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

In the framework of PRRP- Ethiopia

Workshop:
Proposed evaluation tested with pilot compounds
(Human Health and Environment)

Names : **Marloes Busschers, Caroline van der Schoor, Peter van Vliet (Ctgb)**

Date: **27-31 May 2013**

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 methods for human health and the environment were discussed 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. lamba-cyhalothrin for use on cotton , maize, flowers and cabbage
6. Metalaxyl/mancozeb for use on potato, onion and tomato

2. Objectives

The mission has the following goals and objectives.

Goal:

- To finalise into detail the proposed evaluation procedure for Ethiopia on risks concerning human health and environment, including the relevant exposure models and other software.
- To let the dossier evaluation team of the APHRD and the Pesticide Advisory Board gain experience with the agreed evaluation procedure
- To finalise the relevant chapters in the evaluation manual.

Objectives:
Human health (occupational health)

1. Finalise evaluation procedure for occupational health risk assessment and test it for a number of pilot compounds
2. Finalise methodology and exposure assessment tools for occupational health
3. Exercise setting and quality assessment of the toxicity data of the pilot compounds needed to perform the human health risk assessment

4. Finalise nationally applicable criteria for the acceptability of pesticides in Ethiopia (including human toxicity, labeling and packaging)
5. Describe agreed procedure of 1-4 into detail in the relevant chapter of the evaluation manual

MRLs setting and human health (consumer health)

1. Finalise evaluation procedure for consumer health risks and test it for a number of pilot compounds (temporarily based upon the WHO Cluster A diet)
2. Development of procedures in cooperation with relevant Ethiopian stakeholders for MRL setting in Ethiopia, considering consumers health and export crops. Which existing MRLs (Codex MRLs) can be used and which MRLs need to be developed, e.g. for export crops that do not have internationally set MRLs). In case local MRLs need to be developed it is tried to link up with the experiments that will already be executed for Efficacy purposes for approximately 20 Ethiopian crop-pests combinations.
3. Exercise MRL calculations and quality assessment for a number of pilot compounds as proposed in the June 2012 workshop, considering their GAP and relevant crops
4. Evaluation of the MRLs with respect to consumer health (using temporarily the WHO Cluster A diet) as well as for export of crops (compliance with MRLs of importing countries ?)
5. Assistance of the EHNRI in the execution of the Ethiopian food regime study which is intended to replace the WHO Cluster A diet used up to now in the consumer risk assessment
6. Describe agreed procedure of 1-4 into detail in the relevant chapter of the evaluation manual

Environmental risk assessment

1. Presentation of the agreed evaluation procedure, incl risk classification for the various protection goals and tests for a number of pilot compounds and protection goals
   (*act 1.4 and act. 5.2 start)*
2. Presentation and finalization of the exposure assessment procedure for groundwater and surface water as developed in the November 2012 workshop and February 2013 mission *(act.1.3)*
3. Describe agreed procedure of 1-2 into detail in the relevant chapter of the evaluation manual *(act 5.1 cont.)*.

3. Results of activities

Human health (occupational health)

After some introduction presentations, the occupational health part of the workshop started with an introduction into human health (annex 3) with an overview of the issues regarding hazard and risk assessment. The next

presentation (annex 3) went into much more detail on the hazard assessment, and it was followed by the exercises and examples in which it was explained how to deal with it in practice. Remaining issues regarding the data requirements on one or two species and on the classification and labelling were discussed and agreed upon.
Thereafter a more detailed explanation on the use of the models in the exposure assessment was presented (annex 3), including examples and exercises with several of the pilot compounds. Several issues such as the setting of Ethiopians defaults in the chosen models, removing modules from the models, that are not relevant to Ethiopia, and the use of Personal Protective Equipment (PPE) were discussed and agreed upon. The final conclusion with regard to occupation health are presented in Annex 4.

MRLs setting and human health (consumer health)
An introductory presentation was given for the assessment of residues of plant protection products and the principles maximum residue levels of pesticides and consumer risk assessment (annex 5). Following the introduction, a presentation was given on the evaluation of studies in the residue dossier with regard to the validity and quality of studies, crop grouping and methods of analysis (annex 5). In this presentation, a first example and proposition was made regarding crop-to-crop extrapolation for residues. These extrapolation possibilities were amended and agreed on during the discussion at the end of the consumer health workshop.
Due to computer problems, the next items on the program were switched, and consumer risk assessment was considered prior to MRL setting. Unfortunately, it became clear during the workshop, that consumer intake data, specific for the Ethiopian people, will not be ready in time for the finalization of PRIMET and WP B2.1, hence, it was decided that WHO models 2006 will be used for consumer risk assessment. As the commodity teff is not present in the model, but is an important part of the Ethiopian diet, it was decided to extrapolate from a commodity in the WHO diet to teff; a commodity is to be selected.
The model for acute (NESTI) and chronic (TMDI) assessment was exercised by the participants of the workshop, preceded by a presentation of dietary risk assessment (annex 5). The final presentation was given on MRLs and compliance with MRLs of importing countries (annex 5) and MRL calculation, and was finished with an exercise to calculate MRLs using the OECD MRL calculator.
To finish the consumer health workshop, outstanding issues and questions were discussed, such as the minimum number of supervised residue trials required.

Environmental risk assessment
First, a general presentation was given regarding the tool/model PRIMET, followed by a summary of the surface water and groundwater scenario development for Ethiopia. The next presentation was an introduction to environmental risk assessment, followed by a presentation dealing with the selected protection goals and the registration criteria and risk classification criteria for each protection goal. All these presentations are presented in Annex 6.

After all these presentations exercises with some example substances were performed by the participants of the workshop for each protection goal, followed by an evaluation of these exercises. Also it was discussed what to do with e.g. insecticides and the risk to bees and non-target arthropods. A lot of these substances will have a high risk for these protection goals. Risk mitigation measures are difficult to apply. This is a subject for further guidance. Also it was considered necessary by the participants to do an impact assessment, if possible, for a number of active ingredients to get an idea how many of the substances will have a high risk, possible risk or low risk and for which protection goals. This depends, amongst others, on prolongation of the project in 2014.

On the final day small teams of Ctgb and APHRD experts discussed the final details of the Evaluation Manual.

4. Deliverables

According to the work plan of work package B2.1 the following deliverables were delivered as result of the mission and the activities as mentioned under activity 1, 3 and 5 for human health and environment:

- Workshop participants gained further insight in existing international methods and tools to estimate exposure, hazards and risks of pesticides for human health and environment, and gained insight in existing international criteria (act. 1)
- Agreement on methodology to evaluate human health and environmental exposure (act. 1).
- Final details on the proposed new data requirements were discussed and agreed upon (act. 2).
- The nationally applicable criteria for the acceptability of pesticides in Ethiopia has been discussed. The criteria include labeling and packaging among others (act. 3)
- The evaluation procedure for decision making (registration criteria and risk classification criteria) was presented and accepted (environment).
- The surface water and groundwater scenario development for Ethiopia was presented.
- The participants gained insight in the assessment f the quality of data for registration. Detailed guidance is provided in the evaluation manual (act. 4).
- The final details of the evaluation manual for APHRD have been discussed (act. 5.1)
- A general training on the models was given, however, the final PRIMET model is not yet available (act. 5)
- Workshop participants gained insight in existing international methods and tools to estimate consumer exposure and calculate MRLs using the OECD calculator (act. 1.3.a and act. 6.1.b)
- A start has been made to the development of nationally applicable crop-to-crop extrapolation and the number of supervised residue trials required for authorisation (act. 6.1.a and act. 6.1b)

– the draft evaluation manual was discussed with AHPRD staff and was extended with the insights gained during the workshop in May (act 5.1 and act. 8.3.)

5. Organizations and persons met during mission

Eight participants of Animal and Plant Health Regulatory Directorate (APHRD), and 1 participant each from the Federal Environmental Protection Agency, the Ethiopian Institute of Agricultural Research (also a member of the Pesticide Advisory Board) and the Ethiopian Health and Nutrition Research Institute 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.

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

Name	Organisation	Position	E-mail address
Ato Ashenafi Bekele	Ministry of Agriculture/APHRD	Senior expert	ashenafibekele19@gmail.com
Dr. Ayenalem Abebe	Federal Environmental Protection Authority	Lead Expert	dbaynalem@gmail.com
Dr.Dereje Gorfu	Ethiopian Institute of Agricultural Research	Senior Researcher	dgorfu@gmail.com
Ato Meseret W/Yohannes	Ethiopian Health and Nutrition Research Institute	Assistant Researcher	wymesi@yahoo.com
W/o Serkie Mekonen	Ministry of Agriculture /APHRD	Expert	serkiemekonen@gmail.com
Dr Haimanot Abebe	Ministry of Agriculture /APHRD	Expert	abebehaimanot@ymail.com
W/o Hiwot Lemma	Ministry of Agriculture /APHRD	Senior expert	Hiwot.lemma@ymail.com
Ato Alemayehu Woldeamanuel	Ministry of Agriculture /APHRD	PRRP-Ethiopia, Coordinator	Alemaworke1958@gmail.com
Ato Shimelis Hassen	Ministry of Agriculture /APHRD	Coordinator, Africa stockpiles programme project	shimelishassen@yahoocom
Ato Yismaike Yitagesu	Ministry of Agriculture /APHRD	Expert	yismayikey@yahoo.com
Ato Yeraswork Yilma	Ministry of Agriculture /APHRD	Expert	yersget@yahoo.com
Ms Caroline van der Schoor	Ctgb	Expert	caroline.vdschoor@ctgb.nl
Ato Peter van Vliet	Ctgb	Expert	peter.vvliet@ctgb.nl
Ms Marloes Busschers	Ctgb	Expert	marloes.Buschers@ctgb.nl

6. Unsolved issues

Human health (occupational health)
No specific unsolved issues

MRLs setting and human health (consumer health)

1. An Ethiopian consumer intake model is currently not available. Hence, no representative consumer exposure can be performed for the Ethiopian population. The most applicable model is the WHO model cluster diet A. Teff is missing from the model as a commodity. A commodity currently present in the model will be slected to extrapolate to teff, when criteria are available, being the estimated chronic and acute intake per day

Environmental risk assessment

1. A clear picture of the consequences of the chosen registration criteria and risk classification criteria is necessary (impact assessment), if possible. This depends, amongst others, on prolongation of the project in 2014.
2. A further adaptation of the PRIMET tool to the Ethiopian situation.
3. Further guidance on what to do with substances falling in the categories red and orange.

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.
2. Capacity building of the APHRD office in Addis Ababa. 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.
3. Using the training in practice. Currently, the APHRD staff does not apply the information from the workshops in practice. By using the information in practice, APHRD staff will gain experience and skill. Hence, using the information from the workshop should start as soon as possible.

7. Actions to be taken / recommendations

General

1. Capacity building of the APHRD office in Addis Ababa should be started, in order to have the necessary capacaity within reasonable time.
2. The current APHRD staff should preferably be using the training in practice as soon as possible to gain experience.
3. It is very important to organize support for the APHRD during and after their first evaluations, to help them with upcoming problems.

Human health (occupational health)

1. No specific actions needed.

MRLs setting and human health (consumer health)

2. An Ethiopian consumer intake model is currently not available. Hence, no representative consumer exposure can be performed for the Ethiopian population. The most applicable model is the WHO model cluster diet A. Teff is missing from the model as a commodity. A commodity currently present in the model will be slected to extrapolate to teff, when criteria are available, being the estimated chronic and acute intake per day

Environmental risk assessment

2. Further training on environmental risk assessment for Ethiopian staff.
3. Making an analysis of the consequences of the chosen draft registration and risk classification criteria on the total package of available pesticides in Ethiopia, if possible (depending on prolongation of the project in 2014). Depending on the results of the analysis it could be necessary to adjust some of the criteria.

Annex 1: Detailed Program (per day)

Workshop: proposed evaluation tested with pilot compounds (Human health and Environment) for the Pesticide Advisory Board, dossier evaluation team of APHRD and other relevant institutions, 27-31 May 2013, Debre Zeyit, Ethiopia

Date	Time	Activity	Responsible person
Pesticide Risk Reduction Programme –Ethiopia, Work package B2.1			
Monday 27 May		GENERAL	
10 min	9.00-9.10	Welcome, introduction to each other	Alemayehu
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	Peter
		START SUBJECT Human Health (occupational)	
60 min	9.30-10.30	Introduction to hazard and risk assessment	Marloes
30 min	10.30-11.00	COFFEE BREAK	
15 min	11.00-11.15	Hazard assessment	Marloes
75 min	11.15-12.30	Practical exercise with 6 substances (hazard)	Marloes
60 min	12.30-13.30	LUNCH	
45 min	13.30-14.15	Discussion on hazard assessment (data requirements and Evaluation Manual)	Marloes
15 min	14.15-14.30	Introduction on occupational risk assessment (operator, worker)	Marloes
60 min	14.30-15.30	Practical exercise with 6 substances (risk)	Marloes
30 min	15.30-16.00	TEA BREAK	
90 min	16.00-17.30	Practical exercise with 6 substances (risk)	Marloes
		END day 1	

Tuesday 28 May		**DERG Downfall Day 1991**	
Tuesday 28 May		**CONTINUATION SUBJECT Human Health (occupational)**	
120 min	8.30-10.30	Practical exercise with 6 substances (risk), summary	Marloes
30 min	10.30-11.00	COFFEE BREAK	
90 min	11.00-12.30	Discussion on risk assessment, methodology and criteria	Marloes
60 min	12.30-13.30	LUNCH	
		START SUBJECT Human health (consumers) + MRLs	
60 min	13.30-14.30	Introduction to residues and consumer risk assessment	Caroline
30	14:30-15:00	Dossier evaluation	Caroline
30	15:00-15:30	Practical exercise with 6 substances (dossier evaluation)	Caroline
30 min	15.30-16.00	TEA BREAK	Caroline
	16:00-16:45	Practical exercise with 6 substances (dossier evaluation)	Caroline
	16:45-17:00	Introduction on practical exercise MRL calculation with 6 substances	Caroline
	17:00-17:30	Practical exercise MRL calculation with 6 substances	Caroline
		END day 2	
Wednesday 29 May		**CONTINUATION SUBJECT Human health (consumers) + MRLs**	
	8.30-10:00	Practical exercise MRL calculation with 6 substances	Caroline
	10.00-10:30	Discussion on residues and consumer risk assessment (data requirements and Evaluation Manual)	Caroline
30 min	10.30-11.00	COFFEE BREAK	
	11:00-11:30	Introduction on consumer intake calculations	
	11:30-12:00	Practical exercise with 6 substances (consumer risk assessment)	Caroline
60 min	12.00-13.30	LUNCH	
	13:30-15:30	Practical exercise with 6 substances (consumer risk assessment)	Caroline
30 min	15.30-16.00	TEA BREAK	
	16:00-16:30	Finish up practical exercise	

	16.30-17.30	Discussion on risk assessment, methodology and criteria	Caroline
		End day 3	
Thursday 30 May		**START SUBJECT Environment**	
90 min	8.30 – 10.00	Presentations on the proposed evaluation procedure and the risk classification criteria for the different protection goals	Peter
30 min	10,00 – 10.30	Presentation on PRIMET	
30 min	10.30 – 11.00	COFFEE BREAK	
90 min	11.00 – 12.30	Practical exercise with 6 substances (risk) with respect to the different protection goals	Peter
60 min	12.30-13.30	LUNCH	
120 min	13.30 -15.30	Continuation practical exercise with 6 substances (risk) with respect to the different protection goals	Peter
30 min	15.30-16.00	TEA BREAK	
90 min	16.00 – 17.30	Continuation practical exercise with 6 substances (risk) with respect to the different protection goals	Peter
		END day 4	
Friday 31 May		LAST TRAINING ITEMS + MANUAL WRITING (3 parallel groups)	
		Manual writing Human Health (MRL+consumer)	Caroline + ? APHRD
		Manual writing Human Health (Tox+occupational)	Marloes + ? APHRD
		Manual writing Environment	Peter + ? APHRD

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														

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		
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	F	Maize stalk borer	EC	50g/l	Spray	At knee	1	-	Information	0.02	-	

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		
		5%EC						height of the crop When pest appears			not found			
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	Spray	>>	Not given		500	1.8		

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		
						Mancozeb 640g/kg								
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	2 or more	14 days	400-500	1.7-2.04	14	

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		
								irrigation						
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 blight,early blight	WG	Mtalaxyl – M 40g/kg Mancozb 640g/Kg		First application 5-7days after transplanting or when diseases are anticipated followed by further applications at 10-14 days. Repeat application after each heavy rain	2 or more	10-14 days	500-1000	1.7-2.38	7	

Annex 3. Presentations concerning occupational health risk assessment, as given in the 27-30 May 2013 workshops in Debre Zeyit

Introduction
Occupational health

Marloes Busschers, MSc

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

27-31 May 2013

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Hazard x Exposure = Risk

This means that the risk to human health from pesticide exposure depends on both the hazard (toxicity of the pesticide) and the likelihood of people coming into contact with it.

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Hazard x Exposure = Risk

Hazard: reference values
Exposure: model calculations

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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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Dossier active substance

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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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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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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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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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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, incl. 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)

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Input data needed in the models

GAP: Application technique, application rate, water volume

Dermal absorption

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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Workshops April / Dec 2012

- Results:
- Method for hazard assessment
- Protection goals
- Models
- Unsolves issues
- Draft manual
- Revision of data requirements including guideline

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Method hazard assessment

Quality assessment of study reports is essential and should be practiced in Ethiopia.

- Studies performed according to international protocols (OECD, EU, JMPR)
- Studies performed under GLP
- Man power capacity building on quality assessment
- Awareness creation of stakeholders
- No time/man power yet for detailed evaluations per study.

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Method hazard assessment

Revision of data requirements:
- Dossier should contain full study reports (not only summary)
- Applicant to indicate on application form:
  - According to which international protocol
  - GLP status
  - Result
  - Reference values
  - Dermal absorption concentrate and spray dilution

- Check reference values indicated by applicant with internationally available reference values & check dossier for more serious effects

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Protection Goals

Which groups of people should be considered? In decreasing order:

1st.Operators
  a. Small scale / Field
  b. Large scale / Field
  c. Green house / Covered
  d. Aircraft /Field
2nd.Workers

3rd.Bystanders / Flag man
4th.Residents

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Which models to use

- Adopt user friendly models from other countries

- Consider local defaults

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Which models to use

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Which models to use

Operators	
a. Small scale/Field:	UK POEM + German model
b. Large scale/Field:	UK POEM + German model
c. Green house/Covered:	NL Greenhouse model
d. Aircraft /Field:	no model yet for Ethiopia
Workers:	EUROPOEM II
Bystanders / Flag man:	no model yet for Ethiopia
Residents:	no model yet for Ethiopia

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Dermal Absorption

% dermal absorption is parameter in all models
- Concentrate
- Spray dilution

Is formulation specific.

Agreement to use the data provided by applicant as such, without further evaluation.

Advantage
- It saves time

Disadvantage
-May provide unreliable or poor quality data.

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Unsolved issues

- Data requirements: 1 or 2 species
- Use of PPE / RPE
- Classification and labelling
- Criteria for authorisation

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Programme occupational health 27-28 May 2013

- Hazard assessment and practicals:
  - Data requirements + guideline
  - Checking protocol + GLP
  - Reference doses
- Exposure/risk assessment and practicals:
  - Model calculations
  - Assumptions in model
  - Relevance for Ethiopia
  - Open issues
- Discussion on methodology, open issues, criteria
- Final conclusions and agreements

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Data requirements and reference values

Marloes Busschers, MSc

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

marloes.busschers@ctgb.nl

27-31 May 2013

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Data requirements for toxicology

Requirement		Remark
a. Reference values	ADI (mg/kg bw/d)	
	ARfD (mg/kg bw)	e.g. Guidance for the setting of an Acute Reference Dose (ARfD)[3]
	AOEL (mg/kg bw/d)	e.g. EU Guidance for the setting and application of Acceptable Operator Exposure Levels (AOELs)[4]
b. Acute oral toxicity (rat)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline
	GLP: yes/no[2]	Indicate whether study was performed according to GLP
	LD50 (mg/kg bw)	Rat is the preferred species
c. Acute dermal toxicity (rat)	According to international guideline: yes/no Indicate guideline[1]	Indicate whether study was performed according to international guidelines and indicate which guideline
	GLP: yes/no[2]	Indicate whether study was performed according to GLP
	LD50 (mg/kg bw)	Rat is the preferred species

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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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Data requirements active ingredients

- For Ethiopia, the data requirements for active ingredient are indicated in the active ingredient index section of the application form. There is a guideline on how to fill in this application form.
- The applicant has to provide the full study reports and a summary.

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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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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
- lambdacyhalothrin for use on cotton and maize
- Metalaxyl/mancozeb for use on potato, onion and tomato

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Practical

HAZARD ASSESSMENT

1. Quality check of submitted application forms
   - all data requirements fulfilled?
   - standard test protocol used?
   - GLP?
   - Proposal for reference values and dermal absorption?
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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Quality check
GLP Good Laboratory Practice

Practical check:

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

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Quality check
Standard test protocol

Validated test guidelines for study conduct

For example:

- US: EPA harmonized test guidelines
  http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm
- 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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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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Exposure and risk

Marloes Busschers, MSc

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

27-31 May 2013

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Operators	
Small scale - field	UK POEM + German model
Large scale - field	UK POEM + German model
Large scale - greenhouse	NL greenhouse model
Aircraft - field	No model for Ethiopia yet
Workers	
Field / greenhouse	EUROPOEM II
Bystanders/flag men	No model for Ethiopia yet
Residents	No model for Ethiopia yet

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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

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Operator field, German model

Input parameters

- Scenario: tractor field crop (=downwards); tractor high crop, hand-held high crop
- Type of preparation (liquid, WG, WP)
- Application rate (kg a.s./ha)
- AOEL (mg/kg bw/d)
- % dermal absorption for m/l (=concentrate)
- % dermal absorption for appl. (=spray dilution)
- Type of PPE

Defaults:

- Inhalation absorption: 100%
- Area treated (20 ha tractor downward, 8 ha tractor upward, 1 ha hand-held)

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Operator field, UK POEM

Input parameters

- Type of preparation (liquid, solid)
- Scenario: tractor boom sprayer (=downwards); tractor air-assisted (=upwards), hand-held high crop
- Concentration a.s. in preparation
- % dermal absorption from product (=concentrate)
- % dermal absorptionfrom spray (=spray dilution)
- Container size
- Type of PPE
- Dose (kg or L formulation / ha)
- Application volume (L water/ha)

Defaults:

- Inhalation absorption: 100%
- Duration of spraying: 6 hours

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Worker, EUROPOEM II

Field and greenhouse

Input parameters

- Application rate (kg or L a.s./ha)
- Duration of working day
- Transfer coefficient
- % dermal absorption (=highest value, usually spray dilution)
- Type of PPE
- AOEL (mg/kg bw/d)

Defaults:

- Non relevant

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Practical

EXPOSURE + RISK ASSESSMENT

1. Exposure: later PRIMET, now excell sheets
2. Risk assessment for 6 substances
3. Discuss relevance of assumptions in models
4. Discuss relevance of inputs for PRIMET
5. PPE / RPE
6. Criteria for authorisation
7. Consequences for authorisation of pesticides

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Operators		PPE possible?
Small scale - field	UK POEM + German model	no
Large scale - field	UK POEM + German model	yes
Large scale - greenhouse	NL greenhouse model	yes
Aircraft - field	No model for Ethiopia yet	-
Workers		
Field / greenhouse	EUROPOEM II	Small: no Large: yes??
Bystanders/flag men	No model for Ethiopia yet	-
Residents	No model for Ethiopia yet	-

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Operator indoor, NL greenhouse

1 scenario:
Hand-held up- and downward spraying

Input parameters

- Application rate (kg or L a.s./ha)
- % dermal absorption (=highest value, usually spray dilution)
- Type of PPE
- AOEL (mg/kg bw/d)

Defaults:

- Inhalation absorption: 100%
- Area treated: 1 ha

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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
- lambdacyhalothrin for use on cotton and maize
- Metalaxyl/mancozeb for use on potato, onion and tomato

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Practical

Discussion points

- 2 tables in document "Expsoure assessment" (PPE, scenarios)
- Document "Points to be discussed – exposure"

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Crop	**Field**[1]		**Greenhouse**
	Tractor	**Hand**	
Tomato (=veg.fruiting)	?	Down/up?	Yes
Onion (=veg.bulb)	Down	Down	Yes
Cabbage (=veg.leafy)	Down	Down	Yes?
Potato	Down	Down	No
Teff	Down/up?	Down/up?	No
Wheat	Down/up?	Down/up?	No
Maize	Down/up?	Down/up?	No
Barley	Down/up?	Down/up?	No
Faba bean (=pulses)	Down/up?	Down/up?	?
Sweet potato	Down	Down	?
Cotton	Down/up?	Down/up?	?
Mango	Up	Up	?
Sugarcane	Down/up?	Down/up?	No
Banana	Up	Up	?
Citrus (lemon)	Up	Up	?
Coffee	Up	Up	?
Pome/stone fruit (represented by.....)	Up	Up	?
OTHERS (Still to add ??)			
Chat (chata edulis) (include ??)	?	?	?
Flowers (greenhouses)	Down/up?	Down/up?	yes

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Annex 4. Conclusions concerning occupational health risk assessment

Hazard

1. 1-2 species were discussed: text in manual is acceptable
2. application form completeness check and quality check: guidance in Manual
3. International reference values: JMPR preferred. Guidance in Manual
4. C&L according to WHO

Exposure

1. Protection goals Ethiopia
   Operator – small scale
   Operator – large scale
   Operator – green house
   Worker – field and greenhouse

2. Models: UK POEM, German model, NL greenhouse, EUROPOEM II
3. Specific Ethiopian adaption:
   no PPE small scale, but advised to use them
   tractor only for certain crops
   aircraft to be incorporated at a later stage
   PPE reduction values
   Working hours
   Body weight
   No PPE worker

4. Home and garden use, to be incorporated at a later stage when bystanders will be included.

Note: provide link to German model

Risk assessment

Risk management

Evaluation Manual

Glossary
Abbreviations list
Official GLP statement/international GLP list: GLP person at Ctgb

Equivalence check? Harold

Relevance of the different studies in the data requirements

Molecular weight is greater than 500 and logPow in FCE part?

Annex 5. Presentations concerning pesticide residues and dietary risk assessment, as given in the 27-31 May 2013 workshops in Debre Zeyit.

Residues of plant protection products in food assessment and MRLs

PRRP workshop, May 2013

Caroline van der Schoor
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
caroline.vdschoor@ctgb.nl

May 27th-31st, 2013

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Contents

- Programme
- Definitions
- Metabolism
- Residue definition
- Residue trial
- Extrapolation
- Relation with GAP
- MRLs
- Consumer Risk Assessment

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Programme

- Presentation: Residue assessment and and risk assessment
- Practical: Dossier evaluation
- MRL calculation and practical
- Discussion Evaluation Manual
- Consumer risk assessment
- Discussion and wrap up

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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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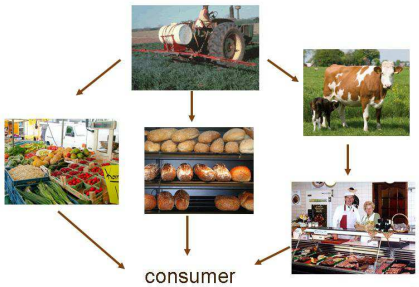
Consumer exposure from the farm to the fork



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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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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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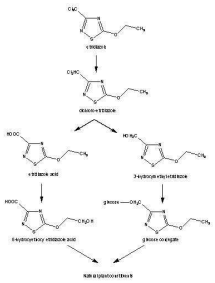
Example of metabolic pathway



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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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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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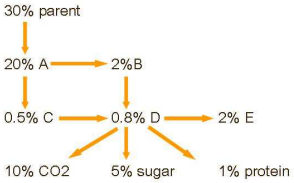
Example of metabolic profile



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

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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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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
- Discussion point: how many trials for Ethiopian authorisation?

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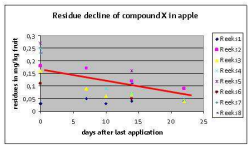
Establishing MRLs (plant)

(Maximum Residue Level in mg/kg)

Residue trials:

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



EU 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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Pesticide label

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

- Active substance
- Crop
- Way of application (foliar, soil, post-harvest, seed)
- 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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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

Discuss possible extrapolations for crops grown in Ethiopia

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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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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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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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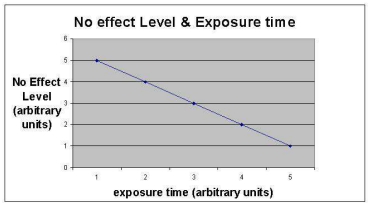
General principle of toxicology



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 Occupational Human Health of Marloes Busschers, May 27th-29th]

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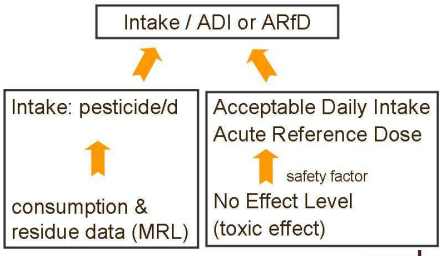
Consumer risk assessment general



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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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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 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: WHO IESTI model

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Consumer risk assessment models

- WHO IEDI: http://www.who.int/foodsafety/chem/IEDI_calculation14_FAO1.xlt
- WHO IESTI: http://www.who.int/foodsafety/chem/acute_data/en/index1.html

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Thank you for your attention!

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Dossier Evaluation

PRRP workshop, May 2013

Caroline van der Schoor
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
caroline.vdschoor@ctgb.nl

May 27th-31st, 2013

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Dossier Evaluation

- Studies performed in representative crops
- Studies performed in accordance with label
- Quality of studies
  - According to guidelines
  - GLP

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Representative crops

- What are considered representative crops
  - Metabolism studies
  - Supervised residue trials
  - Storage stability

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Representative crops: metabolism

Code	Category	Crops
F	Fruit	Citrus fruit Tree nuts Pome fruit Stone fruit Berries Small fruit Grapes Fruiting vegetables Banana Persimmon
R	Root crops	Root and tuber vegetables Bulb vegetables
L	Leafy crops	Brassica vegetables Leaf vegetables Stem vegetables Hops Tobacco
C/G	Cereal/Grass crops	Cereals Grass and forage crops
P/O	Pulses and oilseeds	Legumen vegetables Pulses Oilseeds Peanuts Legume fodder crops Cocoa beans Coffee beans
-	Miscellaneous	In general, crops not listed above or not covered by a grouping are considered as miscellaneous and will not normally be accepted as one of the three crop groups. However, if it is proposed to use such a crop to cover one of the three crop groups due to its national/regional importance, applicants are strongly urged to consult with regulatory authorities.

OECD 501

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Representative crops: field trials

- Vegetables:
  - Tomato
  - Pepper
  - Onion
  - Cabbage
  - Squash
  - Sweet potato/taro/yam
  - potato
- Cereals:
  - Sorghum
  - Millet
  - Teff
  - Wheat
  - Barley
  - Maize/corn
- Coffee
- Chat
- Oilseeds:
  - Niger seed
  - Flax seed
  - Sesame
  - Castor bean
  - Rapeseed
  - Peanut
  - Safflower
  - Sunflower
- Fruits:
  - Mango
  - Banana
  - Citrus

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Supervised residue trials

- According to cGAP
- Sufficient number of trials
- Representative of Ethiopian climate
- According to international guidelines
  - E.g. OECD 509

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Extrapolations

- Vegetables:
  - Tomato → eggplant
  - Pepper → chilli pepper
  - Onion
  - Cabbage
  - Squash → melon
  - Potato → Sweet potato/taro/yam
- Cereals:
  - Teff → Wheat
  - Barley
  - Maize/corn → Millet, Sorghum, teff
- Coffee
- Chat
- Oilseeds:
  - Rapeseed + Sesame → Niger seed, Flax seed, Safflower, Sunflower, Cotton seed
  - Peanut → Castor bean
- Fruits:
  - Mango
  - Banana
  - Citrus:
    - lemons → other citrus

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Storage stability (1)

- OECD 506
- Storage duration of samples from studies should be max. 30 days in frozen storage. Longer duration of storage should be covered by studies to rule out degradation during storage
- Crops consist of different matrices and can be classified in several groups:
  - High oil
  - High water
  - High starch
  - High acid
  - High protein
  - Special matrices
  - Animal commodities: muscle, liver, egg, milk

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Storage stability (2)

Commodity Categories	Commodities included in this category	Typical representative commodities
High water content	Pome fruit Stone fruit Bulb vegetables Fruiting vegetables (cucurbits Brassica vegetables Leafy vegetables and fresh herbs Stem and stalk vegetables Forage fodder crops Fresh legume vegetables Leaves of root and tuber vegetables Sugar cane Fresh grass tea Pitaya	Apples, pears Apricots, cherries, peaches Bulb onions Tomatoes, peppers, cucumber, melon Cauliflower, Brussels sprout, cabbage Lettuce, spinach Leek, celery, asparagus Wheat and barley forage, silkilo, Fresh peas with pods, petit pois, mange tout, broad beans, runner bean, dwarf French bean Sugar beet and fodder beet tops
High oil content	Tree nuts Oilseeds Olives Avocados Hops Cacao beans Coffee beans Spices	Walnut, hazelnut, chestnut Oilseed rape, sunflower, cotton, soybean, peanut
High protein content	Dry legume vegetables/Pulses	Field bean, dried broad bean, dried haricot bean (yellow, white/navy, brown, speckled)
High starch content	Cereal grain Roots of root and tuber vegetables Starchy root crops	Wheat, rye, barley and oat grain Sugar beet and fodder beet roots, carrot Potato, sweet potato
High acid content	Citrus fruit Berries Currants Grapes Kiwifruit Pineapple Rhubarb	Lemon, mandarin, tangerine, orange Strawberry, blueberry, raspberry Black currant, red currant, white currant

IMPORTANT NOTE: The above list of commodities is not a comprehensive list of commodities/ matrices and other commodities may be used. Applicants should consult regulatory authorities for advice on the use of other commodities.

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Methods of analysis

- Sufficiently validated
- Recovery:
  - 70-110%
  - RSD ≤20%
  - n = 5 (for validation, for concurrent recovery 1 or more is also sufficient)

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MRLs

PRRP workshop, May 2013

Caroline van der Schoor
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
caroline.vdschoor@ctgb.nl

May 27th-31st, 2013

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Practical

- Calculating an MRL
  OECD MRL calculator

Discuss results

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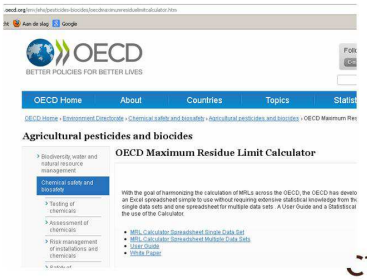
OECD MRL calculator

- http://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm



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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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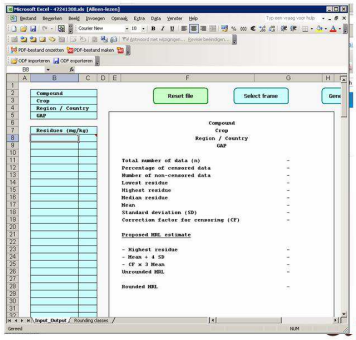
MRL calculator (1)



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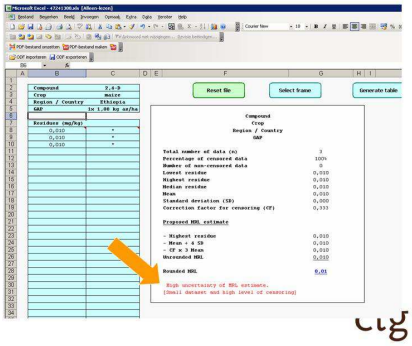
MRL calculator (2)



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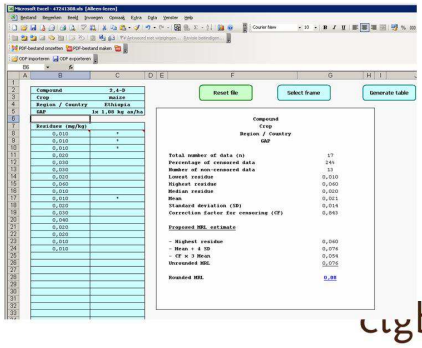
MRL calculator (3)



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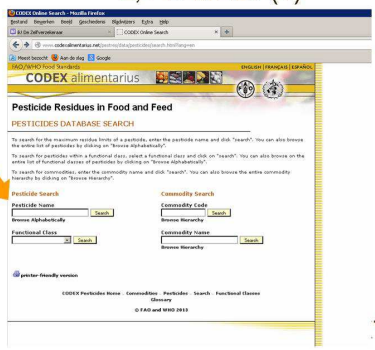
2,4-D MRLs (1)



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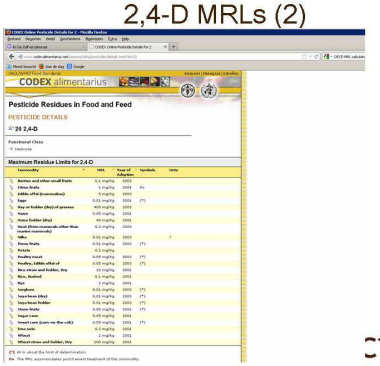
2,4-D MRLs (2)



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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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2,4-D MRLs (3)

- Calculated MRL was 0.08 mg/kg.
- CODEX MRL (CXL) is 2 mg/kg
- The use is covered by CXL.

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2,4-D ADI and ARfD

- ADI:
  - EU: 0.05 mg/kg bw/d
  - JMPR: 0.01 mg/kg bw/d
- ARfD: not necessary

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Dietary risk assessment

PRRP workshop, May 2013

Caroline van der Schoor
Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
caroline.vdschoor@ctgb.nl

May 27th-May 31st, 2013

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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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Dietary risk assessment

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

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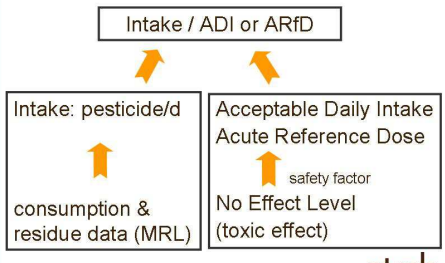
Consumer risk assessment general



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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 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

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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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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Consumer risk assessment - chronic, tiered approach

- Chronic intake (TMDI) $\leq$ 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

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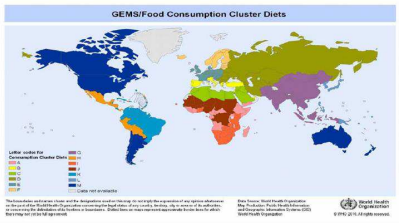
13 WHO-GEMS diets: Ethiopia = A (or C or J or H)?



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Example of WHO GEMS

CODE	GEMS	NOTES	A	B	C	D	E	F	G	H	I	J
	CEREALS											
GC 640	BARLEY	(1)	40,6	16,0	33,9	13,2	49,6	30,1	5,9	20,5	5,9	2,5
	* POT BARLEY		29,0	0,0	11,9	4,8	2,0	12,5	0,7	0,0	0,0	0,7
	* BARLEY, PEARLED		0,0	0,4	27,9	0,4	0,4	0,9	0,5	0,1	0,0	0,0
	* BARLEY FLOUR AND GRITS		0,0	0,3	10,8	0,3	0,5	0,9	0,4	0,0	0,1	0,0
GC 641	BUCKWHEAT	(2)	0,0	0,1	0,0	1,7	1,6	0,1	1,0	0,0	0,2	0,1
	* FLOUR OF BUCKWHEAT		0,0	0,0	0,0	1,3	1,2	0,0	0,7	0,0	0,1	0,0
	* BRAN OF BUCKWHEAT		0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0
GC 645	MAIZE	(3)	82,7	146,4	136,3	31,8	35,3	7,5	36,2	296,6	248,1	67,4
CF 1255	MAIZE FLOUR		68,9	15,4	51,3	16,8	14,7	2,0	28,8	249,8	206,7	47,8
	* GRIRM MAIZE	(4)	0,2	8,9	5,0	1,2	2,0	0,4	0,5	1,2	3,9	0,0
GC 654	WHEAT	(12)	86,4	396,3	436,5	390,2	236,3	216,0	172,9	79,0	68,1	41,9
CF 1210	* WHEAT GERM		0,0	1,2	0,0	1,3	0,9	1,2	0,1	48,1	1,8	0,0
* CF 1211bg	** WHEAT BULGUR WHOLEMEAL		5,5	10,2	0,7	0,2	0,1	0,0	0,0	0,0	0,0	0,0
CF 1211	* WHEAT FLOUR		63,4	296,3	327,5	300,0	181,8	166,2	133,0	60,1	52,4	32,2
* CF 1211mc	** WHEAT MACARONI		0,8	1,1	0,8	1,8	4,8	7,8	1,7	3,6	0,5	0,2
* CF 1211pa	** WHEAT PASTRY		0,4	1,1	0,7	2,8	1,7	5,4	0,3	0,6	0,7	0,2
CF 1211	WHITE BREAD		0,0	0,1	0,0	0,1	0,1	1,0	0,0	2,2	0,1	0,0
CF 1212	WHOLEMEAL BREAD		0,0	0,1	0,0	0,1	0,1	1,0	0,0	2,2	0,1	0,0
	* OATS, ROLLED		0,7	0,3	0,1	2,2	9,0	4,7	0,1	0,7	0,4	0,0

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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	por tion	Gen pop (1-97 yrs) Average bw (kg): 65,8 Cons days (ind 0): 12590 NL-diet (g/kg bw /day)	NL-diet (g/pers /day)	EP %proc	Ntot	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%	2186	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%	3292	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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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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Practical

- Perform a dietary risk assessment using:
  - MRLs, STMRs and HRs: look up
  - ADI
  - ARfD
  - WHO/FAO model (chronic)
  - WHO/FAO model (acute)

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Chronic exposure

- Fill in the relevant parameters (ADI, compoundname and MRLs or STMRs)

	WHO, August v2 2006, GEMS/FoodConsumptionClusterDiets										Version 14, dd 31 August 2011	
		Compound name (in capitals):									International Estimated Daily Intake (IEDI)	
		Compound number:										
		ADI (mg/kg bw):									Diets: g/person/day. Intake = daily intake: ug/person	
					A		B		C		D	
Notes	Codex Code	Name	STMR or STMR-P mg/kg	diet correction factor	diet	intake	diet	intake	diet	intake	diet	intake
-	401	CITRUS FRUIT		-	-	-	-	-	-	-	-	-
1	FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl HS juice)		1	15,7	-	100,5	-	63,2	-	27,8	-
-	FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl HS juice)		1	15,7	-	86,5	-	52,6	-	24,2	-
-	FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, incl HS juice)		1	15,7	-	90,9	-	52,8	-	24,2	-

- Select 'tools'> macro >> macro's >>> calculate >>>> run

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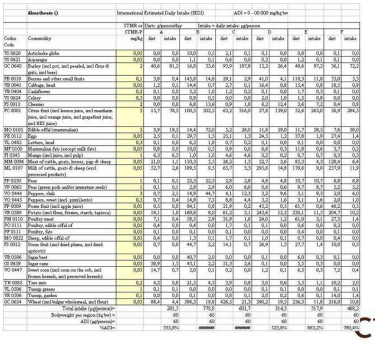
Chronic exposure (2)



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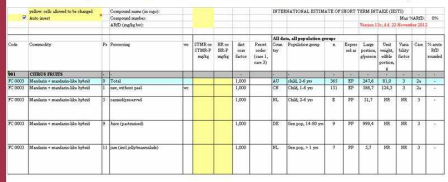
Acute exposure

- Fill in the relevant parameters (ARfD, compound name and STMR or HR)



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Acute exposure (3)

- ARfD is exceeded, refinement is necessary.
  - Processing factors
  - Amending use (longer PHI, less applications)
  - Deleting use

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Chronic exposure (3)

- ADI is exceeded, refinement is necessary.
  - STMRs
  - Processing factors

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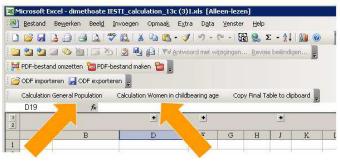
Acute exposure (2)

- Click button on top



or

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Annex 6. Presentations concerning environmental risk assessment, as given in the 27-30 May 2013 workshops in Debre Zeyit

PRIMET

Pesticide RIsks in the tropics for Man, Environment and Trade

May 2013, Mechteld ter Horst, Louise Wipfler, Joost Vlaming

Outline

- Introduction
  - Background
  - Aim and philosophy of PRIMET
  - Projects in which PRIMET was/is used
  - Risk assessment
  - Protection goals
- PRIMET
  - Protection goals
  - Risk assessment
  - Scenario development
  - Safety factors
- Concluding

Introduction: Background

Alterra – ERA research theme

- Capacity building in developing countries
  - Local scale: analysing, understanding and improving farmer practices to promote safe use
  - National scale: develop pesticide registration systems

Introduction: Aim of PRIMET

- Local scale: provide a simple instrument to estimate the risks of pesticide application at the household/community level.

- National scale: assessing the risks of pesticide use as specified on the label for selected protection goals.

Introduction: PRIMET philosophy

- Integrated tool
  - Environmental risk
  - Human health
- Simple models and limited input data needed
  - Aims at identifying the most toxic chemicals
- User friendly user interface
- Runs on windows machines

Introduction: Projects in which PRIMET was/is used

- MAMAS (2003-2005) – local scale
  - Thailand and Sri Lanka
  - Modeling exposure concentrations in aquatic systems and residues present in food items.
  - Start of PRIMET with an aquatic risk assessment and a dietary risk assessment

Introduction: Projects in which PRIMET was/is used

- VEGSYS (2002 – 2006) – local scale
  - Develop approaches to assess risks of pesticide application in crop production for the environment and humans
  - To apply these to two sites representative for intensive peri-urban vegetable farming in Vietnam and China
  - Proposal to improve the situation, both for farmers and the environment
  - Expansion of PRIMET with groundwater assessments for 2 sites

Introduction: Projects in which PRIMET was/is used

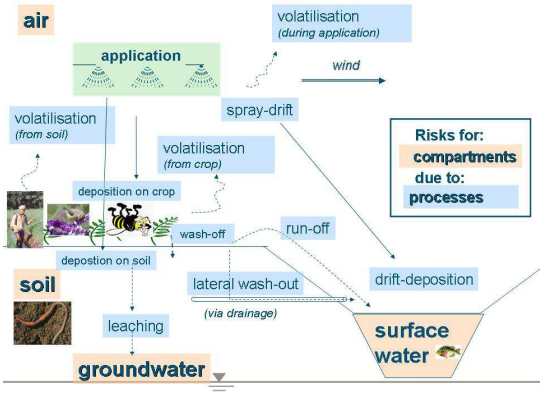
- MAPET (2003-2006) – local scale, Thailand and China
  - collecting farm management data for giving insight in current pesticide management
  - risk assessment of current practices, related to surface water, groundwater, soil pollution and residue levels on marketed products
  - an economic assessment of the opportunities of the sector to export to the EU
  - Propose alternative management to reduce pesticide use

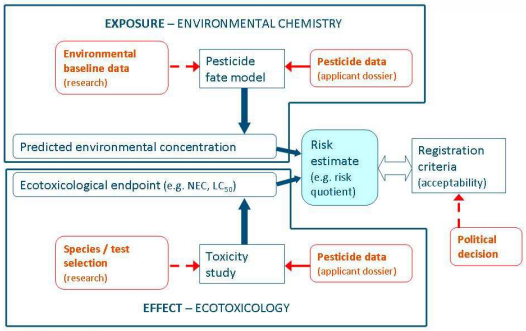
Introduction: Projects in which PRIMET was/is used

- PRRP (2009 – 2013) – national scale
  - PRIMET developed (ongoing) for use as risk assessment tool for pesticide registration
  - Ethiopian scenarios for groundwater and surface water for drinking water and aquatic ecosystem
  - Include risk assessments for operators, workers and consumers
  - Include risk assessments for birds and other terrestrial organisms


Introduction: Risk assessment

- Risk assessment is the combination of an exposure and an effect assessment
- Exposure assessment to calculated the Predicted Environment Concentration (PEC) using usually models and scenarios
- Effects assessment to determine ecotoxicological endpoint (e.g. LC50, NOEC, etc)





Introduction: Risk assessment

Exposure assessment mostly based on models

- Drift
- Drainage and/or run-off
- Fate in water
- Leaching

Effects assessment mostly based on experiments

- Laboratory tests
- (semi) Field experiments


Introduction: Protection goals

- A risk assessment is done per protection goal (e.g. surface water for drinking water, birds, bees, etc)
- Protection goals are defined together with decision makers/government

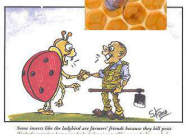
PRIMET: Protection goals

- For each project PRIMET is adapted such that the relevant protection goals for the specific project/country are included.
- For instance in China silkworm is a protection goal.

PRIMET: Protection goals PRRP

- Human health
  - Groundwater for drinking water
  - Surface water for drinking water
  - Operators/workers
  - Consumers (via residues on commodities)

- Environment
  - Aquatic ecosystems
  - Birds
  - Bees
  - Non-target terrestrial plants
  - Non-target arthropods
  - Earthworms

PRIMET: Risk assessment

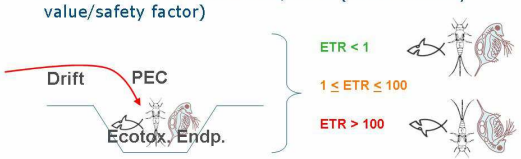
For each protection goal proposals are needed for:

- Exposure
- Toxicity
- Safety factors (might be based on the EU values)
- Criteria for risk classification (ETR approach):

ETR < 1 → low risk
1 ≤ ETR ≤ 100 → possible risk
ETR > 100 → high risk

PRIMET: Risk assessment

- Develop physical scenarios and select models
- Calculate the PEC for that scenario
- Determine the Ecotox. Endp. for that scenario
- Calculate the risk ETR = PEC/PNEC (PNEC=Toxicity value/safety factor)



PRIMET: Scenario development

Always needed for protection goals

- Groundwater for drinking water
- Surface water for drinking water
- Aquatic ecosystems

- Even though relatively simple models are used they need to be applied for vulnerable situations (discussion with decision makers on how vulnerable: e.g. 10% most vulnerable locations)
- These vulnerable situations need to be identified (scenario selection) and models need to be parameterized for these situations.

PRIMET: Scenario development

- Crops
  - Local crops? *e.g.* teff in Ethiopia
  - Local growth conditions

- Local application practices
  - Knapsac sprayers,
  - tractor mounted boom sprayers
- Workers/bystanders
  - Adapt tools for local practices (which personal protection equipment)

PRIMET: Safety factors

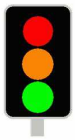
- The ecotoxicological endpoints (environmental protection goals) are usually corrected using safety factors.
- Safety factors might be based on EU values
- An impact assessment is needed afterwards, to investigate their effect on the pesticide package that is currently authorized
  - Classifying the most toxic compounds as risky
  - Total package of products sufficient for farmers

PRIMET: software tool

- Per protection goal ('assessment' in PRIMET) the user needs to provide data on:
  - Pesticide properties
  - Pesticide application (e.g. dose, frequency, etc)
- Per protection goal the user needs to:
  - Select a scenario

PRIMET: software tool

- Communicating the risk via 'traffic light' principle.
  - Red → high risk, no registration
  - Orange → possible risk, risk managers call
  - Green → low risk, registration possible



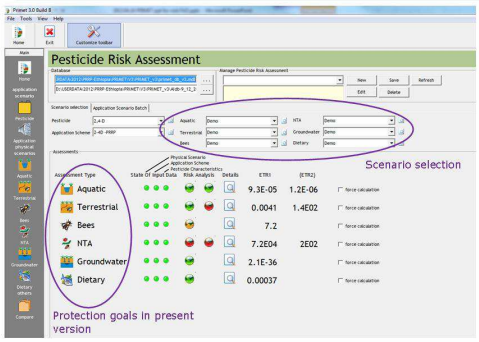
Concluding

- PRIMET is useful as a relatively simple tool for risk assessment in pesticide registration procedures
- Keep in mind that for the following protection goals, specific scenarios need to be developed:
  - Groundwater for drinking water
  - Surface water for drinking water
  - Aquatic ecosystems

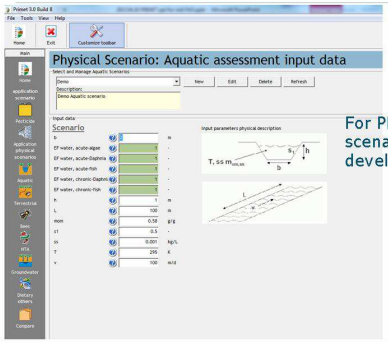
- Risk classification criteria need to be established with decision makers/government and preferably tested via an impact assessment.

Demonstration of the software tool by Joost Vlaming

PRIMET: software tool



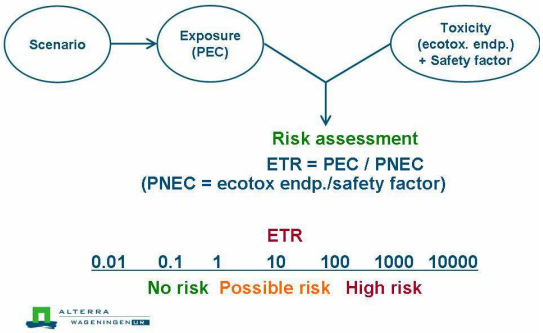
PRIMET: software tool

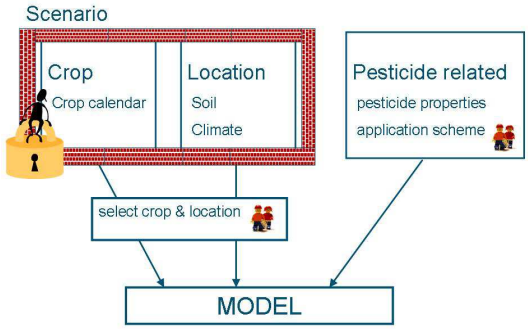


For PRRP new scenarios are developed

Relation model, scenario, input data

PRIMET: Risk assessment





Pesticide Risk Reduction Programme – Ethiopia

Surface water and groundwater scenario development 5-9 November 2012 and further

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

PG	1st	2nd	3rd	4th	5th
Ground water	-	2		3	1
surface water	10	-	-	-	-
Aquatic ecosystem	-	2	2	-	1
Soil ecosystem	-	6	2	1	-
Terrestrial ecosystem	-	-	6	2	

•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)

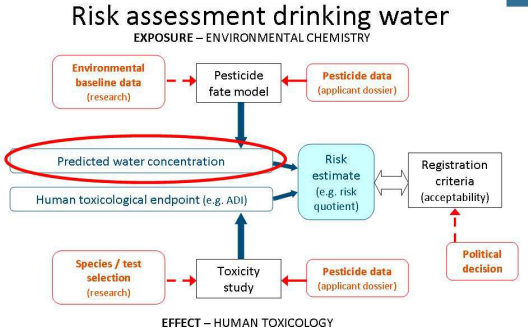
•Second priority is groundwater: 90% rural areas and 40% major towns get drinking water from gw source (Nov'12 workshop, Water Works Design and Supervision Ethiopia)

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

2

Risk assessment drinking water

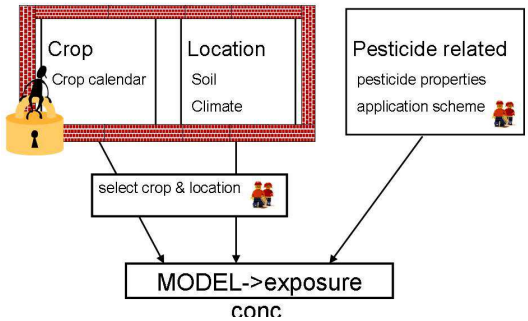


Summary sw and gw scenario development

- 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

2. Relation model, scenario, input data

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 included in Proclamation (Feb 2013)
- Realistic worst-casedness or the vulnerability of the scenario is often translated as '90th-percentile occurrence in time and space'

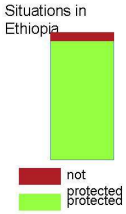
Interludum: Vulnerability

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"

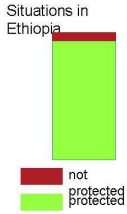


Interludum: Vulnerability

Scenarios should be protective, "realistic worst case"

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

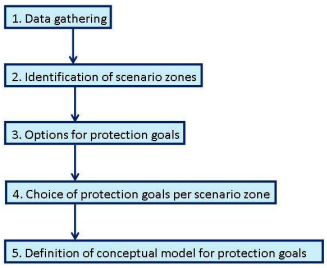
More strict than in EU because human-toxicological standard is used in Ethiopia (exceedance means casualties)



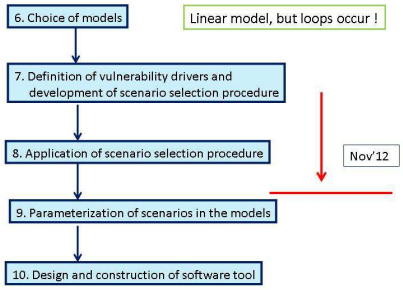
Summary sw and gw scenario development

- 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?

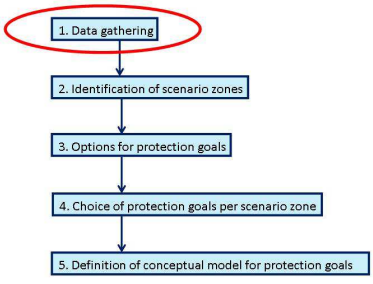
If protection goals have been defined into detail

•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

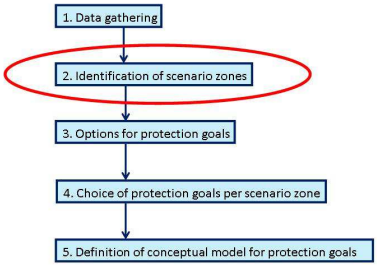


Summary sw and gw scenario development

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



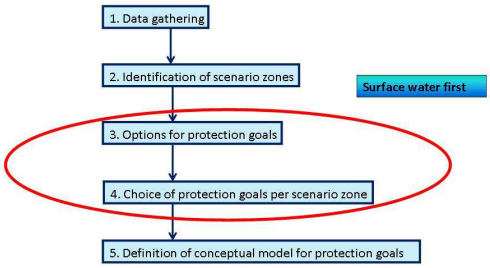
Summary sw and gw scenario development

- 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



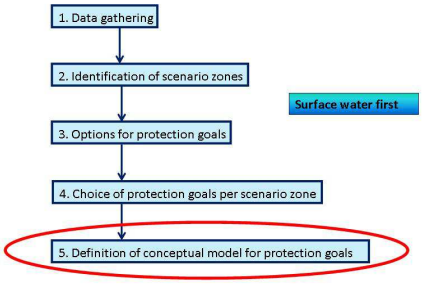
Protection goals: surface water

- 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)

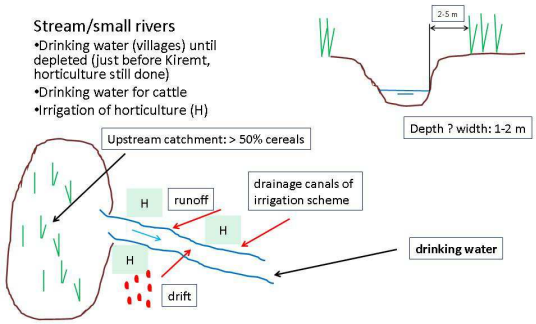
Definition of protection goals



Protection goals #1: surface water

Stream/small rivers

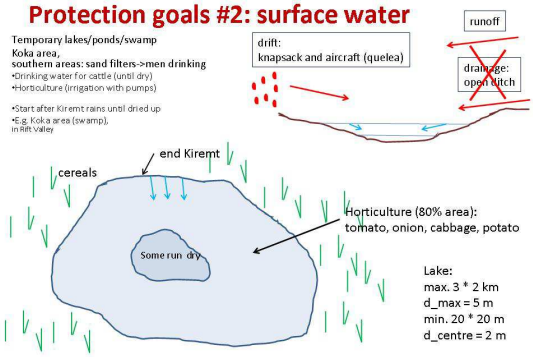
- Drinking water (villages) until depleted (just before Kiremt, horticulture still done)
- Drinking water for cattle
- Irrigation of horticulture (H)



Protection goals #2: surface water

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

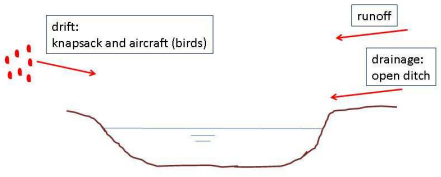
- Drinking water for cattle (until dry)
- Horticulture (irrigation with pumps)
- Start after Kiremt rains until dried up
- E.g. Koka area (swamp), in Rift Valley



Protection goals #3: surface water

Rift Valley lakes

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



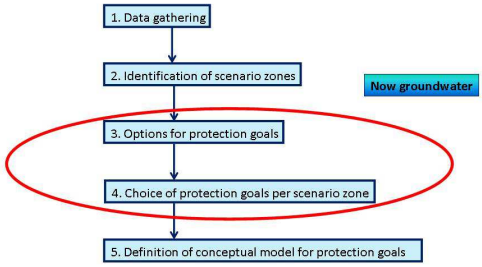
Protection goals sw in scenario zones

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)

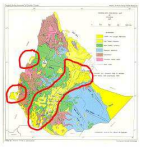
Definition of protection goals



Protection goals gw in scenario zones

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

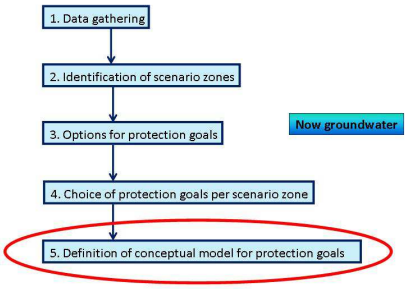
#1 and #2 may be close to each other



#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



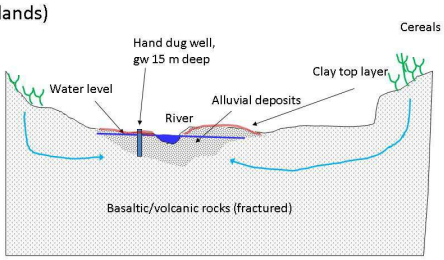
Protection goals#1: groundwater

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)



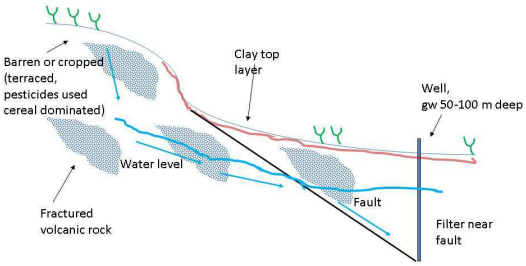
Protection goals#2: groundwater

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

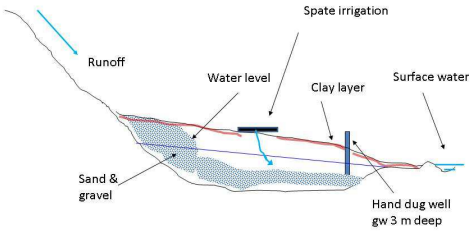
Alluvial aquifers at the Rift Valley margins or lowlands

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

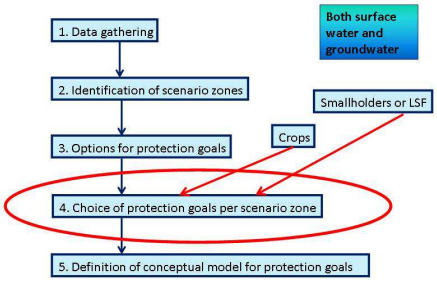
Protection goals gw in scenario zones

#1 Alluvial aquifers along small rivers:
occurs only in scen zone >1500 m — most vulnerable

#2 Volcanic aquifers of shallow wells:
occurs only in scen zone >1500 m
#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):
occurs mostly in scenario zone <1500 m,
may be in scenario zone >1500 m (but then < 2000 m),

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:

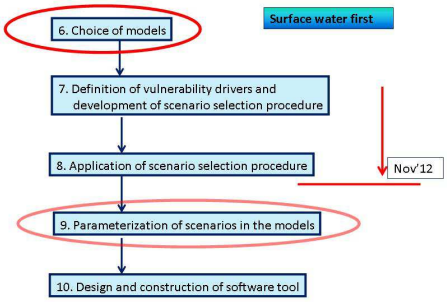
Zone > 1500 m:
Teff, maize, wheat, barley, vegetables (all),
Also potato, pulse (faba bean, field pea, French bean, chickpea, lentils), pome/stone fruit,

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

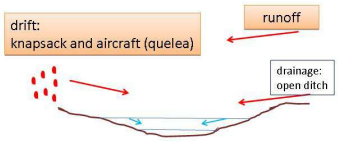


Selected models for surface water

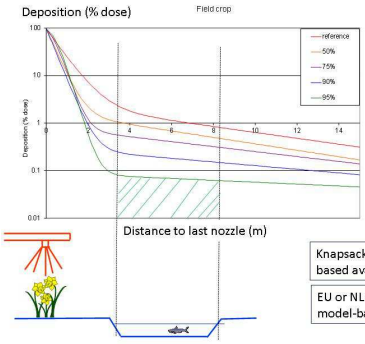
6. Choice of models

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

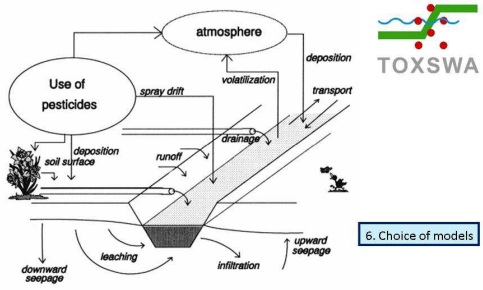
- Selected model: TOXSWA

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



TOXSWA

6. Choice of models

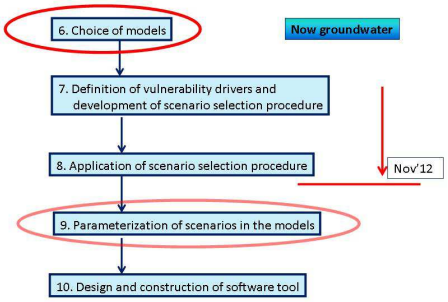
Selected models for surface water: Fate in SW

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:

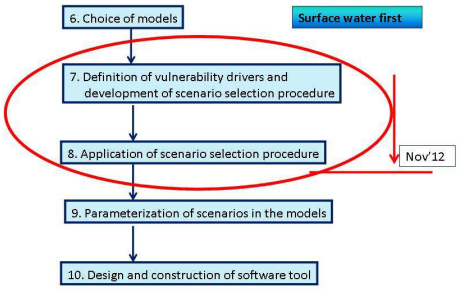
- α_0 , α_1 , α_2 taken for climate zone warm, wet (up to >800 mm rain, >12.5 C)-> most representative for Ethiopia

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: *191 selected* small streams in areas > 1500 m *(streams present + intensive agriculture)*

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: *373 selected*
temporary ponds in areas < 1500 m + > 500 mm rain: *ponds, intensive agriculture, many crops, many people*

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: *217 selected* temporary ponds in areas 1500-2000 m: *ponds, intensive agriculture, many crops*

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 goal #3a: *250 selected* alluvial aquifers in the Rift Valley margins and lowlands < 1500 m: *springs or wells with intensively cultivated, higher situated recharge areas*

Summary sw and gw scenario development

Next steps:

8. Application of scenario selection procedure

•First select scenario locations *DONE*

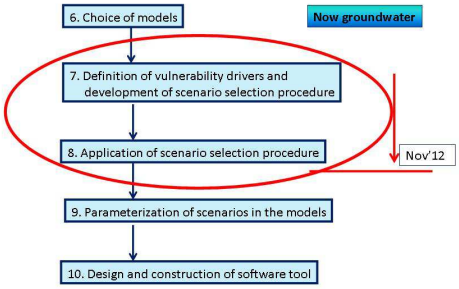
9. Parameterization of scenarios in the models

•Next, start parameterisation:
crop development data, association crops to sw and gw scenarios
obtain horticultural irrigation data *BOTH DONE*
parameterise PRZM (write post-processing program for 33 years Ethiopian meteo) and TOXSWA models for selected crops and scenarios (TOXSWA only for ponds) *BUSY*

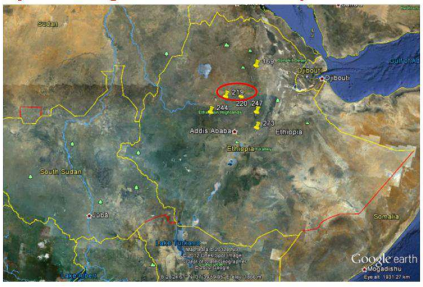
10. Design and construction of software tool

•Adapt PRIMET tool for sw and gw concentrations *BUSY*

Scenario selection and parameterization



Summary sw and gw scenario development



Six candidate locations for groundwater protection goals #1 and 2: 219 *selected* alluvial aquifers along small rivers and volcanic aquifers on shallow wells > 1500 m: *cereals grown, pesticides intensively used*

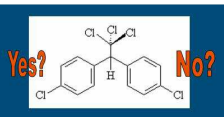
Summary sw and gw scenario development

Six candidate locations for groundwater protection goal #3b: *323 selected (**2056** m)* alluvial aquifers in the Rift Valley margins between 1500-2000 m: *west of lake Ziway, gw from shallow wells, intensive agriculture, high pesticide use, but only 11 out of 256 5*5 km grid cells represent 95-98%-ile*

Summary sw and gw scenario development

Setting environmental criteria for pesticide registration

Introduction



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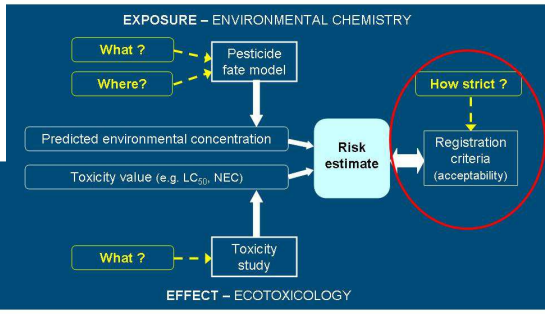
Environmental risk assessment – Questions to answer 2



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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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Risk estimate – European Union

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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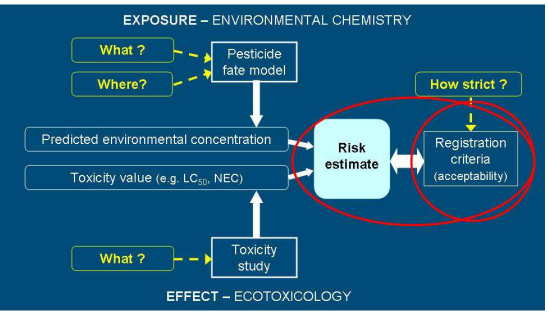
Environmental risk assessment – setting criteria 1



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Risk estimate: different terms – same principle 1

Toxicity Exposure Ratio (TER)

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

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

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Toxicity Exposure Ratio (TER)

[EU-plant protection products]

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

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

[e.g. USA, Australia, EPPO, EU-biocides]

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

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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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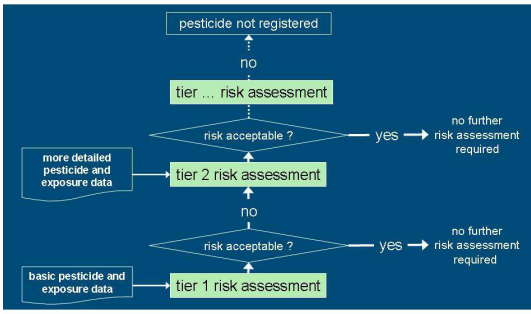
Tiered (=step-wise) risk assessment



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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)

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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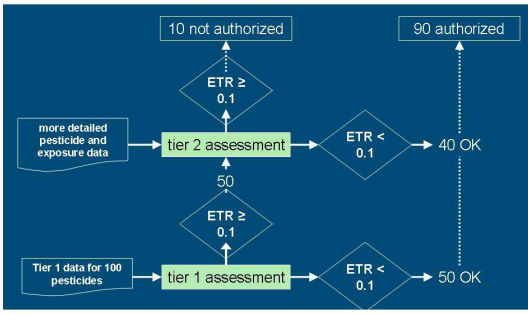
Example 1: two-tier system

ETR < 0.1 is acceptable risk



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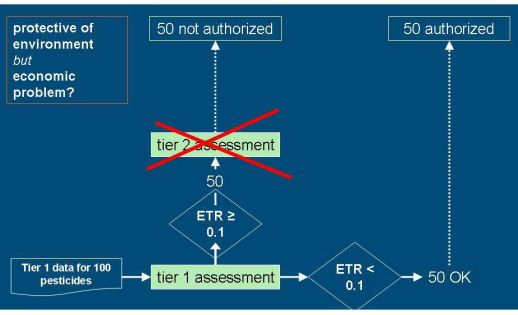
Example 2: one-tier system & same criteria

2

ETR < 0.1 is acceptable risk



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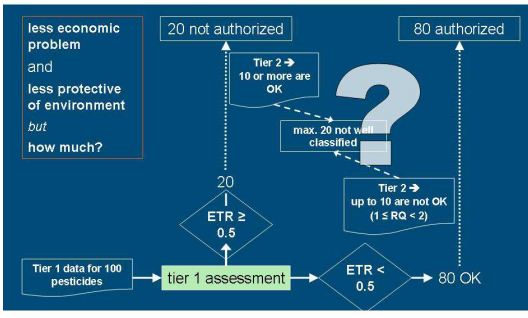
Example 3: one-tier system

ETR < 0.5 is acceptable risk



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Examples summary

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 (= PEC/(Toxicity value/safety factor) < 1 → risk acceptable
- Possible risk: if ETR ≥ 1 but ≤ a certain exceedance factor X (different for different protection goals) → risk uncertain, if risk reduction measures are possible they should be applied
- High risk: if ETR > certain exceedance factor X → 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!!

Proposals for registration criteria (safety factors) and risk classification criteria

Peter van Vliet
CTGB

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)
- ETR = PEC/PNEC (PNEC =Toxicity value/safety factor)
- Criteria for risk classification (ETR approach):

ETR < 1 → low risk
1 ≤ 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 can also play a role (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

Surface water as source of drinking water

Proposal

- Where? At drinking water abstract points
- How strict? Based on human toxicity values (ADI-approach)
- Exposure: PECsw at drinking water abstract points (PECsw-dw): see surface water models Alterra
- 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)

Surface water as source of drinking water

Risk assessment:

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

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

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

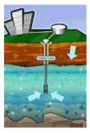
- Because a high safety factor is used to derive the ADI (factor 100) an exceedance factor of 10 is still considered relatively safe)

Groundwater as source of drinking water

Proposal

- Where: different scenarios developed
- Exposure: see groundwater exposure models Alterra
- Toxicity: see surface water as source of drinking water

ETR gw-dw = PECgw-dw / DWS x 1000



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

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Aquatic ecosystem

What? Populations of aquatic species
Where? (temporary) lakes, streams, rivers, storage reservoirs
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

- Exposure: PECsw (see PRIMET)
  - PECmax for acute risk assessment
  - PECmax for chronic risk assessment
- Toxicity:
  - acute LC50 (fish) and EC50 (algae, invertebrates, macrophytes)
  - chronic NOEC (fish and invertebrates)

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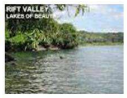
Aquatic ecosystem

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



Risk assessment

1. Fish (vertebrates: higher protection level, so the exceedance factor X is relatively low)

- Acute

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

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Aquatic ecosystem

ETRfish-ac < 1	→Low risk
1 ≤ ETRfish-ac ≤ 10	→Possible risk
ETRfish-ac > 10	→High risk

- Chronic fish

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

ETRfish-chr < 1	→ Low risk
1 ≤ ETRfish-chr ≤ 10	→ Possible risk
ETRfish-chr > 10	→ High risk

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Aquatic ecosystem

2. Invertebrates

- Acute

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

ETRinv-ac < 1	→Low risk
1 ≤ ETRinv-ac ≤ 100	→Possible risk
ETRinv-ac > 100	→ High risk

(invertebrates reproduce fast, so exceedance factor X is relatively high)

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Aquatic ecosystem

- Chronic

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

ETRinv-chr < 1	→Low risk
1 ≤ ETRinv-chr ≤ 100	→Possible risk
ETRinv-chr > 100	→ High risk

3. **Algae**
   - no distinction between acute and chronic; use of PECmax
   - fast reproduction, so factor X can be relatively high

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

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Aquatic ecosystem

ETRalg < 1	→Low risk
1 ≤ ETRalg ≤ 100	→Possible risk
ETRalg > 100	→High risk

4. **Macrophytes (Aquatic plants)**
   - no distinction between acute and chronic; use of PECmax
   - Slow reproduction, so factor X is relatively low

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

- ETRmac < 1	→Low risk
1 ≤ ETRmac ≤ 10	→Possible risk
ETRmac > 10	→ High risk

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Bees

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

- 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

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

Toxicity: LD50 (µg/bee)
Trigger: same as in the EU: 50

Risk assessment:

ETRbee = PECbee / LD50bee

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

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Bees

- 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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Non-target arthropods

Very important in relation to Integrated Pest Management (IPM)

Protection:
- 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

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

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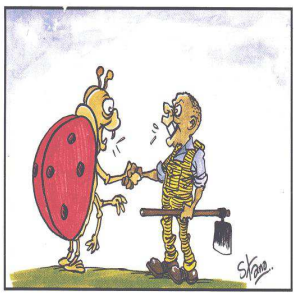
Non-target arthropods



Some insects like the ladybird are farmers' friends because they kill pests

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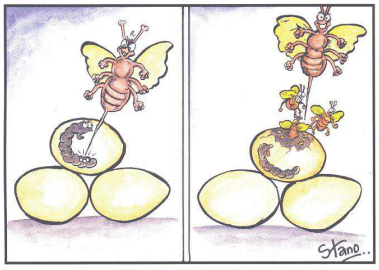
Non-target arthropods



Farmers' friends can kill a pest by laying eggs in it

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Non-target arthropods

Toxicity:
- glass-plate tests (lab tests) with *Aphidius rhopalosiphi* and *Typhlodromus pyri*: LR50 (g as/ha)
- Trigger 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)
- Trigger in the EU: 1 (based on the criterion that less than 50% effect is acceptable)

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Non-target arthropods

Risk assessment:
a) In-crop

ETRnta = PECin-crop / LR50 (lab or extended lab)

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

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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, so exceedance factor X is relatively low

ETRnta = PECoff-crop / LR50 (lab or extended lab)

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

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Earthworms

Protection:
What? Populations of earthworms
Where? In-field
How strict? No long-term effect on populations of earthworms

Exposure: 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)

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Earthworms

Exposure

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)

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Earthworms

$PEC_{soil} = C_{soil} / (\rho_b * 1000)$

PEC_{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

Toxicity:
- acute LC50
- chronic NOEC

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

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Earthworms

Risk assessment:

Acute

ETRearth-ac = PEC_{soil}/(LC50/10) (safety factor is 10)

ETRearth-ac < 1 → Low risk
1 ≤ ETRearth-ac ≤ 5 → Possible risk
ETRearth-ac > 5 → High risk

Chronic

ETRearth-chr = PEC_{soil}/(NOEC/5) (safety factor is 5)

ETRearth-chr < 1 → Low risk
1 ≤ ETRearth-chr ≤ 5 → Possible risk
ETRearth-chr > 5 → High risk

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Birds

Vertebrates: higher protection level
- 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?

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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

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Birds

Standard exposure scenarios for tier 1

ETE = (FIR / bw) * C * AV * PT * PD (mg/kg bw/d)
- FIR = Food intake rate of indicator species (g fresh weight per day
- Bw = bodyweight (g)
- 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

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Birds

In case of multiple applications or long-term considerations:
$C = C_0 * MAF * f_{twa}$
- C0 = Initial concentration after a single application
- MAF = multiple application factor
- f_{twa} = Time weighted average factor

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
t = averaging time

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Birds

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);

- **Acute exposure**
  - residues: 90th percentile of the initial concentration;
  - special MAF-values
- **Long-term exposure**
  - mean residue values
  - twa-value over 21 days (based on a default DT50-value of 10 days) → ftwa = 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)	ftwa	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

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

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

Risk assessment
- Sprays
- Seeds/granules

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Birds

- Sprays

$ETRac = \frac{ETE}{LD50/10}$ $ETRchr = \frac{ETE}{NOEC/5}$

Acute	Long-term	
ETRac < 1	ETRlt < 1	→Low risk
ETRac ≤ 5	1≤ ETRlt ≤ 10	→Risk possible
ETRac > 5	ETRlt > 10	→ High risk

- 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

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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.

Protection:
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

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

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

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Non-target terrestrial plants

Risk assessment

$ETRntp = \frac{PEC\ (off\text{-}field)}{ER50lowest/5}$ **(safety factor = 5)**

ETRntp < 1	→ low risk
1 ≤ ETRntp ≤ 10	→ possible risk
ETRntp > 10	→ high risk

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- Thank you for your attention!!!

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