# PRIMET_Registration_Ethiopia_1.1, technical description and manual

A Decision Support System for assessing Pesticide Risk in the tropics to Man, Environment and Trade, for pesticide registration in Ethiopia

E.L. Wipfler, P.I. Adriaanse, M.M.S. ter Horst, J. Vlaming, P.J. Van den Brink, F.M. Peeters, J.W. Deneer, J.J.T.I. Boesten and J.G. Groenwold

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Abstract
Wipfler, E.L., P.I. Adriaanse, M.M.S ter Horst, J. Vlaming, P.J. van den Brink, F.M. Peeters, J.D. Deneer, J.J.T.I. Boesten and J.G. Groenwold, 2014. PRIMET_Registration_Ethiopia 1.1.1., technical description and manual. A Decision Support System for assessing Pesticide Risk in the tropics to Man, Environment and Trade, for pesticide registration in Ethiopia. Report in the framework of the PRRP project, Wageningen, the Netherlands.

Pesticide exposure via for instance spray drift, runoff to surface water, accumulation in the top soil or leaching to groundwater may potentially pose a risk to water and soil organisms and plants. The use of pesticide may also pose a risk to consumers and operators and workers. PRIMET_Registration_Ethiopia enables the estimation of these risks. The tool has been developed to support the pesticide registration process in Ethiopia. The risk is expressed in Exposure Toxicity Ratio's which are calculated by dividing the predicted exposure by the safe concentration. This report provides the mathematical description of the incorporated risk assessments, as well as a user manual. Also example cases are provided. PRIMET_Registration_Ethiopia 1.1 is freely available at http://www.pesticidemodels.eu/PRIMET-Ethiopia/home.

Keywords: Pesticide registration, Environmental Risk Assessment, Human Health Risk, Ethiopia

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# Preface

The PRIMET Registration tool was developed within the Pesticide Risk Project Ethiopia, work package B2.1, on Dossier Evaluation. The PRIMET Registration tool builds further on the risk assessment tool PRIMET version 2.0, which founding father was Prof. Dr. Paul J. van den Brink. PRIMET 2.0 has been rebuilt into a proper registration tool, while accounting for specific Ethiopian conditions.

The PRRP project ran from February 2010 up to the end of 2014. In a series of seven workshops with representatives of the Plant Health Regulatory Department (PHRD) of the Ministry of Agriculture of Ethiopia and other stakeholders protection goals were set and prioritized and risk assessment procedures were developed, next to procuring capacity building and specific trainings (see www.prrp-ethiopia.org, Activities and Outputs, Dossier Evaluation). In September 2014 the last training was planned on the use of the PRIMET software and the execution of risk assessments in Ethiopia.

All risk assessments in the registration tool have been developed specifically for Ethiopian conditions and practices. Special attention was paid to develop tailor-made scenarios for surface water and groundwater. Many people have contributed to the workshops and the development of the risk assessment procedures which are integrated into the PRIMET_Registration_Ethiopia software tool. On the Dutch side main contributors were Paulien Adriaanse, Mechteld ter Horst, John Deneer, Louise Wipfler and Jos Boesten (all Alterra) as well as Peter van Vliet, Marloes Busschers, Caroline van der Schoor (all Ctgb) and Jan-Hendrik Krook (now Linge Agroconsultancy). The software was programmed by Joost Vlaming (Envista Consultancy). On the Ethiopian side major contributions of the PHRD were given by Alemayehu Woldeamanual, the former work package expert of WP B2.1. Gizachew Assefa, who deceased in November 2012 and the PhD student, Berhan Melese at Wageningen University sponsored by PRRP-Ethiopia project. Major Ethiopian contributions to the development of the surface water and groundwater scenarios for drinking water production were given by Dr Engida Zemedagegenhu of the Water Works Design and Supervision Enterprise-Ethiopia as well as the late Dr Dereje Gorfu of the Ethiopian Institute of Agricultural Research.

We believe that this software will highly contribute to the implementation of a transparent, reproducible and sound pesticide registration system in Ethiopia and we hope it may serve as an example for other African countries or regions.

# 1 Introduction

## 1.1 Background

The PRIMET_Registraton_Ethiopia 1.1 tool is one of the valuable products from the Pesticide Risk Reduction Program – Ethiopia. The tool enables the calculation of environmental and human risks as part of the authorisation process in Ethiopia. PRRP-Ethiopia is a comprehensive program that was initiated by the Government of Ethiopia to improve pesticide registration and management. In the program the Plant Health Regulatory Directorate (PHRD) of the Ministry of Agriculture of Ethiopia (MoA), Alterra, part of Wageningen UR (Netherlands) and FAO of the United Nations work jointly together on pesticide risk reduction in Ethiopia. The program presents all aspects of pesticide legislation in agriculture and public health sectors, setting up a sustainable system and capacity building for pesticide registration and a holistic plan for post-registration aspects: monitoring, inspection, quality control, storage, capacity building.

PRIMET-Registraton_Ethiopia 1.1 builds further on PRIMET 2.0 (Peeters *et al.*, 2008, Van den Brink, 2005). The intended use of PRIMET 2.0 was to estimate environmental risk due to pesticide use as specific tool for raising awareness among farmers on pesticide negative impacts on humans and ecosystems. The PRIMET 2.0 model calculates the risk at the household level, using actual application data from the farmers and expresses the risk in Exposure Toxicity Ratio's which are calculated by dividing the estimated exposure concentration by the safe concentration. The safe concentrations are calculated from toxicity data and extrapolation factors. Risks are assessed for aquatic life, terrestrial life, bees, non-target arthropods, the use of groundwater as drinking water and dietary exposure via the consumption of fish, groundwater, vegetables and macrophytes. PRIMET 2.0 contains a database with physico-chemical and (eco-) toxicological properties of a large number of pesticides.

PRIMET has been redesigned into a proper registration support tool specifically for Ethiopian conditions. This tool is now referred to as PRIMET_Registration_Ethiopia 1.1. Moreover, the tool was extended and now includes the assessment of more risks for environment protection goals as well as for humans (consumption of drinking water, operators and workers) than in the PRIMET 2.0 tool.

## 1.2 Addressed protection goals

The protection goals covered by PRIMET_Registration_Ethiopia are listed below:

**Human risks**

1. Operator in greenhouse.
2. Worker (indoor and outdoor).

**Drinking water**

3. Groundwater as source for drinking water (chronic risk).
4. Surface water as source for drinking water (chronic and acute risks).

**Environmental risks**

5. Aquatic ecosystem (chronic and acute risks).
6. Terrestrial ecosystem (chronic and acute risks).
7. Bees (in-crop and off-crop exposure).
8. Non target arthropods (in-crop and off-crop exposure).
9. Birds (chronic and acute risks).
10. Non-target terrestrial plants.

The software package of PRIMET_Registration_Ethiopia 1.1 is delivered together with four external models. These models can be used independently of PRIMET_Registration_Ethiopia. The protection goals covered by these external models are:

Human Risk (external models)
11. Operator outdoor risk (the German model).
12. Consumer risk (chronic risk (IEDI calculation model) and acute risk (IESTI calculation model)).

## 1.3 Risk quantification concepts

PRIMET_Registration_Ethiopia calculates for each protection goal the exposure concentration, the effect concentration and the Exposure Toxicity Ratio. For each of the protection goals risk criteria are predefined, interpreting the ETR values as an indicator for 'no risk', 'possible risk' or 'high risk'. For most of the protection goals first tier risks are assessed. Higher tier options are only available for operators in greenhouse (allowing for personal protection equipment) and non-target arthropods (allowing for a higher-tier effect assessment).

All calculations are based on the PRRP-Ethiopia evaluation manual (Deneer *et al.*, 2014) which describes the risk assessments to be performed by the pesticide registration authority. Registration is requested for a product and its intended use, via a so-called Product Registration File (PRF). In PRIMET_Registration_Ethiopia each registration is interpreted as a number of unique combinations of active ingredient- crop- application scheme, relevant for the specific registration. Each of these combinations is called a project in the PRIMET_Registration_Ethiopia software.

For the risk assessments pesticide physico-chemical data are required as well as ecotoxicity data, fate data and toxicity data. Also an Ethiopian-specific crop type has to be selected, and the application type, dosage, frequency and time interval have to be entered. As part of the registration procedure, registrants are required to provide pesticide properties in the data requirement form as given in PHRD (2014). These properties should be used/ translated into input data for the risk assessments in PRIMET.

Note that in PRIMET active ingredient properties should be entered only. E.g. in case an ecotoxicological study is available of the product, the user has to express the endpoint in terms of the active ingredient. Hence, if the product contains 40% active ingredient and the endpoint of the product is 10 µg product/L, the endpoint expressed in active ingredient is 4 µg a.i./L. Then, this endpoint should be compared to the toxicity data from the same study but then performed with the active ingredient The lowest endpoint will be used for risk assessment.

For the protection goals 'Groundwater as source of drinking water' and 'Surface water as source for drinking water' as well as for 'Aquatic ecosystem', specific Ethiopian exposure scenarios were derived (Adriaanse *et al.*, 2014). These scenarios have been implemented in PRIMET_Registration_Ethiopia. The exposure scenarios for surface water and aquatic ecosystems make use of the pesticide fate models TOXSWA (Adriaanse, 1996) and PRZM (Carsel *et al.*, 1996). TOXSWA and PRZM are installed along with the installation of PRIMET_Registration_Ethiopia. PRIMET_Registration_Ethiopia runs these models on the background and reads out the calculated exposure concentrations automatically for further use in the risk assessment.

## 1.4 Ethiopian crops

The main crops grown in Ethiopia have been identified in the PRRP framework. These are implemented in the registration tool. Some of the selected crops are considered to be representative for a class of crops. An overview is given in Table 1.

Table 1

*Selected Ethiopian crops and related crop classes.*

| Crop | Representative for the crop class |
|---|---|
| Tomato (grown horizontally) | Fruity vegetables |
| Tomato (grown vertically-greenhouse) | Fruity vegetables |
| Onion | Bulb vegetables |
| Cabbage | Leafy vegetables |
| Potato | - |
| Teff | - |
| Wheat | - |
| Maize | - |
| Barley | - |
| Faba bean | Pulses |
| Sweet potato | - |
| Cotton | - |
| Mango | Pome/stone fruit |
| Sugarcane | - |
| Banana | - |
| Lemon | Citrus |
| Coffee | - |
| Flowers (greenhouse) | - |

## 1.5 Set-up of the report

In this report the technical description is given of the calculations incorporated in PRIMET_Registration_Ethiopia 1.1. In Chapter 2 operator indoor risk is described as well as the risk for workers. Chapter 3 deals with drinking water risks and in Chapter 4 the risks concerning environmental protection goals are addressed. In Chapter 5 practical instructions given on the use of the registration tool. Guidance on how to use the external models is given in Annex 1 and 2. Example cases are provided in Annex 3 to 6.

# 2 Incorporated processes and calculations: Human Risk Assessment

## 2.1 Introduction

In this Chapter two protection goals are discussed, being the operator indoor and the worker (both indoor and outdoor). For both protection goals the derived exposure concentration is described as well as the 'safe' concentration, being the AOEL. The associated risk is then quantified, being the ratio between the predicted exposure concentration and the safe concentration. Each section starts with the description of the exposure calculation, then the safe concentration is described, followed by the risk assessment. Each section ends with an overview of required input and other relevant parameters.

## 2.2 Operator in greenhouse (indoor)

The methodology as implemented in the Dutch Greenhouse Model forms the basis for the risk assessment of this specific protection goal (www.ctgb.nl). This protection goal is only relevant for indoor grown crops being: flowers, unions, cabbage and tomato. The application type considered is manual spraying.

### 2.2.1 Exposure assessment operator indoor

The operator indoor exposure scenario consist of joint exposure via mixing/ loading and exposure via spray application. Two routes are considered, i.e. exposure via inhalation and dermal exposure. Dermal exposure is estimated according to:

$$DE_{oi} = \frac{AR \cdot SV_{DE} \cdot A}{PPE_{DE}} \quad (1)$$

with,

| | | |
|---|---|---|
| $DE_{oi}$ | = | Dermal Exposure for the operator indoor (mg $d^{-1}$) |
| $AR$ | = | Application Rate (kg a.i./ha ) |
| $A$ | = | Treated area (ha $d^{-1}$). Default is 1 ha $d^{-1}$. |
| $SV_{DE}$ | = | Surrogate exposure Value for dermal exposure (mg $kg^{-1}$ ). The default value is 200 mg $kg^{-1}$. |
| $PPE_{DE}$ | = | Personal protection equipment factor (-). Default value is 1 (first tier). For higher tier risk assessments the Personal Protection Equipment (PPE)as suggested for Ethiopia is given in Table 2. In PRIMET the use of PPE results in dermal exposure reduction of 90%. |

Table 2
*Personal protection equipment used by operators indoor (exposure).*

| |
|---|
| Protective gloves (mixing/loading) |
| Protective gloves (appl.) |
| Protective garment + sturdy footwear (appl.) |

Inhalation exposure is estimated according to:

$$IE_{oi} = \frac{AR \cdot SV_{IE} \cdot A}{PPE_{IE}} \quad (2)$$

with,

| | | |
|---|---|---|
| $IE_{oi}$ | = | Inhalation Exposure for the operator indoor (mg $d^{-1}$) |
| $AR$ | = | Application Rate (kg a.i./ha ) |
| $A$ | = | Treated area (ha $d^{-1}$). Default is 1 ha $d^{-1}$. |
| $SV_{IE}$ | = | Surrogate exposure Value for inhalation exposure (mg $kg^{-1}$ ). Default value is 1 mg $kg^{-1}$. |
| $PPE_{IE}$ | = | Personal protection equipment factor (-). Default value is 1 (first tier). For higher tier risk assessments the personal protection equipment as suggested for Ethiopia is given in Table 3. In PRIMET the use of PPE results in an inhalation exposure reduction of 90%. |

Table 3

*Personal protection equipment used by operators indoor(inhalation).*

| |
|---|
| Particle filtering half mask (mixing/loading) |
| Half mask with combined filter (mixing/loading) |
| Particle filtering half mask (appl.) |
| Half mask with combined filter (appl.) |

The systemic exposure, $SE_{oi}$ (mg/ (kg bw d)) is then derived by:

$$SE_{oi} = \frac{DE_{oi} \cdot Ab_{d,oi} + IE_{oi} \cdot Ab_{i,oi}}{bw \cdot 100} \qquad (3)$$

with,

| | | |
|---|---|---|
| $SE_{oi}$ | = | Systemic Exposure for the operator indoor (mg / (kg bw d) ) |
| $DE_{oi}$ | = | Dermal Exposure for the operator indoor (mg $d^{-1}$) |
| $IE_{oi}$ | = | Inhalation Exposure for the operator indoor (mg $d^{-1}$) |
| $Ab_{d,oi}$ | = | Dermal absorption for operators indoor (%). |
| $Ab_{i,oi}$ | = | Inhalation absorption for operators indoor (%), the default value is 100%. |
| $bw$ | = | Body weight (kg). Default 60 kg. |

### 2.2.2 Acceptable exposure level operator indoor

The Acceptable Operator Exposure Level (AOEL, mg/ (kg bw d)) is used as the reference toxicity value.

### 2.2.3 Risk assessment operator indoor

The risk, expressed in *Exposure Toxicity Ratio* $ETR_{oi}$ as result of mixing, loading and application in greenhouses is:

$$ETR_{oi} = \frac{SE_{oi}}{AOEL} \qquad (4)$$

with,

| | | |
|---|---|---|
| $SE_{oi}$ | = | Systemic Exposure for operator indoor (mg/ (kg bw d)) |
| $AOEL$ | = | Acceptable Operator Exposure Level (mg/ (kg bw d)) |
| $ETR_{oi}$ | = | Exposure toxicity ratio for operator indoor (-) |

If:

| | |
|---|---|
| $ETR_{oi}$ =< 1 | No Risk (indicated by a green colour) |
| $ETR_{oi}$ > 1 | High Risk (indicated by a red colour) |

### 2.2.4 Parameters for the operator indoor risk assessment

#### 2.2.4.1 Input scenario parameters

The scenario input default values listed in this section are set to 'read-only; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

| | | |
|---|---|---|
| $A$ | = | Treated area (ha $d^{-1}$). Default is 1 ha $d^{-1}$. |
| $bw$ | = | Body weight (kg). Default 60 kg. |
| $Ab_{i,oi}$ | = | Inhalation absorption for operators indoor (%), the default value is 100%. |
| $SV_{DE}$ | = | Surrogate exposure Value for dermal exposure (mg $kg^{-1}$ ). Default is 200 mg $kg^{-1}$. |
| $SV_{IE}$ | = | Surrogate exposure Value for inhalation exposure (mg $kg^{-1}$ ). Default is 1 mg $kg^{-1}$. |

#### 2.2.4.2 Input pesticide parameters

| | | |
|---|---|---|
| $AOEL$ | = | Acceptable Operator Exposure Level (mg/ (kg bw d)) |

#### 2.2.4.3 Input application parameters

| | | |
|---|---|---|
| $AR$ | = | Application Rate (kg a.i. /ha ) |
| $PPE_{DE}$ | = | Personal protection factor (-) for dermal exposure. If the reduction option is false, $PPE_{DE}$ is 1, if the reduction option is true, $PPE_{DE}$ is 10. |
| $PPE_{IE}$ | = | Personal protection factor (-) for inhalation exposure. If the reduction option is false, $PPE_{DE}$ is 1, if the reduction option is true, $PPE_{DE}$ is 10. |
| $Ab_{d,oi}$ | = | Dermal absorption for operators indoor (%). |

#### 2.2.4.4 Calculated parameters

| | | |
|---|---|---|
| $DE_{oi}$ | = | Dermal Exposure for the operator indoor (mg $d^{-1}$) |
| $IE_{oi}$ | = | Inhalation Exposure for the operator indoor (mg $d^{-1}$) |
| $SE_{oi}$ | = | Systemic Exposure for the operator indoor (mg/ (kg bw d)) |
| $ETR_{oi}$ | = | Exposure toxicity ratio for operator indoor (-) |

## 2.3 Worker (indoor and outdoor)

The methodology of the EUROPOEM II model (www.ctgb.nl) has been implemented in PRIMET_Registration_Ethiopia.

### 2.3.1 Exposure assessment worker

For workers, only dermal exposure is considered. Dermal exposure is estimated according to:

$$DE_{wio} = AR \cdot DFR \cdot TC \cdot T_{wio} \quad (5)$$

with,

| | | |
|---|---|---|
| $DE_{wio}$ | = | Dermal Exposure for the worker (indoor and outdoor) (mg $d^{-1}$) |
| $AR$ | = | Application Rate (kg a.i./ha ) |
| $DFR$ | = | Dislodgeable Foliar Residue (mg a.i. $m^{-2}$ / (kg a.i. $ha^{-1}$)). Default 30 (mg $m^{-2}$) / (kg $ha^{-1}$). |
| $TC$ | = | Transfer coefficient ($m^2$ $hr^{-1}$). See Table 4 for TC values per crop. |
| $T_{wio}$ | = | Duration of tasks (hr $d^{-1}$). Default 8 hr $d^{-1}$. |

The systemic exposure, $SE_{wio}$ (mg/(kg bw/ d)), is then derived with:

$$SE_{wio} = \frac{DE_{wio} \cdot Ab_{d,wio}}{bw \cdot 100} \quad (6)$$

With,

| | | |
|---|---|---|
| $SE_{wio}$ | = | Systemic Exposure for the worker (indoor and outdoor) (mg/(kg bw/ d)) |
| $DE_{wio}$ | = | Dermal Exposure for the worker (indoor and outdoor) (mg $d^{-1}$) |
| $Ab_{d,wio}$ | = | Dermal absorption for the worker (indoor and outdoor) (%). |
| *bw* | = | Body weight (kg). Default 60 kg. |

Table 4

*Default values Transfer Coefficients (TC) for the Ethiopian crops.*

| Crop | *TC* ($m^2$ $hr^{-1}$) |
|---|---|
| Tomato (grown horizontal) | 0.25 |
| Tomato (grown vertical-greenhouse) | 0.45 |
| Onion | 0.25 |
| Cabbage | 0.25 |
| Potato | 0.25 |
| Teff | 0.5 |
| Wheat | 0.5 |
| Maize | 0.5 |
| Barley | 0.5 |
| Faba bean | 0.45 |
| Sweet potato | 0.25 |
| cotton | 0.45 |
| Mango | 0.45 |
| Sugarcane | 0.5 |
| Banana | 0.45 |
| Lemon | 0.45 |
| Coffee | 0.45 |
| Flowers (greenhouse) | 0.5 |

Acceptable exposure level assessment worker

The Acceptable Operator Exposure Level (AOEL, kg/(kg bw d)) is used as the reference toxicity value for workers.

### 2.3.2 Risk assessment worker

The risk, expressed in *Exposure-Toxicity Ratio* ($ETR_{wio}$ ) for workers (indoor and outdoor) is:

$$ETR_{wio} = \frac{SE_{wio}}{AOEL} \qquad (7)$$

with

| | | |
|---|---|---|
| $SE_{wio}$ | = | Systemic Exposure for the worker (indoor and outdoor) (mg/(kg bw d)) |
| *AOEL* | = | Acceptable Operator Exposure Level (mg/(kg bw d)) |
| $ETR_{wio}$ | = | Exposure toxicity ratio for the worker (indoor and outdoor) (-) |

If:

| | |
|---|---|
| $ETR_{wio} < 1$ | No Risk (indicated by a green colour) |
| $ETR_{wio} > 1$ | High Risk (indicated by a red colour) |

### 2.3.3 Parameters for worker indoor and outdoor

#### 2.3.3.1 Input scenario parameters

The scenario input default values listed in this section are ‘read-only; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

*Standard*

| | | |
|---|---|---|
| *DFR* | = | Dislodgeable Foliar Residue (mg a.i. $m^{-2}$ / (kg a.i. $ha^{-1}$)). Default 30 mg $m^{-2}$/(kg $ha^{-1}$). |
| *bw* | = | Body weight (kg). Default 60 kg. |
| $T_{wio}$ | = | Duration of tasks (hr $d^{-1}$). Default 8 hr $d^{-1}$. |

*In database*

| | | |
|---|---|---|
| *TC* | = | Transfer coefficient ($m^2$ $hr^{-1}$). See Table 4 for TC values per crop. |

#### 2.3.3.2 Input pesticide parameters

| | | |
|---|---|---|
| *AOEL* | = | Acceptable Operator Exposure Level (mg/(kg bw d)) |

#### 2.3.3.3 Input application parameters

| | | |
|---|---|---|
| *AR* | = | Application Rate (kg a.i./ha ) |
| $Ab_{d,wio}$ | = | Dermal absorption for the worker (indoor and outdoor) (%). |

#### 2.3.3.4 Calculated parameters

| | | |
|---|---|---|
| $DE_{wio}$ | = | Dermal Exposure for the worker (indoor and outdoor) (mg $d^{-1}$) |
| $SE_{wio}$ | = | Systemic Exposure for the worker (indoor and outdoor) (mg/(kg bw d)) |
| $ETR_{wio}$ | = | Exposure toxicity ratio for the worker (indoor and outdoor) (-) |

# 3 Incorporated processes and calculations: drinking water risk assessment

## 3.1 Introduction

This section describes the risk assessment for humans resulting from the consumption of groundwater or surface water used as a source for drinking water. Ethiopian specific scenarios were designed to generate aimed 99$^{th}$ percentile exposure concentrations (also referred to as Predicted Environmental Concentration, PEC) for each specified protection goal. For surface water, short term and long term risks are considered, whereas for groundwater only long term risks are considered. See for background information on scenario selection and parameterisation of the models, Adriaanse *et al.* (2014).

In this Chapter first an overview is given of the exposure concentrations for groundwater and for surface water and the corresponding intake is derived. Details can be found in Adriaanse *et al.* (2014). Then, the reference intake is discussed (chronic and acute) followed by the risk assessments and the required input parameters and other parameters used.

## 3.2 Exposure assessment for drinking water

### 3.2.1 Groundwater as source of drinking water

#### 3.2.1.1 Groundwater exposure assessment

For groundwater in Ethiopia, four groundwater specific protection goals have been identified. These are provided in the Table 5.

Table 5

*Groundwater specific protection goals for Ethiopia.*

| no | Protection goal | Grid no. | Name location |
|---|---|---|---|
| 1. | Alluvial aquifers along small rivers in areas above 1500 m | 219 | Bichena (Amhara region) |
| 2. | Volcanic aquifers on shallow wells in areas above 1500 m | 219 | Bichena (Amhara region) |
| 3a. | Alluvial aquifers in the Rift Valley margins and lowland areas below 1500m | 346 | Ca. 100 km SW of Jimma (SNNP) |
| 3b. | Alluvial aquifers in the Rift Valley margins between 1500 and 2000m | 323 | Abala Kulito (SNNP) |

For each of these protection goals scenario locations have been selected for which the leaching concentration is calculated in PRIMET_Registration_Ethiopia. Protection goal 1 and 2 have been merged to one scenario location/calculation.

To estimate the leaching of pesticides to groundwater, a meta-model of the spatially distributed European pesticide leaching model EuroPEARL is incorporated into PRIMET_Registration_Ethiopia. The meta-model is based on an analytical expression that describes the mass fraction of pesticide leached (Tiktak *et al.* 2006). The meta-model ignores vertical parameter variations and assumes steady state flow. The meta-model is based on simulations in which the pesticide is applied each year. The metamodel estimates the predicted environmental concentration (PEC) for a standard application of 1

kg a.i./ha and is calibrated to estimate the 80th percentile of the leaching concentration at 1-m depth. This is the so-called predicted environmental concentration (PEC) which can be derived using Eq. (8):

$$\ln(PEC_{gw,1kg/ha}) = \alpha_0 - \alpha_1 X_1 - \alpha_2 X_2 \quad (8)$$

with,

| | | |
|---|---|---|
| $PEC_{gw,\ 1\ kg/ha}$ | = | Predicted Environmental Concentration, annual average concentration leaching from the soil profile at 1 m depth. This concentration is valid for a standard application of 1 kg/ha (µg/L). |
| $a_0$, $a_1$ and $a_2$ | = | Regression coefficients |
| $X_1$ and $X_2$ | = | Independent regression variables (-) |

$X_1$ and $X_2$ are defined by:

$$X_1 = \frac{k_{s\_T}\Theta D_{gw}}{q/365000} \quad (9)$$

$$X_2 = \frac{k_{s\_T}\rho_b f_{om} K_{om} D_{gw}}{q/365000} \quad (10)$$

with,

| | | |
|---|---|---|
| $k_{s\_T}$ | = | Degradation rate coefficient in soil at ambient temperature $T$, $T$ has a default of 293.15 K |
| $\theta$ | = | Volume fraction of water ($m^3m^{-3}$). A default parameter which is 0.25 $m^3m^{-3}$. |
| $D_{gw}$ | = | Depth groundwater (m), default is 1 m. |
| $\rho_b$ | = | Dry bulk density soil (kg $dm^{-3}$). Each groundwater specific protection goal has a different dry bulk density. Values are provided in Table 6. |
| $f_{om}$ | = | Organic matter content (kg $kg^{-1}$). Each groundwater specific protection goal has a different organic matter content. Values are provided in Table 6. |
| $K_{om}$ | = | Sorption coefficient on organic matter ($dm^3kg^{-1}$) |
| $q$ | = | Volume flux of water (mm $yr^{-1}$). The volume flux is different for the 4 protection goals. In Table 6, $q$ is given for each protection goal. |
| 365000 | = | Factor to correct from mm $yr^{-1}$ to m $d^{-1}$. |

The degradation rate coefficient at reference temperature in soil is derived according to:

$$k_{s\_Tref} = \frac{\ln(2)}{DT50_{soil}} \quad (11)$$

with,

| | | |
|---|---|---|
| $k_{s\_Tref}$ | = | Degradation rate coefficient in soil at reference temperature ($d^{-1}$) |
| $DT50_{soil}$ | = | Half-life in soil due to degradation at reference temperature (d) |

The degradation rate coefficient at $T$= 20°C, or 293.15 K can be calculated with the Arrhenius equation from the degradation rate coefficient determined at reference temperature i.e. the temperature at which the $DT50_{soil}$ can be determined, using Eq. (12):

$$k_{s\_T} = k_{s\_Tref} \exp\left[\frac{-E_a}{R}\left(T^{-1} - T_{ref}^{-1}\right)\right] \quad (12)$$

With:

| | | |
|---|---|---|
| $T$ | = | Ambient temperature (K), default is 293.15 K. |
| $T_{ref}$ | = | Reference temperature, at which $DT50_{soil}$ was determined (K) |
| $k_{s\_T}$ | = | Degradation rate coefficient in soil at temperature $T$, $T$ has a default of 293.15 K |
| $k_{s\_Tref}$ | = | Degradation rate coefficient in soil at reference temperature ($d^{-1}$) |
| $E_a$ | = | Molar Arrhenius activation energy (J $mol^{-1}$). A constant parameter, which is 54000 J $mol^{-1}$. |
| $R$ | = | Universal gas constant (J $mol^{-1}$ $K^{-1}$). A constant parameter, which is approx. 8.3144 J $mol^{-1}$ $K^{-1}$. |

The regression coefficients, $a_0$, $a_1$ and $a_2$, have been calibrated for a warm-wet region with a mean annual rainfall > 0.8 m/yr and a mean annual temperature > 12.5 °C (Tiktak *et al.*, 2006) and an annually applied (spring) application of 1kg $ha^{-1}$ in maize, one day before emergence. For these circumstances the regression coefficients are $a_0$ = 4.81, $a_1$ = 0.58 and $a_2$ = 0.46.

If the sorption coefficient on organic matter, $K_{om}$ is not directly available it may be calculated from the more available $K_{oc}$ according:

$$K_{om} = K_{oc} / 1.724 \tag{13}$$

with:

| | | |
|---|---|---|
| $K_{om}$ | = | Sorption coefficient on organic matter ($dm^3kg^{-1}$) |
| $K_{oc}$ | = | Sorption coefficient on organic carbon ($dm^3kg^{-1}$) |

The metamodel estimates the predicted environmental concentration (*PEC*) for a standard application of 1 kg a.i./ha. To estimate the PEC all applications in one year in kg a.i./ha have to be added. Furthermore, a groundwater specific correction factor corrects for the analytical approximation, which is derived for a 80$^{th}$ percentile situation. For Ethiopia the end point of the leaching assessment is defined as 99$^{th}$ percentile. The correction factor $cf_{gw}$ accounts for this difference in percentile. The *PEC* is calculated using[1]:

$$PEC^{n}_{gw} = PEC_{gw,1kg/ha} \cdot AR \cdot n \cdot cf_{gw} \tag{14}$$

with,

| | | |
|---|---|---|
| $PEC_{gw,\ 1\ kg/ha}$ | = | Predicted Environmental Concentration, annual average concentration leaching from the soil profile at 1 m depth. This concentration is valid for a standard application of 1 kg $ha^{-1}$ (µg $L^{-1}$). |
| $PEC^{n}_{gw}$ | = | Predicted Environmental Concentration of *n* applications within one year, annual average concentration leaching from the soil profile at 1 m depth (µg $L^{-1}$). |
| $AR$ | = | Application Rate (kg a.i. $ha^{-1}$ ) |
| $n$ | = | Number of applications (-) |
| $cf_{gw}$ | = | Correction factor to account for the difference in calculated PEC between a 80$^{th}$ percentile (analytical solution) and a 99$^{th}$ percentile (end point). The correction factor is default 3 (-). |

[1] Note that *AR* times *n* is equal to *Mstacked* as referred to in Peeters *et al.*, 2006

Table 6

*Organic matter content, $f_{om}$ (kg kg$^{-1}$) dry bulk density, $\rho_b$ (kg dm$^{-3}$), and annual average volume flux of percolating water to groundwater, q (mm yr$^{-1}$), for the groundwater specific protection goals.*

| Protection goal | Grid no | $f_{om}$ (kg kg$^{-1}$) | $\rho_b$(kg dm$^{-3}$) | $q$ (mm yr-1) |
|---|---|---|---|---|
| 1 + 2 | 219 | 0.0034 | 1.528 | 879 |
| 3a | 346 | 0.0072 | 1.375 | 888 |
| 3b | 323 | 0.0057 | 1.390 | 700 |

The PEC calculated for scenario 1 and 2 is calculated with the same input parameters.

#### 3.2.1.2 Chronic exposure assessment for groundwater as source for drinking water

The chronic daily intake is then equal to:

$$DI_{\text{gw\_chronic}} = \frac{Cons_{\text{water}} \cdot PEC_{gw}^{n}}{1000 \cdot bw} \qquad (15)$$

with,

$DI_{\text{gw\_chronic}}$ = Daily Intake Chronic of groundwater per kg body weight (mg kg$^{-1}$ d$^{-1}$). This value is calculated for each of the 4 protection goals.

$Cons_{\text{water}}$ = Daily drinking water consumption, default is 2L.

$bw$ = Body weight (kg). Default 60 kg.

$PEC^{n}_{gw}$ = Predicted Environmental Concentration of *n* applications within one year, annual average concentration leaching from the soil profile at 1 m depth (µg L$^{-1}$).

1000 = Factor to convert from µg L$^{-1}$ to mg L$^{-1}$.

### 3.2.2 Surface water as source for drinking water

#### 3.2.2.1 Surface water exposure scenarios

The main protection goals for surface water in Ethiopia are considered to be small streams with an upstream catchment and retreating ponds as a source for drinking water. For the ponds, two scenario zones were identified being ponds situated below 1500 m altitude and ponds situated between 1500 and 2000 m altitude. In Table 7, the considered protection goals are listed as well as the scenario zones. For each protection goal-scenario zone combination a specific scenario location has been identified. The selected grid number and the name of the location are given in the Table as well. The grid numbers refer to grid numbers as identified by Adriaanse et al (2014) by selecting from the world wide ERA interim dataset with a grid resolution of about 0.75°x0.75° (Dee *et al.*, 2011) a rectangular area of 572 grids covering Ethiopia.

Table 7

*Selected scenario location for each groundwater protection goal*

| no | Protection goal | Selected grid[2] | Name scenario location |
|---|---|---|---|
| 1. | Small streams in areas above 1500 m | 191 | West of Lake Tana (1682 m altitude and 2581 mm long term average rain) |
| 2a. | Temporary ponds below 1500 m with more than 500 mm long term average rain. | 373 | West of Arba Minch (1288 m altitude and 1702 mm long term average rain) |
| 2b. | Temporary ponds between 1500 - 2000 m. | 217 | South East of Bure (1705 m altitude and 2779 mm long term average rain) |

Each scenario location corresponds to a specific set of crop types grown in the corresponding scenario zone. In Table 8 the relevant crop scenario-crop combinations are indicated with a cross.

[2] ERA interim dataset (Dee *et al.*, 2011)

Table 8

*Crop types valid for the scenario zones for Surface water as source for drinking water.*

| Crop type | Small stream scenario | Temp. pond scenario < 1500 m | Temp. pond scenario 1500-2000 m |
|---|---|---|---|
| Tomato | X | X | X |
| Onion | X | X | X |
| Cabbage | X | X | X |
| Potato | X | X | X |
| Teff | X | X | X |
| Wheat | X | X | X |
| Maize | X | X | X |
| Barley | X | | X |
| Faba bean | X | | X |
| Sweet potato | | X | |
| Cotton | | X | |
| Mango | | X | |
| Sugarcane | | X | |
| Banana | | X | |
| Lemon | X | X | X |
| Coffee | X | X | X |
| Flowers | | | |

After the user has selected a crop and has specified the pesticide properties, PRIMET calculates the annual maximum concentrations in surface water for 1 to 3 scenario locations, while using two pesticide fate models that are ran consecutively. Per scenario location, 33 annual maximum concentrations are calculated over the period 1903-1935 (using meteorological data from the period 1979-2011) and the aimed (overall) 99th percentile concentration is selected (Adriaanse *et al.*, 2014). PRIMET_Registration_Ethiopia accounts for the construction of the correct input files, the consecutive running of the models and for providing the correct end-points to the user, being the aimed 99$^{th}$ percentile concentration, which is used in the next steps in the risk assessment, see Section 3.2.2.3 and further.

PRZM is used to calculate the surface water concentration for the small stream and a post-processing program selects the aimed 99$^{th}$ percentile concentration. For this scenario run-off is considered the most important source of pesticide contamination. PRZM and TOXSWA are used to calculate the surface water concentration in both pond scenarios and a post processing program selects the aimed 99$^{th}$ percentile. For these scenarios, apart from run-off, drift is considered an important source of pesticide contamination.
For information on TOXSWA and PRZM we refer to (Adriaanse, 1996 ) and (Carsel *et al.*, 1996), respectively. In this technical manual only the required input parameters are listed for constructing the input files. We refer to Adriaanse *et al.*(2014) for background information on the scenarios, the models and the parameterization of the models.

#### 3.2.2.2 Required input parameters for the calculation of the *PEC*s

In contrast to other protection goals, exact application dates are required for the calculation of the surface water Predicted Environmental Concentration (PEC). When the first date of the application is known, the other application dates are calculated automatically (based on the number of applications and the time interval between applications). The application dates are used as input for PRZM.

The required application parameters for surface water are then (all are required as input for PRZM):

$AP_{start}$ = Application start date. The application dates are given in the Gregorian (Christian) calendar. The format of the dates depends on the computer settings.
$AR$ = Application rate (kg a.i. ha$^{-1}$)
$i$ = Time interval between applications (d)
$n$ = Number of applications (-)

In addition, the user should define the application method, which can be either by knapsack or tractor mounted. Each application method gives a different drift deposition percentage on the ponds. An overview of spray drift deposition as percentage of the application rate is provided in Table 9 per crop

type and the application types ‘tractor mounted’ and ‘knapsack’. Requested pesticide properties per model are listed in Table 10.

Table 9

*Spray drift deposition as percentage of the application rate for Ethiopian crops.*

| Crop type | Deposition (%), tractor mounted | Deposition (%), knapsack spraying |
|---|---|---|
| Tomato | 0.127 | 0.127 |
| Onion | 0.127 | 0.127 |
| Cabbage | 0.127 | 0.127 |
| Potato | 0.1229 | 0.127 |
| Teff | 0.127 | 0.127 |
| Wheat | 0.1229 | 0.127 |
| Maize | 0.127 | 0.127 |
| Barley | 0.127 | 0.127 |
| Faba bean | 0.1229 | 0.127 |
| Sweet potato | 0.1229 | 0.127 |
| Cotton | 0.1229 | 0.127 |
| Mango | 1.0459 | - |
| Sugarcane | 0.1229 | 0.127 |
| Banana | 0.1204 | 0.127 |
| Lemon | 1.0459 | - |
| Coffee | 1.0459 | - |
| Flowers | - | - |

During the dry season some crops are cultivated with the aid of irrigation. The most common crops being cultivated with irrigation are tomatoes, onions, cabbage and (Irish) potato. These crops are often cultivated twice during the year: one rain fed crop cycle and one irrigated crop cycle. The risk is therefore assessed separately for the first and the second crop. A first and second crop is defined in the crop Table in PRIMET_Registration_Ethiopia. The first crop cycle represents crop cultivation during the rainy season (Kremt; no irrigation) and the second crop cycle represents crop cultivation during the dry season (Bega, irrigated). See Chapter 5 for instructions on the use of the tool.

Table 10

*The required pesticide properties for PRZM and TOXSWA.*

| abbreviation | description | unit | required for |
|---|---|---|---|
| MolMass | molar mass | g $mol^{-1}$ | PRZM & TOXSWA |
| $DT50_{sediment}$ | half-life in sediment due to degradation at reference temperature | d | TOXSWA |
| $T_{refDT50sediment}$ | reference temperature, at which the DT50 in sediment was determined | K | TOXSWA |
| $DT50_{water}$ | half-life in water due to degradation at reference temperature, including processes such as hydrolysis and microbial degradation | d | TOXSWA |
| $T_{refDT50water}$ | reference temperature, at which the DT50 in water was determined | K | TOXSWA |
| $DT50_{soil}$ | half-life in soil due to degradation at reference temperature | d | PRZM |
| $T_{refDT50soil}$ | reference temperature, at which the DT50 in soil was determined | K | PRZM |
| $n_{soil}$ | Freundlich exponent in soil. Default is 0.9. In the TOXSWA calculations it is assumed that the Freundlich exponent for suspended solids and for sediment is the same as for soil. | - | PRZM & TOXSWA |
| $K_{oc\_soil}$ | sorption coefficient of organic carbon in soil. In the TOXSWA calculations it is assumed that the sorption coefficient for suspended solids and for sediment is the same as for soil. | $dm^3kg^{-1}$ | PRZM & TOXSWA |
| $ConRef_{soil}$ | reference concentration in sediment. . In the TOXSWA calculations it is assumed that the concentration for suspended solids and for sediment is the same as for soil. Default is 1 mg $L^{-1}$. | mg $L^{-1}$ | PRZM & TOXSWA |
| $VP_{Tref}$ | saturated vapour pressure of substance at reference temperature | Pa | PRZM & TOXSWA |
| $T_{refVP}$ | reference temperature, at which the saturated vapour pressure was determined | K | PRZM & TOXSWA |
| $SOL_{Tref}$ | solubility of substance in water at reference temperature | mg $L^{-1}$ | PRZM & TOXSWA |
| $T_{refSOL}$ | reference temperature, at which the solubility was determined | K | PRZM & TOXSWA |

Pesticide degradation and volatilization in water are temperature dependent. For PRZM the degradation rate in soil is corrected by PRIMET similar as for groundwater (Eq. 12). TOXSWA accounts internally for the temperature correction while using the Arrhenius equation (Adriaanse *et al.*, 1996).

*Saturated vapour pressure*

The dependency of the saturated vapour pressure on the temperature is derived using the Van 't Hoff equation (Van den Berg en Boesten, 1998):

$$VP_{\mathrm{T}} = VP_{\mathrm{Tref}} \exp\left[ -\frac{\Delta H_{\mathrm{p}}}{R}\left(T^{-1} - T_{\mathrm{refVP}}^{-1}\right)\right] \tag{16}$$

With

| | | |
|---|---|---|
| $VP_T$ | = | Saturated vapour pressure of substance at ambient temperature (Pa) |
| $VP_{\mathrm{Tref}}$ | = | Saturated vapour pressure of substance at reference temperature (Pa) |
| $T_{\mathrm{refVP}}$ | = | Reference temperature, at which $VP_{\mathrm{Tref}}$ was determined (K) |
| $T$ | = | Ambient temperature in scenario (K) |
| $\Delta H_{\mathrm{P}}$ | = | Enthalpy of vaporization (constant parameter = 95000 J/mol) |
| $R$ | = | Universal gas constant (J $mol^{-1}$ $K^{-1}$) A constant parameter, which is approx. 8.3144 J $mol^{-1}$ $K^{-1}$. |

*Solubility*

The effect of the temperature difference on the water solubility is also accounted for using the Van 't Hoff equation (Van den Berg en Boesten, 1998):

$$SOL_{\mathrm{T}} = SOL_{\mathrm{Tref}} \exp\left[ -\frac{\Delta H_{\mathrm{SOL}}}{R}\left(T^{-1} - T_{\mathrm{refSOL}}^{-1}\right)\right] \tag{17}$$

with:

| | | |
|---|---|---|
| $SOL_{\mathrm{T}}$ | = | Solubility of substance in water at ambient temperature (mg/L) |
| $SOL_{\mathrm{Tref}}$ | = | Solubility of substance in water at reference temperature (mg/L) |
| $T$ | = | Ambient temperature in scenario (K) |
| $T_{\mathrm{refSOL}}$ | = | Reference temperature, at which $SOL_{\mathrm{Tref}}$ was determined (K) |
| $\Delta H_{\mathrm{SOL}}$ | = | Enthalpy of dissolution (constant parameter = 27000 J/mol) |
| $R$ | = | Universal gas constant (J $mol^{-1}$ $K^{-1}$) A constant parameter, which is approx. 8.3144 J $mol^{-1}$ $K^{-1}$. |

*Henry coefficient*

The Henry coefficient is required as input for PRZM. The coefficient can be calculated by:

$$K_{\mathrm{h}} = \frac{VP_T \cdot MolMass}{R \cdot T \cdot SOL_{\mathrm{T}}} \tag{18}$$

with,

| | | |
|---|---|---|
| $K_{\mathrm{h}}$ | = | Dimensionless Henry coefficient (-) |
| $VP_{\mathrm{T}}$ | = | Saturated vapour pressure of substance at ambient temperature (Pa), see Eq. (16) for the temperature correction. |
| *MolMass* | = | Molecular weight of the pesticide under investigation (g $mol^{-1}$) |
| $R$ | = | Universal gas constant (J $mol^{-1}$ $K^{-1}$) A constant parameter, which is approx. 8.3144 J $mol^{-1}$ $K^{-1}$. |
| $T$ | = | Ambient temperature in scenario (K), default is 273.15 K |
| $SOL_{\mathrm{T}}$ | = | Solubility of substance in water at ambient temperature (mg $L^{-1}$), see Eq. (17) for the temperature correction. |

#### 3.2.2.3 Acute exposure assessment for surface water as source for drinking water

To assess the short term risk, the risk is associated with drinking a large volume (or Large Portion) of water during 1 day. For Ethiopia a Large Portion is 6 liter per day. The daily intake acute is equal to:

$$DI_{\text{sw\_acute}} = \frac{LP_{\text{water}} \cdot PEC_{sw}}{1000 \cdot bw} \quad (19)$$

with,

| | | |
|---|---|---|
| $DI_{\text{sw\_acute}}$ | = | Daily Intake Acute of surface water per kg body weight (mg $kg^{-1}$ $d^{-1}$). This value is calculated for the relevant protection goals. |
| $LP_{\text{water}}$ | = | Large Portion, default is 6L $d^{-1}$. |
| $bw_{\text{consumption}}$ | = | Body weight (kg). Default 60 kg. |
| $PEC_{\text{sw}}$ | = | Predicted Environmental Concentration, 99$^{th}$ percentile concentration in surface water. This value is calculated for the relevant protection goals. |
| 1000 | = | Factor to convert from µg $L^{-1}$ to mg $L^{-1}$ |

#### 3.2.2.4 Chronic exposure assessment for surface water as source for drinking water

To assess the long term risk the risk, is associated with daily drinking water consumption. In Ethiopia the daily consumption is 2 liter. The daily intake chronic is then equal to:

$$DI_{\text{sw\_chronic}} = \frac{Cons_{\text{water}} \cdot PEC_{sw}}{1000 \cdot bw} \quad (20)$$

with,

| | | |
|---|---|---|
| $DI_{\text{sw\_chronic}}$ | = | Daily Intake Acute of surface water per kg body weight (mg $kg^{-1}$ $d^{-1}$). This value is calculated for the relevant protection goals. |
| $Cons_{\text{water}}$ | = | Daily drinking water consumption, default is 2L $d^{-1}$. |
| $bw_{\text{consumption}}$ | = | Body weight (kg). Default 60 kg. |
| $PEC_{\text{sw}}$ | = | Predicted Environmental Concentration, 99$^{th}$ percentile concentration in surface water. This value is calculated for the relevant protection goals (µg $L^{-1}$). |
| 1000 | = | Factor to convert from µg $L^{-1}$ to mg $L^{-1}$ |

## 3.3 Reference intake for drinking water

### 3.3.1 Acute reference dose

The acute intake is compared to the acute toxic dose, which is the Acute Reference dose, or ARfD. The ARfD is expressed in µg per kg body weight:

| | | |
|---|---|---|
| ARfD | = | Acute Reference dose (mg $kg^{-1}$ $d^{-1}$) |

### 3.3.2 Chronic toxicity standard

The chronic intake is compared to the chronic toxicity standard (chronic risk assessment), which is the Daily Acceptable Intake Chronic.

$$DI_{\text{accept\_chronic}} = ADI \cdot P \quad (21)$$

Where *ADI* is the the Acceptable Daily Intake (mg $kg^{-1}$ $d^{-1}$). The *ADI* can be provided directly by the user or is calculated with:

$$ADI = NOAEL_{\text{mammals}} \; / \; SF_{\text{mammals}} \quad (22)$$

with,

| | | |
|---|---|---|
| $ADI$ | = | Acceptable Daily Intake (mg $kg^{-1}$ $d^{-1}$) |
| $NOAEL_{mammals}$ | = | No Observed Adverse Effect Level for mammals (mg $kg^{-1}$ $d^{-1}$) |
| $SF_{mammals}$ | = | Safety Factor for interspecies and intraspecies extrapolation, adequacy of study, nature and severity of effect (-). The default value is 100. |
| $P$ | = | Fraction of the ADI allocated to drinking-water (-). The default value is 0.1. |
| $DI_{accept\_chronic}$ | = | Daily Acceptable Intake Chronic per kg body weight (mg $kg^{-1}$ $d^{-1}$) |

The *ADI* provided by the user overrules the calculated *ADI*, when both are given.

## 3.4 Risk assessment for drinking water

### 3.4.1 Groundwater chronic risk assessment

The risk, expressed in Exposure Toxicity Ratio ($ETR_{drw\_gw\_chronic}$) for using groundwater as drinking water as a result of all stacked applications is defined as the ratio between the daily intake chronic per body weight and the Daily Acceptable Intake:

$$ETR_{drw\_gw\_chronic} = \frac{DI_{gw\_chronic}}{DI_{accept\_chronic}} \quad (23)$$

with:

| | | |
|---|---|---|
| $ETR_{drw\_gw\_chronic}$ | = | Chronic Exposure Toxicity Ratio for groundwater as a source of drinking water. This value is calculated for each groundwater protection goal. |
| $DI_{gw\_chronic}$ | = | Daily Intake Chronic of groundwater per kg body weight (mg $kg^{-1}$ $d^{-1}$). This value is calculated for each groundwater protection goal. |
| $DI_{accept\_chronic}$ | = | Daily Acceptable Intake Chronic per kg body weight (mg $kg^{-1}$ $d^{-1}$) |

If:

| | | |
|---|---|---|
| $ETR_{drw\_gw\_chronic}$ | =< 1 | No Risk (indicated by a green colour) |
| $ETR_{drw\_gw\_chronic}$ | > 1 | High Risk (indicated by a red colour) |

$ETR_{drw\_gw\_chronic}$ is calculated for each groundwater protection goal.

### 3.4.2 Surface water acute risk assessment

The risk, expressed in Exposure Toxicity Ratio ($ETR_{drw\_sw\_acute}$) for using surface water as source for drinking water is defined as the ratio between the daily intake acute per body weight and the Acute Reference dose, or ARfD:

$$ETR_{drw\_sw\_acute} = \frac{DI_{sw\_acute}}{ARfD} \quad (24)$$

with:

| | | |
|---|---|---|
| $ETR_{drw\_sw\_acute}$ | = | Acute Exposure Toxicity Ratio for surface water as a source of drinking water. This value is calculated for each of the 3 protection goals. |
| $DI_{sw\_acute}$ | = | Daily Intake Acute of surface water per kg body weight (mg $kg^{-1}$ $d^{-1}$). This value is calculated for each of the 3 protection goals. |
| ARfD | = | Acute Reference dose (mg $kg^{-1}$ $d^{-1}$) |

If:

| | | |
|---|---|---|
| $ETR_{drw\_sw\_acute}$ | =< 1 | No Risk (indicated by a green colour) |
| $ETR_{drw\_sw\_acute}$ | > 1 | High Risk (indicated by a red colour) |

$ETR_{drw\_sw\_acute}$ is calculated for 1 to 3 protection goals.

### 3.4.3 Surface water chronic risk assessment

The risk, expressed in Exposure Toxicity Ratio ($ETR_{drw\_sw\_chronic}$) for using surface water as a source for drinking water is defined as the ratio between the daily intake chronic per body weight and the Daily Acceptable Intake:

$$ETR_{drw\_sw\_chronic} = \frac{DI_{sw\_chronic}}{DI_{accept\_chronic}} \quad (25)$$

with:

$ETR_{drw\_sw\_chronic}$ = Chronic Exposure Toxicity Ratio for surface water as a source of drinking water. This value is calculated for each of the 3 protection goals.

$DI_{sw\_chronic}$ = Daily Intake Chronic of surface water per kg body weight (mg $kg^{-1}$ $d^{-1}$). This value is calculated for each of the 3 protection goals.

$DI_{accept\_chronic}$ = Daily Acceptable Intake Chronic per kg body weight (mg $kg^{-1}$ $d^{-1}$)

If:

| | |
|---|---|
| $ETR_{drw\_sw\_chronic} =< 1$ | No Risk (indicated by a green colour) |
| $ETR_{drw\_sw\_chronic} > 1$ | High Risk (indicated by a red colour) |

$ETR_{drw\_gw\_chronic}$ is calculated for 1 to 3 protection goals.

## 3.5 Parameters risk assessment for drinking water

### 3.5.1 Input scenario parameters

The scenario input default values listed in this section are set to 'read-only; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

*Standard*

$bw_{consumption}$ = Body weight (kg). Default parameter, which is 60 kg for adults.

$Cons_{water}$ = Daily drinking-water consumption (L $d^{-1}$). The default value is 2 litres for adults.

$P$ = Fraction of the ADI allocated to drinking-water (-). The default value is 0.1.

$SF_{mammals}$ = Safety Factor for interspecies and intraspecies extrapolation, adequacy of study, nature and severity of effect (-). The default value is 100.

$T$ = Temperature (K), default is 293.15 K.

$D_{gw}$ = Depth groundwater (m), default is 1 m.

$\theta$ = Volume fraction of water ($m^3m^{-3}$), default is 0.25 $m^3m^{-3}$.

$cf_{gw}$ = Correction factor to account for the difference in calculated PEC between a $80^{th}$ percentile (analytical solution) and $99^{th}$ percentile (end point). Default value is 3.

$a_0$, $a_1$ and $a_2$ = Regression coefficients. $a_0$ = 4.81, $a_1$ = 0.58 and $a_2$ = 0.46.

*In database*

$\rho_b$ = Dry bulk density soil (kg $dm^{-3}$). Each groundwater specific protection goal has a different dry bulk density. Values are provided in Table 6.

$f_{om}$ = Organic matter content (kg $kg^{-1}$) Each groundwater specific protection goal has a different organic matter content. Values are provided in Table 6.

$q$ = Volume flux of water (mm $yr^{-1}$). The volume flux is different for the 4 protection goals and varies over the simulated years. In Table 6, $q$ is given for each protection goal.

Dd = Drift deposition (%). See also Table 9.

### 3.5.2 Input pesticide parameters

| | | |
|---|---|---|
| ARfD | = | Acute Reference dose (mg $kg^{-1}$ $d^{-1}$) |
| $NOAEL_{mammals}$ | = | No Observed Adverse Effect Level for mammals (mg $kg^{-1}$ $d^{-1}$) |
| *ADI* | = | Acceptable Daily Intake (mg $kg^{-1}$ $d^{-1}$) |
| Molmass | = | Molar mass (g $mol^{-1}$) |
| $DT50_{sediment}$ | = | Half-life in sediment due to degradation at reference temperature (d) |
| $T_{refDT50sediment}$ | = | Reference temperature, at which the DT50 in sediment was determined (K). |
| $DT50_{water}$ | = | Half-life in water due to degradation at reference temperature, including processes such as hydrolysis and microbial degradation(d) |
| $T_{refDT50water}$ | = | Reference temperature, at which the DT50 in water was determined (K). |
| $DT50_{soil}$ | = | Half-life in soil due to degradation at reference temperature (d) |
| $T_{refDT50soil}$ | = | Reference temperature, at which the DT50 was determined (K). |
| $n_{soil}$ | = | Freundlich exponent in soil (-).Default is 0.9. |
| $K_{om\_soil}$ | = | Sorption coefficient of organic matter in soil ($dm^3kg^{-1}$) |
| $K_{ocsoil}$ | = | Sorption coefficient of organic carbon in soil ($dm^3kg^{-1}$) |
| $ConRef_{sediment}$ | = | Reference concentration in sediment. Default is 1 mg $L^{-1}$. |
| $ConRef_{sussol}$ | = | Reference concentration in suspended solids. Default is 1 mg $L^{-1}$. |
| $VP_{Tref}$ | = | Saturated vapour pressure of substance at reference temperature (Pa) |
| $T_{refVP}$ | = | Reference temperature, at which $VP_{Tref}$ was determined (K) |
| $SOL_{Tref}$ | = | Solubility of substance in water at reference temperature (mg $L^{-1}$) |
| $T_{refSOL}$ | = | Reference temperature, at which $SOL_{Tref}$ was determined (K) |

### 3.5.3 Input pesticide application parameters

| | | |
|---|---|---|
| *AR* | = | Application Rate (kg a.i./ha ) |
| *n* | = | Number of applications (-) |
| i | = | Interval between applications (d) |
| $AP_{start}$ | = | Application start date. The application dates are given in the Gregorian (Christian) calendar. |

### 3.5.4 Constant parameters

| | | |
|---|---|---|
| $E_a$ | = | Molar Arrhenius activation energy (J $mol^{-1}$). A constant parameter, which is 54000 J $mol^{-1}$. |
| *R* | = | Universal gas constant (J $mol^{-1}$ $K^{-1}$) A constant parameter, which is approx. 8.3144 J $mol^{-1}$ $K^{-1}$. |
| $\Delta H_P$ | = | Enthalpy of vaporization (constant parameter = 95000 J $mol^{-1}$) |
| $\Delta H_{SOL}$ | = | Enthalpy of dissolution (constant parameter = 27000 J $mol^{-1}$) |

### 3.5.5 Calculated parameters

*Valid for all protection goals*

| | | |
|---|---|---|
| $k_{s\_T}$ | = | Degradation rate coefficient in soil at temperature *T* ($d^{-1}$), *T* has a default of 293.15 K |
| $k_{s\_Tref}$ | = | Degradation rate coefficient in soil at reference temperature ($d^{-1}$) |
| *ADI* | = | Acceptable Daily Intake calculated (mg $kg^{-1}$ $d^{-1}$) |
| $K_{om\_soil}$ | = | Sorption coefficient of organic matter in soil ($dm^3kg^{-1}$) |

*Protection goal specific values*

| | | |
|---|---|---|
| $X_1$ and $X_2$ | = | Independent regression variables (-) |
| $PEC_{gw,\ 1\ kg/ha}$ | = | Predicted Environmental Concentration for groundwater, annual average concentration leaching from the soil profile at 1 m depth. This concentration is valid for a standard application of 1 kg/ha (µg/L). |
| $PEC^n_{gw}$ | = | Predicted Environmental Concentration for groundwater of n applications within one year, annual average concentration leaching from the soil profile at 1 m depth (µg $L^{-1}$). |

| | | |
|---|---|---|
| $DI_{grw\_chronic}$ | = | Daily Intake Chronic of groundwater per kg body weight (mg $kg^{-1}$ $d^{-1}$). This value is calculated for each groundwater protection goal. |
| $DI_{accept\_chronic}$ | = | Daily Acceptable Intake Chronic of groundwater per kg body weight (mg $kg^{-1}$ $d^{-1}$) |
| $ETR_{drw\_gw\_chronic}$ | = | Chronic Exposure Toxicity Ratio for groundwater as a source of drinking water. This value is calculated for each groundwater protection goal. |
| $PEC_{sw}$ | = | Predicted Environmental Concentration for surface water (µg $L^{-1}$). This value is calculated for each of max 3 protection goals. |
| $DI_{sw\_chronic}$ | = | Daily Intake Chronic of surface water per kg body weight (mg $kg^{-1}$ $d^{-1}$). This value is calculated for max 3 protection goals. |
| $DI_{sw\_acute}$ | = | Daily Intake Acute of surface water per kg body weight (mg $kg^{-1}$ $d^{-1}$). This value is calculated for max 3 protection goals. |
| $ETR_{drw\_sw\_chronic}$ | = | Chronic Exposure Toxicity Ratio for surface water as a source of drinking water. This value is calculated for max 3 protection goals. |
| $ETR_{drw\_sw\_acute}$ | = | Acute Exposure Toxicity Ratio for surface water as a source of drinking water. This value is calculated for max 3 protection goals. |

# 4 Incorporated processes and calculations: Environmental Risk Assessment

## 4.1 Introduction

The environmental risk assessment contains six protection goals being aquatic ecosystem, terrestrial ecosystem, bees, non-target arthropods, birds and non-target plants. These protection goals will be discussed in the next sections.

## 4.2 Aquatic ecosystem risk assessment

For the protection goal Aquatic ecosystem, acute as well as chronic risks are considered. Acute risk is assessed for fish, aquatic invertebrates. A risk assessment for aquatic plants is included specifically for herbicides. A chronic risk assessment is performed for fish and aquatic invertebrates and algae. For both the acute as well as the chronic risk assessment the maximum *PEC* ($PEC_{max}$) is taken as the relevant exposure concentration in surface water.

### 4.2.1 Aquatic exposure assessment

For the derivation of the PEC for aquatic ecosystems, the pesticide fate models PRZM and TOXSWA are used. PRIMET_Registration_Ethiopia takes care that the correct input files are constructed, the models are run and that the correct PEC is read from the output of these models and used in the risk assessment.

The main protection goals for aquatic ecosystems are small streams and retreating ponds (see also Deneer *et al.*, 2014). The approach towards the derivation, selection and parameterisation of scenarios for aquatic ecosystems was the same as for Surface water as source for drinking water. The main difference between both protection goals is that the aimed percentile for aquatic ecosystems is the 90$^{th}$ percentile, whereas for Surface water as source for drinking water the aimed percentile is the 99$^{th}$ percentile.

Both scenario selection procedures resulted in a selection of the same locations and the same model parameterisations for Surface water as source for drinking water and for Aquatic ecosystems. The temporal percentile, however, is different from Surface water as source for drinking water. We refer to Section 3.2.2 for the description of the selection of the scenario locations and the required parameters. As stated above, PRIMET_Registration_Ethiopia takes care that the correct percentiles are used.

### 4.2.2 Aquatic effect assessment

#### 4.2.2.1 Effect assessment acute exposure fish

For fish the predicted no acute effect concentration is:

$$PNEC_{\text{fish-acute}} = LC50_{\text{fish}} \cdot 1000 / SF_{\text{fish-acute}} \quad (26)$$

with,

$PNEC_{\text{fish-acute}}$ = Predicted No Acute Effect Concentration for fish (µg $L^{-1}$)

$LC50_{\text{fish}}$ = Concentration that kills 50% of the test organisms, fish (mg $L^{-1}$)

$SF_{\text{fish-acute}}$ = Safety Factor for acute effect assessment of fish (-). The value is 100.

#### 4.2.2.2 Effect assessment chronic exposure fish

For fish the predicted no acute effect concentration is:

$$PNEC_{\text{fish-chronic}} = NOEC_{\text{fish}} \cdot 1000 / SF_{\text{fish-chronic}} \quad (27)$$

with,

$PNEC_{\text{fish-chronic}}$ = Predicted No Chronic Effect Concentration for fish (µg $L^{-1}$)
$NOEC_{\text{fish}}$ = Concentration that affects 50% of the test organisms, invertebrates (mg $L^{-1}$)
$SF_{\text{fish-chronic}}$ = Safety Factor for chronic effect assessment of invertebrates (-). The value is 10.

#### 4.2.2.3 Effect assessment acute exposure invertebrates

For invertebrates the predicted no acute effect concentration is:

$$PNEC_{\text{invert-acute}} = EC50_{\text{invert}} \cdot 1000 / SF_{\text{invert-acute}} \quad (28)$$

with,

$PNEC_{\text{invert-acute}}$ = Predicted No Acute Effect Concentration for invertebrates (µg $L^{-1}$)
$EC50_{\text{invert}}$ = Concentration that affects 50% of the test organisms, invertebrates (mg $L^{-1}$)
$SF_{\text{invert-acute}}$ = Safety Factor for acute effect assessment of invertebrates (-). The value is 100.

#### 4.2.2.4 Effect assessment chronic exposure invertebrates

For invertebrates the predicted no acute effect concentration is:

$$PNEC_{\text{invert-chronic}} = EC50_{\text{invert}} \cdot 1000 / SF_{\text{invert-chronic}} \quad (29)$$

with,

$PNEC_{\text{invert-chronic}}$ = Predicted No Chronic Effect Concentration for invertebrates (daphnia or chironomus) (µg $L^{-1}$)
$NOEC_{\text{invert}}$ = Concentration that affects 50% of the test organisms, invertebrates invertebrates (daphnia or chironomus) (mg $L^{-1}$)
$SF_{\text{invert-chronic}}$ = Safety Factor for chronic effect assessment of invertebrates (-). The value is 10.

#### 4.2.2.5 Effect assessment exposure algae

For algae the predicted no effect concentration is:

$$PNEC_{\text{algae}} = EC50_{\text{algae}} \cdot 1000 / SF_{\text{algae}} \quad (30)$$

with,

$PNEC_{\text{algae}}$ = Predicted No Effect Concentration for algae (µg $L^{-1}$)
$EC50_{\text{algae}}$ = Concentration that kills 50% of the test organisms, algae (mg $L^{-1}$)
$SF_{\text{algae}}$ = Safety Factor for effect assessment of algae (-). The value is 10.

#### 4.2.2.6 Effect assessment exposure macrophytes

For macrophytes the predicted no effect concentration is:

$$PNEC_{\text{macroph}} = EC50_{\text{macroph}} \cdot 1000 / SF_{\text{macroph}} \quad (31)$$

with,

$PNEC_{\text{macroph}}$ = Predicted No Chronic Effect Concentration for macrophytes (µg $L^{-1}$)
$EC50_{\text{macroph}}$ = Concentration that kills 50% of the test organisms, macrophytes (mg $L^{-1}$)
$SF_{\text{macroph}}$ = Safety Factor for effect assessment of macrophytes (-). The default value is 10.

### 4.2.3 Aquatic risk assessment

#### 4.2.3.1 Acute aquatic risk assessment for fish

The risk, expressed in Exposure Toxicity Ratio ($ETR_{fish\text{-}acute}$) is:

$$ETR_{fish\text{-}acute} = PEC_{water} / PNEC_{fish-acute} \quad (32)$$

with,

$ETR_{fish\text{-}acute}$ = Acute Exposure Toxicity Ratio (-)
$PEC_{water}$ = Concentration in water (µg $L^{-1}$)
$PNEC_{fish\text{-}acute}$ = Predicted No Acute Effect Concentration in water (µg $L^{-1}$)

If:

| | |
|---|---|
| $ETR_{fish\text{-}acute} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{fish\text{-}acute} \leq 10$ | Possible risk (indicated by an orange colour) |
| $ETR_{fish\text{-}acute} > 10$ | High Risk (indicated by a red colour) |

#### 4.2.3.2 Chronic aquatic risk assessment for fish

The risk, expressed in Exposure Toxicity Ratio ($ETR_{fish\text{-}chronic}$) is:

$$ETR_{fish\text{-}chronic} = PEC_{water} / PNEC_{fish-chronic} \quad (33)$$

with,

$ETR_{fish\text{-}chronic}$ = Chronic Exposure Toxicity Ratio (-)
$PEC_{water}$ = Concentration in water (µg $L^{-1}$)
$PNEC_{fish\text{-}chronic}$ = Predicted No Chronic Effect Concentration in water (µg $L^{-1}$)

If:

| | |
|---|---|
| $ETR_{fish\text{-}chronic} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{fish\text{-}chronic} \leq 10$ | Possible risk (indicated by an orange colour) |
| $ETR_{fish\text{-}chronic} > 10$ | High Risk (indicated by a red colour) |

#### 4.2.3.3 Acute aquatic risk assessment for invertebrates

The risk, expressed in Exposure Toxicity Ratio ($ETR_{invert\text{-}ucute}$) is:

$$ETR_{invert\text{-}acute} = PEC_{water} / PNEC_{invert-acute} \quad (34)$$

with,

$ETR_{invert\text{-}acute}$ = Acute Exposure Toxicity Ratio (-)
$PEC_{water}$ = Concentration in water (µg $L^{-1}$)
$PNEC_{invert\text{-}acute}$ = Predicted No Acute Effect Concentration in water (µg $L^{-1}$)

If:

| | |
|---|---|
| $ETR_{invert\text{-}acute} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{invert\text{-}acute} \leq 100$ | Possible risk (indicated by an orange colour) |
| $ETR_{invert\text{-}acute} > 100$ | High Risk (indicated by a red colour) |

#### 4.2.3.4 Chronic aquatic risk assessment for invertebrates

The risk, expressed in Exposure Toxicity Ratio ($ETR_{invert\text{-}chronic}$) is:

$$ETR_{invert\text{-}chronic} = PEC_{water} / PNEC_{invert-chronic} \quad (35)$$

with,

$ETR_{invert\text{-}chronic}$ = Chronic Exposure Toxicity Ratio (-)
$PEC_{water}$ = Concentration in water (µg $L^{-1}$)
$PNEC_{invert\text{-}chronic}$ = Predicted No Chronic Effect Concentration in water (µg $L^{-1}$)

If:

| | |
|---|---|
| $ETR_{invert\text{-}chronic} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{invert\text{-}chronic} \leq 100$ | Possible risk (indicated by an orange colour) |
| $ETR_{invert\text{-}chronic} > 100$ | High Risk (indicated by a red colour) |

#### 4.2.3.5 Aquatic risk assessment for algae[3]

The risk, expressed in Exposure Toxicity Ratio ($ETR_{algae}$) is:

$$ETR_{algae} = PEC_{water} / PNEC_{algae} \quad (36)$$

with,

$ETR_{algae}$ = Chronic Exposure Toxicity Ratio (-)
$PEC_{water}$ = Concentration in water (µg $L^{-1}$)
$PNEC_{algae}$ = Predicted No Effect Concentration in water (µg $L^{-1}$)

If:

| | |
|---|---|
| $ETR_{algae} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{algae} \leq 100$ | Possible risk (indicated by an orange colour) |
| $ETR_{algae} > 100$ | High Risk (indicated by a red colour) |

#### 4.2.3.6 Aquatic risk assessment for macrophytes[3]

The risk, expressed in Exposure Toxicity Ratio ($ETR_{macrophytes}$) is:

$$ETR_{macrophytes} = PEC_{water} / PNEC_{macrophytes} \quad (37)$$

with,

$ETR_{macrophytes}$ = Chronic Exposure Toxicity Ratio (-)
$PEC_{water}$ = Concentration in water (µg $L^{-1}$)
$PNEC_{macrophytes}$ = Predicted No Effect Concentration in water (µg $L^{-1}$)

If:

| | |
|---|---|
| $ETR_{macropphytes} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{macrophytes} \leq 10$ | Possible risk (indicated by an orange colour) |
| $ETR_{macrophytes} > 10$ | High Risk (indicated by a red colour) |

### 4.2.4 Parameters aquatic risk assessment

#### 4.2.4.1 Input scenario parameters

The scenario input default values listed in this section are set to 'read-only; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

*Standard*

$SF_{fish\text{-}acute}$ = Safety Factor for acute effect assessment of fish (-). The value is 100.
$SF_{fish\text{-}chronic}$ = Safety Factor for chronic effect assessment of fish (-). The value is 10.
$SF_{invert\text{-}acute}$ = Safety Factor for acute effect assessment of invertebrates (-). The value is 100.
$SF_{invert\text{-}chronic}$ = Safety Factor for chronic effect assessment of invertebrates (-). The value is 10.
$SF_{algae}$ = Safety Factor for effect assessment of algae (-). The value is 10.
$SF_{macroph}$ = Safety Factor for effect assessment of macrophytes (-). The default value is 10.

[3] For convenience, the risks for waterplants ( algae and macropytes) are listed under chronic aquatic risks ( see also Table 20 in Chapter 5.

#### 4.2.4.2 Input pesticide parameters

$LC50_{fish}$ = Concentration that kills 50% of the test organisms, fish (mg $L^{-1}$)
$NOEC_{fish}$ = Concentration that affects 50% of the test organisms, invertebrates (mg $L^{-1}$)
$EC50_{invert}$ = Concentration that affects 50% of the test organisms, invertebrates (mg $L^{-1}$)
$NOEC_{invert}$ = Concentration that affects 50% of the test organisms, invertebrates (mg $L^{-1}$)
$EC50_{algae}$ = Concentration that kills 50% of the test organisms, algae (mg $L^{-1}$)
$EC50_{macroph}$ = Concentration that kills 50% of the test organisms, macrophytes (mg $L^{-1}$)

#### 4.2.4.3 Input pesticide application parameters

$AR$ = Application Rate of single treatment (kg a.i./ha)
$n$ = Number of applications (-)
$i$ = Time interval between applications (d)
$AP_{start}$ = Application start date. The application dates are given in the Gregorian (Christian) calendar.

#### 4.2.4.4 Calculated parameters

$PEC_{water}$ = Concentration in water (µg $L^{-1}$)
$PNEC_{fish\text{-}acute}$ = Predicted No Acute Effect Concentration for fish (µg $L^{-1}$)
$PNEC_{fish\text{-}chronic}$ = Predicted No Chronic Effect Concentration for fish (µg $L^{-1}$)
$PNEC_{invert\text{-}acute}$ = Predicted No Acute Effect Concentration for invertebrates (µg $L^{-1}$)
$PNEC_{invert\text{-}chronic}$ = Predicted No Chronic Effect Concentration for invertebrates (µg $L^{-1}$)
$PNEC_{algae}$ = Predicted No Effect Concentration for algae (µg $L^{-1}$)
$PNEC_{macroph}$ = Predicted No Effect Concentration for macrophytes (µg $L^{-1}$)
$ETR_{fish\text{-}acute}$ = Acute Exposure Toxicity Ratio (-)
$ETR_{fish\text{-}chronic}$ = Chronic Exposure Toxicity Ratio (-)
$ETR_{invert\text{-}acute}$ = Acute Exposure Toxicity Ratio (-)
$ETR_{invert\text{-}chronic}$ = Chronic Exposure Toxicity Ratio (-)
$ETR_{algae}$ = Exposure Toxicity Ratio (-)
$ETR_{macrophytes}$ = Exposure Toxicity Ratio (-)

## 4.3 Terrestrial risk assessment for earthworms

### 4.3.1 Terrestrial exposure assessment for earthworms

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

$$C_{soil} = AR / \left(d_{field} \cdot 10^4\right) \quad (38)$$

with,

$C_{soil}$ = Concentration in the upper part of the soil (kg $m^{-3}$ soil)
$AR$ = Application rate of treatment (kg a.i./ha)
$d_{field}$ = Depth of the field (m). The default value is 0.05 m.

The Predicted Environmental Concentration ($PEC^1_{soil}$) for the soil compartment after one application is:

$$PEC^1_{soil} = 10^6 C_{soil} / \rho_b \quad (39)$$

with,

$PEC^1_{soil}$ = Concentration in the upper part of the soil from one application (mg $kg^{-1}$ soil)
$\rho_b$ = Dry bulk density soil (kg $m^{-3}$). The default value is 1000 kg $m^{-3}$.

The realistic worst case bulk dry density for an average soil is 1000 kg $m^{-3}$.
The *PEC* from a series of *n* applications with fixed time interval between applications is calculated using (FOCUS Soil Modeling Workgroup,1997):

$$PEC^{n}_{soil} = PEC^{1}_{soil} \frac{1 - e^{-nk_s i}}{1 - e^{-k_s i}} \quad (40)$$

with,

$PEC^{1}_{soil}$ = Concentration in the upper part of the soil from one application (mg kg$^{-1}$ soil)

$PEC^{n}_{soil}$ = Concentration in the upper part of the soil from n application (mg kg$^{-1}$soil)

$n$ = Number of applications (-)

$k_s$ = Degradation rate coefficient in soil (d$^{-1}$), where $k_s$ = ln(2)/DT50$_{soil}$. $k_s$ is temperature dependent (see Eq. 12 for the derivation of $k_s$ at ambient temperature)

$i$ = Time interval between applications (d)

## 4.3.2 Terrestrial effect assessment for earthworms

### 4.3.2.1 Effect assessment acute exposure

The acute No Effect Concentration is calculated using:

$$PNEC_{soil\text{-}acute} = LC50_{earthworms} / SF_{soil-acute} \quad (41)$$

with,

$PNEC_{soil\text{-}acute}$ = Predicted No Acute Effect Concentration for the soil compartment (mg kg$^{-1}$)

$LC50_{earthworms}$ = Concentration that kills 50% of the test organisms, earthworms (mg kg$^{-1}$)

$SF_{soil\text{-}acute}$ = Safety Factor for acute effect assessment of earthworms (-). The default value is 10.

### 4.3.2.2 Effect assessment chronic exposure

The chronic Predicted No Effect Concentration is calculated using:

$$PNEC_{soil\text{-}chronic} = NOEC_{earthworms} / SF_{soil-chronic} \quad (42)$$

with,

$PNEC_{soil\text{-}chronic}$ = Predicted No chronic Effect Concentration for the soil compartment (mg kg$^{-1}$)

$NOEC_{earthworms}$ = No observed effect concentration of earthworms (mg kg$^{-1}$)

$SF_{soil\text{-}chronic}$ = Safety Factor for chronic effect assessment of earthworms (-). The default value is 5.

## 4.3.3 Terrestrial risk assessment for earthworms

### 4.3.3.1 Acute terrestrial risk assessment to earthworms

The risk, expressed in Exposure Toxicity Ratio ($ETR_{soil\text{-}acute}$) as a result of all stacked applications is:

$$ETR_{soil\text{-}acute} = PEC^{n}_{soil} / PNEC_{soil-acute} \quad (43)$$

with,

$ETR_{soil\text{-}acute}$ = Acute Exposure Toxicity Ratio due to $n$ applications (-)

$PEC^{n}_{soil}$ = Concentration in the upper part of the soil from $n$ applications (mg kg$^{-1}$soil)

$PNEC^{n}_{soil\text{-}acute}$ = Predicted No Acute Effect Concentration for the soil compartment (mg kg$^{-1}$)

If:

| | |
|---|---|
| $ETR_{soil\text{-}acute} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{soil\text{-}acute} \leq 5$ | Possible risk (indicated by an orange colour) |
| $ETR_{soil\text{-}acute} > 5$ | High Risk (indicated by a red colour) |

### 4.3.3.2 Chronic terrestrial risk assessment to earthworms

The risk, expressed in Exposure Toxicity Ratio ($ETR_{soil\text{-}chronic}$) as a result of all stacked applications is:

$$ETR_{soil\text{-}chronic} = PEC^{n}_{soil} / PNEC_{soil-chronic} \quad (44)$$

with,

$ETR_{soil\text{-}chronic}$ = Chronic Exposure Toxicity Ratio due to $n$ applications (-)

$PEC^{n}_{soil}$ = Concentration in the upper part of the soil from $n$ applications (mg kg$^{-1}$soil)

$PNEC^{n}_{soil\text{-}chronic}$ = Predicted No Chronic Effect Concentration for the soil compartment (mg kg$^{-1}$)

If:

| | |
|---|---|
| $ETR_{soil\text{-}chronic} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{soil\text{-}chronic} \leq 5$ | Possible risk (indicated by an orange colour) |
| $ETR_{soil\text{-}chronic} > 5$ | High Risk (indicated by a red colour) |

Since the chronic toxicity tests for earthworms are static tests the (acute) $PEC^{n}_{soil}$ will be used to calculate the chronic risk to earthworms.

### 4.3.4 Parameters terrestrial risk assessment

#### 4.3.4.1 Input scenario parameters

The scenario input default values listed in this section are set to 'read-only; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

*Standard*

$d_{field}$ = Depth of the field (m). The default value is 0.05 m.

$\rho_b$ = Dry bulk density soil (kg $m^{-3}$). The default value is 1000 kg $m^{-3}$.

$SF_{soil\text{-}acute}$ = Safety Factor for acute effect assessment of earthworms (-). The default value is 10.

$SF_{soil\text{-}chronic}$ = Safety Factor for chronic effect assessment of earthworms (-). The default value is 5.

#### 4.3.4.2 Input pesticide parameters

$LC50_{earthworms}$ = Concentration that kills 50% of the test organisms, earthworms (mg $kg^{-1}$)

$NOEC_{earthworms}$ = No observed effect concentration of earthworms (mg $kg^{-1}$)

$DT50_{soil}$ = Half-life for degradation in soil (d)

#### 4.3.4.3 Input pesticide application parameters

$AR$ = Application Rate of single treatment (kg a.i./ha)

$n$ = Number of applications (-)

$i$ = Time interval between applications (d)

#### 4.3.4.4 Calculated parameters

$C_{soil}$ = Concentration in the upper part of the soil (kg $m^{-3}$ soil)

$k_s$ = Degradation rate coefficient in soil ($d^{-1}$), where $k_s = \ln(2)/DegT50_{soil}$

$PEC^{1}_{soil}$ = Concentration in the upper part of the soil from one application (kg $m^{-3}$ soil)

$PEC^{n}_{soil}$ = Concentration in the upper part of the soil from $n$ application (kg $m^{-3}$ soil)

$PNEC^{n}_{soil\text{-}acute}$ = Predicted No Acute Effect Concentration for the soil compartment (mg $kg^{-1}$)

$PNEC^{n}_{soil\text{-}chronic}$ = Predicted No Chronic Effect Concentration for the soil compartment (mg $kg^{-1}$)

$ETR_{soil\text{-}acute}$ = Acute Exposure Toxicity Ratio due to $n$ applications (-)

$ETR_{soil\text{-}chronic}$ = Chronic Exposure Toxicity Ratio due to $n$ applications (-)

## 4.4 Risk assessment for bees

The risk assessment focusses on the protection of beehives and honeybees at the treated crop and outside the treated crop.

### 4.4.1 Exposure assessment for bees

Two exposure scenarios are considered; one in-crop scenario and one off-crop scenario (toevoegen in PRIMET). The exposure concentration is calculated as the concentration due to a single application (spraying):

$$PEC_{bee,in\text{-}crop} = AR \cdot 1000 \quad (45)$$

$$PEC_{bee,off\text{-}crop} = AR \cdot df \cdot 1000 \quad (46)$$

With,

$PEC_{bee}$ = Exposure concentration to bees (g/ha)

$AR$ = Application Rate of single treatment (kg a.i./ha)

$df$ = Drift factor, the fraction of the applied mass that corresponds to spray drift. $df$ depends on the type of crop and the application type (see Table 11)(-)

Table 11

*Drift factors used in the exposure assessment for bees (off-crop). These factors give the fraction of spray drift for the main crops in Ethiopia.*

| Crop type | knap sack spraying | air borne |
|---|---|---|
| Tomato | 0.028 | 0.028 |
| Onion | 0.028 | 0.028 |
| Cabbage | 0.028 | 0.028 |
| Potato | 0.028 | 0.028 |
| Teff | 0.028 | 0.028 |
| Wheat | 0.028 | 0.028 |
| Maize | 0.028 | 0.028 |
| Barley | 0.028 | 0.028 |
| Faba bean | 0.028 | 0.028 |
| Sweet potato | 0.028 | 0.028 |
| Cotton | 0.08 | 0.332 |
| Mango | - | 0.157 |
| Sugarcane | 0.08 | 0.332 |
| Banana | - | 0.157 |
| Lemon | - | 0.157 |
| Coffee | - | 0.157 |
| Flowers | - | - |

### 4.4.2 Effect assessment for bees

For the effect assessment a 'safe' concentration is calculated from toxicity values and an Empirical Correction Factor (ECF). This factor is introduced to translate the commonly used approach, where *PEC* (g /ha) divided by $LD50_{bees}$ (µg / bee) should be smaller than 50 to obtain a no effect situation. The risk classification value 50 is not unitless, which does not correspond to the ETR concept. Therefore, the correction factor has been introduced.
The Predicted No Effect Concentration for bees is then calculated according to:

$$PNEC_{bee} = LD50_{bee} \cdot ECF_{bee} \quad (47)$$

with,

$PNEC_{bee}$ = Predicted No effect concentration for bees (g $ha^{-1}$)

$LD50_{bee}$ = Concentration (oral or contact) that kills 50% of bees (µg/bee), the most sensitive endpoint of oral *LD50* and contact *LD50*

$ECF_{bee}$ = Empirical Correction Factor for effect assessment of bees (bee $ha^{-1}$). This is a constant with the value 1 bee $ha^{-1}$. [4]

[4] ECF has to correct for the units used, i.e. PEC / LD50 = 50 g/ha * bee / µg = 50 * ($10^6$ µg/ha * bee / µg) = 50 * ($10^6$ bee / ha). However, to convert the LD50 in Eq. (10) to gram, it has to be multiplied by $10^6$, hence overall the conversion results in ECF is 1 bee /ha.

## 4.4.3 Risk assessment for bees

### 4.4.3.1 Risk assessment for bees, in-crop

The risk, expressed in Exposure Toxicity Ratio ($ETR_{bee,\ in\text{-}crop}$) as a result of applications is:

$$ETR_{bee,\ in\text{-}crop} = PEC_{bee,\ in\text{-}crop} \ / \ PNEC_{bee} \quad (48)$$

with,

$ETR_{bee,in\text{-}crop}$ = In-crop Exposure Toxicity Ratio due to application (-)

$PEC_{bee,\ in\text{-}crop}$ = In-crop exposure concentration to bees, i.e. the individual dose applied (g $ha^{-1}$)

$PNEC_{bee}$ = Predicted No effect concentration for bees (g $ha^{-1}$)

If:

| | |
|---|---|
| $ETR_{bee,\ in\text{-}crop} < 50$ | No Risk (indicated by a green colour) |
| $50 \leq ETR_{bee,\ in\text{-}crop} \leq 400$ | Possible risk (indicated by an orange colour) |
| $ETR_{bee,\ in\text{-}crop} > 400$ | High Risk (indicated by a red colour) |

### 4.4.3.2 Risk assessment for bees, off-crop

The risk, expressed in Exposure Toxicity Ratio ($ETR_{bee,\ off\text{-}crop}$) as a result of applications is:

$$ETR_{bee,\ off\text{-}crop} = PEC_{bee,\ off\text{-}crop} \ / \ PNEC_{bee} \quad (49)$$

with,

$ETR_{bee,off\text{-}crop}$ = Off-crop Exposure Toxicity Ratio due to application (-)

$PEC_{bee,\ off\text{-}crop}$ = Off-crop exposure concentration to bees, i.e. the individual dose applied (g $ha^{-1}$)

$PNEC_{bee}$ = Predicted No effect concentration for bees (g $ha^{-1}$)

If:

| | |
|---|---|
| $ETR_{bee,\ off\text{-}crop} < 50$ | No Risk (indicated by a green colour) |
| $50 \leq ETR_{bee,\ off\text{-}crop} \leq 400$ | Possible risk (indicated by an orange colour) |
| $ETR_{bee,\ off\text{-}crop} > 400$ | High Risk (indicated by a red colour) |

## 4.4.4 Parameters risk assessment for bees

### 4.4.4.1 Input scenario parameters

The scenario input default values listed in this section are set to 'read-only; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

*Standard*

$ECF_{bee}$ = Empirical Correction Factor for effect assessment of bees (bee $ha^{-1}$). This is a default value of 1 bee $ha^{-1}$.

*In database*

*df* = Drift factor, the fraction of the applied mass that corresponds to spray drift . *df* depends on the type of crop and the application type (see Table 11)(-)

### 4.4.4.2 Input pesticide parameters

$LD50_{bee}$ = Concentration (oral or contact) that kills 50% of bees (µg/bee), the most sensitive endpoint of oral LD50 and contact LD50

### 4.4.4.3 Input pesticide application parameters

*AR* = Application Rate of single treatment (kg a.i./ha)

#### 4.4.4.4 Calculated parameters

$ETR_{bee,in\text{-}crop}$ = In-crop Exposure Toxicity Ratio due to application (-)

$PEC_{bee,\ in\text{-}crop}$ = In-crop exposure concentration to bees, i.e. the individual dose applied ($g\ ha^{-1}$)

$ETR_{bee,off\text{-}crop}$ = Off-crop Exposure Toxicity Ratio due to application (-)

$PEC_{bee,\ off\text{-}crop}$ = Off-crop exposure concentration to bees, i.e. the individual dose applied ($g\ ha^{-1}$)

$PNEC_{bee}$ = Predicted No effect concentration for bees ($g\ ha^{-1}$)

## 4.5 Risk assessment for non target arthropods

### 4.5.1 Exposure assessment for non target arthropods

The following equations are used to describe the exposure in-crop and off-crop (single dose). For both exposures, the key input is the nominal field application rate:

$$PEC_{nta,in\text{-}crop} = AR \cdot maf \cdot 1000 \quad (50)$$

$$PEC_{nta,off\text{-}crop} = AR \cdot maf \cdot df \cdot 1000 \quad (51)$$

with,

$PEC_{nta,in\text{-}crop}$ = Exposure in-crop (g a.i./ha)

$PEC_{nta,off\text{-}crop}$ = Exposure off-crop (g a.i./ha)

*AR* = Application Rate of single treatment (kg a.i./ha)

*maf* = Multiple application factor (concentration immediately after the last application compared to a single application

*df* = Drift factor, the fraction of the applied mass that corresponds to spray drift. *df* depends on the type of crop and the application type (knapsack, airborne)(-). The values of *df* are the same as for bees, they are provided in Table 11.

The multi-application factor is calculated according to:

$$maf = \left(1 - e^{-nki}\right) / \left(1 - e^{-ki}\right) \quad (52)$$

With,

*n* = Number of applications (-)

*k* = The overall dissipation rate coefficient, being $\ln(2)/DT50_{leaves}$ ($d^{-1}$)

*i* = Interval between applications (d)

for *n* is equal to 1, *maf* is 1.

For the calculation of the multiple application factor, a default $DT50_{leaves}$ is used of 16 days. Table 12 provides an indication of *MAF* values for an interval of 7 days.

Table 12

*Example MAF-values after n applications (default values for leaf dwelling arthropods).*

| n applications | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | >8 |
|---|---|---|---|---|---|---|---|---|---|
| MAF after n applications | 1.0 | 1.7 | 2.3 | 2.7 | 3.0 | 3.2 | 3.4 | 3.5 | 3.5 |

### 4.5.2 Effect assessment for non target arthropods

The Acceptable Effect Concentration is calculated using:

$$AEC_{nta} = LR50_{nta} / SF_{nta} \quad (53)$$

with,

| | | |
|---|---|---|
| $AEC_{NTA}$ | = | Acceptable Effect Concentration for Non Target Arthropods (g a.i./ha) |
| $LR50_{NTA}$ | = | Rate that kills 50% of *Typhlodromus pyri* or *Aphidius rhopalosiphi*, the most sensitive endpoint of the two organisms will be taken (ga.i./ha). |
| $SF_{NTA}$ | = | Safety factor for the effect assessment of Non Target Arthropods. The default value is 1. |

Note that for Non Target Arthropods a tiered approach can be followed as for the Effect assessment two types of tests can be performed: a Glassplate test (first tier) and an Extended Laboratory test (second tier). See for the risk assessment paragraph 4.5.3.

### 4.5.3 Risk assessment for non target arthropods

#### 4.5.3.1 Risk assessment for non target arthropods, in- crop

The risk, expressed in Exposure Toxicity Ratio ($ETR_{in\text{-}crop}$) as a result of applications is:

$$ETR_{nta,in\text{-}crop} = PEC_{nta,in\text{-}crop} / AEC_{nta} \quad (54)$$

with,

| | | |
|---|---|---|
| $ETR_{nta,in\text{-}crop}$ | = | Exposure Toxicity Ratio in-crop due to n applications (-) |
| $PEC_{nta,in\text{-}crop}$ | = | Exposure in-crop (g a.i./ha) |
| $AEC_{NTA}$ | = | Acceptable Effect Concentration for Non Target Arthropods (g a.i. /ha) |

**FIRST TIER:**

In case the AEC has been derived with the glass Plate Test:

If:

| | |
|---|---|
| $ETR_{nta,incrop,1st\ tier} < 2$ | No Risk (indicated by a green colour) |
| $2 \leq ETR_{nta,\ incrop,\ 1st\ tier} \leq 100$ | Possible risk (indicated by an orange colour) |
| $ETR_{nta,\ incrop,\ 1st\ tier} > 100$ | High Risk (indicated by a red colour) |

**SECOND TIER:**

In case the AEC has been derived with the Extended Lab Test:

If:

| | |
|---|---|
| $ETR_{nta,\ incrop,\ 2nd\ tier} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{nta,\ incrop,\ 2nd\ tier} \leq 50$ | Possible risk (indicated by an orange colour) |
| $ETR_{nta,\ incrop,\ 2nd\ tier} > 50$ | High Risk (indicated by a red colour) |

#### 4.5.3.2 Risk assessment for non target arthropods, off-crop

The risk, expressed in Exposure Toxicity Ratio ($ETR_{off\text{-}crop}$) as a result of applications is:

$$ETR_{nta,off\text{-}crop} = PEC_{nta,off\text{-}crop} / AEC_{nta} \quad (55)$$

with,

| | | |
|---|---|---|
| $ETR_{nta,off\text{-}crop}$ | = | Exposure Toxicity Ratio off-crop due to application (-) |
| $PEC_{nta,off\text{-}crop}$ | = | Exposure off-crop (g a.i./ha) |
| $AEC_{NTA}$ | = | Acceptable Effect Concentration for Non Target Arthropods (g a.i. /ha) |

**FIRST TIER:**
In case the AEC has been derived with the Glass Plate Test:

If:

| | |
|---|---|
| $ETR_{nta,off\text{-}crop,1st\ tier} < 2$ | No Risk (indicated by a green colour) |
| $2 \leq ETR_{nta,\ off\text{-}crop,\ 1st\ tier} \leq 20$ | Possible risk (indicated by an orange colour) |
| $ETR_{nta,\ off\text{-}crop,\ 1st\ tier} > 20$ | High Risk (indicated by a red colour) |

**SECOND TIER:**
In case the AEC has been derived with the Extended Lab Test:

If:

| | |
|---|---|
| $ETR_{nta,\ off\text{-}crop,\ 2nd\ tier} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{nta,\ off\text{-}crop,\ 2nd\ tier} \leq 10$ | Possible risk (indicated by an orange colour) |
| $ETR_{nta,\ off\text{-}crop,\ 2nd\ tier} > 10$ | High Risk (indicated by a red colour) |

## 4.5.4 Parameters risk assessment for non target arthropods

### 4.5.4.1 Input scenario parameters

The scenario input default values listed in this section are set to 'read-only; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

*Standard*

$SF_{NTA}$ = Safety factor for the effect assessment of Non Target Arthropods. The default value is 1.

*In database*

*df* = Drift factor, i.e. the fraction of spray drift. *df* depends on the type of crop and the application type (knapsack, airborne)(-) --> see Table 11 for bees.

$DT50_{leaves}$ = Assumed half-life of pesticide on leaves, default is 16 days. Not pesticide specific.

### 4.5.4.2 Input pesticide parameters

$LR50_{NTA}$ = Rate that kills 50% of *Typhlodromus pyri* or *Aphidius rhopalosiphi*, the most sensitive endpoint of the two organisms will be taken (g a.i./ha).

### 4.5.4.3 Input pesticide application parameters

*AR* = Application Rate of single treatment (kg a.i./ha)

*n* = Number of applications (-)

*i* = Time interval between applications (d)

### 4.5.4.4 Calculated parameters

*General*

*maf* = Multiple application factor (concentration immediately after the last application compared to a single application (Gonzales-Valero *et al.* 2000).

*k* = Overall dissipation rate coefficient, being $\ln(2)/DT50_{leaves}$ ($d^{-1}$)

$PEC_{nta,in\text{-}crop}$ = Exposure in-crop (g a.i./ha)

$PEC_{nta,off\text{-}crop}$ = Exposure off-crop (g a.i./ha)

*Tier-specific*

$ETR_{nta,in\text{-}crop}$ = Exposure Toxicity Ratio in-crop due to n applications (-)

$ETR_{nta,off\text{-}crop}$ = Exposure Toxicity Ratio off-crop due to application (-)

$AEC_{NTA}$ = Acceptable Effect Concentration to *Typhlodromus pyri* and *Aphidius rhopalosiphi* (g/ha)

## 4.6 Risk assessment for birds

The assessment focuses on the protection of non-target birds at the treated crop field. Both acute and chronic risks are assessed. For each crop category a number of indicator species have been identified. Table 13 provides the crop class and the considered indicator species. The crop class for each of the Ethiopian crops is listed in Table 14. Only spray application is considered for birds. Seed treatment is not assessed in PRIMET_Registration_Ethiopia. For the crops teff, wheat and barley the crop class cereals-early is used. None of the considered crops are classified as Cereals-Late.

Table 13

*Relevant indicator species that will be used in the assessment according to crop class and crop stage.*

| crop class | crop stage | indicator species-body weight | example |
|---|---|---|---|
| grassland | - | large herbivorous bird - 3000 g | Goose |
| | | insectivorous bird - 10 g | Wren, Tit |
| cereals | early | Large herbivorous bird - 3000 g | Goose |
| | | insectivorous bird - 10 g | Wren, Tit |
| | late | insectivorous bird - 10 g | Wren, Tit |
| leafy crops | early / late | medium herbivorous bird - 300 g | Partridge, Pigeon |
| | | insectivorous bird - 10 g | Wren, Tit |
| orchard / vine / hops | early / late | insectivorous bird - 10 g | Wren, Tit |

Table 14

*Crop class per crop type in Ethiopia.*

| Crop type | Crop class |
|---|---|
| Tomato | leafy crops |
| Onion | leafy crops |
| Cabbage | leafy crops |
| Potato | leafy crops |
| Teff | cereals-early |
| Wheat | cereals-early |
| Maize | leafy crops |
| Barley | cereals-early |
| Faba bean | leafy crops |
| Sweet potato | leafy crops |
| Cotton | leafy crops |
| Mango | orchard/vine/hops |
| Sugarcane | leafy crops |
| Banana | orchard/vine/hops |
| Lemon | orchard/vine/hops |
| Coffee | orchard/vine/hops |
| Flowers | no bird risk assessed |

### 4.6.1 Exposure assessment for birds

The main scenarios and procedures are taken from the risk assessment scheme for sprayed products (SANCO/4145/2000), which covers intake via contaminated feed, generally considered to be the most important exposure route. The following equations are used to describe the exposure. These generic equations are valid for acute and chronic risk assessments.

Basically the Estimated Daily Uptake, *ETE* (mg/ kg bw /d), of a compound is given by the following equation:

$$ETE = (FIR / bw_{bird}) \cdot C_{diet} \cdot AV \cdot PT \cdot PD \quad (56)$$

With,

*FIR* = Food intake rate of indicator species (kg fresh weight/ day)

$bw_{bird}$ = Bird Body Weight (kg)

$C_{diet}$ = Concentration of compound in fresh diet of bird (mg $kg^{-1}$)

*AV* = Avoidance factor (1 = no avoidance, 0 = complete avoidance, value is 1)
*PT* = Fraction of diet obtained in treated area (number between 0 and 1, value is 1)
*PD* = Fraction of food type in diet (number between 0 and 1; one type or more types, value is 1).

#### 4.6.1.1 Acute exposure assessment for birds

For acute exposure the concentration of a compound in the diet is calculated as:

$$C_{\text{diet\_acute}} = RUD_{90\%} \cdot AR \cdot maf \quad (57)$$

With,
$RUD_{90\%}$ = Standard residues normalized to an application rate of 1 kg/ha (mg $kg^{-1}$), i.e. 90$^{th}$ percentile of the initial residue concentration
*maf* = Multiple application factor (-).
*AR* = Application Rate of single treatment (kg a.i./ha)
$C_{diet\_acute}$ = Concentration of compound in fresh diet of bird for acute exposure assessment (mg $kg^{-1}$)

In Table 15 values are given for *FIR/ bw* and *RUD* for each indicator species:

Table 15
*Standard characteristics for indicator species for acute exposure assessment.*

| Indicator species | *FIR/bw* | *RUD* (90%) |
|---|---|---|
| large herbivorous bird | 0.44 | 142 |
| medium herbivorous bird | 0.76 | 87 |
| Insectivorous bird | 1.04 | 54 |

The multi-application factor is calculated with:

$$maf = \left(1 - e^{-nki}\right) / \left(1 - e^{-ki}\right) \quad (58)$$

With,
*n* = Number of applications (-)
*k* = Overall dissipation rate coefficient, being LN(2)/$DT50_{food\_item}$ ($d^{-1}$)
*i* = Interval between applications (d)

for *n* is equal to 1, *maf* is 1.

while using a $DT50_{food\_item}$ of 6.5 days for intervals up to and including 7 days, a $DT50_{food\_item}$ of 9.5 days for intervals up to and including 14 days and a $DT50_{food\_item}$ of 11 days for intervals of 15 days and longer. Example maf values are provided in Table 16.

Table 16
*Example Multiple Applications Factors (maf) to be used in connection with 90$^{th}$ percentiles for residues on short grass and leafy crops according to Fletcher et al. (1994).*

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

#### 4.6.1.2 Chronic exposure assessment for birds

For chronic exposure assessment time-weighted average residues are used to better reflect the long-term exposure. The concentration of a compound in the diet is calculated as:

$$C_{diet\_chronic} = RUD_{mean} \cdot AR \cdot maf \cdot f_{twa} \quad (59)$$

With,

| | | |
|---|---|---|
| $AR$ | = | Application Rate of single treatment (kg a.i./ha) |
| $RUD_{mean}$ | = | Standard residues (mean value) normalized to an application rate of 1 kg/ha (mg $kg^{-1}$) |
| $maf$ | = | Multiple application factor (-) |
| $C_{diet\_chronic}$ | = | Concentration of compound in fresh diet of bird for chronic exposure assessment (mg $kg^{-1}$) |
| $f_{twa}$ | = | Time-weighted-average factor (average concentration during a certain time interval compared to the initial concentration after single resp. last application). This factor is calculated according to equation (21, Technical document), i.e.: |

$$f_{twa} = \frac{[1 - e^{-kt_{twa}}]}{kt_{twa}} \quad (60)$$

With,

| | | |
|---|---|---|
| $k$ | = | Overall dissipation rate coefficient ($d^{-1}$) , being $ln(2)/DT50_{food\_item}$ ($d^{-1}$). The value used for DT50 is 10 days |
| $t_{twa}$ | = | Length of period for TWA (d), value is 21 days |

In Table 17 values are given for FIR/ bw and RUD for each indicator species:

Table 17

*Standard characteristics for indicator species for chronic exposure assessment.*

| Indicator species | *FIR/bw* | *RUD* (mean) |
|---|---|---|
| large herbivorous bird | 0.44 | 76 |
| medium herbivorous bird | 0.76 | 40 |
| Insectivorous bird | 1.04 | 21 |

*maf* is calculated with:

$$maf = \left(1 - e^{-nki}\right) / \left(1 - e^{-ki}\right) \quad (61)$$

with,

| | | |
|---|---|---|
| $n$ | = | Number of applications (-) |
| $k$ | = | Overall dissipation rate coefficient, being $ln(2)/DT50_{food\_item}$ ($d^{-1}$) |
| $i$ | = | Interval between applications (d) |

for $n$ is equal to 1, *maf* is 1.

The value used for $DT50_{food\_item}$ is 10 days. In the Table below example Maf values for intervals of 7 days, 14 days and 21 days is given.

Table 18

*Example Multiple Applications Factors (maf). These values have been calculated with Eq. (61)*

| | Number of applications | | | | | |
|---|---|---|---|---|---|---|
| Interval (d) | 2 | 3 | 4 | 5 | 6 | 8 |
| 7 | 1.6 | 2.0 | 2.2 | 2.4 | 2.5 | 2.5 |
| 10 | 1.4 | 1.5 | 1.6 | 1.6 | 1.6 | 1.6 |
| 14 | 1.2 | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 |

## 4.6.2 Effect assessment for birds

### 4.6.2.1 Effect assessment acute exposure

The Acute Predicted No Effect Concentration is calculated using:

$$PNEC_{\text{birds-acute}} = LD50_{\text{birds}} \,/\, SF_{\text{birds-acute}} \quad (62)$$

with,

$PNEC_{\text{birds-acute}}$ = Predicted No Effect Concentration for birds (mg/ kg bw)

$LD50_{\text{birds}}$ = Rate that kills 50% of the test organisms, birds (mg $kg^{-1}$ bw). For the assessment the lowest value is chosen.

$SF_{\text{birds-acute}}$ = Safety Factor for acute effect assessment of birds (value = 10)

### 4.6.2.2 Effect assessment chronic exposure

The chronic No Effect Concentration is calculated using:

$$PNEC_{\text{birds-chronic}} = NOEC_{\text{birds}} \,/\, SF_{\text{birds-chronic}} \quad (63)$$

with,

$PNEC_{\text{birds-chronic}}$ = Predicted No chronic Effect Concentration for birds (mg/ kg bw /d)

$NOEC_{\text{birds}}$ = No observed effect concentration of birds (mg $kg^{-1}$)

$SF_{\text{birds-chronic}}$ = Safety factor for chronic effect assessment of birds (value = 5)

## 4.6.3 Risk assessment for birds

### 4.6.3.1 Acute risk assessment

The risk, expressed in Exposure Toxicity Ratio ($ETR_{\text{birds-acute}}$) is:

$$ETR_{\text{birds-acute}} = ETE_{\text{birds-acute}} \,/\, PNEC_{\text{birds-acute}} \quad (64)$$

with,

$ETR_{\text{birds-acute}}$ = Acute Exposure Toxicity Ratio (-)

$ETE_{\text{birds-acute}}$ = Estimated daily uptake (mg/ kg bw )

$PNEC_{\text{birds-acute}}$ = Predicted No acute Effect Concentration for birds (mg/ kg bw )

If:

| | |
|---|---|
| $ETR_{\text{birds-acute}} < 1$ | No Risk (indicated by a green colour) |
| $1 \le ETR_{\text{birds-acute}} \le 5$ | Possible risk (indicated by an orange colour) |
| $ETR_{\text{birds-acute}} > 5$ | High Risk (indicated by a red colour) |

The $ETR_{\text{birds-acute}}$ is calculated for all the relevant indicator species (see Table 13 and 14).

### 4.6.3.2 Chronic risk assessment

The risk, expressed in Exposure Toxicity Ratio ($ETR_{\text{birds-chronic}}$) as a result of all stacked applications is:

$$ETR_{\text{birds-chronic}} = ETE_{\text{birds-chronic}} \,/\, PNEC_{\text{birds-chronic}} \quad (65)$$

with,

$ETR_{\text{birds-chronic}}$ = Chronic Exposure Toxicity Ratio (-)

$ETE_{\text{birds-chronic}}$ = Estimated daily uptake (mg/ kg bw )

$PNEC_{\text{birds-chronic}}$ = Predicted No Chronic Effect Concentration for birds (mg/ kg bw )

If:

| | |
|---|---|
| $ETR_{birds\text{-}chronic} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{birds\text{-}chronic} \leq 10$ | Possible risk (indicated by an orange colour) |
| $ETR_{birds\text{-}chronic} > 10$ | High Risk (indicated by a red colour) |

The $ETR_{birds\text{-}chronic}$ is calculated for all the relevant indicator species (see Table 13 and 14).

## 4.6.4 Parameters risk assessment for birds

### 4.6.4.1 Input scenario parameters

The scenario input default values listed in this section are set to 'read-only'; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

*Standard*

| | | |
|---|---|---|
| *AV* | = | Avoidance factor (1 = no avoidance, 0 = complete avoidance, default value is 1) |
| *PT* | = | Fraction of diet obtained in treated area (number between 0 and 1, value is default 1) |
| *PD* | = | Fraction of food type in diet (number between 0 and 1; one type or more types, value is default 1) |
| $SF_{birds\text{-}acute}$ | = | Safety Factor for acute effect assessment of birds (default value = 10) |
| $SF_{birds\text{-}chronic}$ | = | Safety factor for chronic effect assessment of birds (default value = 5) |
| $t_{twa}$ | = | Length of period for TWA (d), default value is 21 days |

*In database*

| | | |
|---|---|---|
| *FIR* | = | Food intake rate of indicator species (kg fresh weight/ day) |
| *Bw_bird* | = | Bird Body Weight (kg) |
| $RUD_{90\%}$ | = | Standard residues normalized to an application rate of 1 kg/ha (mg $kg^{-1}$), i.e. 90$^{th}$ percentile of the initial residue concentration |
| $RUD_{mean}$ | = | Standard residues (mean value) normalized to an application rate of 1 kg/ha (mg $kg^{-1}$) |
| $DT50_{food\text{-}item}$ | = | Half-life in food-item. Not pesticide specific<br>– for calculation of dissipation rate, k and $maf_{acute}$: default 10 days<br>– for calculation of $maf_{chronic}$: 6.5, 9.5 and 11 days |

### 4.6.4.2 Input pesticide parameters

| | | |
|---|---|---|
| $LD50_{birds}$ | = | Rate that kills 50% of the test organisms, birds (mg $kg^{-1}$). For the assessment the lowest value is chosen. |
| $NOEC_{birds}$ | = | No observed effect concentration of birds (mg $kg^{-1}$) |

### 4.6.4.3 Input pesticide application parameters

| | | |
|---|---|---|
| *AR* | = | Application Rate of single treatment (kg a.i./ha) |
| n | = | Number of applications (-) |
| *i* | = | The interval between applications (d) |

### 4.6.4.4 Calculated parameters

*Valid for all birds*

| | | |
|---|---|---|
| *k* | = | Overall dissipation rate coefficient, being $ln(2)/DT50_{food\_item}$ ($d^{-1}$) |
| *maf* | = | Multiple application factor (concentration immediately after the last application compared to a single application (Gonzales-Valero *et al.* 2000). Used values for $DT50_{food\_item}$ are constant (see values given in text). These are different for the acute and chronic assessment. |
| $PNEC_{birds\text{-}acute}$ | = | Predicted No acute Effect Concentration for birds (mg $kg^{-1}$ bw) |
| $PNEC_{birds\text{-}chronic}$ | = | Predicted No chronic Effect Concentration for birds (mg $kg^{-1}$ bw) |

*Bird specific*

| | | |
|---|---|---|
| $C_{diet\_acute}$ | = | Concentration of compound in fresh diet of bird for acute exposure assessment (mg $kg^{-1}$ bw) |
| $C_{diet\_chronic}$ | = | Concentration of compound in fresh diet of bird for chronic exposure assessment (mg $kg^{-1}$ bw) |
| $ETE_{birds\text{-}acute}$ | = | Estimated daily uptake acute (mg $kg^{-1}$ bw) |
| $ETE_{birds\text{-}chronic}$ | = | Estimated daily uptake chronic (mg $kg^{-1}$ bw) |
| $ETR_{birds\text{-}acute}$ | = | Acute Exposure Toxicity Ratio (-) |
| $ETR_{birds\text{-}chronic}$ | = | Chronic Exposure Toxicity Ratio (-) |

## 4.7 Risk assessment for non-target terrestrial plants

### 4.7.1 Exposure assessment for non-target terrestrial plants

Only off-crop exposure is considered. The key input is the nominal field application rate:

$$PEC_{nttp} = AR \cdot maf \cdot df \quad (66)$$

with,

| | | |
|---|---|---|
| $PEC_{nttp}$ | = | Exposure concentration NTTP (kg a.i./ha) |
| *AR* | = | Application Rate of single treatment (kg a.i./ha) |
| *maf* | = | Multiple application factor (concentration immediately after the last application compared to a single application (Gonzales-Valero *et al.* 2000) |
| *df* | = | Drift factor, i.e. the percentage of spray drift divided by 100. *df* depends on the type of crop and the application type (knapsack, airplane)(-) --> see Table bees |

The *maf* depends on the number of application (*n*) and the interval between applications. They are calculated as explained for NTA. If the number of applications is one, *maf* is equal to one.

### 4.7.2 Effect assessment for non-target terrestrial plants

The Acceptable Effect Concentration is calculated using:

$$PNEC_{nttp} = ER50_{nttp} / SF_{nttp} \quad (67)$$

with,

| | | |
|---|---|---|
| $PNEC_{nttp}$ | = | Predicted No Effect Concentration for Non Target Terrestrial Plants (kg a.i./ha) |
| $ER50_{nttp}$ | = | 50% Effect Rate (kg $ha^{-1}$) |
| $SF_{nttp}$ | = | Safety factor for in-crop effect assessment of Non Target terrestrial plant. The default value is 5. |

### 4.7.3 Risk assessment for non-target terrestrial plants

The risk, expressed in Exposure Toxicity Ratio ($ETR_{nttp}$) as a result of 1 application is:

$$ETR_{nttp} = PEC_{nttp} / PNEC_{nttp} \quad (68)$$

with,

| | | |
|---|---|---|
| $ETR_{nttp}$ | = | Exposure Toxicity Ratio off-crop NTTP due to application (-) |
| $PEC_{nttp}$ | = | Exposure off-crop NTTP (kg a.i./ha) |
| $PNEC_{nttp}$ | = | Predicted No Effect Concentration NTTP (kg/ha) |

If:

| | |
|---|---|
| $ETR_{nttp} < 1$ | No Risk (indicated by a green colour) |
| $1 \leq ETR_{nttp} \leq 10$ | Possible risk (indicated by an orange colour) |
| $ETR_{nttp} > 10$ | High Risk (indicated by a red colour) |

## 4.7.4 Parameters risk assessment for non-target terrestrial plants

### 4.7.4.1 Input scenario parameters

The scenario input default values listed in this section are set to 'read-only; the scenarios defined in the risk assessment for registration are predefined and should not be changed by the user.

*Standard*

| | | |
|---|---|---|
| $SF_{nttp}$ | = | Safety factor for in-crop effect assessment of Non Target Terrestrial Plant. The default value is 5. |

*In database*

| | | |
|---|---|---|
| *df* | = | Drift factor, i.e. the fraction of spray drift. *df* depends on the type of crop and the application type (knapsack, airplane)(-) |

### 4.7.4.2 Input pesticide parameters

| | | |
|---|---|---|
| $ER50_{nttp}$ | = | 50% Effect Rate (kg $ha^{-1}$) |

### 4.7.4.3 Input pesticide application parameters

| | | |
|---|---|---|
| *AR* | = | Application Rate of single treatment (kg a.i./ha) |
| n | = | Number of applications (-) |
| *i* | = | Interval between applications (d) |

### 4.7.4.4 Calculated parameters

| | | |
|---|---|---|
| $PEC_{nttp}$ | = | Exposure concentration NTTP off-crop (kg a.i./ha) |
| $ETR_{nttp}$ | = | Exposure Toxicity Ratio NTTP off-crop due to n applications (-) |
| $PNEC_{nttp}$ | = | Predicted No Effect Concentration NTTP (kg $ha^{-1}$) |
| *maf* | = | Multiple application factor (-) |

# 5 User manual PRIMET_Registration_Ethiopia 1.1

## 5.1 PRIMET_Registration_Ethiopia overview

This manual describes the use of the PRIMET_Registration_Ethiopia software package, henceforth referred to as PRIMET.
The PRIMET software package 1.1 is delivered together with three external models. These models can be used independently. Guidance for the external models is given in Annex 1 and 2. The protection goals covered by these external models are:

- ✓ Operator outdoor (the German model)
- ✓ Consumer chronic risk (IEDI calculation model) and acute risk (IESTI calculation model)

Risks assessments in PRIMET are organised in projects. One project consists of risk assessments for one active ingredient with one application on a single crop. Each project corresponds to one line in the Table of Intended use as part of the Product Registration File. A database may contain several projects. One project covers three main assessments being the Environment risk assessment, the Occupational Health risk assessment and the Drinking water risk assessment. Each of these main assessments is sub-divided into a number of protection goal specific assessments. Protection goals covered by PRIMET are listed in Table 19.

Results of the assessment are shown directly after the input data have been entered. Only for the protection goals Aquatic ecosystem and Surface water as source for drinking water a 'Calculate' button should be pressed to start the calculation. For these protection goals the pesticide fate models TOXSWA and PRZM are run. See Section 5.11 for further information.

## 5.2 Getting started

### 5.2.1 Hard and software requirements

Operating systems:
PRIMET has been tested on Windows Vista and Windows 7. Windows XP is no longer officially supported.
Access rights:
To install PRIMET it is necessary to have administrator rights on your PC.
Preinstalled software:
PRIMET requires MS Office Excel for export of the results. The software uses MS Access databases to store its information but MS Access does not need to be installed on the PC.
Hard disk memory:
PRIMET, including its auxiliary models, requires around 40 Mb for installation.
Display:
Monitor with at least 1280 x 740, at 256 colours.
Processor and memory:
At least 2 GB of memory is needed and the faster the processor, the better.

Table 19

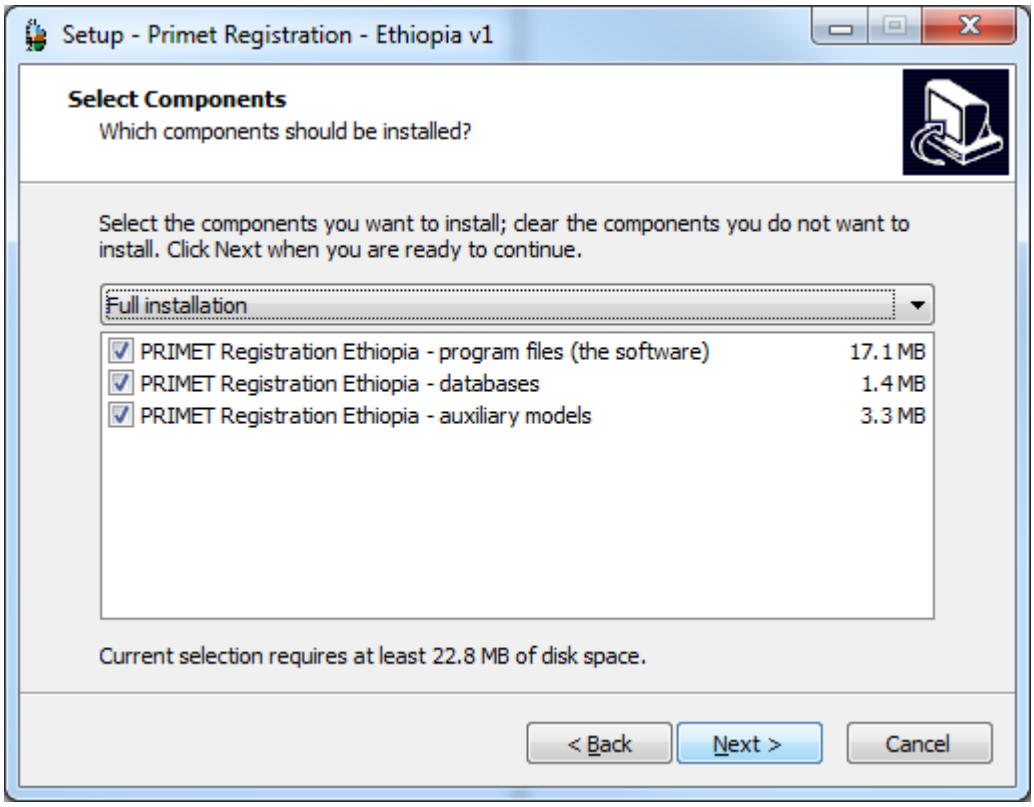
*Main assessments and their protection goals.*

| | | |
|---|---|---|
| **Assessment: Occupational health** | | |
|  | Operator | indoor (greenhouse) |
|  | Worker | indoor- outdoor |
| **Assessment: Drinking water** | | |
|  | Groundwater as source for drinking water | chronic risk |
|  | Surface water as source for drinking water | chronic risk - acute risk |
| **Assessment: Environment** | | |
|  | Aquatic ecosystem | chronic risk - acute risk |
|  | Birds | chronic risk - acute risk |
|  | Bees | in-crop - off-crop |
|  | Non target arthropods | in-crop - off-crop |
|  | Terrestrial ecosystem | chronic risk - acute risk |
|  | Non-target terrestrial plants | off-crop |

### 5.2.2 Installation

PRIMET_Registration_Ethiopia 1.1 can be downloaded from the website: http://www.pesticidemodels.eu/primet-ethiopia/home . Save the package to your hard drive and double click the file to start the set up procedure.
The PRIMET software, including the additional calculation spreadsheets and the PRZM and TOXSWA models, will be installed to your “My Documents” folder by default. The exact location differs per user and depends on its computer settings. If this default folder is a network drive we strongly advise to change this to a folder on a local drive to guarantee a proper working of the software. The user can select another location for installation. For a proper performance of the assessment calculations, the path length is limited. During installation the path length of the directory is checked automatically. It is recommended not to use special characters or spaces in the path.

The installation procedure will create a shortcut to the software in the Windows start menu and (optionally) on the desktop. Alternatively the software can be started by double-clicking the PRIMET_Reg_Eth_1.1.1.exe file in the PRIMET_Reg_Eth_1.1 folder.
**Note that you require Administrator rights on Windows 7 or higher to start the installation procedure!**




### 5.2.3 Databases

PRIMET is distributed with two MS Access databases; (1) the PRIMET database which contains scenarios and the software configuration as well as the projects, and (2) the active ingredient database that contains the relevant properties of the pesticides. At first start PRIMET will ask for the location of these databases.
By default and after installation the main and active ingredient databases will be stored in the \Database\ folder in the main PRIMET folder and will be named “PRIMETdb_Main_Reg_Eth_1.mdb” and “PRIMETdb_AI_Reg_Eth_1.mdb” respectively. PRIMET checks the database type after selection and will produce an error message when the wrong type of database (e.g. an Active Ingredient database where a PRIMET database is expected) is selected. It is possible to place the databases in another folder or to rename them. PRIMET will then ask for the correct location on the next start.

The current database selection is visible on the home screen (top right) and the name and location of the database is stored after closing the program for consecutive use.

## 5.3 The home screen

The home screen of PRIMET is shown after closing the database selection screen, at the first start, and immediately at any subsequent starts. The home screen consists of a menu bar at the top of the screen, a vertical tool bar on the left, a Manage Projects section and a Database info section. A section for selecting pesticides, crops and application schemes is situated in the centre of the screen. The lower part of the screen is reserved for showing the risk assessment main indicators. Each assessment has a separate tab and on each tab the corresponding risk indicators are shown. In Figure 1 the home screen is given, with the Environment tab selected. The main indicators of the protection goals Aquatic ecosystem, Birds, Bees, Non-Target Arthropods, Terrestrial ecosystem and Non-Target Plants are listed in this tab.

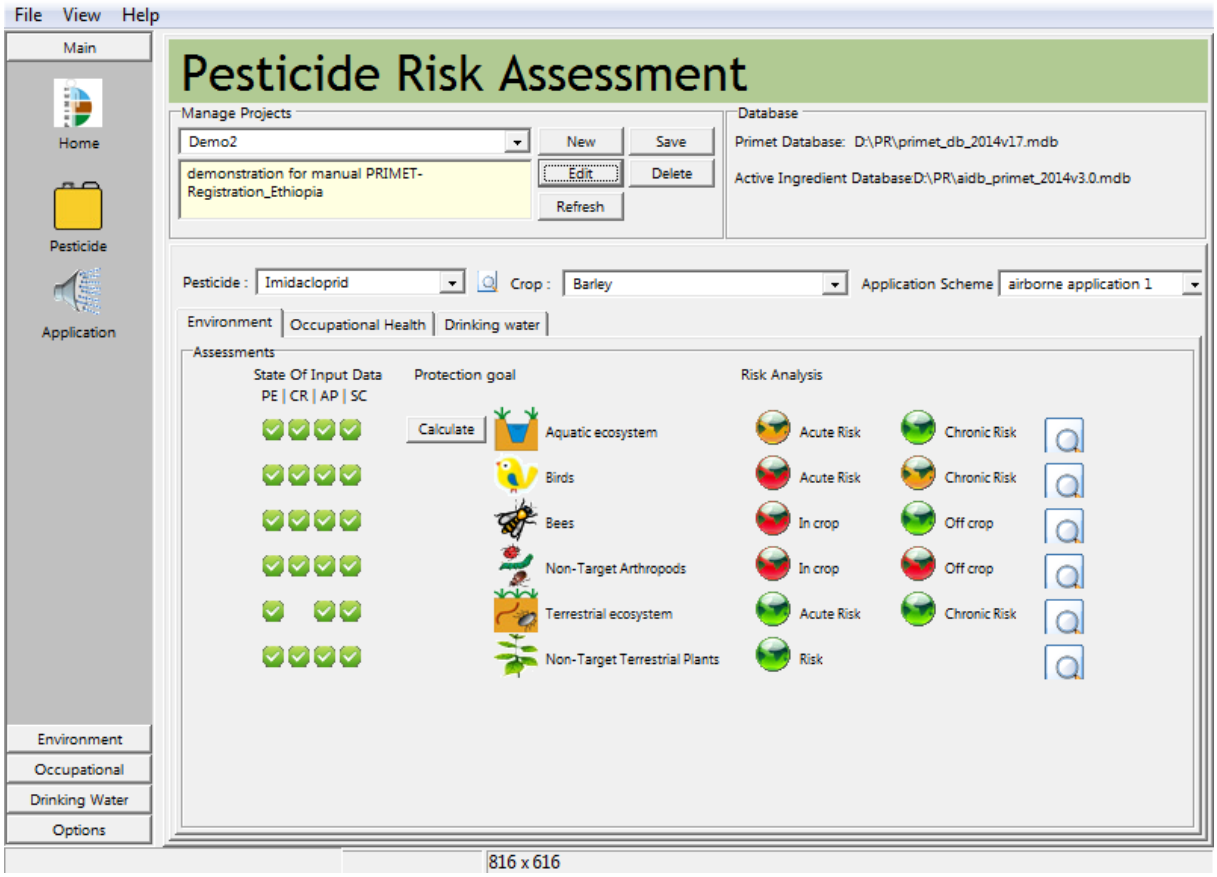



***Figure 1*** *Home screen of PRIMET_Registration_Ethiopia.*

**The menu bar.** The menu bar has three options; File, View and Help. Via the File menu the Manage databases option is provided. In addition, via the File menu PRIMET can be closed. The management of databases is explained in Section 5.13. The View menu (see Figure 2) provides access to the Home screen, to the Pesticide management screen (see also Section 5.5), to the Application scheme management screen (see also Section 5.5) and the risk assessment tabs Environment, Occupational Health and Drinking Water on the home screen. The Pesticide reference list provides a list of all pesticides that are listed in the pesticide database.

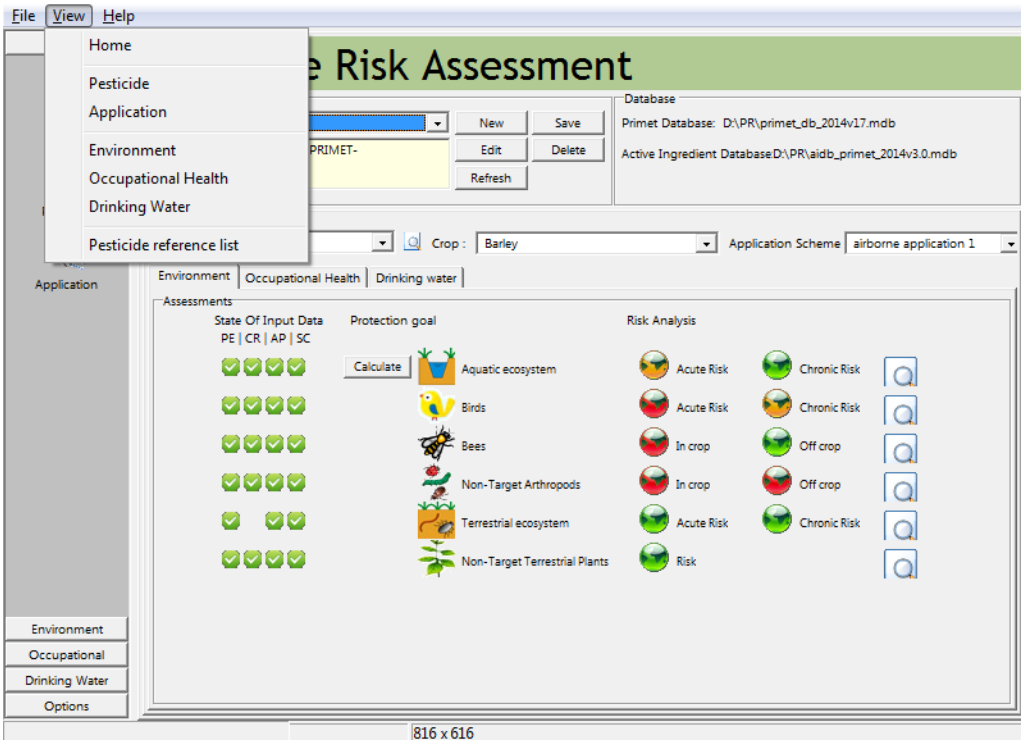



***Figure 2*** *The menu View on the menu bar.*

The help menu option on the menu bar provides access to the PRIMET website, the manual and to the About screen of PRIMET.

**The vertical tool bar**. The vertical tool bar to the left duplicates the functionality of the menu with easily accessible buttons. It has five pages, the first of which, Main, provides quick access to the home screen, the Pesticide management screen and the Application scheme management screen. There are three other pages, one for each main assessment, that display the properties of the different protection goal specific settings. The Options page has buttons for exiting the application, viewing the About screen and the legend page.

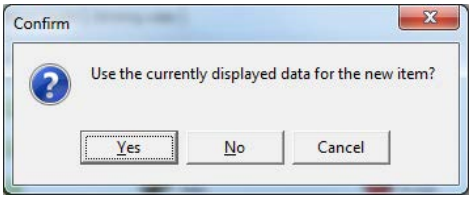



***Figure 3*** *Screen to allow for reuse of the data of an existing project.*

## 5.4 Managing PRIMET projects

Projects form the core of the PRIMET tool. Each project consists of a combination of a pesticide, a crop, an application scheme and a set of protection goal specific settings. Go to the Manage Project section of the Home screen to add a new project and click on the 'New' button. PRIMET will ask you whether you would like to copy the data of the current project in the new project (Figure 3).

After selecting one of the options on the screen, PRIMET will ask you to provide the name of the project and a project description. After clicking the 'ok' button a new project is added. Projects can also be Edited, Saved and Deleted using the buttons in the Manage Projects section. To allow for the risk assessments to be performed, one pesticide must be selected, one crop and one application scheme. These can be selected from the crop down menus in the centre of the Home screen. The application method selected in the Application scheme may not be appropriate for the selected crop. For these crop-application combinations PRIMET gives a warning: 'Invalid crop-application method combination!'. This warning is given for unusual crop-application method combinations: mango-knapsack, lemon-knapsack, coffee-knapsack. In Figure 4, the selection of an application scheme is shown; the selection of a crop and a pesticide is similarly.

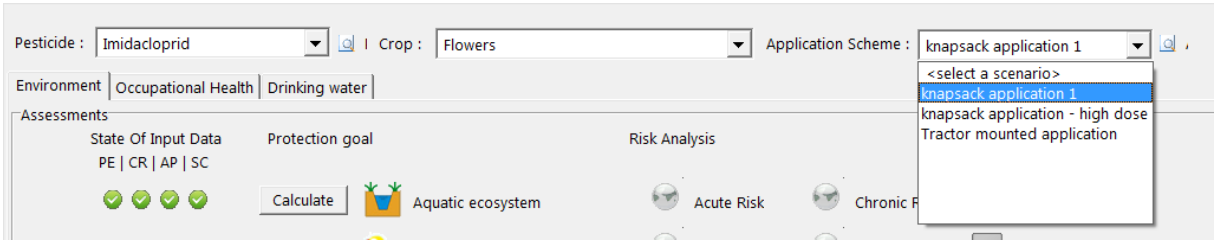



***Figure 4*** *Selection of an application scheme.*

## 5.5 Managing items (Pesticides and Application schemes)

The following items can be viewed, added, modified and deleted:

- Pesticides
- Application schemes

Note that the list of crops is fixed and cannot be modified by the user. Also, the different protection goal specific settings can be viewed but not modified in this version of PRIMET (via vertical tool bar). Pesticide and Application schemes management screens can be accessed either through the menu or through the tool bar as previously explained. The top of the screen consists of a 'Select and manage' section which is similar in functionalty to that of Projects. New pesticides or application schemes can be added, either from scratch or copied from the currently selected item. The Edit button allows the user to change the name and description of the selected item and the delete button removes the selected item from the database with a confirmation dialog but *without an undo function!*

## 5.6 Updating item properties (Pesticides and Application schemes)

The lower part of the item (pesticide or application scheme) management screen is reserved for Input data, i.e. the properties of the selected pesticide or application scheme. This part consists of two columns in which the properties of the item are listed. The input data are organized according to the protection goal they are required for. For some of the protection goals, the same properties are needed. E.g. for pesticides Kom soil is required to assess the risk for 'Surface water for drinking

water', 'Aquatic ecosystem' as well as 'Groundwater for drinking water'. When one of the input fields of Kom soil is entered, it is automatically copied to all input fields of the same property.

A vertical scrollbar will appear in case the input fields do not vertically fit on the form. A short description and the units of the input parameters are provided left and right to each input field. The question mark button next to the input field shows a popup text with additional information about the selected property, such as a full description of the property and its allowed range (minimum and maximum value).
Once a new item is added the user can start entering the property values and move from one field to the next using the mouse or the TAB button.
The input fields are colour coded to guide the user with colours based on the status of the data for that input field. The meaning of the different colours is as follows:

- White: a valid required value has been entered
- Yellow: a required value is missing
- Brown: a interrelated value is undefined
- Light yellow: undefined value, can optionally be entered
- Green: a default value is available and has been entered

Figure 5 shows the legend for the input field colours. To perform the risk assessments all yellow and brown fields should beentered. Input fields of type 'default' (green) will automatically contain the value as defined by the system. These fields cannot be left blank, the value can be changed by the user only.
Interrelated input fields (brown) are those for which at least one of the fields indicated with the same number (in brackets) has to have a value. The other field of the pair can then either be calculated from the first (e.g. Koc soil and Kom soil) or the value is optional. This is explained below for the relevant pesticide properties.

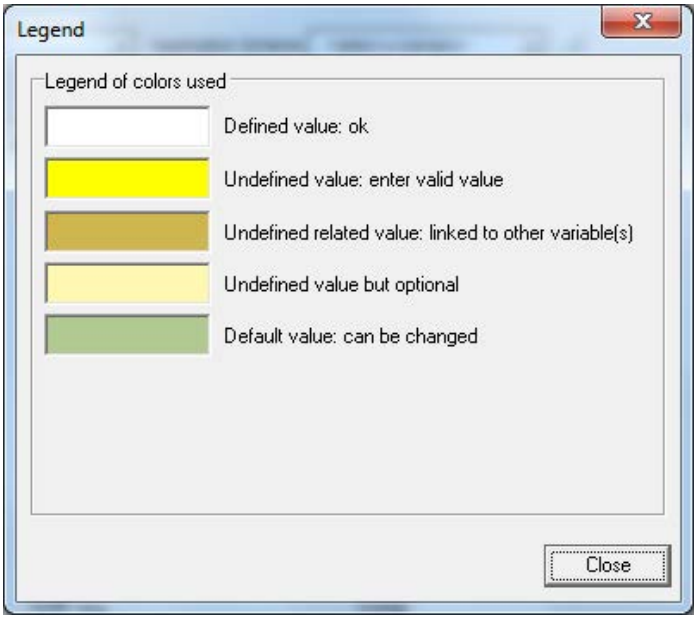



***Figure 5*** *Legend for the colours used in the input fields.*

### 5.6.1 Interrelated pesticide properties

The Pesticide input screen as shown in Figure 6, contains a number of interrelated fields with the following meaning:

13. Koc and Kom, see for the relationship between Koc and Kom Section 3.2, Eq. 13
14. LR50 nta, glass plate test and LR50 nta, extended lab test. The glass plate test is considered the first tier effect assessment and the extended lab test the second tier effect assessment. One of

these LR50 values should be enteredto perform the Non Target Arthropod risk assessment. See also Section 4.5 for elaboration on the NTA risk assessment.

15. NOAEL mammals and ADI, in case no ADI is available, it can be derived from the NOEAL mammals, see for the relationship Section 3.3, Eq.22.

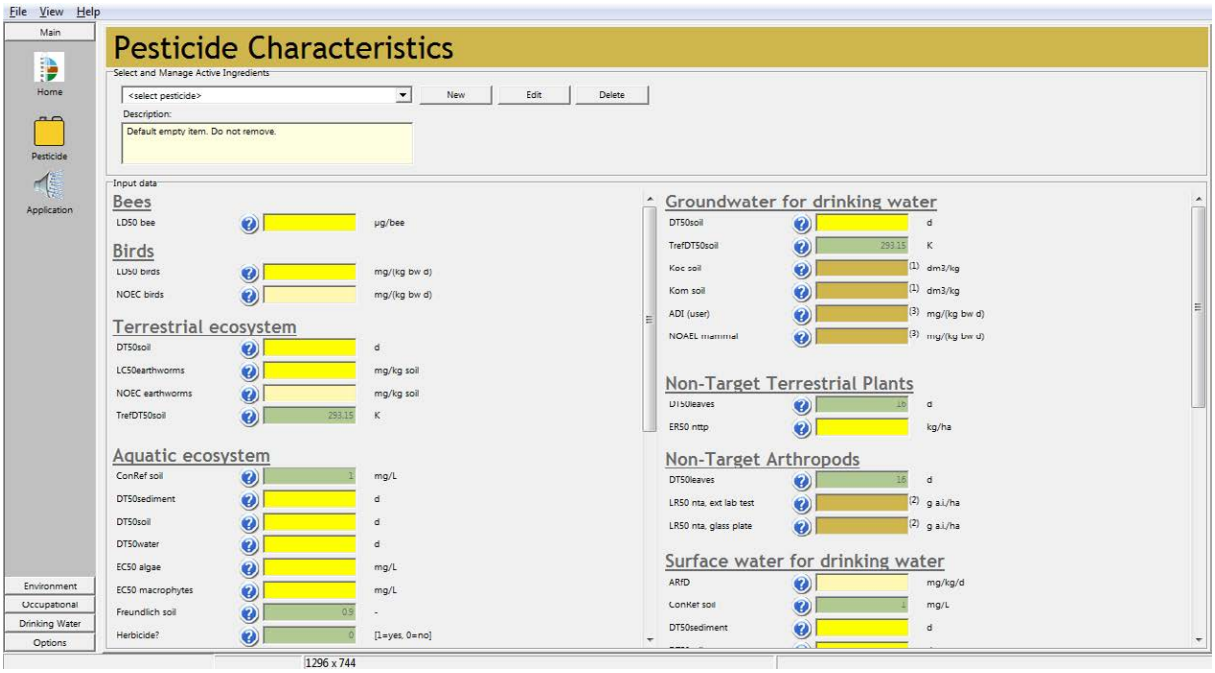



***Figure 6*** *The Pesticide Characteristics input screen. The screen consists of a Select and Manage Active Ingredients section and an Input data section.*

### 5.6.2 Exceptions for application scheme

The Application input scheme screen is shown in Figure 7. Note that for workers and for operator indoor also Absorption dermal (only operator) is required. Strictly speaking this is not an application property but for convenience the property is added to the application scheme screen.
For operator indoor additional higher tier personal protection equipment may be selected.

## 5.7 Crop selection

The list of crops that can be selected is predefined. Additional crops cannot be added by the user. For tomato, onion, cabbage and potato, two crop cycles can be selected. The first crop cycle represents crop cultivation during the rainy season (Kremt; no irrigation) and the second crop cycle represents crop cultivation during the dry season (Bega, irrigated). This is relevant for the protection goals Aquatic ecosystem and for Surface water as source for drinking water. See for further detail on the risk assessment Section 3.2 and 4.2 or Adriaanse *et al.* (2014). For the other protection goals, both the first and the second cycle will result in the same exposure risk.

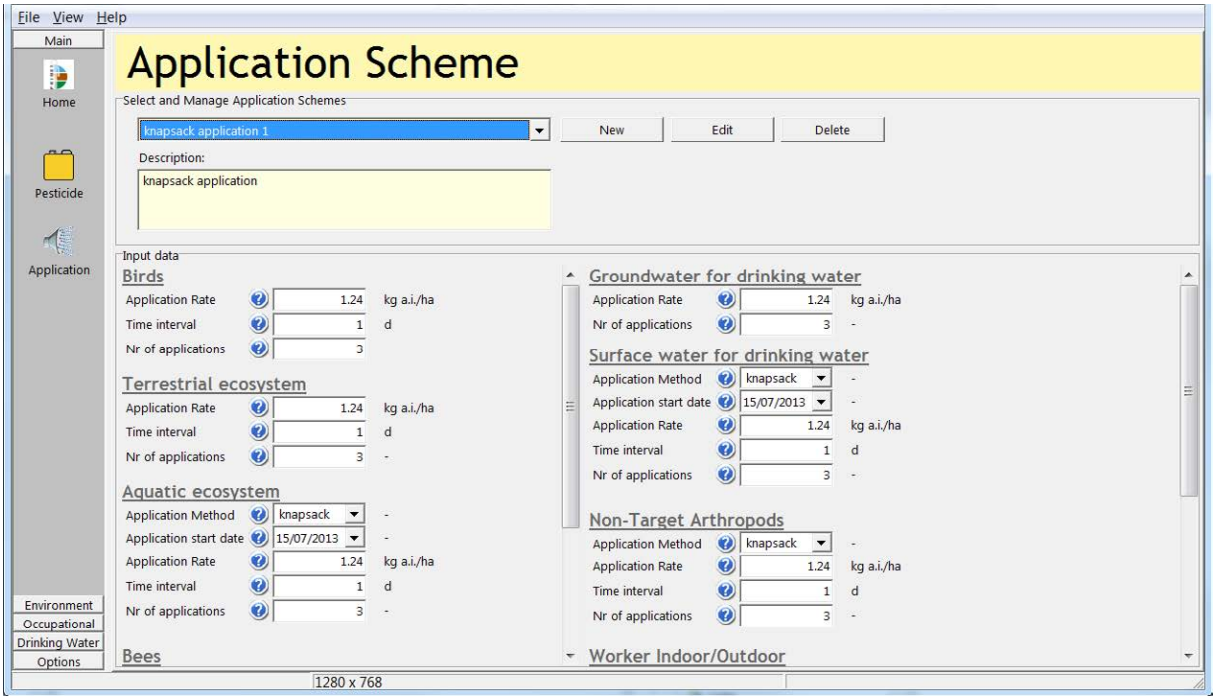



**Figure 7** *Application Scheme screen. The screen consists of a Select and Manage Application Scheme section and an Input data section.*

## 5.8 Main assessment results

The results are organized according to the tabs Environment, Occupational health and Drinking water (for the protection goal environment see Figure 8). On each tab the protection goals for each specific main assessment are listed. From left to right the user is informed about the status of input data and the main results of each protection goal:

i. Left: the status of the input data of the pesticide (column PE), the crop (column CR), the Application schema (Column AP), and the specific scenario settings (column SC). The status can be either OK ( ) or not OK ( ). Only when all input data are given, the status switches to OK. Scenario properties are fixed and cannot be changed by the user, hence the status of CR is always OK.
   Tip 1: a click on the red or green icons will take you to the relevant property page.
   Tip 2: hovering the cursor above the (red) icon displays a popup hint that shows how many properties and which are missing.

ii. Centre: the protection goals including a pictogram for each protection goal. A calculate button is shown for Aquatic ecosystem and Surface water as source for drinking water. The explanation of this button is given in Section 5.11.

iii. Right: an indication of the risk by coloured globes. The risk associated is represented by one or two globes per protection goal. For example the protection goal Birds has a globe for acute risk and for chronic risk. The colours of the globes can be green (no risk), orange (possible risk) or red (high risk). In case the input data is incomplete, i.e. one of the status indicators is red, the globes will remain grey, indicating that the risk cannot be assessed. For a detailed protection goal specific overview the zoom buttons to the right can be pressed ( ).

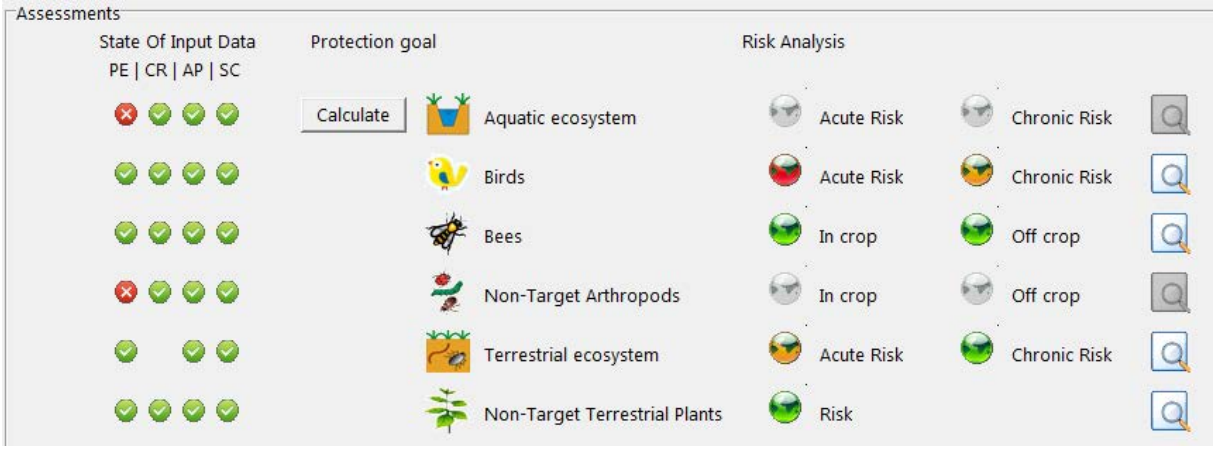



***Figure 8*** *Main assessment results for Environment (with some incomplete input data).*

## 5.9 Detailed results of the assessments per protection goal

For a detailed overview of the results the zoom buttons ( ) to the right of each protection goal on the home screen, can be pressed. This opens the protection goal overview screen. The screen consists of two tabs, one Summary tab and one Details tab. In Figure 9 the screen is shown for the environmental protection goal Birds, with the tab Summary selected.

**Summary tab.** The Summary tab lists the main characteristics of the assessment, being the date and time, the protection goal, the active ingredient, the applied mass, the number of applications and the selected crop. In addition, the Summary tab shows the main information behind the indicated risks (globes) on the Home screen.

In PRIMET, risk is expressed by an Exposure Toxicity Ratio (ETR). The ETR consists of an exposure part in the numerator and an effect (reference) part in the denominator. For each of the protection goals a lower limit ETR is defined below which no risk is expected. Also an upper limit is defined above which high risk is expected. In between these ETR limits 'possible risk' is expected. For some of the protection goals the lower and upper limits have the same value. For these protection goals there is only no risk or high risk.

The Summary tab is organized along the calculation and interpretation of the ETR. It has the same structure for each of the protection goals. Each specific protection goal is plotted on one row. In each row, the ETR limits are given first, then the effect concentration and the exposure concentration. The row ends with the ETR values and colours indicating the risk.

For the protection goals Birds, Aquatic ecosystem, Surface water as source for drinking water and Groundwater as source for drinking water, the exposure concentration is given for multiple scenarios. The ETR is calculated for each of these scenarios. When a scenario is not relevant for the specific crop-application combination, the cell remains empty. Risk indicators are provided for each relevant scenario in this detailed overview. This enables the user to obtain a quick overview for which of the considered scenarios there is a low, possible or high risk. An overview of the Summary tabs per protection goal is given in Table 20.

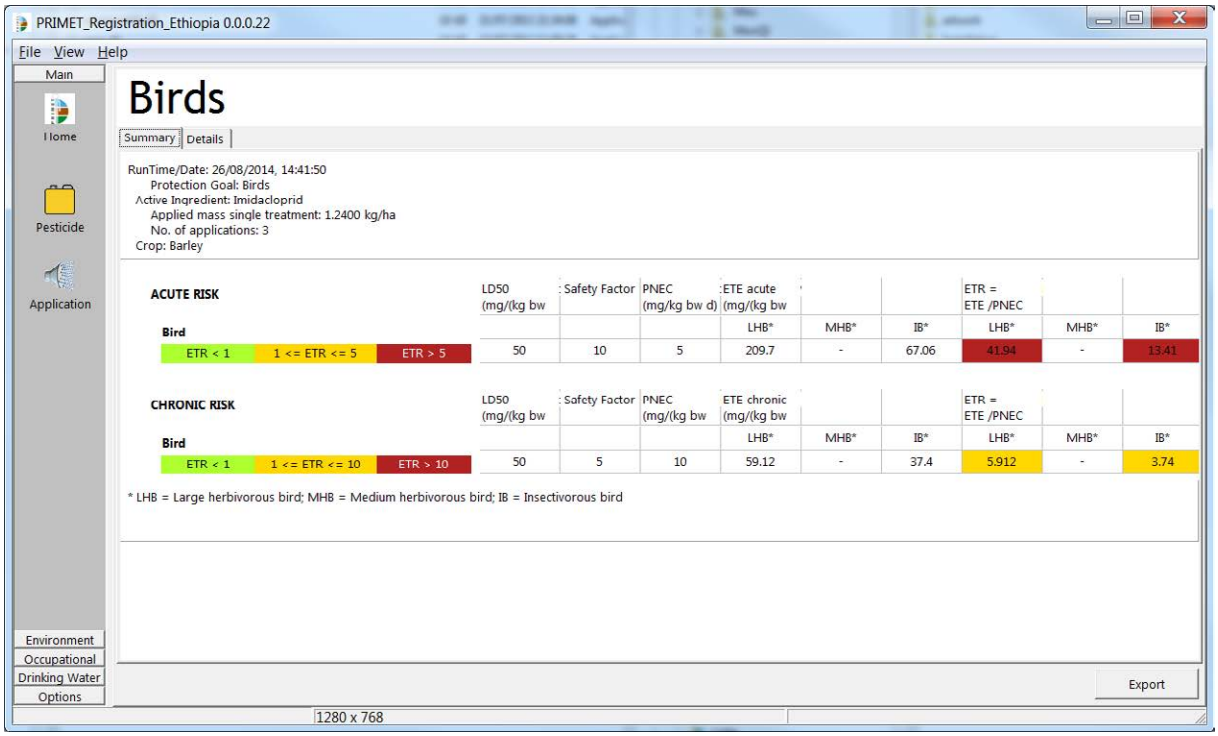



***Figure 9*** *Overview screen of the protection goal Birds, with the tab Summary selected*

Table 20

*Overview of the Summary tab contents per protection goal.*

| protection goal | sub-prot.goal | exposure | effect | unit | nr of ETR | risk definition per ETR | assessment colour on home screen |
|---|---|---|---|---|---|---|---|
| **operator** | indoor | Systemic exposure | AOEL | mg/(kg d) | 1 | if ETR<= 1 then no risk else high risk | if risk indicator is green then green else red |
| **worker** | indoor | Systemic exposure | AOEL | mg/(kg d) | 1 | if ETR<= 1 then no risk else high risk | if risk indicator is green then green else red |
| **worker** | outdoor | Systemic exposure | AOEL | mg/(kg d) | 1 | if ETR<= 1 then no risk else high risk | if risk indicator is green then green else red |
| **groundwater for drinking water** | chronic risk | Daily Intake chronic for the protection goals 1,2 ,3a and 3b as listed in Table 5, Chapter 3. | Daily accepted intake chronic | mg/(kg d) | 3 | if ETR<= 1 then no risk else high risk | if all risk indicators are green then green,else red |
| **surface water for drinking water** | acute risk | Daily intake acute for the protection goals 1,2a an 2b as given in Table 7, Chapter 3. | Daily accepted intake acute | mg/(kg d) | 3 | if ETR<= 1 then no risk else high risk | if all risk indicators are green then green,else red |
| **surface water for drinking water** | chronic risk | Daily intake chronic for the protection goals 1,2a an 2b as given in Table 7, Chapter 3. | Daily accepted intake chronic | mg/(kg d) | 3 | if ETR<= 1 then no risk else high risk | if all risk indicators are green then green,else red |
| **aquatic ecosystem** | acute risk | PEC for the protection goals 1,2, 3a and 3b as listed in Table 5, Chapter 3. | PNEC for fish and invertebrates | µg/L | 6 | fish: if ETR <=1 then no risk, else if ETR <= 10 then possible risk, else high risk. Invertebrates: if ETR <=1 then no risk, else if ETR <= 100 then possible risk, else high risk. | if risk indicator fish and invertebrates are green, then green, if one or more are red, then red, else orange |
| **aquatic ecosystem** | chronic risk | PEC for the protection goals 1,2, 3a and 3b as listed in Table 5, Chapter 3. | PNEC for fish, invertebrates, algae and macrophytes | µg/L | 12 | fish and macrophytes: if ETR <=1 then no risk, else if ETR <= 10 then possible risk, else high risk. Invertebrates, algae, macrophytes: if ETR <=1 then no risk, else if ETR <= 100 then possible risk, else high risk. | if risk indicator fish, invertebrates, algae and macrophytes are green , then green, if one or more are red, then red, else orange*. |
| **birds** | acute risk | ETE for 1 to 3 birds | PNEC | mg/kg bw | 1 to 3 | for each bird: if ETR< 1 then no risk else if ETR <= 5 then possible risk else high risk | if all risk indicators are green then green,else if one or more indicators are red, then red, else orange |
| **birds** | chronic risk | ETE for 1 to 3 birds | PNEC | mg/kg bw | 1 to 3 | for each bird: if ETR< 1 then no risk else if ETR <= 5 then possible risk else high risk | if all risk indicators are green then green,else if one or more indicators are red, then red, else orange |
| **bees** | In-crop | PEC | PNEC | g/ha | 1 | if ETR< 50 then no risk else if ETR <= 400 then possible risk else high risk | if risk indicator is green then green, if risk indicator is orange then orange, else red |
| **bees** | off-crop | PEC | PNEC | g/ha | 1 | if ETR< 50 then no risk else if ETR <= 400 then possible risk else high risk | if risk indicator is green then green, if risk indicator is orange then orange, else red |
| **terrestrial ecosystem** | acute risk | PEC | PNEC | mg/kg soil | 1 | if ETR< 1 then no risk else if ETR <= 5 then possible risk else high risk | if risk indicator is green then green, if risk indicator is orange then orange, else red |

* The risk for Algae and Macrophytes is neither acute nor chronic risk. However, for the risk indicator on the home page they are considered a chronic risks.

| protection goal | sub-prot.goal | exposure | effect | unit | nr of ETR | risk definition per ETR | assessment colour on home screen |
|---|---|---|---|---|---|---|---|
| terrestrial ecosystem | chronic risk | PEC | PNEC | mg/kg soil | 1 | if ETR< 1 then no risk else if ETR <= 5 then possible risk else high risk | if risk indicator is green then green, if risk indicator is orange then orange, else red |
| non target arthropods | in-crop | PEC | AEC for first tier and second tier | kg/ha | 2 | first tier: if ETR< 2 then no risk else if ETR <= 100 then possible risk else high risk. Second tier: if ETR< 1 then no risk else if ETR <= 50 then possible risk else high risk. | if risk indicator second tier is green then green, if risk indicator is orange then orange, if risk indicator is red then red. If the risk indicator is grey ( no second tier available) then use the first tier indicator |
| non target arthropods | off-crop | PEC | AEC for first tier and second tier | kg/ha | 2 | first tier: if ETR< 2 then no risk else if ETR <= 20 then possible risk else high risk. Second tier: if ETR< 1 then no risk else if ETR <= 10 then possible risk else high risk. | if risk indicator second tier is green then green, if risk indicator is orange then orange, if risk indicator is red then red. If the risk indicator is grey ( no second tier available) then use the first tier indicator |
| non-target plants | off-crop | PEC | PNEC | kg/ha | 1 | if ETR< 1 then no risk else if ETR <= 10 then possible risk else high risk | if risk indicator is green then green, if risk indicator is orange then orange, else red |

**Details tab.** The details tab lists all input data vallues, intermediate (calculated) values and the calculated output data. The screen consists of three sections:

1. The upper section lists the (output) ETR values for each detailled protection goal.
2. The Log section will only display if errors occurred.
3. The Values section lists all relevant values used in the calculations (input, intermediate and output) with a label, the units and a short description for each parameter. This enables the user to trace back the calculated values for each scenario and for each protection goal.

## 5.10 Exporting results

Although projects are saved as part of the databases, it is recommended, for robustness and retraceability of the assessments, to use the export option in the detailed output screens.
This export function creates a MS Excel file that mirrors the assessment results, both the summary and the details tab. The assessor can always trace back the steps and input data that are behind the calculated risks and replicate the calculations. Hence, the results can always be traced back to the original input data.
Exporting of assessments is done per protection goal. For exporting the assessment data go to the zoom button of the specific protection goal and select the export button (bottom right) below the Summary and Details tabs. PRIMET will suggest a name for the export file (see Figure 11). The suggested name consists of the active ingredient, the crop and the protection goals together with the date (YYYYMMDD) and the time (HHMMSS), respectively. It is recommended to create a proper archive structure and save the exported file under the right dossier folder as suggested and discussed separately. The suggested structure is Archive\prf number-product name\Application number\PRIMET\... as discussed in the PRRP workshop d.d. 29/8-2/9 2014. In figure 10 the slides discussed in the workshop are shown for reference.

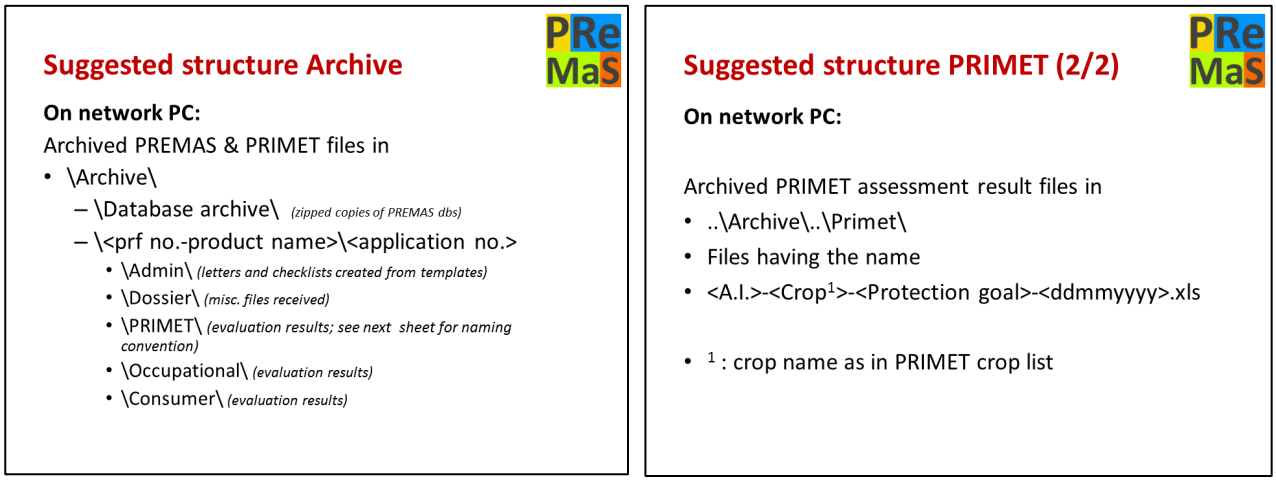



***Figure 10*** *Suggested archive structure for saving export files.*

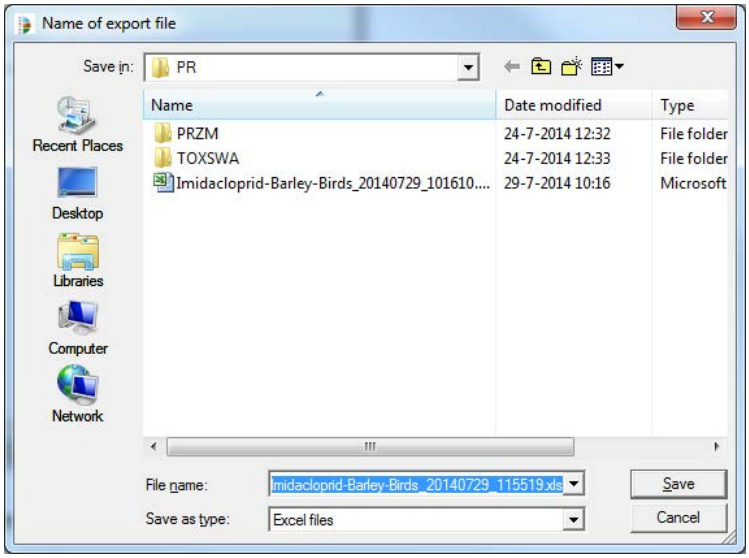



***Figure 11*** *Screen to manage export files. PRIMET suggests a name for the export file. The exported file contains two tabs. The first tab contains a copy of the Summary tab of the assessment and the second tab contains all detailed input, intermediate and output data.*

## 5.11 Special: Aquatic ecosystem and surface water as source for drinking water

To assess the risk for the protection goals Aquatic ecosystem and Surface water as source for drinking water, the calculate button, to the left of the protection goal name on the home screen, should be used. Make sure that all input data are available, i.e. that the input status check boxes are all OK, before starting the calculation. Then, PRIMET starts to run the pesticide fate models FOCUS_PRZM_SW 3.1.1, TOXSWA version 3.3.1 and a post-processing model in the foreground. In Figure 12 the PRZM screen is shown while performing the calculation for the Demo project[5]. PRIMET is locked for editing and viewing during the time that the models are run. For the small stream scenario only PRZM is run together with a post-processing program and for the pond scenarios PRZM is run as well as TOXSWA and a post-processing program. The number of scenarios that are assessed depends on the selected crop. See Table 8 in Chapter 3 for the scenarios considered per crop.

After finishing the model calculations the results are shown similarly to the other protection goals. PRIMET checks whether the results from previous PRZM/TOXSWA runs are consistent with the project input data and available when a new selection of pesticide, crop and application is made. If previous calculations are still valid then the globes on the Home screen indicate a risk by colouring either green, orange or red directly without a need to restart the calculations. When changes are made in the input data of the project, the results of the runs become invalid, which is indicated with grey globes. See Section 5.8 and 5.9 on the access to risk assessment results.

The protection goals Aquatic ecosystem and Surface water as source for drinking water make use of the same scenarios. Once the concentrations in stream and/or the ponds have been calculated, the results of the calculations can be used by both protection goals to derive the relevant PECs. This implies that the user should only press the calculate button once to obtain the results of the risk assessment for both protection goals.

[5] The PRZM screen shows that the version WIN_PRZM 3.52 is used. This is correct; after FOCUS_PRZM_SW_3.1.1 is installed this screen appairs while running.

PRIMET writes the results of the PRZM and TOXSWA model runs to folders in the main PRIMET directory where the PRIMET execuTable is also located. The corresponding folders are called PRZM and TOXSWA. Within each folder, PRZM and TOXSWA, the results are organised by scenario. For PRZM a folder is available for each crop, for TOXSWA the results are overwritten at each run.
It is recommended for the PRIMET end-user to not interfere with the files in either PRZM or TOXSWA folder as this can potentially lead to the non-functioning of the tool.

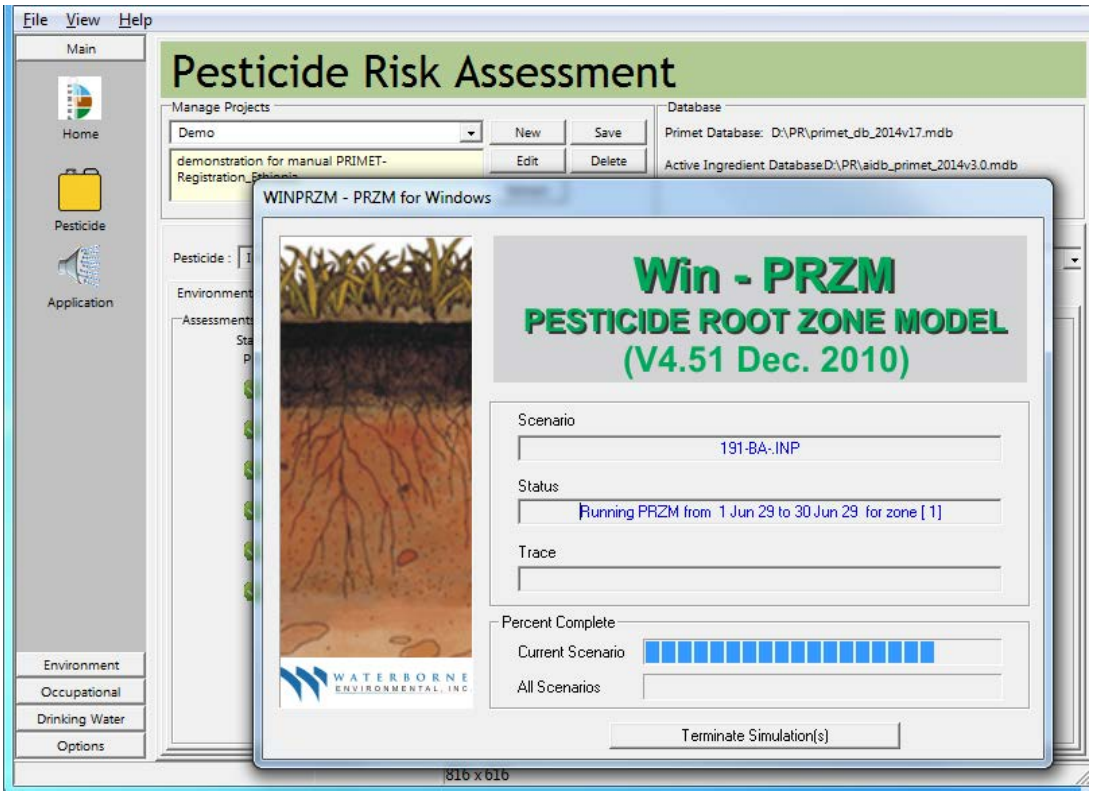



***Figure 12*** *After pressing the Calculate button, the PRZM model has started to run the simulations for the protection goal related to the Aquatic ecosystem risk in Ethiopia.*

## 5.12 Viewing scenario properties


The scenario properties are predefined properties which can, in principle, not be altered. Scenario properties can be viewed (1) via the SC button on the Assessment part of the home screen, or (2) by using the button in the toolbar.
Note that for Surface water as source for drinking water and for Aquatic ecosystem, not all scenario properties are shown; for these protection goals external models are used and scenarios are therefore defined outside the PRIMET database.

## 5.13 Databases management

Databases can be selected from a selection screen. Select the menu 'File' on the menu bar at the top of the screen and select 'Select and Manage databases'. A Database management screen pops up containing two tabs. The first tab, i.e. Database selection, enables the user to select a PRIMET database as well as an active ingredient database (Figure 13). Use the browse button to select the databases and the Close button to save the selection and go back to the PRIMET home screen.
Note that this screen will also pop up at the first start of PRIMET when no databases are selected yet or in any other situation when a previous selection is invalidated due to the removal or deletion of previously selected databases.
The user does not need to re-select the database at a next start of the software as it will save the previous selection.

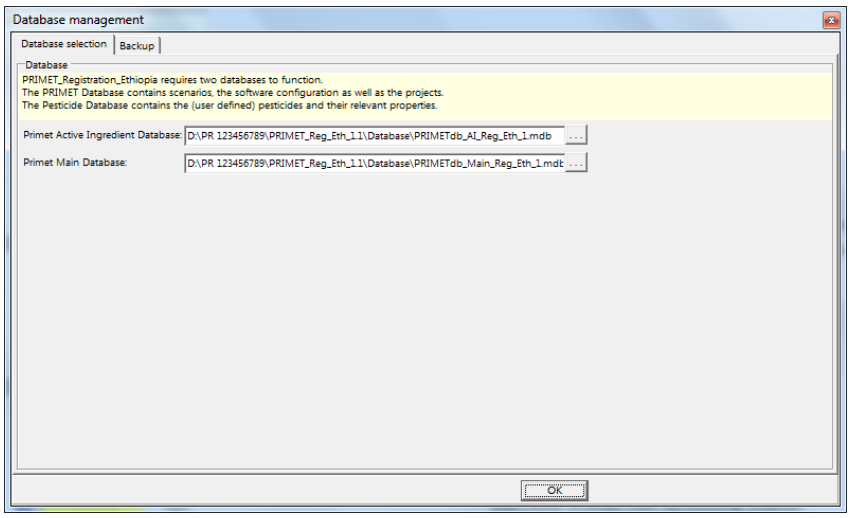



***Figure 13*** *The Data management screen enables to select databases. The names of the databases installed during PRIMET installation procedure are referred to as PRIMETdb_Main_Eth_1.mdb (main database) and PRIMETdb_AI_Eth_1.mdb (active ingredient database).*

## 5.14 Archiving of the databases

PRIMET databases can be archived via the Database management screen. The PRIMET database contains the project information while the Active Ingredient database contains the pesticide properties. Select File on the menu bar and 'Select and Manage databases'. Then select the tab Backup (see Figure 14). After selecting the back-up destination folder, press on the Backup button. This function will create a zipped copy of the databases in the selected location. The files will be marked with their original name and date stamp according to YYMMDD_sn# format where sn# is a serial number for backups made on the same day. The databases are archived using the zip protocol that is commonly used in Windows. Subsequently, a backup can be restored by unzipping the archived files to the desired location, using regular Zip tools (Winzip, 7-zip, WinRar etc.). it is recommended to save the archive databases in the Archive\ Database archive folder.

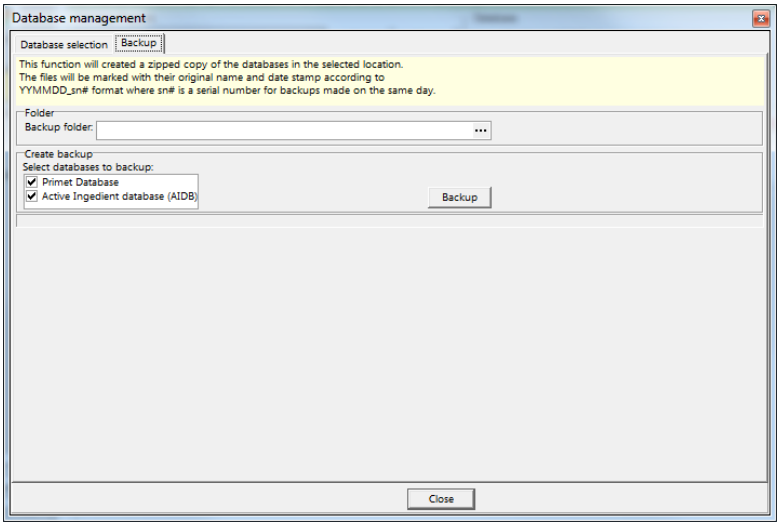



***Figure 14*** *Databases can be zipped and saved via the back-up option on the Database management screen.*

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Van den Brink, P.J., M.M.S. Ter Horst, W.H.J. Beltman, J. Vlaming, H. van den Bosch (2005) PRIMET version 2.0, technical description and manual. A Decision Support System for assessing Pesticide RIsks in the tropics to Man, Environment and Trade, Alterra-rapport 1185, Wageningen, The Netherlands.

# Annex 1 User guide to calculate the chronic and acute consumer risk with external models

## A1.1 Introduction

This annex contains instruction for the use of the models available along with PRIMET_Registration Ethiopia 1.1 to calculate the risks related to the protection goals:

- Chronic consumer exposure
- Acute consumer exposure

For the chronic consumer risk assessment the WHO-GEMS IESTI model version revision 14 is used using the GEMS food consumer cluster diets from August 2006. The model has been slightly adapted to Ethiopian circumstances by marking irrelevant commodities in red and by adding teff as a commodity.
For the acute consumer risk assessment the WHO-GEMS IEDI model is used. The concepts of both WHO-GEMS models are described in Van der Velde-Koerts *et al.* (2010). The models are MS Excell based and part of the software package of PRIMET_Registration- Ethiopia 1.1. The chronic consumer risk model is referred to as ***IEDI_calculation_Ethiopia.xltm*** and the acute consumer risk model is referred to as ***IESTI_calculation_Ethiopia.xltm***.

## A1.2 Chronic consumer risk

The model ***IEDI_calculation_Ethiopia.xltm*** enables the calculation of the International Estimated Daily Intake (IEDI) based on estimated Supervised Trial Median Residue (STMR, STMR-P) or the Maximum Residue Level (MRL) for relevant commodities. It summarizes the total intake in mg/person/day and calculates the total intake as percentage of the Acceptable Daily Intake (ADI) for 13 world food clusters. Food cluster A is considered appropriate for Ethiopia.

The spreadsheet consists of six tabs:

- the tab '*Manual*' containing instructions,
- the tab '*GEMS_food_diet*' containing the actual list of commodities
- the tab '*Final_table*' collects the results of the calculations
- the tab '*Diets*' describes the composition of the food clusters
- the tab '*Check_Aug06_v2*' and '*Diet_list_Aug06_v2*' provide background information.

MRLs can be derived from databases (see also Deneer *et al.*, 2014). Supervised residue trials are currently not available for Ethiopia, however they may become available in the near future. In that case the MRL calculator may be used to derive MRLs from the supervised residue trials. Further guidance on long-term dietary intake is given in Deneer *et al.* (2014).

The use of the MRL calculator can be downloaded at:

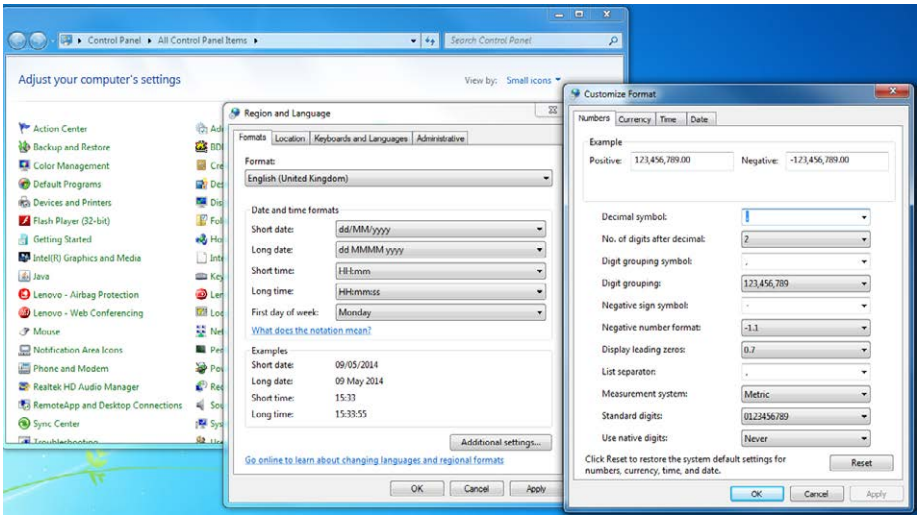
http://www.oecd.org/env/chemicalsafetyandbiosafety/agriculturalpesticidesandbiocides/oecdmaximumresiduelimitcalculator.htm

## How to use the template IEDI_calculation_Ethiopia.xltm?

The consecutive steps for the IEDI calculation are explained in the next sections. These steps can also be found in the manual tab of the template.

***Step 0: PC configuration***

Left at the bottom of the computer screen, Choose Start-Control Panel. Then, double click on Region and Language, and select the formats-tab. Click on Additional settings and take care that the Decimal symbol is a . (dot), the Digit grouping symbol is a , (comma) and the list separator is a , (comma). See figure below.

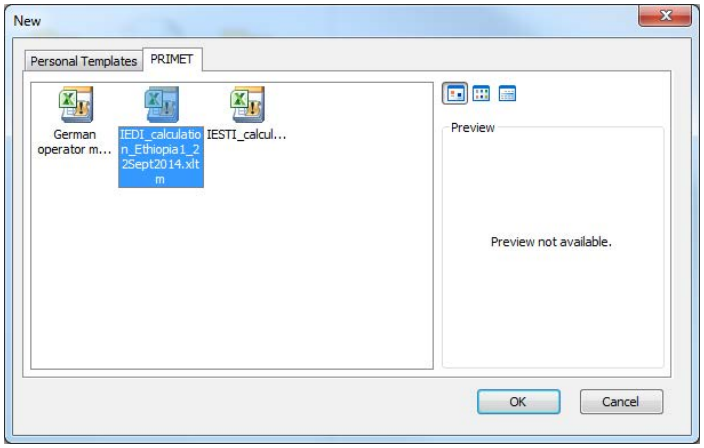



***Step 1*** *Installing the template.*

The template should be saved in the correct directory or folder (once-only action). During installation PRIMET will automatically save the template in the Microsoft templates folder under the tab PRIMET. If this had not been tha case, templates can alternatively found under \PRIMET\ auxiliary models\ . After openening Excel and select File, the location of the template directory will become visible - Save As and select save as type: template (*.xltm). After saving the template close and restart Excel.

***Step 2*** *Opening the template.*

i. Open the template always by going to File – New (see figure below). Then, choose the template: IEDI_calculation_Ethiopia. Save the spreadsheet as a macro enabled file (xlsm to ensure that the name gets automatically an extension with an additional number). To ensure that you start with a fresh template (without old data) and that the original template will not be overwritten, the template should not be opened via File-Open. Take care that retraceable names will be given to the files and that you organize the files properly in folders. The suggested file name is: <active ingredient><crop><chronic cons. risk><date (ddmmyyy)>



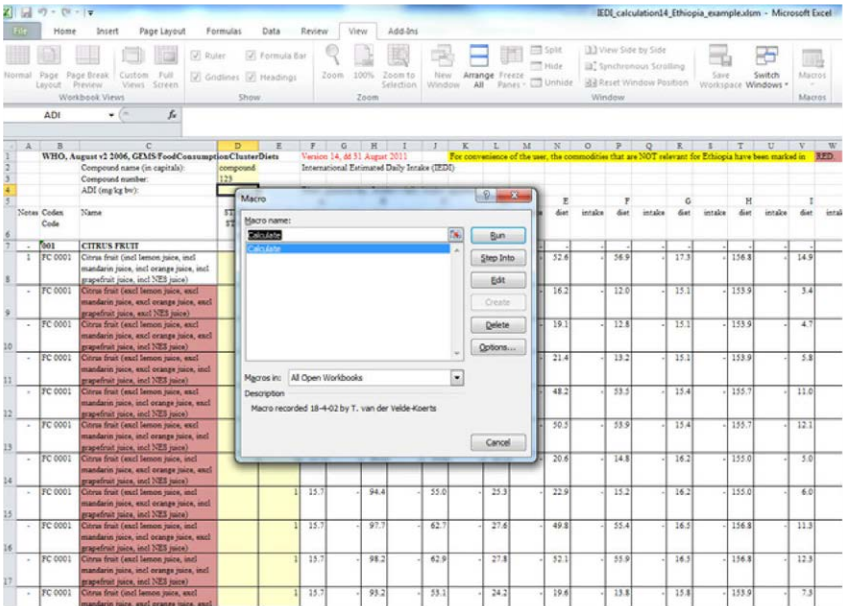

***Step 3*** *Entering the product/ active ingredient specific information.*

i. Select tab "GEMS_Food_diet"
ii. Enter compound name, compound number and ADI (in yellow cells)
iii. Enter STMR or STMR-P and diet correction factors for relevant commodities (in yellow columns). The commodities that are NOT relevant For Ethiopia have been marked in red, which means that they can be neglected. When STMR or STMR-P are at LOQ (Limit of Quantitation), just enter the value for LOQ (in Excel calculations * or < is not permitted).
iv. If you have only MRLs, change the column titles (in GEMS_Food_diet and Final_table) into MRL and change "International Estimated Daily Intake" into Theoretical Maximum Daily Intake (TMDI) (in GEMS_Food_diet).

For guidelines for entering residue values please consult the Evaluation manual or the tab: Manual in: IEDI_calculation_Ethiopia.xltm

***Step 4*** *Start calculations*

Go to the View-tab and select Macros. Then select Calculate and press the Run-button.




***Step 5*** *Post-processing.*

Go to Word and open a new document. Put the cursor in the position where you want the Table and go to Excel and choose tab Final_table. Select the area with diets A-F (columns A-P, cell A1 to bottom) and choose Edit-Copy. Go to Word and choose Edit-Paste as picture. Save both the Word and the Excel document with correct names. For Ethiopia, food-cluster A is considered representative. The suggested folder to store the files is Archive\ prf no.-product name\application no.\PRIMET\.., the suggested file name is:
<active ingredient><crop><chronic cons. risk><date (ddmmyyy)>

***Repeating the calculation***
When an ADI, STMR or STMR-P has to be modified or newly introduced, just change the value in tab "GEMS_food_diet". Repeat from step 3 onwards.

## A1.3 Short term intake

The model ***IESTI_calculation_Ethiopia.xltm*** enables the calculation of the acute or short term exposure. This model calculates the acute risk based on the assumption that someone consumes a Large Portion (LP) and that this large portion contains a higher residue level than based on the composite sampling in residue trials. A risk assessment for short-term dietary intake is conducted for each commodity-compound combination by expressing the International Estimated Short Term Intake (IESTI) as a percentage of the Acute Reference Dose (ARfD).

The spreadsheet consists of four tabs:

- the tab '*Abbreviations*' containing a list of abbreviation and definitions,
- the tab '*Manual*' containing guidance on the calculation of acute risk and explanation on the model versions and sources,
- the tab '*IESTI calculation'* containing the actual Table with commodities,
- the tab '*Final_table*' containing the results of the calculations.

The model calculates the IESTI for one of three distinguished cases. The selected case depends of the unit weight of the commodity and the weight of the edible portion of the commodity:

**Case 1**
The concentration of residue in a composite sample (raw or processed) reflects that in the large portion size of the commodity. This is assumed to be the case when the unit weight is < 25 g. This case also applies to meat, liver, kidney, edible offal and eggs.

IESTI = (LP * (HR or HR-P) * v) / bw

Where:
LP = Large Porion (kg)
HR = Highest Residue in composite sample (mg/kg)
HR-P = Highest Residue in processed commodity (mg/kg)
v = variability factor (-)
bw = body weight, provided by the country in which the LP was used (kg)

**Case 2**
The typical unit, such as a single piece of fruit or vegetable, might have a higher residue than the composite such as when a unit weight of a commodity is > 25 g. The variability factors, v are applied in the equations. When sufficient data are available on residues in single units to calculate a more realistic variability factor for a commodity, the calculated value should replace the default value of 3 for all commodities.
When data are available on residues in a single unit and thus allow estimation of the 97.5th percentile residue in a single unit, this value should be used in the first part of the equation for case 2a, with no variability factor, and the HR value derived from data on composite samples should be used in the second part of the equation. For case 2b, the estimated 97.5th percentile residue in a single unit should be used in the equation with no variability factor.

**Case 2a.** The unit weight of the whole portion is lower than that of the large portion, LP:

IESTI = (U * (HR or HR-P) * v+ (LP-U) * (HR or HR-P)) / bw
**Case 2b.** The unit weight of the whole portion is higher than that of the large portion, LP:

IESTI = (LP * (HR or HR-P) * v) / bw

Where:
U = Unit weight (kg)
HR = Highest Residue in composite sample (mg/kg)
HR-P = Highest Residue in processed commodity (mg/kg)
v = variability factor (-)
bw = body weight, provided by the country in which the LP was used (kg)

**Case 3**
When a processed commodity is bulked or blended, the STMR-P value represents the probable highest concentration of residue. This case also applies to milk

IESTI = (LP * STMR-P) / bw

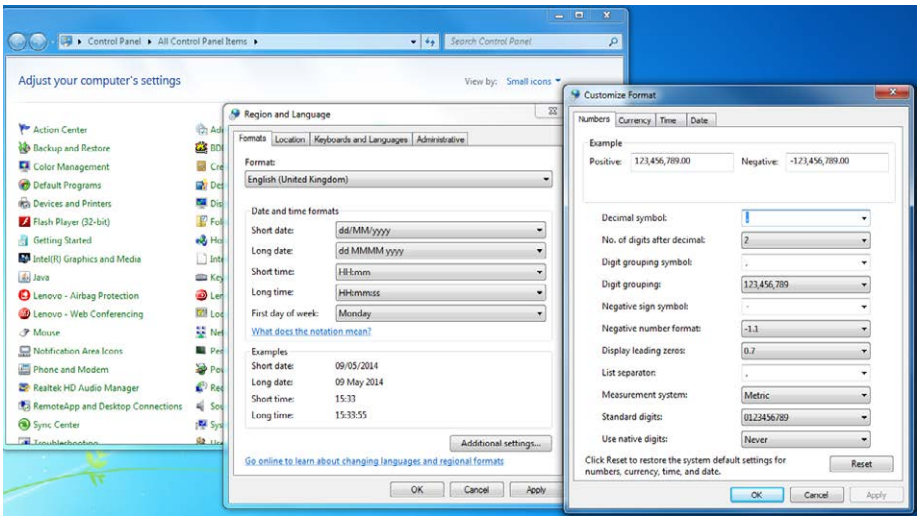
Where:
LP = Large Porion (kg)
STMR-P = Supervised Trial Median Residue in processed commodity (mg/kg)
bw = body weight, provided by the country in which the LP was used (kg)

**How to use the template IESTI_calculation_Ethiopia.xltm?**

The consecutive steps for the IESTI calculation are explained in the next sections. These steps can also be found in the manual tab of the template.

***Step 0*** *PC configuration.*

Left at the bottom of the computer screen, Choose Start-Control Panel. Then, double click on Region and Language, and select the formats-tab. Click on Additional settings and take care that the Decimal symbol is a . (dot), the Digit grouping symbol is a , (comma) and the list separator is a , (comma). See figure below.

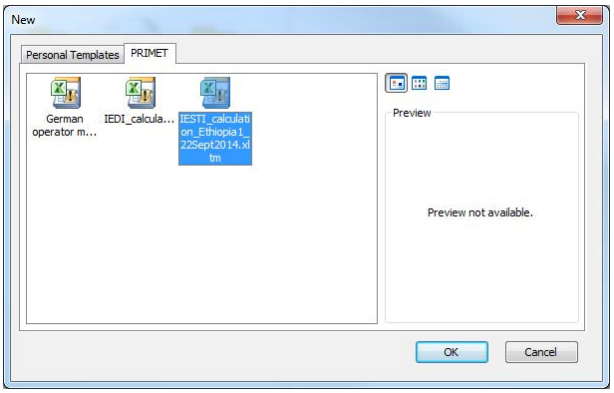



***Step 1*** *Installing the template.*

The template should be saved in the correct directory or folder (once-only action). PRIMET will automatically save the template in the Microsoft templates folder under the tab PRIMET. Templates can alternatively be found under \PRIMET\ auxiliary models\ . After opening Excel and select File, the location of the template directory will become visible - Save As and select save as type: template (*.xltm). After saving the template close and restart Excel.

***Step 2*** *Opening the template.*

ii. Open the template always by going to File – New (see figure below). Then, choose the template: IESTI_calculation_Ethiopia. Save the spreadsheet as a macro enabled file (xlsm to ensure that the name gets automatically an extension with an additional number). To ensure that you start with a fresh template (without old data) and that the original template will not be overwritten, the template should not be opened via File-Open. Take care that retraceable names will be given to the files and that you organize the files properly in folders. The suggested file name is: <active ingredient><crop><acute cons. risk><date (ddmmyyy)>

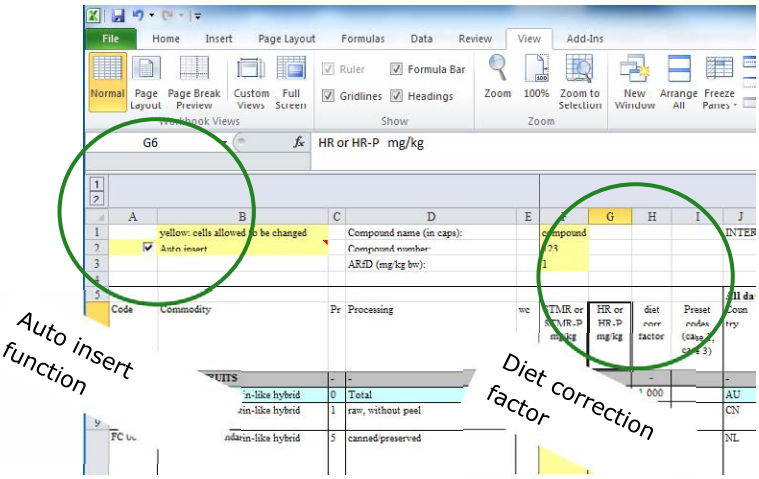


***Step 3*** *Entering the product/ active ingredient specific information.*

i. Select the tab "*IESTI calculation*"

ii. Enter compound name, compound number, Acute RfD (in yellow cells)

iii. Enter STMR, STMR-P, HR or HR-P for the relevant commodities (in yellow columns).When STMR or HR are at LOQ (Limit Of Quantitation), just enter the value (in Excel calculations * or < is not permitted). Consider using "Auto insert" function (tick auto insert box). At the top left of the spreadsheet a checkbox for the "Auto insert" feature is placed. "Auto insert" supports quick data entry. If STMR or HR values are entered into the row of the "total" commodity (see the column "processing"), all sub-commodities are automatically filled with the same value, if the Case of the sub-commodity support the value. E.g. if a HR for Lemons, total is entered, all Case 1 and Case 2a/b commodities for lemons are entered with the same value. Auto insert" does not overwrite present values and does not work for Commodities without Codex Code ("-"). When "Auto insert" is enabled, only an STMR or and HR may be entered, depending on the Case of the specific commodity. For meats and milks the "Auto insert" feature is disabled because of special needs for entering data.




***Step 4*** *Follow guidelines for entering residue values (see below)*

Enter STMR and HR values as complete as possible i.e. for all lines of the crop in question. When you have an STMR or HR, do not change the diet correction factor. When you have an STMR-P or HR-P, change the diet correction factor in 1.000.

***Step 5*** *Start calculations.*

Start the calculations via the tool bar button ("Calculation General Population" or "Calculation Women in childbearing age"). When the calculation is finished, a message box "Calculation is ready" will appear and the results can be found in the tab "Final Table". The current calculation procedure summarises all cases for one commodity, which result in <100% of the ARfD. When the IESTI for all sub-commodities and populations is <100%, the information is summarised in one single row named "COMMODITY (all commodities)". STMRs, HRs and ARfDs are presented as a range of values, representing the minimum and maximum for each parameter (e.g. ARfD 0-50%). Since the summarised data is based on multiple diets, no consumption or sub-commodity specific information can be presented. When the IESTI for at least one sub-commodity exceeds 100% of the ARfD, these commodities are presented with full detailed information. Other sub-commodities <100% are summarised as described under 2, but named as "COMMODITY (all other commodities)". When all sub-commodities exceed 100% of the ARfD, no summary is generated.

***Step 6*** *Post-processing*

iii. Go to Word and open the template JMPR_annexes.dot

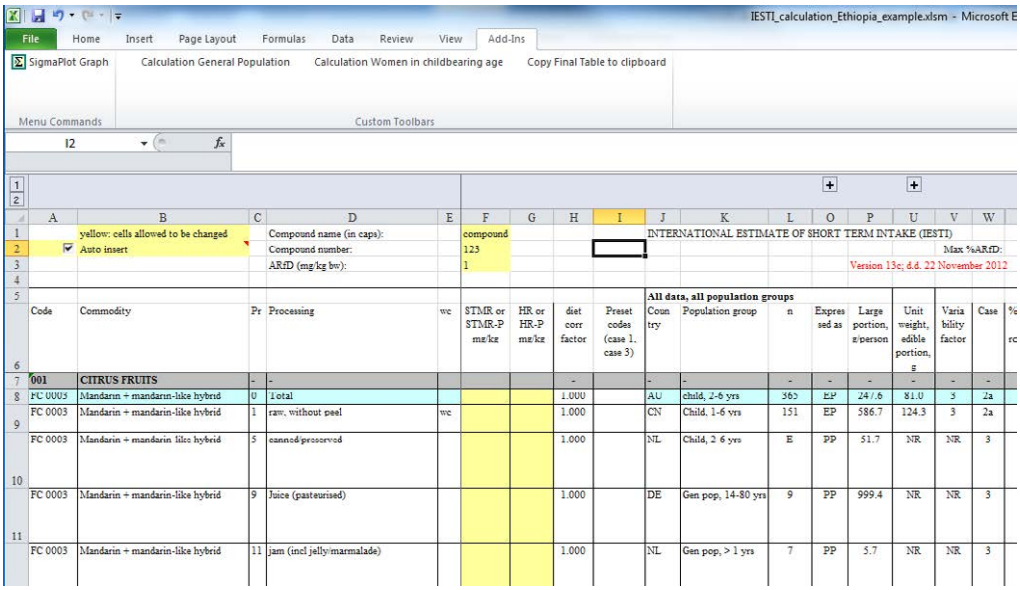
iv. Go to Excel and choose tab "Final_table".

v. Press tool bar button "Copy to clipboard". When the Table is very large, the clipboard cache may not be sufficient. Then select an area of maximum 150 rows and copy the Table in pieces to Word or increase the general virtual memory in the windows system properties.

vi. Go to Word and put the cursor in the right position.

vii. Choose Edit-Paste. The Table is now converted into a Word document.

viii. Save both the Word and the Excel document. The suggested folder to store the results is Archive\ prf no.-product name\application no.\PRIMET\.., the suggested file name is: <active ingredient><crop><acute cons. risk><date (ddmmyyy)>




***Step 7*** *Repeating the calculation.*

When an ARfD, STMR, STMR-P, HR, HR-P or diet correction factor has to be modified or newly introduced, just change the value in tab "IESTI calculation". Repeat from point 5 onwards.

## A1.4 List of abbreviations

| Abbrevation | Description | Unit |
|---|---|---|
| ADI | Acceptable Daily Intake | mg/kg bw |
| STMR | Supervised Trial Median Residue | mg/kg |
| STMR-P | Supervised Trial Median Residue in processed commodity | mg/kg |
| MRL | Maximum Residue Level | mg/kg |
| IEDI | International Estimated Daily Intake | mg/kg bw |
| ARfD | Acute Reference Dose | mg/kg bw |
| DCF | diet correction factor. Factor used to avoid underestimation or overestimation of IESTI | - |
| EP | commodity expressed as raw edible portion | - |
| HR | highest residue in composite sample of edible portion found in data from supervised trials data from which the MRL or STMR was derived | mg/kg |
| HR-P | highest residue in the processed commodity | mg/kg |
| IESTI | International estimated short term intake | mg/kg bw |
| LP | highest large portion provided (97.5th percentile of eaters) | kg food/day |
| PP | Consumption value expressed as processed product | |
| v | variability factor represents the ratio of the 97.5th percentile residue to the mean residue in single units. Default factors for various commodities are listed below | - |

## A1.5 References

Deneer, J.W., P.I. Adriaanse, P. De Boer, M. Busschers, J. Lahr, C. Van der Schoor, P. Van Vliet and A. Woldeamanual (2014). A scientific evaluation system for the registration of pesticides in Ethiopia, Alterra-report 2547, Wageningen, the Netherlands

Van der Velde-Koerts, T., G. van Donkersgoed, N. Koopman, B.C. Ossendorp, 2010. Revision of Dutch dietary risk assessment models for pesticide authorisation purposes, RIVM report 320005006.

# Annex 2 User guide to calculate small scale and large scale operator risk with external models

## A 2.1 Introduction

To calculate the risk for small scale operators (hand held equipment) and large scale operators (tractor mounted application) for field (outdoor) applications, two models are available, the UK POEM model and the German model.

Both models are used for:

- Field (outdoor) spraying operations
- Vehicle equipment (tractor mounted), downward as well as upward spraying
- Hand held equipment (knapsack), upward spraying
- Downward as well as upward spraying
- Home garden low level spraying
- Powder, granules, liquid formulations
- The POEM UK model is additionally used for hand held equipment, downward spraying. The models are to be used both in the risk assessment procedure.

The UK POEM model is based on the report of the Scientific Subcommittee on Pesticides of the British Agrochemical Association Joint Medical Panel (1986) . This model is not incorporated in the PRIMET_registration_Ethiopia 1.1 software package.

The German model for the protection of operators is based on the a report by the Biologischen Bundesanstalt fur Land- u Forstwirtschaft (BBA, 1992). This publication was converted into a computer-supported mathematical model by the Federal Institute for Risk Assessment (BfR). The model is incorporated in the PRIMET_registration_Ethiopia 1.1 software package and is referred to as ***German operator model_Ethiopia.xltx***. The protection equipment and the exposure reduction factors have been modified to Ethiopian conditions.

In the Table below, an indication is given whether a crop is treated outdoors with hand held equipment (knapsack sprayer), with vehicle equipment (tractor mounted) or both and whether the application is downward and/or upward (taken from Deneer *et al.*, 2014). Protective equipment is only relevant for large scale operators.

| Crop | Application<br>Vehicle equipment (large scale) | Hand held equipment (small scale) |
|---|---|---|
| Tomato | Down | Down |
| Onion | Down | Down |
| Cabbage | Down | Down |
| Potato | Down | Down |
| Teff | - | Down |
| Wheat | Down | Down |
| Maize | Down | Down |
| Barley | Down | Down |
| Faba bean | - | Down |
| Green beans | Down | Down |
| Sweet potato | - | Down |
| Cotton | Down | Down |
| Mango | Up | Up |
| Sugarcane | Down/up | Down/up |
| Banana | Up | Up |
| Lemon | Up | Up |
| Coffee | Up | Up |
| Chat (chata edulis) | - | Down/up |
| Flowers (greenhouses) | - | Down |

## A 2.2 German model

The model ***German operator model_Ethiopia.xltx*** calculates the exposure of small scale and large scale operators as well, but with a different approach. The model calculates the operator exposure with and without PPE. The operator exposure is the summation of dermal exposure during application and mixing/ loading and the inhalation exposure during application and mixing and loading. The model calculates additionally the exposure as percentage of the Accepted Operator Exposure Level (AOEL).

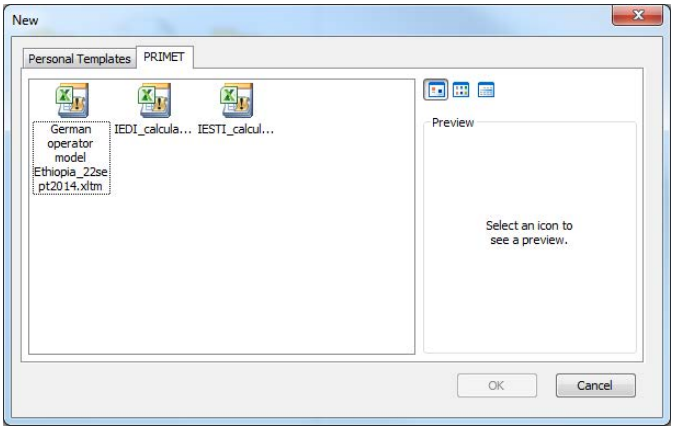
### How to use the German operator model_Ethiopia.xltx model?

***Step 1*** *Installing the template.*

The template should be saved in the correct directory or folder (once-only action). PRIMET will automatically save the template in the Microsoft templates folder under the tab PRIMET. Templates can alternatively be found under \PRIMET\ auxiliary models\ . After opening Excel and select File, the location of the template directory will become visible - Save As and select save as type: template (*.xltm). After saving the template close and restart Excel.

***Step 2*** *Opening the template.*

Open the template always by going to File – New (see figure below). Then, choose the template (My templates/ PRIMET): German operator model_Ethiopia. Save the spreadsheet as a normal excell file (xlsx to ensure that the name gets automatically an extension with an additional number). To ensure that you start with a fresh template (without old data) and that the original template will not be overwritten, the template should not be opened via File-Open. The suggested folder to store the files is Archive\ prf no.-product name\application no.\PRIMET\.., the suggested file name is: <active ingredient><crop><operator risk outdoor><date (ddmmyyy)>




***Step 3*** *Fill out the orange fields.*

Enter the active substance name, the product and the intended use (crop types). Then select from the drop down menu the application type and the type of preparation. After the selection enter the Application rate for the active substance (kg a.s./ha), the systemic AOEL (mg/kg bw/d), Dermal absorption for mixing/loading and for application (%),and the body weight (default 60 kg). The default for inhalation absorption is always 100%.

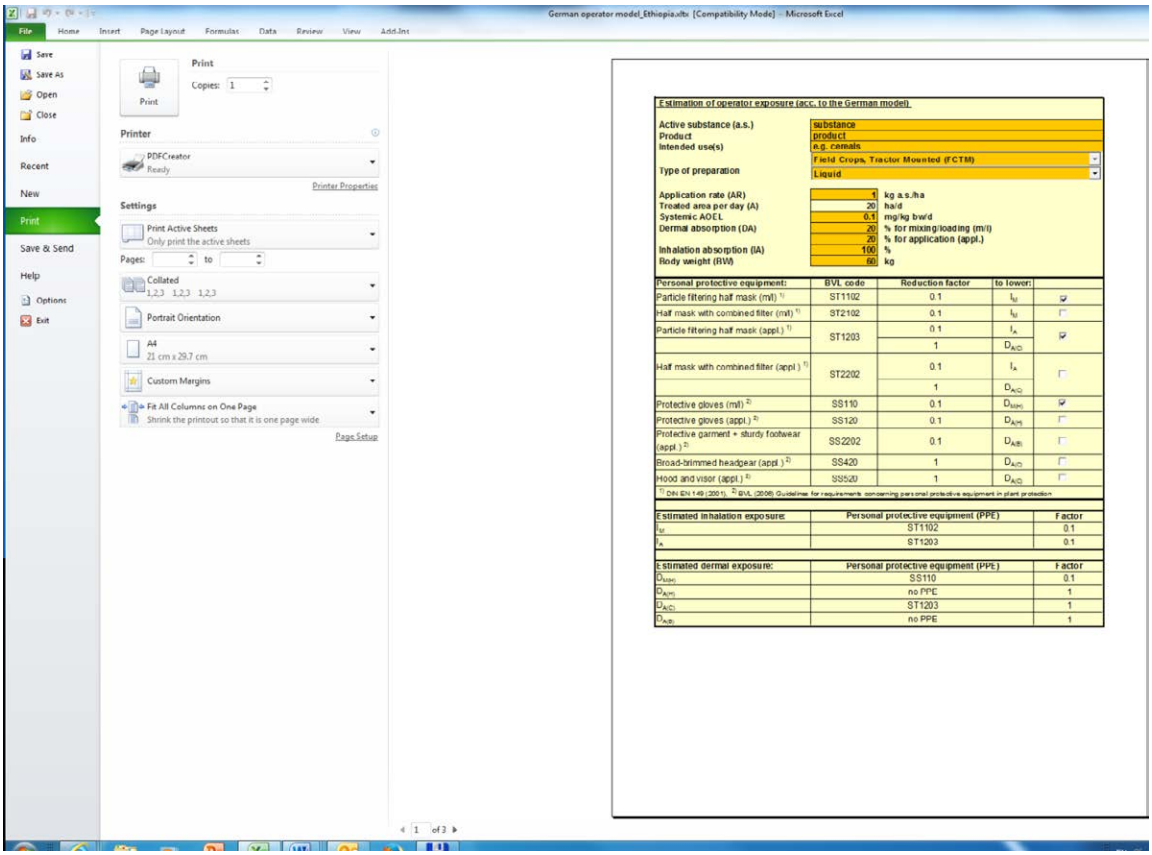
The model enables the calculation of the effect of protective equipment for a wide range of protective equipment. Protective equipment is only considered for large scale operators (vehicle equipment). The protection factors in the model have been adapted for Ethiopia as explained in (Deneer *et al.*, 2014). The protective equipment can be selected by clicking the selection box.

***Step 4*** *Post-processing.*

In the Table with results the dermal exposure and inhalation exposure are presented. The left side of the Table shows the exposure without PPE, the right side the exposure with PPE. Note that PPE is only allowed if 'field crops, tractor mounted' or 'high crops , tractor mounted' was selected. The exposure is given as external exposure, and also as a systemic (internal) exposure by using the dermal or inhalation absorption value.
Press on the print button and selected pdfcreator and archive the document (three pages). The suggested folder to store the calculations and the results is Archive\ prf no.-product name\application no.\PRIMET\.., the suggested file name is: <active ingredient><crop><operator risk outdoor><date (ddmmyyy)>

## A2.3 How to assess the risk for small scale and large scale operators?

The first tier risk assessment is performed by assuming that no PPE is used. In that case:
No adverse effects on humans expected (safe use) if the total systemic exposure is < AOEL and adverse effects on humans cannot be excluded (no safe use) if the total systemic exposure > AOEL for both models. If adverse effects on humans cannot be excluded (no safe use without PPE), a refinement of the risk assessment should be considered with risk reduction measures. See for further instructions Deneer at al. (2014).




## A 2.4 References

BBA, 1992. Uniform principles for assuring the protection of operators' health when using plant protection products (uniform principles for operator protection), Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Heft 277, Berlin 1992 (in German).

Scientific Subcommittee on Pesticides of the British Agrochemical Association Joint Medical Panel (1986) . ESTIMATION OF EXPOSURE AND ABSORPTION OF PESTICIDES BY SPRAY OPERATORS. http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/updates/updates-to-the-uk-poem-operator-exposure-model.

# Annex 3 Example cases Environment

The example cases were part of the instruction workshop held in September 2014, while using a preliminary version of PRIMET_Registration_Ethiopia. Therefore the instruction and results may differ slightly from the final version of PRIMET_Registration_Ethiopia.

***Dimethoate (insecticide)***

- **GAP (see appendix A3.1)**

***Endpoints***

- **Birds**
  - acute oral LD50: 10.5 mg ai/kg bw
  - chronic NOEC: 1.0 mg ai/kg bw

- **Aquatic organisms**
  Fish
  - acute LC50: 30.2 mg ai/L
  - chronic NOEC: 0.4 mg ai/L

  Daphnia
  - acute EC50: 2.0 mg ai/L
  - chronic NOEC: 0.04 mg ai/L

  Algae
  - EC50: 90.4 mg ai/L

  Chironomus
  - chronic NOEC: 0.08 mg ai/L

- **Bees**
  - acute oral LD50: 0.1 µg/bee
  - acute contact LD50: 0.1 µg/bee

- **Other non-target arthropods**
  - *Aphidius rophalosiphi*: LR50 = 0.014 g ai/ha (glassplate test)
  - *Typhlodromus pyri*: LR50 = 2.24 g ai/ha (glassplate test)

  - *Aphidius rophalosiphi*: LR50 = 1.5 g ai/ha (extended lab test)
  - *Typhlodromus pyri*: LR50 = 40 g ai/ha (extended lab test)

- **Earthworms**
  - acute LC50: 31 mg ai/kg soil
  - chronic NOEC: 2.87 mg ai/kg soil

- **Soil micro-organisms**
  - Nitrogen mineralization: <25% effect up to 8.0 mg as/kg soil
  - Carbon mineralization: <25% effect up to 8.0 mg as/kg soil

- **Non-target terrestrial plants**
  - lowest EC50 > 1.8 kg ai/ha

***Results risk assessment***

**Birds**

The use in cabbage is a glasshouse application, hence no direct exposure to birds.

Table A3.1a

*Acute risk for birds for the use in barley and citrus.*

| Substance | FIR/bw | RUD (90%) | Applica-tion rate (kg a.s./ha) | MAF (90$^{th}$ perc) | Acute ETE (mg/kg bw/d) | LD50 (mg/kg bw/d) | ETR (= ETE/(LD50/10)) |
|---|---|---|---|---|---|---|---|
| Barley [large herbivorous bird] | | | | | | | |
| dimethoate | 0.44 | 142 | 0.6 | 1.474 | 55.3 | 10.5 | 52.6 |
| Barley [insectivorous bird] | | | | | | | |
| dimethoate | 1.04 | 54 | 0.6 | 1.474 | 49.7 | 10.5 | 47.3 |
| Citrus [insectivorous bird] | | | | | | | |
| dimenthoate | 1.04 | 54 | 0.6 | 1.474 | 49.7 | 10.5 | 47.3 |

Table A3.1b

*Long-term risk for birds for the use in barley and citrus.*

| Substance | FIR / bw | RUD (mean) | Applica-tion rate (kg a.s./ha) | MAF | ftwa | Long-term ETE (mg/kg bw/d) | NOEC (mg/kg bw/d) | ETR (= ETE/(NOEC/5)) |
|---|---|---|---|---|---|---|---|---|
| Barley [large herbivorous bird] | | | | | | | | |
| dimethoate | 0.44 | 76 | 0.6 | 1.616 | 0.527 | 17.1 | 1.0 | 85.1 |
| Barley [insectivorous bird] | | | | | | | | |
| dimethoate | 1.04 | 21 | 0.6 | 1.616 | 0.527 | 11.2 | 1.0 | 55.8 |
| Citrus [insectivorous bird] | | | | | | | | |
| dimenthoate | 1.04 | 21 | 0.6 | 1.616 | 0.527 | 11.2 | 1.0 | 55.8 |

## Aquatic organisms

Dimethoate-Barley

| Acute Risk | | | ETR = PEC/PNEC | | |
|---|---|---|---|---|---|
| Fish | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 10 | ETR > 10 | 0.08662 | - | 0.04192 |
| Invertebrates | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 1.308 | - | 0.633 |
| **Chronic Risk** | | | ETR = PEC/PNEC | | |
| Fish | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 10 | ETR > 10 | 0.654 | - | 0.3165 |
| Invertebrates | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 6.54 | - | 3.165 |
| **Aquatic Plants** | | | ETR = PEC/PNEC | | |
| Algae | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 0.002894 | - | 0.0014 |

* 1 = grid no. 191, small stream west of Lake Tana, highland (> 1500m altitude);
2a = grid no. 373, temporary pond west of Arba Minch, low/midland (< 1500m altitu
2b = grid no. 217, temporary pond south-east of Bure, highland (> 1500m altitude)

Dimethoate-Citrus

| Acute Risk | | | ETR = PEC/PNEC | | |
|---|---|---|---|---|---|
| Fish | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 10 | ETR > 10 | 0.03808 | 0.003798 | 0.009742 |
| Invertebrates | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 0.575 | 0.05735 | 0.1471 |
| **Chronic Risk** | | | ETR = PEC/PNEC | | |
| Fish | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 10 | ETR > 10 | 0.2875 | 0.02867 | 0.07355 |
| Invertebrates | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 2.875 | 0.2868 | 0.7355 |
| **Aquatic Plants** | | | ETR = PEC/PNEC | | |
| Algae | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 0.001272 | 0.0001269 | 0.0003254 |

* 1 = grid no. 191, small stream west of Lake Tana, highland (> 1500m altitude);
2a = grid no. 373, temporary pond west of Arba Minch, low/midland (< 1500m altitud
2b = grid no. 217, temporary pond south-east of Bure, highland (> 1500m altitude)

**Bees**

Barley
- ETRin-crop = dose rate (g ai/ha) / LD50 (µg/bee) = 600/0.1 = **6000**
- ETRoff-crop = dose rate (g ai/ha) * drift rate / LD50 (µg/bee) = 600 * 0.028 / 0.1 = **168**

Citrus
- ETRin-crop = dose rate (g ai/ha) / LD50 (µg/bee) = 600/0.1 = **6000**
- ETRoff-crop = dose rate (g ai/ha) * drift rate / LD50 (µg/bee) = 600 * 0.157 / 0.1 = **942**

Cabbage
Glasshouse application: no relevant exposure to bees assumed**.**

**Other non-target arthropods**

Barley
*Aphidius rophalosiphi (glassplate test)*
- ETRin-crop = dose rate (g as/ha) * MAF/ LR50 (g ai/ha) = 600 x 1.738/0.014 = **74486**
- ETRoff-crop = dose rate (g as/ha)* MAF * drift rate / LR50 (g ai/ha) = 600 * 1.738 * 0.028 / 0.014 = **2086**

*Typhlodromus pyri (glassplate test)*
- ETRin-crop = dose rate (g as/ha) * MAF/ LR50 (g ai/ha) = 600 x 1.738/2.24 = **466**
- ETRoff-crop = dose rate (g as/ha) * MAF * drift rate / LR50 (g ai/ha) = 600 * 1.738 * 0.028 / 2.24 = **13.0**

*Aphidius rophalosiphi (extended lab test)*
- ETRin-crop = dose rate (g as/ha) * MAF/ LR50 (g ai/ha) = 600 x 1.738/1.5 = **695**
- ETRoff-crop = dose rate (g as/ha)* MAF * drift rate / LR50 (g ai/ha) = 600 * 1.738 * 0.028 / 1.5= **19.5**

*Typhlodromus pyri (extended lab test)*
- ETRin-crop = dose rate (g as/ha) * MAF/ LR50 (g ai/ha) = 600 x 1.738/40 = **26.1**
- ETRoff-crop = dose rate (g as/ha) * MAF * drift rate / LR50 (g ai/ha) = 600 * 1.738 * 0.028 / 40 = 0.73

Citrus
*Aphidius rophalosiphi (glassplate test)*
- ETRin-crop = dose rate (g as/ha) * MAF/ LR50 (g ai/ha) = 600 x 1.738/0.014 = **74486** ETRoff-crop = dose rate (g as/ha)* MAF * drift rate / LR50 (g ai/ha) = 600 * 1.738 * 0.157 / 0.014 = **11694**

*Typhlodromus pyri (glassplate test)*
- ETRin-crop = dose rate (g as/ha) * MAF/ LR50 (g ai/ha) = 600 x 1.7/2.24 = **466**
- ETRoff-crop = dose rate (g as/ha) * MAF * drift rate / LR50 (g ai/ha) = 600 * 1.738 * 0.157 / 2.24 = **73.1**

*Aphidius rophalosiphi (extended lab test)*
- ETRin-crop = dose rate (g as/ha) * MAF/ LR50 (g ai/ha) = 600 x 1.7/1.5 = **695**
- ETRoff-crop = dose rate (g as/ha)* MAF * drift rate / LR50 (g ai/ha) = 600 * 1.738 * 0.157 / 1.5= **109**

*Typhlodromus pyri (extended lab test)*
- ETRin-crop = dose rate (g as/ha) * MAF/ LR50 (g ai/ha) = 600 x 1.7/40 = **26.1**
- ETRoff-crop = dose rate (g as/ha) * MAF * drift rate / LR50 (g ai/ha) = 600 * 1.738 * 0.157 / 40 = **4.1**

Cabbage (glasshouse)
Only IMP issues are important regarding glasshouse uses. It is clear that there is a high initial effect on beneficial arthropods. Hence, a warning sentence should be placed on the label.

**Earthworms**

PECsoil, max = 1.386 mg /kg soil

- ETRacute = PECsoil, max / (LC50/10) = 1.386 /(31/10) = **0.447**
- ETRchronic = PECsoil, max / (NOEC/5) = 1.386 / (2.87/5) = **2.414**

**Soil micro-organisms**

- Nitrogen mineralization: <25% effect up to 8.0 mg ai/kg soil → low risk
- Carbon mineralization: <25% effect up to 8.0 mg ai/kg soil → low risk

**Non-target terrestrial plants**

Barley
PECoff-field = single dose rate * MAF * drift factor = 0.0292 kg ai/ha

- ETR = PEC(off-field) / (ER50/5) = 0.0292 / (>1.8/5) = < 0.08

Citrus
PECoff-field = single dose rate * MAF * drift factor = 0.164 kg ai/ha

- ETR = PEC(off-field) / (ER50/5) = 0.164 / (>1.8/5) = <0.45

Cabbage
Glasshouse application: no off-crop exposure. Hence, no risk to non-target terrestrial plants.

***2,4 –D (herbicide)***

- **GAP (see appendix A3.1)**

***Endpoints***

- **Birds**
  - acute oral LD50: 663 mg ai/kg bw
  - chronic NOEC: 150 mg ai/kg bw

- **Aquatic organisms**
  Fish
  - acute LC50: >1.9 mg ai/L
  - chronic NOEC: 0.12 mg ai/L

  Daphnia
  - acute EC50: >1.9 mg ai/L
  - chronic NOEC: 1.35 mg ai/L

  Algae
  - EC50: 0.23 mg ai/L

  Macrophytes[6]
  - EC50: 0.50 mg ai/L

  Chironomus
  - chronic NOEC: -

- **Bees**
  - acute oral LD50: >100 µg/bee
  - acute contact LD50: >100 µg/bee

- **Other non-target arthropods**
  - *Aphidius rophalosiphi*: LR50 = 100 g ai/ha (glassplate test)
  - *Typhlodromus pyri*: LR50 = >564 g ai/ha (glassplate test)

- **Earthworms**
  - acute LC50: 350 mg ai/kg soil
  - chronic NOEC[7]: -

- **Soil micro-organisms**
  - nitrogen mineralization: no adverse effects up to 10 kg as/ha over a period of 28 days in field soil
  - carbon mineralization: no adverse effects up to 10 kg as/ha over a period of 28 days in field soil

- **Non-target terrestrial plants**
  - lowest EC50 = 0.07 kg ai/ha (= 70 g ai/ha)

6 Note that in PRIMET – screen Pesticide characteristics – Aquatic Ecosystem the field Herbicide should be set to 1

7 PRIMET needs input in order to give results, hence enter 1000 mg/kg. However keep in mind that in fact a chronic risk assessment is not possible because the chronic toxicity value is not available

***Results risk assessment***

**Birds**

Table A3.2a

*Acute risk for birds for the use in teff.*

| Substance | FIR/bw | RUD | Applica-tion rate (kg a.s./ha) | MAF | Acute ETE (mg/kg bw/d) | LD50 (mg/kg bw/d) | ETR (= ETE/(LD50/10)) |
|---|---|---|---|---|---|---|---|
| Teff [large herbivorous bird] | | | | | | | |
| 2,4D | 0.44 | 142 | 0.72 | 1.0 | 45.0 | 663 | 0.68 |
| Teff [insectivorous bird] | | | | | | | |
| 2,4D | 1.04 | 54 | 0.72 | 1.0 | 40.4 | 663 | 0.61 |

Table A3.2b

*Long-term risk for birds for the use in teff.*

| Substance | FIR/bw | RUD | Applica-tion rate (kg a.s./ha) | MAF | ftwa | Long-term ETE (mg/kg bw/d) | NOEC (mg/kg bw/d) | ETR (= ETE/(NOEC/5)) |
|---|---|---|---|---|---|---|---|---|
| Teff [large herbivorous bird] | | | | | | | | |
| 2,4D | 0.44 | 76 | 0.72 | 1.0 | 0.527 | 12.7 | 150 | 0.42 |
| Teff [insectivorous bird] | | | | | | | | |
| 2,4D | 1.04 | 21 | 0.72 | 1.0 | 0.527 | 8.3 | 150 | 0.28 |

## Aquatic organisms

| Acute Risk | | | ETR = PEC/PNEC | | |
|---|---|---|---|---|---|
| **Fish** | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 10 | ETR > 10 | 1.28 | 0.007242 | 0.2902 |
| **Invertebrates** | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 1.28 | 0.007242 | 0.2902 |

| Chronic Risk | | | ETR = PEC/PNEC | | |
|---|---|---|---|---|---|
| **Fish** | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 10 | ETR > 10 | 2.027 | 0.01147 | 0.4594 |
| **Invertebrates** | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 0.1801 | 0.001019 | 0.04084 |

| Aquatic Plants | | | ETR = PEC/PNEC | | |
|---|---|---|---|---|---|
| **Algae** | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 100 | ETR > 100 | 1.057 | 0.005983 | 0.2397 |
| **Macrophytes** | | | 1 | 2a | 2b |
| ETR < 1 | 1 <= ETR <= 10 | ETR > 10 | 0.4864 | 0.002752 | 0.1103 |

### Bees

Teff

- ETRin-crop = dose rate (g ai/ha) / LD50 (µg/bee) = 720/>100 = <7.2
- ETRoff-crop = dose rate (g ai/ha) * drift rate / LD50 (µg/bee) = 720 * 0.028 / >100 = <0.2

### Other non-target arthropods

Teff

*Aphidius rophalosiphi (glassplate test)*

- ETRin-crop = dose rate (g ai/ha) * MAF/ LR50 (g ai/ha) = 720 x 1.0/100 = **7.2**
- ETRoff-crop = dose rate (g ai/ha)* MAF * drift rate / LR50 (g ai/ha) = 720 * 1.0 * 0.028/ 100 = 0.2

*Typhlodromus pyri (glassplate test)*

- ETRin-crop = dose rate (g ai/ha) X MAF/ LR50 (g as/ha) = 720 x 1.0/564 = 1.3
- ETRoff-crop = dose rate (g ai/ha) * MAF * drift rate / LR50 (g ai/ha) = 720 * 1.0 * 0.028 / 564 = 0.04

**Earthworms**

PECsoil, max = 1.44 mg /kg soil

- ETRacute = PECsoil, max / (LC50/10) = 1.44 /(350/10) = 0.04
- No chronic toxicity value available; hence, no chronic risk assessment possible.

**Soil micro-organisms**

- nitrogen mineralization: no adverse effects up to 10 kg as/ha over a period of 28 days in field soil → low risk
- carbon mineralization: no adverse effects up to 10 kg as/ha over a period of 28 days in field soil → low risk

**Non-target terrestrial plants**

Teff
PECoff-field = single dose rate * MAF * drift factor = 0.0202 kg ai/ha

- ETR = PEC(off-field) / (ER50/5) = 0.0202 / (0.070/5) = **1.4**

**Appendix A3.1: Hypothetical GAPs for formulations based on dimethoate and 2,4-D**

## Dimethoate

| 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 ai/ha min max | | |
| Barley | Danadim | F | Russian Wheat Aphid | EC | 40% | Ground, downwards | Nymphs & adults | 1 to 2 | 1 week | 200 | 0.4 -0.6 | 14 - 20 days | |
| Citrus | Danadim | F | Russian Wheat Aphid | EC | 40% | Ground, upwards | Nymphs & adults | 1 to 2 | 1 week | 200 | 0.4 -0.6 | 14 - 20 days | |
| Cabbage | XXX | G | Cabbage Aphid | EC | 50% | Ground | Nymphs & adults | 1 | - | 400 | 0.6 | 14 - 20 days | |

## 2,4-D

| 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 ai/ha min max | | |
| Teff | Agro 2,4D Amine 720 | F | Broad leafed weeds | SL | 720g/l | Spray | Post emergence to young vigorously growing weeds | 1 | - | 400 | 0.72 | - | |

**Appendix A3.2: Pesticide input properties for PRIMET**

## Dimethoate - insecticide

| Pesticide property (fate) | value | unit | Protection goal(s) |
|---|---|---|---|
| $DT50_{soil}$ | 2.6 | d | Terrestrial ecosystem, Aquatic ecosystem, surface water for drinking water, Groundwater for drinking water |
| Reference temperature (temp. $DT50_{soil}$ measured at) | 293.15 | K | |
| | | | |
| $K_{oc,soil}$ | 28.3 | L/kg | Aquatic ecosystem, surface water for drinking water, Groundwater for drinking water |
| $K_{om,soil}$ | 16.42 | L/kg | |
| Freundlich exponent soil | 1 | - | Aquatic ecosystem, surface water for drinking water |
| Reference concentration in liquid phase - soil | 1 | mg/L | |
| | | | |
| Molar mass | 229.26 | g/mol | Aquatic ecosystem, surface water for drinking water |
| Saturated vapour pressure | $0.13^{E}$-3 | Pa | |
| Reference temperature (temp. sat. vapour pressure measured at) | 293.15 | K | |
| Solubility in water | 39800 | mg/L | |
| Reference temperature (temp. solubility measured at) | 293.15 | K | |
| $DT50_{water}$ | 68 | d | |
| Reference temperature (temp. $DT50_{water}$ measured at) | 293.15 | K | |
| DT50sediment | 1000 | d | |
| Reference temperature (temp. $DT50_{sediment}$ measured at) | 293.15 | K | |
| $K_{om,sediment}$ | 16.42 | L/kg | |
| Freundlich exponent sediment | 1 | - | |
| Reference concentration in liquid phase - sediment | 1 | mg/L | |
| $K_{om,suspended\ solids}$ | 16.42 | L/kg | |
| Freundlich exponent suspended solids | 1 | - | |
| Reference concentration in liquid phase – suspended solids | 1 | mg/L | |
| | | | |
| $DT50_{leaves}$ | 16 | d | Non-target terrestrial plants, Non-target terrestrial arthropods |

| Pesticide property (effect) | value | unit | Protection goal(s) |
|---|---|---|---|
| $LD50_{bees}$ | 0.1 | µg/bee | Bees |
| $LD50_{birds}$ | 10.5 | mg /kg bw | Birds |
| $NOEC_{birds}$ | 1.0 | mg /kg bw | |
| LC50 earthworms | 31 | mg /kg soil | Terrestrial ecosystem |
| NOEC earthworms | 2.87 | mg /kg soil | |
| $ER50_{nttp}$ | 1.8 | kg/ha | Non-target terrestrial plants |
| $LR50_{nta, ext lab test}$ | 0.014 | g ai/ha | Non-target terrestrial arthropods |
| $LR50_{nta, glass plate}$ | 2.24 | g ai/ha | |
| $EC50_{algae}$ | 90.4 | mg/L | Aquatic ecosystem |
| $EC50_{macrophytes}$ | - | mg/L | |
| $L(E)C50_{fish}$ | 32.0 | | |
| $L(E)C50_{invertebrates}$ | 2.0 | mg/L | |
| $NOEC_{fish}$ | 0.4 | mg/L | |
| $NOEC_{invertebrates}$ | 0.04 | mg/L | |
| AOEL | 0.001 | mg/ (kg bw d) | Operator Indoor, Worker Indoor/Outdoor |
| ADI (user) | 0.002 | mg/ (kg bw d) | |
| NOAEL mammal | * | mg/ (kg bw d) | Surface water for drinking water, Groundwater for drinking water |
| ARfD | 0.02 | mg/kg | Surface water for drinking water |

* PRIMET needs a value for the NOAEL, so enter a dummy value (for instance 0.01). The ADI provided overrules the ADI calculated using the $NOAEL_{mammals}$, when both are given.

## 2-4 D - herbicide[8]

| Pesticide property (fate) | value | unit | Protection goal(s) |
|---|---|---|---|
| $DT50_{soil}$ | 14 | d | Terrestrial ecosystem, Aquatic ecosystem, surface water for drinking water, Groundwater for drinking water |
| Reference temperature (temp. $DT50_{soil}$ measured at) | 293.15 | K | |
| | | | |
| $K_{oc,soil}$ | 88.4 | L/kg | Aquatic ecosystem, surface water for drinking water, Groundwater for drinking water |
| $K_{om,soil}$ | 51.28 | L/kg | |
| Freundlich exponent soil | 1 | - | Aquatic ecosystem, surface water for drinking water |
| Reference concentration in liquid phase - soil | 1 | mg/L | |
| | | | |
| Molar mass | 221.04 | g/mol | Aquatic ecosystem, surface water for drinking water |
| Saturated vapour pressure | $0.97^{E}$-5 | Pa | |
| Reference temperature (temp. sat. vapour pressure measured at) | 293.15 | K | |
| Solubility in water | 23180 | mg/L | |
| Reference temperature (temp. solubility measured at) | 293.15 | K | |
| $DT50_{water}$ | 1000 | d | |
| Reference temperature (temp. $DT50_{water}$ measured at) | 293.15 | K | |
| DT50sediment | 1000 | d | |
| Reference temperature (temp. $DT50_{sediment}$ measured at) | 293.15 | K | |
| $K_{om,sediment}$ | 51.28 | L/kg | |
| Freundlich exponent sediment | 1 | - | |
| Reference concentration in liquid phase - sediment | 1 | mg/L | |
| $K_{om,suspended\ solids}$ | 51.28 | L/kg | |
| Freundlich exponent suspended solids | 1 | - | |
| Reference concentration in liquid phase – suspended solids | 1 | mg/L | |
| | | | |
| $DT50_{leaves}$ | 16 | d | Non-target terrestrial plants, Non-target terrestrial arthropods |

8 In case of a herbicide, the PRIMET user should set the field 'herbicide' in the 'Pesticide characteristics' screen to the value '1'. The summary output will then provide output for macrophytes

| Pesticide property (effect) | value | unit | Protection goal(s) |
|---|---|---|---|
| $LD50_{bees}$ | 100 | µg/bee | Bees |
| | | | |
| $LD50_{birds}$ | 663 | mg /kg bw | Birds |
| $NOEC_{birds}$ | 150 | mg /kg bw | |
| | | | |
| LC50 earthworms | 350 | mg /kg soil | Terrestrial ecosystem |
| NOEC earthworms | -* | mg /kg soil | |
| | | | |
| $ER50_{nttp}$ | 0.07 | kg/ha | Non-target terrestrial plants |
| | | | |
| $LR50_{nta, ext lab test}$ | - | g ai/ha | Non-target terrestrial arthropods |
| $LR50_{nta, glass plate}$ | 100 | g ai/ha | |
| | | | |
| $EC50_{algae}$ | 0.23 | mg/L | Aquatic ecosystem |
| $EC50_{macrophytes}$ | 0.50 | mg/L | |
| $L(E)C50_{fish}$ | 1.9 | mg/L | |
| $L(E)C50_{invertebrates}$ | 1.9 | mg/L | |
| $NOEC_{fish}$ | 0.12 | mg/L | |
| $NOEC_{invertebrates}$ | 1.35 | mg/L | |
| | | | |
| AOEL | 0.15 | mg/ (kg bw d) | Operator Indoor, Worker Indoor/Outdoor |
| | | | |
| ADI (user) | 0.01 | mg/ (kg bw d) | |
| NOAEL mammal | -** | mg/ (kg bw d) | Surface water for drinking water, Groundwater for drinking water |
| | | | |
| ARfD | -*** | mg/kg | Surface water for drinking water |

* The NOECearthworms is not available. However, PRIMET needs input in order to give results of the acute assessment for this protection goal, hence enter for instance 1000 mg/kg. However keep in mind that the value for the chronic assessment is not valid.

** PRIMET needs a value for the NOAEL, so enter a dummy value (for instance 0.01). The ADI provided overrules the ADI calculated using the NOAELmammals, when both are given.

*** The ARfD was not deemed necessary for the risk assessment and was therefore not derived. Hence, an acute exposure assessment is not performed for protection goal surface water for drinking water. However, PRIMET needs input in order to give results of the chronic assessment for this protection goal, hence enterfor instance 99. However keep in mind that the value for the acute assessment is not valid.

## Appendix A3.3: Application scheme input in PRIMET

| Active ingredient | Crop | Dose (kg/ha) | Number of applications | Time interval (d) | Application start date | Application method |
|---|---|---|---|---|---|---|
| dimethoate | barley | 0.6 | 2 | 7 | 29 July | Tractor mounted |
| dimethoate | citrus | 0.6 | 2 | 7 | 29 July | Tractor mounted |
| | | | | | | |
| 2,4 D | Teff | 0.72 | 1 | -* | 10 July | Tractor mounted |

* After enteringa dummy value PRIMET will automatically enterl the value ‘0’. However, not that in case of 1 application, the multiple application factor (birds, NTA) will not be calculated, but set to the value of ‘1’.

# Annex 4 Example cases Drinking water

The example cases were part of the instruction workshop held in September 2014, while using a preliminary version of PRIMET_Registration_Ethiopia. Therefore the instruction and results may differ slightly from the final version of PRIMET_Registration_Ethiopia.

***Dimethoate (insecticide)***

- **GAP (see appendix A3.1)**

***Endpoints***

- **Birds**
  - acute oral LD50: 10.5 mg ai/kg bw
  - chronic NOEC: 1.0 mg ai/kg bw

- **Aquatic organisms**
  Fish
  - acute LC50: 30.2 mg ai/L
  - chronic NOEC: 0.4 mg ai/L

  Daphnia
  - acute EC50: 2.0 mg ai/L
  - chronic NOEC: 0.04 mg ai/L

  Algae
  - EC50: 90.4 mg ai/L

  Chironomus
  - chronic NOEC: 0.08 mg ai/L

- **Bees**
  - acute oral LD50: 0.1 µg/bee
  - acute contact LD50: 0.1 µg/bee

- **Other non-target arthropods**
  - *Aphidius rophalosiphi*: LR50 = 0.014 g ai/ha (glassplate test)
  - *Typhlodromus pyri*: LR50 = 2.24 g ai/ha (glassplate test)

  - *Aphidius rophalosiphi*: LR50 = 1.5 g ai/ha (extended lab test)
  - *Typhlodromus pyri*: LR50 = 40 g ai/ha (extended lab test)

- **Earthworms**
  - acute LC50: 31 mg ai/kg soil
  - chronic NOEC: 2.87 mg ai/kg soil

- **Soil micro-organisms**
  - Nitrogen mineralization: <25% effect up to 8.0 mg as/kg soil
  - Carbon mineralization: <25% effect up to 8.0 mg as/kg soil

- **Non-target terrestrial plants**
  - lowest EC50 > 1.8 kg ai/ha

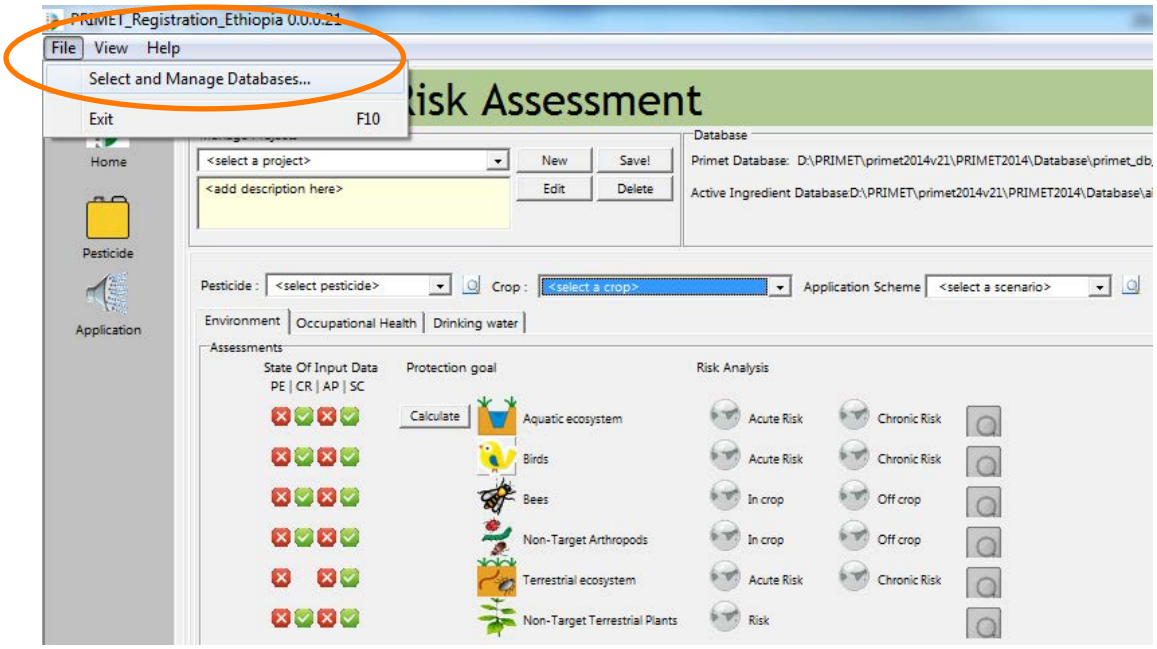
## Example runs PRIMET for protection goals Surface water for drinking water and Groundwater for drinking water.

1. Dimethoate (insecticide) in barley
2. Dimethoate (insecticide) in cabbage – field application
3. 2,4D (herbicide) in teff

**Start PRIMET by double clicking the PRIMET short cut on your desktop or in the start menu**

- Load empty databases into PRIMET

- Click File -> Select and Manage Databases…

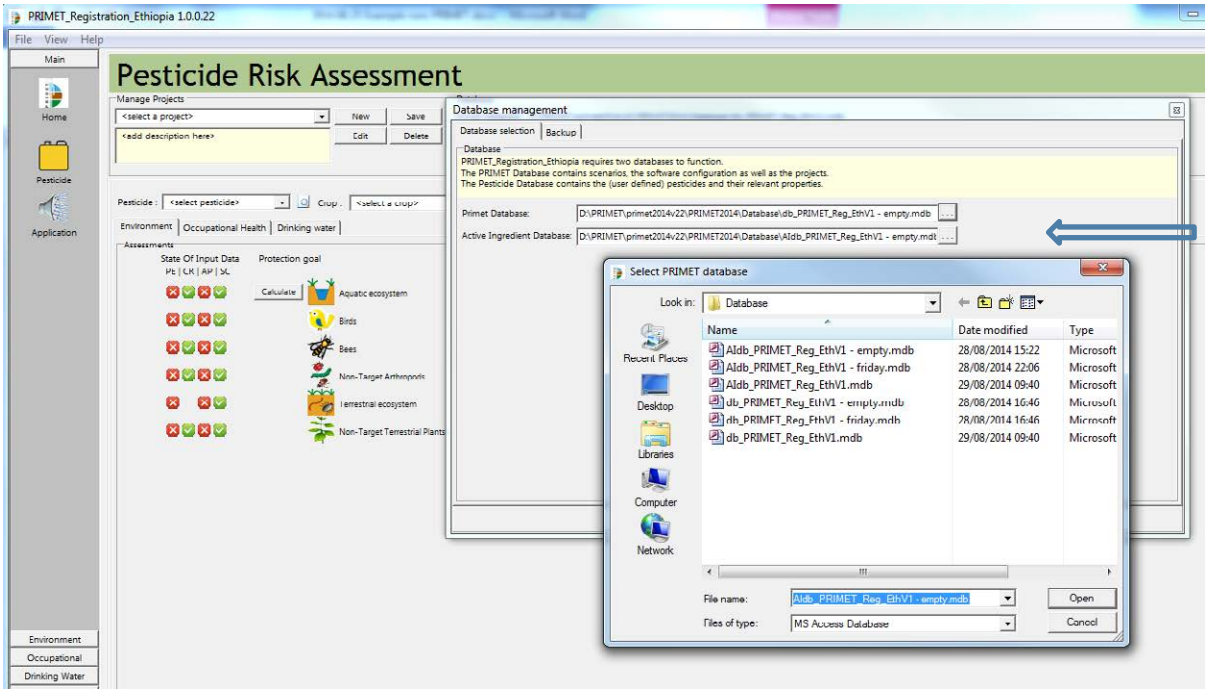



- The database management screen opens

- Click on the button '…' of 'Primet Database'
- Go to folder D:\PRIMET_Reg_EthV1\Database
- Select file: db_PRIMET_Reg_EthV1 – empty.mdb

- Click on the button '…' of 'Active Ingredient Database'
- Go to folder D:\ PRIMET_Reg_EthV1\Database
- Select file: AIdb_PRIMET_Reg_EthV1 - empty.mdb

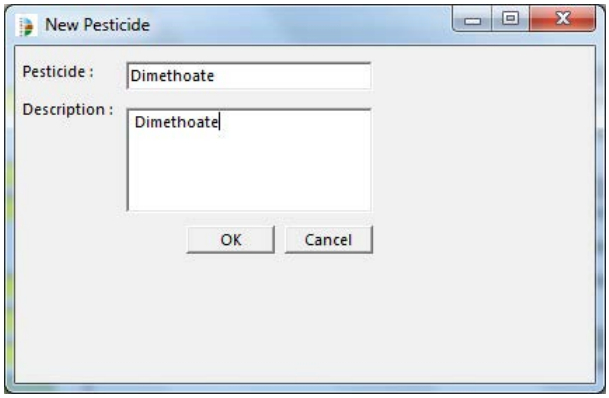
- Click on the button 'Close'




- **Add the pesticides Dimethoate and 2,4 D to PRIMET**

  - Click the pesticide button on the left hand site of the 'Pesticide Risk Assessment' screen:


  - The 'Pesticide Characteristics' screen opens.
  - Click on the button 'New' to add a new pesticide
  - Enter the fields 'Pesticide' and 'Description' (optional)




  - Enter the pesticide properties using the data sheet in Appendix 1. Start with Dimethoate

The input fields are colour coded to guide the user with colours based on the status of the data for that input field. The meaning of the different colours is as follows:

- White: a valid required value is entered
- Yellow: a required value is missing
- Brown: a interrelated value is undefined
- Green: a default value is entered (note that these can be modified if necessary)

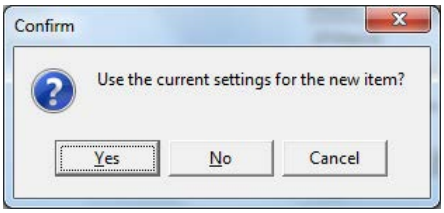
The 'Pesticide Characteristics' screen, contains a number of interrelated fields with the following meaning:

(1) Koc and Kom, see for the relationship between Koc and Kom Section 3.2, Eq. 13 in the PRIMET manual (Wipfler *et al.*)

(2) LR50 nta, glass plate test and LR50 nta, extended lab test. The glass plate test is considered the first tier effect assessment and the extended lab test the second tier effect assessment. One of these LR50 values should be entered to perform the Non Target Arthropod risk assessment. See also Section 4.5 in the PRIMET manual (Wipfler *et al.*) for elaboration on the NTA risk assessment.

(3) NOAEL mammals and ADI, see for the relationship Eq. 2.2 in Section 3.3 in the PRIMET manual (Wipfler *et al.*)

- Once all pesticide properties for Dimethoate are inserted, click the button 'New', to add 2,4D.
- A pop up will appear asking the user to use the current settings for the new item. If 'Yes' then all pesticide properties of Dimethoate will be copied in to the input screen for the new pesticide. This is tricky in case of a new pesticide, because it is easy to forget to change a parameter**. So please select 'No'.**




- Procedure for adding 2,4 D is as for Dimethoate

- **Add the application schemes for dimethoate-barley, dimethoate-cabbage 1st cropcycle , dimethoate-cabbage 2nd cropcycle and 2,4D-teff to PRIMET**

  - Click the application button on the left hand site of the 'Pesticide Risk Assessment' screen:


  - The 'Application Scheme' screen opens.
  - Click on the button 'New' to add a new application scheme.
  - A pop up will appear asking the user to use the current settings for the new item. Select 'No'
  - Fill out the fields 'Application' and 'Description' (optional). It is convenient to enter a caption that reflects both the pesticide and the crop (for instance dimethoate-barley)

During the dry season some crops are cultivated with the aid of irrigation. The most common crops being cultivated with irrigation are tomatoes, onions, cabbage and (Irish) potato. These crops are often cultivated twice during the year: one rain fed crop cycle and one irrigated crop cycle. The risk assessment is therefore done for the first and the second crop separately. For these crops a first and second crop are defined in the crop table in PRIMET. The first crop cycle represents crop cultivation during the rainy season (Kremt; no irrigation) and the second crop cycle represents crop cultivation during the dry season (Bega, irrigated).
In the registration process, the different 'crops' relating to either the 1st or the 2nd crop cycle should be handled as follows:

1. In case an authorisation is asked for applying a PPP in a specific season (rainy or dry) or under specific circumstances (irrigated, non-irrigated) the corresponding crop (e.g. either 1st or 2nd crop cycle) should be used in the assessment.

2. In case an authorisation is asked for applying a PPP in the crop in general, assessments should be done for both the 1st and 2nd crop cycle, and the assessment resulting in the highest ETR should be used in the authorisation process. Note that only the results of the assessments of protection goals 'Aquatic ecosystem' and 'Surface water for drinking water' will result in different ETR values for the different crop cycles.

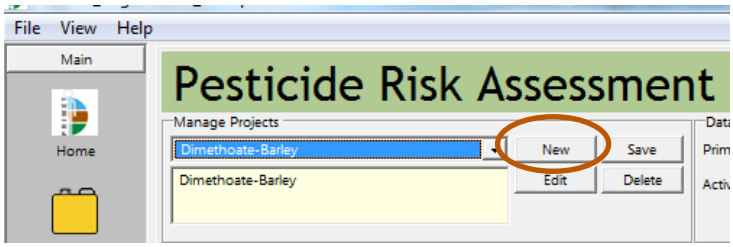
- Fill out the application scheme properties using the data sheet in Appendix 2. Start with dimethoate-barley

- Procedure for adding application schemes for dimethoate-cabbage 1st crop cycle, dimethoate-cabbage 2nd crop cycle and 2,4 D-teff is as for dimethoate-barley

- **Add projects for dimethoate-barley, dimethoate-cabbage, and 2,4D-teff to PRIMET**

  - Go back to the 'Pesticide Risk Assessment' screen by clicking the home button


  - Click on the button 'New' in the 'Manage Projects' part of the screen to add a project.




  - A pop up will appear asking the user to use the current settings for the new item. Select 'No'

- Fill out the fields 'Project' and 'Description' (optional). It is convenient to enter a caption that reflects both the pesticide and the crop (for instance dimethoate-barley). Optionally the name of the product can be added to the caption (for instance Danadim-dimethoate-barley).

- To allow for the risk assessments to be done for the added project, one pesticide should be selected, one crop and one application scheme. These can be selected from the crop down menus in the centre of the 'Pesticide Risk Assessment' screen. Therefore click the button with arrow.


- Check that the 'state of the input data' of all protection goalson all tabs of OK (see coloured textbox below).

- Click the '**Calculate**' button (either on the tab Environment or on the tab Drinking water, both buttons will start the same series of simulations)

- Now relax for a few minutes; take a cup of coffee or tea


- Check out the results for projection goals surface water for drinking water and groundwater for drinking water by clicking the zoom button.

- Enter the ETR values in the 'report results' Table in Appendix 3

- Add projects for dimethoate-cabbage-1$^{st}$ crop cycle, dimethoate-cabbage-2$^{nd}$ crop cycle and 2,4 D-Teff, perform calculations for surface water for drinking water and report results in the in the 'report results' Table in Appendix 3

Results of the risk assessment are shown on the 'Pesticide Risk Assessment' screen using coloured globes (traffic light idea). The results are organized according to the main assessments, being Environment, Occupational health and Drinking water. There is one tab for each assessment. On each tab the protection goals for this specific main assessment are listed. From left to right the user is informed about the status of input data of each protection goal:

- Left: the **state of the input data** of the pesticide (column PE), the crop (column CR), the Application schema (Column AP), and the specific scenario settings (column SC). The status can be either OK ( ) or not OK ( ). Only when all input data are given, the status goes to OK. Scenario properties are fixed and not to be provided by the user, hence the status of CR will always be OK.
  Tip 1: a click on the red or green icons will take you to the relevant property page.
  Tip 2: hovering the cursor above the (red) icon displays a popup hint that shows how many properties and which are missing. Note that for dimethoate a yellow icon with an exclamation mark is shown. This means that the EC50macrophytes and that a risk assessment for Aquatic ecosystem is done without showing results for macrophytes. A risk assesssment for macrophytes is only necessary for herbicides.
- Centre: the protection goals including a pictogram for each protection goal. A calculate button may be shown for Aquatic ecosystem and surface water as source for drinking water. The button needs to be clicked to start the series of models to be executed
- Right: an indication of the risk, while using coloured globes. The risk associated is represented by one or two globes per protection goal. For example the protection goal Birds has a globe for acute risk and for chronic risk. The colours of the globes can be green (no risk), orange (possible risk) or red (high risk). In case the input data is incomplete, i.e. one of the status indicators is red, the globes will remain grey, indicating that the risk cannot be assessed. To inspect the detailed results of the specific protection goal the zoom button can be pressed.

**Appendix A4.1: Pesticide input properties for PRIMET**

## Dimethoate - insecticide

| Pesticide property (fate) | value | unit | Protection goal(s) |
|---|---|---|---|
| $DT50_{soil}$ | 2.6 | d | Terrestrial ecosystem, Aquatic ecosystem, surface water for drinking water, Groundwater for drinking water |
| Reference temperature (temp. $DT50_{soil}$ measured at) | 293.15 | K | |
| | | | |
| $K_{oc,soil}$ | 28.3 | L/kg | Aquatic ecosystem, surface water for drinking water, Groundwater for drinking water |
| $K_{om,soil}$ | 16.42 | L/kg | |
| Freundlich exponent soil | 1 | - | Aquatic ecosystem, surface water for drinking water |
| Reference concentration in liquid phase - soil | 1 | mg/L | |
| | | | |
| Molar mass | 229.26 | g/mol | Aquatic ecosystem, surface water for drinking water |
| Saturated vapour pressure | $0.25^{E}$-3 | Pa | |
| Reference temperature (temp. sat. vapour pressure measured at) | 298.15 (25C) | K | |
| Solubility in water | 39800 | mg/L | |
| Reference temperature (temp. solubility measured at) | 293.15 | K | |
| $DT50_{water}$ | 68 | d | |
| Reference temperature (temp. $DT50_{water}$ measured at) | 293.15 | K | |
| DT50sediment | 1000 | d | |
| Reference temperature (temp. $DT50_{sediment}$ measured at) | 293.15 | K | |
| $K_{om,sediment}$ | 16.42 | L/kg | |
| Freundlich exponent sediment | 1 | - | |
| Reference concentration in liquid phase - sediment | 1 | mg/L | |
| $K_{om,suspended\ solids}$ | 16.42 | L/kg | |
| Freundlich exponent suspended solids | 1 | - | |
| Reference concentration in liquid phase – suspended solids | 1 | mg/L | |
| | | | |
| $DT50_{leaves}$ | 16 | d | Non-target terrestrial plants, Non-target terrestrial arthropods |

| Pesticide property (effect) | value | unit | Protection goal(s) |
|---|---|---|---|
| $LD50_{bees}$ | 0.1 | µg/bee | Bees |
| $LD50_{birds}$ | 10.5 | mg /kg bw | Birds |
| $NOEC_{birds}$ | 1.0 | mg /kg bw | |
| LC50 earthworms | 31 | mg /kg soil | Terrestrial ecosystem |
| NOEC earthworms | 2.87 | mg /kg soil | |
| $ER50_{nttp}$ | 1.8 | kg/ha | Non-target terrestrial plants |
| $LR50_{nta, ext lab test}$ | 0.014 | g ai/ha | Non-target terrestrial arthropods |
| $LR50_{nta, glass plate}$ | 2.24 | g ai/ha | |
| $EC50_{algae}$ | 90.4 | mg/L | Aquatic ecosystem |
| $EC50_{macrophytes}$ | - | mg/L | |
| $L(E)C50_{fish}$ | 32.0 | | |
| $L(E)C50_{invertebrates}$ | 2.0 | mg/L | |
| $NOEC_{fish}$ | 0.4 | mg/L | |
| $NOEC_{invertebrates}$ | 0.04 | mg/L | |
| AOEL | 0.001 | mg/ (kg bw d) | Operator Indoor, Worker Indoor/Outdoor |
| ADI (user) | 0.002 | mg/ (kg bw d) | |
| NOAEL mammal | -* | mg/ (kg bw d) | Surface water for drinking water, Groundwater for drinking water |
| ARfD | 0.02 | mg/kg/d | Surface water for drinking water |

* PRIMET needs a value for the NOAEL, so enter a dummy value (for instance 0.01). The ADI provided overrules the ADI calculated using the $NOAEL_{mammals}$, when both are given.

## 2-4 D - herbicide[9]

| Pesticide property (fate) | value | unit | Protection goal(s) |
|---|---|---|---|
| $DT50_{soil}$ | 14 | d | Terrestrial ecosystem, Aquatic ecosystem, surface water for drinking water, Groundwater for drinking water |
| Reference temperature (temp. $DT50_{soil}$ measured at) | 293.15 | K | |
| | | | |
| $K_{oc,soil}$ | 88.4 | L/kg | Aquatic ecosystem, surface water for drinking water, Groundwater for drinking water |
| $K_{om,soil}$ | 51.28 | L/kg | |
| Freundlich exponent soil | 1 | - | Aquatic ecosystem, surface water for drinking water |
| Reference concentration in liquid phase - soil | 1 | mg/L | |
| | | | |
| Molar mass | 221.04 | g/mol | Aquatic ecosystem, surface water for drinking water |
| Saturated vapour pressure | $0.97^{E}$-5 | Pa | |
| Reference temperature (temp. sat. vapour pressure measured at) | 293.15 | K | |
| Solubility in water | 23180 | mg/L | |
| Reference temperature (temp. solubility measured at) | 293.15 | K | |
| $DT50_{water}$ | 1000 | d | |
| Reference temperature (temp. $DT50_{water}$ measured at) | 293.15 | K | |
| DT50sediment | 1000 | d | |
| Reference temperature (temp. $DT50_{sediment}$ measured at) | 293.15 | K | |
| $K_{om,sediment}$ | 51.28 | L/kg | |
| Freundlich exponent sediment | 1 | - | |
| Reference concentration in liquid phase - sediment | 1 | mg/L | |
| $K_{om,suspended\ solids}$ | 51.28 | L/kg | |
| Freundlich exponent suspended solids | 1 | - | |
| Reference concentration in liquid phase – suspended solids | 1 | mg/L | |
| | | | |
| $DT50_{leaves}$ | 16 | d | Non-target terrestrial plants, Non-target terrestrial arthropods |

9 In case of a herbicide, the PRIMET user should set the field 'herbicide' in the 'Pesticide characteristics' screen to the value '1'. The summary output will then provide output for macrophytes

| Pesticide property (effect) | value | unit | Protection goal(s) |
|---|---|---|---|
| $LD50_{bees}$ | 100 | µg/bee | Bees |
| | | | |
| $LD50_{birds}$ | 663 | mg /kg bw | Birds |
| $NOEC_{birds}$ | 150 | mg /kg bw | |
| | | | |
| LC50 earthworms | 350 | mg /kg soil | Terrestrial ecosystem |
| NOEC earthworms | -* | mg /kg soil | |
| | | | |
| $ER50_{nttp}$ | 0.07 | kg/ha | Non-target terrestrial plants |
| | | | |
| $LR50_{nta, ext lab test}$ | - | g ai/ha | Non-target terrestrial arthropods |
| $LR50_{nta, glass plate}$ | 100 | g ai/ha | |
| | | | |
| $EC50_{algae}$ | 0.23 | mg/L | Aquatic ecosystem |
| $EC50_{macrophytes}$ | 0.50 | mg/L | |
| $L(E)C50_{fish}$ | 1.9 | mg/L | |
| $L(E)C50_{invertebrates}$ | 1.9 | mg/L | |
| $NOEC_{fish}$ | 0.12 | mg/L | |
| $NOEC_{invertebrates}$ | 1.35 | mg/L | |
| | | | |
| AOEL | 0.15 | mg/ (kg bw d) | Operator Indoor, Worker Indoor/Outdoor |
| | | | |
| ADI (user) | 0.01 | mg/ (kg bw d) | |
| NOAEL mammal | -** | mg/ (kg bw d) | Surface water for drinking water, Groundwater for drinking water |
| | | | |
| ARfD | -*** | mg/kg/d | Surface water for drinking water |

* The $NOEC_{earthworms}$ is not available. However, PRIMET needs input in order to give results of the acute assessment for this protection goal, hence enter for instance 1000 mg/kg. However keep in mind that the value for the chronic assessment is not valid.

** PRIMET needs a value for the NOAEL, so enter a dummy value (for instance 0.01). The ADI provided overrules the ADI calculated using the $NOAEL_{mammals}$, when both are given.

*** The ARfD was not deemed necessary for the risk assessment and was therefore not derived. Hence, an acute exposure assessment is not performed for protection goal surface water for drinking water. However, PRIMET needs input in order to give results of the chronic assessment for this protection goal, hence enterfor instance 99. However keep in mind that the value for the acute assessment is not valid.

## Appendix A4.2: Application scheme input in PRIMET

| Active ingredient | Crop | Dose (kg/ha) | Number of applications | Time interval (d) | Application start date | Application method |
|---|---|---|---|---|---|---|
| dimethoate | barley | 0.6 | 2 | 7 | 29 July | Tractor mounted |
| dimethoate | cabbage 1st crop cycle | 0.025 | 5 | 10 | 4 June | Knapsac |
| dimethoate | cabbage 2nd crop cycle | 0.025 | 5 | 10 | 21 November | Knapsac |
| 2,4 D | teff | 0.72 | 1 | -* | 10 July | Tractor mounted |

* After entering a dummy value PRIMET will automatically enter the value '0'. However, not that in case of 1 application, the multiple application factor (birds, NTA) will not be calculated, but set to the value of '1'.

## PROTECTION GOAL: DRINKING WATER FROM GROUNDWATER

| CHRONIC RISK<br>ETR < / ETR >= | ETR | | |
|---|---|---|---|
| | ***1 + 2*** | ***3a*** | ***3b*** |
| Dimethoate - barley | | | |
| Dimethoate - cabbage 1st crop cycle | | | |
| Dimethoate - cabbage 2nd crop cycle | | | |
| 2,4D - teff | | | |

*1+2 = Grid no. 219, Bichena (Amhara region); 3a = Grid no 346, Ca 100 km SW of Jimma (SNNP); 3b = Grid no 323, Abala Kulito (SNNP)*


***Figure A3.1*** *Selected scenarios locations for the three groundwater protection goals. Grid 219 for goals 1 and 2: alluvial aquifers along small rivers and volcanic aquifers on shallow wells in areas above 1500 m; grid 346 for goal 3a: alluvial aquifers in the Rift Valley margins and lowlands below 1500 m altitude; grid 323 for goal 3b: alluvial aquifers in the Rift Valley margins and lowlands between 1500 - 2000 m altitude.*

## PROTECTION GOAL: DRINKING WATER FROM SURFACE WATER

| ACUTE RISK<br>ETR < ETR >= | ETR | | |
|---|---|---|---|
| | *1* | *2a* | *2b* |
| Dimethoate - barley ○ | ○ | ○ | ○ |
| Dimethoate - cabbage 1st crop cycle ○ | ○ | ○ | ○ |
| Dimethoate - cabbage 2nd crop cycle ○ | ○ | ○ | ○ |
| 2,4D - teff ○ | ○ | ○ | ○ |

## PROTECTION GOAL: DRINKING WATER FROM SURFACE WATER

| CHRONIC RISK<br>ETR < ETR >= | ETR | | |
|---|---|---|---|
| | *1* | *2a* | *2b* |
| Dimethoate - barley ○ | ○ | ○ | ○ |
| Dimethoate - cabbage 1st crop cycle ○ | ○ | ○ | ○ |
| Dimethoate - cabbage 2nd crop cycle ○ | ○ | ○ | ○ |
| 2,4D - teff ○ | ○ | ○ | ○ |

*1 = Grid no. 191, small stream West of Lake Tana, highland (> 1500 m altitude);*
*2a = Grid no. 373, temporary pond West of Arba Minch, low/midland (< 1500 m altitude);*
*2b = Grid no. 217, temporary pond South East of Bure, highland (> 1500 m altitude)*


***Figure A3.2*** *Selected scenarios locations for the three surface water protection goals. Grid 119 for goal 1: small streams in areas above 1500 m; grid 373 for goal 2a: temporary ponds below 1500 m altitude and with more than 500 mm rain (long term, annual average); grid 217 for goal 2b: temporary ponds between 1500 -2000 m altitude.*

| protection goal | sub-prot.goal | exposure | effect | unit | nr of ETR | risk definition per ETR | assessment colour on home screen |
|---|---|---|---|---|---|---|---|
| groundwater for drinking water | chronic risk | Daily Intake chronic for the protection goals 1,2 ,3a and 3b | Daily accepted intake chronic | mg/(kg d) | 3 | if ETR< = 1 then no risk else high risk | if all risk indicators are green then green, else if one or more indicators are red, then red, else orange |
| surface water for drinking water | acute risk | Daily intake acute for the protection goals 1,2a and 2b | Daily accepted intake acute | mg/(kg d) | 3 | if ETR< = 1 then no risk else high risk | if all risk indicators are green then green, else if one or more indicators are red, then red, else orange |
| surface water for drinking water | chronic risk | Daily intake chronic for the protection goals 1,2a and 2b | Daily accepted intake chronic | mg/(kg d) | 3 | if ETR< = 1 then no risk else high risk | if all risk indicators are green then green, else if one or more indicators are red, then red, else orange |

## Appendix A4.4 Results

### Groundwater for drinking water – dimethoate – Barley

RunTime/Date: 29/08/2014, 10:05:00
Protection Goal: Groundwater for drinking water
Active Ingredient: dimethoate
Applied mass single treatment: 0.6000 kg/ha
No. of applications: 2
Crop: Barley

**CHRONIC RISK**

**groundwater**

ETR =< 1 | ETR > 1

| ADI (mg/kg/d) | P (-) | DI accept chronic (mg/kg/d) | DI gw chronic (mg/kg/d) | | | ETR = DI gw chronic/DI accept chronic | | |
|---|---|---|---|---|---|---|---|---|
| | | | 1+2* | 3b* | 3a* | 1+2* | 3b* | 3a* |
| 0.002 | 0.1 | 0.0002 | 1.977E-10 | 2.174E-14 | 1.816E-12 | 9.885E-07 | 1.087E-10 | 9.078E-09 |

* 1+2 = Grid no. 219, Bichena (Amhara region); 3a = Grid no. 346, Ca. 100 km SW of Jimma (SNNP); 3b = Grid no. 323, Abala Kulito (SNNP)

### Groundwater for drinking water – dimthoate – Cabbage 1st crop cycle

RunTime/Date: 29/08/2014, 10:05:37
Protection Goal: Groundwater for drinking water
Active Ingredient: dimethoate
Applied mass single treatment: 0.6000 kg/ha
No. of applications: 1
Crop: Cabbage, 1st crop cycle

**CHRONIC RISK**

**groundwater**

ETR =< 1 | ETR > 1

| ADI (mg/kg/d) | P (-) | DI accept chronic (mg/kg/d) | DI gw chronic (mg/kg/d) | | | ETR = DI gw chronic/DI accept chronic | | |
|---|---|---|---|---|---|---|---|---|
| | | | 1+2* | 3b* | 3a* | 1+2* | 3b* | 3a* |
| 0.002 | 0.1 | 0.0002 | 9.885E-11 | 1.087E-14 | 9.078E-13 | 4.942E-07 | 5.436E-11 | 4.539E-09 |

* 1+2 = Grid no. 219, Bichena (Amhara region); 3a = Grid no. 346, Ca. 100 km SW of Jimma (SNNP); 3b = Grid no. 323, Abala Kulito (SNNP)

### Groundwater for drinking water – dimethoate – Cabbage 2nd crop cycle

RunTime/Date: 29/08/2014, 10:05:57
Protection Goal: Groundwater for drinking water
Active Ingredient: dimethoate
Applied mass single treatment: 0.6000 kg/ha
No. of applications: 1
Crop: Cabbage, 2nd crop cycle

| CHRONIC RISK | ADI (mg/kg/d) | P (-) | DI accept chronic (mg/kg/d) | DI gw chronic (mg/kg/d) | | | ETR = DI gw chronic/DI accept chronic | | |
|---|---|---|---|---|---|---|---|---|---|
| groundwater | | | | 1+2* | 3b* | 3a* | 1+2* | 3b* | 3a* |
| ETR =< 1 / ETR > 1 | 0.002 | 0.1 | 0.0002 | 9.885E-11 | 1.087E-14 | 9.078E-13 | 4.942E-07 | 5.436E-11 | 4.539E-09 |

* 1+2 = Grid no. 219, Bichena (Amhara region); 3a = Grid no. 346, Ca. 100 km SW of Jimma (SNNP); 3b = Grid no. 323, Abala Kulito (SNNP)

### Groundwater for drinking water – 2,4 D - Teff

RunTime/Date: 29/08/2014, 09:46:55
Protection Goal: Groundwater for drinking water
Active Ingredient: 2,4 D
Applied mass single treatment: 0.7200 kg/ha
No. of applications: 1
Crop: Teff

| CHRONIC RISK | ADI (mg/kg/d) | P (-) | DI accept chronic (mg/kg/d) | DI gw chronic (mg/kg/d) | | | ETR = DI gw chronic/DI accept chronic | | |
|---|---|---|---|---|---|---|---|---|---|
| groundwater | | | | 1+2* | 3b* | 3a* | 1+2* | 3b* | 3a* |
| ETR =< 1 / ETR > 1 | 0.01 | 0.1 | 0.001 | 0.0005613 | 1.432E-05 | 3.465E-05 | 0.5613 | 0.01432 | 0.03465 |

* 1+2 = Grid no. 219, Bichena (Amhara region); 3a = Grid no. 346, Ca. 100 km SW of Jimma (SNNP); 3b = Grid no. 323, Abala Kulito (SNNP)

## Surface water for drinking water – dimethoate - Barley

RunTime/Date: 29/08/2014, 10:05:12
Protection Goal: Surface water for drinking water
Active Ingredient: dimethoate
Applied mass single treatment: 0.6000 kg/ha
No. of applications: 2
Crop: Barley

**Acute Risk**

**Surface water as source of drinking water**

ETR =< 1 | ETR > 1

| | ARfD (µg/kg/d) | DI sw acute (mg/kg/d) | | | ETR = DI sw acute/ARfD | | |
|---|---|---|---|---|---|---|---|
| | | 1 | 2a | 2b | 1 | 2a | 2b |
| - | 0.02 | 27.43 | - | 21.68 | 0.1372 | - | 0.1084 |

**Chronic Risk**

**Surface water as source of drinking water**

ETR =< 1 | ETR > 1

| ADI (mg/kg/d) | P - | DI accept chronic (mg/kg/d) | DI sw chronic (mg/kg/d) | | | ETR = DI_accept_chronic/ | | |
|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2a | 2b | 1 | 2a | 2b |
| 0.002 | 0.1 | 0.0002 | 27.43 | - | 21.68 | 4.572 | - | 3.613 |

## Surface water for drinking water – dimethoate – Cabbage 1st crop cycle

RunTime/Date: 29/08/2014, 10:25:23
Protection Goal: Surface water for drinking water
Active Ingredient: dimethoate
Applied mass single treatment: 0.6000 kg/ha
No. of applications: 1
Crop: Cabbage, 1st crop cycle

**Acute Risk**

**Surface water as source of drinking water**

ETR =< 1 | ETR > 1

| | ARfD (µg/kg/d) | DI sw acute (mg/kg/d) | | | ETR = DI sw acute/ARfD | | |
|---|---|---|---|---|---|---|---|
| | | 1 | 2a | 2b | 1 | 2a | 2b |
| - | 0.02 | 28.69 | 0.2552 | 4.25 | 0.1435 | 0.001276 | 0.02125 |

**Chronic Risk**

**Surface water as source of drinking water**

ETR =< 1 | ETR > 1

| ADI (mg/kg/d) | P - | DI accept chronic (mg/kg/d) | DI sw chronic (mg/kg/d) | | | ETR = DI_accept_chronic/ | | |
|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2a | 2b | 1 | 2a | 2b |
| 0.002 | 0.1 | 0.0002 | 28.69 | 0.2552 | 4.25 | 4.782 | 0.04253 | 0.7083 |

* 1 = grid no. 191, small stream west of Lake Tana, highland (> 1500m altitude);
2a = grid no. 373, temporary pond west of Arba Minch, low/midland (< 1500m altitude);
2b = grid no. 217, temporary pond south-east of Bure, highland (> 1500m altitude)

### Surface water for drinking water – dimethoate – Cabbage 2nd crop cycle

RunTime/Date: 29/08/2014, 11:08:19
Protection Goal: Surface water for drinking water
Active Ingredient: dimethoate
Applied mass single treatment: 0.6000 kg/ha
No. of applications: 1
Crop: Cabbage, 2nd crop cycle

**Acute Risk**

**Surface water as source of drinking water**

ETR =< 1 | ETR > 1

| | ARfD (µg/kg/d) | DI sw acute (mg/kg/d) | | | ETR = DI sw acute/ARfD | | |
|---|---|---|---|---|---|---|---|
| | | 1 | 2a | 2b | 1 | 2a | 2b |
| - | 0.02 | 8.249 | 0.6373 | 0.3072 | 0.04125 | 0.003187 | 0.001536 |

**Chronic Risk**

**Surface water as source of drinking water**

ETR =< 1 | ETR > 1

| ADI (mg/kg/d) | P - | DI accept chronic (mg/kg/d) | DI sw chronic (mg/kg/d) | | | ETR = DI_accept_chronic | | |
|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2a | 2b | 1 | 2a | 2b |
| 0.002 | 0.1 | 0.0002 | 8.249 | 0.6373 | 0.3072 | 1.375 | 0.1062 | 0.0512 |

### Surface water for drinking water – 2,4D – Teff

RunTime/Date: 29/08/2014, 09:50:31
Protection Goal: Surface water for drinking water
Active Ingredient: 2,4 D
Applied mass single treatment: 0.7200 kg/ha
No. of applications: 1
Crop: Teff

**Acute Risk**

**Surface water as source of drinking water**

ETR =< 1 | ETR > 1

| | ARfD (µg/kg/d) | DI sw acute (mg/kg/d) | | | ETR = DI sw acute/ARfD | | |
|---|---|---|---|---|---|---|---|
| | | 1 | 2a | 2b | 1 | 2a | 2b |
| - | 0.001 | 28.28 | 0.4756 | 11 | 2.828 | 0.04756 | 1.1 |

**Chronic Risk**

**Surface water as source of drinking water**

ETR =< 1 | ETR > 1

| ADI (mg/kg/d) | P - | DI accept chronic (mg/kg/d) | DI sw chronic (mg/kg/d) | | | ETR = DI_accept_chronic | | |
|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2a | 2b | 1 | 2a | 2b |
| 0.01 | 0.1 | 0.001 | 28.28 | 0.4756 | 11 | 0.9427 | 0.01585 | 0.3667 |

* 1 = grid no. 191, small stream west of Lake Tana, highland (> 1500m altitude);
2a = grid no. 373, temporary pond west of Arba Minch, low/midland (< 1500m altitude);
2b = grid no. 217, temporary pond south-east of Bure, highland (> 1500m altitude)

# Annex 5 Example cases Consumer health

## Case studies

**Consumer exposure**
PRIMET Workshop 2014

Since it is not expected that supervised residue trials, for the generation of expected residue levels after crop treatment, will be conducted in Ethiopia in the near future (see 3.6.2 of the handbook), the case studies focus on MRLs from databases available (see 3.6.3.2 of the handbook)

The most relevant databases for MRLs are listed below.

Worldwide MRLs can be found from:
http://www.mrldatabase.com/ by EPA (only for pesticides for which a permanently established EPA tolerance is available).

European MRLs can be obtained from Pesticide Web:
http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection
for pesticides reported to the European Commission.

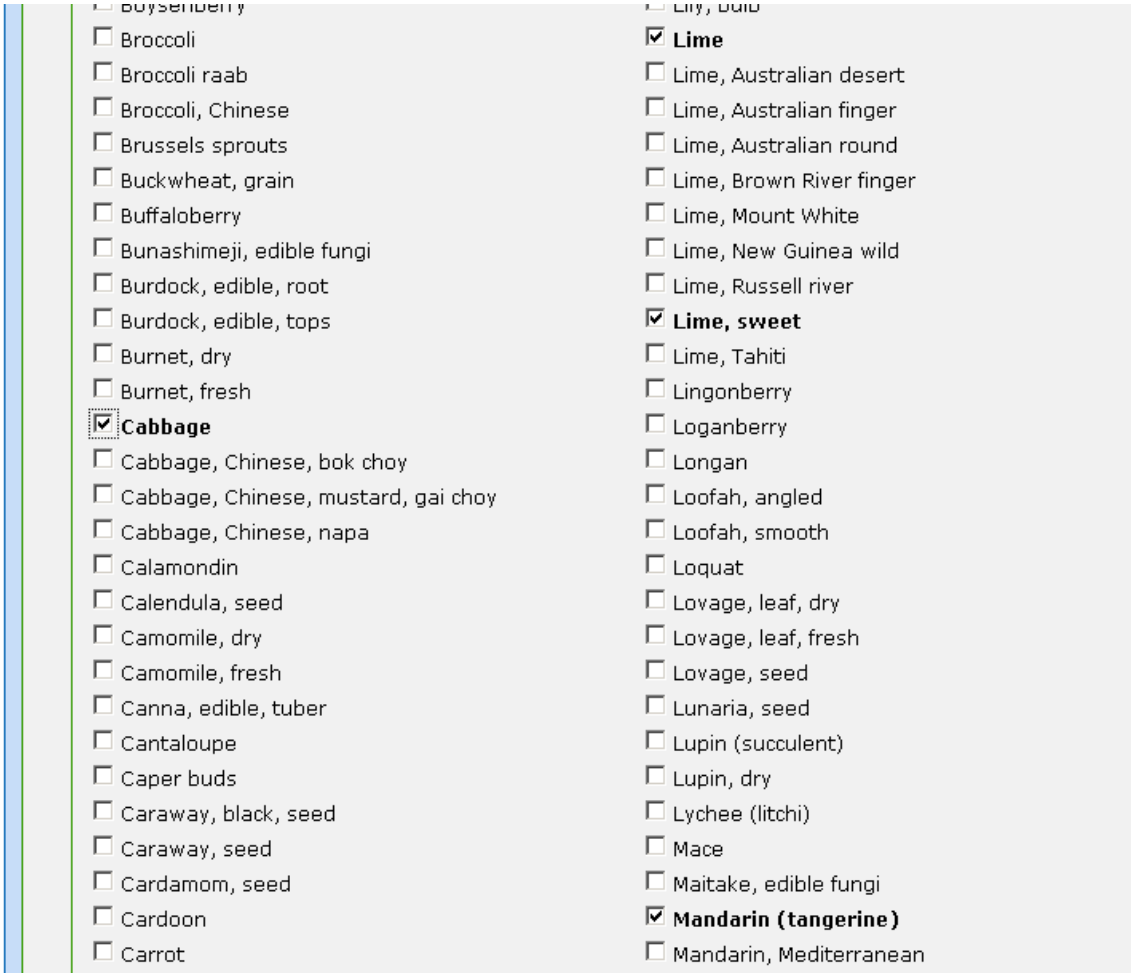
MRLs set for WHO and FAO member states (including Ethiopia) are set in the framework of CODEX Alimentarius, and can be found at:
http://www.codexalimentarius.net/pestres/data/pesticides/search.html.

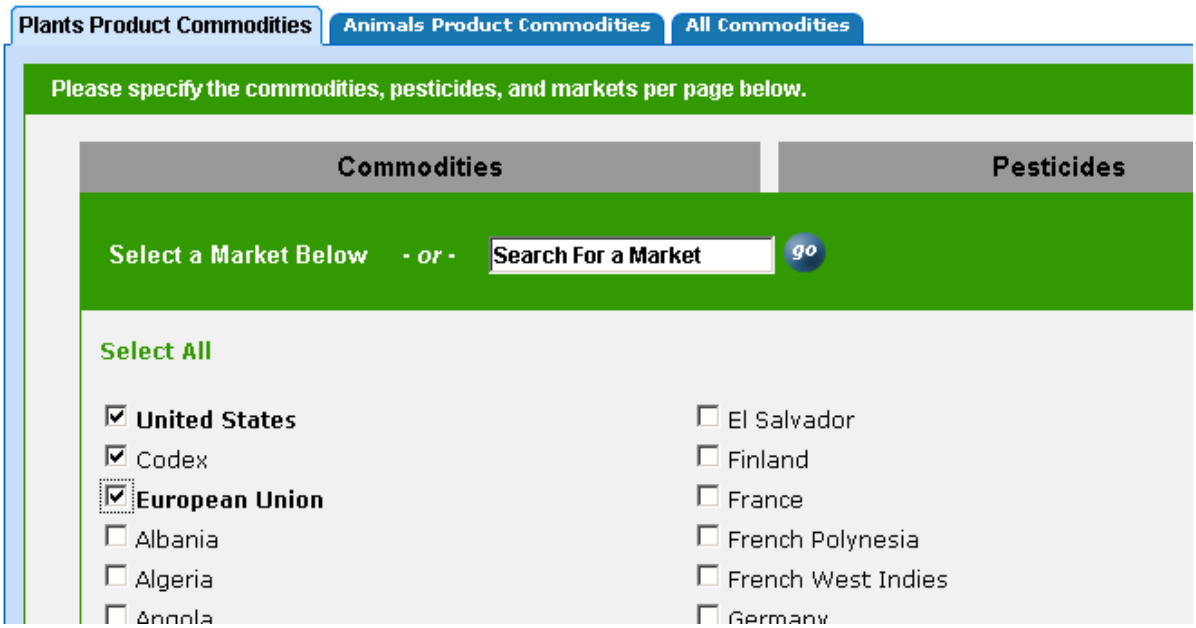
## 1. Dimethoate

**Dimethoate**

| 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, downwards | Nymphs & adults | 1 to 2 | 1 week | 200 | 0.4 -0.6 | 14 - 20 days | |
| Citrus | Danadim | F | Russian Wheat Aphid | EC | 40% | Ground, upwards | Nymphs & adults | 1 to 2 | 1 week | 200 | 0.4 -0.6 | 14 - 20 days | |
| Cabbage | XXX | G | Cabbage Aphid | EC | 50% | Ground | Nymphs & adults | 1 | - | 400 | 0.6 | 14 - 20 days | |

**the EPA MRL database is used:**


Broccoli
Broccoli raab
Broccoli, Chinese
Brussels sprouts
Buckwheat, grain
Buffaloberry
Bunashimeji, edible fungi
Burdock, edible, root
Burdock, edible, tops
Burnet, dry
Burnet, fresh
Cabbage
Cabbage, Chinese, bok choy
Cabbage, Chinese, mustard, gai choy
Cabbage, Chinese, napa
Calamondin
Calendula, seed
Camomile, dry
Camomile, fresh
Canna, edible, tuber
Cantaloupe
Caper buds
Caraway, black, seed
Caraway, seed
Cardamom, seed
Cardoon
Carrot
Lime
Lime, Australian desert
Lime, Australian finger
Lime, Australian round
Lime, Brown River finger
Lime, Mount White
Lime, New Guinea wild
Lime, Russell river
Lime, sweet
Lime, Tahiti
Lingonberry
Loganberry
Longan
Loofah, angled
Loofah, smooth
Loquat
Lovage, leaf, dry
Lovage, leaf, fresh
Lovage, seed
Lunaria, seed
Lupin (succulent)
Lupin, dry
Lychee (litchi)
Mace
Maitake, edible fungi
Mandarin (tangerine)
Mandarin, Mediterranean


Plants Product Commodities
Animals Product Commodities
All Commodities
Please specify the commodities, pesticides, and markets per page below.
Commodities
Pesticides
Select a Market Below
- or -
Search For a Market
go
Select All
United States
Codex
European Union
Albania
Algeria
Angola
El Salvador
Finland
France
French Polynesia
French West Indies
Germany

- MRL values in *Red Italics* are more restrictive than US
- All numeric values listed are in parts per million (ppm), unless otherwise noted
- --- (dashes) indicate that no specific MRL for the commodity or relevant crop group is established. A default MRL may apply for countries that have default MRLs (see Default MRLs section below). Additionally, inadvertent or extraneous MRLs are not included in the database; and the database does not indicate substances that are banned in a country or exempt from requiring an MRL.
- ! indicates there is a note to scroll over with your mouse.
- Cod (Codex), EU (European Union), US (United States) and EXP (exporting market) indicate the source of the MRL for countries which defer to other markets' MRL regulations.
- Section 18, Time-Limited, or Regional: indicates that the US MRL is a temporary Section 18, Time-Limited Tolerance, or Regional Tolerance.

**Default MRLs**

These countries have a default MRL which may be applicable if a specific MRL is not established. However, default MRL regulations vary by country. Before assuming a default MRL applies, the country's specific regulations governing the default MRLs should be consulted. Country MRL regulations are summarized in market information pages located at the "Market Information" link on the toolbar at the top of this page.

European Union: 0.01 ppm | Argentina: 0.01 | Canada: 0.1 ppm | Iceland: 0.01 | Japan: 0.01 ppm | Malaysia: 0.01 ppm | New Zealand: 0.1 ppm | Norway: 0.01 | South Africa: 0.01 ppm

## Grapefruit - Dimethoate

Show Legend

| US ! | Cod ! | EU ! |
|---|---|---|
| 2 | 5 | *{0.02}* |

## Mandarin (tangerine) - Dimethoate

Show Legend

| US ! | Cod ! | EU ! |
|---|---|---|
| 2 | 5 | *{0.02}* |

## Orange, sweet - Dimethoate

Show Legend

| US ! | Cod ! | EU ! |
|---|---|---|
| 2 | 5 | *{0.02}* |

It can be concluded that MRLs are not available for barley and cabbage. A conclusion why this is the case would only be speculative:

- are there no registered uses in the countries/organisations?
- Are MRLs set at LOQ, since no detecTable residues are expected?

Derive the ADI and ARfD as is done for Human toxicology.

In this case, JMPR ADI of 0.002 mg/kg bw/d and ARfD of 0.02 mg/kg bw.

**First Tier**

**Chronic exposure**

Perform a ITMDI calculation, but first tier input is the MRL instead of STMR (see 3.6.5 of the handbook)

| | WHO, August v2 2006, GEMS/FoodConsumptionClusterDiets | | | | Version 14, dd 31 August 2011. Adapted for Ethiopia dd 23 July 2014 by L.Wipfler, Alterra | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Compound name (in capitals): | | | International Estimated Daily Intake (IEDI) | | | | | | For convenience of the user, the commodities that are NOT relevant for Ethiopia have been marked in | | | | | | | | | | | | RED. |
| | | Compound number: | | | | | | | | | | | | | | | | | | | | | |
| | | ADI (mg/kg bw): | 0,002 | | Diets: g/person/day. Intake = daily intake: µg/person | | | | | | | | | | | | | | | | | | |
| | | | | | A | | B | | C | | D | | E | | F | | G | | H | | I | | J |
| Notes | Codex Code | Name | STMR or STMR-P mg/kg | diet correction factor | diet | intake | diet | intake | diet | intake | diet | intake | diet | intake | diet | intake | diet | intake | diet | intake | diet | intake | diet |
| - | **001** | **CITRUS FRUIT** | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 1 | FC 0001 | Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice) | 5 | 1 | 15,7 | 78,5 | 100,5 | 502,5 | 63,2 | 316,0 | 27,8 | 139,0 | 52,6 | 263,0 | 56,9 | 284,5 | 17,3 | 86,5 | 156,8 | 784,0 | 14,9 | 74,5 | 42,5 |
| - | FC 0001 | Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice) | | 1 | 15,7 | - | 86,5 | - | 52,6 | - | 24,2 | - | 16,2 | - | 12,0 | - | 15,1 | - | 153,9 | - | 3,4 | - | 41,7 |
| - | FC 0001 | Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 90,9 | - | 52,8 | - | 24,2 | - | 19,1 | - | 12,8 | - | 15,1 | - | 153,9 | - | 4,7 | - | 41,7 |
| - | FC 0001 | Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 91,3 | - | 53,0 | - | 24,4 | - | 21,4 | - | 13,2 | - | 15,1 | - | 153,9 | - | 5,8 | - | 41,7 |
| - | FC 0001 | Citrus fruit (excl lemon juice, excl mandarin juice, incl orange juice, excl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 94,7 | - | 60,8 | - | 26,7 | - | 48,2 | - | 53,5 | - | 15,4 | - | 155,7 | - | 11,0 | - | 41,7 |
| - | FC 0001 | Citrus fruit (excl lemon juice, excl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 95,1 | - | 61,0 | - | 26,9 | - | 50,5 | - | 53,9 | - | 15,4 | - | 155,7 | - | 12,1 | - | 41,7 |
| - | FC 0001 | Citrus fruit (excl lemon juice, incl mandarin juice, excl orange juice, excl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 94,0 | - | 54,8 | - | 25,1 | - | 20,6 | - | 14,8 | - | 16,2 | - | 155,0 | - | 5,0 | - | 41,7 |
| - | FC 0001 | Citrus fruit (excl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 94,4 | - | 55,0 | - | 25,3 | - | 22,9 | - | 15,2 | - | 16,2 | - | 155,0 | - | 6,0 | - | 41,7 |
| - | FC 0001 | Citrus fruit (excl lemon juice, incl mandarin juice, incl orange juice, excl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 97,7 | - | 62,7 | - | 27,6 | - | 49,8 | - | 55,4 | - | 16,5 | - | 156,8 | - | 11,3 | - | 41,7 |
| - | FC 0001 | Citrus fruit (excl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 98,2 | - | 62,9 | - | 27,8 | - | 52,1 | - | 55,9 | - | 16,5 | - | 156,8 | - | 12,3 | - | 41,7 |
| - | FC 0001 | Citrus fruit (incl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 93,2 | - | 53,1 | - | 24,2 | - | 19,6 | - | 13,8 | - | 15,8 | - | 153,9 | - | 7,3 | - | 42,5 |
| - | FC 0001 | Citrus fruit (incl lemon juice, excl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice) | | 1 | 15,7 | - | 93,6 | - | 53,3 | - | 24,4 | - | 21,9 | - | 14,2 | - | 15,8 | - | 153,9 | - | 8,4 | - | 42,5 |

| | | | | |
|---|---|---|---|---|
| | O | International Estimated Daily In | | |
| | | | | |
| | | STMR or | Diets: g/person/da | |
| | | STMR-P | A | |
| Codex Code | Commodity | mg/kg | diet | intake |
| FC 0001 | Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice) | 5 | 15,7 | 78,5 |
| FC 0203 | Grapefruit (incl juice) | 5 | 0,1 | 0,5 |
| FC 0204 | Lemon (incl juice) | 5 | 0,0 | 0,0 |
| FC 0002 | Lemon + lime + citrus fruit NES (incl lemon juice, incl NES juice) | 5 | 10,4 | 52,0 |
| FC 0205 | Lime (incl juice) | 5 | ND | - |
| FC 0208 | Orange, sweet (incl juice) | 5 | 2,1 | 10,5 |
| FC 0004 | Orange, sweet, sour + orange-like hybrid (incl juice) | 5 | 4,2 | 21,0 |
| FC 0005 | Shaddock or pomelo + shaddock-like hybrid (incl juice) | 5 | 0,5 | 2,5 |
| FC 4031 | Tangelo | 5 | ND | - |
| | Total intake (µg/person)= | | | 165,0 |
| | Bodyweight per region (kg bw) = | | | 60 |
| | ADI (µg/person)= | | | 120 |
| | %ADI= | | | 137,5% |
| | Rounded %ADI= | | | 140% |

The only difference between an ITMDI calculation and a IEDI is that the input parameters; the ITMDI is a first tier in which the MRL is used. The IEDI is a refined calculation where processing factors and STMR are used. The model is the same.

| | yellow: cells allowed to be changed | | Compound name (in caps): | | DIMETHOATE | | | | INTERNATIONAL ESTIMATE OF SHORT TERM INTAKE (IESTI) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ☑ | Auto insert | | Compound number: | | | | | | | | | | | | Max %ARfD: | | 1460% |
| | | | ARfD (mg/kg bw): | | 0,02 | | | | | | | | Version 13c; d.d. 22 November 2012 | | | | |
| | | | | | | | | | **All data, all population groups** | | | | | | | | |
| Code | Commodity | Pr | Processing | wc | STMR or STMR-P mg/kg | HR or HR-P mg/kg | diet corr factor | Preset codes (case 1, case 3) | Country | Population group | n | Expressed as | Large portion, g/person | Unit weight, edible portion, g | Variability factor | Case | % acute RfD rounded |
| **001** | **CITRUS FRUITS** | - | - | | | | - | | - | - | - | - | - | - | - | - | - |
| FC 0003 | Mandarin + mandarin-like hybrid | 0 | Total | | | 5 | 1,000 | | AU | child, 2-6 yrs | 365 | EP | 247,6 | 81,0 | 3 | 2a | 540% |
| FC 0003 | Mandarin + mandarin-like hybrid | 1 | raw, without peel | wc | | 5 | 1,000 | | CN | Child, 1-6 yrs | 151 | EP | 586,7 | 124,3 | 3 | 2a | 1290% |
| FC 0003 | Mandarin + mandarin-like hybrid | 5 | canned/preserved | | | | 1,000 | | NL | Child, 2-6 yrs | E | PP | 51,7 | NR | NR | 3 | - |
| FC 0003 | Mandarin + mandarin-like hybrid | 9 | Juice (pasteurised) | | | | 1,000 | | DE | Gen pop, 14-80 yrs | 9 | PP | 999,4 | NR | NR | 3 | - |
| FC 0003 | Mandarin + mandarin-like hybrid | 11 | jam (incl jelly/marmalade) | | | | 1,000 | | NL | Gen pop, > 1 yrs | 7 | PP | 5,7 | NR | NR | 3 | - |
| FC 0003 | Mandarin + mandarin-like hybrid | 53 | canned babyfood | | | | 1,000 | | NL | toddler, 8-20 m | 1 | PP | 2,1 | NR | NR | 3 | - |
| FC 0003 | Mandarin + mandarin-like hybrid | 98 | sec processing / composite foods | | | | 1,000 | | NL | Child, 2-6 yrs | 882 | PP | 5,6 | NR | NR | 3 | - |
| FC 0004 | Orange, sweet, sour + orange-like hybrid | 0 | Total | wc | | 5 | 1,000 | | AU | Child, 2-6 yrs | 1735 | EP | 800,8 | 155,8 | 3 | 2a | 1460% |
| FC 0004 | Orange, sweet, sour + orange-like hybrid | 1 | raw, without peel | | | 5 | 1,000 | | DE | Child, 2-4 yrs | 92 | EP | 238,4 | 121,3 | 3 | 2a | 740% |
| FC 0004 | Orange, sweet, sour + orange-like hybrid | 2 | Peel | | | 5 | 1,000 | | AU | Gen pop, > 2 yrs | 698 | PP | 15,1 | - | - | - | - |
| FC 0004 | Orange, sweet, sour + orange-like hybrid | 9 | Juice (pasteurised) | | | | 1,000 | | NL | Child, 2-6 yrs | 224 | PP | 537,2 | NR | NR | 3 | - |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | **DIMETHOATE ()** | | | | | | | | | | | | |
| | | | Acute RfD= 0,02 mg/kg bw (20 µg/kg bw) | | | | | | | Maximum %ARfD: | | | 1460% | 810% | 1460% |
| | | | | | | | | | | | | | all | gen pop | child |
| Codex Code | Commodity | Processing | STMR or STMR-P mg/kg | HR or HR-P mg/kg | diet corr fact | Country | Population group | n | Large portion, g/person | Unit weight, edible portion, g | Variability factor | Case | % acute RfD rounded | % acute RfD rounded | % acute RfD rounded |
| FC 0204 | Lemon | Total | | 5 | 1,000 | FR | child, 3-6 yrs | 16,1% | 58,2 | 64,0 | 3 | 2b | 230% | 150% | 230% |
| FC 0204 | Lemon (all other commodities) | highest utilisation: raw with peel | | 5 | 1,000 | JP | Gen pop, > 1 yrs | 344 | 40,8 | 116,4 | 3 | 2b | 30 - 60% | 30 - 60% | 0,2 |
| FC 0205 | Lime | Total | | 5 | 1,000 | AU | Gen pop, > 2 yrs | 579 | 259,2 | 49,0 | 3 | 2a | 130% | 130% | 110% |
| FC 0205 | Lime (all other commodities) | highest utilisation: raw, without peel | | 5 | 1,000 | DE | Gen pop, 14-80 yrs | 13 | 64,7 | 67,9 | 3 | 2b | 0,6 | 0,6 | 0,2 |
| FC 0003 | Mandarin + mandarin-like hybrid | Total | | 5 | 1,000 | AU | child, 2-6 yrs | 365 | 247,6 | 81,0 | 3 | 2a | 540% | 310% | 540% |
| FC 0003 | Mandarin + mandarin-like hybrid | raw, without peel | | 5 | 1,000 | CN | Child, 1-6 yrs | 151 | 586,7 | 124,3 | 3 | 2a | 1290% | 590% | 1290% |
| FC 0004 | Orange, sweet, sour + orange-like hybrid | Total | | 5 | 1,000 | AU | Child, 2-6 yrs | 1735 | 800,8 | 155,8 | 3 | 2a | 1460% | 810% | 1460% |
| FC 0004 | Orange, sweet, sour + orange-like hybrid | raw, without peel | | 5 | 1,000 | DE | Child, 2-4 yrs | 92 | 238,4 | 121,3 | 3 | 2a | 740% | 430% | 740% |
| FC 0005 | Shaddock or pomelo + shaddock-like hybrid | Total | | 5 | 1,000 | AU | gen pop, > 2 yrs | 165 | 975,6 | 207,0 | 3 | 2a | 520% | 520% | 580% |
| FC 0005 | Shaddock or pomelo + shaddock-like hybrid | raw, without peel | | 5 | 1,000 | DE | Child, 2-4 yrs | 12 | 358,6 | 178,5 | 3 | 2a | 1110% | 690% | 1110% |

**Conclusion**

See 3.6.6 of the handbook for the conclusion to be drawn.

No adverse effects on consumers are expected (**safe use**):

Total dietary exposure (ITMDI) is ≤ 100% of ADI.

Acute dietary exposure (IESTI) is ≤ 100% of ARfD.

Adverse effects on consumers cannot be excluded (**no safe use**):

Total dietary exposure (ITMDI) >100% of ADI,

Acute dietary exposure is (IESTI) > 100% of ARfD.

Since both chronic and acute adverse effect for consumers cannot be excluded, the calculation needs to be refined.

**Second Tier**

STMR is generally 1/3 of MRL, when no data is available.
Since peel/pulp distribution can make a difference, these data should be made available by the applicant.
JMPR '98 reports a processing factor of 0.14 for orange juice.

IEDI: diet correction factor: replace 1,00 with 0,14 for citrus fruits, MRL:
IESTI: diet correction factor: replace 1,00 with 0,14 for citrus fruits

| | **DIMETHOATE ()** | International Estimated Daily In | | |
|---|---|---|---|---|
| | | STMR or | Diets: g/person/da | |
| | | STMR-P | A | |
| Codex Code | Commodity | mg/kg | diet | intake |
| FC 0001 | Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice) | 1,66 | 15,7 | 3,6 |
| - | Citrus juice NES | 1,66 | 0,0 | 0,0 |
| FC 0203 | Grapefruit (incl juice) | 1,66 | 0,1 | 0,0 |
| FC 0204 | Lemon (incl juice) | 1,66 | 0,0 | 0,0 |
| FC 0002 | Lemon + lime + citrus fruit NES (incl lemon juice, incl NES juice) | 1,66 | 10,4 | 2,4 |
| FC 0205 | Lime (incl juice) | 1,66 | ND | - |
| FC 0206 | Mandarin (incl juice) | 1,66 | 0,0 | 0,0 |
| FC 0003 | Mandarin + mandarin-like hybrid (incl juice) | 1,66 | 0,6 | 0,1 |
| FC 0004 | Orange, sweet, sour + orange-like hybrid (incl juice) | 1,66 | 4,2 | 1,0 |
| FC 0005 | Shaddock or pomelo + shaddock-like hybrid (incl juice) | 1,66 | 0,5 | 0,1 |
| FC 4031 | Tangelo | 1,66 | ND | - |
| | Total intake (µg/person)= | | | 7,3 |
| | Bodyweight per region (kg bw) = | | | 60 |
| | ADI (µg/person)= | | | 120 |
| | %ADI= | | | 6,1% |
| | Rounded %ADI= | | | 6% |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | **DIMETHOATE ()** | | | | | | | | | | | | |
| | | | Acute RfD= 0,02 mg/kg bw (20 µg/kg bw) | | | | | | | Maximum %ARfD: | | | 200% all | 110% gen pop | 200% child |
| Codex Code | Commodity | Processing | STMR or STMR-P mg/kg | HR or HR-P mg/kg | diet corr fact | Country | Population group | n | Large portion, g/person | Unit weight, edible portion, g | Variability factor | Case | % acute RfD rounded | % acute RfD rounded | % acute RfD rounded |
| FC 0204 | Lemon (all commodities) | highest utilisation: Total | | 5 | 0,140 | FR | child, 3-6 yrs | 16,1% | 58,2 | 64,0 | 3 | 2b | 4% - 30% | 4% - 20% | 3% - 30% |
| FC 0205 | Lime | raw, without peel | | 5 | 0,140 | DE | Gen pop, 14-80 yrs | 13 | 64,7 | 67,9 | 3 | 2b | 9% | 9% | - |
| FC 0003 | Mandarin + mandarin-like hybrid | raw, without peel | | 5 | 0,140 | CN | Child, 1-6 yrs | 151 | 586,7 | 124,3 | 3 | 2a | 180% | 80% | 180% |
| FC 0003 | Mandarin + mandarin-like hybrid (all other commodities) | highest utilisation: Total | | 5 | 0,140 | AU | child, 2-6 yrs | 365 | 247,6 | 81,0 | 3 | 2a | 0,8 | 0,4 | 0,8 |
| FC 0004 | Orange, sweet, sour + orange-like hybrid | Total | | 5 | 0,140 | AU | Child, 2-6 yrs | 1735 | 800,8 | 155,8 | 3 | 2a | 200% | 110% | 200% |
| FC 0004 | Orange, sweet, sour + orange-like hybrid (all other commodities) | highest utilisation: raw, without peel | | 5 | 0,140 | DE | Child, 2-4 yrs | 92 | 238,4 | 121,3 | 3 | 2a | 1 | 0,6 | 1 |
| FC 0005 | Shaddock or pomelo + shaddock-like hybrid | raw, without peel | | 5 | 0,140 | DE | Child, 2-4 yrs | 12 | 358,6 | 178,5 | 3 | 2a | 160% | 100% | 160% |
| FC 0005 | Shaddock or pomelo + shaddock-like hybrid (all other commodities) | highest utilisation: Total | | 5 | 0,140 | AU | gen pop, > 2 yrs | 165 | 975,6 | 207,0 | 3 | 2a | 0,7 | 0,7 | 0,8 |

After refinement, the same conclusion can be drawn as after the first tier:

No adverse effects on consumers are expected (**safe use**):
Total dietary exposure (IEDI) is ≤ 100% of ADI.
Acute dietary exposure (IESTI) is ≤ 100% of ARfD.

Adverse effects on consumers cannot be excluded (**no safe use**):
Total dietary exposure (IEDI) >100% of ADI,
Acute dietary exposure is (IESTI) > 100% of ARfD.

| | |
|---|---|
| Conclusion dimethoate: | Safe use: Y/N |

## 2. 2,4D in teff, field

**2,4-D**

| 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 | | |
| Teff | Agro 2,4D Amine 720 | F | Broad leafed weeds | SL | 720g/l | Spray | Post emergence to young vigorously growing weeds | 1 | - | 400 | 0.72 | - | |

**No MRLs are set at CODEX for teff or 'other cereals'. Therefore, other cereals are selected and highest MRL is chosen.**


JMPR ADI: 0.01 mg/kg bw/d and ARfD not necessary

## Chronic exposure

| | A | B | C | D | E | F |
|---|---|---|---|---|---|---|
| 1 | | **WHO, August v2 2006, GEMS/FoodConsumptionClusterDiets** | | | | Version 14 |
| 2 | | | Compound name (in capitals): | 2,4-D | | Internatio |
| 3 | | | Compound number: | | | |
| 4 | | | ADI (mg/kg bw): | 0,01 | | Diets: g/pe |
| 5 | | | | | | A |
| 6 | Notes | Codex Code | Name | STMR or STMR-P mg/kg | diet correction factor | diet |
| 436 | - | GC 0649 | Rice (incl husked, excl polished) | | 1 | 46,3 |
| 437 | - | GC 0649 | Rice (excl husked, incl polished) | | 1 | 44,7 |
| 438 | - | CM 0649 | Rice, husked (incl milled) | | 1 | 35,6 |
| 439 | - | - | Rice, milled husked | | 1 | 0,0 |
| 440 | - | CM 1205 | Rice, polished (incl flour) | | 1 | 29,8 |
| 441 | - | -d | Rice flour | | 1 | 0,0 |
| 442 | - | CM 1206 | Rice bran, unprocessed | | 1 | ND |
| 443 | - | GC 0655 | Wild rice | | 1 | ND |
| 444 | 93 | GC 0650 | Rye (incl flour) | | 1 | 0,1 |
| 445 | - | GC 0650 | Rye (excl flour) | | 1 | 0,1 |
| 446 | - | CF 1250 | Rye flour | | 1 | 0,0 |
| 447 | 93 | CF 1251 | Rye wholemeal | | 1 | 0,1 |
| 448 | 94 | GC 0651 | Sorghum (incl flour, incl beer) | | 1 | 36,9 |
| 449 | - | GC 0651 | Sorghum (excl flour, excl beer) | | 1 | 0,0 |
| 450 | - | GC 0651 | Sorghum (excl flour, incl beer) | | 1 | 0,0 |
| 451 | - | GC 0651 | Sorghum (incl flour, excl beer) | | 1 | 36,9 |
| 452 | - | - | Sorghum flour | | 1 | 33,5 |
| 453 | 95 | - | Sorghum beer | | 1 | 62,3 |
| 454 | 96 | GC 0652 | Teff (incl flour) | 2 | 1 | 44,3 |
| 455 | 97 | GC 0653 | Triticale (incl flour) | | 1 | 0,0 |
| 456 | - | GC 0653 | Triticale (excl flour) | | 1 | 0,0 |
| 457 | - | - | Triticale flour | | 1 | 0,0 |
| 458 | 98 | GC 0654 | Wheat (incl bulgur wholemeal, incl flour) | | 1 | 88,4 |
| 459 | - | GC 0654 | Wheat (excl bulgur wholemeal, excl flour) | | 1 | 0,0 |
| 460 | - | GC 0654 | Wheat (excl bulgur wholemeal, incl flour) | | 1 | 82,4 |
| 461 | - | GC 0654 | Wheat (incl bulgur wholemeal, excl flour) | | 1 | 6,0 |
| 462 | - | CF 1210 | Wheat germ | | 1 | 0,0 |
| 463 | - | -d | Wheat bulgur wholemeal | | 1 | 5,5 |
| 464 | - | CF 1212 | Wheat wholemeal | | 1 | ND |

| | | | | |
|---|---|---|---|---|
| | **2,4-D ()** | International Estimated Daily In | | |
| | | STMR or | Diets: g/person/da | |
| | | STMR-P | A | |
| Codex Code | Commodity | mg/kg | diet | intake |
| - | - | | - | - |
| GC 0654 | Teff (incl flour) | 2 | 44,3 | 88,6 |
| | Total intake (µg/person)= | | | 88,6 |
| | Bodyweight per region (kg bw) = | | | 60 |
| | ADI (µg/person)= | | | 600 |
| | %ADI= | | | 14,8% |
| | Rounded %ADI= | | | 10% |

**Acute exposure**

Since 2,4-D does not show acute toxic effects, an ARfD was not deemed necessary and was derived. Hence, an acute exposure assessment is not pertformed.

**Conclusion**

See 3.6.6 of the handbook for the conclusion to be drawn.

No adverse effects on consumers are expected (**safe use**):

Total dietary exposure (ITMDI) is $\leq$ 100% of ADI.

Acute dietary exposure (IESTI) is $\leq$ 100% of ARfD.

Adverse effects on consumers cannot be excluded (**no safe use**):

Total dietary exposure (ITMDI) >100% of ADI,

Acute dietary exposure is (IESTI) > 100% of ARfD.

| | |
|---|---|
| Conclusion 2,4-D: | Safe use: Y/N |

# Annex 6 Example cases Occupational health

**Case studies**

**Occupational toxicology**
PRIMET Workshop 2 September 2014

***General remark:*** *With* ***PRIMET*** *the worker exposure (field and greenhouse) and the operator exposure in greenhouses can be calculated. To calculate the operator exposure in the field, the* ***German model (modified to Ethiopia)*** *should be used.*

**1. Danadim in barley, field**

Further information needed:
- See Handbook, Table 3.13: barley can be sprayed by tractor and hand (knapsack), downward spraying.
- No greenhouse application.

*Input parameters provided in GAP:*

| Type of formulation | liquid |
|---|---|
| Concentration active in formulation | 40% |
| Type of application | field, downward |
| Amount of water in spray | 200 L/ha |
| Maximum application rate for active | 0.6 kg active/ha |
| Maximum application rate for formulation | not provided* |

* can be calculated as follows:
application rate active / concentration active in formulation = 0.6 kg/ha / 40% = 0.6 kg/ha / 0.4 kg/L = 1.5 L/ha

*Input parameters on the active substance:*

| AOEL | 0.001 mg/kg bw/d |
|---|---|
| Dermal absorption (dermal penetration) | |
| - concentrate / mixing & loading | 0.15% |
| - spray dilution / application | 2% |

*Default parameters:*

| Inhalation absorption | 100% |
|---|---|
| Body weight | 60 kg |

*Result operator (German model, Ethiopian version)*

| Operator | ETR | | | |
|---|---|---|---|---|
| **Model** | **No PPE** | **With PPE** | | |
| | | **With dermal protection** | **With respiratory protection** | **With dermal and respiratory protection** |
| ***Tractor*** | | | | |
| **German model** | 9.2 | 1.4 | 8.9 | 1.1 |
| ***Handheld*** | | | | |
| **German model*** | 14.7 | n.a. | n.a. | n.a. |

* only upward spraying module available in model.

*Result worker (PRIMET)*

| Worker | ETR |
|---|---|
| **Model** | **No PPE** |
| | |
| ***Field/greenhouse*** | |
| **Europoem II** | 24 |

## 2. Danadim in citrus, field

Further information needed:

- See Handbook, Table 3.13: citrus can be sprayed by tractor and hand (knapsack), upward spraying.
- No greenhouse application.

*Input parameters provided in GAP:*

| Type of formulation | liquid |
|---|---|
| Concentration active in formulation | 40% |
| Amount of water in spray | 200 L/ha |
| Type of application | field, upward |
| Maximum application rate for active | 0.6 kg active/ha |
| Maximum application rate for formulation | not provided* |

* can be calculated as follows:

application rate active / concentration active in formulation = 0.6 kg/ha / 40% = 0.6 kg/ha / 0.4 kg/L = 1.5 L/ha

*Input parameters on the active substance:*

| AOEL | 0.001 mg/kg bw/d |
|---|---|
| Dermal absorption (dermal penetration) | |
| - concentrate / mixing & loading | 0.15% |
| - spray dilution / application | 2% |

*Default parameters:*

| Inhalation absorption | 100% |
|---|---|
| Body weight | 60 kg |

*Result operator (German model, Ethiopian version)*

| Operator | | ETR | | |
|---|---|---|---|---|
| **Model** | **No PPE** | **With PPE** | | |
| | | **With dermal protection** | **With respiratory protection** | **With dermal and respiratory protection** |
| ***Tractor*** | | | | |
| **German model** | 20.2 | 5.1 | 18.9 | 3.8 |
| ***Handheld*** | | | | |
| **German model** | 14.7 | n.a. | n.a. | n.a. |

*Result worker (PRIMET)*

| Worker | ETR |
|---|---|
| **Model** | **No PPE** |
| | |
| ***Field/greenhouse*** | |
| **Europoem II** | 22 |

### 3. XXX in cabbage, greenhouse

Further information needed:

- See Handbook, Table 3.13: cabbage can be sprayed in greenhouses.
- Cabbage can also be sprayed by tractor and hand (knapsack), downward spraying; for operator results see example Danadim in barley.

*Input parameters provided in GAP:*

| **Type of formulation** | **liquid** |
|---|---|
| Concentration active in formulation | 50% |
| Amount of water in spray | 400 L/ha |
| Type of application | Greenhouse (up/downward) |
| Maximum application rate for active | 0.6 kg active/ha |
| Maximum application rate for formulation | not provided* |

*Input parameters on the active substance:*

| **AOEL** | **0.001 mg/kg bw/d** |
|---|---|
| Dermal absorption (dermal penetration) | |
| - concentrate / mixing & loading | 0.15% |
| - spray dilution / application | 2% |

*Default parameters:*

| **Inhalation absorption** | **100%** |
|---|---|
| Body weight | 60 kg |

*Result operator (PRIMET)*

| **Operator** | | **ETR** | | |
|---|---|---|---|---|
| **Model** | **No PPE** | **With PPE** | | |
| | | **With dermal protection** | **With respiratory protection** | **With dermal and respiratory protection** |
| ***Greenhouse*** | | | | |
| **Dutch greenhouse model** | 50 | 14 | 41 | 5 |

*Result worker (PRIMET)*

| **Worker** | **ETR** |
|---|---|
| **Model** | **No PPE** |
| | |
| ***Field/greenhouse*** | |
| **Europoem II** | 12 |

### 4. Agro 2,4D in teff, field

Further information needed:

- See Handbook, Table 3.13: teff is sprayed by hand (knapsack).
- No greenhouse application.

*Input parameters provided in GAP:*

| Type of formulation | liquid |
|---|---|
| Concentration active in formulation | 720 g/l |
| Amount of water in spray | 400 L/ha |
| Type of application | field, downward |
| Maximum application rate for active | 0.72 kg active/ha |
| Maximum application rate for formulation | not provided* |

* can be calculated as follows:

application rate active / concentration active in formulation = 0.72 kg/ha / 0.72 kg/L = 1 L/ha

*Input parameters on the active substance:*

| AOEL | 0.15 mg/kg bw/d |
|---|---|
| Dermal absorption (dermal penetration) | |
| - concentrate / mixing & loading | 2% |
| - spray dilution / application | 2% |

*Default parameters:*

| Inhalation absorption | 100% |
|---|---|
| Body weight | 60 kg |

*Result operator (German model, Ethiopian version)*

| **Operator** | | **ETR** | | |
|---|---|---|---|---|
| **Model** | **No PPE** | **With PPE** | | |
| | | **With dermal protection** | **With respiratory protection** | **With dermal and respiratory protection** |
| ***Tractor*** | | | | |
| **Not sprayed by tractor in Ethiopia** | | | | |
| ***Handheld*** | | | | |
| **German model*** | 0.4 | n.a. | n.a. | n.a. |

* only upward spraying module available in model.

*Result worker (PRIMET)*

| **Worker** | **ETR** |
|---|---|
| **Model** | **No PPE** |
| | |
| ***Field/greenhouse*** | |
| **Europoem II** | 0.2 |

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The mission of Wageningen UR (University & Research centre) is 'To explore the potential of nature to improve the quality of life'. Within Wageningen UR, nine specialised research institutes of the DLO Foundation have joined forces with Wageningen University to help answer the most important questions in the domain of healthy food and living environment. With approximately 30 locations, 6,000 members of staff and 9,000 students, Wageningen UR is one of the leading organisations in its domain worldwide. The integral approach to problems and the cooperation between the various disciplines are at the heart of the unique Wageningen Approach.