Mission report (WP B2.1 /HH+Env3)

In the framework of PRRP- Ethiopia

Workshop at Ctgb-NL, 10-14 Dec 2012: Proposed evaluation tested with pilot compounds (Human Health and Environment)

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Pesticide Risk Reduction Programme - Ethiopia

1. Introduction

The goal of one of the work packages within PRRP-Ethiopia (WP B) is to develop technical and scientific capacity in Ethiopia, and in particular at APHRD, to ensure sound pesticide management in Ethiopia at pesticide registration stage. Technical assistance for this work package is provided by amongst others the Dutch Board for the Authorisation of Pesticides, Ctgb and Alterra.

The work package (WP B2.1) focuses on developing guidelines and procedures for the human health risk assessment, (including occupational and consumer health) as well as environmental risk assessment and to develop the capacity at the APHRD to apply these guidelines and procedures. This has to result in an evaluation manual for the Animal and Plant Health Regulatory Department (APHRD) of the Ministry of Agriculture of Ethiopia. In this workshop the proposed evaluation method was tested for a combination of 6 compounds and crops, that have been identified as possibly bearing risks for drinking water production or consumers:

1. Dimethoate, for use on barley and cabbage
2. Endosulfan, for use on maize and cotton
3. Deltamethrin for use on cotton, miaze, flowers and cabbage
4. 2-4 D for use on teff and maize
5. ß-cyfluthrin for use on cotton , maize, flowers and cabbage (was replaced by lamba-cyhalothrin, because dossier of ß-cyfluthrin was very small)
6. Metalaxyl/mancozeb for use on potato, onion and tomato

2. Objectives

The mission has the following goals and objectives.

Goal:

- To finalise the proposed evaluation procedure for Ethiopia on risks concerning human health and environment, including the relevant exposure models and other software.
- To let the APHRD gain experience with this proposed evaluation procedure
- To extend the draft evaluation manual in close cooperation between Ctgb and APHRD.

Objectives:
Human health (occupational health)

1. Propose an evaluation procedure for occupational health risk assessment and test it for a number of pilot compounds *(act 1.4 and act. 5.2 start)*
2. Finalise the methodology and exposure assessment tools for occupational health *(act 1.2)*

3. Exercise setting and quality assessment of the toxicity data of the pilot compounds needed to perform the human health risk assessment *(act 3.1)*
4. Finalise nationally applicable criteria for the acceptability of pesticides in Ethiopia (including human toxicity, labeling and packaging) *(act 3.1)*
5. Incorporate the results of 1-4 in the draft evaluation manual *(act 5.1 cont.)*

MRLs setting and human health (consumer health)

1. Propose an evaluation procedure for consumer health risks and test it for a number of pilot compounds *(act 1.4 and act. 5.2 start)*
2. Exercise MRL setting and quality assessment for a number of pilot compounds as proposed in the June 2012 workshop, considering their GAP and relevant crops *(act 6.1b)*
3. Define the Ethiopian food regime to use in the consumer risk assessment *(act 1.3)*
4. Evaluate the MRLs with respect to export of crops (compliance with MRLs of importing countries ?) *(act. 6.1b)*
5. Extend the draft evaluation manual with the results of activities 1-4 *(act 5.1 cont.)*

Environmental risk assessment

1. Present the proposed evaluation procedure, incl risk classification for the various protection goals and test it for a number of pilot compounds and protection goals (*act 1.4 and act. 5.2 start)*
2. Present and exercise with the current PRIMET version (to be adapted for Ethiopia) *(act.1.3)*
3. Present the exposure assessment procedure for groundwater and surface water as developed in the November 2012 workshop *(act.1.3)*
4. Extend the draft evaluation manual with the results of activity 1 *(act 5.1 cont.)*.

3. Results of activities

The following results have been executed during the mission:

Human health (occupational health)

1. General training on criteria and methodologies for an evaluation procedure for occupational health risk assessment and the quality of studies *(act 1 and 3)*
2. Training on the quality assessment of the toxicity data of several of the pilot compounds and setting of reference values needed to perform the human health risk assessment *(act 3.1)*
3. Training on the use of exposure models for operator, worker and bystander for several of the pilot compounds and scenarios *(act 1.1d)*
4. Discussion on nationally applicable criteria for the acceptability of pesticides in Ethiopia (including human toxicity, labeling and packaging) *(act 3.1)*

5. Extend the draft evaluation manual with the insights gained during the workshop in December *(act 5.1)*

MRLs setting and human health (consumer health)

1. General training on international criteria and methodologies for residue evaluation and the quality of studies (*act. 1 and act. 3*)
2. Exercise MRL setting using the OECD MRL calculator (*act. 6.1.b*)
3. Training on calculation of TMDI for different pesticides (*act. 1.3.a*)
4. Training on calculation of NESTI for different pesticides (*act. 1.3.a*)
5. Evaluate the MRLs with respect to export of crops (compliance with MRLs of importing countries) and discussion on European, US and CODEX MRLs *(act. 6.1.a and act. 6.1b)*
6. Extend the draft evaluation manual with the insights gained during the workshop in December *(act 5.1 and act. 8.3.)*

Environmental risk assessment

1. General training on criteria and methodologies for an evaluation procedure for the environmental risk assessment , incl. risk classification for the various environmental protection goals *(act 1.4)*
2. Tool/model (PRIMET (adapted for Ethiopia)) presented for environmental risk assessment in Ethiopia, incl. exposure assessment in surface water and groundwater (as developed in the November 2012 workshop) (*act 1.3*)
3. Training on the use of the environmental risk assessment procedures for the various environmental protection goals for several of the pilot compounds, including exercising with the adapted PRIMET version (*act 1.4 and act. 5.2 start*)
4. Extend the draft evaluation manual with the insights gained during the workshop in December *(act 5.1).*

4. Deliverables

1. Ethiopian staff trained on principles of occupational health and residue evaluation, consumer exposure and MRL setting and environmental risk assessment (*(HH+Env start act 5.2)*
2. Writing draft chapters in Manual for the evaluation of dossiers with respect to human health and environment *(HH+Env cont. act 5.1)*
3. Agreement on the methodology and (operator, worker, flagman and bystander and consumer) exposure assessment tools that will be used in Ethiopia *(HH act. 1.1)*
4. Ethiopian staff acquainted with selected tools for exposure assessment (human health) *(HH act.1.2)*
5. Draft national applicable criteria for the acceptability of pesticides agreed (human health aspects) *(HH act 3.1)*
6. A start has been made towards an agreement on which existing MRLs will be used and which MRLs need to be developed *(HH act 6.1b)*

7. Decision on which food regime to use for Ethiopia *(HH act. 1.3)*
8. Evaluation procedure for decision making presented and accepted (environment) *(Env act 1.4)*
9. Tool/model presented for environmental risk assessment in Ethiopia, incl exposure assessment in surface water and groundwater *(Env act 1.3)*
10. Copies of all presentations given and documents provided during the training workshop.
11. This report of the training workshop in the form of a Back to Office/Mission Report in the standard format of the PRRP Ethiopia project. This BtOR will include all activities, progress and conclusions of the workshop as well as recommendations for continuation of the evaluation work on Human Health and Environment of PRRP Ethiopia.

5. Organizations and persons met during mission

Four participants of Animal and Plant Health Regulatory Directorate (APHRD) and Paulien Adriaanse (Alterra) joined the workshops and discussions. Workshops regarding consumer risk assessment and MRLs, toxicology and occupational exposure and environmental risk assessment were given by employees of Ctgb and by Alterra (environmental risk assessment only).

Dr Haimanot of APHRD and Paul de Boer of Linge Agroconsultancy met to discuss issues of other WPs of PRRP Ethiopia.

A complete list of participants and their affiliation is presented below.

Organization / person	**Contact information (address, e-mail, telephone number, etc)**
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6. Unsolved issues

Human health (occupational health)

1. National data requirements: for several data points the EU, US EPA and others require studies in 2 species, however, it can be argued that at this stage this is too strict for Ethiopia, and for example it is not a data requirement for the WHO/JMPR evaluations.
2. The use of Personal Protective Equipment (PPE). PPE can reduce the risk, however, in many cases farmers can or will not use PPE. If, based on the exposure estimation, there is only a safe use expected with the use of PPE, the applicability of this requirement and the risk-benefit analysis will be expert judgment.
3. Labeling of the pesticides is only based on WHO classification for acute toxicity. More in depth classification is not discussed yet, but this seems too far-reached at this stage.

MRLs setting and human health (consumer health)

1. Extrapolation. Guidance on crop-crop extrapolation for crops cultivated in Ethiopia is not available currently.
2. Minimum number of supervised residue trials to be submitted for an application for authorization for a statistically reliable data set. Identifying which crops should be classified as major or minor is also an important factor in this issue. A section discussing this should be added in the Evaluation manual. Possibly residue trials may be combined with the Efficacy trials.
3. An Ethiopian consumer intake model is currently not available. Hence, no representative consumer exposure can be performed for the Ethiopian population.

Environmental risk assessment

1. A clear picture of the consequences of the chosen draft registration criteria and risk classification criteria is necessary (impact assessment).
2. A further adaptation of the PRIMET tool to the Ethiopian situation.
3. Waterfowl is not taken into account
   - may be more sensitive?
   - exposure is different
   - sometimes overspray by aerial application.
   This need to be discussed in the Evaluation manual

4. Some pesticides also for public health: different exposure of the environment (Same Risk Assessment Criteria?) See also links WHO in Tox part of Evaluation manual.
5. Labelling of pesticides (treat in Evaluation manual)
6. Risk mitigation is to be discussed at next workshop and to be incorporated in the Evaluation manual.

Other unresolved issues:

1. Re-registration. Currently, there is no procedure or guidance how to handle re-registrations of authorizations in Ethiopia. Guidance could be provided by in the framework of the PRRP. To be taken up by Harold in WP B.1 ?
2. Capacity building of the APHRD office in Addis Ababa. The current capacity within APHRD for risk assessment is very small. It takes about two years to extend the number of people at the APHRD office. Hence, activities should already start now to get the necessary capacity within reasonable time.

7. Actions to be taken / recommendations

Human health (occupational health)

1. Further training on occupation health risk assessment for Ethiopian staff of APHRD and other stakeholders.
2. Based on further training and experience, the unsolved issue regarding the requirement of studies with 2 species and the use of PPE should be discussed within the APHRD. This could include a risk-benefit assessment, since being too strict will result in a reduction of the authorized pesticides, which may impact the food production.
3. How to treat aerial applications ?

MRLs setting and human health (consumer health)

4. Draft guidance on crop-crop extrapolation regarding pesticide residues
5. Draft guidance on minimum number of supervised residue trials to be submitted for an application for authorization.
6. A dietary intake model containing food consumption data representing regional Ethiopian diets in the different agro-ecological zones with varying dietary habits for chronic and acute intake assessment. The Ethiopian Health and Nutrition Research Institute (EHNRI) is said to have generated data from food consumption surveys recently.
7. Further training on residue evaluation and consumer risk assessment for Ethiopian staff.

Environmental risk assessment

8. Further training on environmental risk assessment for Ethiopian staff.
9. Making an analysis of the consequences of the chosen draft registration and risk classification criteria on the total package of available pesticides

in Ethiopia. Depending on the results of the analysis it could be necessary to adjust some of the criteria.

10. Looking at pesticides used for public health.
11. Formalization of the selected protection goals in the Regulation (support from a lawyer of the FAO?)
12. To start activities on capacity building of the APHRD office in Addis Ababa, taking into account the long procedure (at least 2 years) to appoint new people

Annex 1: Detailed Program (per day)

Workshop: proposed evaluation tested with pilot compounds (Human Health and Environment)
10-14 December 2012, Wageningen, The Netherlands
Venue: Ctgb

Date	Time	Activity	Responsible person
Pesticide Risk Reduction Programme –Ethiopia, Work package B2.1			
Monday 10 Dec		GENERAL	
10 min	9.00-9.10	Welcome, introduction to each other	Paulien
10 min	9.10-9.20	Short introduction to PRRP and WP B2.1	Alemayehu
10 min	9.20-9.30	Outline and aim of this workshop	Paulien
		MRLs AND CONSUMER HEALTH	
60 min	9:30-10:30	Presentation on residue assessment and MRLs: recap	Caroline
30 min	10.30-11.00	COFFEE BREAK	
20 min	11:00-11:20	Practical: assess the quality of studies	Caroline
		- metabolism	
10 min	11:20-11:30	Practical: residue definition	Caroline
20 min	11:30-11:50	Practical: assess the quality of studies	Caroline
		- supervised residue trial	
20 min	11:50-12:10	Extrapolations	Caroline
20 min	12:10-12:30	Interpolations	Caroline
60 min	12.30-13.30	LUNCH	
40 min	13:30-14:10	Practical: OECD MRL calculator	Caroline
15 min	14:10-14:25	results OECD MRL calculator	Caroline
20 min	14:25-14:45	CODEX MRLs, USDA MRLs and EU MRLs	Caroline
10 min	14:45-14:55	Toxicological reference values	Caroline

35 min	14:55-15:30	Presentation on dietary risk assessment and Ethiopian food regime	Caroline
30 min	15.30-16.00	TEA BREAK	
60 min	16:00-17:00	Practical: Performing dietary risk assessment	Caroline
		END day 1	
Tuesday 11 Dec		CONTINUATION MRLs AND CONSUMER HEALTH	
45 min	9:00-9:45	Practical: Performing dietary risk assessment	Caroline
45 min	9:45-10:30	Discussion and trouble shooting	Caroline
30 min	10.30-11.00	COFFEE BREAK	
		START TOX DATA AND OCCUPATIONAL HEALTH	
90 min	11.00-12.30	Presentation and practical on data requirements, quality of studies, and reference values	Marloes
60 min	12.30-13.30	LUNCH	
120 min	13.30-15.30	Presentation and practical on operator and worker exposure	Marloes
30 min	15.30-16.00	TEA BREAK	
60 min	16:00-17:00	Presentation and practical on operator and worker exposure	Marloes
		END day 2	
	19.30-21.30	DINNER ALL TOGETHER	ALL + Floor
Wednesday 12 Dec		CONTINUATION TOX DATA AND OCCUPATIONAL HEALTH	
90 min	9.00-10.30	Presentation and practical on operator and worker risk assessment	Marloes
30 min	10.30-11.00	COFFEE BREAK	
60 min	11.00-12.00	Discussion and trouble shooting	Marloes
60 min	12.00-13.30	LUNCH	
		START ENVIRONMENT	

	13.30-15.30	Presentation on the proposed evaluation procedure and the risk classification criteria for the different protection goals	Peter
30 min	15.30-16.00	TEA BREAK	
45 min + 15 min	16.00-17.00	Summary of exposure assessment for surface water and groundwater protection goals, as developed in the November 2012 workshop, + discussion	Paulien + all
		End day 3	
Thursday 13 Dec		CONTINUATION ENVIRONMENT	
	9.00-10.00	Presentation of PRIMET for risk assessments	Mechteld
	10.00-12.30	Practical: performing risk assessments for the different protection goals and substances	Peter+Mechteld
60 min	12.30-13.30	LUNCH	
	13.30-15.30	Practical: performing risk assessments for the different protection goals and substances	Peter+Mechteld
30 min	15.30-16.00	TEA BREAK	
	16.00-17.00	Discussion and trouble shooting	Peter+Mechteld
		END day 4	
Friday 14 Dec		DATA REQUIREMENTS + MANUAL WRITING (3 parallel groups)	
60 min	9.00-10.00	Data requirements	Marloes, Caroline, Peter, Paulien, Alemayehu + other APHRD
	9.00-10.00	Discussion SAICM	Paul de Boer and Dr Haimanot
30 min	10.00-10.30	Manual writing Human Health (MRL+consumer)	Caroline + ?
		Manual writing Human Health (Tox+occupational)	Marloes + ?
		Manual writing Environment	Peter + ?

30 min	10.30-11.00	COFFEE	
90 min	11.00-12.30	Continuation manual writing	See above
	11.00-12.00	Discussion Joost-Alemayehu	Joost Lahr and Alemayehu
60 min	12.30-13.30	LUNCH	
	12.30-afternoon	Discussions Floor-Alemayehu	Floor and Alemayehu
90 min		Continuation manual writing	See above
30 min	15.00-15.30	TEA BREAK	
60 min	15.30-16.30	Wrap up, appointments for follow-up	All
	16.30	Closure	

Annex 2. GAP table of 6 pilot compounds used in the workshop exercises

Application Patterns of dimethoate, endosulfan and deltamethrin

Crop &/or Situation (a)	Product name	F, G or I (b)	Pests or Group of pests controlled ©	Formulation		Application				Application rate per treatment		PHI (days) (l)	Remarks (m)
				Type (d-f)	Conc. Of as (i)	Method kind (f-h)	Growth stage & season (l)	Number min max (k)	Interval b/n applications (min)	Water l/ha min max	Kg as/ha min max		
Barley	Danadim	F	Russian Wheat Aphid	EC	40%	Ground & Aerial	Nymphs & adults	1 to 2	1 week	200	0.4 -0.6	14 - 20 days	
Cabbage	Agro-thoate	F	Cabbage Aphid	EC	40%	Ground	Nymphs & adults	1	-	200	0.6	14 - 20 days	
Cotton	Ethiosulfan	F	ABW,Aphids, thrips, bugs, caterpillars	ULV	25%	Ground & Aerial	Larvae (ABW), Nymphs & adults	1 to 3	> 1 month	-	0.75	35 days	
Cotton	Thiodan	F	ABW	EC	35%	Ground	Larvae	1 to 3	> 1 month	20-30	0.7	20 days	
Maize	Thionex	F	ABW	ULV	25%	Ground & Aerial	Larvae	1	-	-	0.75	3 weeks	
Maize	Thiodan	F	ABW	EC	35%	Ground	Larvae	1	-	200-300	0.7-1.05	14 - 20 days	

Cotton	Decis	F	ABW & leafhoppers	EC/ULV	0.5	Ground & Aerial	Larvae (ABW), Nymphs & adults	1 to 3	> 1 month	20-30 (for EC)	0.25-0.37	10 days	
Cotton	Decis	F	ABW & leafhoppers	ULV	0.6	Ground & Aerial	Larvae (ABW), Nymphs & adults	1 to 3	> 1 month	-	0.18	10 days	
Cotton	Decis	F	ABW & leafhoppers	EC	2.5	Ground	Larvae (ABW), Nymphs & adults	1 to 3	> 1 month	20-30	0.0075-0.015	15 days	
Flowers	Decis	G	Aphids, thrips, caterpillars	EC	2.5	Ground & Aerial	Nymphs, adults & larvae	1	-	30 - 1000	0.0125-0.0165	15 days	
Maize	Deltacol	I	Maize weevil	DP	0.2	Mix with cobs or grain	Adfults & larvae	1	-	-	0.1	1 month	
Maize	Ethiodemethrin	F	MSB	WDP	2.5	Ground	Larvae	1	-	200	21	5-10 days after treatment	Product of China
Cabbege	Ethiodemethrin	F	Mealy cabbage aphid	EC	2.5	Ground	Nymphs & adults	1	-	200	0.025	20 days	

Good Agricultural Practice (GAP) Table / Form

Crop and/or situation (a)	Member state or Country	Product name	F,GorI (b)	Pest or Group of Pests controlled (c)	Formulation		Application				Application rate per treatment		PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of ai (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval b/n applications (min)	Water l/ha min max	Kg as/ha min max		
2,4-D														
118 Teff	Ethiopia	Agro 2,4D Amine 720	F	Broad leafed weeds	SL	720g/l	Spray	Post emergence to young vigorously growing weeds	1	-		0.72	-	
129 Teff	>>	Desorme Liquid	F	Broad leafed weeds	EC	720g/l	Spray	>>	1	-	150-400	0.72-1.26	-	
134 Teff	>>	Ethio 2,4D 720 SL	F	Broad leafed weeds	SL	720g/l	Spray	>>	1	-	120-220	0.72	-	
170 Teff	>>	U-46 KV Fluid	F	Broad leafed weeds	EC	720g/l	Spray	>>	1	-	Information not found	0.72	-	
172 Teff	>>	2,4D PA	F	Broad leafed weeds	SL	720g/l	Spray	>>	1	-	Information not found	0.72	-	
173 Teff	>>	Weed Killer	F	Broad leafed weeds	SL	720g/l	Spray	>>	1	-	200	0.72	-	
118 Maize	>>	Agro 2,4D Amine 720	F	Broad leafed weeds	SL	720g/l	Spray	>>	1	-	150-400	0.54-1. 08	-	
129 Maize	>>	Desorme Liquid	F	Broad leafed weeds	EC	720g/l	Spray	>>	1	-	Information not found	0.72	60-70	
170 Maize	>>	U-46 KV Fluid	F	Broad leafed weeds	EC	720g/l	Spray	>>	1	-	Not found	0.72	-	
174 Maize	>>	Zura Herbicide	F	Broad leafed weeds	EC	720g/l	Spray	>>	1	-	200-300	0.72		
Cereals	>>	Dicopur	F	Broadleaf weeds	SL	720g/l	Spray	>>	1		Information not found	0.78-2.4		

Lambdacyhalothrin										-			
65 Cotton	>>	Karate 0.8 ULV	F	Cotton pests	UL	8g/l	Spray	When pest appears(1-3 enstar) during square stage of cotton (ABW)	1	-	-	0.02-0.024	-	
66 Cotton		Karate 5%EC		Cotton pests	EC	50g/l	Spray	>>	1	-	250	0.01-0.025	-	
114 Cotton		Winner 0.8 ULV	F	African BW	UL	80g/l	Spray	>>			-	0.02	-	
67 Maize		Lambdacyhalothrin 5%EC	F	Maize stalk borer	EC	50g/l	Spray	At knee height of the crop When pest appears	1	-	Information not found	0.02	-	
68 Maize		Lamdex 5%EC	F	Maize stalk borer	EC	50g/l	Spray	>>		-	Information not found	0.01	14	

Metalaxyl + Mancozeb														
177 Potato		Agro-Laxyl	F	Late blight, Downy mildew, Pythium, Phytophthora,	WP	Metalaxyl 75g/kg Mancozeb 560	Spray	Spray before outbreak with two weeks interval	For more than one times	14 days	500-1000	1.905-2.54	8-14	
Tomato		Agro-Laxyl	F	Late blight, Downy mildew, Pythium, Phytophthora,	WP	>>	Spray	Start spraying 3-5 days after transplanting and repeat every week thereafter	>> >>	7 days	500-1000	1.905-2.54	8-14	
204 Potato		Manoxyl 72%WP	F	Late blight,	EC	Metalaxyl 80g/kg Mancozeb 640g/kg	Spray	Spray when disease appears	Not given	Not given	750	0.36-0.72	14	
205 Potato		Matco	F	Late blight,	WP	Metalaxyl 80g/kg Mancozeb 640g/kg	Spray	During outbreak	Not given	Not given	1000	1.8	-	
Tomato		Matco	F	Late blight	WP	Metalaxyl 80g/kg Mancozeb 640g/kg	Spray	>>	Not given		1000	1.8		
Onion		Matco	F	Late blight	WP	Metalaxyl 80g/kg Mancozeb 640g/kg	Spray	>>	Not given		500	1.8		
221 Potato Tomato		Ridomil MZ 63.5	F	Fungus spp.	WP	Metalaxyl 75g/kg Mancozeb 560g/kg	Spray			Not found	Not found	1.5875	-	
201 Tomato		Mancolaxyl72%WP	F	Late blight,	WP	80g/kg	Spray					2	-	
220 Tomato		Ridomil 5 G	F	Fungus spp.	GR	50g/kg	Spray			Informationn not found			-	

221 Onion		Ridomil MZ 63.5	F	Fungus spp.	WP	Metalaxyl 75g/kg Mancozeb 560g/kg	Spray			14 days	400-500 ??	1.5875	-	
221 Potato		Ridomil MZ 63.5	F	Fungus spp	WP	Metalaxyl 75g/kg Mancozeb 560g/kg				Information not found	400-500??	1.5875		
Potato		Ridomil MZ 68	F	Downy mildew,late blight,early blight	WG	Mtalaxyl – M 40g/kg Mancozb 640g/Kg	Spray	Before out break of disease is anticipated followed by further application at 14 days interval during dry conditions Season= during long rainy season and using irrigation	2 or more	14 days	400-500	1.7-2.04	14	
Tomato		Ridomil MZ 68	F	Downy mildew,late blight,early blight	WG	Mtalaxyl – M 40g/kg Mancozb 640g/Kg		3-5 days after transplanting followed by further application at 7-10 days interval during dry weather conditions. Rpeat application after each heavy rain	2 or more	7-10 days	500-1000	1.7-2.72	3	
Onion		Ridomil MZ68	F	Downy mildew,late	WG	Mtalaxyl –		First	2 or		500-1000	1.7-2.38	7	

				blight,early blight		M 40g/kg Mancozb 640g/Kg		application 5-7days after transplanting or when diseases are anticipated followed by further applications at 10-14 days. Repeat application after each heavy rain	more	10-14 days				

Annex 3. Presentations concerning pesticide residues and dietary risk assessment, as given in the 10-14 December 2012 workshops in Wageningen.

Residues of plant protection products in food assessment and MRLs

PRRP workshop, December 2012

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December 10th, 2012

ctgb

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Definitions (1)

Residues of plant protection products

one or more substances present in/on plants/ products of plant origin, edible animal products or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites and products resulting from their degradation or reaction.

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Definitions (2)

MRL
Maximum Residue Level

Specific value for each active substance/crop combination

Example: Deltamethrin	apple	0.2 mg/kg
	potato	0.2 mg/kg
	lettuce	0.5 mg/kg
	(…..)	

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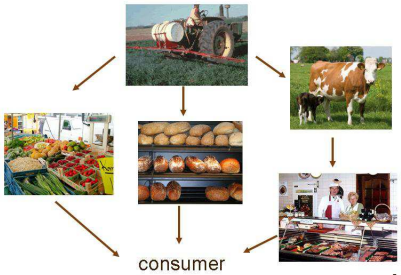
Consumer exposure from the farm to the fork



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Dossier requirements for residues

- Uptake and metabolism in appropriate plant group (leaf, root, fruit, grain, bean)
- Method for analysis of residue
- Residue trials in crops (critical GAP)
- Stability of stored samples
- Uptake, metabolism, distribution and excretion in livestock (laying hens, lactating goat, pigs)
- Livestock feeding studies
- Succeeding crops
- Processing data

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Residue definition

- Why
- Studies required
- Crops
- Criteria for setting a residue definition

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Residue definition – why?

Definition: Remaining parts of a PPP after application on crops according to a certain use:

- Parent and/or one of more metabolites
- All metabolites which are toxicologically relevant')

- For approval: risk assessment for authorisation
- After approval: for enforcement/monitoring by food safety authority

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Studies required

Metabolism studies with ^{14}C-labelled active substance in:

- Leafy crop
- Root/tuber crop
- Fruit
- Cereal
- Pulses/oilseeds

Way of application (foliar spray, soil or seed treatment)

If metabolism is similar in 3 different plant groups investigated, metabolism is assumed similar in all plants

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Criteria for setting Residue Definition

Metabolites are relevant when:

- > 0.05 mg/kg
- >10% total residue
- Toxicological relevant ('toxic')

Two types of residue definitions:

- *Monitoring:* as simple as possible
- *Risk Assessment:* all toxic relevant components

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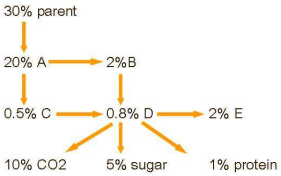
Example of metabolic profile



28.7% of residue non extractable ('bound residue')

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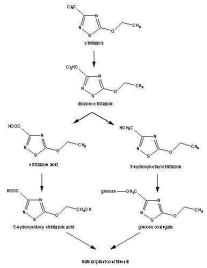
Example of metabolic pathway



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Analysis of residues

- Appropriate analytical methods need to be used for determining residues in crops
- Analytical methods need to be validated
- Recovery rates 70-110%, minimum number of analysis and RSD <20%

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Guidelines for analysis

- FAO Manual on the Submission and Evaluation of Pesticide Residues Data (2009), page 22
  http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-docs/en/
- Codex Secretariat (2003) Revised Guidelines on Good Laboratory Practice in Residue Analysis CAC/GL 40 1993, Rev.1-2003, http://www.codexalimentarius.net/download/standards/378/cxg_040e.pdf

  OECD Guidance Document on Pesticide Residue Analytical Methods, Series on Pesticides Number 39, Series on Testing And Assessment Number 72, 2007 ENV/JM/MONO(2007)17, 13 Aug 2007
- EU SANCO/825/00 http://ec.europa.eu/food/plant/protection/resources/guide_doc_825-00_rev7_en.pdf

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Residue level

- Each crop has own legally allowed level for each active substance: maximum residue level (MRL)
- For each crop a set of representative residue trials is needed or should be extrapolated from an closely related crop

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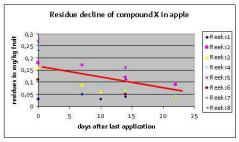
Establishing MRLs (plant)

(Maximum Residue Level in mg/kg)

Residue trials:

- according to intended use
- Intended crop
- region (N-EU)
- definition of residue



Requirements:

- per crop 8 trials (4 for minor crop)
- 4 different locations, at least 2 seasons
- quality of studies (guidelines, GLP)

ALARA principle:

As **L**ow **A**s **R**easonably **A**chievable

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Sources for established MRLs

CODEX Alimentarius:

- http://www.codexalimentarius.net/pestres/data/pesticides/search.html?lang=en

USDPA:

- http://www.mrldatabase.com/

Europe:

- Pestcide web:
- http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection

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Pesticide label

A Maximum Residue Level (MRL) is coupled to a well defined use:

- Active substance
- Crop
- Way of application (foliar, soil, post-harvest)
- Dose level
- Repetitions
- Pre harvest interval (PHI, Safety interval) or growth stage (BBCH scale)
- Sometimes climatic conditions are also of influence, for instance if the first step of metabolism is photo-oxidation.

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Information on label

Example

Insecticide (deltamethrin) on cabbage: foliar application of 2 x 7,5g/ha, interval 7d and PHI 7d.

Fungicide (mancozeb + metalaxyl-m) on potatoes: foliar application of 1.47 kg mancozeb/ha and 0.089 kg metalaxyl-m/ha, interval 7-10d, PHI 7d.

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Extrapolation of residue data (MRL)

In EU an 'extrapolation document' is in use. The document allows to make extrapolation between closely related crops in order to prevent the performance of too many studies.

Examples

- Apple => pear
- Black currants => all other small berries
- Tomato => aubergine
- Cucumber => courgette
- Beans => peas
- Onion => garlic, shallot
- Maize => teff, millet

http://ec.europa.eu/food/plant/protection/pesticides/docs/app-d.pdf

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Consumer risk assessment

When a pesticide is authorised there might be life lasting, permanent exposure = chronic exposure

How to act if residue is found higher than MRL?
One time, occasional exposure = acute exposure

How to act to residues > MRL:

- Exceeding MRL: grower might be fined (financial penalty)
- Exceeding MRL and risk: rapid alert, withdrawal of product from market

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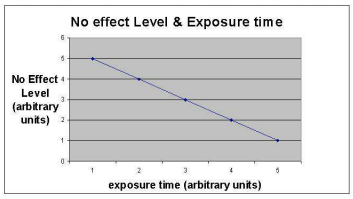
General principle of toxicology



Conclusion

long term acceptable exposure level is lower, short-term acceptable exposure level is higher

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Toxicological reference values

= ADI

Acceptable Daily Intake: no effect level derived from long term animal study, divided by 100

ARfD

= Acute Reference Dose: no effect level from a short term of reproduction animal study, divided by 100

[workshop on operator exposure of Marloes Busschers, 11-12 December]

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Toxicological reference values

- http://www.atsdr.cdc.gov/toxprofiles/index.asp
- http://www.inchem.org/pages/jmpr.html
- Pesticide web
- http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection

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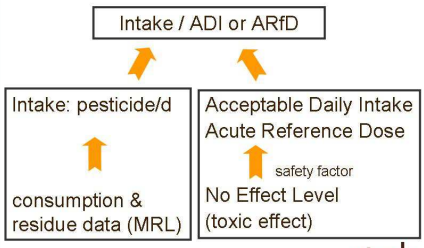
Consumer risk assessment general



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Consumer risk assessment - chronic, tiered approach

- Chronic intake (TMDI) ≤ ADI
  - Safe use
- Chronic intake (TMDI) > ADI
  - *Refinement* of calculation using processing data and median residue values
- Refined chronic intake > ADI
  - No safe use, restriction of application needed / authorisation cannot be granted.

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Consumer risk assessment acute, tiered approach

- Acute intake ≤ ARfD
  - Safe use
- Acute intake > ARfD

  Refinement of calculation using:
  - New toxicity studies
  - New residue trials
  - Specific variability factor
  - New/other processing data
  - Other statistic methods
- Refined acute intake > ARfD
  - No safe use, restriction of application needed / authorisation cannot be granted.

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Consumer risk assessment chronic exposure

Input:

- MRLs
- *mean* dietary intake data
- during whole course of life

Calculation:

- Total intake (TMDI = Theoretical Maximum Daily Intake):
  - $\Sigma x,y = (MRL\ x,y * intake\ x,y)$

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Consumer risk assessment acute exposure

Why is an acute consumer exposure calculation necessary

- Large portion instead of mean portion
- Variation in residue levels between different units while MRL has been based on composite sample.
- To decide whether a risk can be expected when consuming a large portion with a unit with a high residues level (eg one whole melon)

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Consumer risk assessment acute exposure

Input:

- Residue data (MRL/HR)
- Large Portion Dietary Intake data (LP, children, adults, …)
- Unit weight of the particular crop
- Standard variability factor for particular crop (v)
- one time/occasional intake

Calculation:

$$IESTI = \frac{LP \times (HR \text{ or } HR\text{-}P) \times v}{bw}$$

ESTI = Estimate of Short-Term Intake

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Consumer risk assessment models

- Intake is estimated using statistic models
- Relevant Ethiopian diet model not (yet) available
- Chronic intake: WHO Cluster diet A for African countries
  - Teff not included
- Acute intake: Dutch NESTI model

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Thank you for your attention!

Coffee break!

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Plant metabolism studies

PRRP workshop, December 2012

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December 10th, 2012

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Practical

- Metabolism studies with deltamethrin
  - Cotton
  - Corn
  - Apple
- Read study reports
- Assess residue definition for monitoring and risk assessment

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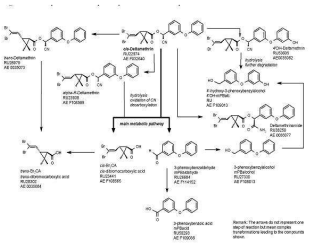
Applicant's conclusion (1)



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EFSA's conclusion (2)

- In apples deltamethrin and its isomers were the main components at all intervals accounting for 92-100% of the TRR. *Cis*- deltamethrin was predominant (59-71% TRR) with varying amounts of *alpha*-R-(19-34% TRR) and *trans*-deltamethrin (5.8-19% TRR). In tomatoes 79-93% TRR consisted of deltamethrin and its isomers (the ratio was not reported as they were not separated).
- In corn forage, foliage and husks, 80-100% of the TRR consisted of deltamethrin or deltamethrin isomers (*alpha*-R isomer (21% in mature corn foliage and husk) and *trans*-isomer (11-13% in mature corn foliage and husk)). TRR in grains were ≤0.06 mg/kg.
- In cotton seed (II) 38-47% TRR was characterised as deltamethrin, *trans*-deltamethrin and/or *alpha*-Rdeltamethrin. In study I with cotton, hydroponic and soil treatments resulted in a significant root uptake. After foliar treatment only a limited translocation throughout the plant was observed.
- The peer review concluded to establish risk assessment and enforcement residue definition for plant commodities as deltamethrin (*cis*-deltamethrin) only.

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Supervised residue trials

PRRP workshop, December 2012

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December 10th, 2012

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Practical

- Supervised residue trials with deltamethrin
  - Cotton
  - Winter wheat
  - Potato
- Read study reports
- Select relevant results

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cGAP

- Potato
  - 3x 7.5 g as/ha, interval 14d, PHI 7d
- Cotton
  - 2x 17.5 g as/ha, interval 14d, PHI 30d
- Cabbage
  - 2x 12.5 g as/ha, interval 7d, PHI 7d

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Check studies for:

- Application rates, interval and PHI
- Weather details
- Indoor/outdoor
- Varieties used
- Sample size
- Storage of samples
- Analytical method used

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Extrapolations

Examples

- Apple => pear
- Black currants => all other small berries
- Tomato => aubergine
- Cucumber => courgette
- Beans => peas
- Onion => garlic, shallot
- Maize => teff, millet

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Interpolations (1)

- Decline supervised residue trials
- Residue levels needed on timepoint not sampled
  0d:0.17 mg/kg
  3d:0.07 mg/kg
  7d:0.04 mg/kg
- Level at 10d?

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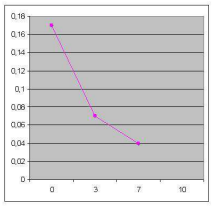
Interpolations (2)



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MRLs

PRRP workshop, December 2012

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December 10th, 2012

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Practical

- Calculating an MRL

OECD MRL calculator

Presented data set

Discuss results

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Established MRLs

CODEX Alimentarius:

- http://www.codexalimentarius.net/pestres/data/pesticides/search.html?lang=en

USDPA:

- http://www.mrldatabase.com/

Europe:

- Pestcide web:
- http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection

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Deltamethrin MRLS

crop	EU	USDPA	CODEX
Cotton	0.05 mg/kg	0.04 mg/kg	-
Cabbage	0.1 mg/kg	0.05 mg/kg	-
Potato	0.2 mg/kg	0.04 mg/kg	0.01 mg/kg

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Toxicological reference values

- http://www.atsdr.cdc.gov/toxprofiles/index.asp
- http://www.inchem.org/pages/jmpr.html
- Pesticide web
- http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection

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Deltamethrin ADI and ARfD

- ADI: 0.01 mg/kg bw/d
- ARfD: 0.01 mg/kg bw

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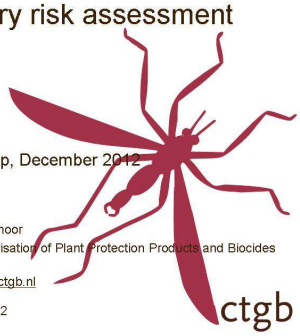
Dietary risk assessment



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December 10th, 2012

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Dietary risk assessment

- To assess whether is safe for consumers, a dietary risk assessment needs to be performed
- Chronic
- Acute

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Consumer risk assessment

When a pesticide is authorised there might be life lasting, permanent exposure = chronic exposure

How to act if residue is found higher than MRL?
One time, occasional exposure = acute exposure

How to act to residues > MRL:
- Exceeding MRL: grower might be fined (financial penalty)
- Exceeding MRL and risk: rapid alert, withdrawal of product from market

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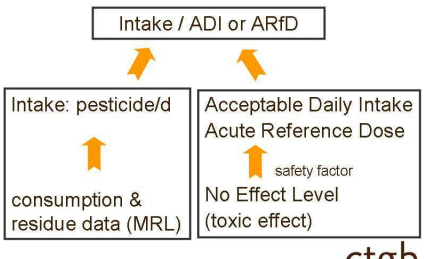
Consumer risk assessment general



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Consumer risk assessment chronic exposure

Input:
- MRLs
- *mean* dietary intake data
- during whole course of life

Calculation:
- Total intake (TMDI = Theoretical Maximum Daily Intake):
  - Σ x,y = (MRL x,y * intake x,y)

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Consumer risk assessment - chronic, tiered approach

- Chronic intake (TMDI) ≤ ADI
  - Safe use
- Chronic intake (TMDI) > ADI
  - *Refinement* of calculation using processing data and median residue values
- Refined chronic intake > ADI
  - No safe use, restriction of application needed / authorisation cannot be granted.

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Consumer risk assessment acute exposure

Why is an acute consumer exposure calculation necessary

- Large portion instead of mean portion
- Variation in residue levels between different units while MRL has been based on composite sample.
- To decide whether a risk can be expected when consuming a large portion with a unit with a high residues level (eg one whole melon)

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Consumer risk assessment acute exposure

Input:
- Residue data (MRL/HR)
- Large Portion Dietary Intake data (LP, children, adults, …)
- Unit weight of the particular crop
- Standard variability factor for particular crop (v)
- one time/occasional intake

Calculation:

$$IESTI = \frac{LP \times (HR \text{ or } HR\text{-}P) \times v}{bw}$$

ESTI = Estimate of Short-Term Intake

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Consumer risk assessment acute exposure

Why is an acute consumer exposure calculation necessary

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- To decide whether a risk can be expected when consuming a large portion with a unit with a high residues level (eg one whole melon)

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WHO-GEMS diets

WHO = World Health Organisation
GEMS = Global Environment Monitoring System

In different parts of the world people consume different food items, dependent on habits, agricultural circumstances, availability of sea/lakes, etc.

WHO composed 13 diets for different regions in the world: 'WHO-GEMS cluster diets'.

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Food basket or diet: definition and context

Definition

'Combination of food items consumed by someone in a certain time period'

Why do we need the food basket

With the food basket, residue level and reference values we can perform risk assessments

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Characteristics WHO GEMS

- Based on agricultural and trade data
- Minor uses might not be taken into account

Disadvantage:
- In general data overestimated since it is a compilation of data which also contain other factors like animal feed consumption
- No statistical information or distribution so all individuals are the same (no distinguishing between different consumer groups)

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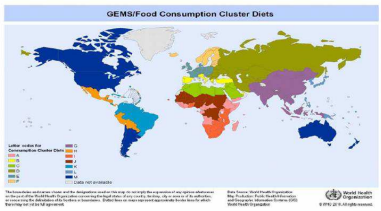
13 WHO-GEMS diets: Ethiopia = A (or C or J or H)?



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Example of WHO GEMS

CODE	GEMS	NOTES	A	B	C	D
	CEREALS					
GC 640	BARLEY	(1)	40,6	16,8	93,9	13,2
	* POT BARLEY		29,0	0,0	11,9	4,0
	* BARLEY, PEARLED		0,0	0,4	27,9	0,4
	* BARLEY FLOUR AND GRITS		0,0	0,3	10,8	0,3
GC 641	BUCKWHEAT	(2)	0,0	0,1	0,0	1,2
	* FLOUR OF BUCKWHEAT		0,0	0,0	0,0	1,3
	* BRAN OF BUCKWHEAT		0,0	0,0	0,0	0,0
GC 645	MAIZE	(3)	82,7	148,4	135,9	31,8
CF 1255	MAIZE FLOUR		68,9	15,4	51,3	16,8
	* GERM MAIZE	(4)	0,2	8,9	5,0	1,2
GC 654	WHEAT	(12)	88,4	396,3	426,5	390,
CF 1210	WHEAT GERM		0,0	1,3	0,0	1,3
* CF 1211bu	* WHEAT BULGUR WHOLEMEAL		5,6	10,2	0,7	0,2
CF 1211	WHEAT FLOUR		63,4	296,3	327,5	300,
* CF 1211ma	* WHEAT MACARONI		0,8	1,1	0,8	1,8
* CF 1211pa	* WHEAT PASTRY		0,4	1,1	0,7	2,6
CP 1211	WHITE BREAD		0,0	0,1	0,0	0,1
CP 1212	WHOLEMEAL BREAD		0,0	0,1	0,0	0,1
	* OATS, ROLLED		0,7	0,3	0,1	2,2

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Diet based on Food Consumption survey

- 1000-2000 Individual consumers with their characteristics (age, habitual situation, gender, ….)
- 2 days overview of all consumed food items
- different seasons

Advantages:
- Distribution of consumption data: food basket can be divided into different consumer subgroups and in chronic and acute data
- Processing data

Disadvantage
- Time consuming research
- Data from processed consumption product (bread, pizza, jam) which should be converted to raw agricultural products

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Example of diet based on food consumption data (1): Dutch diet

EN name	pr	processing	portion	Gen pop (1-97 yrs) Average bw (kg): 65,8 Cons days (2x2 D): 12500 NL-diet (g/kg bw/day)	NL-diet (g/pers/day)	EP %proc	Nfct	NEDI (µg/kg bw/day)	%ADI
grapefruit	1	raw	EP	0,019	1,3	30%	137	ND	ND
grapefruit	5	canned	PP	0,000	0,0	0%	86	ND	ND
grapefruit	9	juice	PP	0,042	2,8	65%	376	ND	ND
grapefruit	12	oil	PP	0,000	0,0	0%	0	ND	ND
grapefruit	98	sec processing	PP	0,003	0,2	5%	1225	ND	ND
oranges	1	raw	EP	0,216	14,2	21%	1219	ND	ND
oranges	9	juice	PP	0,772	50,8	77%	3495	ND	ND
oranges	11	jam (incl jelly/marmalade)	PP	0,003	0,2	0%	2195	ND	ND
oranges	12	oil	PP	0,000	0,0	0%	0	ND	ND
oranges	53	canned baby/food	PP	0,001	0,1	0%	7	ND	ND
oranges	98	sec processing	PP	0,017	1,1	2%	2513	ND	ND
lemons	1	raw	EP	0,001	0,1	7%	25	ND	ND
lemons	9	juice	PP	0,009	0,6	43%	439	ND	ND
lemons	11	jam (incl jelly/marmalade)	PP	0,000	0,0	0%	0	ND	ND
lemons	12	oil	PP	0,000	0,0	0%	0	ND	ND
lemons	53	canned baby/food	PP	0,000	0,0	0%	0	ND	ND
lemons	98	sec processing	PP	0,011	0,7	50%	3293	ND	ND

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Remarks

For all alternatives:
- data will be outdated after several years since food consumption patterns change
- Composition of population changes due to migration
- Data have to be treated for composing a model which is always an simplification (e.g. choice of body weight, number of consumer sub groups, etc.)

Uncertainties in risk assessment
- Food basket data and subgroup selection
- Overall safety factor of ~100 will compensate for most of the uncertainties

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Practical

- Perform a dietary risk assessment using:
  - MRLs: look up
  - ADI
  - ARfD
  - WHO model (chronic)
  - Dutch model (acute)

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Drinking water (1)

Water intake in the **Netherlands** will take place:
- From deep ground water (generally pure)
- from big rivers. Due of dilution of the pesticide on it's way from the agricultural field to the river, pesticide levels are quite low.

water: 1-10µg/L *crop: 10-1000 µg/L*

What situation applies to Ethiopia?

If water intake will take place near agricultural field, pesticides might be a bigger problem.

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Deltamethrin MRLS

crop	EU	USDPA	CODEX
Cotton	0.05 mg/kg	0.04 mg/kg	-
Cabbage	0.1 mg/kg	0.05 mg/kg	-
Potato	0.2 mg/kg	0.04 mg/kg	0.01 mg/kg

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Deltamethrin ADI and ARfD

- ADI: 0.01 mg/kg bw/d
- ARfD: 0.01 mg/kg bw

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Annex 4. Presentations concerning occupational health risk assessment, as given in the 10-14 December 2012 workshops in Wageningen

Introduction

Marloes Busschers, MSc

Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)

10-14 December 2012

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Hazard x Exposure = Risk

Hazard: reference value
Exposure: model calculations

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Dossier active substance

- Toxicokinetics
- Acute toxicity
- Short-term toxicity
- Sub-chronic toxicity
- Genotoxicity testing
- Long-term toxicity and carcinogenicity
- Reproductive toxicity
- Delayed neurotoxicity studies
- Other toxicological studies
- Medical data

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Reference values are derived from most critical studies

- ADI: Acceptable Daily Intake (by consumption)
- ARfD: Acute Reference Dose (accidental high consumption)
- AOEL: Acceptable operator exposure level

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Hazard x Exposure = Risk

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Hazard is based on active substance dossier:

- Efficacy
- Human toxicology
- Ecotoxicology
- Fate en behavior in environment
- Physical-chemical properties and analytical methodes

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Quality check

Studies should be performed according to:
- standard test protocol (e.g.OECD=validated)
- GLP (Good Laboratory Practice)

Public (peer reviewed) literature often does not fulfill standard requirements, but can give additional information

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Deriving an AOEL

- Step 1: select relevant NOAEL
- Step 2: determine oral absorption value
- Step 3: define the safety factor
  - Standard factor: 100
- Step 4: derive the AOEL

AOEL (mg/kg bw/day) =
(NOAEL x oral absorption) / safety factor

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Deriving an ADI

= The amount of a substance that can be consumed on a daily basis over a lifetime without appreciable health risk.

- Step 1: select chronic NOAEL
- Step 2: define the safety factor
  - Standard factor: 100
- Step 3: derive the ADI

$ADI = NOAEL_{chronic}$ / safety factor (100)

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ARfD

- "An estimate of a chemical substance in food (or drinking water), expressed on a bodyweight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer."

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Deriving an ARfD

- Step 1: select (sub)acute NOAEL
- Step 2: define the safety factor
  - Standard factor: 100
- Step 3: derive the ARfD

ARfD = NOAEL / safety factor (100)

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Hazard x Exposure = Risk

Hazard: reference value

Exposure: model calculations

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Exposure

- Population(s) exposed
  - Operators
  - Workers
  - Bystanders, including flagman
  - Residents
- Exposure scenario
  - Route
  - Duration
  - Frequency
  - Level of exposure

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Exposure assessment

Tiered approach:

Tier 1: Models

Tier 2 Refinement:
Measurement of actual exposure for the application under consideration

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Which model to select?

- Different model, some specific for 1 scenario (indoors: NL greenhouse model), some have different scenarios (field crop high low, tractor and handheld: UK POEM and German model)
- Basic work clothing (= without PPE) differs for models (UK POEM: long sleeves + trousers; German model: short sleeves and shorts)

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Evaluation report on models

EFSA Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents.
http://www.efsa.europa.eu/en/scdocs/doc/26e.pdf

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Input data needed in the models

Dermal absorption

- Based on physical/chemical properties (MW, log Pow)
- Based on dermal absorption studies
  - *in vitro* (rat and/or human skin)
  - *in vivo* (rat)

Defaults

- Body weight
- Time of exposure
- Area treated

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Hazard x Exposure = Risk

Hazard: reference value
Exposure: model calculations

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Risk assessment

Risk Assessment in basic is a simple method, based on two values:

1. Reference value (AOEL)
2. Exposure (estimated or measured)

Safe use = AOEL ≥ Exposure

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Data requirements and reference values

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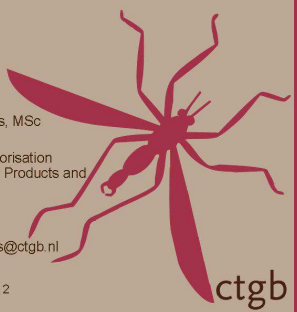
10-14 December 2012



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Ethiopian data requirements

Based on SEARCH format and

- country (Ethiopia) specific requirements

The proposed revision will be used during the workshop, to check applicability

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Data requirements active substance

- Toxicokinetics
- Acute toxicity
- Short-term toxicity
- Sub-chronic toxicity
- Genotoxicity testing
- Long-term toxicity and carcinogenicity
- Reproductive toxicity
- Other toxicological studies
- Medical data

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Data requirements product

- Acute toxicity studies
  - Oral, dermal, inhalation
  - Skin and eye irritation
  - Skin sensitisation
- Dermal absorption

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EU Data requirements Regulation (EC) 1107/2009

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF

Data requirements

- Active substance:
  Commission Regulation (EU) No 544/2011
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:155:0001:0066:EN:PDF
- Product:
  Commission Regulation (EU) No 545/2011
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:142:0001:0739:EN:PDF

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Quality check of study reports

Studies should be performed according to:

- standard test protocol (e.g. EC/OECD=validated)
- GLP (Good Laboratory Practice)

Public (peer reviewed) literature often does not fulfill standard requirements, but can give additional information

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Quality check GLP Good Laboratory Practice

Practical check:

- Study report must contain:
  - signed Quality Assurance (QA) statement
  - inspection dates

Wikipedia has a good description:
http://en.wikipedia.org/wiki/Good_Laboratory_Practice

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US EPA data requirements

- Data requirements described in **Federal Register** / Vol. 72, No. 207 / Friday, October 26, 2007 / Rules and Regulations. Pesticides; Data Requirements for conventional chemicals.
  http://www.gpo.gov/fdsys/pkg/FR-2007-10-26/pdf/E7-20826.pdf
- Data requirements mainly the same as those required by the EU.
  - Distinction made between food patterns and non-food use patterns (e.g. forestry use, aquatic nonfood crop use, indoor residential use).

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Quality check Standard test protocol

Validated test guidelines for study conduct

For example:

- EU: Regulation (EC) No 440/2008
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:142:0001:0739:EN:PDF
- US: EPA harmonized test guidelines
  http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm
- Both EU and US guidelines are equivalent to the **OECD test guidelines** for toxicity testing.
  http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788

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Proposal for Practical

6 Pilot applications for the registration of formulations based on:

- Dimethoate, for use on barley and cabbage
- Endosulfan, for use on maize and cotton
- Deltamethrin for use on cotton, maize, flowers and cabbage
- 2-4 D for use on teff and maize
- ß-cyfluthrin for use on cotton, maize, flowers and cabbage
- Metalaxyl/mancozeb for use on potato, onion and tomato

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Proposal for Practical

HAZARD ASSESSMENT

1. Quality check of submitted application forms
   - all data requirements fulfilled?
   - standard test protocol used?
   - GLP?
   - Proposal for reference values?
2. Check international AOEL, ADI, ARfD
   - see internet links
3. Compare dossier with international values
   - Is submitted dossier in line with international reference values?

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References

- EU Regulation (EC) 1107/2009 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF
- EU Commission Regulation (EU) 544/2011 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:155:0001:0066:EN:PDF
- EU Commission Regulation (EU) No 545/2011http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:142:0001:0739:EN:PDF
- Regulation (EC) No 440/2008 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:142:0001:0739:EN:PDF
- US data requirements: http://www.gpo.gov/fdsys/pkg/FR-2007-10-26/pdf/E7-20826.pdf
- EPA test guidelines: http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm
- OECD test guidelines: http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788

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Sources for AOELs/ADI/ARfD

- Pesticide Properties DataBase http://sitem.herts.ac.uk/aeru/footprint/en/index.htm
- EU Review reports http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection&a=1
- EFSA conclusions http://www.efsa.europa.eu/en/pesticides/pesticidesscdocs.htm
- JMPRs http://www.inchem.org/pages/jmpr.html
- US EPA http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList

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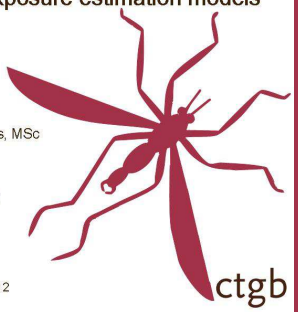
Operator exposure estimation models



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Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)

10-14 December 2012

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Introduction

- Exposure scenarios:
  - Operators: persons involved in the mixing/loading and application of a pesticide
  - Workers: persons who enter an area or handle crop previously treated with a pesticide
  - Bystanders: persons who are located within or directly adjacent to the area where PPP application is taking place or has recently been completed.

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Exposure models: operator

- EUROPOEM
- German model
- UK POEM
- NL model
- NL and Southern Greenhouse
- NA PHED
- ….

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Exposure models: operator

Evaluation of available exposure models:

EFSA Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents.
http://www.efsa.europa.eu/en/scdocs/doc/26e.pdf

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Exposure models: operator

- In EU mainly three basic models:
  - UK-POEM
  - German model
  - NL model

Developed in isolation

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Exposure models: operator

UK POEM

- Developed by UK industry and regulatory authorities
- wettable powder (WP), wettable granules (WG), water soluble bags (WB) and liquid formulations
- Exposure scenarios:
  - Vehicle equipment: downwards and upwards
  - Handheld equipment: downwards and upwards
  - Home garden low level spraying
- 75th percentile
- Updated with data from EUROPOEM and PHED
- No PPE = single layer of work clothing for professional use, T-shirt and shorts for home garden use.

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Exposure models: operator

PHED (Pesticide Handlers Exposure Database)

- Developed by N. American Industry, EPA & Health Canada
- Liquids and solids, including fry-flowable materials, dusts, wettable powders and granules.
- Application scenarios, e.g.:
  - vehicle up- and downwards
  - hand-held up- and downwards (field)
  - hand-held (green-house)
  - paint brush
  - aerosol can
  - aerial
- No PPE = long pants, short sleeves, shoes, socks

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Which model to select for operator exposure?

- Depends on type of application:
  - Indoors vs outdoors
  - Manual vs mechanical
  - Upwards vs downwards
- No consensus on which model to use for which situation.

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Exposure models: operator

German model

- Developed by German industry and regulatory authority
- Wettable powder (WP), wettable granules (WG) and liquids
- Exposure scenarios:
  - Vehicle equipment: downwards and upwards
  - Handheld equipment: upwards only
  - Home and garden
- Geometric mean
- Underlying database relatively small for mixing/loading of WP and WG and for downward spraying with tractor-mounted equipment.
- No PPE = moderately dressed with shoes and socks, half of upper arms, forearms, thighs and lower legs unprotected

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Exposure models: operator

NL greenhouse

- Developed by Dutch authorities
- Manual spraying assumed
- No distinction between up- and downwards spraying
- 90th percentile used
- Exposure during mixing/loading and applications not separated

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Exposure models: operator

PHED (cont'd)

- Model difficult to use
- Studies are dated (up to 30 years)
  - Do not meet current guidelines
  - Modern spraying equipment not adequately represented
- Software platform no longer available
- Replacement (AHED) in development.

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Which model to select for operator exposure?

Within Europe

- UK-POEM
- German model (except for manual downward spraying)
- Sometimes NL greenhouse model

Outside Europe:

- PHED surrogate exposure guide (awaiting replacement with AHED)

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Proposal for Practical

Calculate exposure using:

Outdoor
- German model
- (Possibly also UK POEM)

Indoor
- NL greenhouse

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Proposal for Practical

6 Pilot applications for the registration of formulations based on:

- Dimethoate, for use on barley and cabbage
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- Metalaxyl/mancozeb for use on potato, onion and tomato

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Exposure scenarios

Crop	Field tractor	Field hand	Upward or downward	Greenhouse
Barley				
Teff				
Maize				
Cabbage				
Onion				
Potato				
Cotton				
Flowers				
Tomato				

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References

- German model: http://www.bvl.bund.de/EN/04_PlantProtectionProducts/11_Applicants/02_AuthorisationProcedure/06_Toxicology/PlantProtectionProducts_toxicol_node.html
- UK POEM: http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/updates/updates-to-the-uk-poem-operator-exposure-model
- NL greenhouse: www.ctgb.nl click on "full text and Guidance documents" under "Regulation placing of ppp on the market"

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Background information

- **EFSA Guidance on the assessment of exposure** for operators, workers, residents and bystanders in risk assessment for plant protection products
  http://www.efsa.europa.eu/en/efsajournal/doc/1501.pdf
- **EFSA Project to assess current approaches** and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents.
  http://www.efsa.europa.eu/en/scdocs/doc/26e.pdf
- **UK CRD website**
  http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/data-requirements-handbook/toxicity-working-documents
- **German BVL website**
  http://www.bvl.bund.de/EN/04_PlantProtectionProducts/11_Applicants/02_AuthorisationProcedure/06_Toxicology/PlantProtectionProducts_toxicol_node.html

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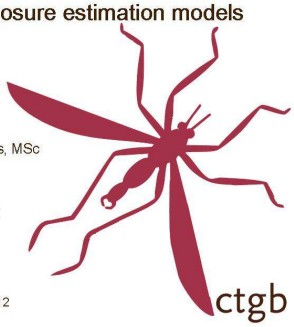
Worker exposure estimation models



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Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)

10-14 December 2012

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Introduction

- Exposure scenarios:
  - Operators: persons involved in the mixing/loading and application of a PPP
  - Workers: persons who enter an area or handle crop previously treated with a PPP
  - Bystanders: persons who are located within or directly adjacent to the area where PPP application is taking place or has recently been completed.

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Exposure models - worker

EUROPOEM II

- Developed in Europe by representatives for industry, regulatory authorities and research institutes
- Estimates dermal exposure for worker in a crop previously treated with PPP
- Scenarios: re-entry in field crops and greenhouse
- Can be used as conservative, first tier approach
- Step 1: Residue decline not taken into account

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Proposal for Practical

Calculate worker exposure using:

EUROPOEM II

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Proposal for Practical

6 Pilot applications for the registration of formulations based on:

- Dimethoate, for use on barley and cabbage
- Endosulfan, for use on maize and cotton
- Deltamethrin for use on cotton, maize, flowers and cabbage
- 2-4 D for use on teff and maize
- ß-cyfluthrin for use on cotton, maize, flowers and cabbage
- Metalaxyl/mancozeb for use on potato, onion and tomato

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References

- EUROPOEM: www.ctgb.nl click on "full text and Guidance documents" under "Regulation placing of ppp on the market"

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Background information

- EFSA Guidance on the assessment of exposure for operators, workers, residents and bystanders in risk assessment for plant protection products http://www.efsa.europa.eu/en/efsajournal/doc/1501.pdf
- EFSA Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents. http://www.efsa.europa.eu/en/scdocs/doc/26e.pdf

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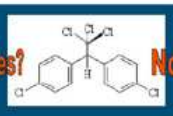
Annex 5. Presentations concerning environmental risk assessment, as given in the 10-14 December 2012 workshops in Wageningen

Setting environmental criteria for pesticide registration

Introduction



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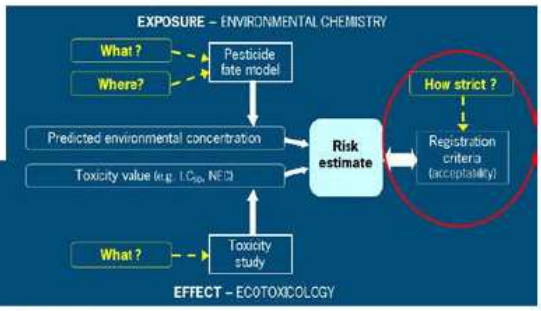
Environmental risk assessment – Questions to answer

2



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Registration criteria – different definitions

Risk-based criteria
- What level of environmental effect is acceptable in Ethiopia?
  - *example:* no acute fish mortality in lakes and rivers when pesticide is used according to the label

Hazard-based criteria
- What level of a pesticide characteristic is acceptable in Ethiopia?
  - *example:* maximum DT_{50} in soil

Environmental quality standards
- What level of pesticide residue is acceptable in Ethiopia?
  - *example:* maximum pesticide concentration in groundwater

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General issues relevant for setting risk criteria

1. Quantification of risk
2. Tiered assessment of risk

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Registration criteria – different definitions

Risk-based criteria
- Good option (uses both data on toxicity and exposure)

Hazard-based criteria
- Simple option (only uses intrinsic properties of pesticides (e.g. toxicity, DT_{50}), but does not estimate actual risk

Environmental quality standards
- Can be based on risk assessment (e.g. WHO guidance values for drinking water)
- Can be based on political choice (e.g. EU general drinking water criterion)

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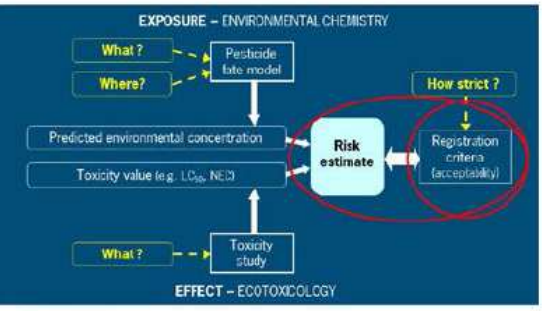
Environmental risk assessment – setting criteria

1



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Risk estimate – European Union

1

Toxicity Exposure Ratio (TER)

= comparison between an estimate of an ecological effect and of exposure

$$TER = \frac{\text{toxicity value } (LD_{50}, LC_{50}, NOEC)}{\text{predicted environmental concentration (PEC)}}$$

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Risk estimate: different terms – same principle

1

Toxicity Exposure Ratio (TER)

(EU plant protection products)

$$TER = \frac{\text{toxicity value } (LD_{50}, LC_{50}, NOEC)}{\text{predicted environmental concentration (PEC)}}$$

Risk Quotient (RQ) or **Exposure Toxicity Ratio** (ETR)

(e.g. USA, Australia, EPPO, EU biocides)

$$ETR = \frac{\text{predicted environmental concentration (PEC)}}{\text{toxicity value } (LD_{50}, LC_{50}, NOEC)}$$

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Risk estimate: different terms – same principle

Examples:

TER = 0.1 ⇔ RQ or ETR = 10

or

TER < 100 ⇔ RQ or ETR > 0.01

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1 Risk estimate: different terms – same principle 1

- Project proposes to use ETR approach
- Advantages:
  - more widely used
  - more logical
    - + higher ETR means higher risk
    - + lower ETR means lower risk
- But: be careful how trigger values are used in background documents from different sources!!

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Risk estimate compared to registration criterion

$$ETR = \frac{\text{predicted environmental concentration (PEC)}}{\text{toxicity value } (LD_{50}, LC_{50}, NOEC)}$$

Depends on uncertainty of toxicity estimate → Registration criterion

Pesticide acceptable? yes/no

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1 Uncertainty in risk estimate – toxicity 1

Registration criteria often comprise a **safety factor** (also: **assessment factor**, **uncertainty factor**, **extrapolation factor**)

- Variation between individuals
  - because tests are done in different laboratories
- Variation between species
  - if protection goal is more than tested species
- Acute to long-term effects
  - if only acute tests are available
- Laboratory to field extrapolation
  - if toxicity data only come from the laboratory

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Uncertainty in risk estimate

- Ideal situation

$$ETR = \frac{\text{exact environmental concentration}}{\text{no effect concentration of ecosystem to protect}}$$

acceptable: <1

- Real situation for Tier 1

$$ETR = \frac{\text{predicted environmental concentration (PEC)}}{\text{acute } LC_{50} \text{ for 3 aquatic species}}$$

<0.01

- Need to extrapolate:
  - acute → chronic
  - 3 species → community/ecosystem
  - laboratory test → field situation

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Registration criteria for environmental risk

- Registration criteria (safety factors) depend on the organism being assessed
  - example: different for bees than for aquatic organisms
- Criteria will (often) depend on the quantity and quality of the available data used for the ETR
  - Better and/or more data → often lower safety factor is acceptable

Normally step-wise risk assessment is done

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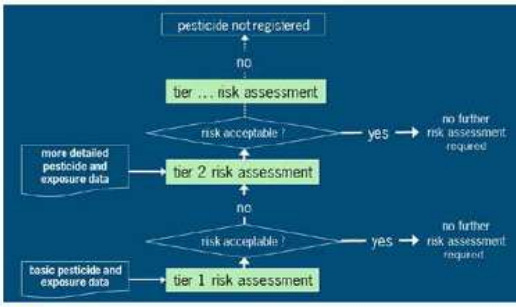
Tiered (=step-wise) risk assessment



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2 What if ETR of 1st tier does not meet criteria? 1

Options

- Refine exposure estimate
- Refine effects assessment (higher tiers)
- Re-evaluate risk in more detail (magnitude, probability and ecological significance of effects)
- Consider risk reduction measures
- Do not authorize certain uses of particular concern
- Do not authorize pesticide for all uses

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What if ETR of 1st tier does not meet criteria?

Options for Ethiopia

- Refinement options are for the time being no option
  - too complex
  - more capacity of people needed
  - → Tier 1 assessment is the highest step for the time being
- Other options can be applied (risk reduction measures; non-authorisation of certain uses; no authorisation at all)

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Decision criteria

1

- But:
- Limited data often means higher levels of uncertainty – higher safety factor needed
- 1st tier criteria are therefore relatively conservative
- Criteria debated:
  - too strict: high economic consequences?
  - too weak: high ecological consequences?

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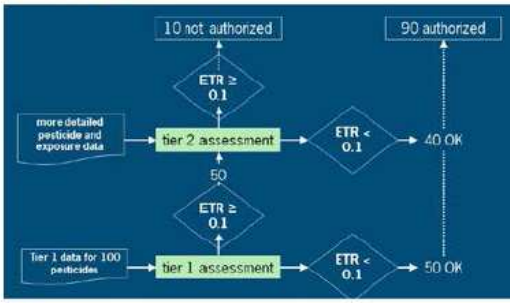
Example 1: two-tier system

ETR < 0.1 is acceptable risk



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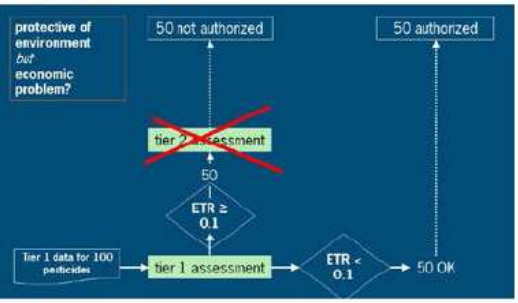
2

Example 2: one-tier system & same criteria

ETR < 0.1 is acceptable risk

2



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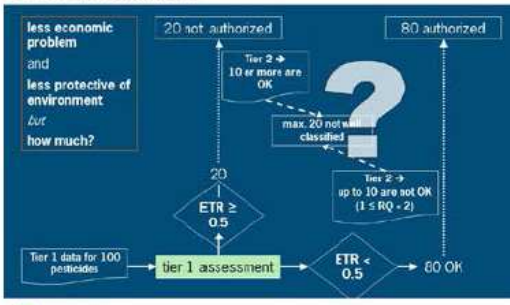
Example 3: one-tier system

ETR < 0.5 is acceptable risk



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Examples summary

2

2

System	Acceptable ETR	Number of pesticides		
		Authorized	Not authorized	
2 tiers	< 0.1	90	10	"Ideal"
1 tier	< 0.1	50	50	Economic constraint
1 tier	< 0.5	80	20	Environmental constraint

- 30 pesticides have maybe a risk for the environment
- If only Tier 1 data/assessments possible → find best balance between economic and environmental interests

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Proposal for Ethiopia

- Determination of risk classification criteria
  - low risk
  - possible risk
  - high risk
- Low risk: if ETR < 1/safety factor of the EU → risk acceptable
- Possible risk: if ETR ≥ 1/safety factor of the EU but ≤ a certain exceedance factor (different for different protection goals) → risk acceptable for the time being, but if risk reduction measures are possible they should be applied
- High risk: if ETR > certain exceedance factor → risk unacceptable; authorisation not possible, unless sufficient risk reduction measures can be applied to reduce the risk to an acceptable level

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Proposal for Ethiopia

Advantages of this approach:

- the focus can be directed on the real high risk pesticides
- No high economic consequences due to loss of too many pesticides

In future refinement steps can be introduced → the risk of pesticides with a possible risk can be estimated in a better way

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Thank you for your attention!!

Questions??????

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Annex 6. Summary of exposure scenario development for surface water and groundwater protection goals, as developed in the 5-9 November 2012 workshop in Wageningen.

Pesticide Risk Reduction Programme – Ethiopia

Surface water and groundwater scenario development
5-9 November 2012

Alemayehu Woldeamanual,Dereje Gorfu, Engida Zemedagegenhu, PRRP-Ethiopia,
Paulien Adriaanse, Mechteld ter Horst, John Deneer, Jos Boesten, Alterra

joint collaborative programme on pesticide registration and post-registration

MoA ALTERRA

Towards a sustainable use of pesticides in Africa

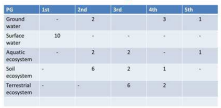
Summary sw and gw scenario development

- B2.1: Development of a scientific evaluation system for the registration of pesticides – Evaluation of dossiers of chemical pesticides

So:

- Registration procedure:
- Developing scientific methods to assess risks in Ethiopian context and for use pattern requested by registrant
- Nov '11 workshop: Environment – drinking water high priority
- Nov '12 workshop: Focus on risks for drinking water production from surface water and groundwater

Definition of protection goals: results



- First priority to protect is surface water, used for drinking water (Nov '11 workshop, important rural areas + main source for drinking water in Rift Valley)
- Second priority is groundwater: 90% rural areas and 40% major towns get drinking water from gw source (Nov'12 workshop, Water Works Design and Supervision Ethiopia)

Summary sw and gw scenario development

- Workshop 5-9 November 2012 development of scenarios to estimate concentrations in surface water and groundwater used for drinking water production.
- Present were:
  # Alemayehu Woldeamanual- APHRD- PRRP coordinator
  # Dr Dereje Gorfu –EIAR- crop characteristics
  # Mr Engida Zemedagegenhu- Water Works Design and Supervision Ethiopia- groundwater knowledge
- From Alterra: several gw and sw scenario development and model experts: Mechteld ter Horst, John Deneer, Jos Boesten and Paulien Adriaanse

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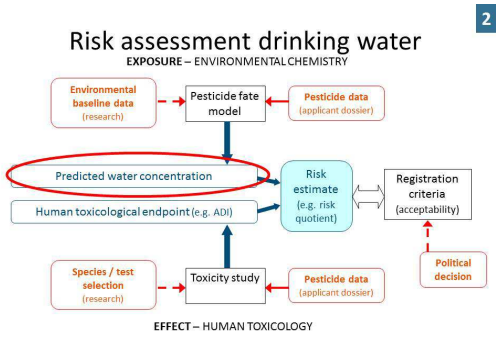
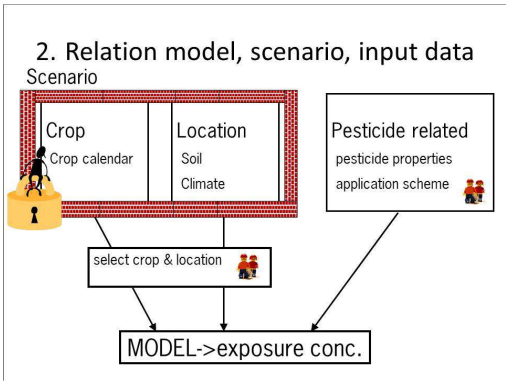


Summary sw and gw scenario development

- PEC: local relevant concentrations, so specific for Ethiopian conditions
- Concentrations according to GAP use (not point sources, industry)
- Concentration depends on
  # protection goal (what, where, how strict)
  # agro-environmental conditions, compound properties
- Fixed set of agro-environmental conditions is called scenario



Summary sw and gw scenario development

- Scenario should be based upon
  EU: 'realistic worst case approach'
  (Directive 91/414/EC of EU)
  Ethiopia: phrase in Proclamation ??
- Realistic worst-casedness or the vulnerability of the scenario is often translated as '90th-percentile occurrence in time and space'

Interludum: Vulnerability

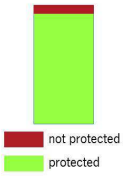
Scenarios should be protective

x % of in reality existing situations (in time and space) in Ethiopia are protected

50% means half of all situations in Ethiopia are protected = average situation

90% means that 90% all situations in Ethiopia are protected = EU translation of "realistic worst case situation"

Situations in Ethiopia



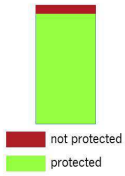
Interludum: Vulnerability

Scenarios should be protective, "realistic worst case"

Proposal: 99th%-ile occurrence in time and space is protected, so 1% is not protected

More strict than in EU because human-toxicological standard is used in Ethiopia (exceedance means casualties)

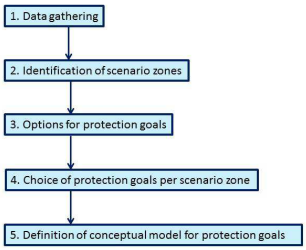
Situations in Ethiopia



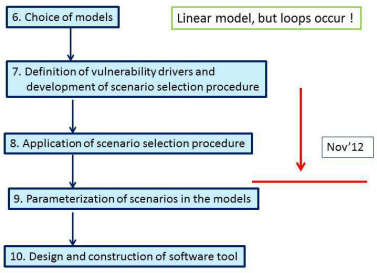
Summary sw and gw scenario development

- Scenario development according to scheme developed by Alterra, based on experience in scenario development in EU since early '90 (soil, groundwater, surface water, greenhouses in NL and EU, groundwater and surface water in China)
- See next slides: in Nov '12, we walked through procedure for surface water and groundwater, separately
- First define protection goals into detail, next develop scenarios, parameterise these and develop software

Definition of protection goals



Scenario selection and parameterization



Definition of protection goals

How to define protection goals into detail ?

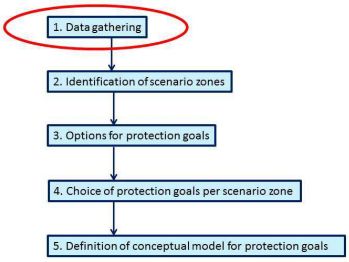
Answer questions:

- What do you want to protect ?
- Where ?
- When and how strict ?

Why is definition of protection goals important?

- If protection goals have been defined into detail
- we know which exposure concentrations we need to assess, so
- we can design scenarios, so
- we can perform standardized, cheap, reproducible risk assessments for registration

Definition of protection goals

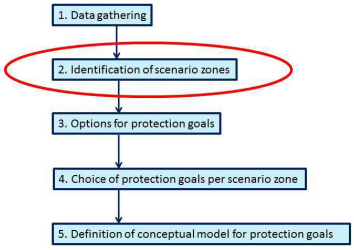


Summary sw and gw scenario development

1. Data gathering

- Inventory of agro-environmental characteristics and existing environmental standards in Ethiopia (CR1, Nov '11) + workshop Nov '11
- More details on meteorology (precipitation, yearly totals, daily totals, evaporation, 30 years, model-based, so no data gaps, 80*80 km^2), soils (oc, 5*5 km^2, ISRIC, HWSD)
- More details on groundwater (Mr Engida)
- More details on crops and pesticide use (Dr Dereje)
- More details on pesticide use, registration (Alemayehu)

Definition of protection goals



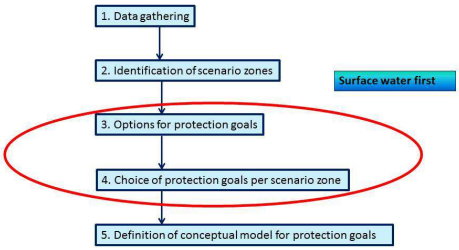
Summary sw and gw scenario development

- Two zones identified: < 1500 m and > 1500 m, same for sw and gw scenarios, similar to zones used for Efficacy assessments in Ethiopia

2. Identification of scenario zones

- Correspond to distinction between Kolla and Woina Dega traditional agro-ecological zones
- Use of more than 1 zone gives flexibility in registration procedure, but may be difficult to uphold
- Important for scenario selection procedure (%-ile selection)
- To be approved by political level, i.e. Pesticide Advisory Board ?

Definition of protection goals



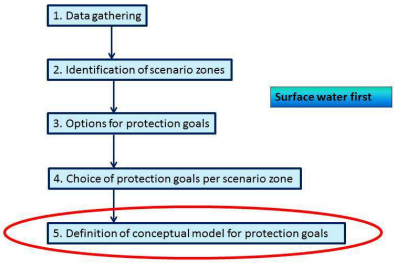
Protection goals: surface water

- We need set priorities, so limit number of protection goals for which we can work out the scenarios
- Proposal: take 2 most vulnerable goals, i.e. where we expect the highest concentrations

Proposal

1. River type: stream/small river near villages, entire Ethiopia (most vulnerable + widespread)
2. Pond/lake type: temporary pond, (cattle drinking) Rift Valley, east Ethiopia (also vulnerable)
3. (Rift Valley lakes: used when groundwater unsuitable for drinking water, less vulnerable because of size)

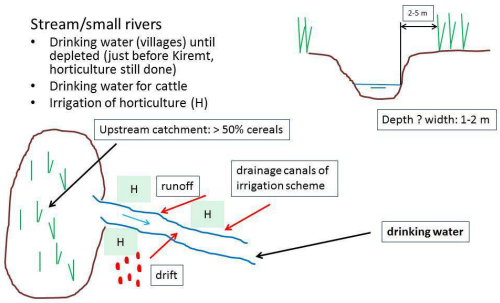
Definition of protection goals



Protection goals #1: surface water

Stream/small rivers

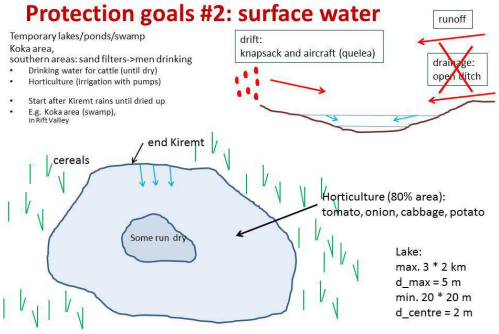
- Drinking water (villages) until depleted (just before Kiremt, horticulture still done)
- Drinking water for cattle
- Irrigation of horticulture (H)



Protection goals #2: surface water

Temporary lakes/ponds/swamp
Koka area,
southern areas: sand filters->men drinking

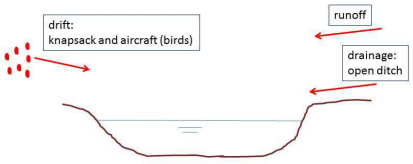
- Drinking water for cattle (until dry)
- Horticulture (irrigation with pumps)
- Start after Kiremt rains until dried up
- E.g. Koka area (swamp), in Rift Valley



Protection goals #3: surface water

Rift Valley lakes

- Drinking water for man and cattle
- E.g. lake Ziway, lake Nagano, select smallest lake



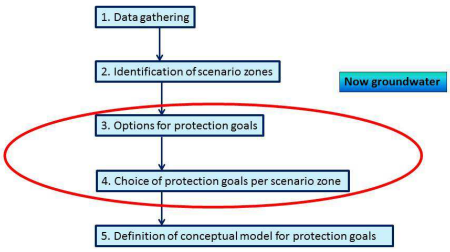
Protection goals sw in scenario zones

most vulnerable

#1 Small river:
occurs only in scen zone >1500 m

#2 Temporary pond occurs both in
scen zone > 1500 m (but <2000 m) and
scen zone < 1500 m (but >500 mm rain)

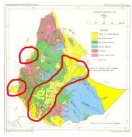
Definition of protection goals



Protection goals gw in scenario zones

#1 Alluvial aquifers along small rivers
#2 Volcanic aquifers of shallow wells

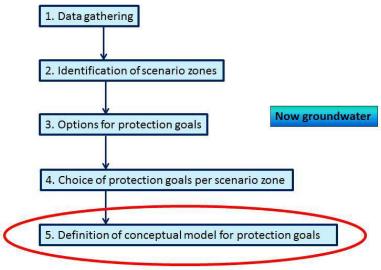
#1 and #2 may be close to each other



#3 Alluvial aquifers at RV margins and lowlands (map circles around yellow locations, overlain with scenario zones)

#4 Fractured basement rocks of shallow wells

Definition of protection goals



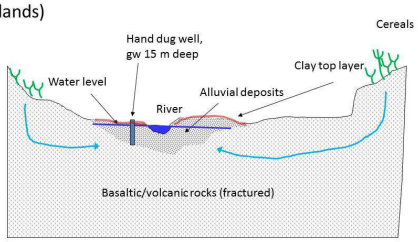
Protection goals#1: groundwater

Alluvial aquifers along small rivers (diverging rivers, highlands)

Hand dug wells, min 3 m deep, average 15 m deep
Top layer is clay, thickness varies
Water infiltrates from soils above with mainly cereal production
Gentle slopes
General there is water in well, esp. if rain is high and geological formation favourable
Close to gw #2 (some km)

Protection goals#1: groundwater

Alluvial aquifers along small rivers (diverging rivers, highlands)



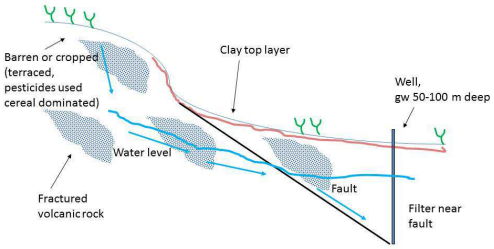
Protection goals#2: groundwater

Volcanic aquifers of shallow wells

Drilled wells, min depth 50 m, up to 100 m deep
Clay layer on top
Water from above fractured volcanic rocks, either barren (bushes), or cultivated: then often terraced (otherwise erosion) with pesticide use. Cereals dominate, some pulses (faba bean)
Can be flat land, steep slopes, but gw is deep or population is high (therefore deeper)
Close to gw#1 (some km)

Protection goals#2: groundwater

Volcanic aquifers of shallow wells



Protection goals#3: groundwater

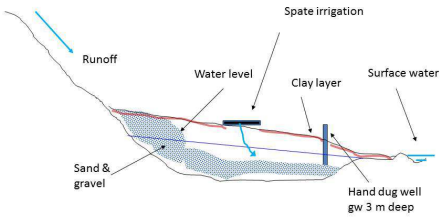
Alluvial aquifers at the Rift Valley margins or lowlands

Most vulnerable are shallow wells (3 m, hand drilled), then near surface water. (Otherwise depth from artesian to 230 m)
Top layer of clay.

Water comes from runoff/percolation from hills/mountains, runoff from volcanic rocks, irrigation return water (spate irrigation)

Protection goals#3: groundwater

Alluvial aquifers at the Rift Valley margins or lowlands



Protection goals#4: groundwater

Fractured basement rocks of shallow wells

Drilled wells, min 10-12 m deep, max 50 m deep,
Fed by runoff from massive basement rocks

If fractured zone thick: water all year round, if thin, dry from Dec to June. Fractured zone often near small rivers

More arid zones, sorghum, limited teff, so limited pesticide use, so not so vulnerable

Protection goals gw in scenario zones

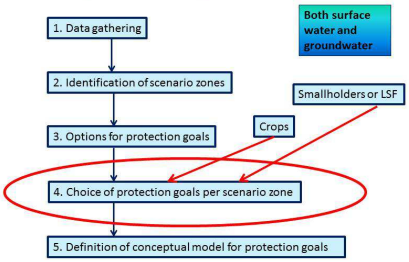
#1 Alluvial aquifers along small rivers:
occurs only in scen zone >1500 m
#2 Volcanic aquifers of shallow wells:
occurs only in scen zone >1500 m
#1 and #2 may be close to each other

most vulnerable

#3 Alluvial aquifers at RV margins and lowlands (map circles around yellow locations, overlain with scenario zones):
occurs mostly in scenario zone <1500 m,
may be in scenario zone >1500 m (but then < 2000 m),

#4 Fractured basement rocks of shallow wells
not considered, less vulnerable

Definition of protection goals



Types of farming in scenario zones

Smallholders
- these are evenly distributed across scenario zone >1500 m,
- these are evenly distributed in zone 1000-1500 m in scenario zone < 1500 m

Large Scale Farms (LSFs)
- these occur in both scenario zones, irrigated, along major rivers (4, 5 up to max 10 km away)
(dominant < 1500 m because big rivers, flat, fertile alluvial, less >1500 m, may be irrigated, mostly rain fed, mostly cereals)

Crops in types of farming and scenario zones

Large Scale Farms, LSFs:

zone > 1500 m:
wheat, barley, maize
Also pulses (faba bean, field pea, French bean, chickpea), coffee, citrus, vegetables (on, tom, pepp, cabb)

zone < 1500 m:
sorghum, sesame, French bean (Faseolis vulgaris)
sugarcane, cotton, maize
Also citrus, sweet potato (for planting mat.), vegetables (tom, on, pepp, cabb)

Vegetables are: onions, tomato, pepper, cabbage, French beans

Crops in types of farming and scenario zones

Smallholders:

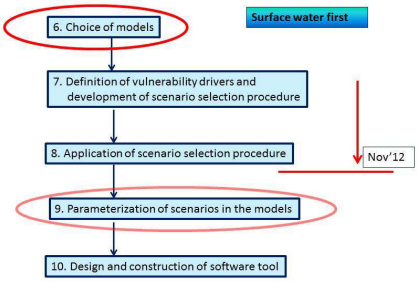
Zone > 1500 m:
Teff, maize, wheat, barley, vegetables (all),
Also potato, pulse (faba bean, field pea, French bean, chickpea, lentils), pome/stone fruit,

Zone < 1500 m (1000-1500 m):
Teff, maize, wheat, barley, vegetables (all),
Also potato, sweet potato, banana (few pesticides), mango

Coffee (no pesticides, so not needed)

Vegetables are: onions, tomato, pepper, cabbage, French beans

Scenario selection and parameterization

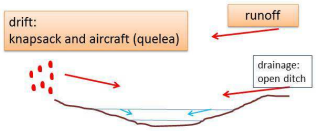


Selected models for surface water

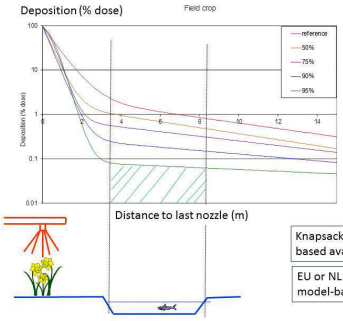
6. Choice of models

Entry routes

Most important entry routes of pesticides in to the surface water



Selected models for surface water: Drift



6. Choice of models

Different types of nozzles (% drift reducing)

Drift curve is function of
- Application technique
- Nozzle type
- Pressure

Knapsack sprayer: IDEFICS model-based available

EU or NL data for tractor mounted: model-based and measured available

Selected models for surface water: Runoff

6. Choice of models

Proposed model:

- PRZM (Pesticide Root Zone Model) model (Carsel et al., 1998)
  - Simulates pesticide runoff from agricultural fields
  - Used in USA and EU

N.B. PRZM calculates sheet runoff flow, not via gullies !

Selected models for surface water: Runoff

Proposal for Ethiopia

9. Parameterization of scenarios in the models

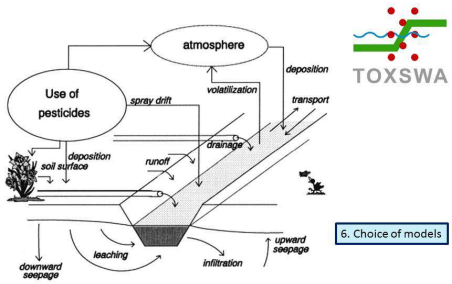
- Take the R4 (worst case EU) standard PRZM input
  - Parameterising soil for PRZM is too ambitious in PRRP
- Use Ethiopian weather (daily rainfall and evapotranspiration)
- Use Ethiopian crops

Selected models for surface water: Fate in SW

- Selected model: TOXSWA
- Developed by ERA team of Alterra
- Used in NL and EU pesticide registration
- Ditch, stream and pond scenarios parameterised for TOXSWA in EU

6. Choice of models

Selected models for surface water: Fate in SW



6. Choice of models

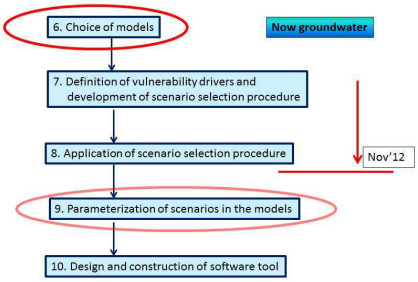
Selected models for surface water: Fate in SW

9. Parameterization of scenarios in the models

Proposal for Ethiopia

- Temporary lakes
  - EU FOCUS pond properties (sediment, sus.sol, macrophytes)
  - Ethiopian lake dimensions
    - E.g. minimal dimension of lake were people and/or cattle still drink water
  - EU FOCUS pond properties (sediment, sus.sol, macrophytes)
  - Ethiopian contributing area and crops

Scenario selection and parameterization



Groundwater protection goal

6. Choice of models

The EuroPEARL meta-model

$Ln\,(C_L) = \alpha_0 + \alpha_1 * X_1 + \alpha_2 * X_2$

C_L : the concentration (µg/L) in leaching water at 1 m depth, given a net soil deposition of 1 kg/ha

α_0 , α_1 , α_2 : regression parameters that depend on
- temperature and annual rainfall
- not compound specific, but specific to a region

X_1, X_2 depend on
- soil properties (organic matter and water content)
- compound properties (K_{om}, DT_{50} degradation)

TIKTAK ET AL.: MAPPING GROUND WATER VULNERABILITY TO PESTICIDES

J. ENVIRON. QUAL., VOL. 35, JULY–AUGUST 2006

Groundwater protection goal

6. Choice of models

Parameters α_0 , α_1 , α_2 determined by regression of output of EuroPEARL (spatially distributed model, used in NL and EU) and the metamodel output:

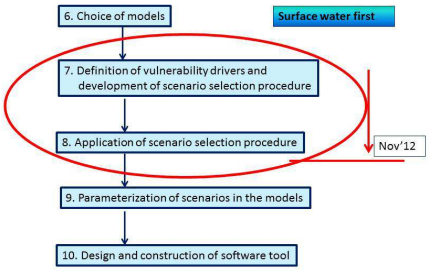
- α_0 , α_1 , α_2 taken for climate zone warm, wet (up to >800 mm rain, >12.5 C)-> most representative for Ethiopia

Consequences of extrapolating the EuroPEARL metamodel to Ethiopia

- Ethiopia → more wet and higher temperature
- Meta model → increasing q results in increasing concentration

Defensible because conservative

Scenario selection and parameterization



Summary sw and gw scenario development

7. Definition of vulnerability drivers and development of scenario selection procedure

- Simple back-of-envelope calculations demonstrated that runoff is main driver for concentration in surface water (dimensions water body and spray drift are less important)
- Main vulnerability driver is runoff, translated as number of days with daily rainfall above 20 mm
- Determine probability of P_{day}>20 mm in time and space
- Repeat procedure for selected protection goals, i.e.
  # small streams >1500 m
  # temporary pond 1500-2000 m
  # temporary pond < 1500 m but > 500 mm

Summary sw and gw scenario development

7. Definition of vulnerability drivers and development of scenario selection procedure

- Procedure (small streams):
  # use grids (80*80 km^2) and select grids > 1500 m
  # each grid, each year: Number of d with P_{day}>20 mm -> 33 values (33 yrs)-> rank per grid and select 99th%ile = nr 33 for each grid (now *temporal* %-ile)

  # plot this single value per grid on the map
  # rank all grids (>1500 m) and select 3 grids with highest %-ile (96.5, 98.2 and 100%) (now *spatial* %-ile)
  # next, select most suitable grid for protection goal:

  here: small streams in agricultural areas

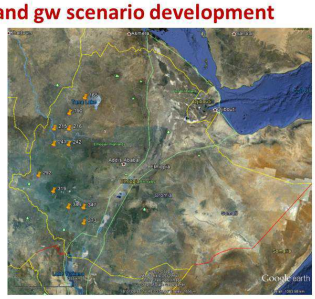
Summary sw and gw scenario development

Three candidate locations for surface water protection goal #1: small streams in areas > 1500 m

Summary sw and gw scenario development

Temporary ponds:

Criteria:
streams >10 km apart
flat area
cultivated area



Top eleven candidate locations for surface water protection goal #2a: temporary ponds in areas < 1500 m and with more than 500 mm rain

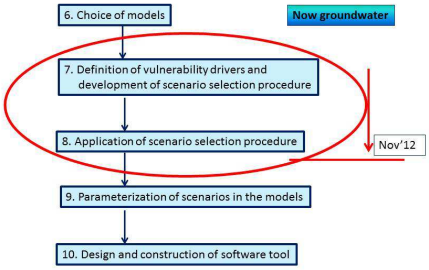
Summary sw and gw scenario development

Temporary ponds:

Criteria:
streams >10 km apart
flat area
cultivated area

Top twelve candidate locations for surface water protection goal #2b: temporary ponds in areas between 1500-2000 m

Scenario selection and parameterization



Summary sw and gw scenario development

7. Definition of vulnerability drivers and development of scenario selection procedure

- Scenario selection procedure possible with aid of simple analytical model (metaPEARL) run for spatial distributed data (percolation, oc- 5*5 km)
- Thus leaching calculated for selected grids (e.g. 1500 m)

- Done for 49 compounds (leaching is f(properties), K_{om} = 10, 20, 30, 60, 120, 240, 480 L/kg and DT_{50} = 10, 20, 30, 60, 120, 240, 480 d)
- 98-100%ile selected for each compound, -> 49 compounds overlain-> common grids qualify as candidate locations

Summary sw and gw scenario development

Six candidate locations for groundwater protection goals #1 and 2: alluvial aquifers along small rivers and volcanic aquifers on shallow wells > 1500 m

Summary sw and gw scenario development

Six candidate locations for groundwater protection goal #3a: alluvial aquifers in the Rift Valley margins and lowlands < 1500 m

Summary sw and gw scenario development

Three candidate locations for groundwater protection goal #3b: alluvial aquifers in the Rift Valley margins between 1500-2000 m

Summary sw and gw scenario development

Next steps:

8. Application of scenario selection procedure

- First select scenario locations

9. Parameterization of scenarios in the models

- Next, start parameterisation:
  # crop development data
  # confirm layout small streams and temporary ponds
  # obtain horticultural irrigation data

10. Design and construction of software tool

- Adapt PRIMET tool for sw and gw concentrations

Summary sw and gw scenario development

Annex 7. Risk assessment for the Ethiopian protection goals for the environment, using the PRIMET tool (to be adapted)

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Practicum: performing risk assessment for the Ethiopian protection goals

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Proposal Registration Criteria (safety factors) and criteria for risk classification Ethiopia for each protection goal

- Registration criteria based on the EU (safety factors)
- Criteria for risk classification based on an estimation of low risk, possible risk and high risk
- Protection goals as selected for Ethiopia:
  - surface water as source of drinking water
  - groundwater as source of drinking water
  - aquatic ecosystem
  - birds
  - bees
  - non-target arthropods
  - earthworms
  - non-target terrestrial plants

Registration criteria and criteria for risk classification

For each protection goal proposals for:
- Exposure
- Toxicity
- Registration criteria (safety factors; based on the EU)
- Criteria for risk classification (ETR approach):

ETR < 1/safety factor	→ low risk
1/safety factor ≤ ETR ≤ X	→ possible risk
ETR > X	→ high risk

Registration criteria and criteria for risk classification

- Low risk: acceptable and registration possible

- Possible risk: uncertainty about risk
  - take into account assessments of other countries (e.g. EU (EFSA conclusions)
  - if risk reduction measures are possible, they should be applied
- High risk: not acceptable, unless sufficient risk reduction measures can be applied

Criteria for risk classification

Where are choices for factor X (risk classification) based on?
- Depends on type of organism:
  - vertebrates (fish, birds) have a higher protection level than non-vertebrates (dead birds and fish are not desired)
  - organisms which can reproduce fast have a higher ability of recovery after suffering from effects
- Depends also on how conservative the first tier assessment is (e.g. safety factor of 100 for aquatic invertebrates is quite strict; exposure calculation may be conservative)

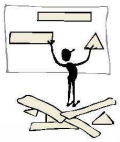
Criteria for risk classification

- The economic consequences are also taken into account (which % of pesticides will have a high risk and maybe have to be banned)
  - a rough estimate has been made based on experience, but this is a topic for further research
- Some choices for factor X are not so easy to underpin, but are more a gut feeling

- It could be that some choices must be adjusted, based on further analysis and experiences in practice

Registration criteria and criteria for risk classification

- Only **proposals** are presented here!
- The proposals should be discussed and **you** must make the final choices for registration criteria and risk classification criteria!!!!!



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- Practice the risk assessment procedure as proposed
- Step by step → protection goal by protection goal
- For 2 substances + GAP:
  - endosulfan
  - 2-4 D
- Just exposure or exposure + ETR → use present PRIMET version in case possible
- Fill in data requirements form

Practicum today

- **Protection goals Ethiopia**

1. Surface water as source of drinking water
2. Groundwater as source of drinking water
3. Aquatic ecosystem
4. Bees
5. Non-target arthropods
6. Earthworms
7. Birds
8. Non-target terrestrial plants

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PRIMET: Introduction

- **Risk assessment scheme in Europe**
  - **PRIMET based on metaversions of models and concepts used in the registration procedure in Europe**
  - **Exposure assessment to calculate the Predicted Environmental Concentration (PEC)**
  - **Effects assessment to calculate the Predicted No Effect Concentration (PNEC)**

TOXSWA Pearl herbestperpest

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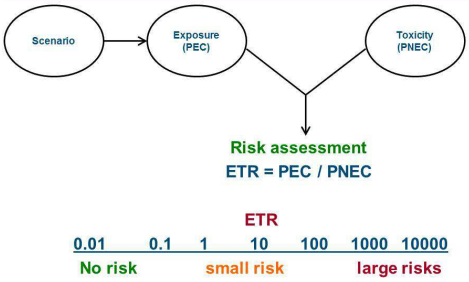
PRIMET: Introduction



Risk assessment
ETR = PEC / PNEC

ETR

0.01	0.1	1	10	100	1000	10000
No risk			small risk		large risks	

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PRIMET : Introduction

- **Risk assessment scheme in Europe**
  - **Exposure assessment mostly based on models**
    - **+ Drift**
    - **+ Drainage**
    - **+ Run-off**
    - **+ Fate in water**
    - **+ Leaching**
  - **Effects assessment mostly based on experiments**
    - **+ Laboratory tests**
    - **+ (semi) Field experiments**

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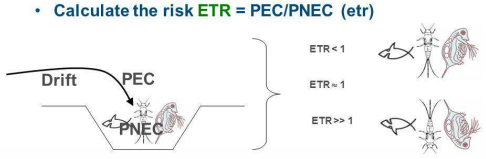
PRIMET: Scientific background

- **Stages in Ecological Risk Assessment**

- **Develop a physical and application scenario (sc)**
- **Calculate the PEC for that scenario (pec)**
- **Calculate the PNEC for that scenario (pnec)**
- **Calculate the risk ETR = PEC/PNEC (etr)**



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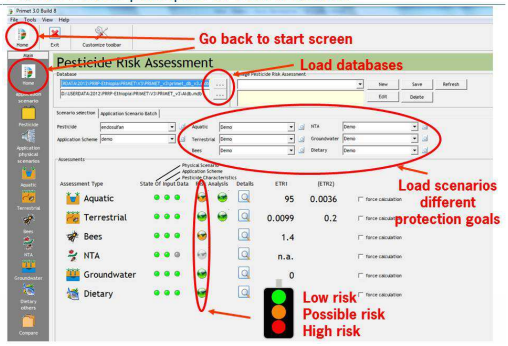
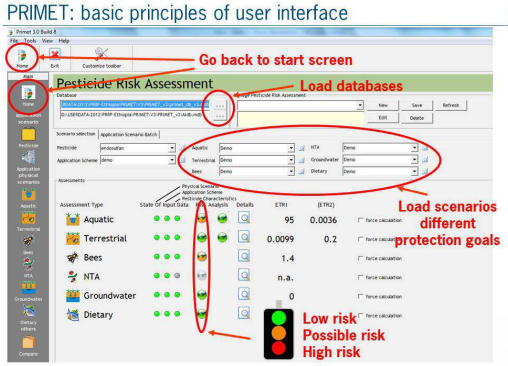
PRIMET: basic principles of user interface



PRIMET: basic principles of user interface



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Protection goals Ethiopia

1. Surface water as source of drinking water
2. Groundwater as source of drinking water
3. Aquatic ecosystem
4. Bees
5. Non-target arthropods
6. Earthworms
7. Birds
8. Non-target terrestrial plants

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Surface water as source of drinking water

- **What?** Surface water as source of drinking water
- **Where?** Scenarios will be developed for:
  - Stream/small rivers
  - temporary ponds
- **How strict**? Based on human toxicity values (ADI-approach)

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Surface water as source of drinking water

Steps

1. Exposure → PRIMET (assessment aquatic)
2. Toxicity → Calculate Drinking Water Standard (DWS)
3. Risk assessment → Calculate ETR

Fill in the relevant sections of the data requirement form after each step

4. Evaluate procedure
   - Any difficulties?

Surface water as source of drinking water

- **Step 1: Exposure**
  - Needed: PECsw-dw at scenario location
  - scenarios need to be put in PRIMET
  - however surface water as drinking water not in present PRIMET version
  - therefore we use the PRIMET assessment 'aquatic' for calculating PECsw-dw in a small stream (demo, so not a specific Ethiopian scenario)

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Surface water as source of drinking water

- **Step 1: Exposure – PRIMET**
- Goal: Calculate PECsw-dw
- Mechteld shows on screen what to do

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Surface water as source of drinking water

- **Step 2: Toxicity**
- Drinking Water Standard (DWS): based on ADI (Acceptable Daily Intake)

$$DWS = \frac{ADI * bw * P}{ConsWater}$$

ADI	= Acceptable Daily Intake (mg/kg * d) (safety factor of 100 included)
bw	= body weight (60 kg for adults)
P	= fraction of the ADI allocated to drinking water (DF= 0.1)
ConsWater	= daily drinking water consumption (DF = 2 L for adults, L/d)

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Surface water as source of drinking water

- **Step 3: Risk assessment**

$$ETRsw\text{-}dw = \frac{PECsw\text{-}dw}{DWS \times 1000}$$

(1000 = factor to correct from mg/L to ug/L)

ETRsw-dw < 1	→ low risk
1 ≤ ETRsw-dw ≤ 10	→ possible risk
ETRsw-dw > 10	→ high risk

- Because a high safety factor is used to derive the ADI (factor 100) an exceedance factor of 10 is still considered relatively safe)

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Surface water as source of drinking water

- **Step 4: Evaluation of the procedure**

5 minutes time to write down any difficulties experienced during the risk assessment and ideas for improvements

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- **Protection goals Ethiopia**

1. Surface water as source of drinking water
2. Groundwater as source of drinking water
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8. Non-target terrestrial plants

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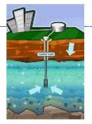
Groundwater as source of drinking water



- **What?** Groundwater as source of drinking water
- **Where**? Scenarios will be developed for:
  - Alluvial aquifers along small rivers
  - Volcanic aquifers of shallow wells
  - Alluvial aquifers at the Rift Valley margins or lowlands
- **How strict**? Based on human toxicity values (ADI-approach)

Artesian well in volcanic aquifer near Addis Q =115 l/s

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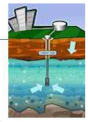
Groundwater as source of drinking water



Steps

1. Exposure → PRIMET
2. Toxicity → Calculate Drinking Water Standard (DWS)
3. Risk assessment → Calculate ETR

Fill in the relevant sections of the data requirement form after each step

The entire assessment can be done in PRIMET

4. Evaluate procedure
   - Any difficulties?

PRIMET

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Groundwater as source of drinking water

- **Step 1: Exposure**
  - Needed: PECgw-dw at scenario location
  - scenarios need to be put in PRIMET
  - Ethiopian scenarios not in present PRIMET version
  - therefore we use the PRIMET assessment 'groundwater'. PRIMET does not give the PECgw-dw as result

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Groundwater water as source of drinking water

- **Step 1: Exposure – PRIMET**
- Goal: Pesticide properties → fill in fate properties in PRIMET for assessment 'Groundwater'
- Mechteld shows on screen what to do

PRIMET

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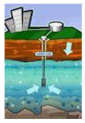
Groundwater as source of drinking water

- **Step 2: Toxicity**
- Drinking Water Standard (DWS): based on ADI (Acceptable Daily Intake)



$$DWS = \frac{ADI * bw * P}{ConsWater}$$

ADI	= Acceptable Daily Intake (mg/kg * d) (safety factor of 100 included)
bw	= body weight (60 kg for adults)
P	= fraction of the ADI allocated to drinking water (P= 0.1)
ConsWater	= daily drinking water consumption (ConsWater = 2 L for adults, L/d)

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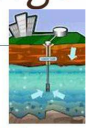
Groundwater as source of drinking water



- **Step 2: Toxicity – PRIMET**
- Goal 1: Toxicity properties for assessment 'Groundwater'

bw	= body weight (60 kg for adults)
P	= fraction of the ADI allocated to drinking water (P= 0.1)
ConsWater	= daily drinking water consumption (ConsWater = 2 L for adults, L/d)

- Goal 2: Pesticide properties for assessment 'Groundwater'
- fill in NOAEL mammals and EF mammals to calculate ADI; EF = 100

OR

- Fill in ADI directly (if so, this over rules calculation with NOAEL and EF

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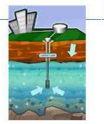
Groundwater as source of drinking water

Step 3: Risk assessment



$$ETR\ gw\text{-}dw = \frac{PECgw\text{-}dw}{DWS \times 1000}$$

ETRgw-dw < 1	→ low risk
1 ≤ ETRgw-dw ≤ 10	→ possible risk
ETRgw-dw > 10	→ high risk

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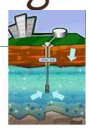
Groundwater as source of drinking water



- **Step 3: Risk assessment – PRIMET**
- Extract the ETRs from PRIMET. However the PRIMET 'No risk, possible risk, high risk' classification is different (see PRIMET manual p. 41)
- Mechteld shows on screen what to do

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Groundwater as source of drinking water

- **Step 4: Evaluation of the procedure**

5 minutes time to write down any difficulties experienced during the risk assessment and ideas for improvements

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- **Protection goals Ethiopia**

1. Surface water as source of drinking water
2. Groundwater as source of drinking water
3. Aquatic ecosystem
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6. Earthworms
7. Birds
8. Non-target terrestrial plants

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Aquatic ecosystem

What? Populations of aquatic species

Where? (temporary) lakes, streams, rivers, storage reservoirs

- No scenarios selection procedure defined yet. Probably conservative approach chosen.

How strict? Sustainability of aquatic ecosystems should be ensured. Therefore, survival and reproduction of the most sensitive aquatic species should not, or only briefly, be affected

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Aquatic ecosystem

Steps

1. Exposure → calculate PECsw using PRIMET
2. Toxicity → from dossier + safety factors
   - fish (acute, chronic)
   - algae (acute)
   - invertebrates (acute, chronic)
   - macrophytes (acute)
3. Risk assessment → Calculate ETRs by hand (not PRIMET)

Fill in the relevant sections of the data requirement form after each step

4. Evaluate procedure
   - Any difficulties?

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Aquatic ecosystem

- **Step 1: Exposure:** Needed → PECsw
  - PECmax for acute risk assessment
  - PECmax or PECtwa for chronic risk assessment

- No scenarios selected or developed for Ethiopia yet.

- Therefore: practice with demo scenario in present PRIMET version

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Aquatic ecosystem

- **Step 1: Exposure – PRIMET**

- Goal:
  - Fill in fate properties and application scheme in PRIMET for assessment 'Aquatic'
  - Extract PECsw (in µg/L) from PRIMET (Mechteld will show how to do so)

- Filling in fate properties and application scheme: already done for protection goal surface water for drinking water

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Aquatic ecosystem

Step 2: Toxicity:

Take the following values from the dossier:

- acute LC50 (fish)
- EC50 (algae, invertebrates, macrophytes)
- chronic NOEC (fish and invertebrates)

Safety factors used in the EU:

- acute LC50 fish:	100
- acute EC50 invertebrates:	100
- EC50 algae and macrophytes:	10
- chronic NOEC fish:	10
- chronic NOEC invertebrates:	10

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Aquatic ecosystem

Step 3: Risk assessment

1. Fish (vertebrates)
   - Acute
   - Chronic

2. Invertebrates
   - Acute
   - Chronic

3. Alg
   - no distinction between acute and chronic; use of PECmax

4. Macrophytes
   - no distinction between acute and chronic; use of PECmax

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Aquatic ecosystem


Step 3: Risk assessment → Fish

Acute

ETR = PECsw-max (µg/L) / LC50fish (µg/L) (safety factor = 100)

ETRfish-ac < 0.01	→Low risk
0.01 ≤ ETRfish-ac ≤ 0.1	→Possible risk
ETRfish-ac > 0.1	→High risk

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Aquatic ecosystem


Step 3: Risk assessment → Fish

Chronic

ETR = PECsw (µg/L) / NOECfish (µg/L) (safety factor = 10)

→ 2 options

a) Use of PECmax	b) Use of PECtwa	
ETRfish-chr < 0.1	ETRfish-chr < 0.1	→ Low risk
0.1 ≤ ETRfish-chr ≤ 1	0.1 ≤ ETRfish-chr ≤ 0.5	→ Possible risk
ETRfish-chr > 1	ETRfish-chr > 0.5	→ High risk

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Aquatic ecosystem


Step 3: Risk assessment → Invertebrates

Acute

ETR = PECsw-max (µg/L) / EC50inv (µg/L) (safety factor = 100)

ETRinv-ac < 0.01	→Low risk
0.01 ≤ ETRinv-ac ≤ 1	→Possible risk
ETRinv-ac > 1	→ High risk

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Aquatic ecosystem


Step 3: Risk assessment → Invertebrates

Chronic

ETR = PECsw (µg/L) / NOECinv (µg/L) (safety factor = 10)

→ 2 options

a) Use of PECmax	b) Use of PECtwa	
ETRinv-chr < 0.1	ETRinv-chr < 0.1	→Low risk
0.1 ≤ ETRinv-chr ≤ 10	0.1 ≤ ETRinv-chr ≤ 1	→Possible risk
ETRinv-chr > 10	ETRinv-chr > 1	→ High risk

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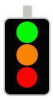
Aquatic ecosystem


Step 3: Risk assessment → Algae

- no distinction between acute and chronic; use of PECmax

ETR = PECsw-max (µg/L) / EC50alg (µg/L) (safety factor = 10)

ETRalg < 0.1	→Low risk
0.1 ≤ ETRalg ≤ 10	→Possible risk
ETRalg > 10	→High risk



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Aquatic ecosystem


Step 3: Risk assessment → Macrophytes (Aquatic plants)

- no distinction between acute and chronic; use of PECmax

ETR = PECsw-max (µg/L) / EC50mac (µg/L) (safety factor = 10)

ETRmac < 0.1	→Low risk
0.1 ≤ ETRmac ≤ 1	→Possible risk
ETRmac > 1	→ High risk

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Aquatic ecosystem

• Step 4: Evaluation of the procedure

5 minutes time to write down any difficulties experienced during the risk assessment and ideas for improvements

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Practicum today

- **Protection goals Ethiopia**

1. Surface water as source of drinking water
2. Groundwater as source of drinking water
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6. Earthworms
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8. Non-target terrestrial plants

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Bees

- **What?** Beehives of honeybees
- **Where?** Everywhere
- **How strict?** No long-term effects on beehives of honey

- Note that only honey bees are assessed, no wild bees. Assumption is that the assessment of honeybees will also cover the wild bees.
- From literature it is likely that the western honeybee is reasonably representative for the African honeybee, but this comparison is only based on one compound.
- For the time being only sprays are taken into account.

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Bees

Step 1: Exposure

- in-crop: single dose rate (g as/ha)
- off-crop: single dose rate (g as/ha) * drift factor

PRIMET:
Fill in fate properties and application scheme in PRIMET for assessment 'Bees'

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Bees

Step 2: Toxicity

- LD50 (µg/bee)
- Safety factor: same as in the EU: 50

PRIMET:
Fill in LD50 value in PRIMET for assessment 'Bees'

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Bees

Step 3: Risk assessment

ETRbee = PECbee / LD50bee

ETRbee < 50 → Low risk
50 ≤ ETRbee ≤ 400 → Possible risk
ETR > 400 → High risk

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Bees

- **Step 3: Risk assessment – PRIMET**
- Extract the ETR from PRIMET (in-crop value only).
- However the PRIMET 'No risk, possible risk, high risk' classification is different (see PRIMET manual p. 34)
- Mechteld shows on screen what to do

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Bees

Step 3: Risk assessment

- Validation of registration criteria: empirical
  - assessment of observed bee kills/colony effects for various pesticides and different application rates
  - two studies with UK data (Mineau et al., 2008)
- No field incidents at ETR < 50
- About 50% probability of hive mortality at ETR > 400
- No compliance with the criteria almost always leads to risk management, not refusal of registration.

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Bees

Step 4: Evaluation of the procedure

5 minutes time to write down any difficulties experienced during the risk assessment and ideas for improvements

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- **Protection goals Ethiopia**

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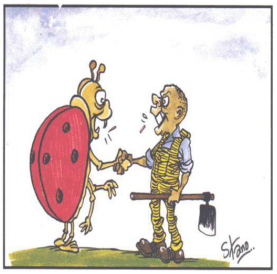
Non-target arthropods

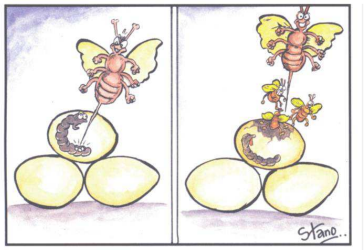
Very important in relation to Integrated Pest Management (IPM)

- **What?** Populations of non-target arthropods
- **Where?** In-crop as well as off-crop
- **How strict?** No long-term effects on populations of non-target arthropods

Non-target arthropods



Non-target arthropods



Non-target arthropods

Step 1: Exposure

- PEC (in-field): single dose rate (g as/ha) * MAF
- PEC (off-field): single dose rate (g as/ha) * MAF * drift factor

MAF: depends on the number of applications (see table 1 p. 35 PRIMET manual)

Non-target arthropods

Step 2: Toxicity

- glass-plate tests (lab tests) with *Aphidius rhopalosiphi* and *Typhlodromus pyri*: LR50 (g as/ha)
- Safety factor in the EU: 2 (based on empirical data)
- In a lot of cases extended laboratory tests are available (tests on natural substrate): LR50 (g as/ha)
- Safety factor in the EU: 1 (based on the criterion that less than 50% effect is acceptable)

Non-target arthropods

Step 3: Risk assessment

a) In-crop

ETRnta = PECin-crop / LR50

ETRnta-glass < 2	→ low risk
2 ≤ ETRnta-glass ≤ 100	→ possible risk
ETRnta-glass > 100	→ high risk

ETRnta-ext < 1	→ low risk
1 ≤ ETRnta-ext ≤ 50	→possible risk
ETRnta-ext > 50	→ high risk

Non-target arthropods

b) Off-crop

- Protection level off-crop is more strict, because severe in-crop effects should be compensated by recolonisation of organisms from the off-crop area

ETRnta = PECin-crop / LR50

ETRnta-glass < 2 →Low risk
2 ≤ ETRnta-glass ≤ 20 →Possible risk
ETRnta-glass > 20 →High risk

ETRnta-ext < 1 →Low risk
1 ≤ ETRnta-ext ≤ 10 →Possible risk
ETRnta-ext > 10 →High risk

Non-target arthropods

- **Step 4: Evaluation of the procedure**

5 minutes time to write down any difficulties experienced during the risk assessment and ideas for improvements

Practicum today

- **Protection goals Ethiopia**

1. Surface water as source of drinking water
2. Groundwater as source of drinking water
3. Aquatic ecosystem
4. Bees
5. Non-target arthropods
6. Earthworms
7. Birds
8. Non-target terrestrial plants

Earthworms

What? Populations of earthworms

Where? In-field

How strict? No long-term effect on populations of earthworms

Earthworms

Step 1: Exposure (1)

The concentration for the within field soil compartment is calculated from the dose of the pesticide divided by the amount of soil (kg) in the upper part of the soil (default depth of upper part of the soil = 0.05 m)

$$C_{soil} = 0.1 * M / DEPTH$$

C_{soil} = concentration in the upper part of the soil (mg pesticide / m^3 soil)
0.1 = correction factor to convert from g/ha to mg/m^3
M = individual dose applied (g as/ha)
DEPTH = depth of the field (default value = 0.05 m)

Earthworms

Step 1: Exposure (2)

PEC^1_{soil} → 1 application:

$$PEC^1_{soil} = C_{soil} / (\rho_b * 1000)$$

PEC^1_{soil} = concentration in the upper part of the soil from one application (in mg pesticide /kg soil)
C_{soil} = concentration in the upper part of the soil (in mg pesticide /m^3 soil
ρ_b = dry bulk density of the soil (default value = 1.0 kg /dm^3)
1000 = factor to convert from kg /dm^3 to kg /m^3

Earthworms

Step 1: Exposure (3)

PEC^n_{soil} → n applications:

$$PEC^n_{soil} = PEC^1_{soil} \frac{1 - e^{-nk_s\Delta t}}{1 - e^{-k_s\Delta t}}$$

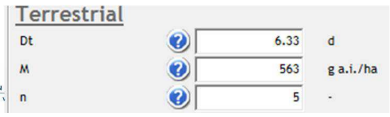
PEC^1_{soil} = concentration in the upper part of the soil from n applications (in mg pesticide /kg soil)
n = number of applications
k_s = degradation rate coefficien in soil (1/d), where k_s = ln(2)/$DT50_{soil}$
Δt = time interval between applications (d)

Earthworms

Step 1: Exposure – PRIMET

PRIMET - assessment 'Terrestrial'
Goal – get **PEC^n_{soil}**

Fill in:
–Pesticide properties → DT50soil
–Application scheme:
- dose (M)
- Δt (Dt)
- n



Earthworms

Step 2: Toxicity

- acute LC50
- chronic NOEC

Safety factors used in the EU:
- acute: 10
- chronic: 5

Earthworms

Step 2: Toxicity – PRIMET

PRIMET - assessment 'Terrestrial' → Fill in:

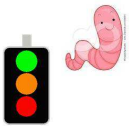
Pesticide properties →
- acute LC50
- chronic NOEC

Earthworms

Step 3: Risk assessment

a) Acute

$$\text{ETRearth-ac} = \frac{\text{PEC}^{n}_{soil}}{\text{LC50}}$$ (safety factor is 10)



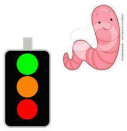
ETRearth-ac < 0.1	→ Low risk
0.1 ≤ ETRearth-ac ≤ 0.5	→ Possible risk
ETRearth-ac > 0.5	→ High risk

Earthworms

Step 3: Risk assessment

b) Chronic

$$\text{ETRearth-chr} = \frac{\text{PEC}^{n}_{soil}}{\text{NOEC}}$$ (safety factor is 5)



ETRearth-chr < 0.2	→ Low risk
0.2 ≤ ETRearth-chr ≤ 1	→ Possible risk
ETRearth-chr > 1	→ High risk

Earthworms

Step 3: Risk assessment – PRIMET

PRIMET - assessment 'Terrestrial' → Extract:

- ETR soil-acute
- ETR soil-chronic

- Mechteld shows on screen what to do
- However the PRIMET 'No risk, possible risk, high risk' classification is different (see PRIMET manual p. 31)

Earthworms

- **Step 4: Evaluation of the procedure**

5 minutes time to write down any difficulties experienced during the risk assessment and ideas for improvements

Practicum today

- **Protection goals Ethiopia**

1. Surface water as source of drinking water
2. Groundwater as source of drinking water
3. Aquatic ecosystem
4. Bees
5. Non-target arthropods
6. Earthworms
7. Birds
8. Non-target terrestrial plants

Birds

- **What?** Populations of non-target birds
- **Where?** Treated crop fields or other treated locations, i.e. no consideration of the risk at landscape level
- **How strict?** No individual mortality or reproduction effects

- Use of indicator species for different crops in the EU (mostly small, sensitive birds)
- Proposal: to use these indicator species also for the Ethiopian situation
- Is this agreed? Or are there special species to be protected?

Birds

Table 1: Relevant indicator species according to crop and crop stage

Crop	Crop stage	Indicator species	Example
Grassland	-	Small herbivorous mammal - 25 g	Vole
		Large herbivorous bird - 3000 g	Goose
Cereals	Early	Small herbivorous mammal - 25 g	Vole
		Large herbivorous bird - 3000 g	Goose
	Late	Insectivorous mammal - 10 g	Shrew
		Insectivorous bird - 10 g	Wren, tit
Leafy crops	Early / late	Medium herbivorous mammal - 3000 g	Hare
		Medium herbivorous bird - 300 g	Partridge, pigeon
Orchard / vine / hops	Early / late	Small herbivorous mammal - 25 g	Vole
		Insectivorous bird - 10 g	Wren, tit
Seed treatment	-	Granivorous mammal - 25 g	Wood mouse
		Granivorous bird - 15 g	Linnet

Birds

Step 1: Exposure (1)

Standard exposure scenarios for tier 1

ETE = (FIR / bw) * C * AV * PT * PD (mg/kg bw/d)

- ETE = estimated daily uptake of a compound (mg/kg bw/d)
- FIR = food intake rate of indicator species (kg fresh weight per day)
- Bw = bodyweight (kg)
- C = concentration of compound in fresh diet (mg/kg)
- AV = avoidance factor
- PT = fraction of diet obtained in the treated area
- PD = fraction of food type in diet

Birds

Step 1: Exposure (2)

In case of multiple applications or long-term considerations:

$C = C_0 * MAF * f_{twa}$

- CO = Initial concentration after a single application
- MAF = multiple application factor
- f_{twa} = Time weighted average factor

C_0 = RUD * actual appl. rate

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Birds

Step 1: Exposure (3)

First tier: AV, PT and PD are 1

MAF = function of number of applications, interval and DT50;
in first tier for DT50 on vegetation a default value of 10 days is used

$f_{twa} = (1-e^{-kt})/kt$ → k = ln2/DT50 and t = averaging time

Uniform approach of the first step of the risk assessment:

- use of indicator species for the different crops and crop-stage;
- MAF values applied (based on a default DT50 value of 10 days);

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Birds

Step 1: Exposure (4)

- **Acute exposure**
  - residues: 90th percentile of the initial concentration (table 4 RUD 90%);
  - special MAF-values
- **Long-term exposure**
  - mean residue values (table 7 RUD mean);
  - twa-value over 21 days (based on a default DT50-value of 10 days) → f_{twa} = 0.53

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Birds: Acute exposure estimate

Table 4: Standard scenarios for the acute exposure estimate

1	2	3	4	5	6	7
Crop	Crop stage	Indicator species	FIR / bw	Category	RUD (90 %)	MAF
Grassland	-	Small herbivorous mammal	1.15	short grass	142	Table 3
		Large herbivorous bird	0.44	short grass	142	Table 3
Cereals	Early	Small herbivorous mammal	1.15	short grass	142	Table 3
		Large herbivorous bird	0.44	short grass	142	Table 3
	Late	Insectivorous mammal	0.51	insects	14	n.a.
		Insectivorous bird	1.04	insects	14	n.a.
Leafy crops	Early / late	Medium herbivorous mammal	0.25	leafy crops	87	Table 3
		Medium herbivorous bird	0.76	leafy crops	87	Table 3
Orchard / vine / hops	Early / late	Small herbivorous mammal	1.15	short grass* I, F: IF=0.5	H: 142 I, F: 71	Table 3
		Insectivorous bird	1.04	insects	14	n.a.
Seed treatment	-	Granivorous mammal	0.19	seeds	n.a.	n.a.
		Granivorous bird	0.38	seeds	n.a.	n.a.

*) For insecticides (I) and fungicides (F) but not for herbicides (H) an interception factor of 0.5 is assumed

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Birds: long-term exposure estimate

Table 7: Standard scenarios for the long-term exposure estimate

1	2	3	4	5	6	7	8
Crop	Crop stage	Indicator species	FIR / bw	Category	RUD (mean)	f_{twa}	MAF
Grassland	-	Small herbivorous mammal	1.15	short grass	76	0.53	Table 5
		Large herbivorous bird	0.44	short grass	76	0.53	Table 5
Cereals	Early	Small herbivorous mammal	1.15	short grass	76	0.53	Table 5
		Large herbivorous bird	0.44	short grass	76	0.53	Table 5
	Late	Insectivorous mammal	0.51	insects	5.1	n.a.	n.a.
		Insectivorous bird	1.04	insects	5.1	n.a.	n.a.
Leafy crops	Early / late	Medium herbivorous mammal	0.25	leafy crops	40	0.53	Table 5
		Medium herbivorous bird	0.76	leafy crops	40	0.53	Table 5
Orchard / vine / hops	Early / late	Small herbivorous mammal	1.15	short grass I, F: IF=0.5	H: 76 I, F: 38	0.53	Table 5
		Insectivorous bird	1.04	insects	5.1	n.a.	n.a.
Seed treatment	-	Granivorous mammal	0.19	seeds	n.a.	n.a.	n.a.
		Granivorous bird	0.38	seeds	n.a.	n.a.	n.a.

*) For insecticides (I) and fungicides (F) but not for herbicides (H) an interception factor of 0.5 is assumed

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Birds

Step 2: Toxicity (2)

- Acute: LD50 value from acute study
- Long-term: NOEC from reproduction study

Safety factors: same as in the EU:
- Acute: 10
- Long-term: 5

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Birds

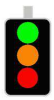
Step 3: Risk assessment (1)

1. Sprays
2. Seeds/granules

1. Sprays

$ETRac = \frac{ETE}{LD50}$ $ETRchr = \frac{ETE}{NOEC}$

Acute	Long-term	
ETRac < 0.1	ETRlt < 0.2	→Low risk
0.1 ≤ ETRac ≤ 0.5	0.2 ≤ ETRlt ≤ 2	→Risk possible
ETRac > 0.5	ETRlt > 2	→ High risk



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Birds

Step 3: Risk assessment (2)

2. Seeds/granules

One seed/granule criterion: if consumption of one seed/granule is already enough to exceed the LD50/10, then there is a very high risk

Specific calculation method not yet worked out for Ethiopia

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Birds

- **Step 4: Evaluation of the procedure**

5 minutes time to write down any difficulties experienced during the risk assessment and ideas for improvements

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Practicum today

- **Protection goals Ethiopia**

1. Surface water as source of drinking water
2. Groundwater as source of drinking water
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Non-target terrestrial plants

A healthy terrestrial plant ecosystem is very important for all kinds of insects. These insects are important for IPM purposes and are also important as food for birds.

What? Populations of non-target terrestrial plants off-field

Where? Along agricultural fields

How strict? No long-term effects on populations of non-target terrestrial plants off-field.

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Non-target terrestrial plants

Step 1: Exposure

PEC (off-field): single dose rate (g as/ha) * MAF * drift factor

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Non-target terrestrial plants

Step 2: Toxicity

- Lowest ER50 from test with several plant species
- Safety factor in the EU: 5

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Non-target terrestrial plants

Step 3: Risk assessment

$$ETRntp = \frac{PEC\ (off\text{-}field)}{ER50min}$$

ETRntp < 0.2	→ low risk
0.2 ≤ ETRntp ≤ 2	→ possible risk
ETRntp > 2	→ high risk

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Non-target terrestrial plants

- **Step 4: Evaluation of the procedure**

5 minutes time to write down any difficulties experienced during the risk assessment and ideas for improvements

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- Thank you for your attention!!!

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