken into account, 29 out of 30 insecticides evaluated (98%) resulted in RQ > 1 for one or more crops (Table 3.2); 10% of the insecticides showed an exceedance of the acceptable RQ in all crops.

It should be stressed that these results are very similar to the situation encountered in Europe or the USA, where a large fraction of pesticides being registered poses a high risk to honeybees in the first tier assessment. Generally, as a next step in the risk assessment, higher tier tests and evaluations are carried out and/or risk mitigation is done through labelling. Very few pesticides are refused registration only because of risk to bees in these regions.

The present evaluation of the risk assessment method primarily covers sprayed pesticides (both systemic and not systemic). The risk of systemic pesticides applied to the soil or as seed treatment has not been evaluated yet in much detail. The risk to honeybees from insect growth regulators could not be assessed either, as it requires specific toxicity test data, which are presently not a standard data requirement by ICAMA.

### 3.4.3 Risk mitigation measures

If the risk quotient is greater than one, various risk mitigation options can be considered to reduce the risk for honeybees to an acceptable level. Based on a review of risk mitigation options (Tao and Van der Valk, 2011), the following risk mitigation measures were considered to be the most realistic and feasible under Chinese agronomic conditions:

- reduction of application rate (dosage)
- requirement of a label statement warning about toxicity to bees
- refusal of registration in specific crops
- refusal of registration in all crops

#### **Reduction of application rate**

Given the way that pesticides and crops were selected for this study (highest and lowest application rates and frequencies, for each pesticide), it is not possible to assess for each pesticide whether the application rate on a specific crop can be reduced without loss of efficacy. Figure 3.1 indicates, however, that for 34 out of 82 pesticides no RQ values met the acceptability criteria (including those for the lowest application rates) and therefore a reduction of dosage is unlikely to be possible for these compounds on any crop.

Another way of evaluating the feasibility for a reduction in application rate as a risk mitigation measure is to assess the level of exceedance of the RQ. For the purpose of this study, it was

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considered that if the  $RQ_{\text{spray}}$  was exceeded by a factor 2 or more, risk mitigation through dose reduction would be very unlikely to succeed without a clear adverse effect on efficacy. Of the total of 112 cases where the  $RQ_{\text{spray}} > 1$  (Table 3.2), 103 cases showed an  $RQ_{\text{spray}} > 2$ . Therefore, in more than 90% of the cases exceeding the acceptable RQ, a dose reduction would likely not be a feasible risk mitigation measure.

This assessment does not apply to the systemic pesticides, because the (worst case) RQ calculation is independent of application rate.

### **Refusal of registration in specific crops**

The limitation of a pesticide registration to crops where the risk to bees would be acceptable, and refusal in crops where the risk is too high, is another possible risk mitigation measure. A recent survey among OECD countries showed that label restrictions are the preferred regulatory response for reducing risks to pollinators in 94% of surveyed countries. However, Tao and van der Valk (2011) suggest that such restrictions may be more difficult to apply in the Chinese situation since label restrictions might not be followed and are difficult to enforce.

It was indicated in section 3.3.3 that almost half of the cases evaluated in this study concerned crops not attractive to honeybees. This suggests that a considerable fraction of the cases that would be submitted for registration do not pose a high risk to honeybees because they concern crops that would not be visited much by the bees. For those crops, registration could be allowed.

### **Label statements**

The requirement of label statements warning about toxicity of the pesticide to bees and recommending risk reduction measures, can also be applied as risk mitigation measure. Risk reduction recommendations would typically ask farmers to avoid spraying when crops are flowering or at the time of day when bees are foraging, or ask beekeepers to temporarily close their hives. Such advisory labelling is at present applied by 71% of OECD countries (OECD, 2010).

As indicated above, the potential effectiveness of such measures could not be assessed in any detail in this study. However, the review by of risk mitigation measures feasible in China indicates that this measure would have only limited applicability because farmers would often not respect such advice (Tao and van der Valk, 2011).

## **3.5 Acceptability criteria**

The principle of the risk assessment method evaluated in this study is that no effect will occur on the long-term survival of the honeybee colony. The risk assessment procedure used in the ICAMA handbook is basically the same as the one applied in Europe, and the acceptability criteria (RQ values triggering higher tier assessment or risk mitigation) are also the same. This implies that the risk of pesticides to Asian honeybees (e.g. *Apis cerana*) is considered similar to the European honeybees (*Apis mellifera*).

Even though a large fraction of pesticides, and in particular of insecticides, does not pass the acceptable RQ value in the first tier assessment, this is not fundamentally different from the situation encountered in Europe or the USA.

Mineau *et al.* (2008) recently carried out the most extensive validation of the honeybee risk assessment procedure applied in Europe and proposed also for China. They confirmed that there seems to be negligible risk from applications of pesticides with an  $RQ_{\text{spray}} < 1$ . Therefore, at this stage, there is no scientific justification to change the acceptability criteria used in the ICAMA risk assessment procedure. However, while there is not data to suggest that Asian honeybees are more sensitive to pesticides than the European honeybee, it is recommended that this is validated through comparative laboratory toxicity tests and (semi-)field studies.

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In the European risk assessment procedure, exceedance of the acceptable RQ values triggers higher tier tests and/or refined risk assessments. In China, higher tier testing procedures for honeybees are being developed and/or locally validated, but are not yet included in the data requirements. Most Chinese pesticide companies or contract laboratories do not have the expertise and experience to carry out higher tier testing.

One way of limiting the requirement for higher tier testing, at least until these studies can be commonly carried out in China, is to apply an upper RQ threshold above which the pesticide can be considered to pose a high risk to bees, irrespective of the results of further higher tier tests. Originally, EPPO (2002) has set such an upper threshold at  $RQ_{\text{spray}} > 50$ , but since the EU does not apply upper thresholds in its decision making, it was deleted from the most recent version of the risk assessment procedure (EPPO, 2010).

More recently, Mineau *et al.* (2008) concluded that beyond an RQ of 8, the risk of recording hive mortality incidents is extreme (50% probability) for any pesticide in broad use. Therefore, ICAMA could consider not to require higher tier tests for pesticides with  $RQ_{\text{spray}} > 8$ , but immediately decide either to refuse or restrict registration, or require advisory labelling.

In conclusion, on the basis of the study described in this chapter, there does not seem to be a reason to amend the risk assessment procedure for honey bees proposed in the ICAMA ERA Handbook (ICAMA 2010), nor the proposed acceptability criteria. However, an upper trigger, set at  $RQ > 8$ , may be considered by ICAMA to limit the requirement for certain second tier studies.

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## 4 Silkworm

### 4.1 Principle of the risk assessment procedure

#### 4.1.1 General

The risk of pesticides to silkworm is assessed by the ERA procedure developed for pesticide registration in China (ICAMA, 2010). Risk to the silkworm is assessed for two scenarios: i. pesticides applied to mulberry fields from which leaves are harvested as silkworm food, and ii) pesticides applied to other crops on fields adjacent mulberry fields which may drift onto mulberry. Both scenarios only concern sprayed pesticides.

The principle of the risk assessment procedure is that risk for silkworm is characterized by a risk quotient:

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

with PEC being the predicted environmental concentration and PNEC the predicted no effect concentration. If  $RQ > 1$ , then the risk of the pesticide to silkworm is considered unacceptable. As a result, higher tier risk assessments are triggered, risk mitigation measures are required, or the pesticide will not be registered.

#### 4.1.2 Predicted environmental concentration

The predicted environmental concentration (PEC) used in both scenarios is an estimate of the residue of the pesticide on mulberry leaves (in mg a.i./kg fresh vegetation), calculated immediately after spraying, or after the last pesticide application if the crop is treated more than once.

For the first scenario, pesticide application in the mulberry field, the PEC is calculated on the basis of the application rate and a worst case residue unit dose (RUD) obtained from an international database.

For the second scenario, pesticide application to a crop adjacent a mulberry field, a drift factor is taken into account to estimate the PEC. The PEC is then calculated for the first row of mulberry plants adjacent to the treated crop, and for the second row. Residues are estimated in the top part of the plants, where leaves are generally harvested.

In both scenarios, the effect of a pre-harvest period for the mulberry leaves can be taken into account.

#### 4.1.3 Predicted no effect concentration

The predicted no effect concentration (PNEC) used for both scenarios is the  $LC_{50}$  obtained from an acute dietary laboratory toxicity test with silkworm. An uncertainty factor of 50 is applied to the acute  $LC_{50}$  to extrapolate from acute to chronic toxicity and to take into account inter-hybrid variability (Sun *et al.*, 2010, 2012).

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#### 4.1.4 Protection goal

The risk assessment procedure aims to ensure that the application of the pesticide will not cause an effect on the quality and quantity of commercial silk production. All hybrid strains of the silkworm that are widely used in China are expected to be protected by this approach.

More details on the exact calculations carried out for the risk assessments are provided in the ERA handbook (ICAMA, 2010).

## 4.2 Methodology

### 4.2.1 Input data used for the calculations

All input parameters required for the silkworm risk assessment are listed in Annex 12. This annex also defines the way in which each of the input parameters were chosen and used for the risk assessment. Some important parameter choices are described below.

#### **Crops, dose rates and application frequencies**

For all pesticides registered on mulberry fields, the highest and the lowest application rate were selected from the CAU database, irrespective of the application frequency. However, corresponding application frequencies and application intervals were then used in the calculations. The basic calculations of the PECs did not apply any pre-harvest intervals, but they were taken into account in the discussion about risk mitigation measures.

For pesticides applied to adjacent fields the highest and the lowest application rate were selected for the assessment selected the CAU database, irrespective of the crop or the application frequency. Again, corresponding application frequencies and application intervals were then used in the calculations. It was assumed that any crop from the CAU database could have been grown adjacent to mulberry fields, and no specific selection was made.

#### **Pesticide parameters**

In the risk assessment, a default residue unit dose (RUD) of 950 mg a.i./kg leaf/kg sprayed a.i. is used. This value is the 95<sup>th</sup> percentile of initial residues from similarly structured crops as the mulberry tree, obtained from an international database (Baril *et al.*, 2005). This can be considered a worst case exposure parameter. However, measured residues on mulberry leaves were not available to refine the risk assessment, and the default RUD was used for the basic calculations in this study. The effect of lowering the RUD on the risk assessment is discussed in the risk mitigation section.

DT<sub>50</sub> values on plant foliage were obtained from a database compiled by Van der Valk (unpublished) comprising pesticide half-lives on vegetation. Only the half-lives on foliage were used, but not those on fruits. When DT<sub>50</sub> values based both on dislodgeable residues and total residues were listed, only data on total residues were selected. When more DT<sub>50</sub> values were available for a given pesticide, the geometric mean was used in the risk assessment. For those pesticides without DT<sub>50</sub> values on foliage, a default DT<sub>50</sub> of 10 days was applied (ICAMA, 2010).

Risk assessments were only carried out for sprayed pesticides. No pre-harvest interval was taken into account in the basic calculations.

#### **Toxicity**

The toxicity endpoint used for the risk assessment is the acute LC<sub>50</sub> expressed as mg a.i./kg fresh vegetation. However, only few studies have been carried out so far that generate this endpoint (Sun *et al.*, 2010). Most silkworm toxicity tests that have been submitted to ICAMA result in an LC<sub>50</sub> expressed as mg a.i./L test solution (so-called "dipping tests"). A conversion factor of 0.46 L/kg was applied to such LC<sub>50</sub> values as recommended by Sun *et al.* (2010) and ICAMA (2010).



## 4.2.2 Selection of compounds

The risk of only parent pesticide compounds was assessed; no risk assessment for metabolites was carried out, as this is not recommended in the ICAMA ERA handbook (ICAMA, 2010). The original list of pesticides consisted of 100 parent compounds (Section 1.2.1). Not all of these compounds could be evaluated for various reasons. These compounds were: rodenticides, which normally do not expose silkworm; pesticides for which no silkworm acute toxicity data were available; pesticide mixtures; and pesticides for which no appropriate application schemes/rates were defined (Table 4.1). In total, 58 pesticides could be included in the analysis.

Table 4.1

*Reasons for non-inclusion of certain pesticides in the silkworm risk assessment. For more details see Annex 13.*

Data set	Reason for non-inclusion	Number of compounds
Total compounds		100
	Biological pesticides	1
	Rodenticides	2
	Mixtures of active ingredients	4
	No LC <sub>50</sub> values available (with or without application schemes)	28
	No relevant application schemes available	7
	<b>Total compounds not included</b>	<b>42</b>
Total compounds included		58

## 4.3 Results

### 4.3.1 Data set

A total of 58 pesticides were included in the evaluation of the silkworm risk assessment procedure. Of these, 27 (47% of the total) were insecticides, 12 (21%) were herbicides, 14 (24%) were fungicides, 3 (5%) were acaricides and 2 (3%) were plant growth regulators (Table 4.2). Only 2 compounds were insect growth regulators (both insecticides).

Six dietary LC<sub>50</sub> values were available based on the new test guideline (sprayed pesticide test), while 57 LC<sub>50</sub> values were used based on the old guideline (dipping test). Pesticide half-lives on foliage were available for 27 pesticides; the default DT<sub>50</sub> value of 10 days had to be used for 31 pesticides.

In total, 14 cases of 8 different pesticides applied in the mulberry field were evaluated (a case being a combination of a pesticide with dose rate and a crop); 160 cases were assessed of 58 pesticides applied to adjacent fields.

A summary of the results is provided in Table 4.2; more details are provided in Annex 14 and in the silkworm spreadsheet accompanying this report.

### 4.3.2 Pesticides exceeding the risk quotient

#### Mulberry

All eight pesticides applied to mulberry in all 14 cases resulted in a RQ >1 (Table 4.2). In no situation was the risk of a pesticide applied within the mulberry field acceptable. This was the case not only for insecticides, but also for the other groups of pesticides evaluated. Furthermore, the level of exceedance of the RQ was always high. For insecticides, the RQ was always greater than 3500; for herbicides and fungicides it was always greater than 160.

It should be underlined that in this first tier risk assessment, no pre-harvest intervals (PHIs) were taken into account; the risk was assessed when mulberry leaves would be harvested immediately after spraying. The effect of applying PHIs is discussed in chapter 4.4

Table 4.2

Results of the evaluation of the risk assessment for silkworm in China. Further details are provided in Annex 14. If  $RQ > 1$ , the risk is considered not acceptable.

	All pesticides	Number <i>(percentage)</i> of which:				
		insecticides	herbicides	fungicides	acaricides	PGRs
Summary statistics						
Total compounds assessed <i>(percentage of all)</i>	58	27 <i>(47%)</i>	12 <i>(21%)</i>	14 <i>(24%)</i>	3 <i>(5%)</i>	2 <i>(3%)</i>
<i>of which:</i>						
insect growth regulators	2	2	0	0	0	0
pesticides applied in mulberry	8	4	2	1	1	0
pesticides applied to adjacent crops	58	27	12	14	3	2
Total cases assessed	174					
<i>of which:</i>						
cases in mulberry	14					
cases to adjacent crops	160					
Summary evaluation						
<i>Pesticides applied to mulberry</i>						
Cases with RQ > 1	14					
Pesticides with at least 1 RQ > 1	8	4	2	1	1	0
<i>of which:</i> pesticides with all RQ > 1	8	4	2	1	1	0
Pesticides with all RQ ≤ 1	0	0	0	0	0	0
<i>Pesticides applied to adjacent crops</i>						
<i>1<sup>st</sup> row of mulberry plants</i>						
Cases with RQ > 1 <i>(percentage of pesticides applied to adjacent crops)</i>	150 <i>(94%)</i>					
Pesticides with at least 1 RQ > 1	55	27	11	12	3	2
<i>of which:</i> pesticides with all RQ > 1	51	27	10	11	3	0
Pesticides with all RQ ≤ 1	3	0	1	2	0	0
<i>2<sup>nd</sup> row of mulberry plants</i>						
Cases with RQ > 1 <i>(percentage of pesticides applied to adjacent crops)</i>	116 <i>(73%)</i>					
Pesticides with at least 1 RQ > 1	44	27	7	7	3	0
<i>of which:</i> pesticides with all RQ > 1	34	23	6	2	3	0
Pesticides with all RQ ≤ 1	14	0	5	7	0	2

### Adjacent crops

The large majority of cases of pesticides that were applied to adjacent crops exceeded the acceptable RQ value for silkworm risk. This occurred both for mulberry leaves harvested from the first row of trees (94% exceedance) and from the second row (73% exceedance) (Table 4.2).

The fraction of pesticides for which at least one RQ exceeded the acceptable limit was similarly high: 95% of pesticides for the first row of mulberry trees and 76% for the second. All RQ values exceeded the acceptable limit for 88% of pesticides in the first row, and 59% in the second.

The level of exceedance of the RQ was high in many cases.

The application of only three pesticides resulted in acceptable risk in all cases when evaluated in the first row of mulberry trees, and this was the case for 14 pesticides in the second row. Certain herbicides, fungicides and plant growth regulators comprised these acceptable compounds; the insecticides and acaricides evaluated, on the other hand, never resulted in acceptable risk.

Like for the mulberry scenario, no pre-harvest intervals (PHIs) were taken into account for the adjacent crop scenario.

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### 4.3.3 Refinement evaluations

#### **Use of field-based pesticide half-lives**

The ICAMA ERA handbook (ICAMA, 2010) applies a default  $DT_{50}$  on foliage of 10 days, as standard input parameter. We have used field-based pesticide half-lives whenever these were available, which was for 27 pesticides (47% of total). For only three out of these 27 pesticides were the field-based  $DT_{50}$  values greater than the default value of 10 days. For all other pesticides, were field-based half-lives on foliage less than 10 days. It should be noted, however, that the  $DT_{50}$  is only used in the calculation of the RQ when a PHI is applied, or when pesticides applied several times in the season (as it is an element of the calculation of the multiple application factor). Therefore, the actual impact of using field-based  $DT_{50}$  values on the RQ estimates was limited. The use of field-based  $DT_{50}$  values becomes more important when PHIs are being used as a risk mitigation measure (see chapter 4.4).

## 4.4 Discussion

### 4.4.1 Data set

The assessment of the risk of pesticides to silkworm in China was carried out with a considerable data set. Overall, risk quotients could be calculated with the procedures described in the environmental risk assessment handbook (ICAMA 2010) for 58 pesticides. This corresponded with about 170 individual cases. This data set can be considered sufficiently large to allow a good evaluation of the risk assessment method and the acceptability criteria. It is not expected that an assessment of a larger data set would lead to fundamentally different conclusions.

Data which are needed to be able to carry out the risk assessment, but which were often not available, were the acute dietary  $LC_{50}$  values, in particular those generated with the new procedure. For 28% of the pesticides, no acute dietary  $LC_{50}$  were available at all (Table 4.1).

Furthermore, generally no pesticide residue levels on mulberry leaves are collected, which can be used to refine the risk assessment. Therefore, the default RUD had to be applied for all assessments.

Finally, as was already indicated in the earlier chapters, basic pesticide application data (dosage per surface area, application frequency, application interval) were also sometimes missing on the pesticide label, which was used as the main data source for these parameters in this study, which precluded a risk assessment being carried out.

### 4.4.2 First tier risk assessment

The evaluation carried out in chapter 4.3 shows that all pesticides registered in mulberry fields pose an unacceptable risk to silkworm when mulberry leaves are harvested immediately after treatment.

In addition, a very large fraction of pesticides applied on adjacent crops also poses an unacceptable risk to silkworm. In total, the application of 51 out of 58 pesticides (88%) resulted in unacceptable risk in all evaluated cases, for the first row of mulberry trees neighbouring the treated crop; this was still the case for 34 pesticides (59%) for the second row.

There are various reasons for this high risk. First, silkworm are generally very sensitive to pesticides, not only to insecticides but also to other groups of pesticides. Second, due to the very close proximity between mulberry fields and adjacent crops in most of China (generally there are no uncultivated strips of land between fields), the estimated fraction of drift onto mulberry is relatively high (10% of the application rate for the first row, and still 0.6% for the second). Third, as indicated above, no PHIs were applied in this assessment. And finally, it can be argued that the Residue Unit Dose (RUD) used is relatively high.

The RUD value used in the silkworm risk assessment (950 mg /kg) is the 95<sup>th</sup> percentile of RUDs established for mulberry-type trees/crops, obtained from an international database reviewed by Baril

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*et al.* (2005). In other words, an application of 1 kg a.i./ha to a mulberry type crop would not lead to initial residue levels exceed 950 mg /kg leaves in 95% of the cases. This high percentile for the RUD was chosen because a very high level of protection is required for silkworm: No effects on silk production and quality are acceptable (ICAMA, 2010).

However, the crop group defined by Baril *et al.* (2005), orchards and vineyards, which was considered similar to mulberry trees, shows very high variability in initial residue levels. As a result, the 50<sup>th</sup> percentile RUD (50 mg/kg) was a factor 19 lower than the 95<sup>th</sup> percentile (950 mg/kg) , a wider range than any of the other crop groups. This means that a more precise definition of the real 95<sup>th</sup> RUD for mulberry, rather than using the "surrogate from the international database, may result in a lower initial residues while still providing the required high level of protection. Therefore, it seems worthwhile to compile data on initial residues on mulberry leaves of pesticides applied within a mulberry field as well as applied in adjacent crops. It should be stressed, however, that the level of exceedance of the RQ was so high in many cases that a reduction of the RUD by even 50% would not lead to many more pesticides posing an acceptable risk. For instance, almost 60% of cases had a RQ > 1000, and still 44 % had a RQ > 100.

#### 4.4.3 Risk mitigation measures

If the risk quotient is greater than one, various risk mitigation options can be considered to reduce the risk for silkworm to an acceptable level. Based on a review of risk mitigation options (Tao and Van der Valk, 2011), the following risk mitigation measures were considered to be the most realistic and feasible under Chinese agronomic conditions:

##### *Pesticide application in mulberry plantation*

- Reduce the application rate
- Reduce the application frequency
- Apply an effective pre-harvest interval
- Limit application to periods when no silkworm rearing takes place (e.g. cold season)
- Refuse registration
- *Pesticide application adjacent to mulberry plantation*
- Grow wind breaks (by mulberry farmer)
- Do not harvest first row of mulberry trees (mulberry itself is "wind break") (by mulberry farmer)
- Refuse registration

##### **Reduction of application rate**

Given the way that pesticides and crops were selected for this study (highest and lowest application rates and frequencies, for each pesticide), it is not possible to assess for each pesticide whether the application rate on a specific crop can be reduced without loss of efficacy. However, for many pesticides was the RQ > 1 for all assessed cases, including those for the lowest application rates and frequencies. This was the case for all pesticides applied in mulberry, and for 88% (1<sup>st</sup> row) and 59% (2<sup>nd</sup> row) of pesticides applied to adjacent crops. Therefore, a significant reduction of dosage is unlikely to be possible for these pesticides on any crop.

The feasibility for a reduction in application rate as a risk mitigation measure can also be assessed by the level of exceedance of the RQ. For the purpose of this study, it was considered that if the RQ was exceeded by a factor 2 or more, risk mitigation through dose reduction would be very unlikely to succeed without a clear adverse effect on efficacy.

All 14 cases of pesticides applied to mulberry with RQ > 1 also had RQ > 2. In the scenario of pesticides applied to adjacent crops, of a total of 150 cases where the RQ > 1 for the 1<sup>st</sup> row of mulberry, 145 cases showed a RQ > 2 (97%). Similarly, of the 116 cases where the RQ > 1 for the 2<sup>nd</sup> row of mulberry, 104 cases showed a RQ > 2 (90%). (Table 3.2)

Therefore, in the large majority of the cases that are exceeding the acceptable RQ, a dose reduction would not likely be a feasible risk mitigation measure, neither for pesticides applied in mulberry nor in adjacent crops.

### Application of a pre-harvest interval

The evaluations carried out in this study did not apply a pre-harvest interval (PHI) for the mulberry leaves. Therefore, for all cases with  $RQ > 1$ , PHI values were calculated that would lead to  $RQ \leq 1$ , using the ERA model. Subsequently, for each pesticide the longest PHI was selected with the aim to ensure that all cases for that pesticide would have  $RQ \leq 1$ . This was done since many different crops may be grown around a mulberry field and proposing different PHIs for all possible pesticide-crop combinations may not be practicable to transit to farmers on the label or through extension services.

The PHIs needed to achieve acceptable risk of the pesticides registered in mulberry are listed in Table 4.3. Only for dichlorvos would a relatively short PHI of 3 days lead to acceptable risk to silkworm. The other insecticides registered on mulberry (phoxim, chlorpyrifos and methomyl) would all require a PHI ranging from 25 to 40 days. This means that these insecticides might be applied during the off-season, or possibly very early in the growing season of the mulberry plant, but it is unlikely that they can be used safely during the silkworm rearing period. The two herbicides used in mulberry, glyphosate and paraquat, both have long PHIs (2 – 6 months). These herbicides would likely be used in the off-season when exposure of mulberry leaves will not occur. However, use of these herbicides during the silkworm breeding period does not seem to be without risk, even when sprays would be directed against low-growing weeds between the mulberry trees as drift onto leaves may occur. This might also cause damage to the mulberry plants themselves. The fungicide thiophanate-methyl requires a 7-month PHI to reduce risk to silkworm to an acceptable level. Based on these estimates, it is unlikely that this fungicide could be used safely in mulberry at any time.

Table 4.3

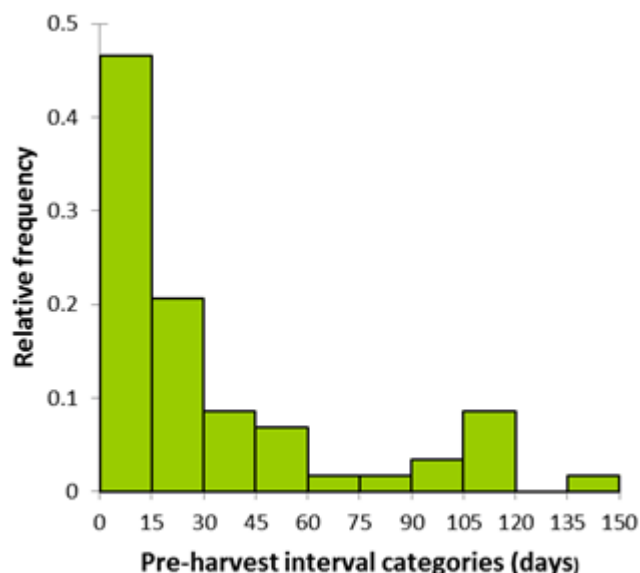
*Pre-harvest intervals needed to achieve  $RQ \leq 1$  for pesticides (applied) registered in mulberry in China. (see annex 14 for more details)*

Pesticide	Type	Application rate (kg a.i./ha)	LC <sub>50</sub> (mg a.i./kg leaf)	DT <sub>50</sub> on foliage (day)	PHI required for all $RQ \leq 1$ (day)
Dichlorvos	Insecticide	0.6 – 1.5	6.2	0.2	3
Phoxim	Insecticide	0.3 – 0.6	0.46	1.8	29
Chlorpyrifos	Insecticide	0.3 – 0.4	0.44	2.5	39
Methomyl	Insecticide	0.08 – 0.15	0.34	1.7	25
Glyphosate	Herbicide	1.1 – 2.3	11.1	14	202
Paraquat	Herbicide	0.75	100	10 (default)	74
Thiophanate-methyl	Fungicide	1.9	229	28	211

Of the 58 pesticides that were evaluated when applied to adjacent crops, 44 (76%) showed an  $RQ > 1$  for the second row of mulberry trees. Fourteen pesticides did not require a PHI to achieve acceptable risk for the second row of mulberry. PHIs were calculated again for all other cases exceeding the acceptable  $RQ$  (Annex 14).

Figure 4.1 shows the relative frequencies of the required PHIs. Twenty-seven pesticides (47% of total) required a PHI of less than 15 days, to ensure an acceptable risk to silkworm. This includes the 14 pesticides which had  $PHI = 0$  and 13 pesticides with a PHI ranging from 2 – 14 days (Annex 14). A considerable fraction, 29%, required a PHI ranging from 15 to 44 days, while still 24% required longer PHIs, up to 136 days.

It is unlikely that silkworm farmers would be able to respect pre-harvest intervals exceeding 30 days during the silkworm breeding season. The use of these pesticides in adjacent fields therefore poses a real risk to silkworm production. Other risk mitigation measures than respecting a pre-harvest interval, would be required for these pesticides.



**Figure 4.1** Relative frequency of pre-harvest intervals for mulberry required to ensure that  $RQ \leq 1$  in the second row of mulberry trees, after application of the pesticide to an adjacent crop ( $n = 56$  pesticides). The graph includes pesticides for which no PHI was required ( $PHI = 0$ ) (see Annex 14 for more details).

## 4.5 Acceptability criteria

The risk assessment procedure for silkworm described by ICAMA (2010) is unique in the world. No other country has developed such a model to assess pesticide risk to silk production at the registration stage. Therefore, a comparison of the outcome of this study with experiences elsewhere cannot be made.

The evaluation of the ERA procedure carried out here shows that a large fraction of the pesticides poses an unacceptable risk to silkworm.

The acceptable risk level in the ICAMA ERA procedure is defined by various parameters, of which the main are: the toxicity of the pesticide to the silkworm, the residue estimate on mulberry, the  $DT_{50}$  of the pesticide on mulberry foliage, the drift factor (for pesticides applied to adjacent crops), and the pre-harvest interval.

A basic parameter for the risk assessment is the acute dietary  $LC_{50}$  of the pesticide for silkworm. In this study, most  $LC_{50}$  values were based on the results of dipping tests. As was explained by Sun *et al.* (2010), the dipping method has various drawbacks for the definition of a precise and relevant toxicity endpoint for risk assessment. At this point, it is not clear how precise and reliable the test results of the existing dipping tests are. The generation of more test results using the new test method described by Sun *et al.* (2010, 2012), should lead to better toxicity data being used in the risk assessment. It cannot be predicted, however, whether the use of better  $LC_{50}$  values would lead to a systematic upward or downward correction of the risk estimate.

The residue estimate on mulberry is determined by the application rate and the RUD. As was discussed above, the RUD default used can be considered relatively high, which to a large extent is the result of the variable data used to estimate it. Obtaining more precise values of initial pesticide residues in mulberry, and the estimation of a specific  $RUD_{mulberry}$  would be very useful for the risk assessment. It would likely lead to a downward correction of the risk estimates.

A default value of 10 days is presently being used for the pesticide half-life on foliage, in the ICAMA ERA handbook. Our assessment has shown that field-based  $DT_{50}$  values on plant foliage are generally

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less than 10 days. It is therefore important that a relevant  $DT_{50}$  on plant foliage (either mulberry or another leafy plant) is included in the Chinese data requirements for registration.

The drift factor used in the risk assessment procedure was estimated using a computer model, and is based on current pesticide application practices in China (Francke *et al.*, 2010). Further validation of this model for Chinese conditions may lead to slightly different drift fractions, and would increase the precision of the ERA procedure.

The effect of applying a pre-harvest interval was assessed in more detail above. In particular for pesticides which have a low  $DT_{50}$  on foliage, incorporation of a PHI may considerably reduce the risk of the pesticide to silkworm.

Most of the above parameters, when further refined as discussed, would reduce the RQ estimate, although the size of these reductions would probably not lead to many more pesticides posing an acceptable risk. Therefore, if these pesticides were to be registered, risk mitigation measures should be taken to reduce the risk. Tao and Van der Valk (2011) suggest that for pesticides which are to be applied in the mulberry plantation, all the listed risk mitigation measures are considered to be well feasible in China. This is the case because of the high economic value of silk, and because silkworm farmers that manage the mulberry plantations are well aware of the risks of pesticides to the silkworm. In contrast, most of the measures listed to reduce the risk of pesticides applied in fields adjacent to mulberry plantations are difficult to implement. This is mainly because these fields and crops are often owned by other farmers, who do not have a direct interest in silk production.

In conclusion, on the basis of the study described in this chapter, there does not seem to be a reason to amend the risk assessment procedure for silkworm proposed in the ICAMA ERA Handbook (ICAMA 2010), nor the proposed acceptability criteria. However, better data in particular on toxicity, initial residues on mulberry and pesticide half-lives on plant foliage would likely reduce the risk estimates somewhat, and are therefore important to collect.





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# Annex 1 Pesticides used for the study

The 100 pesticides that were most used in China, on a volume basis, in the period 2005 – 2008, according to the Chinese Ministry of Agriculture.

No.	中文名称	Common name	类别	Type
1	敌敌畏	dichlorvos	杀虫剂	insecticide
2	乙草胺	acetochlor	除草剂	herbicide
3	硫酸铜	copper-sulphate	杀菌剂	fungicide
4	杀虫双	thiosultap-sodium (=bisultap)	杀虫剂	insecticide
5	草甘膦	glyphosate	除草剂	herbicide
6	辛硫磷	phoxim	杀虫剂	insecticide
7	甲胺磷	methamidophos	杀虫剂	insecticide
8	敌百虫	trichlorfon	杀虫剂	insecticide
9	多菌灵	carbendazim	杀菌剂	fungicide
10	丁草胺	butachlor	除草剂	herbicide
11	氧乐果	omethoate	杀虫剂	insecticide
12	杀虫单	monosultap	杀虫剂	insecticide
13	甲基硫菌灵 (甲基托布津)	thiophanate-methyl	杀菌剂	fungicide
14	乐果	dimethoate	杀虫剂	insecticide
15	2,4--滴丁酯	2,4-D butylate	杀虫剂	herbicide
16	莠去津 (阿特拉津)	atrazine	除草剂	herbicide
17	甲基对硫磷	parathion-methyl	杀虫剂	insecticide
18	三唑磷	triazophos	杀虫剂	insecticide
19	井冈霉素	validamycin (=jinggangmycin)	杀菌剂	fungicide
20	百菌清	chlorothalonil	杀菌剂	fungicide
21	百草枯 (克芜踪)	paraquat	除草剂	herbicide
22	毒死蜱	chlorpyrifos	杀虫剂	insecticide
23	三环唑	tricyclazole	杀菌剂	fungicide
24	敌磺钠 (敌克松)	fenaminosulf (=diazoben)	杀菌剂	fungicide
25	三唑酮 (粉锈宁)	triadimefon	杀菌剂	fungicide
26	水胺硫磷	isocarbophos	杀虫剂	insecticide, acaricide
27	乙酰甲胺磷	acephate	杀虫剂	insecticide
28	氢氧化铜 (靠山、可杀得)	copper-hydroxide	杀菌剂	fungicide
29	噻嗪酮 (扑虱灵)	buprofezin	杀虫剂	insecticide, acaricide
30	马拉硫磷	malathion	杀虫剂	insecticide
31	久效磷*	monocrotophos	杀虫剂	insecticide
32	哒螨灵 (速螨酮、扫螨净)	pyridaben	杀螨剂	acaricide, insecticide
33	三氯杀螨醇	dicofol	杀螨剂	acaricide
34	吡虫啉	imidacloprid	杀虫剂	insecticide
35	对硫磷*	parathion	杀虫剂	insecticide
36	甲拌磷	phorate	杀虫剂	insecticide
37	精吡氟禾草灵 (精稳杀得)	fluazifop-P-butyl	除草剂	herbicide
38	稻瘟灵 (富士一号)	isoprothiolane	杀菌剂	fungicide, plant growth regulator
39	克百威 (呋喃丹)	carbofuran	杀虫剂	insecticide
40	乙烯利	ethephon	植物生长调节剂	plant growth regulator
41	氟乐灵	trifluralin	除草剂	herbicide
42	甲基异柳磷	isofenphos-methyl	杀虫剂	insecticide
43	异稻瘟净	iprobenfos	杀菌剂	fungicide
44	氯氰菊酯	cypermethrin	杀虫剂	insecticide
45	炔螨特 (克螨特)	propargite	杀螨剂	acaricide
46	霜脲氰 (克露)	cymoxanil	杀菌剂	fungicide
47	灭多威	methomyl	杀虫剂	insecticide
48	灭草松 (苯达松)	bentazon	除草剂	herbicide
49	异丙威 (叶蝉散)	isoprocarb	杀虫剂	insecticide
50	三乙膦酸铝 (乙膦铝)	fosetyl-aluminium	杀菌剂	fungicide
51	抗蚜威	pirimicarb	杀虫剂	insecticide
52	甲氰菊酯	fenpropathrin	杀虫剂	insecticide
53	氟戊菊酯	fenvalerate	杀虫剂	insecticide
54	阿维菌素	abamectin	杀虫剂	insecticide
55	二甲四氯	MCPA	除草剂	herbicide
56	禾草敌 (禾大壮)	molinate	除草剂	herbicide
57	异丙甲草胺 (都尔)	metolachlor	除草剂	herbicide
58	五氯硝基苯	quintozene	杀菌剂	fungicide
59	甲草胺	alachlor	除草剂	herbicide

No.	中文名称	Common name	类别	Type
60	苯磺隆（巨星）	tribenuron-methyl	除草剂	herbicide
61	杀螟硫磷	fenitrothion	杀虫剂	insecticide
62	腐霉利（速克灵）	procymidone	杀菌剂	fungicide
63	灭幼脲	chlormezuron	植物生长调节剂	insecticide
64	叶枯唑（噻枯唑）	bismerthiazol	除草剂	fungicide
65	氟磺胺草醚（虎威）	fomesafen	除草剂	herbicide
66	二氯喹啉酸（快杀稗、杀稗王）	quinclorac	除草剂	herbicide
67	拌种双（混剂：福美双+拌种灵）	amicarbazol	杀菌剂	bactericide, fungicide
68	多效唑	paclobutrazol	植物生长调节剂	plant growth regulator
69	异丙隆	isoproturon	除草剂	herbicide
70	赤霉素	gibberellins	植物生长调节剂	plant growth regulator
71	霜霉威（普力克）	propamocarb	除草剂	fungicide
72	敌鼠钠盐	sodium-diphacinone	杀鼠剂	rodenticide
73	绿麦隆	chlortoluron	除草剂	herbicide
74	扑草净	prometryn	除草剂	herbicide
75	硫丹	endosulfan	杀虫剂	insecticide
76	咪鲜胺（施保克）	prochloraz	杀菌剂	fungicide
77	杀扑磷	methidathion	杀虫剂	insecticide
78	杀鼠醚	coumatetralyl	杀鼠剂	rodenticide
79	三唑锡	azocyclotin	杀螨剂	acaricide
80	涕灭威	aldicarb	杀虫剂	insecticide
81	灭线磷（益舒宝）	ethoprophos	杀虫剂	insecticide
82	高效氯氟氰菊酯	lambda-cyhalothrin	杀虫剂	insecticide
83	啶硫磷	quinalphos	杀虫剂	insecticide
84	苏云金杆菌（Bt）	bacillus thuringiensis	杀虫剂	insecticide
85	溴氰菊酯	deltamethrin	杀虫剂	insecticide
86	烯唑醇	diniconazole	杀菌剂	fungicide
87	氟吡甲禾灵	haloxyfop	除草剂	herbicide
88	甲基毒死蜱	chlorpyrifos-methyl	杀虫剂	insecticide
89	丙溴磷	profenofos	杀虫剂	insecticide
90	速灭威	metolcarb	杀虫剂	insecticide
91	混灭威	dimethacarb	杀虫剂	insecticide
92	啉虫脒	acetamiprid	杀虫剂	insecticide
93	噻螨酮	hexythiazox	杀螨剂	acaricide
94	异菌脲	iprodione	杀菌剂	fungicide
95	倍硫磷	fenthion	杀虫剂	insecticide
96	氟虫腈	fipronil	杀虫剂	insecticide
97	单甲脒	monoamitraz	杀虫剂	acaricide, insecticide
98	甲哌鎓（缩节胺、助壮素）	mepiquat chloride	植物生长调节剂	plant growth regulator
99	噁霜灵	oxadixyl	杀菌剂	fungicide
100	福美甲肿	urbacide	杀菌剂	fungicide

## Annex 2 Pesticide property data (endpoints) collected for the study

Input parameters and/or endpoints that were collected for the risk assessments for the different protection goals evaluated in this study. Between square brackets [...] are conditions under which the endpoints have to be determined. Units are the required units for the models/ERA procedures. Data sources are those used in this study.

Required input parameters / endpoints	Unit	Parameter needed for ERA of:					Data source <sup>4</sup>	
		Groundwater	Aquatic organisms	Honey bee	Silkworm	Birds	Registration dossier	Secondary sources
Identity								
Common name		✓	✓	✓	✓	✓	✓	
Parent or metabolite		✓					✓	B, C
Classification <sup>1</sup>							✓	
Formulation type	ICAMA code	✓	✓	✓	✓	✓	✓	
Use pattern / application								
Crop		✓	✓	✓	✓	✓	✓	
Application rate	g a.i./ha	✓	✓	✓	✓	✓	✓	
Target (insect, weed, disease, etc.)		✓					✓	A
Application frequency	#/year or #/crop season	✓	✓	✓	✓	✓	✓	A
Application interval	days	✓	✓	✓	✓	✓	✓	A
Application depth	cm	✓					✓	
Application timing	crop stage or absolute time or relative to emergence/ harvest	✓	✓	✓	✓	✓	✓	A
Mode of application <sup>2</sup>		✓	✓	✓	✓	✓	✓	
Pre-harvest interval	days				✓		✓	
Attractiveness of crop to honeybees				✓				E
Environmental fate								
Molar mass	g/mol	✓	✓					B, C
Saturated vapour pressure [temp.]	Pa	✓	✓					B, C
Solubility in water [temp.]	mg/L	✓	✓					B, C
Fraction transformed (into metabolite)	--	✓	✓					B
K <sub>oc</sub> – soil (coefficient for sorption on organic carbon in soil) [soil type] or K <sub>om</sub> – soil (coefficient for sorption on organic matter in soil) [soil type]	L/kg	✓	✓					B, C
K <sub>om</sub> – sediment (coefficient for sorption on organic matter in sediment) and/or K <sub>om</sub> – suspended solids (coefficient for sorption on organic matter on suspended solids)	L/kg		✓					B, C
pK <sub>a</sub> (acid dissociation constant)	--	✓	✓					B
K <sub>ow</sub> (octanol-water partition coefficient)	--		✓			✓		B, C
Degradation half-life in water (DegT <sub>50</sub> ) [temp.] or DT <sub>50</sub> - hydrolysis	days		✓					B, C
Degradation half-life in soil – aerobic (DegT <sub>50</sub> ) [temp., soil type]	days	✓	✓					B, C
Degradation half-life in soil – anaerobic	days		✓					B, C

Required input parameters / endpoints	Unit	Parameter needed for ERA of:					Data source <sup>4</sup>	
		Groundwater	Aquatic organisms	Honey bee	Silkworm	Birds	Registration dossier	Secondary sources
(DegT <sub>50</sub> ) [temp, soil type]								
Degradation half life in sediment (DegT <sub>50</sub> ) [temp., sediment type]	days		✓					B, C
Dissipation half life on vegetation (DT <sub>50</sub> ) [temp.]	days				✓	✓		D
<b>Ecotoxicology</b>								
Acute LC <sub>50</sub> (fish) [species, time]	mg/L		✓					B, C
Chronic NOEC (fish) [species, time]	mg/L		✓					B, C
Acute EC <sub>50</sub> /LC <sub>50</sub> ( <i>Daphnia</i> ) [time]	mg/L		✓					B, C
Chronic NOEC ( <i>Daphnia</i> ) [time]	mg/L		✓					B, C
Acute LC <sub>50</sub> (aquatic invertebrates) <sup>3</sup> [species, time]	mg/L		✓					B, C
EC <sub>50</sub> (algae) [species, time]	mg/L		✓					B, C
Bioconcentration factor (BCF) (fish) [species]	--		✓					B, C
Acute oral LD <sub>50</sub> (honey bee)	µg/bee			✓				B, C
Acute contact LD <sub>50</sub> (honey bee)	µg/bee			✓				B, C
Acute toxicity LC <sub>50</sub> (silkworm) {dipping test}	mg/L				✓			G
Acute dietary LC <sub>50</sub> (silkworm)	mg/kg diet				✓			H
Acute oral LD <sub>50</sub> (bird) <sup>3</sup> [species]	mg/kg b.w.					✓		B, C
Short-term dietary LC <sub>50</sub> (bird) [species, time]	mg/kg diet					✓		B, C
Chronic NOEC (bird) [species, time]	mg/kg diet					✓		B, C
<b>Human toxicology</b>								
Acceptable Daily Intake (ADI)	mg/kg b.w./day	✓						B, F, I, J
<sup>1</sup> Classification: insecticide, acaricide, herbicide, fungicide, rodenticide, plant growth regulator <sup>2</sup> Mode of application: spray – to the crop canopy /to the soil surface; spray / granules –soil incorporation; seed dressing –soil incorporation; dusting – to the crop canopy / to the soil surface <sup>3</sup> Data for other aquatic invertebrates, as far as available <sup>4</sup> Secondary data sources: A: CAAS Institute of Plant Protection (IPP) and/or Provincial Institutes for the Control of Agrochemicals (ICAs) B: Footprint Pesticide Products Database (Footprint, undated) C: e-Pesticide manual (Tomlin, 2010) D: Pesticide dissipation on vegetation (van der Valk, unpublished) E: Klein <i>et al.</i> (2007) F: Codex Alimentarius – Joint FAO/WHO Meeting on Pesticide Residues (JMPR, undated) G: ICAMA data on toxicity of pesticides to silkworm (EFED, unpublished) H: Sun <i>et al.</i> (2010) I: Bundesinstitut für Risikobewertung (Germany) (2010) Pflanzenschutzmittel-Wirkstoffe: ADI-Werte und gesundheitliche Trinkwasser-Leitwerte. J: Acceptable daily intakes for agricultural and veterinary chemicals (2008). Department of Health and Ageing, Australia								

# Annex 3 Input parameters for the dry land groundwater calculations

The following data and input parameters for China-PEARL were used for the calculations of leaching concentrations in dry land agriculture groundwater scenarios, and the subsequent evaluation of risk for human drinking water consumption. Column headers refer to the input/output data table which is provided together with this report

Column header	Remarks
<b>China-PEARL Main tab: Scenario</b>	
<b>Substance</b>	
No.	Sequence number (Not a China-PEARL input parameter)
Common name	Common name of the pesticide active substance (Not a China-PEARL input parameter)
Parent or metabolite	Note if the substance is a parent pesticide or metabolite.
Formulation type	Code for the type of the formulation (formulation codes listed on the ICAMA web site) (Not a China-PEARL input parameter)
Classification	Type of pesticide (e.g. insecticide, herbicide, fungicide, etc.) (Not a China-PEARL input parameter)
Pearl substance name	Name of the pesticide used in Pearl (in case it is different from the common name)
<b>China-PEARL Box: Scenario</b>	
Location [Note: this entire tab page in China-PEARL is default – ref. ter Horst et al., . 2014]	Choice of 6 locations in northern China, with each one or more crops. The model was run for all the location/crop combinations in which the pesticide can realistically be used, based on the registration specifications.
Crop calendar [Note: this entire tab page in China-PEARL is default – ref. ter Horst et al., . 2014]	Crops and cropping calendar data for each scenario location. The model was run for all the location/crop combinations in which the pesticide can realistically be used, based on the registration specifications. Default crop cycle = fixed
Insect or disease or weed	Names of the pest(s) listed for the selected (highest) registered dose (Not a China-PEARL input parameter)
Registration code	ICAMA Registration number/code for the pesticide (Not a China-PEARL input parameter)
Manufacturer	Manufacturer of the pesticide (Not a China-PEARL input parameter)
Irrigation [Note: this entire tab page in China-PEARL is default – ref. ter Horst et al., . 2014]	Default = Northern China Surface Irrigation
Tillage [Note: this entire tab page in China-PEARL is default – ref. ter Horst et al., . 2014]	Default = no tillage
<b>China-PEARL Box: Pesticide and scenario dependent</b>	
<b>Application</b>	
Application absolute or relative?	Relative or absolute application, depending on label information. For apple, vine, and alfalfa, all were absolute applications. If no data are provided on the label, the table in Annex 5 was used
For relative application: Crop event	Emergence or harvest, depending on how the moment of pesticide application has been specified on label, or if not available from Annex 5
Application type	Relevant application type. If: “to the crop canopy”, then “interception calculated by model” was always used.
Depth	Unit: m Application soil depth (if relevant)
For absolute application: Date	Date of application, if available from label
For relative application: First application time, compared to emergence or harvest:	Unit: days Negative values are before the event; positive values are after the event Information from the label, or if not available from Annex 5
Source	Source of information on application dates “Questionnaire” refers to ICAMA questionnaire among Provincial ICAs and the IPP (Not a China-PEARL input parameter)

Column header	Remarks
Dosage	Unit: kg active substance ha <sup>-1</sup> Maximum dosage from the labels was used
Crop number	Default value = 1
Frequency of applications	Unit: number season <sup>-1</sup> Maximum frequency indicated on the label was used. If no data are provided on the label, frequency = 1
Interval between applications	Unit: days Information from the label, or if not available from Annex 5 (Not a China-PEARL input parameter)
<b>Substance</b>	
<b>Pesticide properties – general</b>	
Molar mass	Unit: g mol <sup>-1</sup> If no data for metabolite: 50% of parent was used as default
Saturated vapour pressure	Unit: Pa Specify the temperature (°C) at which it was determined. If temperature was not specified: 20 °C was assumed If more values available: the (normal) mean was calculated and used If no data available: 0 Pa at 20 °C was used
Molar enthalpy of vaporisation	Unit: kJ mol <sup>-1</sup> Default value = 95
Solubility in water	Unit: mg L <sup>-1</sup> Specify the temperature (°C) at which it was determined If temperature was not specified: 20 °C was assumed If more values available: the (normal) mean was calculated and used If no data available: 1 mg L <sup>-1</sup> at 20 °C was used
Molar enthalpy of dissolution	Unit: kJ mol <sup>-1</sup> Note: default value = 27
If metabolite is formed: Transformation scheme: fraction transformed into metab.	Unit: dimensionless (between 0 – 1) Fraction of parent compound that is transformed into the metabolite
<b>Pesticide properties – sorption</b>	
Info on pH dependency?	If information is available on pH dependency of sorption (yes/no) (Not a China-PEARL input parameter)
pH dependent	If information is available on pH dependency: is sorption pH dependent (yes/no) (Not a China-PEARL input parameter)
Option: pH dependent in Pearl	If information is available on pH dependency: is sorption pH dependent (yes/no) If <u>no</u> information is available on pH dependency: choose pH independent as default
K <sub>om</sub> soil (Coefficient of sorption on organic matter)	Unit: L kg <sup>-1</sup> Specify the temperature (°C) at which it was determined. If temperature was not specified: 20 °C was assumed If more values available: the (normal) mean was calculated and used If K <sub>om</sub> is not available, K <sub>oc</sub> was used instead. The spreadsheet will calculate: K <sub>om</sub> = K <sub>oc</sub> / 1.724
K <sub>oc</sub> soil (Coefficient of sorption on organic carbon)	Unit: L kg <sup>-1</sup> Specify the temperature (°C) at which it was determined. If temperature was not specified: 20 °C was assumed If more values available: the (normal) mean was calculated and used If only a range of values is available: the lowest value was used If no K <sub>oc</sub> (and K <sub>om</sub> ) values available: do not run China-PEARL for this pesticide
Molar enthalpy of sorption	Unit: kJ mol <sup>-1</sup> Default value = 0
If sorption is pH dependent: K <sub>oc</sub> soil (acid and base) (Coefficient of sorption on organic carbon)	Unit: L kg <sup>-1</sup> Specify the temperature (°C) at which it was determined. If temperature was not specified: 20 °C was assumed If sorption is pH dependent, but no K <sub>oc</sub> acid and base are available, then: “pH independent” was chosen and: if pH is stated, K <sub>oc</sub> of soils with pH 7 – 9 was used if pH is not stated, lowest K <sub>oc</sub> was used
pK <sub>a</sub> Acid dissociation constant	Unit: dimensionless If more values available: the (normal) mean was calculated and used
Equilibrium sorption: Reference concentration in liquid phase	Unit: mg L <sup>-1</sup> Default value = 1
Equilibrium sorption: Freundlich sorption exponent [Note: in Pearl = N; in EU and Footprint = 1/n. these are identical!]	Unit: dimensionless Enter value, if available. If no data: default value = 0.9
Non equilibrium sorption Desorption rate coefficient	Unit: d <sup>-1</sup> Default value = 0
Non equilibrium sorption Factor relating CoffreNeq and CoffreEq	Unit: dimensionless Default value = 0



Column header	Remarks
If sorption is dependent on other soil properties rather than the organic matter content: $K_f$	Unit: $L\ kg^{-1}$ Specify the temperature ( $^{\circ}C$ ) at which it was determined. If temperature was not specified: $20\ ^{\circ}C$ was assumed
<b>Pesticide properties – transformation</b>	
Half life (= Aerobic half life ( $DegT_{50}$ ) in soil)	Unit: day Specify if data are from laboratory or from field if both laboratory and field data available: only laboratory data were used if only field data are available: the highest $DT_{50}$ value was used Specify the temperature ( $^{\circ}C$ ) at which it was determined. If temperature was not specified: $20\ ^{\circ}C$ was assumed If more values available for different soils: the geometric mean of all values was used If no $DT_{50}$ values available: do not run China-PEARL for this pesticide
Optimum moisture conditions (pF = 2 or wetter)	Default = yes (✓)
Exponent for the effect of liquid	Unit: dimensionless Default value = 0.7
Molar activation energy	Unit: $kJ\ mol^{-1}$ Default value = 65.4
<b>Pesticide properties – diffusion</b> [Note: this entire tab page is default! – do not change inputs]	
Reference temperature for diffusion	Unit: $^{\circ}C$ Default value = 20
Reference diffusion coefficient in water	Unit: $m^2\ d^{-1}$ Default value = $4.3 \times 10^{-5}$
Reference diffusion coefficient in air	Unit: $m^2\ d^{-1}$ Default value = 0.43
<b>Pesticide properties – crop</b> [Note: this entire tab page is default]	
Wash-off factor	Unit: $m^{-1}$ Default value = 0.001
Canopy process option	Default = lumped
Lumped: half-life at crop surface	Unit: d Default value = 1000000
Coefficient of uptake by plant	Unit: dimensionless Default value = 0.5
<b>Deposition</b> [Note: this heading is default – no changes were made]	
<b>China-PEARL main tab: Simulation control</b>	
[Note: this entire tab page is default – no changes were made]	
<b>China-PEARL main tab: Output control</b>	
[Note: this entire tab page is default – no changes were made]	
<b>China-PEARL main tab: Swap hydrological module</b>	
[Note: this entire tab page is default – no changes were made]	
<b>China-PEARL main tab: Run status</b>	
[Note: this entire tab page is default – no changes were made]	
<b>Toxicological data</b>	
Guidance value (GV)	Acceptable concentration in groundwater (for use as drinking water without treatment) Unit: $\mu g\ a.s.\ L^{-1}$ GV is calculated according to the following equation: $GV = (ADI \times bw \times fdw \times 1000) / (C)$
ADI (acceptable daily intake)	Unit: $mg\ a.si / kg\ body\ weight / day$
Body weight (bw)	Unit: kg Default = 60
Fraction of pesticide ingested through drinking water (fdw)	Unit: dimensionless Default = 0.2
Daily water consumption (C)	Unit: $L\ day^{-1}$ Default = 2



# Annex 4 Conversion factors for pesticide dosages

## 1. Sprays: only dilution ratio of pesticide formulation is recommended on the label

*Assumption:* volume application rate of diluted pesticides = 1500 litres/ha (this is standard recommended rate for field crops in China)

*Conversion used:*

$$\text{Dosage (kg a.i./ ha)} = \frac{\text{form. conc. (g a.i./ L)}}{\text{dilution ratio (L/ L)}} \times \frac{1500 \text{ (L)}}{1000}$$

(form. conc. = formulation concentration)

## 2. Seed treatment: only dosage of pesticide on the seed is recommended on the label

*Assumption:* If seeding densities were not mentioned on the label, standard recommended seeding densities in China were applied as follows:

Crop	Seeding density (kg seed/ha)
Cotton	90
Soybean	65
Maize	30
Sugarbeat	22.5
Spring wheat	360
Winter wheat	180
Potato	3000
Paddy rice (seed bed)	2250

*Conversion used:*

$$\text{Dosage (kg a.i./ ha)} = \frac{\text{seed dosage (g a.i./ kg seed)}}{1000} \times \text{seeding density (kg seed / ha)}$$

## 3. Seed treatment: Only dilution ratio of pesticide formulation on the seed is recommended on the label

*Assumption:* If seeding densities were not mentioned on the label, standard recommended seeding densities in China were applied as under 2

*Conversion used:*

$$\text{Dosage (kg a.i./ ha)} = \text{dilution ratio (g formulation / g seed)} \times \frac{\text{form. conc. (g a.i./ L)}}{1000} \times \text{seeding density (kg seed / ha)}$$

(form. conc. = formulation concentration)

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**4. Seed treatment: Only dilution ratio of pesticide formulation for a soaking solution is recommended on the label**

*Assumptions:*

- standard recommended seeding densities in China were applied as under 2; and
- volume of soaking solution is twice the seed weight, and all active ingredient in the soaking solution will be absorbed by the seeds

*Conversion used:*

*Dosage (kg a.i. / ha) =*

$$\frac{\text{form. conc. (g a.i./ L)}}{\text{dilution ratio (L/ L)}} \times \frac{2 \text{ (L form./ kg seed)}}{1000} \times \text{seeding density (kg seed / ha)}$$

*(form. conc. = formulation concentration)*

## Annex 5 Default pesticide application parameters

Standardized pesticide application parameters, in cases where insufficient information is provided on the label. (Sources: ICAMA, Beijing; Plant Protection Research Institute, Beijing; Provincial ICAs)

Note: negative timing of application is before the event; positive timing is after the event

Crop	Type of pesticide	Insect or disease or weed	Type of treatment	Crop stage at application	Timing of application			Application interval (days)
					Absolute	Relative (days, relative to emergence)	or (days, relative to harvest)	
All (unless defined differently below)	all	all	seed treatment or seed dressing			-7		
All (unless defined differently below)	all	all	incorporation (furrow application)			-7		
All (unless defined differently below)	herbicide	non-selective				-7		
Soybean	insecticide	蚜虫aphid	to the canopy			50		10
Soybean	insecticide	大豆食心虫soybean borer	to the canopy				-30	10
Soybean	insecticide	lima bean pod borer (豆荚螟)	to the canopy				-30	10
Soybean	insecticide	hawk moth (天蛾)	to the canopy				-45	10
Soybean	insecticide	cotton leaf caterpillar (造桥虫)	to the canopy			30		10
Soybean	fungicide	Anthracnose rust disease (炭疽病、锈病)	to the canopy			5		10
Soybean	plant growth regulator	growth control (控制生长)	to the canopy			20		
Soybean	herbicide	annual growth broadleaf weed (一年生阔叶杂草)	to the soil			-7		
Soybean	herbicide	Perennial grassy weed	to the crop canopy			14		
Cotton	insecticide	cotton bollworm (棉铃虫)	to the canopy			40		10

Crop	Type of pesticide	Insect or disease or weed	Type of treatment	Crop stage at application	Timing of application			Application interval (days)
					Absolute	Relative (days, relative to emergence)	or (days, relative to harvest)	
Cotton	insecticide	aphid (蚜虫)	to the canopy	苗期		7		10
Cotton	insecticide	cotton red spider mite (棉红蜘蛛=棉叶螨)	to the canopy	苗期		7		10
Cotton	insecticide	cotton leaf caterpillar (造桥虫)	to the canopy			60		10
Cotton	insecticide	Mirids (盲蝽蟊)	to the canopy			40		10
Cotton	insecticide	Pink bollworm(红铃虫)	to the canopy			40		10
Cotton	acaricide	cotton red spider mite (棉红蜘蛛=棉叶螨)	to the canopy	苗期		7		20
Cotton	fungicide	Pestilence(疫病)	to the canopy	苗期		7		10
Cotton	plant growth regulator	Ripening (催熟)	to the canopy				-30	
Cotton	herbicide	Grassy weeds	to the canopy			14		
Apple	insecticide	Carposina niponensis (桃小食心虫)	to the canopy		15th May			14
Apple	insecticide	soybean borer(食心虫)	to the canopy		15th May			14
Apple	insecticide	Woolly apple aphid (绵蚜)	to the canopy		16th March			14
Apple	insecticide	yellow aphids (黄蚜)	to the canopy		20th May			14
Apple	insecticide	aphid (蚜虫)	to the canopy		20th May			14
Apple	insecticide	Aphis citricota (绣线菊蚜=黄蚜)	to the canopy		20th May			14
Apple	insecticide	hawthorn spider mite (山楂红蜘蛛)	to the canopy		15th April			14
Apple	acaricide	red spider (红蜘蛛)	to the canopy		15th April			10
Apple	insecticide	olethreutid (小卷叶蛾)	to the canopy		16th March			14
Apple	insecticide	Lithocolletis ringoniella Mats (金纹细蛾)	to the canopy		16th April			14
Apple	insecticide	spanworm (尺蠖)	to the canopy		20th March			14
Apple	insecticide	Stinkbugs (蝽蟊)	to the canopy		15th April			14
Apple	fungicide	anthracnose (炭疽病)	to the canopy		16th March			10
Apple	fungicide	Alternaria leaf spot (斑点落叶病)	to the canopy		1st May			10

Crop	Type of pesticide	Insect or disease or weed	Type of treatment	Crop stage at application	Timing of application			Application interval (days)
					Absolute	Relative (days, relative to emergence)	or (days, relative to harvest)	
Apple	fungicide	Brown patch (褐斑病)	to the canopy		21st May			10
Apple	fungicide	Ring spot (轮纹病)	to the canopy		16th March			10
Apple	fungicide	Plant disease (病害)	to the canopy		16th March			10
Apple	herbicide	weed (杂草)			5th May			30
Alfalfa	insecticide	locust (蝗虫)	to the canopy		20th May			40
Alfalfa	insecticide	Meadow moth (草地螟)	to the canopy		16th April			40
Alfalfa	herbicide	Weed (杂草)	to the canopy		1th April			
Alfalfa	herbicide	Weed (杂草)	to the canopy		15th March			
Alfalfa	fungicide	Brown patch(褐斑病)	to the canopy		1st May			40
Maize	insecticide	Ostrinia furnacalis (玉米螟)	to the canopy				-50	Spring: 10 Summer 14
Maize	insecticide	Armyworm (粘虫)	to the canopy	拔节期		30		Spring: 10 Summer 14
Maize	plant growth regulator	increasing production (调节生长、增产)	to the canopy	心叶末期			-70	
Maize	herbicide	weed (杂草)				-7		14
Spring wheat	insecticide	armyworm (粘虫)	to the canopy	抽穗期			-40	10
Spring wheat	insecticide	aphid(蚜虫)	to the canopy	拔节期		40		10
Spring wheat	insecticide	midge (吸浆虫)	to the canopy	孕穗期		50		10
Spring wheat	fungicide	Gibberellic disease (赤霉病)	to the canopy	分蘖期		20		10
Spring wheat	fungicide	Leaf rust disease (叶锈病)	to the canopy	分蘖期		20		10
Spring wheat	fungicide	Powdery Mildew (白粉病)	to the canopy	拔节期		40		10
Spring wheat	fungicide	Rhizoctonia solani(纹枯病)	to the canopy	苗期		7		10
Spring wheat	plant growth regulator	growth regulation, production (调节生长、增产)	to the canopy	拔节期		40		
Spring wheat	herbicide		to the canopy			7		14
Winter wheat	insecticide	aphid (蚜虫)	to the canopy				-50	14
Winter wheat	insecticide	armyworm (粘虫)	to the canopy	孕穗期			-45	14
Winter wheat	insecticide	midge (吸浆虫)	to the canopy				-50	14
Winter wheat	fungicide	Gibberellic disease (赤霉病)	to the canopy				-35	14

Crop	Type of pesticide	Insect or disease or weed	Type of treatment	Crop stage at application	Timing of application			Application interval (days)
					Absolute	Relative (days, relative to emergence)	or (days, relative to harvest)	
Winter wheat	fungicide	Leaf rust disease (叶锈病)	to the canopy	refer to 条锈病				-25
winter wheat	fungicide	Powdery Mildew (白粉病)	to the canopy					-60 7
Winter wheat	fungicide	Rhizoctonia solani (纹枯病)	to the canopy	返青期				-90 14
Winter wheat	plant growth regulator	growth regulation, production (调节生长、产)	to the canopy	拔节期前10天				-80
Winter wheat	herbicide		to the canopy					-7, -55
Vine	fungicide	Botrytis cinerea (灰霉病)	to the canopy	幼果期	1st May			20
Vine	fungicide	Peronospora tabacina (霜霉病)	to the canopy	幼果期	1st May			20
Vine	fungicide	Powdery Mildew (白粉病)	to the canopy	出现二次穗果	1st July			20
Vine	fungicide	Spot anthracnose (黑痘病)	to the canopy	伤流期	1st March			20
Vine	plant growth regulator	increasing production, seedless (增产、无核)	to the canopy	花后1周处理果穗	1st May			
Sugar beet	insecticide	kmangold fly (甜菜叶蝇)	to the canopy			30		
Sugar beet	fungicide	Brown patch (褐斑病)	to the canopy				-90	10
Tobacco	insecticide	Aphid (蚜虫)	to the canopy			60		10
Tobacco	insecticide	Leaf-eating insects (食叶害虫)	to the canopy	refer to aphid		60		10
Tobacco	insecticide	mite, Aphid (螨、蚜虫)	to the canopy	refer to aphid		60		10
Tobacco	insecticide	Tobacco budworm (烟青虫)	to the canopy			15		10
Tobacco	insecticide	小地老虎	to the canopy	苗期		7		10
Tobacco	fungicide	Black shank (黑胫病)	to the canopy	苗期		7		
Tobacco	fungicide	Brown spot (赤星病)	to the canopy				-30	
Tobacco	fungicide	mosaic disease (花叶病)	to the canopy	苗期		7		
Tobacco	fungicide	Powdery mildew (白粉病)	to the canopy	苗期		7		
Tobacco	fungicide	wildfire (野火病)	to the canopy			45		
Potato	fungicide	(晚疫病)	to the canopy			60		
Potato	fungicide	Scab (疮痂病)	to the soil(土壤消毒)			-1		
Potato	herbicide	Annual grass weed and broad leaf weed (一年生禾本科杂草及部分阔叶杂草)	to the canopy			0		



Crop	Type of pesticide	Insect or disease or weed	Type of treatment	Crop stage at application	Timing of application			Application interval (days)
					Absolute	Relative (days, relative to emergence)	or (days, relative to harvest)	
Paddy rice	herbicide	Weed (杂草)	to the canopy	抛秧前10-15天		15		
Paddy rice	herbicide	Weed (杂草)	to the soil surface	2叶一心—3叶期, 回青		-7; 17		
Paddy rice	insecticide	<i>Tryporyza incertulas</i> Walker (三化螟)	to the canopy	苗期,播种 (秧苗期) 后7天		7		
Paddy rice	insecticide	<i>Chilo suppressalis</i> (二化螟)	to the canopy	分蘖期		35		
Paddy rice	insecticide	<i>Cnaphalocrocis medinalis</i> (稻纵卷叶螟)	to the canopy	苗期		17		
Paddy rice	insecticide	Rice Planthopper (稻飞虱)	to the canopy	分蘖期		30		
Paddy rice	insecticide	thrips (蓟马)	to the canopy	苗期		17		
Paddy rice	insecticide	<i>Pachydiplosis oryzae</i> wood-mason (稻瘿蚊)	to the canopy	3月下旬-四月上旬, 苗期		17		7
Paddy rice	fungicide	Fujikuroi (恶苗病)	seed coating			-7		
Paddy rice	fungicide	Rhizoctonia rot (立枯病)	to the soil surface (苗床撒施)	播种前		-15		
Paddy rice	fungicide	Rhizoctonia solani (纹枯病)	to the canopy	孕穗-破口		75		
Paddy rice	fungicide	rice blast (稻瘟病)	to the canopy	孕穗-破口		75		10
Paddy rice	fungicide	Tip blight (叶尖枯病)	to the canopy	水稻拔节至孕穗期始病		75		10
Paddy rice	plant growth regulator	ripening (催熟)	to the canopy	孕穗-破口			-45	7
Paddy rice	plant growth regulator	growth control (控制生长)	to the canopy	秧苗期		0		



# Annex 6 Pesticides not included in the evaluation of the dry land groundwater risk assessment

List of pesticides (parents and metabolites) not included in the evaluation of the dry land groundwater risk assessment, and the reasons for their non inclusion.

Compound	Type	Reason for non inclusion
2,4-D butylate	parent	Insufficient physico-chemical data
Amicarbazol	parent	Mixture; insufficient physico-chemical data
Bacillus thuringiensis	parent	Biological pesticide
Bismethiazol	parent	Only registered on paddy rice in China; insufficient physico-chemical data; no ADI
Buprofezine	Parent	Only registered on paddy rice in China;
Butachlor	Parent	Only registered on paddy rice in China;
Chlorbenzuron	Parent	Insufficient physico-chemical data
Coumatetralyl	Parent	Rodenticide
Cymoxanil	Parent	Mixture
1-ethyl 5,6-di-2,4(1H,3H)pyridenedione	Metabolite (of cymoxanil)	Mixture; no ADI metabolite
2-cyano-2-methoxyiminoacetic acid	Metabolite (of cymoxanil)	Mixture; no ADI metabolite
3-ethyl-4-(methoxyamino)-2,5-dioxoimidazolidine-4-carboxamide	Metabolite (of cymoxanil)	Mixture; no ADI metabolite
3-ethyl-4-(methoxyamino)-2,5-dioxoimidazolidine-4-carbonitrile	Metabolite (of cymoxanil)	Mixture; no ADI metabolite
Dimethacarb	Parent	Only registered on paddy rice in China; insufficient physico-chemical data; no ADI
Diniconazole	Parent	Insufficient physico-chemical data
Ethoprophos	Parent	Only registered on paddy rice in China
Gibberellins	Parent	Insufficient physico-chemical data
Haloxypop	Parent	No application details
Iprobenfos	Parent	Only registered on paddy rice in China
N-(3,5-dichlorophenyl)3-isopropyl-2,4-dioxoimidazoline-1-carboxamide	Metabolite (of iprodione)	Metabolite only formed in anaerobic soils
Isofenphos-methyl	Parent	Insufficient physico-chemical data
Isocarbophos	Parent	Insufficient physico-chemical data
Isoprocarb	Parent	Only registered on paddy rice in China; insufficient physico-chemical data
Isoprothialone	Parent	Only registered on paddy rice in China
Methidathion	Parent	No application details
Methomyl oxime	Metabolite (of methomyl)	EU considers minor fraction, not relevant
Metolcarb	Parent	Only registered on paddy rice in China; insufficient physico-chemical data; no ADI
Molinate	Parent	Only registered on paddy rice in China
Monoamitraz	Parent	Insufficient physico-chemical data; no application details
Monosultap	Parent	Only registered on paddy rice and cabbage in China; insufficient physico-chemical data
Oxadixyl	Parent	Mixture
Parathion-methyl	Parent	Incomplete application details
Propamocarb	Parent	No application details
Quinclorac	Parent	Only registered on paddy rice in China; no ADI
Sodium diphacinone	Parent	Rodenticide
Thiosultap-sodium	Parent	Insufficient physico-chemical data
Tricyclazole	Parent	Only registered on paddy rice in China
Urbacide	Parent	Mixture
Validamycin	Parent	Insufficient physico-chemical data; no ADI



## Annex 7 Summary of the evaluation of the dry land groundwater risk assessment

### Notes:

- PEC = predicted environmental concentration in groundwater; RQ = risk quotient; ttc = threshold of toxicological concern (=0.75 µg/L)
- highlighted in yellow: some or all of the cases for the pesticide resulted in RQ > 1
- highlighted in blue: some or all of the cases for the non relevant metabolite resulted in RQ > TTC

Pesticide	Parent or metabolite	Number of locations	Number of crops	Number of cases	Model run?	Tox run?	RQ≤0.5 (number of cases)	0.5<RQ≤1 (number of cases)	RQ>1 (number of cases)	RQ>1 - total residues (number of cases)	PEC=0 (number of cases)	Remarks
abamectin	parent	4	3	6	yes	yes	6	0	0	0	6	
abamectin	8a-hydroxyavermectin B1a	4	3	6	yes	no	6	0	0		6	No ADI metabolite; EU considers relevant
abamectin	8a-oxo-avermectine B1a	4	3	6	yes	no	6	0	0		6	No ADI metabolite; EU considers relevant
abamectin	4,8a-dihydroxy-avermectin	4	3	6	yes	no	6	0	0		6	No ADI metabolite; EU considers minor but relevant
abamectin	8a-oxo-4-hydroxy-avermectin B1a	4	3	6	yes	no	6	0	0		6	No ADI metabolite; EU considers minor but relevant
acephate	parent	6	7	18	yes	yes	18	0	0	0	15	
acetamiprid	parent	6	4	12	yes	yes	12	0	0		12	
acetamiprid	N-methyl(6-chloro-3-pyridyl)methylamine	6	4	12	yes	ttc	12	0	0		2	No ADI metabolite; EU considers major fraction but not relevant; PEC compared to TTC
acetochlor	parent	6	5	16	yes	yes	16	0	0	16	0	
acetochlor	t-sulfonic acid	6	5	16	yes	no	??	??	??		0	No ADI metabolite; EU considers relevant

<i>Pesticide</i>	<i>Parent or metabolite</i>	<i>Number of locations</i>	<i>Number of crops</i>	<i>Number of cases</i>	<i>Model run?</i>	<i>Tox run?</i>	<i>RQ≤0.5 (number of cases)</i>	<i>0.5&lt;RQ≤1 (number of cases)</i>	<i>RQ&gt;1 (number of cases)</i>	<i>RQ&gt;1 - total residues (number of cases)</i>	<i>PEC=0 (number of cases)</i>	<i>Remarks</i>
acetochlor	t-oxanilic acid	6	5	16	yes	no	??	??	??		0	No ADI metabolite; EU considers relevant
acetochlor	t-sulfinylacetic acid	6	5	16	yes	no	??	??	??		0	No ADI metabolite; EU considers relevant
alachlor	parent	5	2	8	yes	yes	8	0	0		0	
aldicarb	parent	4	2	5	yes	yes	5	0	0	3	3	
aldicarb	2-methyl-2-(methylsulfinyl)propanal O-((methylamino)carbonyl)oxime	4	2	5	yes	no	??	??	??		0	No ADI metabolite; EU considers relevance unknown; presumed relevant
aldicarb	aldoxycarb	4	2	5	yes	yes	2	3	0		0	ADI = 0.001 mg/kg; EU considers relevance unknown; presumed relevant
atrazine	parent	6	4	8	yes	yes	2	4	2	7	0	
atrazine	deethylatrazine	6	4	8	yes	no	??	??	??		0	No ADI metabolite; EU considers relevant
azocyclotin	parent	1	1	1	yes	yes	1	0	0		1	
bentazon	parent	6	3	11	yes	yes	11	0	0		0	
carbendazim	parent	6	6	17	yes	yes	15	0	2		0	
carbofuran	parent	6	4	15	yes	yes	10	3	2	3	0	
carbofuran	3-hydroxycarbofuran	6	4	15	yes	no	3	??	??		3	No ADI metabolite; EU considers minor fraction but relevant
carbofuran	3-ketocarbofuran	6	4	15	yes	no	??	??	??		0	No ADI metabolite; EU considers minor fraction but relevant
carbofuran	2,3-dihydro-2,2-diemethyl-7-benzofuranol	6	4	15	yes	no	4	??	??		4	No ADI metabolite; EU considers minor fraction but relevant
chlorothalonil	parent	6	6	13	yes	yes	13	0	0	8	13	
chlorothalonil	4-hydroxy-2,5,6-trichloroisophtalonitrile	6	6	13	yes	yes	13	0	0		1	ADI=0.01 mg/kg; EU considers relevant
chlorothalonil	2-amido-3,5,6-trichlo-4-cyanobenzenesulphonic acid	6	6	13	yes	yes	12	1	0		0	ADI=0.06 mg/kg; EU considers relevant

Pesticide	Parent or metabolite	Number of locations	Number of crops	Number of cases	Model run?	Tox run?	RQ≤0.5 (number of cases)	0.5<RQ≤1 (number of cases)	RQ>1 (number of cases)	RQ>1 - total residues (number of cases)	PEC=0 (number of cases)	Remarks
chlorothalonil	3-carbamyl-2,4,5-trichlorobenzoic acid	6	6	13	yes	no	??	??	??		1	No ADI metabolite; EU considers relevant
chlorpyrifos	parent	6	7	21	yes	yes	21	0	0		21	
chlorpyrifos	3,5,6-trichloro-2-pyridinol	6	7	21	yes	ttc	13	0	??		8	No ADI metabolite; EU considers major but not relevant; PEC compared to TTC
chlorpyrifos methyl	parent	4	1	4	yes	yes	4	0	0		4	
chlorpyrifos methyl	3,5,6-trichloro-2-pyridinol	4	1	4	yes	ttc	4	0	0		4	No ADI metabolite; EU considers major but not relevant; PEC compared to TTC
chlortoluron	parent	6	4	12	yes	yes	11	1	0		0	
chlortoluron	3-(3-chloro-p-tolyl)-1-methylurea	6	4	12	yes	ttc	0	0	??		0	No ADI metabolite; EU considers major but not relevant; PEC compared to TTC
copper hydroxide	parent	2	2	2	yes	yes	2	0	0		2	
copper sulphate	parent	1	1	1	yes	yes	1	0	0		1	
cypermethrin	parent	6	7	24	yes	yes	24	0	0		24	
deltamethrin	parent	6	5	15	yes	yes	15	0	0	0	15	
deltamethrin	decamethrin acid	6	5	15	yes	no	14	??	??		14	No ADI metabolite; EU considers relevant
fenamino-sulf	parent	6	6	14	yes	no	??	??	??		0	=diazoben; no ADI available
dichlorvos	parent	6	4	11	yes	yes	11	0	0		10	
dico-fol	parent	4	2	5	yes	yes	5	0	0		5	
dimethoate	parent	6	5	12	yes	yes	12	0	0		9	
dimethoate	omethoate	6	5	12	yes	yes	11	1	0		6	ADI=0.0003; EU considers minor fraction; assumed relevant
endosulfan	parent	4	3	6	yes	yes	6	0	0		6	
ethephon	parent	6	3	10	yes	yes	10	0	0		10	
fenitrothion	parent	4	2	5	yes	yes	5	0	0	0	5	

<i>Pesticide</i>	<i>Parent or metabolite</i>	<i>Number of locations</i>	<i>Number of crops</i>	<i>Number of cases</i>	<i>Model run?</i>	<i>Tox run?</i>	<i>RQ≤0.5 (number of cases)</i>	<i>0.5&lt;RQ≤1 (number of cases)</i>	<i>RQ&gt;1 (number of cases)</i>	<i>RQ&gt;1 - total residues (number of cases)</i>	<i>PEC=0 (number of cases)</i>	<i>Remarks</i>
fenitrothion	3-methyl-4-nitrophenol	4	2	5	yes	yes	5	0	0		5	No ADI metabolite; EU considers relevant
fenpropathrin	parent	4	2	5	yes	yes	5	0	0		5	
fenthion	parent	6	6	16	yes	yes	16	0	0		16	
fenvalerate	parent	5	3	9	yes	yes	9	0	0		9	
fipronil	parent	1	1	1	yes	yes	1	0	0	0	1	
fipronil	fipronil amide	1	1	1	yes	no	??		??			No ADI metabolite; EU considers relevant
fipronil	fipronil sulfone	1	1	1	yes	no	1	0	0		1	No ADI metabolite; EU considers relevant
fipronil	fipronil sulfide	1	1	1	yes	no	1	0	0		1	No ADI metabolite; EU considers relevant
fluazifop-P-butyl	parent	5	3	9	yes	yes	9	0	0		9	
fomesafen	parent	4	1	4	yes	yes	0	0	4		0	
glyphosate	parent	6	4	11	yes	yes	11	0	0		0	
glyphosate	aminomethylphosphonic acid	6	4	11	yes	yes	11	0	0		0	ADI=0.3; EU considers relevant
hexythiazox	parent	4	2	5	yes	yes	5	0	0	0	5	
hexythiazox	5-(4-chlorophenyl)-N-(4-oxocyclohexyl)-4-methyl-2-oxothiazolidine-3-carboxamide	4	2	5	yes	ttc	5	0	0		0	No ADI metabolite; EU considers major but not relevant; PEC compared to TTC
hexythiazox	trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-3-carboximide	4	2	5	yes	no	5	0	0		5	No ADI metabolite; EU considers relevant
hexythiazox	trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine	4	2	5	yes	no	5	0	0		5	No ADI metabolite; EU considers relevant
imidacloprid	parent	6	8	29	yes	yes	29	0	0		0	
iprodione	parent	2	2	3	yes	yes	3	0	0		1	
isoproturon	parent	6	2	6	yes	yes	6	0	0	0	0	
isoproturon	desmethylisoproturon	6	2	6	yes	no	??	??	??		0	No ADI metabolite; EU considers relevant
lambda-cyhalothrin	parent	6	7	22	yes	yes	22	0	0	0	22	



Pesticide	Parent or metabolite	Number of locations	Number of crops	Number of cases	Model run?	Tox run?	RQ≤0.5 (number of cases)	0.5<RQ≤1 (number of cases)	RQ>1 (number of cases)	RQ>1 - total residues (number of cases)	PEC=0 (number of cases)	Remarks
lambda-cyhalothrin	(RS)-alpha-cyano-3-(4-hydroxyphenoxy)benzyl-(Z)-(1RS)-cis-3-(2-chloro-3, 3, 3-trifluoropropenyl)-2, 2-dimethylcyclopropanecarboxylate	6	7	22	yes	no	22	0	0		22	No ADI metabolite; EU considers major fraction but relevancy unknown - presumed relevant
malathion	parent	6	6	16	yes	yes	16	0	0	0	16	
malathion	malathion dicarboxylic acid	6	6	16	yes	no	9	??	??		14	No ADI metabolite; EU considers relevant
mepiquat chloride	parent	4	1	4	yes	yes	4	0	0		4	
MCPA	parent	6	2	6	yes	yes	6	0	0		0	
methamidophos	parent	6	5	22	yes	yes	22	0	0		16	
methomyl	parent	6	4	11	yes	yes	11	0	0		6	
metolachlor	parent	6	4	11	yes	yes	11	0	0		3	
monocrotophos	parent	6	4	11	yes	yes	8	??	??		7	3 runtime errors
omethoate	parent	6	3	10	yes	yes	7	1	2		5	
paclobutrazol	parent	6	4	11	yes	yes	11	0	0	0	2	
paclobutrazol	(2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-one	6	4	11	yes	no	2	??	??		2	No ADI metabolite; EU considers relevant
paclobutrazol	1,2,4-triazole	6	4	11	yes	no	2	??	??		2	No ADI metabolite; EU considers relevant
paraquat	parent	6	8	19	yes	yes	19	0	0		0	
parathion	parent	6	6	30	yes	yes	30	0	0		30	
triazophos	parent	4	3	6	yes	yes	6	0	0		4	
phorate	parent	6	3	20	yes	yes	20	0	0		20	
fosethyl aluminium	parent	4	2	5	yes	no	5	0	0		5	
phoxim	parent	6	8	28	yes	yes	28	0	0		28	
pirimicarb	parent	6	4	11	yes	yes	11	0	0	0	7	
pirimicarb	2-dimethylamino-5,6-dimethylpyrimidin-4-ol	6	4	11	yes	no	10	??	??		10	No ADI metabolite; EU considers relevant
pirimicarb	5,6-dimethyl-2-(methylamino)pyrimidin-4-ol	6	4	11	yes	no	11	0	0		11	No ADI metabolite; EU considers relevant

<i>Pesticide</i>	<i>Parent or metabolite</i>	<i>Number of locations</i>	<i>Number of crops</i>	<i>Number of cases</i>	<i>Model run?</i>	<i>Tox run?</i>	<i>RQ≤0.5 (number of cases)</i>	<i>0.5&lt;RQ≤1 (number of cases)</i>	<i>RQ&gt;1 (number of cases)</i>	<i>RQ&gt;1 - total residues (number of cases)</i>	<i>PEC=0 (number of cases)</i>	<i>Remarks</i>
pirimicarb	5,6-dimethyl-2-(methylformamido)pyrimidin-4-yl dimethylcarbamate	6	4	11	yes	no	9	??	??		10	No ADI metabolite; EU considers relevant
prochloraz	parent	6	5	9	yes	yes	9	0	0	0	8	
prochloraz	N-formyl-N'-propyl-N'-2(2,4,6-trichlorophenoxy)ethylurea	6	5	9	yes	no	8	??	??		8	No ADI metabolite; EU considers relevant
procymidone	parent	1	1	2	yes	yes	1	1	0		0	
profenofos	parent	4	1	4	yes	yes	4	0	0		4	
prometryn	parent	6	5	15	yes	yes	15	0	0		3	
propargite	parent	4	2	5	yes	yes	5	0	0		5	
propargite	TBPC	4	2	5	yes	no	5	0	0		5	No ADI metabolite; EU considers relevant
pyridaben	parent	4	2	5	yes	yes	5	0	0	0	5	
pyridaben	2-tert-butyl-5-(4-(1-carboxy-1-methylethyl) benzylthio)4-chloropyridazin-3 (2H)-one	4	2	5	yes	no	5	0	0		5	No ADI metabolite; EU considers minor but relevant
quinalphos	parent	4	1	4	yes	no	4	0	0		4	
quintozene	parent	6	4	12	yes	yes	12	0	0		12	
thiophanate methyl	parent	6	8	16	yes	yes	16	0	0		16	
thiophanate methyl	carbendazim	6	8	16	yes	yes	13	2	1		0	ADI metabolite carbendazim=0.03 mg/kg; EU considers relevant
triadimefon	parent	6	4	12	yes	yes	12	0	0		12	
tribenuron-methyl	parent	6	2	6	yes	yes	6	0	0		5	
trichlorfon	parent	6	5	15	yes	yes	15	0	0		0	
trichlorfon	dichlorvos	6	5	15	yes	yes	12	3	0		10	ADI metabolite dichlorvos = 0.00008 mg/kg; EU considers major and relevant
trifluralin	parent	5	2	8	yes	yes	8	0	0		8	

# Annex 8 Input parameters for the honeybee calculations

The following data and input parameters were used for the calculations of the predicted exposure concentration and the predicted no effect concentration and the subsequent evaluation of risk for honeybees. Column headers refer to the input/output data table which is provided together with this report

Column header	Remarks
<b>Substance</b>	
No.	Sequence number
Common name	The common name of the pesticide active substance
Formulation type	Code for the type of the formulation: The formulation codes listed on the ICAMA web site are used
IGR? (yes/no)	Is the pesticide an insect growth regulator (IGR)? Based on following sources: Pesticide Manual (Tomlin, 2010): under " <i>Mode of action</i> " and Footprint database (Footprint, undated): under " <i>Description</i> " or " <i>Mode of action</i> "
Systemic? (yes/no)	Is the pesticide systemic? Based on following sources: Pesticide Manual (Tomlin, 2010): under " <i>Mode of action</i> " and Footprint database (Footprint, undated): under " <i>Description</i> " or " <i>Mode of action</i> "
<b>Crop</b>	
Crop	Crop(s) to be treated with the pesticide. The crop(s) with the highest and the crop (s) with the lowest application rate were included.
Time of flowering	Estimated date of flowering for each crop (for example: mid-April) Parameter was not used for this study.
Crop attractive to bees? (yes/no)	Is the crop attractive to bees? For Tier-1 assessment: all crops = yes For refinement, data from Annex 9 were used.
<b>Application</b>	
Is bee exposure possible? (yes/no)	Check the label to know which uses of the pesticide are allowed. Pesticide uses where bee exposure is unlikely are, for instance: Indoor uses, such as glasshouses (if bees are not used for pollination), domestic premises, factories, grain stores Use in winter when bees are not flying Pre-emergence use of herbicides (if the weeds are not attractive to bees) Seed treatments or granules (unless the pesticide is systemic) Products for dipping bulbs For this study, in all assessed cases it was assumed that exposure was possible (=yes)
Application rate	Unit: kg <u>active substance</u> ha <sup>-1</sup> The maximum and minimum dosage from the CAU database were used.
Frequency of applications	Unit: number season <sup>-1</sup> The maximum and minimum frequency from the CAU database were listed, but the impact of a single application was assessed.
Interval between applications	Unit: days The smallest interval between applications from the CAU database was listed, but this parameter was not used for this study.
Application type	The application type on the label: spray, soil treatment, seed treatment
Time of application	Enter the estimated date in the year when the application takes place (for example: mid-April) This parameter was not used in the study.
<b>Pesticide parameters – toxicity</b>	
LD <sub>50</sub> -oral	Unit: microgram/bee Acute oral median lethal dose (LD <sub>50</sub> ), for exposure time of 48, 72 or 96 hours. If exposure time was not mentioned, it was assumed to be acute. If more values were available, the lowest LD <sub>50</sub> was used
LD <sub>50</sub> -contact	Unit: microgram/bee Acute oral median lethal dose (LD <sub>50</sub> ), for exposure time of 48, 72 or 96

Column header	Remarks
	hours. If exposure time was not mentioned, it was assumed to be acute. If more values were available, the lowest LD <sub>50</sub> was used
Lowest LD <sub>50</sub>	Unit: microgram/bee Lowest value of either the oral or the contact LD <sub>50</sub>
<b>Pesticide parameters – fate</b>	
<i>Values on fate only need to be entered if: the pesticide is systemic <u>and</u> the application type is soil treatment or seed treatment</i>	
Default residue	Unit: mg active substance/kg vegetation Default = 1
<b>Risk quotient calculations</b>	
<b>Scenario 1 – spray</b>	
<i>This RQ is only relevant if application type is spray</i>	
RQ-spray	Risk quotient (RQ) for a sprayed pesticide. Value is calculated as: $RQ = (\text{application rate} * 1000) / (\text{lowest LD}_{50} * 50)$
<b>Scenario 2 – systemic</b>	
<i>This RQ is only relevant if the pesticide is systemic <u>and</u> the application type is soil treatment or seed treatment</i>	
ETE-syst	Estimated theoretical exposure for a systemic pesticide Unit: microgram/bee Value is calculated as: $ETE\text{-syst} = 0.128 * \text{default residue}$
Uncertainty factor (UF)	Uncertainty factor (UF) to extrapolate from acute to chronic toxicity Default = 10
RQ-syst	Risk quotient (RQ) for a systemic soil applied pesticide or seed treatment Value is calculated as: $RQ = (ETE\text{-syst} * UF) / LD_{50}\text{-oral}$

## Annex 9 Crops attractive to honey bees

Crops known to be visited by honey bees, and impact of animal pollinators on production of the crop (e.g. increased fruit set, fruit weight and/or quality, seed number and/or quality) (Based on Klein *et al.* (2007)<sup>3</sup>. This list still needs to be brought up-to-date for the Chinese situation.

Crop species	Crop name	Increased production due to animal pollination
<b>Vegetable crops</b>		
<i>Abelmoscus esculentus</i>	Okra (Gumbo)	Modest
<i>Cajanus cajan</i>	Pigeon pea	Little
<i>Capsicum annuum</i> , <i>C. frutescens</i>	Chile pepper, red pepper, bell pepper, green pepper	Little
<i>Cicer arietinum</i>	Chickpea	No increase
<i>Citrullus lanatus</i>	Watermelon	Essential
<i>Cucumis melo</i>	Melon	Essential
<i>Cucumis sativus</i>	Cucumber, gherkin	Great
<i>Cucurbita</i> spp.	Pumpkin, squash, gourd, zucchini	Essential
<i>Cyamopsis tetragonoloba</i>	Guar bean, Goa bean	Little
<i>Dolichus biflorus</i> , <i>D. lablab</i>	Hyacinth bean, horsegram, lablab	Modest
<i>Fagopyrum esculatum</i>	Buckwheat	great
<i>Lens esculenta</i>	Lentils	No increase
<i>Lycopersicon esculentum</i>	Tomato	Little (in open fields) Great (in greenhouses)
<i>Phaseolus</i> spp.	Kidney bean, haricot bean, lima bean, mungo bean, string bean	Little
<i>Solanum melongena</i>	Eggplant, aubergine	Modest
<i>Vigna unguiculata</i>	Cowpea, blackeye pea, blackeye bean	Little
<b>Fruit crops</b>		
<i>Actinidia deliciosa</i>	Kiwi fruit	Essential
<i>Arbutus unedo</i>	Tree-strawberry	Modest
<i>Averrhoa carambola</i>	Carambola, starfruit	Great
<i>Carica papaya</i>	Papaya	Little
<i>Citrus</i> spp.	Orange, lemon, lime, mandarine, grapefruit, kumquat, pomelo, etc.	Little
<i>Crataegus azarolus</i>	Azarole, Azzerulo	Little
<i>Dimocarpus longan</i>	Longan	Little
<i>Diospyros kaki</i> , <i>D. virginiana</i>	Persimmon	Little
<i>Durio zibethinus</i>	Durian	Great
<i>Eriobotrya japonica</i>	Loquat, Japanese plum	Great
<i>Feijoa sellowiana</i>	Feijoa	Great
<i>Fragaria</i> spp.	Strawberry	Modest
<i>Litchi chinensis</i>	Litchi, lychee	Little
<i>Malus domestica</i>	Apple	Great
<i>Mammea americana</i>	Mammee	Modest
<i>Mangifera indica</i>	Mango	Great
<i>Mespilus germanica</i>	Medlar	Unknown
<i>Nephelium lappaceum</i>	Rambutan	Little
<i>Persea americana</i>	Avocado	Great
<i>Pouteria sapota</i>	Sapote, mamey colorado	Unknown
<i>Prunus domestica</i> , <i>P. spinosa</i>	Plum, mirabelle, sloe	Great
<i>Prunus persica</i> , <i>Persica laevis</i>	Peach, Nectarine	Great
<i>Prunus avium</i>	Sweet cherry	Great
<i>Prunus armeniaca</i>	Apricot	Great
<i>Prunus cerasus</i>	Sour cherry	Great
<i>Psidium gujava</i>	Guava, guayaba	Modest
<i>Punica granatum</i>	Pomegranate	Modest
<i>Pyrus communis</i>	Pear	Great
<i>Ribes nigrum</i> , <i>R. rubrum</i>	Black currant, red currant	Modest

<sup>3</sup> Klein A-M, Vaissière BE, Cane JH, Steffan-Dewenter I, Cunningham SA, Kremen C & Tschrntke T (2007) Importance of pollinators in changing landscapes for world crops. *Proceedings of the Royal Society B* **274**: 303-313 (+ electronic supplementary material on the journal web site)

Crop species	Crop name	Increased production due to animal pollination
<i>Rosa spp.</i>	Rose hips, dogroses	Great
<i>Rubus spp.</i>	Raspberry, blackberry, dewberry	Great
<i>Sambucus nigra</i>	Elderberry	Modest
<i>Sorbus aucuparia</i>	Rowanberry	Essential
<i>Sorbus domestica</i>	Service-apple	Modest
<i>Spondias spp.</i>	Hog plum, mombin	Little
<i>Tamarindus indica</i>	Tamarind	Little
<i>Vaccinium spp.</i>	Blueberry, cranberry	Great
<i>Vitis vinifera</i>	Grapes	No increase
<i>Zizyphus jujuba</i>	Jujube	Modest
<b>Nut crops</b>		
<i>Amygdalus communis</i>	Almond	Great
<i>Anacardium occidentale</i>	Cashew nut and cashew apple	Great
<i>Arachis hypogea</i>	Peanut, groundnut	Little
<i>Castanea sativa</i>	Chestnut	Modest
<i>Macadamia ternifolia</i>	Macadamia	Essential
<b>Edible oil and proteinaceous crops</b>		
<i>Brassica alba</i> , <i>B. hirta</i> , <i>B. nigra</i>	Mustard seeds	Modest
<i>Brassica napus oleifera</i>	Rapeseed, oilseed rape	Modest
<i>Brassica rapa</i>	Turnip rape, canola	Great
<i>Carthamus tinctorius</i>	Safflower	Little
<i>Cocos nucifera</i>	Coconut	Modest
<i>Glycine max</i> , <i>G. soja</i>	Soybean	Modest
<i>Gossypium spp.</i>	Cotton	Modest
<i>Helianthus annuus</i>	Sunflower	Modest
<i>Linum usitatissimum</i>	Flaxseed	Little
<i>Olea europaea</i>	Olive	No increase
<i>Sesamum indicum</i>	Sesame	Modest
<i>Vicia faba</i>	Broad bean, field bean	Modest
<i>Vitellaria paradoxa</i>	Karite nuts, sheanuts	Modest
<b>Stimulant crops</b>		
<i>Coffea arabica</i> , <i>C. canephora</i>	Coffee	Modest
<i>Theobroma cacao</i>	Cocoa	Essential
<b>Spices and condiments</b>		
<i>Coriandrum sativum</i>	Coriander	Great
<i>Elettaria cardamomum</i>	Cardamom	Great
<i>Foeniculum vulgare</i>	Fennel seed	Great
<i>Pimenta dioica</i>	Allspice, pimento	Great
<i>Piper nigrum</i> , <i>P. longum</i>	Pepper	No increase
<i>Pimpinella anisum</i>	Anise	Unknown

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## Annex 10 Pesticides not included in the evaluation of the honeybee risk assessment

List of pesticides not included in the evaluation of the honeybee risk assessment, and the reasons for their non-inclusion.

Compound	Reason for non-inclusion
Thiosultap-sodium	No LD <sub>50</sub> values available
Phoxim	No LD <sub>50</sub> values available
Parathion-methyl	No relevant application scheme defined
Isocarbophos	No LD <sub>50</sub> values available
<i>Bacillus thuringiensis</i>	No LD <sub>50</sub> values available
Metolcarb	No LD <sub>50</sub> values available
Dimethacarb	No LD <sub>50</sub> values available
Bismerthiazol	No LD <sub>50</sub> values available
Haloxypop	No LD <sub>50</sub> values available; no relevant application scheme defined
Urbacide	Mixture
Cymoxanil	Mixture
Oxadixyl	Mixture
Amicarbazol	Mixture
Sodium diphacinone	Rodenticide
Coumatetralyl	Rodenticide
Mepiquat chloride	No relevant application schemes defined
Quintozene	No relevant application scheme defined
Trifluralin	No relevant application scheme defined





# Annex 11 Summary of the evaluation of the honey bee risk assessment

## Notes:

- Type: A = acaricide; F = fungicide; H = herbicide; I = insecticide; PGR = plant growth regulator
- IGR = insect growth regulator
- RQ<sub>spray</sub> = risk quotient for sprayed pesticides; RQ<sub>syst</sub> = risk quotient for systemic pesticides
- n.a. = calculation not applicable; c?? = calculation not possible, generally because oral LD<sub>50</sub> absent
- highlighted in yellow: some or all of the cases for the pesticide resulted in RQ > 1

Common name	Type	IGR	Systemic	No. cases evaluated		LD <sub>50</sub> available		Worst case risk assessment		Risk assessment including crop attractiveness		Worst case risk assessment (only for cases when RQ>1)	
				all crops sprayed	crops attractive to soil/ bees seed	oral	contact	RQ <sub>spray</sub> >1 (no. cases)	RQ <sub>syst</sub> >1 (any case)	RQ <sub>spray</sub> >1 (no. cases)	RQ <sub>syst</sub> >1 (any case)	RQ <sub>spray</sub> highest value	RQ <sub>syst</sub> lowest value
pyridaben	A	no	no	2	2	yes	yes	2	n.a.	2	n.a.	113	19
dicofof	A	no	no	3	3	yes	yes	0	n.a.	0	n.a.		
propargite	A	no	no	2	2	no	yes	0	n.a.	0	n.a.		
azocyclotin	A	no	no	2	2	yes	no	0	n.a.	0	n.a.		
hexythiazox	A	no	no	2	2	yes	no	0	n.a.	0	n.a.		
propamocarb	F	no	yes	2	2	yes	yes	0	no	0	no		0.02
copper sulfate	F	no	no	2	1	no	yes	0	n.a.	0	n.a.		
carbendazim	F	no	yes	4	4	no	yes	0	c??	0	c??		
thiophanate methyl	F	no	yes	4	3	yes	no	0	no	0	no		0.01
validamycin	F	no	no	2	0	yes	no	2	n.a.	n.a.	n.a.	25	10
chlorothalonil	F	no	no	4	3	yes	no	1	n.a.	1	n.a.	1.5	0.15
tricyclazole	F	no	yes	3	0	yes	no	0	no	n.a.	n.a.		0.01
fenaminosulf	F	no	no	2	1	no	yes	1	n.a.	0	n.a.	1.8	0.52
triadimefon	F	no	yes	3	0	yes	no	0	no	n.a.	n.a.		0.05
copper hydroxide	F	no	no	3	3	no	yes	1	n.a.	1	n.a.	1.04	0.13
isoprothiolane	F	no	yes	2	0	yes	yes	0	no	n.a.	n.a.		0.01
iprobenfos	F	no	yes	2	0	no	yes	0	c??	n.a.	n.a.		
fosethyl aluminium	F	no	yes	2	1	yes	no	0	no	0	no		0.03

Common name	Type	IGR	Systemic	No. cases evaluated		LD <sub>50</sub> available		Worst case risk assessment		Risk assessment including crop attractiveness		Worst case risk assessment (only for cases when RQ>1)		
				all crops sprayed	crops attractive to soil/ bees seed	oral	contact	RQ <sub>spray</sub> >1 (no. cases)	RQ <sub>syst</sub> >1 (any case)	RQ <sub>spray</sub> >1 (no. cases)	RQ <sub>syst</sub> >1 (any case)	RQ <sub>spray</sub> highest value	lowest value	RQ <sub>syst</sub>
procymidone	F	no	yes	3	3	no	yes	0	c??	0	c??			
prochloraz	F	no	no	2	2	yes	yes	0	n.a.	0	n.a.			
diniconazole	F	no	yes	2	0	no	yes	0	c??	n.a.	n.a.			
iprodione	F	no	no	3	3	no	yes	1	n.a.	1	n.a.	0.3	1.2	
acetochlor	H	no	yes	2	0	yes	yes	0	no	n.a.	n.a.			0.01
glyphosate	H	no	yes	4	3	yes	yes	0	no	0	no			0.01
butachlor	H	no	yes	2	0	yes	yes	0	no	n.a.	n.a.			0.01
atrazine	H	no	yes	2	1	yes	yes	0	no	0	no			0.01
paraquat	H	no	yes	2	2	yes	yes	1	no	1	no	2	0.66	0.14
fluazifop-P-butyl	H	no	yes	2	2	yes	yes	0	no	0	no			0.006
bentazon	H	no	no	2	2	yes	no	0	n.a.	0	n.a.			
MCPA	H	no	yes	2	0	yes	yes	0	no	n.a.	n.a.			0.006
molinat	H	no	yes	2	0	yes	no	2	no	n.a.	n.a.	5.5	3.6	0.12
metolachlor	H	no	yes		2	yes	yes	n.a.	no	n.a.	n.a.			0.01
alachlor	H	no	yes		2	yes	yes	n.a.	no	2	no			0.01
tribenuron	H	no	yes	2	0	yes	yes	0	no	n.a.	n.a.			0.14
fomesafen	H	no	yes	2	2	yes	yes	0	no	0	no			0.03
quinclorac	H	no	yes	2	0	no	yes	0	c??	n.a.	n.a.			
isoproturon	H	no	yes	2	0	yes	no	0	no	n.a.	n.a.			0.03
chlortoluron	H	no	no	2	0	yes	yes	0	n.a.	n.a.	n.a.			
prometryne	H	no	yes	1	1	yes	yes	0	no	0	no			0.01
2,4-D butylate	H	no	yes	2	0	no	yes	1	c??	n.a.	n.a.	1.1	0.26	
dichlorvos	I	no	no	4	1	yes	no	4	n.a.	1	n.a.	86	21	
methamidophos	I	no	yes	2	0	yes	no	2	yes	n.a.	n.a.	82	17	5.8
trichlorfon	I	no	no	4	1	yes	no	4	n.a.	1	n.a.	90	23	
omethoate	I	no	yes	2	0	yes	no	2	yes	n.a.	n.a.	250	25	27
monosultap	I	no	yes	4	0	yes	yes	4	yes	n.a.	n.a.	169	38	8.5
dimethoate	I	no	yes	4	2	yes	yes	4	yes	2	Yes	222	29	13
monoamitraz	I	no	no	2	2	no	yes	0	n.a.	0	n.a.			
triazophos	I	no	no	3	1	no	yes	2	n.a.	1	n.a.	2.1	0.17	
chlorpyrifos	I	no	no	4	2	yes	yes	4	n.a.	2	n.a.	854	24	
acephate	I	no	yes	4	2	no	yes	4	c??	2	c??	23	2.6	
buprofezin	I	yes	no	3	0	yes	yes	0	n.a.	n.a.	n.a.			
malathion	I	no	no	3	2	yes	yes	3	n.a.	2	n.a.	188	9.4	
monocrotophos	I	no	yes	2	1	yes	yes	2	yes	1	yes	750	150	64
imidacloprid	I	no	yes	4	2	yes	yes	4	yes	2	yes	1622	30	346
parathion	I	no	no	2	1	yes	no	2	n.a.	1	n.a.	375	188	

Common name	Type	IGR	Systemic	No. cases evaluated			LD <sub>50</sub> available		Worst case risk assessment		Risk assessment including crop attractiveness		Worst case risk assessment (only for cases when RQ>1)		
				all crops	crops attractive to		oral	contact	RQ <sub>spray</sub> >1 (no. cases)	RQ <sub>syst</sub> >1 (any case)	RQ <sub>spray</sub> >1 (no. cases)	RQ <sub>syst</sub> >1 (any case)	RQ <sub>spray</sub> highest value	lowest value	RQ <sub>syst</sub>
				sprayer/soil/ seed	bees										
phorate	I	no	yes	2	0		no	yes	1	c??	n.a.	n.a.	7.5	0.27	
carbofuran	I	no	yes	3	1		yes	yes	3	yes	1	yes	1250	375	32
Isofenphos-methyl	I	no	yes	2	1		no	yes	2	c??	1	c??	197	16	
cypermethrin	I	no	no	4	1		yes	yes	4	n.a.	1	n.a.	150	15	
methomyl	I	no	yes	3	1		yes	yes	3	yes	1	yes	68	11	4.6
isoprocarb	I	no	no	2	0		yes	no	2	n.a.	n.a.	n.a.	6	4.5	
pirimicarb	I	no	yes	3	0		yes	yes	1	no	n.a.	n.a.	1.1	0.23	0.32
fenpropathrin	I	no	no	2	1		no	yes	2	n.a.	1	n.a.	120	9	
fenvalerate	I	no	no	4	4		no	yes	4	n.a.	4	n.a.	261	13	
abamectin	I	no	yes	4	2		yes	yes	4	yes	2	yes	298	12	142
fenitrothion	I	no	no	4	1		no	yes	4	n.a.	1	n.a.	113	31	
chlorbenzuron	I	yes	no	2	1		yes	yes	2	n.a.	1	n.a.	3410	341	
endosulfan	I	no	no	3	2		no	yes	1	n.a.	1	n.a.	2.4	0.34	
methidathion	I	no	no	3	3		yes	yes	3	n.a.	3	n.a.	154	25	
aldicarb	I	no	yes		2	2	yes	no	n.a.	yes	n.a.	yes			14.2
ethoprophos	I	no	no	2		1	no	yes	2	n.a.	1	n.a.	19	2.7	
lambda-cyhalothrin	I	no	no	4		2	yes	yes	4	n.a.	2	n.a.	142	1.8	
quinalphos	I	no	yes	3		0	yes	yes	3	yes	n.a.	n.a.	176	43	18
deltamethrin	I	no	no	3		1	yes	yes	3	n.a.	1	n.a.	175	30	
chlorpyrifos methyl	I	no	no	1		1	yes	no	1	n.a.	1	n.a.	191		
profenofos	I	no	no	3		2	no	yes	3	n.a.	2	n.a.	197	63	
acetamiprid	I	no	yes	4		3	yes	yes	1	no	1	no	2.2	0.19	0.09
fenthion	I	no	no	2		1	no	yes	2	n.a.	1	n.a.	150	38	
fipronil	I	no	yes	3		1	yes	no	3	yes	1	yes	360	19	307
ethephon	PGR	no	yes	2		1	no	yes	0	c??	0	c??			
paclobutrazol	PGR	no	yes	2		0	yes	yes	1	no	n.a.	n.a.	4.5	0.77	0.64
gibberellins	PGR	no	yes	1	1	1	no	yes	0	c??	0	c??			



# Annex 12 Input parameters for the silkworm calculations

The following data and input parameters were used for the calculations of the predicted exposure concentration and the predicted no effect concentration and the subsequent evaluation of risk for silkworm. Column headers refer to the input/output data table which is provided together with this report

Column header	Remarks
<b>Substance</b>	
No.	Sequence number
Common name	The common name of the pesticide active substance
Formulation type	Code for the type of the formulation: The formulation codes listed on the ICAMA web site were used.
<b>Crop</b>	
Where is pesticide applied?	Either in mulberry field <b>or</b> in adjacent crop
Crop name	Adjacent crop(s) treated with the pesticide.
<b>Application</b>	
Is mulberry exposure possible? (yes/no)	Check the label to know which uses of the pesticide are allowed. Pesticide uses where exposure of mulberry trees is unlikely are, for instance: Indoor uses, such as glasshouses, domestic premises, factories, grain stores Seed treatments or granules (unless the pesticide is systemic) Products for dipping bulbs Pesticide applications to crops that are only grown in provinces where there is no sericulture Only crops/uses where mulberry exposure would be possible have been included in the assessment.
Application rate	Unit: kg active substance ha <sup>-1</sup> The maximum dosage and minimum dosage from the database were used If the pesticide was registered on mulberry trees and on adjacent crops, the maximum and minimum dose for each were used.
Frequency of applications	Unit: number season <sup>-1</sup> The application frequency associated with the highest and lowest dose mentioned above were used If no data are provided on the label, assume 1 application only
Interval between applications	Unit: days Only relevant if frequency of applications > 1 If no data were provided on the label, the table in Annex 5 was used.
Application type	Only sprayed pesticides were assessed.
Pre-harvest interval	Unit: days Only relevant for pesticides applied <b>in</b> the mulberry plantation. If no data were available, 0 days was assumed.
<b>Pesticide parameters – toxicity</b>	
LC <sub>50</sub> (acute-spray)	Unit: mg a.s./kg mulberry leaf Acute median lethal concentration (LC <sub>50</sub> ), based on a dietary toxicity test where pesticide is sprayed onto mulberry leaves (new protocol) If more values are available, the mean LC <sub>50</sub> was used Data source: CABET report on new test method (Sun <i>et al.</i> , . 2010)
LC <sub>50</sub> (acute-dipping)	Unit: mg a.s./litre spray solution Acute median lethal concentration (LC <sub>50</sub> ), based on a dietary toxicity test where mulberry leaves are dipped in the pesticide solution (old protocol) If more values are available, the mean LC <sub>50</sub> was used Data source: CABET database of contract laboratory data
Corrected LC <sub>50</sub>	Unit: mg a.s./kg mulberry leaf LC <sub>50</sub> (acute-dipping) converted to LC <sub>50</sub> (acute-spray), using the dipping correction factor. Value is calculated by spreadsheet as: Corrected LC <sub>50</sub> = LC <sub>50</sub> (acute-dipping) * 0.46
LC <sub>50</sub> used for RQ	Unit: mg a.s./kg mulberry leaf Lowest value of either dipping or spray LC <sub>50</sub>
<b>Pesticide parameters – fate</b>	
RUD	Residue unit dose Unit: mg a.s./kg leaf/kg a.s. Default value = 950
DT <sub>50</sub> -vegetation	Half-life of the pesticide on vegetation

Column header	Remarks
	Unit (days) If no data are available: Default = 10
Degradation factor (DF <sub>phi</sub> )	Fraction of the residue on the leaf, which remains after the pre-harvest interval Value is calculated by spreadsheet as: $DF_{phi} = \exp((0.693 * PHI)/DT_{50})$
Multiple application factor (MAF)	Factor to allow for accumulation of residues, in case more than one application. Value is calculated by spreadsheet (for formula, see ERA handbook)
Pesticide drift factor (PDF) – 1 <sup>st</sup> row	Fraction of the application rate which drifts from the adjacent field onto the 1 <sup>st</sup> row of mulberry trees Default = 0.10
Pesticide drift factor (PDF) – 2 <sup>nd</sup> row	Fraction of the application rate which drifts from the adjacent field onto the 2 <sup>nd</sup> row of mulberry trees Default = 0.006
<b>Risk quotient calculations</b>	
<b>Scenario 1: pesticide in mulberry – single or multiple application</b>	
ETE-mulberry	Unit: mg a.s./kg leaf Estimated theoretical exposure of mulberry leaves Value is calculated by spreadsheet as: $ETE\text{-mulberry} = \text{application rate} * RUD * DF_{phi} * MAF$
Uncertainty factor (UF)	Default = 50
RQ-mulberry	Risk quotient (RQ) for a pesticide applied in a mulberry plantation Value is calculated by spreadsheet as: $RQ = (ETE\text{-mulberry} * UF) / LC_{50}$
<b>Scenario 2 - pesticide in adjacent field - single or multiple application</b>	
ETE-neighb. 1 <sup>st</sup> row	Unit: mg a.s./kg leaf Estimated theoretical exposure on the first row of mulberry trees, adjacent the sprayed field Value is calculated by spreadsheet as: $ETE\text{-mulberry} = \text{application rate} * RUD * DF_{phi} * MAF * PDF_{1st\ row}$
Uncertainty factor (UF)	Uncertainty factor (UF) to extrapolate from acute to chronic toxicity Default = 50
RQ- 1 <sup>st</sup> row	Risk quotient (RQ) for the first row of mulberry trees, adjacent the sprayed field Value is calculated by spreadsheet as: $RQ = (ETE\text{-neighb } 1^{st} \text{ row} * UF) / LD_{50}\text{-oral}$
ETE-neighb. 2 <sup>nd</sup> row	Unit: mg a.s./kg leaf Estimated theoretical exposure on the second row of mulberry trees, adjacent the sprayed field Value is calculated by spreadsheet as: $ETE\text{-mulberry} = \text{application rate} * RUD * DF_{phi} * MAF * PDF_{2nd\ row}$
RQ- 2 <sup>nd</sup> row	Risk quotient (RQ) for the second row of mulberry trees, adjacent the sprayed field Value is calculated by spreadsheet as: $RQ = (ETE\text{-neighb } 2^{nd} \text{ row} * UF) / LD_{50}\text{-oral}$

# Annex 13 Pesticides not included in the evaluation of the silkworm risk assessment

List of pesticides not included in the evaluation of the silkworm risk assessment, and the reasons for their non-inclusion.

Compound	Reason for non-inclusion
Parathion-methyl	No LD <sub>50</sub> values available; no relevant application scheme defined
Isocarbophos	No LD <sub>50</sub> values available
Monocrotophos	No LD <sub>50</sub> values available
Parathion	No LD <sub>50</sub> values available
Phorate	No relevant application schemes defined
Carbofuran	No LD <sub>50</sub> values available; no relevant application scheme defined
Isufenphos-methyl	No relevant application schemes defined
Pirimicarb	No LD <sub>50</sub> values available
Fenpropathrin	No LD <sub>50</sub> values available
Fenvalerate	No LD <sub>50</sub> values available
Fenitrothion	No LD <sub>50</sub> values available
Endosulfan	No LD <sub>50</sub> values available
Methidathion	No LD <sub>50</sub> values available
Aldicarb	No LD <sub>50</sub> values available; no relevant application scheme defined
Ethoprophos	No LD <sub>50</sub> values available; no relevant application scheme defined
Quinalphos	No LD <sub>50</sub> values available
<i>Bacillus thuringiensis</i>	No LD <sub>50</sub> values available; no relevant application scheme defined
Dimethacarb	No LD <sub>50</sub> values available
Fenthion	No LD <sub>50</sub> values available
Fluazifop-P-butyl	No LD <sub>50</sub> values available
Trifluralin	No relevant application scheme defined
Molinate	No LD <sub>50</sub> values available
Metolachlor	No relevant application scheme defined
Alachlor	No relevant application scheme defined
Bismerthiazol	No LD <sub>50</sub> values available
Chlortoluron	No LD <sub>50</sub> values available
Haloxifop	No relevant application scheme defined
2,4-D butylate	No LD <sub>50</sub> values available
Fenamiosulf	No LD <sub>50</sub> values available
Urbacide	Mixture
Cymoxanil	Mixture
Oxadixyl	Mixture
Fosetyl aluminium	No LD <sub>50</sub> values available
Quintozene	No LD <sub>50</sub> values available; no relevant application scheme defined
Amicarbazol	Mixture, no LD50 values
Diniconazole	No LD <sub>50</sub> values available
Azocyclotin	No LD <sub>50</sub> values available
Hexythiazox	No LD <sub>50</sub> values available
Sodium diphacinone	Rodenticide
Coumatetralyl	Rodenticide
Gibberellins	No relevant application scheme defined
Mepiquat chloride	No LD <sub>50</sub> values available; no relevant application scheme defined





## Annex 14 Summary of the evaluation of the silkworm risk assessment

Notes:

- Type: A = acaricide; F = fungicide; H = herbicide; I = insecticide; PGR = plant growth regulator
- IGR = insect growth regulator; RQ = risk quotient; PHI = pre-harvest interval
- highlighted in yellow: some or all of the cases for the pesticide resulted in RQ > 1

Common name	Type	IGR	No. of cases		LC <sub>50</sub> diet		DT <sub>50</sub>		No. RQ > 1 (no PHI)			Minimum PHI needed for all RQ ≤ 1 (days)	
			mulberry	adjacent crop	spraying (mg/kg leaf)	dipping (mg/L solution)	field	default	mulberry	1 <sup>st</sup> row	2 <sup>nd</sup> row	mulberry	2 <sup>nd</sup> row
pyridaben	A	no	0	2	no	yes		10		2	2		52
dicofol	A	no	0	3	no	yes	7.7			3	3		24
propargite	A	no	1	2	no	yes	2.2		1	2	2	22	5
propamocarb	F	no	0	2	no	yes		10		2	0		0
copper sulphate	F	no	0	2	no	yes		10		0	0		0
carbendazim	F	no	0	4	no	yes	9.0			4	4		112
thiophanate methyl	F	no	1	4	no	yes	28.1		1	4	2	211	43
validamycin	F	no	0	2	no	yes		10		0	0		0
chlorothalonil	F	no	0	4	no	yes	3.7			4	0		3
tricyclazole	F	no	0	3	no	yes		10		3	0		0
triadimefon	F	no	0	3	no	yes		10		3	2		9
copper hydroxide	F	no	0	3	no	yes		10		2	0		0
isoprothiolane	F	no	0	2	no	yes		10		2	1		7
iprobenfos	F	no	0	2	no	yes		10		2	2		21
procymidone	F	no	0	3	no	yes	11.0			3	1		3
prochloraz	F	no	0	2	no	yes		10		2	0		0
iprodione	F	no	0	3	no	yes	10.2			3	2		19
acetochlor	H	no	0	2	no	yes		10		2	2		47
glyphosate	H	no	2	4	no	yes	14.0		2	4	4	202	107
butachlor	H	no	0	2	no	yes		10		2	2		31

Common name	Type	IGR	No. of cases		LC <sub>50</sub> diet		DT <sub>50</sub>		No. RQ > 1 (no PHI)			Minimum PHI needed for all RQ ≤ 1 (days)	
			mulberry	adjacent crop	spraying (mg/kg leaf)	dipping (mg/L solution)	field	default	mulberry	1 <sup>st</sup> row	2 <sup>nd</sup> row	mulberry	2 <sup>nd</sup> row
atrazine	H	no	0	2	no	yes		10		2	2		49
paraquat	H	no	1	2	no	yes		10	1	2	1	74	5
bentazon	H	no	0	2	no	yes	2.5			2	0		0
MCPA	H	no	0	2	no	yes		10		1	0		0
tribenuron	H	no	0	2	no	yes		10		0	0		0
fomesafen	H	no	0	2	no	yes		10		2	0		0
quinclorac	H	no	0	2	no	yes		10		2	2		136
isoproturon	H	no	0	2	no	yes		10		2	0		0
prometryne	H	no	0	1	no	yes		10		1	1		27
dichlorvos	I	no	3	4	yes	yes	0.2		3	4	4	3	2
thiosultap-sodium	I	no	0	3	no	yes		10		3	3		103
phoxim	I	no	2	4	yes	yes	1.8		2	4	4	29	16
methamidophos	I	no	0	2	no	yes	3.6			2	1		2
trichlorfon	I	no	0	4	no	yes	2.3			4	4		20
omethoate	I	no	0	2	no	yes		10		2	1		35
monosultap	I	no	0	4	yes	yes		10		4	4		110
dimethoate	I	no	0	4	yes	no	2.9			4	4		14
monoamitraz	I	no	0	2	no	yes		10		2	1		6
triazophos	I	no	0	3	no	yes		10		3	3		112
chlorpyrifos	I	no	2	4	no	yes	2.5		2	4	4	39	27
acephate	I	no	0	4	no	yes	2.9			4	4		14
buprofezin	I	yes	0	3	no	yes		10		3	3		82
malathion	I	no	0	3	no	yes	1.9			3	3		9
imidacloprid	I	no	0	4	yes	yes	1.1			4	4		10
cypermethrin	I	no	0	4	yes	yes	4.2			4	4		44
methomyl	I	no	2	3	no	yes	1.7		2	3	3	25	16
isoprocarb	I	no	0	2	no	yes		10		2	2		95
abamectin	I	no	0	4	no	yes	1.6			4	4		21
chlorbenzuron	I	yes	0	2	no	yes		10		2	2		105
lambda-cyhalothrin	I	no	0	4	no	yes	3.4			4	4		63
deltamethrin	I	no	0	3	no	yes	4.1			3	3		46

Common name	Type	IGR	No. of cases		LC <sub>50</sub> diet		DT <sub>50</sub>		No. RQ > 1 (no PHI)			Minimum PHI needed for all RQ ≤ 1 (days)	
			mulberry	adjacent crop	spraying (mg/kg leaf)	dipping (mg/L solution)	field	default	mulberry	1 <sup>st</sup> row	2 <sup>nd</sup> row	mulberry	2 <sup>nd</sup> row
chlorpyrifos methyl	I	no	0	1	no	yes	1.5			1	1		16
profenofos	I	no	0	3	no	yes	1.1			3	3		12
metolcarb	I	no	0	2	no	yes		10		2	1		14
acetamiprid	I	no	0	4	no	yes	2.0			4	4		25
fipronil	I	no	0	3	no	yes	4.2			3	3		32
ethephon	PGR	no	0	2	no	yes		10		1	0		25
paclobutrazol	PGR	no	0	2	no	yes		10		1	0		14

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