



Environmental data requirements for the Chinese Pesticide Registration

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Sino – Dutch Pesticide Environmental
Risk Assessment Project

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1. Introduction

Project brief

Background

China has to feed 21% of the world's population with 10% of world's arable land. Intensification through increased use of agro-chemicals (fertilizers and pesticides) is an important goal in China's agricultural policies. This has led to one of the highest use rates for pesticides (280 kg/ha) in the world, leading to high emissions to the environment. In the 11th 5-year Policy Programme of the Chinese government sustainable agriculture is promoted through rational use of pesticides. The Institute for the Control of Agrochemicals (ICAMA) is in China responsible for the pesticide registration procedures. Up to now the main criteria for pesticide admission were efficacy and food safety. In 2006 and 2007 ICAMA has to include environmental criteria in the registration procedures and it has to re-consider the admission of the 600 formulations already allowed on the market. ICAMA wants to adopt procedures and tools used in the EU pesticide registration process for the prediction of possible emissions and ecotoxicological effects on the ecosystems.

Wageningen – UR has extensive knowledge on pesticide fate and risks in the environment and plays a significant scientific role in the scientific underpinning and formulation of the EU registration procedure. Due to this expertise Wageningen-UR was asked by ICAMA to provide assistance in this process.

Objectives

To support national legislation authorities in China to include environmental risk assessment including criteria in pesticide registration procedures and to form a local science platform that is able to support the regulators with scientific advice in the future.

Partners

Institute for the Control of Agrochemicals Ministry of Agriculture, China (ICAMA), represented by Mr. Tao Chuanjiang.

Alterra, part of Wageningen University and Research Centre, represented by H van den Bosch.

Plant Research International, part of Wageningen University and Research Centre, represented by Dr. Corné Kempenaar.

Project duration

2006-2007

Outputs 2006

1. A clear mutual understanding of the current challenges for ICAMA to include environmental risk assessment and criteria, and the needs in terms of methods and tools, training and institutional reform.
2. Development of a detailed mutually agreed action plan for 2007 – 2009 to meet these challenges. This includes content (requirements for training, laboratory facilities, model testing and validation), mutual responsibilities and budget agreements.
3. Set-up of new data requirements to be issued December 2006 and in line with the activities for 2007

This visit

In July 2006 an identification mission was done and reported by Van den Bosch and Tao Chuanjiang (2006) to meet output 1. This was followed by an inception workshop from September 4 to 8, 2006, to meet output 2. This resulted in a draft workplan for the period 2007-2010, which will be finalised early 2007. The 3rd main activity in 2006 is this trip.

2. Aim of this visit

A pesticide registration authority issues data requirements for registration, which is a document describing which tests have to be executed and data delivered by the pesticide industry when they apply for registration for a new pesticide. These data requirements are usually updated periodically following new insights, priorities and scientific developments. ICAMA agreed with MoA to issue new data requirements in December 2006. This involves data for efficacy, food safety and environment.

As this project is revisiting the environmental part of the registration procedures the result of the project will be newly developed environmental test and guidelines and from that data requirements for the industry will follow. By coincidence data requirements are renewed at the beginning of the project because of agreements within the ministry, whereas this will also be the final results of the project in 2010. Therefore it is important as this stage to anticipate as good as possible on the final outcome of the project in 2010 while developing data requirements at this point in time.

The aim of this visit to assist ICAMA staff in developing data requirements for 2007 and make sure they match anticipated outcome of the project is good as possible.

3. Program

The following table contains the main activities of this workshop.

Day	Activities
13, Nov.	<ul style="list-style-type: none">- Make a work plan;- Define the different categories of pesticides including clear definitions;- Define the protection goals of the overall project;- Start with creating a table with: x-axis = different categories of pesticides and y-axis = different data requirements.
14, Nov.	<ul style="list-style-type: none">- Discuss if metabolites are taken into account in the risk assessment and in the data requirements.- Define data requirements for each category of pesticides (product / A.I.)
15, Nov.	<ul style="list-style-type: none">- Define data requirements for each category of pesticides (product / A.I.)- Discuss about the use of the List of Endpoints into the risk assessment and the data requirements.

16, Nov.	<ul style="list-style-type: none"> - Define data requirements for each category of pesticides (product / A.I.) - Define the parameters necessary for PEC calculations.
17, Nov.	<ul style="list-style-type: none"> - Discuss the results - Make an overview of activities which have to be done - Finish the report

4. Results

This section gives the results of the workshop:

- An overview of the different categories of pesticides;
- An overview of the different types of registration of pesticides;
- Data requirements needed for each category of pesticides;
- Conditions, guidelines and endpoints of the different studies required;
- Metabolites;
- The parameters needed for PEC calculations.

4.1 Different categories of pesticides:

This section gives an overview of the different categories of pesticides according to the Chinese registration system.

✧ **Agricultural chemical pesticide**

- a). Herbicides (**Group 1**)
- b). Insecticides (**Group 2**)
- c). Fungicides (**Group 3**)
- d). Chemical insect growth regulator (**Group 4**)

✧ **Special pesticides**

a). Public health pesticide (not for agricultural use)

a-1). Public health insecticide

Definition: Insecticides, acaricides and products used for the control of other arthropods (e.g. insects, fleas, arachnids and crustaceans) and repellents or attractants used to control organisms harmful for human health.

a-1.1). Indoor use (**Group 5**)

a-1.2). Outdoor use (**Group 6**)

a-2). Wood preservatives (**Group 7**)

Definition: Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms. This category includes both preventive and curative

products.

a-3). Antifouling (**Group 8**)

Definition: Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

b). Rodenticide (Group 9)

Definition: products used for the control of mice, rats and other rodents.

c). Bio-chemical pesticide: agricultural and not agricultural (Group 10)

Definition: bio-chemical pesticide is one kind of the biological pesticides. A bio-chemical pesticide must meet the following two conditions:

Condition 1: It has no direct toxicity to the target, but only the special function of growth adjustment, interference of the mating or attraction.

Condition 2: It must be a natural compound, if it is synthetic, its structure must be the same as the natural one (proportion difference of isomers is acceptable).

c-1). Pheromone

The chemical matter exuded by the plant and animal can change receptor organism behavior of the same homogeneity and different homogeneity, including pheromones

c-2). Hormone

Biochemical matter synthesized by part of the organism and conducted to other part to have control and adjustment.

c-3). Natural Plant Growth Regulator and Insect Growth Regulator

Natural PGR is generated by the plant or the micro-organism. For the growing and developing of the same homogeneity and different homogeneity of the plant (including sprouting, growth, flowering, fecundation, fruit, ripe and falling etc.), having function of inhibition and irritating or adjust chemical matter against adverse conditions (cold, hot, dry, wet and wind etc.) of the plant.

Insect growth regulator is the chemical matter having function of inhibition and irritation.

c-4). Enzyme

Enzyme is the carrier during the gene reaction and the in the reaction of the organism is the protein molecule for the catalytic function.

d). Microbial pesticide (Group 11)

Microbial pesticide is the one kind of biological pesticides, including formulation naturally produced by bacteria, fungi, virus and protozoa or micro organism modified by gene etc. to control the harmful organisms such as insect, weed and rats etc.

e). Genetically modified organism

(to be updated later).

f). Natural enemy

(to be updated later).

4.2 Different types of registration of pesticides

There are three types of registration:

- ✧ Field trial;
- ✧ Temporary registration;
- ✧ Full registration.

For field trial, no data are required for the environmental part. For environmental part, there's no difference between temporary and full registrations.

This report is focused on the data requirements for the temporary and full registration.

In China the Active ingredient (a.i.) and the formulations are registered separately. In this report the data requirements are given both for the a.i. and the formulation. The Active Ingredient itself must be registered and so all the data have to be fulfilled for all kind of products / formulations. Between the different categories there might be a difference but not within one category. For example: In some cases in EU a bird study is not required because the application is only for glass houses. In China a bird study is always required because the A.I. is the basis for all formulations in one category.

4.3 Data requirements needed for each category of pesticides

In this section an overview of the data requirements is given for each group of pesticides for the a.i. (see table 1) and for the formulation (see table 2). For the definitions of the groups see section 5.1.

There might be a possibility that some pesticide belong to category a and c. In this case the application must fulfill the requirements for both categories.

Besides the data in table 1 and 2, extra data or studies might be required. This will be decided by ICAMA case by case (e.g. when a risk for the environment cannot be excluded and more information is necessary.).

In the table “**G**” represents a group of pesticides.
Pesticide group 11 will be finished after further discussion.

Table 1 Data requirements for the Active Ingredient/Technical grade

Data requirement	G1	G2	G3	G4	G5	G6	G7	G8	G9	G10	G11
Fate and behavior											
Volatility	+	+	+	+	-	+	+	+	+	-	
Route of degradation in Soil***	+	+	+	+	-	+	-	-	+	-	
Soil Degradation	+	+	+	+	-	+	+	-	+	-	
Photolysis (soil)	+	+	+	+	-	+	-	-	+	-	
Soil absorption and desorption	+	+	+	+	-	+	-	-	+	-	
Leaching*	+	+	+	+	-	+	-	-	+	-	
Water-sediment Study (Route of degradation)***	+	+	+	+	-	+	-	+	+	-	
Hydrolysis	+	+	+	+	-	+	-	+	+	-	
Leaching from the ship to the water	-	-	-	-	-	-	-	-	-	-	
Photolysis(water)	+	+	+	+	-	+	-	+	+	-	
Bio-concentration	+	+	+	+	-	+	-	+	+	-	
Eco-toxicology											
Acute oral toxicity to Bird	+	+	+	+	-	+	-	-	+	-	
Short-term Dietary toxicity to bird	+	+	+	+	-	+	-	-	+	-	
Chronic toxicity to Bird**	-	-	-	-	-	-	-	-	+	-	
Acute toxicity to Honeybee	+	+	+	+	-	+	-	-	-	+	
Acute toxicity to Trichogramma	+	+	+	+	-	+	-	-	-	-	
Acute toxicity to Frog	+	+	+	+	-	+	-	+	+	-	
Acute toxicity to Fish	+	+	+	+	-	+	+	+	+	+	
Chronic toxicity to Fish	+	+	+	+	-	+	-	+	+	-	
Acute toxicity to Daphnia	+	+	+	+	-	+	+	+	+	+	
Chronic toxicity to Daphnia	+	+	+	+	-	+	-	+	+	-	
Acute toxicity to Algae	+	+	+	+	-	+	+	+	+	+	
Acute toxicity to Silkworm(leaf)	+	+	+	+	+	+	-	-	-	+	
Chronic toxicity to Silkworm	+	+	+	+	+	+	-	-	-	-	
Acute toxicity to Earthworm**	+	+	+	+	-	+	+	-	+	-	
Soil micro-organism**	+	+	+	+	-	+	+	-	+	-	
Sensitivity for the rotational crops**	+	-	-	-	-	-	-	-	-	-	
Further studies(field tests, etc.)	+	+	+	+	+	+	+	+	+	+	
* to be developed into field test in the future											
** protection goals not included in the project, but need to be dealt with in the future.											
*** tests necessary for identifying metabolites and also generate important data such as DT50soil, DT50water, etc., New test guidelines need to be developed during the project.											

Group 1: Agricultural pesticides, herbicides

Group 2: Agricultural pesticides, insecticides

Group 3: Agricultural pesticides, fungicides

Group 4: Agricultural pesticides, Chemical Insect Growth Regulators

Group 5: Special pesticides, public health, indoor use

Group 6: Special pesticides, public health, outdoor use

Group 7: Special pesticides, wood preservatives

Group 8: Special pesticides, antifouling

Group 9: Special pesticides, rodenticides

Group 10: Special pesticides, bio-chemical pesticides

Group 11: Special pesticides, microbial pesticides

Table 2 Data requirements for End-use Product/Formulation

Data requirement	G1	G2	G3	G4	G5	G6	G7	G8	G9	G10	G1 1
Fate and behavior											
Volatility	-	-	-	-	-	-	-	-	-	-	
Route of degradation in Soil***	-	-	-	-	-	-	-	-	-	-	
Soil Degradation	+	+	+	+	-	+	-	-	+	-	
Photolysis(soil)	-	-	-	-	-	-	-	-	-	-	
Soil absorption and desorption	+	+	+	+	-	+	-	-	+	-	
Leaching*	-	-	-	-	-	-	-	-	-	-	
Water-sediment Study (Route of degradation)***	-	-	-	-	-	-	-	-	-	-	
Hydrolysis	-	-	-	-	-	-	-	-	-	-	
Leaching from the ship to the water	-	-	-	-	-	-	-	+	-	-	
Photolysis(water)	-	-	-	-	-	-	-	-	-	-	
Bio-concentration	-	-	-	-	-	-	-	-	-	-	
Eco-toxicology											
Acute oral toxicity to Bird	+	+	+	+	-	+	-	-	+	-	
Short-term Dietary toxicity to bird	-	-	-	-	-	-	-	-	-	-	
Chronic toxicity to Bird**	-	-	-	-	-	-	-	-	-	-	
Acute toxicity to Honeybee	+	+	+	+	-	+	-	-	-	-	
Acute toxicity to Trichogramma	+	+	+	+	-	+	-	-	-	-	
Acute toxicity to Frog	-	-	-	-	-	-	-	-	-	-	
Acute toxicity to Fish	+	+	+	+	-	+	-	+	+	-	
Chronic toxicity to Fish	+	+	+	+	-	+	-	+	+	-	
Acute toxicity to Daphnia	+	+	+	+	-	+	-	+	+	-	
Chronic toxicity to Daphnia	+	+	+	+	-	+	-	+	+	-	
Acute toxicity to Algae	+	+	+	+	-	+	-	+	+	-	
Acute toxicity to Silkworm(leaf)	+	+	+	+	+	+	-	-	-	+	
Chronic toxicity to Silkworm	-	-	-	+	+	-	-	-	-	-	
Acute toxicity to Earthworm**	+	+	+	+	-	+	-	-	+	-	
Soil micro-organism**	-	-	-	-	-	-	-	-	-	-	
Sensitivity for the rotational crops**	-	-	-	-	-	-	-	-	-	-	
Further studies (field tests, etc.)	+	+	+	+	+	+	+	+	+	+	
<p>* to be developed into field test in the future ** protection goals not included in the project, but need to be dealt with in the future. *** tests necessary for identifying metabolites and also generate important data such as DT50soil, DT50water, etc., New test guidelines need to be developed during the project.</p>											

Notes for table 1 & 2:

General remark:

In EU there are some extra requirements which are not required for China according to table 1 and 2:

- higher tier requirements are not described in this document; a general remark is made in table 1 and 2: further studies (field tests, etc.)
- ready biodegradability study (A.7.2.1.3.1a)
- Sub-Chronic toxicity and reproduction to birds (All.8.1.3a); In China this test is only required for Rodenticides.
- Effects on sediment dwelling organisms (All.8.2.7)
- Toxicity to aquatic plants (All 8.2.8)
- Chronic toxicity to earthworms (All.8.4.2)
- Effects on arthropods; In EU tests with several species is required; In China only a study is required for Trichogramma.

Group 1: Herbicide

In EU effects on algal growth and growth rate in a second species is required for herbicides. At this moment this will not be a requirement for China; in the future this can be discussed again.

Group 4: Chemical insect growth regulator

The honeybee food breeding test is required in EU and might be developed in China in the future.

Group 5 and 6: Public Health insecticides

There's no difference in data requirements between Group 5 and Group 6 in terms of active ingredients, while there are different requirements in terms of formulations. Because this group is very important a complete set of data of a.i. will be asked for the future.

Group 7: Wood preservatives

a) for wood preservatives, different models are needed for calculating PECs compared with the agricultural models. In the model for wood preservatives a lot of scenarios are included (at storage site; indoor and outdoor use; contact with seawater; contact with fresh water; contact with soil).

b) Wood preservative is not a priority in the project.

c) Studies are required only for the purpose of the comparison with Chinese criteria which already exist. Because this group is not very important a complete set of data will not yet be asked.

d) If this group of pesticides will be taken into account as a prior group and risk assessment will be done 2 new extra studies should be required for leaching of the wood to the water and soil.

Group 8: Anti-fouling

For antifouling a different model is needed for calculating PECs compared with the agricultural models., In the model for antifouling a lot of scenarios are included (big harbor; small harbor; open sea; lines), while the model itself is not very complicated.

Group 9: Rodenticide

- a) For rodenticide a different model is needed for calculating PECs compared with the agricultural models., In the model for rodenticide a lot of scenarios are included (indoor use; outdoor use; use in sewage; use in open field; covered; uncovered)
- b) The chronic toxicity to bird” will only be asked for the rodenticides. Some other categories of pesticide will need this test in the future; rodenticide is very important and special research centers can perform the test; in the project we will focus on the risk assessment but not on the test methods. Also in case fields tests are necessary for rodenticides these institutes can perform them.

Group 10 Biochemical pesticides

- a) Bio-chemical pesticides are not a priority in the project
- b) Studies are required only for the purpose of the comparison with Chinese criteria which already exist. Because this group is not very important a complete set of data will not yet be asked.

4.4 Conditions, guidelines and endpoints of the different studies required

In this section an overview is given of the conditions, guidelines and endpoints of the different studies required. **The conditions describe when (under which circumstances) a study is required; sometimes, if relevant details of the study are given like: the test period; soil type; type of species etc.**

The number of the guideline recommended is given. A guideline is a text that provides instructions and advice for performing a study and suggests possible approaches.

An endpoint refers to an assessment variable that are used for risk assessment e.g. mortality levels (LD50), effect concentration (EC50) or a degradation Time 50% ($DT_{50,soil}$).

Table 3 represents the information for the fate and behaviour part, table 4 represents the ecotoxicology part.

When it can be scientifically justified that there will not be exposure to a compartment (such as water, soil, etc), there may be a possibility that some of the tests are not required. This will be decided by ICAMA case by case.

In the tables 3 and 4 all the EU test methods come from the newly revised version of

Annex 2&3 of 91/414; all the Annex numbers in the second column come from the old version.

Table 3 conditions, guidelines and endpoints of the different studies required for fate and behavior

Data requirement	Annex II & III of 91/414	Conditions for active ingredient	Conditions for formulation	Chinese Guideline	Recommended EU Guideline	End point/ Test results
Volatility		Always required Test should be done: -For 3 different pathways of volatilization;	-	*		
Route of degradation in Soil (aerobic)	7.1.1.1.1	- Always required. - Metabolites which at any time account for more than 10 % of the amount of the a.i. must be identified. Test should be done: -For 1 soil (for soil type: case by case) -test period: Normally 120 days.	-	NA	OECD 307	The degradation pathway with the percentage, identification, etc of the metabolites; DT50 of a.i. & DT50 of the metabolites (1 soil)
Route of degradation in Soil (anaerobic)	7.1.1.1.2	Always required. Metabolites which at any time account for more than 10 % of the amount of the a.i. must be identified. Test should be done: -For 1 soil(for soil type: case by case) -Normally for 120 days.	-	NA	OECD 307	The degradation pathway with the percentage, identification, etc of the metabolites; DT50 of a.i. & DT50 of the metabolites (1 soil)
Soil Degradation (aerobic)	7.1.1.2.1 (a.i.) 9.1.1.1	Always required. Test should be done: -For 3 different soils (soil types are defined in the Chinese guideline) -Normally for 120 days	Required in the case of slow release formulation	* NA for formulation	OECD 307	DT50
Soil Degradation (anaerobic)	7.1.1.2.1 (a.i.) 9.1.1.1	Always required. Test should be done: -For 1 soils (soil type: case by case) -Normally for 120 days	Required in the case of slow release formulation	* NA for formulation	OECD 307	DT50
Photolysis(soil)	7.1.1.1.2	Always required.	-	-	OECD draft new	DT50

		Test should be done: - For 1 soil (soil type: case by case).			guideline January 2002 or later revision	
Soil absorption and desorption	7.1.2(a.i.) 9.1.2	Always required. -For 3 soils (soil types are defined in the Chinese guideline)	Required in the case of slow release formulation	* NA for formulation	OECD 106	Koc / Kom (Kd / Kom in Chinese guideline)
Leaching	7.1.3.1.	Always required. (3 different fresh soils)	-	*	OECD 312	Rf/Ri %
Water-sediment Study (Route of degradation)	7.2.1.3.2.	Always required Metabolites which at any time account for more than 10 % of the amount of the a.i. must be identified. Test should be done: -for two sediments (different organic carbon content, texture, pH) -Normally 100 days	-	-	OECD308	The degradation pathway with the percentage, identification, etc of the metabolites; DT50 of a.i. & DT50 of the metabolites
Hydrolysis (Route of degradation)	7.2.1.1	Always required Test should be done: -for 3 pH values	-	*	OECD111	Identification of metabolites; DT50 of a.i.
Leaching from the ship to the water	Directive 98/8/EEC / Biocides	-	Always	-	ASTM-D5108-90	Ug/L/d
Photolysis(water)	7.2.1.2	Always required Test should be done: -for pure water	-	*	OECD draft new guideline August 2000 or later revisions	DT50
Bio-concentration	8.2.3	Required where: -log pow \geq 3	-	*	OECD 305	BCF
NA: Not Available *:Chinese guideline: The environmental test guideline for chemical pesticide ** SETAC: Procedures for assessing the environmental fate and ecotoxicity of pesticides *** different methods for different species						

Table 4 conditions, guidelines and endpoints of the different studies required for ecotoxicology

Data requirement	AnnexII & III of 91/414	Conditions for active ingredient	Conditions for formulations	Chinese Guideline	Recommended EU Guideline	End point/ Test results
Acute oral toxicity to Bird	8.1.1.(a.i.) 10.1.1	Always required Test should be done: -for one species: Japanese quail (Bobwhite is acceptable) -the highest dose used in tests need not exceed 1 000 mg/kg* body weight.	Required where the a.i. is highly toxic to bird (LD50 from acute oral test of the ai <50 mg/kg bw) or where results from mammal testing give evidence of a significantly higher toxicity of the formulation compared to the a.i. Test should be done: -for one species: Japanese quail (Bobwhite is acceptable) -the highest dose used in tests need not exceed 1 000 mg/kg* body weight.	*	OECD 401 or SETAC**	LD50 mg/kg bw (NOEL)
Short-term Dietary toxicity to bird	8.1.2(a.i.).	Always required for one species: Japanese quail (Bobwhite is acceptable)		*	OECD 205	LC50 mg/kg bw·d or mg/kg food
Chronic toxicity to Bird	8.1.3(a.i.)	Always required		-	OECD 206	NOEC mg/kg food or NOAEL mg/kg bw·d
Acute toxicity to Honeybee	8.3.1.1 (a.i.)	Always required for acute oral and acute	Required where -the product contains more	*	OECD 213 & 214	LC50 or LD50 for oral

	10.4.1	contact tests	than one active substance; -or the a.i. is highly toxic to honeybees (LC50 from acute oral test of the ai <20mg/L or LD50 from the acute contact test of the a.i.< 2.0ug/bee)		Eppo 170	LD50 for contact mg/L ug/bee
Acute toxicity to <i>Trichogramma</i>	8.3.2.(a.i.)	Always required	Required where -the product contains more than one active substance; - or the a.i. is highly toxic to <i>Trichogramma</i> (criteria: to be defined)	*	SETAC***	LC50 mg/L or LD50 ug/ <i>Tricho.</i>
Acute toxicity to Frog	-	Always required		*		LC50 mg/L
Acute toxicity to Fish	8.2.1(a.i.) 10.2.1	Always required Test should be done: -for two species: one is a warm water species (<i>Brachydonio rerio</i>); the other is a cold species; -concentration up to 100mg/L must be tested, except for poorly soluble substances, for which lower concentration maybe accepted;	Required where -the a.i. is highly toxic to fish(LC50 from acute test of the ai <1.0mg/L) -Or the intended use includes direct application on water. -the formulation contains more than one active substance. If from the data of acute tests of a.i.(fish, daphnia, algae), it can be concluded one of the three taxonomic groups is the most sensitive(100 times more sensitive),tests on only the most sensitive species of	*	OECD 203 or EU Testing Method C 1 (annex V to Directive 67/548/EEC)	LC50 mg/L

			<p>the relevant group have to be performed, otherwise, all the three groups have to be tested.</p> <p>Test should be done:</p> <p>-for one species: the most sensitive one, concluded from the ai acute tests;</p>			
Chronic toxicity to Fish	8.2.2(a.i.) 10.2.4.	<p>Always required for at least one of the following tests:</p> <ul style="list-style-type: none"> - Fish early life stage toxicity test - Chronic toxicity test in juvenile fish - Fish full life cycle test(test method to be decided case by case) <p>Test should be done:</p> <p>-for two species: one is a warm water species (<i>Brachydonio rerio</i>); the other is a cold species (species is not yet defined).</p>	<p>Required where</p> <ul style="list-style-type: none"> -the formulation is more acutely toxic than the a.i. by a factor of 10, unless it is demonstrated that continued or repeated exposure will not occur. <p>Test should be done:</p> <p>-for one species: the most sensitive one, concluded from the a.i. chronic tests.</p>	-	OECD 210 OECD 215	NOEC mg/L
Acute toxicity to <i>Daphnia</i>	8.2.4(a.i.) 10.2.1	<p>Always required</p> <p>Test should be done:</p> <ul style="list-style-type: none"> -for one species: <i>Daphnia magna</i> -concentration up to 100mg/L must be tested, except for poorly soluble substances, for which lower concentration maybe accepted; 	<p>Required where</p> <ul style="list-style-type: none"> -the a.i. is highly toxic to <i>Daphnia</i> EC50 from acute test of the ai <1.0mg/L) -Or the intended use includes direct application on water. -the formulation contains more than one active substance. 	*	OECD 202 part 1	EC50 mg/L

			<p>If from the data of acute tests of a.i.(fish, daphnia, algae), it can be concluded one of the three taxonomic groups is the most sensitive(100 times more sensitive),tests on only the most sensitive species of the relevant group have to be performed, otherwise, all the three groups have to be tested.</p> <p>Test should be done: -for one species: <i>Daphnia magna</i></p>			
Chronic toxicity to <i>Daphnia</i>	8.2.5(a.i.) 10.2.4.	<p>Always required</p> <p>Test should be done: -for one species: <i>Daphnia magna</i></p>	<p>Required where -the formulation is more acutely toxic than the a.i. by a factor of 10, unless it is demonstrated that continued or repeated exposure will not occur.</p> <p>Test should be done: -for one species: <i>Daphnia magna</i></p>		OECD 211	NOEC mg/L
Acute toxicity to Algae	8.2.6(a.i.) 10.2.1	<p>Always required</p> <p>Test should be done: -for one species of the following three: 1. <i>Chlorella vulgaris</i>; 2. <i>Scenedesmus obliquus</i>; 3. <i>Seonastrum capricornutum</i></p>	<p>Required where -the a.i. is highly toxic to Algae (EC50 from acute test of the ai < 0.3mg/L) -Or the intended use includes direct application on water.</p>	*	OECD 201	EC50 (NOEC) mg/L

		-concentration up to 100mg/L must be tested, except for poorly soluble substances, for which lower concentration maybe accepted;	-the formulation contains more than one active substance. If from the data of acute tests of a.i. (fish, daphnia, algae), it can be concluded one of the three taxonomic groups is the most sensitive (100 times more sensitive),tests on only the most sensitive species of the relevant group have to be performed, otherwise, all the three groups have to be tested. Test should be done: - for one species of the following three: <i>1. Chlorella vulgaris;</i> <i>2. Scenedesmus obliquus;</i> <i>3.Seonastrum capricornutum</i>			
Acute toxicity to Silkworm(leaf)	-	Always required Test should be done: -for one species.	Required where -the a.i. is highly toxic to silkworm (LC50 from acute test of the ai <20 mg/L or < 20 mg/kg leaf) -the formulation contains more than one active substance. - for group 5: public health pesticide indoor use; if pesticide in form of spray or	*	-	LC50 Mg/L Mg/kg leaf

			incense etc. Test should be done: -for one species.			
Chronic toxicity to Silkworm	-	Always required Test should be done: -for one species.	Required where: -the formulation is more acutely toxic than the a.i. by a factor of 10, unless it is demonstrated that continued or repeated exposure will not occur. Test should be done: -for one species.	-	-	NOEC Mg/L Mg/kg leaf
Acute toxicity to Earthworm	8.4.1 (a.i.) 10.6.1	Always required. Test should be done: -for one species: <i>Eisenia Foelide</i>	Required where: -the a.i. is highly toxic to earthworm (LC50 of the ai <1.0 mg/kg soil) -the formulation contains more than one active substance. Test should be done: -for one species: <i>Eisenia Foelide</i>	*	EU testing method C.8 (Annex V of Directive 67/548/EEC)	LC50 Mg/kg soil
Soil micro-organisms****	-	Always required Test should be done: - for two different typical Chinese fresh soils	-	*	-	Effect rate (%)
Sensitivity for the rotational crops	-	Always required.	-	*	-	EC10 and EC50 Mg/L
Further studies(field tests, etc.)	-	Where necessary a higher tiered study should be carried out case by case.				
<p>* Chinese guideline: The environmental test guideline for chemical pesticide ** SETAC: Procedures for assessing the environmental fate and ecotoxicity</p>						

of pesticides

*** different methods for different species

**** Chinese and EU system is different, not prior in project, stay to Chinese system

4.5 Metabolites

Introduction

The active ingredient of a pesticide may be transformed in the environment by either abiotic or biotic processes. The potential risks that these metabolites pose to the environment organisms must be assessed. **This section describes the data requirements for metabolites.**

Definition

Metabolite

All breakdown products of an active ingredient of a pesticide formulation, which are formed in the environment by biotic or abiotic processes after the application.

Major metabolite

All metabolites that are formed in amounts of $\geq 10\%$ of the applied amount of active substance at any timepoint evaluated during the degradation studies in the appropriate compartment under consideration.

Minor metabolite

All metabolites, degradation and reaction products that are formed in amounts of $< 10\%$ of the applied amount of substance of active substance at any time during the degradation studies under consideration.

Relevant compartments and requirements

When assessing risks to the environment, metabolites in the following media and compartments have to be considered and the potential risk for the respective compartments and organisms should be addressed:

Soil

Data on metabolites in soil come from the environmental fate section, including information on time course of appearance and concentration level. These metabolites are relevant for leaching to the groundwater, persistence in soil and soil organisms. After identifying major metabolites in soil which at any time account for more than 10% of the amount of the a.i. the following studies are also required for these metabolites:

- Soil degradation (aerobic and / or anaerobic);
- Soil absorption and desorption;
- Photolysis in soil;
- Acute toxicity to earthworms;
- Toxicity to soil micro organisms.

Water

Data on metabolites in water and sediment come from the environmental fate section, including information on time course of appearance and concentration level. These metabolites are relevant for the BCF and toxicity to aquatic organisms. After identifying major metabolites in water (water sediment study, hydrolysis) which at any time account for more than 10% of the amount of the a.i. the following studies are also required for these metabolites:

- Hydrolysis;
- Photolysis in water;
- Bioconcentration factor;

- Acute toxicity to fish, daphnia and algae;
- Chronic toxicity to fish and daphnia;
- Acute toxicity to frog.

As a general principle, it should be understood that assessments raised in this context do not always have to be addressed by experimental studies. Notifiers are invited to address the open questions by any other available information in support of a scientific and rational assessment. As a matter of course more supporting evidence is needed for major metabolites whereas a qualitative approach can be used for minor metabolites. Valuable sources of information include, but are not limited to:

- consideration of molecular structure of the metabolite (active part intact?);
- the occurrence of metabolites in the medium in existing tests with the active substance or major metabolites;
- general knowledge on the relationship between the toxicity of the metabolite and its parent substance (e.g. from the aquatic base set (fish, daphnia, algae);
- information on pesticidal activity from biological screening data;
- available knowledge on related compounds;
- risk indicators (TER, HQ) calculated for the parent compound (clearly on the safe side of the trigger?).

If the metabolite is CO₂ or an inorganic compound, not being or containing a heavy metal; or, if it is an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and has no "structures" or functional groups which are known to be of ecotoxicological concern, then no further studies are required and the metabolite is not considered to be ecotoxicologically relevant and is of low risk to the environment.

Tests with metabolites may not be required where they are formed relatively rapidly and are short-lived, as their toxicity may be exerted in the tests on the parent compound. This conclusion should be supported by analytical measurements or other justifiable arguments (e.g. data from laboratory or field studies). If there is more than one metabolite it may be sufficient to conduct only tests with the most important metabolite (highest amount, most comparable in structure with a.s.). If higher tier studies have been conducted with the active substance, or a relevant formulation, these studies may have also encompassed the exposure to metabolites (depending on the duration of the study and the degradation behaviour of active substance and metabolites).

4.6 Parameters needed for PEC calculation

This section gives an overview of all the data needed as the input parameters for the PEC calculation in the Sino-Dutch project. **These data are required and will be included in the list of data requirements.** The PEC input parameters are listed as below:

- Kom (Koc is the test result of Chinese soil absorption and desorption study. Koc can be calculated into Kom).
- DT_{50 soil}
- DT_{50 water}

- $DT_{50 \text{ sediment}}$ (advisable, not essential)
- leaching rate (only for antifouling)
- Molar mass
- Vapor pressure
- Solubility in water

5 Follow up activities

Apart from the data requirements we also discussed the protection goals of the entire project.

In this report, a new suggestion is made about the range of the project:

- ✧ The following categories of pesticides should be taken into account in the project:
 - a) General agricultural pesticide
 - b) Rodenticide (including higher tier if necessary)
 - c) Anti-fouling
 - d) Microbial pesticide (to be decided)

- ✧ The metabolites will be taken into account in the project

- ✧ The following studies of pesticides will be taken into account in the project:

a) Eco-toxicological test:

 - Acute toxicity to fish, algae, daphnia, bird, silkworm, honey bee (update);
 - Dietary toxicity to bird (update);
 - Chronic toxicity to silkworm, fish & daphnia (new tests).

b) Fate and behavior test:

 - Tests for $DT_{50 \text{ lab}}$ and Kom (update);
 - Route of degradation in soil (new test);
 - Soil degradation (anaerobic) test (new test);
 - Route of degradation water sediment system (new test)
 - Leaching to the water (only for anti fouling; new test);
 - Photolysis in soil.(new test)

- ✧ Chronic toxicity to bird is not included in the project. ICAMA will deal with this test with the research centers.

- ✧ Higher tier test methods in general are not included in the project, only if time and money allow.

6. Other agreements