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The use of a simple model for the regulatory environmental risk assessment of pesticides in Ethiopia

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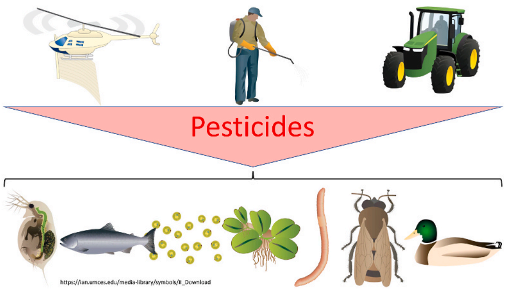
HIGHLIGHTS

- Environmental risks of pesticides currently registered in Ethiopia were evaluated.
- A modelling approach was used requiring only standard data.
- 37 and 17% of the pesticides are predicted to pose a risk to aquatic fauna and flora, respectively.
- 23 and 36% are predicted to pose a risk to in-crop bees and birds, respectively.
- Modelling approaches are suitable to be included in the registration system of developing countries.

GRAPHICAL ABSTRACT



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ABSTRACT

Pesticide registration in developing countries like Ethiopia is often not supported by substantiated risk assessment procedures. In this study, we evaluated the PRIMET (Pesticide Risks in the Tropics for Man, Environment and Trade) Registration_Ethiopia_1.1 model which is a tool developed to assess the risks to non-target protection goals. All the 103 registered active ingredients (a.i.) in Ethiopia, except those used for flower and storage pest control purposes, were evaluated on their environmental risks. Data on physico-chemical characteristics, toxicity and pesticide use patterns were mined from either the information given in the dossier or public databases. Together with scenarios specifically developed for Ethiopia, these data were used to perform a risk assessment for the aquatic and terrestrial environment as well as for vertebrates including humans via contaminated drinking water exposure. Results indicated that 11 and 16% of the a.i.s are indicated to pose high acute risk and 7.3 and 11% high chronic risks for fish and aquatic invertebrates, respectively. Similarly, 5.5 and 8.7% high acute risks and 6.8 and 3.9% high chronic risks were observed for the soil ecosystem and birds, respectively. 23% of the evaluated active ingredients were indicated to be highly risky to bees when beehives are present inside the sprayed crop while 7.8% of them are highly risky when beehives are present outside the field of the sprayed crop. The fungicide metalaxyl, the herbicides acetochlor, alachlor, mecoprop and tembotrion, and the insecticides carbaryl, chlorpyrifos, diazinon and methidathion were predicted to pose high acute or chronic risks to humans or other vertebrates if surface water is used as a source of drinking water. Future studies should give emphasis on how the risk assessment results of this study can be implemented to aid the registration process.

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1. Introduction

Global occurrence of acute pesticide poisoning of humans is estimated to be around three million cases every year, making it a worldwide public health problem (Damalas and Koutroubas, 2016). The human and environmental pesticide poisoning associated with their use in developing countries may be frequent as these areas often have a high biodiversity on the one hand (Tang et al., 2021), but also a high trade of pesticides in response to the increase in agricultural activities and the associated high prevalence of inappropriate handling, distribution and use of pesticides, on the other hand (Mengistie et al., 2016; Negatu, 2019). This is facilitated by a lack of effective and functional regulatory bodies with appropriate policies, rules and regulations of pesticide risk quantification and management systems, that support the pesticide registration. Also, a lack of environmental monitoring and certified laboratories for pesticide exposure and effect assessment makes it difficult to perform an informative risk assessment in developing countries (Mengistie et al., 2016; Negatu et al., 2016; Onwona Kwakye et al., 2019). Safe use of pesticides is ensured by a functioning registration and post-registration monitoring framework established through performing administrative, scientific and laboratory evaluations of the active ingredients and the formulated products of the pesticides (Handford et al., 2015; Teklu et al., 2016a; Vijver et al., 2017).

Risk assessment (RA) of pesticides before registration is an approach undertaken by many regulatory bodies around the world, especially in the EU countries (Brock et al., 2006). Only a few trials are done to assist the risk assessment of pesticides before registration in developing countries and are performed with e.g., the FAO (Food and Agriculture Organization of the United Nations) pesticide registration toolkit developed with the intention of helping registrars with the evaluation and authorization of pesticides (http://www.fao.org/pesticide-registration-toolkit/en/). Such toolkits help the regulatory bodies in developing countries to have easy access to necessary data through links to other developed pesticide regulatory systems. This is believed to help decision making through simple data comparison based on available foreign information for the pesticide to be registered.

Model based risk assessment of pesticides before registration allows protection of humans and the aquatic and terrestrial environment, as pesticides are potentially toxic to many non-target organisms in nature (Brock et al., 2011). The main objective of pre-determining the risk of a pesticide through a RA and evaluating its actual risk after registration through post registration monitoring is minimizing the probability of future unacceptable risks to humans and the environment (Fargnoli et al., 2019; Beketov et al., 2013; Hallmann et al., 2014; Vijver et al., 2017). Many EU countries adopt model-based risk assessment as a method for evaluating the impacts of pesticides to non-target organisms (Schäfer et al., 2019; FOCUS, 2001). The experience of the EU using model-based approaches can be used as an example for many pesticide regulatory bodies around the world, keeping in mind that the model-based risk assessment has its own limitations and strengths (Van den Brink, 2008).

The Pesticide Risks In the Tropics for Man, Environment and Trade (PRIMET) model is one of the tools developed by the Pesticide Risk Reduction Program – Ethiopia (prrp-ethiopia.wur.nl). The tool was developed to calculate environmental and human risks as part of registration process in Ethiopia. The PRIMET_Registraton_Ethiopia 1.1 model was built further on the PRIMET 3.0 model (Peeters et al., 2008; www.primet.wur.nl). The intended use of the PRIMET 3.0 model was to estimate environmental risks due to pesticide use using a minimum of input data and to raise awareness among stakeholders on negative impacts of pesticides on humans and ecosystems. The PRIMET_Registraton_Ethiopia 1.1 model was made to include more protection goals than the PRIMET 3.0 model and exposure scenarios specific for Ethiopia.

The PRIMET_Registraton_Ethiopia 1.1 model can determine the risks for the protection goals: humans and other vertebrates using surface water as a source of drinking water, the aquatic ecosystem, the soil ecosystem, in- and off-crop bees and birds. The model was developed to integrate fate, effects, and risk assessment of pesticides to the aquatic and terrestrial environment in order to improve the current registration system in Ethiopia and in other countries of the continent of Africa. Unlike assessments based on an older version of the PRIMET model which only included very simple risk assessment procedures (Peeters et al., 2008; Ansara Ross et al., 2008; Malherbe et al., 2013), the PRIMET_Registration_Ethiopia_1.1 model is a tool capable of providing a realistic risk assessment based on exposure scenarios supporting the decision-making process of pesticide registration. It helps both in the registration and the post registration monitoring process by combining both local and global databases and taking specific Ethiopian exposure scenarios into consideration (Wipfler et al., 2014).

The objectives of the present study are i) to use the PRIMET_Registration_Ethiopia_1.1 model to evaluate the risks posed by the active ingredients of pesticides registered in Ethiopia and ii) to evaluate the applicability of the model-based risk assessment for the registration of pesticides in developing countries like Ethiopia, as an example for other countries with similar geographical and socio-economic characteristics.

2. Materials and methods

2.1. Data mining and processing

Of all active ingredients (a.i.) registered in Ethiopia, 103 were evaluated with respect to their risks to the environment and the use of contaminated drinking water (Fig. 1), excluding those (36 a.i.) that are registered for flower production and seed treatment purposes as the use of the latter pesticides do not meet the exposure scenarios developed for the PRIMET_Registration_Ethiopia_1.1 model (Teklu et al., 2016b). The needed data was obtained from either the supplementary information provided by the registrants for the registration or the Pesticides Properties Data Base (PPDB) (University of Hertfordshire, 2013, https://sitem.herts.ac.uk/aeru/ppdb/en/index.htm). The risks were quantified using the PRIMET_Registraton_Ethiopia 1.1 tool (Wipfler et al., 2014).

The names of the agents or the registrants in Ethiopia are not listed for the reason of confidentiality. The risk assessment can be referred to as a first tier one as it is performed using basic and readily accessible

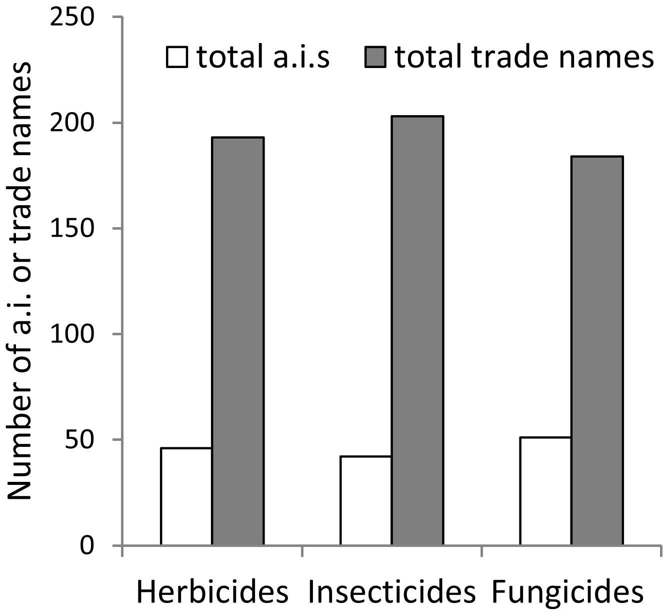


Fig. 1. Total number of pesticides (herbicide, insecticide and fungicide), based on active ingredient and trade names, currently registered in Ethiopia (Source PHRD, 2021).

data expected to be delivered by the registrant as part of the information included in the submitted dossier. Needed data include basic toxicological, physicochemical and pesticide use information like LC50 bees (μg $bees^{-1}$), LC50 birds (mg kg^{-1} bw^{-1} d^{-1}), NOEC birds (mg kg^{-1} bw^{-1} d^{-1}), LC50 earthworms (mg kg^{-1}), NOEC earthworms (mg kg^{-1}), EC50 algae (mg L^{-1}), EC50 macrophytes (mg L^{-1}), L(E)C50 fish (mg L^{-1}), NOEC fish (mg L^{-1}), L(E)C50 invertebrates (mg L^{-1}), NOEC invertebrates (mg L^{-1}), ARfD (mg kg^{-1} bw^{-1} d^{-1}), ADI (mg kg^{-1} bw^{-1} d^{-1}), DT50 water (d), DT50 sediment (d), DT50 soil (d), molecular weight of pesticide (M), solubility (mg L^{-1}), vapour pressure at 25 °C (mPa), Koc soil (dm^3 kg^{-1}), application rate (kg a.i. ha^{-1}), time interval between applications (d) and frequency of application (–). Final output is designed to provide indicative risk categories for non-target organisms like bees and birds, soil dwelling organisms (earthworms as representative organism) and aquatic organisms (fish, aquatic invertebrates, algae and macrophytes), and risks associated with drinking surface water in a rural Ethiopian setting.

2.2. *Aquatic ecosystem*

For the aquatic ecosystem, protection goals were set for humans using surface water as a source of drinking water without prior purification and aquatic organisms living in surface water (fish, algae, invertebrates and macrophytes). These protection goals were set after a discussion between stakeholders and following recommendations from workshops including experts from the Animal and Plant Health Regulatory Directorate, Addis Ababa University Institute of Biodiversity and the Ethiopian Agricultural Research Institute (Adriaanse et al., 2015). While setting scenario locations, three locations which are aimed to be protective of the entire Ethiopian agricultural area were chosen. Criteria for selection of these representative locations were the presence of the protection goal, the presence of crops with high use of pesticides and being a densely populated area.

The three scenario locations listed in the PRIMET_Registraton_Ethiopia 1.1 model, i.e., 1, 2a and 2b, are considered valid for the risk assessment for aquatic ecosystems requested for registration in Ethiopia. Scenario locations 1 are representative for small streams, elevated above 1500 m with an annual rain fall of >20 mm for at least 46 days per annum and a long term average annual precipitation around 2581 mm. Scenario locations 2a represent areas with temporary ponds below 1500 m, with annual rain fall of >20 mm for at least 46 days per annum and with long term average annual precipitation around 1702 mm. Scenario locations 2b represents areas with temporary ponds between 1500 m and 2000 m elevation, with annual rain fall of >20 mm for at least 21 days per annum and a long term average annual precipitation around 2779 mm. Details of the scenario locations and how they are developed can be found in Adriaanse et al. (2015) and Teklu et al. (2015).

Risks are expressed as the Exposure Toxicity Ratio (ETR), calculated by taking the Predicted Environmental Concentration (PEC) as the numerator and the Predicted No effect Concentration (PNEC) as the denominator. PEC values were determined using the PRZM (Pesticide in Root Zone Model) and TOXSWA (TOXic substances in Surface WAter) models (Carsel et al., 2005; Adriaanse, 1996; FOCUS, 2001; European Commission, 2011). These models were parametrized for the Ethiopian scenarios using Ethiopian crop, meteorology and irrigation data included in the PRIMET_Registraton_Ethiopia 1.1. model (Teklu et al., 2015; Adriaanse et al., 2015). The 90th percentile concentration of the determined annual maximum PEC values from the 33 years of simulation was used for ETR calculation for the aquatic organisms.

The PNEC values were determined by dividing acute LC/EC50 and chronic NOEC values of the different aquatic endpoints by an assessment factor. As the risks calculated are expected to vary for each scenario location, the highest risk was taken as a worst-case estimate for the whole of Ethiopia. Acute and chronic risks are calculated for fish and aquatic invertebrates (eqs (1) and (2)). For primary producers (algae and macrophytes) only herbicides are considered for acute risk determination (eqs (3) and (4)) (Wipfler et al., 2014).

Acute and chronic risks for fish and invertebrates expressed in Exposure Toxicity Ratio ($ETR_{\text{fish acute}}$) are calculated using eqs (1) and (2). *Oncorhynchus mykiss* and *Daphnia magna* were used as representative species for fish and aquatic invertebrates, respectively.

$$ETR_{\text{fish-acute/chronic}} = PEC_{90th}/PNEC_{\text{fish-acute/chronic}} \tag{1}$$

The $PNEC_{\text{fish-acute}}$ and $PNEC_{\text{fish-chronic}}$ were calculated by dividing the acute EC50 and chronic NOEC by a factor of 100 and 10, respectively.

$$ETR_{\text{invertebrates-acute/chronic}} = PEC_{90th}/PNEC_{\text{invertebrates-acute/chronic}} \tag{2}$$

The $PNEC_{\text{invertebrates-acute}}$ and $PNEC_{\text{invertebrates-chronic}}$ were calculated by dividing the acute EC50 and chronic NOEC by a factor of 100 and 10, respectively.

The ETR for the risk assessment of algae and macrophytes are calculated using eqs (3) and (4). For algae and macrophytes no distinction is made between acute and chronic risk assessment. The EC50 values based on growth rate were used for the ETR calculations. For this study *Pseudokirchneriella subcapitata* and *Lemna gibba* were taken as a representative species for algae and macrophytes, respectively.

$$ETR = PEC_{90th}/PNEC_{\text{algae}} \tag{3}$$

The $PNEC_{\text{algae}}$ was calculated by dividing the EC50 by a factor of 10.

The ETR for the risk assessment of macrophytes is calculated as follows:

$$ETR = PEC_{90th}/PNEC_{\text{macrophytes}} \tag{4}$$

The $PNEC_{\text{macrophytes}}$ was calculated by dividing the EC50 by a factor of 10.

For all aquatic endpoints the following risk classifications were used (Wipfler et al., 2014):

Low risk: ETR <1.

Possible risk: $1 \leq$ ETR <10.

High risk: ETR ≥ 10.

For humans using surface water as a source of drinking water the 99^{th} percentile PEC was used as a worst-case exposure concentration to calculate risks. The acute risk was calculated as the Estimated Short Term Intake ratio (ESTI) which was determined by comparing predicted 99^{th} percentile PEC of a pesticide in a surface water to the acute human toxicity value i.e., the Acute Reference Dose (ARfD). The chronic risk was calculated as the International Estimated Daily Intake ratio (IEDI). It was calculated using the 99^{th} percentile PEC and Acceptable Daily Intake (ADI) values. In both acute and chronic risk assessment a body weight of 60 kg and a large portion of drinking water of 2 L per day was assumed. The fraction of ADI allocated to drinking water was taken as 0.1 for Ethiopia (Adriaanse et al., 2015). Background calculation formulas are given in eqs (5) and (6) and in other publications (Teklu et al., 2015, 2016b; Wipfler et al., 2014).

$$IESTI_{\text{water}} = (\text{LP-DW} * PEC_{99th})/(\text{ARfD} * \text{BW}) \tag{5}$$

$IESTI_{\text{water}}$ = Internationally Estimated Short-Term Intake ratio for water (intake by water as fraction of ARfD); LP-dw = Large Portion of Drinking Water (L d^{-1}); PEC_{99th} = Predicted Environmental Concentration 99^{th} percentile value (mg L^{-1}); ARfD = Acute Reference Dose (mg kg^{-1} BW^{-1} d^{-1}) and BW = Body Weight (kg).

$$IEDI_{\text{water}} = (\text{LP-DW} * PEC_{99th})/(\text{ADI} * F_{dw} * \text{BW}) \tag{6}$$

$IEDI_{\text{water}}$ = Internationally Estimated Daily Intake ratio for water (intake by water as fraction of ADI); LP-DW = Large Portion of Drinking Water (L d^{-1}); PEC_{99th} = Predicted Environmental Concentration the 99^{th} percentile value; (mg L^{-1}); ADI = Acceptable Daily Intake (mg kg^{-1} BW^{-1} d^{-1}), F_{dw} = fraction of ADI allocated to drinking water (–) and BW = Body Weight (kg).

For all drinking water related endpoints the following risk classifications were used (Wipfler et al., 2014):

Low risk: $IESTI_{water}$ or $IEDI_{water} < 1$.
High risk: $IESTI_{water}$ or $IEDI_{water} \geq 1$.

2.3. Soil ecosystem, bees and birds

Risks for the soil ecosystem, bees and birds were determined without taking scenario locations into considerations (Wipfler et al., 2014). For determining the risks for the soil ecosystem, earthworms were taken as indicator species in the PRIMET_Registraton_Ethiopia 1.1 model. For the acute risk assessment, the PNEC was calculated by dividing the LC50 value for earthworms with a European safety factor of 10. Similarly, NOEC values of earthworms were divided by a safety factor of 5 for the calculation of the chronic PNEC (eq (7)) (Wipfler et al., 2014). For determining the PEC_{soil}, first the concentration within the field soil compartment was determined simply by dividing the dose of pesticide applied to the amount of the soil (kg) in the upper 0.05 m part, then further divided by the bulk density of the soil (default value 1 kg dm^{-3}) (Wipfler et al., 2014).

$$ETR_{soil\ ecosystem\text{-}acute/chronic} = PEC_{soil}/PNEC_{soil\ ecosystem\text{-}acute/chronic} \quad (7)$$

For all soil ecosystem endpoints, the following risk classifications were used (Wipfler et al., 2014):

Low risk: $ETR_{soil\ ecosystem\text{-}acute/chronic} < 1$.
Possible risk: $1 \leq ETR_{soil\ ecosystem\text{-}acute/chronic} \leq 5$.
High risk: $ETR_{soil\ ecosystem\text{-}acute/chronic} \geq 5$.

For bees, a similar risk assessment approach using the ETR, was used. As both oral and contact LD50 values are normally available for bees, the lower of the two values was considered in the risk assessment. Calculation was done for an in crop (when bee-hive is present with in the sprayed field) and off-crop (when bee hive is away from a specified buffer zone from the sprayed field) situation using a single application (eqs (8) and (9)).

$$ETR_{in\text{-}crop} = \text{dose rate}/PNEC_{bee} \quad (8)$$

$$ETR_{off\text{-}crop} = (\text{dose rate} * \text{drift factor})/PNEC_{bee} \quad (9)$$

With dose rate in g ha^{-1}, $PNEC_{bee}$ (g ha^{-1}) calculated from the $LD50_{bee}$ (g bee^{-1}) times an empirical correction factor from bee to ha (bee ha^{-1}) of 1 (Wipfler et al., 2014). The drift factor is the fraction of spray drift ending off-crop. The drift factor depends on the type of crop and the application type (knapsack, airplane) (–). For their values is referred to Table 11 of Wipfler et al. (2014).

For the bees endpoints the following risk classifications were used (Wipfler et al., 2014):

Low risk: $ETR_{in/off\text{-}crop} < 50$.
Possible risk: $50 \leq ETR_{in/off\text{-}crop} < 400$.
High risk: $ETR_{in/off\text{-}crop} \geq 400$.

The acute and chronic Estimated Theoretical Exposure (ETE) values for birds were calculated considering the Food Intake Rate (FIR, kg fresh weight day^{-1}) of representative species, its body weight (BW) in kg, concentration of the compound in fresh diet as Residue Per Unit dose (RUD, mg kg^{-1}) and the application rate of active substance considering spray application and the Multiple Application Factor (MAF, -) and additionally by considering time weighted average factor (f_{twa}) in case of determining long term exposure (eqs (11) and (13)). The MAF is the concentration immediately after the last application compared to a single application expressed as a function of the number of applications, interval and DT50 of the a.i. in concern on vegetation while the f_{twa} indicates average concentration during a certain time interval compared to the initial concentration after single or last application (Deneer et al., 2014). Acute and chronic risks for birds were estimated as a ratio of acute/chronic ETE (mg kg bw^{-1}) or daily dose (mg kg^{-1} bw^{-1} d^{-1}) to LD50 or NOEC values of birds divided by a safety factors (eqs (12) and (13)). The PRIMET_Registraton_Ethiopia 1.1. model determined risks for Large Herbivorous (LH); Medium Herbivorous Birds (MHB) and Insectivorous Birds (IB) (Wipfler et al., 2014), using the LD50 and NOEC values of species *Anas platyrhynchos* and *Colinus virginianus* as obtained from the PPDB.

$$ETE_{acute} = FIR/(BW * RUD * \text{application rate active substance} * MAF)(10)$$

$$ETE_{chronic} = (FIR/BW * RUD * \text{application rate active substance} * MAF * f_{twa}) \quad (11)$$

$$ETR_{birds\text{-}acute} = ETE_{birds\text{-}acute}/(LD50_{birds} * 0.1) \quad (12)$$

$$ETR_{birds\text{-}chronic} = ETE_{birds\text{-}acute/chronic}/(NOEC_{birds} * 0.2) \quad (13)$$

For the acute birds endpoint, the following risk classifications were used (Wipfler et al., 2014):

Low risk: $ETR_{birds\text{-}acute} < 1$.
Possible risk: $1 \leq ETR_{birds\text{-}acute} < 5$.
High risk: $ETR_{birds\text{-}acute} \geq 5$.

For the chronic birds endpoint, the following risk classifications were used (Wipfler et al., 2014):

Low risk: $ETR_{birds\text{-}chronic} < 1$.
Possible risk: $1 \leq ETR_{birds\text{-}chronic} < 10$.
High risk: $ETR_{birds\text{-}chronic} \geq 10$.

3. Results and discussion

3.1. Pesticide use and type

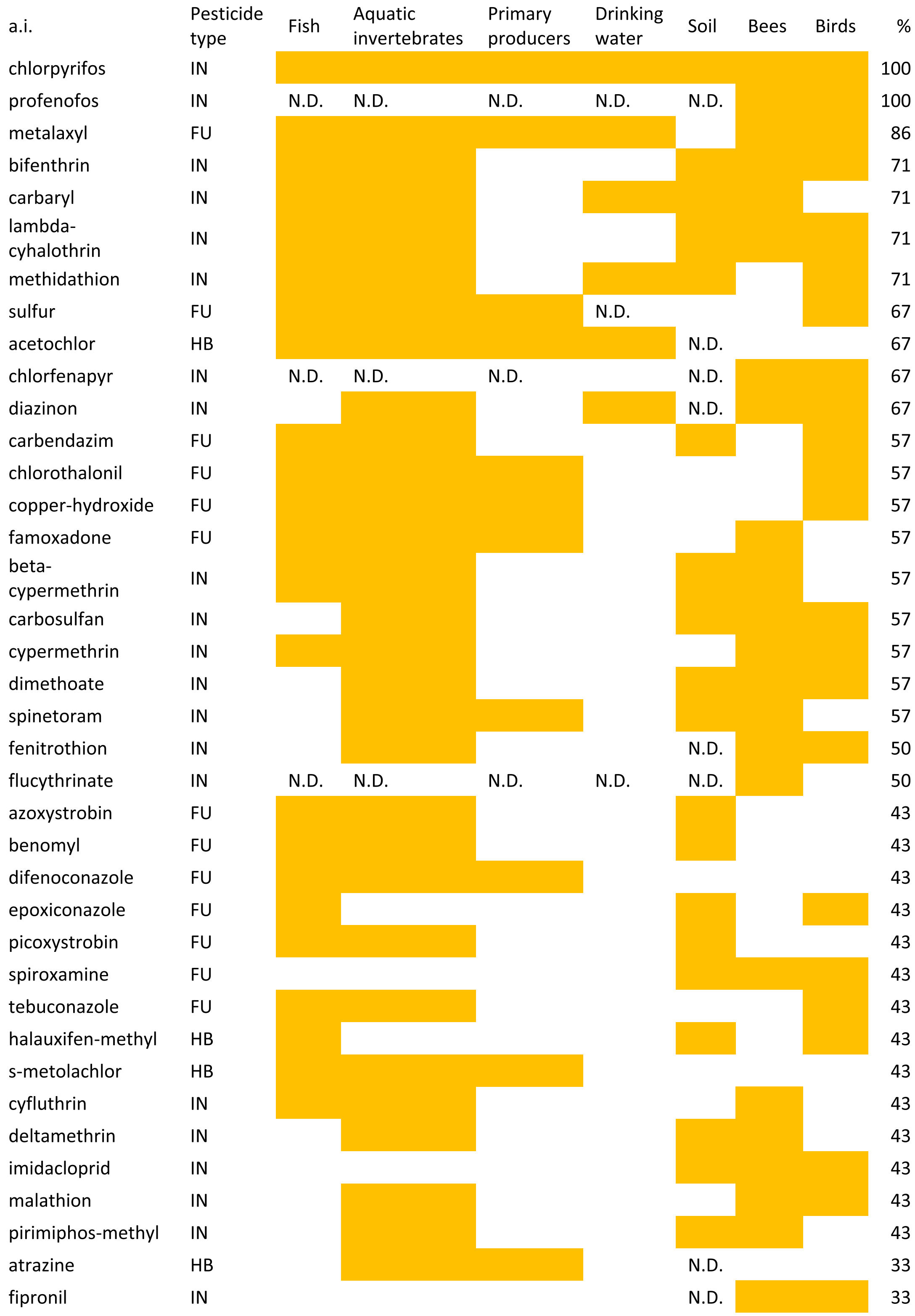
Pesticide type with their dose rate, usage frequency and application interval are the factors determining the PEC (Predicted Environmental Concentrations) values in environmental compartments, while the risk associated with a specific active ingredient (a.i.) released to the environment depends on the toxicity of that particular a.i. to the endpoint of concern. Risk is expressed as the ratio between the exposure and the toxicity for the specific environmental matrix it is released to (Teklu et al., 2015). The required physico-chemical and toxicity and application schemes data are given as a supplementary material (Tables S1 and S2). Of the examined 103 pesticides, 30 (29%) of them are insecticides, 30 (29%) of them are fungicides and 43 (42%) of them are herbicides. Examining approval status in EU revealed that 18 (17%) of them are approved for use only in few or some of the EU countries while 41 (40%) are not approved at all. The remaining 44 (43%) pesticides are approved for use in all EU countries.

3.2. Risk assessment results

Table 1 summarises the results of the different risk assessments, by indicating in orange whether a risk assessment indicated a possible of high acute or chronic risks for 1 of the evaluated scenarios. The risk assessment results indicated that the insecticides chlorpyrifos and profenofos pose a risk to all endpoints (groups of organisms), although due to a lack of data only bees and birds could be evaluated for profenofos. For the insecticides bifenthrin, carbaryl, chlorfenapyr, diazinon, lambda-cyhalothrin and methidathion, the herbicide acetochlor and the fungicides metalaxyl and sulphur a risk was indicated in more than 65% of the risk assessments. For 29 pesticides no risks were indicated for all performed risk assessments, consisting of 5 insecticides, 17 herbicides and 7 fungicides (Table 1). Chlorpyrifos is currently identified as a Highly Hazardous Pesticides (HHPs) posing risks to pregnant women (Taheri et al., 2022), aquatic organisms, birds, bees (pollinators) and humans (Giddings et al., 2014).

Some of the pesticides posing risks to a large number of endpoints identified by this study are found to be categorized to pose similar high risks in former studies performed in Ethiopia (Teklu et al., 2015, 2016b). There are only a few African studies outside of Ethiopia known to us

Table 1
Pesticides posing a possible or high risk, either chronic or acute (in- and off-crop for bees) for the different endpoints are indicated by orange. N.D. = Not all data are available to perform the risk assessment. HB = herbicide, IN = insecticide and FU = fungicide.



a.i.	Pesticide type	Fish	Aquatic invertebrates	Primary producers	Drinking water	Soil	Bees	Birds	%
chlorpyrifos	IN	🟧	🟧	🟧	🟧	🟧	🟧	🟧	100
profenofos	IN	N.D.	N.D.	N.D.	N.D.	N.D.	🟧	🟧	100
metalaxyl	FU	🟧	🟧	🟧	🟧		🟧	🟧	86
bifenthrin	IN	🟧	🟧			🟧	🟧	🟧	71
carbaryl	IN	🟧	🟧		🟧	🟧	🟧		71
lambda-cyhalothrin	IN	🟧	🟧			🟧	🟧	🟧	71
methidathion	IN	🟧	🟧		🟧	🟧		🟧	71
sulfur	FU	🟧	🟧	🟧	N.D.			🟧	67
acetochlor	HB	🟧	🟧	🟧	🟧	N.D.			67
chlorfenapyr	IN	N.D.	N.D.	N.D.		N.D.	🟧	🟧	67
diazinon	IN		🟧		🟧	N.D.	🟧	🟧	67
carbendazim	FU	🟧	🟧			🟧		🟧	57
chlorothalonil	FU	🟧	🟧	🟧				🟧	57
copper-hydroxide	FU	🟧	🟧	🟧				🟧	57
famoxadone	FU	🟧	🟧	🟧			🟧		57
beta-cypermethrin	IN	🟧	🟧			🟧	🟧		57
carbosulfan	IN		🟧			🟧	🟧	🟧	57
cypermethrin	IN	🟧	🟧				🟧	🟧	57
dimethoate	IN		🟧			🟧	🟧	🟧	57
spinetoram	IN		🟧	🟧		🟧	🟧		57
fenitrothion	IN		🟧			N.D.	🟧	🟧	50
flucythrinate	IN	N.D.	N.D.	N.D.	N.D.	N.D.	🟧		50
azoxystrobin	FU	🟧	🟧			🟧			43
benomyl	FU	🟧	🟧			🟧			43
difenoconazole	FU	🟧	🟧	🟧					43
epoxiconazole	FU	🟧				🟧		🟧	43
picoxystrobin	FU	🟧	🟧			🟧			43
spiroxamine	FU					🟧	🟧	🟧	43
tebuconazole	FU	🟧	🟧					🟧	43
halauxifen-methyl	HB	🟧				🟧		🟧	43
s-metolachlor	HB	🟧	🟧	🟧					43
cyfluthrin	IN	🟧	🟧				🟧		43
deltamethrin	IN		🟧			🟧	🟧		43
imidacloprid	IN					🟧	🟧	🟧	43
malathion	IN		🟧				🟧	🟧	43
pirimiphos-methyl	IN		🟧			🟧	🟧		43
atrazine	HB		🟧	🟧		N.D.			33
fipronil	IN					N.D.	🟧	🟧	33

cymoxanil	FU		🟨					🟨	29
folpet	FU					🟨		🟨	29
pyraclostrobin	FU	🟨	🟨						29
triadimefon	FU	🟨	🟨						29
alachlor	HB			🟨	🟨				29
mecoprop	HB				🟨			🟨	29
mesotrione	HB	🟨		🟨					29
metribuzin	HB			🟨				🟨	29
paraquat	HB			🟨				🟨	29
tembotrione	HB			🟨	🟨				29
thiamethoxam	IN					🟨	🟨		29
mancozeb	FU					N.D.		🟨	17
ametryn	HB			🟨		N.D.			17
bentazon	HB					N.D.		🟨	17
dicamba	HB					N.D.		🟨	17
diclosulam	HB			🟨		N.D.			17
mesosulfuron-methyl	HB			🟨	N.D.				17
thiencarbazone-methyl	HB			🟨		N.D.			17
tribenuron-methyl	HB			🟨		N.D.			17
bixafen	FU	🟨							14
fluopyram	FU							🟨	14
propiconazole	FU					🟨			14
triadimenol	FU							🟨	14
zoxamide	FU	🟨							14
clomazone	HB					🟨			14
glyphosate	HB							🟨	14
hexazinone	HB							🟨	14
iodosulfuron-methyl-sodium	HB			🟨					14
isoproturon	HB			🟨					14
nicosulfuron	HB			🟨					14
pendimethalin	HB							🟨	14
penoxsulam	HB			🟨					14
pyroxsulam	HB			🟨					14
alpha-cypermethrin	IN						🟨		14
indoxacarb	IN						🟨		14
methoxyfenozide	IN							🟨	14
bupirimate	FU								0
fluopicolide	FU								0
mandipropamid	FU					N.D.			0
myclobutanil	FU								0
penconazole	FU								0

propamocarb-hydrochloride	FU						0
trifloxystrobin	FU						0
2,4-D	HB					N.D.	0
amidosulfuron	HB					N.D.	0
aminopyralid	HB					N.D.	0
bispyribac-sodium	HB					N.D.	0
butachlor	HB	N.D.	N.D.	N.D.	N.D.	N.D.	0
clodinafop-propargyl	HB						0
diclofop-methyl	HB					N.D.	0
fenoxaprop-p-ethyl	HB					N.D.	0
florasulam	HB					N.D.	0
fluazifop-p-butyl	HB					N.D.	0
flucarbazone-sodium	HB	N.D.	N.D.	N.D.	N.D.	N.D.	0
glufosinate-ammonium	HB						0
haloxyfop-p-methyl	HB						0
oxyfluorfen	HB						0
pinoxaden	HB					N.D.	0
saflufenacil	HB	N.D.	N.D.	N.D.	N.D.		0
topramezone	HB					N.D.	0
acetamiprid	IN						0
clorantraniliprole	IN	N.D.	N.D.	N.D.			0
flubendiamide	IN					N.D.	0
lufenuron	IN					N.D.	0
sulfoxaflor	IN						0

which evaluated the risks of pesticides to both aquatic and terrestrial endpoints. Onwona-Kwakye et al. (2020) evaluated the effects of pesticides currently used by farmers in Ghana on aquatic and terrestrial endpoints using the PRIMET 2.0 model. They concluded that many pesticides may pose serious risks to Ghanaian aquatic and terrestrial organisms and that pesticide use was a factor of 1.3–13 times higher than recommended, which is not taken into account in the current study as we evaluated recommended rates. Jepson et al. (2014) used the ipmPRiME (integrated pest management Pesticide Risk Mitigation Engine) risk assessment tool to evaluate the effects of pesticides used in West African agriculture on human and different environmental (including terrestrial and aquatic) endpoints by calculating impact areas. They found widespread risks to terrestrial and aquatic wildlife throughout the region. So, all studies incorporating terrestrial and aquatic endpoints in their risk assessment of pesticide use in Africa reported wide-spread risks. Below, the results of these two papers will be compared in detail for the different endpoints separately.

Of the total 96 a.i.s, for which sufficient data were accessed to perform an aquatic risk assessment, 12 and 16 pose a high acute risk to fish and aquatic invertebrates, respectively, while 8 and 12 are posing high chronic risks, respectively. The insecticides beta-cypermethrin, bifenthrin, carbaryl, chlorpyrifos, cyfluthrin and lambda-cyhalothrin, the fungicides carbendazim, chlorothalonil and copper-hydroxide and sulphur, and the herbicide acetochlor posed either an acute or chronic high risk to both fish and aquatic invertebrates, while difenoconazole, diazinon, fenitrothion and malathion only posed a high risk to aquatic invertebrates and triadimefon to fish (Table 1, S3 and S4; Fig. 2). Recently reported pesticide monitoring (i.e., using field samples and model prediction) and risk assessment studies for Lake Ziway, Ethiopia indicated high level of pollution and risk category for both aquatic flora and fauna and humans in the area (Merga et al., 2021; Teklu et al., 2016b). A risk assessment study using the PRIMET model, conducted to assess the risks of pesticide use to fish and aquatic invertebrate in surface water systems in South Africa, reported that deltamethrin showed the highest probability of risks to aquatic organisms while cypermethrin, parathion, dichlorvos, carbaryl, bromoxynil, linuron, methomyl and aldicarb were all indicated to have possible risk (Ansara-Ross et al., 2008). Fai et al. (2019) assessed the risks of commonly used pesticides by rice and vegetable farmers on two major streams in the Ndop flood plain in Cameroon also using the PRIMET model. The authors (Fai et al., 2019) identified thirty pesticide formulations containing 17 active ingredients of which five posed acute and/or chronic risks to aquatic life in the streams. Chlorpyriphos-ethyl, chlorothalonil, and cypermethrin posed a high acute and/or chronic risk while mancozeb and lambda-cyhalothrin posed a possible risk (Fai et al., 2019). In other risk evaluations performed in Africa, dimethoate, methamidophos, deltamethrin and zeta-cypermethrin were associated with high risks to aquatic invertebrates in West Africa (Jepson et al., 2014), while

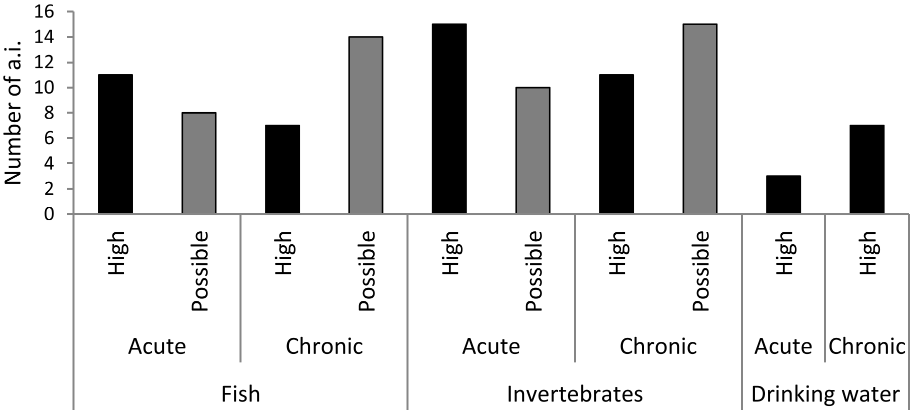


Fig. 2. Number of pesticide a.i. with acute and chronic (possible and high) risks for fish, invertebrates and human/cattle via contaminated surface water for drinking water use. As a total of 96 a.i.s were evaluated for all endpoints, the numbers can almost be interpreted as %.

Onwona-KwakyeHogarh and Van den Brink (2020) identified lambda-cyhalothrin, chlorpyrifos, cypermethrin, dimethoate, mancozeb, carbendazim, sulphur, maneb and copper hydroxide posing the highest risks to the Ghanaian aquatic ecosystems. There is a large overlap in a.i.s between the different studies and it seems that, not surprisingly, insecticides, especially pyrethroids, followed by organophosphates, pose high risks to aquatic animals.

Of the 96 a.i.s for which an aquatic risk assessment was performed, 17 pose a high or possible risk to algae, while for macrophytes 39 a.i.s were evaluated of which 15 pose a risk (Fig. 3; Table S5). The herbicides acetochlor, ametryn, metribuzin and nicosulfuron are reported to pose high risks to algae, while the herbicides acetochlor, alachlor, atrazine, iodosulfuron-methyl-sodium, mesosulfuron-methyl, metribuzin, saflufenacil and thiencarbazone-methyl pose a high risk to macrophytes in at least one of the scenarios (Table S5). Onwona-KwakyeHogarh and Van den Brink (2020) also identified several herbicides posing high risks to aquatic primary producers under normal agricultural practices in Ghana, although the a.i.s were different as the herbicidal a.i.s they evaluated only partly overlapped with our study.

The herbicides acetochlor and alachlor and the insecticide chlorpyrifos are indicated to pose high acute risks to humans/cattle using pesticides contaminated surface water as a source of drinking, while the herbicides mecoprop and tembotrion, the insecticides carbaryl, chlorpyrifos, diazinon and methidathion and the fungicide metalaxyl posed a high chronic risk in at least one of the scenarios (Fig. 2; Table S6). This result is not in line with the results of Teklu et al. (2015) in which all the examined a.i.s indicated no or negligible risks although this work examined only few a.i.s for a similar protection goal, not including the ones listed here.

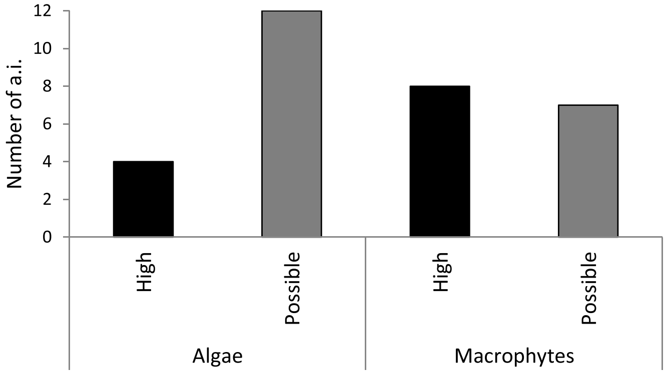


Fig. 3. Number of a.i. with high and possible risks for algae and macrophytes. As a total of 96 a.i.s were evaluated for algae the numbers can almost be interpreted as %. Only 36 a.i.s were evaluated for their risks to macrophytes.

Of the total 73 a.i.s, for which sufficient data were accessed to perform a soil risk assessment, 4 a.i.s pose high acute and 5 a.i.s pose high chronic risk to the soil organisms. The insecticides bifenthrin, carbaryl and pirimiphos-methyl were predicted to pose a high acute while the insecticides bifenthrin, deltamethrin, imidacloprid and pirimiphos-methyl and the fungicide carbendazim are associated to high chronic risks (Fig. 4; Table S7). Risks of pesticides to the soil ecosystem are usually determined by its effect on organisms like earthworms (Wipfler et al., 2014). Miglani and Bisht (2019) reviewed the literature on the effects of pesticides on earthworms and concluded that the population of earthworm and other non-target soil biota are influenced by pesticides, especially insecticides, and the impact is wide-ranging and may be causing an unwanted shift in the community. Jepson et al. (2014) identified the insecticides methamidophos, dimethoate, acetamiprid, diclofol, carbofuran, endosulfan and imidacloprid and the fungicide thiophanate-methyl to pose high risks to earthworms. This indicated that insecticides generally show high risks to earthworms, and they are not restricted to a specific group.

Of the examined 103 a.i.s, 24 a.i.s indicted a high level of risk to bees when bee hives are present within the crop field (in-crop) while 8 may pose a high risk only at off-crop situation (Fig. 4; Table S8). The 24 a.i.s identified with high in-crop risks include a variety of different insecticides and one herbicide, indoxacarb. The insecticides alpha-cypermethrin, bifenthrin, cyfluthrin, deltamethrin, imidacloprid, methidathion, spinetoram and thiamethoxam also show high level of risk for the off-crop situation. Field studies in Ethiopia have also indicated that pesticide risk to bees is expected to be high due to the improper use of the chemicals in agricultural field (Tesfaye et al., 2021; Fikadu, 2020). The insecticides negatively impact the overall pollination services provided by these pollinators by affecting the bees' survival, behaviour and communication. Risks to bees could be reduced by adding the requirement to the registration procedures that candidate pesticide products may be applied only when bees are not actively foraging or pollinating.

Birds are also under high acute and chronic risks by 9 and 4 of the 103 a.i.s examined in this study, respectively. The insecticides carbosulfan, chlorfenapyr, chlorpyrifos, diazinon, dimethoate, fenitrothion, imidacloprid, methidathion and profenofos pose high acute risks to birds as identified in this study, while the insecticides carbosulfan and chlorpyrifos and the fungicides epoxiconazole and mancozeb pose chronic ones in at least one of the scenarios. The effect of pesticides on birds has been indicated in various studies, some describing it as threatening 87 percent of the bird species globally (Arya et al., 2019). This is mainly caused by an agricultural application of pesticides with impact observed as a decline in avian populations sometimes causing the local extinction, behavioural changes, loss of safe habitat and population decline in several birds (Anindita et al., 2011).

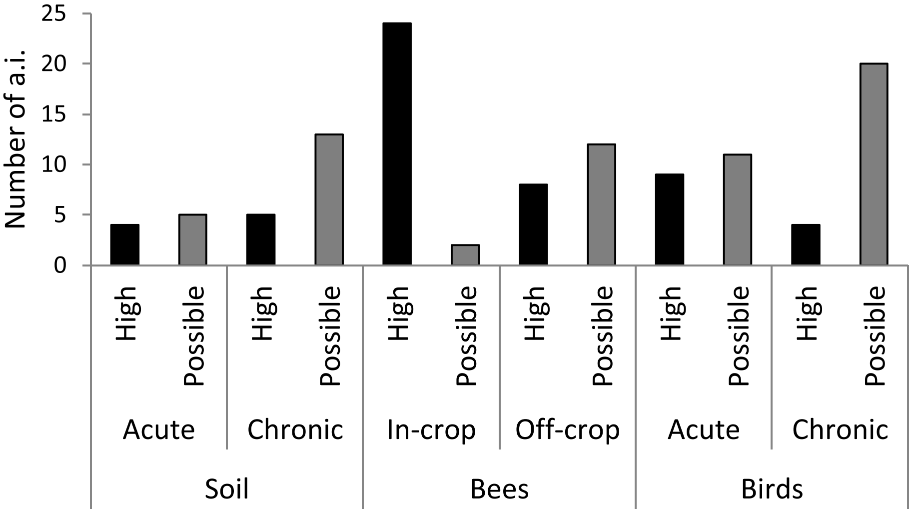


Fig. 4. Number of a.i. with high and possible acute and chronic risks for the soil ecosystem and birds and acute in- or off-crop risks to bees. As a total of 73, 103 and 103 a.i.s were evaluated for soil ecosystem, bees and birds, respectively, so for the latter two the numbers can almost be interpreted as %.

3.3. Decision making and policy implications

Many studies performed in Africa only focus on analysing residue levels of a.i.s in water and other different environmental compartments (Merga et al., 2021; Loha et al., 2020). Most monitoring studies evaluate only a few pesticides and quantify risks only to a specific protection goal and endpoint (Teklu et al., 2015, 2016b; Onwona Kwakye et al., 2019; Malherbe et al., 2013), as this already requires expensive resources like sophisticated analytical instruments. In many African countries including Ethiopia registration of pesticides is not supported by a proper risk assessment procedure, usually information given by the registrant are basic physico-chemical properties of the a.i., some toxicological data and information related to manufacturing factory (Mengistie et al., 2016). This information is not enough to assess the exact risks associated with the use of these a.i.s to non-target organisms (Teklu et al. 2016a, 2016b, 2016c; Onwona Kwakye et al., 2019) and to help the registration procedure in filtering out Highly Hazardous Pesticides (HHPs) from the African agricultural system (Fuhrimann et al., 2022). To fill in this gap, paucity of studies used simple models like the PRIMET model to quantify risks to various endpoints.

Pesticide registration procedures in developing countries miss scientific elements to evaluate the impact of pesticides on environment and human health (Wesseling et al., 2005). Most regulatory bodies are lacking the desired skilled manpower to evaluate risks (Mengistie et al., 2016; Ecobichon, 2001). Even though the development and introduction of decision support tools for managing pesticide risks to terrestrial and aquatic ecosystems and human health in Africa is at its infant stage, such simple modelling approaches were found to be reliable and should be encouraged to be used more widely. Results of this study indicated that evaluating dossier data using the PRIMET_Registraton_Ethiopia 1.1 model is applicable and helps the decision-making process of the pesticide registration in Ethiopia. These novel modelling tools are thus useful to identify hotspot areas across the country, prioritize pesticides based on their risk to non-target organisms including human and the terrestrial and aquatic ecosystem, identify important transport routes and inform which pesticides should be included in the monitoring programs (Adriaanse et al., 2015; Van den Brink, 2013). A successful implementation of these tools in developing countries is, however, much dependent on the training of people to use these models and the acceptance of their outcomes by regulatory bodies and industry.

Risk assessment is an important step for making informed decisions on pesticide registration in developed countries like those belonging to the EU. The use of toxicity data collected in the temperate zone to represent species sensitivity in tropical area is among the concerns raised, but confirmed to be suitable for most chemicals by a few comparative studies (Teklu et al., 2016c; Rico et al., 2010; Kwok et al., 2007). A recent study by Merga and van den Brink (2021), however, indicated elevated sensitivity of tropical species to imidacloprid relative to counterparts in the temperate areas. Comparison of modelled PEC with actual measurement values of pesticides provide promising results for Ethiopia, although further large scale studies are needed for a full validation (Teklu et al., 2016a, 2016b).

Tools, like the PRIMET_Registraton_Ethiopia 1.1 model, can be used to indicate the risk profile of the intended uses of an a.i. to be registered by performing risk assessment for all the endpoints considered to be protected. Thus, the registration process and the environmental monitoring programs in developing countries can be pushed one-step forward (Teklu et al., 2015, 2016a, 2016b) as it is clearly stated in the Pesticide Registration and Control Proclamation 674/2010 of Ethiopia Article 5: 1 (c) and (d) that no pesticide shall be registered if it is believed to be posing serious risk to human, animals and non-target species.

4. Conclusions and recommendations

Results of the present study indicated that of all the investigated 103 registered a.i.s in Ethiopia, only 28 are indicated to pose no risks in terms of the proposed protection goals including the risks to humans, aquatic and soil ecosystems, bees and birds. Thus, it is important to evaluate the actual impacts of the rest of the pesticides using higher tier methods so that a clear picture of the risks associated with a particular non-target organism can be obtained. Furthermore, re-evaluating the registration procedure using this model is advocated and also bring into focus the identification of Highly Hazardous Pesticides in Ethiopia. This will make farmers aware of the risks associated with these pesticides and facilitate possible mitigation actions including banning of the products from the market. Such measures are needed as reports and papers which indicate high risks to non-target species, including humans, through pesticide use in Africa pile up, while ample action seems to be taken to ban chemicals which are banned or restricted in use in developed countries.

Credit

Berhan M. Teklu: Conceptualization, Investigation, Project administration, Writing original draft, Formal analysis. **Sevil Deniz Yakan**: Conceptualization, Writing-review and editing, Methodology, Project

administration. **Paul J. Van den Brink**: Conceptualization, Supervision, Writing-review and editing, Formal analysis.

Ethics committee approval

The authors declare that this study does not need any ethics committee approval.

Supplementary information can be found in the tables in the accompanying Excel file.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data available as supplementary material

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.chemosphere.2023.137794.

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