



Decision-Making Guidance for Pesticide Registration

Pesticide Risk Reduction Programme - Ethiopia

Harold van der Valk, Peter van Vliet and Floor Peeters

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This document focuses on the considerations relevant for procedures established for the registration of pesticides in Ethiopia. The assessment of risks, values and alternatives are considered, as well as the subsequent risk management decisions that the Ethiopian Ministry of Agriculture may take.

Keywords: Ethiopia, pesticides, registration

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Preface

This guidance document was originally prepared by Peter van Vliet (Board of the Registration of Plant Protection Products and Biocides of the Netherlands) and Harold van der Valk (Consultant, Alterra, The Netherlands).

The first draft was discussed during a workshop in Addis Ababa in April 2014, which included staff from the *Plant Health Regulatory Directorate* of the Ministry of Agriculture of Ethiopia, members of the Pesticide Advisory Board of Ethiopia and selected researchers. Additional comments were received from Paulien Adriaanse, Theo Brock and Floor Peeters of Alterra.

The present version of the guidance document was discussed at a workshop at Alterra, The Netherlands, in September 2014.

1 Introduction

When making a decision on whether a pesticide should be registered in Ethiopia, the *Plant Health Regulatory Directorate* of the Ministry of Agriculture (MoA/PHRD) will take into account various aspects, some of them potentially contradictory. These include the economic and agronomic benefits of introducing the pesticide, its risks to human health and the environment, and the long-term sustainability of using the pesticide. The PHRD will have to carefully consider the legal, economic, social and political acceptability of each these aspects.

The overall decision-making framework for pesticide registration by the *Plant Health Regulatory Directorate* is shown in a schematic way in Figure 1.

The main **scope** of pesticide registration is for MoA/PHRD to assess whether the product is effective for its intended purposes and does not pose an unacceptable risk to human health, animal health or the environment, under the conditions of use in Ethiopia (FAO, 2013).

What level of efficacy is required, and what are unacceptable risks, is determined by national legislation. The *Proclamation 674/2010 to provide for the registration and control of pesticides* stipulates in its Article 5 that the Ministry shall authorize the registration of a pesticide if:

- it is (b) 'effective for the purpose for which it is intended'
- it (c) 'does not cause human and animal health hazards when handled and applied in accordance with the instructions'
- (d) 'the effect of the pesticide on the environment and non-target species is insignificant in comparison with its benefits and the effects of other substitutable alternatives'
- (e) 'the residue is not toxic or persistent when metabolized'
- (f) 'other products which may be equally or more effective but less hazardous are not available'
- (i) 'the benefits outweigh the risks of use under local socio-economic conditions'

These provisions form the basic legal framework for decision-making on the acceptability of the use of a pesticide in Ethiopia. They have been further detailed in the Draft – *Pesticide Registration and Control Regulation* (Version July 2013), which defines evaluation criteria for decision-making on pesticide registration in its Schedule II. These evaluation criteria are discussed in more detail below.

The **context** of the assessment of the pesticide is framed by the different types of registration applications that may be submitted to MoA/PHRD. A request for a new registration of a product may require a different assessment from a re-registration of the use of an already registered product to a new crop, or from a minor amendment in the formulation.

The **assessment** of the pesticide comprises the evaluation of its **risks** to human health and the environment, its **value**, as well as possible **alternatives**. Both risks and value should be acceptable before a pesticide will be accepted for registration. Therefore, in principle, a pesticide which is not efficacious, does not bring (potential) economic benefits to the user, or cannot be used in a sustainable manner, will not be registered, irrespective of whether its risks are acceptable or not. Similarly, if risks to human health or the environment are considered unacceptable, a pesticide will not be registered, even if it may have high value. Risks and values are also assessed against existing or possible alternatives, with the aim of deciding the need for registration of the pesticide.

The outcome of the **risk management** step is a **registration decision** for the pesticide with possible associated **risk mitigation** measures. This may be a positive decision to register the product for a specific use, with or without risk mitigation measures. It can also be a (severely) restricted registration, or a refusal to register the product.

Finally, **monitoring and evaluation** of the use of the product, either through inspections, surveys or user feedback, will allow the Ministry to re-assess the risks and values of the product after registration.

The focus of this guidance document is on the assessment of risks, values and alternatives of a pesticide submitted for registration, as well as the subsequent risk management decisions that the Ministry may be taking.



Figure 1 Overall decision-making framework for pesticide registration by MoA/PHRD.

2 Protection goals

The *Pesticide Registration and Control Proclamation* provides general criteria that should be met to protect human health and the environment. However, these criteria are not specific enough for risk assessment. Therefore, the (draft) *Pesticide Registration and Control Regulation* defines more concrete decision-making criteria. The *Handbook of a scientific evaluation system for the registration of (chemical) pesticides in Ethiopia* (PHRD/Alterra, 2014) operationalizes the criteria into specific protection goals, which describe:

- i. **what to protect** (e.g. which species; what type of person; which component of the environment)
- ii. **where to protect** this (e.g. in larger lakes and streams; pesticide applicators in all situations where pesticides are sprayed), and
- iii. **how strictly to protect** this (e.g. no chronic health effects in pesticide applicators are acceptable; no long-term adverse effects on honeybee colonies are acceptable)

Detailed protection goals have been defined in Ethiopia for the following aspects:

- a. Pesticide operators (e.g. spray applicators, mixers and loaders of pesticides)
- b. Workers in fields/locations that have been sprayed with pesticides
- c. Consumers of pesticide-treated commodities
- d. Consumers of drinking water derived from surface water or groundwater
- e. Aquatic ecosystems
- f. Birds
- g. Bees
- h. Non-target arthropods
- i. Earthworms
- j. Soil micro-organisms
- k. Non-target terrestrial plants

The detailed protection goals are summarized in Annex 1 and described in more detail in the PHRD/Alterra Evaluation Handbook.

For each of the aspects, a risk quotient is calculated. A risk quotient is the ratio between the predicted exposure of the organism (or other assessment endpoint) to the pesticide on the one hand, and the predicted toxicological no-effect level on the other. If the predicted exposure level is less than the predicted no-effect level, the risk can be considered acceptable from a scientific point of view. The higher the level of exceedance of the risk quotient, the higher the risk of adverse effects.

Exposure is estimated for realistic worst-case situations, i.e. situations that are more vulnerable than the 'average' situation. This is in accordance with the Regulation. In addition, exposure is estimated for Good Agricultural Practice, i.e. use of the pesticide according to the recommended dose, intervals and other use guidance, as approved by the Ministry as part of the registration.

It is important to underline that the risk assessments conducted during pesticide registration evaluate whether the protection goals defined by PHRD are likely to be adversely affected by the pesticide or not. The number of protection goals identified in Ethiopia, and evaluated during pesticides registration, is considerable. However, organisms, human activities or components of the environment that have not been listed as a protection goal, are not explicitly evaluated. For instance, at present the risks of pesticide applications to bystanders or residents are not evaluated. Similarly, the effects of the pesticide on reptiles are not assessed either.

3 Risk assessment

MoA/PHRD employs a risk-based approach for the assessment of the potential environmental and health impacts of pesticides in Ethiopia. The risk assessment (RA) procedures have been described in detail in the *Handbook of a scientific evaluation system for the registration of (chemical) pesticides in Ethiopia* (PHRD/Alterra, 2014).

Risk assessment is generally conducted by employing a tiered approach, with the lower tier being the most conservative (worst-case) evaluation of the exposure to and toxicity of the pesticide. If the risk of the pesticide in the lower tier is low, there is no impediment to registration. If a risk is identified, the assessment moves to a higher tier, which represents a more realistic evaluation of the exposure to and toxicity of the pesticide, generally using more comprehensive and realistic data. This tiered approach is applied by PHRD for the human health risk assessments. Refining the human health risk assessment in a higher tier is primarily done by refining the exposure estimate (e.g. using more precise exposure models or measured pesticide residue or exposure data).

For environmental risk assessment, only first tier evaluations have been developed so far. An alternative approach is therefore chosen if the outcome of the tier-1 assessment indicates a high risk. In such cases, registrations by reputable foreign authorities are reviewed to assess whether, for similar uses, the environmental risk in Ethiopia may be considered acceptable, taking into account realistic and effective risk mitigation measures for the Ethiopian situation. This is generally a qualitative review.

In any tier of the risk assessment, the effect of risk mitigation measures can be evaluated. If the risk is low when implementing risk mitigation, there would be no impediment to registration of the pesticide. However, registration should then only be granted under the condition that risk mitigation measures can realistically be implemented.

If, on the other hand, after refinement of the assessment or review of foreign registrations, the risk is still considered to be high, or if refinement of the risk assessment was not possible, various options are open with respect to risk management of the particular pesticide:

- Deny registration of the high risk use(s) of the pesticide; but allow use(s) with acceptable risks;
- Deny registration of all uses of the pesticide (e.g. if the risks of using the product are high, and the probability of it being used on other crops or in other use situations, is high);
- Authorize the pesticide, with or without risk mitigation measures, but accept a certain level of risk (e.g. for pesticides which have a great agronomic importance and for which no alternative products or pest management options are available). This is a political decision, and goes beyond scientific assessment of risks.

The relationship between risk assessment and decision-making is further described in Chapter 7.

4 Value assessment

The value assessment of the pesticide submitted for registration consists, in principle, of three aspects:

- i. Evaluation of biological efficacy of the pesticide
- ii. Evaluation of sustainability of the use of the pesticide
- iii. Evaluation of the economic costs and benefits of using the pesticide

4.1 Efficacy

The *Pesticide Registration and Control Regulation* states in its Schedule 2 that a pesticide shall only be registered if the proposed use:

- a. produces a clear and meaningful benefit to the user when compared to an untreated control, a reference product and other available pest management approaches, as appropriate;
- b. does not result in unacceptable phytotoxic effects on the crop, or unacceptable effects on the quality or yield of the crop or its produce, unless the risk of such effects can be minimized using locally realistic risk-mitigation measures;
- c. is accompanied by a realistic resistance management scheme, unless it can be shown that the risk and speed of resistance development of the pest to the pesticide is negligible;
- d. does not result in unacceptable adverse effects on succeeding or adjacent crops, unless the risk of such effects can be minimized using locally realistic risk-mitigation measures.

Acceptable efficacy is a pre-supposition for registration of the pesticide in Ethiopia: a pesticide that does not result in an effective level of control or reduction of the pest will not be a candidate for registration, even if it does not pose risks to human health or the environment.

As outlined in the *Directive on Efficacy Testing of Pesticides*, effectiveness of the pesticide may be defined either as 'control' or 'reduction' of the pest. Where other pest management methods are applied simultaneously with the pesticide, such as in IPM, reduction or suppression of the development of a target pest/disease/weed may be an acceptable level of effectiveness. In such cases, 'control' of the pest should not be claimed by the applicant. Alternatively, whenever 'control' is claimed, the applicant should show that the treatment with the pesticide product either kills the target pest/disease/weed, or keeps it below the damage threshold level.

In principle, the pesticide tested in the efficacy trials should demonstrate effectiveness, at least equal to that of a reference product. However, it may be justified to accept a lower level of control (or reduction) if the pesticide, when compared to the reference product:

- results in less, or no, adverse effects;
- has a broader spectrum of activity;
- allows for a broader period of application;
- reduces the risk of resistance development;
- can be better used in IPM.

The final outcome of the efficacy assessment is a definition of the minimum effective dose, the minimum frequency of application, and the recommended timing of the treatment(s), that result in the required effectiveness. This information is summarized in the *Good Agricultural Practice* (GAP) table. The GAP recommendations should result in acceptable effectiveness of the product, but also minimize phytotoxicity or adverse effects on rotational and adjacent crops.

The GAP table is the basis for the directions for use stated on the label of the pesticide. It is also the starting point for the human health and environmental risk assessments.

If the minimum effective dose and application frequency for a given crop/pest combination have been established as per GAP, there will be limited or no possibility to reduce risks through modification of the GAP. However, in many cases the efficacy testing conducted in Ethiopia is only intended to confirm the dose rate recommended by the applicant. In such cases, there may be an opportunity to reduce unacceptable risks by decreasing the dose rate or application frequency, or by increasing the spray interval.

4.2 Sustainability

In principle, the registration of the pesticide should strengthen the sustainability of Ethiopian agricultural systems, that is the long-term productivity and diversity of agricultural production in the country. At least, the pesticide to be registered should not compromise agronomic sustainability. Pesticides may compromise agronomic sustainability in various ways, including:

- development of pest resistance, resulting in a reduction of pesticide efficacy, and an increase in pesticide use;
- adverse effects on pollinators, leading to a decrease in production quantity and/or quality;
- adverse effects on natural enemies, leading to the development of secondary pests or resurgence of existing pests;
- adverse effects on succeeding (rotational) crop, or on adjacent crops;
- adverse effects on soil organisms, which may affect nutrient cycling and soil fertility.

The risk that the pesticide may adversely affect pollinators, natural enemies of crop pests and soil organisms, is assessed as part of the environmental evaluation. Possible adverse effects on rotational and adjacent crops are typically assessed as part of the efficacy evaluation. However, if any such risks are identified, the PHRD will also need to appraise what the possible long-term impact may be on agricultural sustainability, and whether such effects are acceptable. This will often be a qualitative assessment, based on case studies from other countries or possibly from Ethiopia itself. If adverse effects on groups of organisms are observed, but the long-term impact on sustainability is likely to be limited, then the pesticide may still be registered (with appropriate risk mitigation measures).

The risk of development of pest resistance against the pesticide will also need to be evaluated. In order to assess the risk of practical resistance in the target pest(s), different factors are evaluated, i.e. the characteristics of the compound and the pest (the inherent risk) and those that might result from the intended use pattern (the agronomic risk). If the risk of resistance development is low when the pesticide is applied without any restriction, the registration may proceed. However, if this risk is unacceptable, risk mitigation measures need to be identified and a resistance management plan or strategy developed.

Many potential adverse effects on sustainability can be managed through risk mitigation measures. In exceptional cases, registration of the pesticide may be denied; e.g. when widespread resistance has already developed in Ethiopia against pesticides with the same mode of action; or if case studies from other countries, for the same pesticide and its use, clearly indicate widespread effects on pollination, or secondary pests appear after the use of the pesticide.

On the other hand, if a pesticide contributes to, or strengthens agronomic sustainability, the decision to register can be favoured. This may be the case, for instance, if the pesticide can be integrated easily into biological control programmes or IPM, or when the pesticide represents a new mode of action and can become part of a strategy to manage existing resistance problems.

4.3 Costs and benefits

The *Pesticide Registration and Control Proclamation* stipulates, in Article 5, that a pesticide may be registered if it is ascertained that 'the effect of the pesticide on the environment and non-target species is insignificant in comparison with its benefits and the effects of other substitutable alternatives', and that 'the benefits outweigh the risks of use under local socio-economic conditions'. This provision in the Proclamation provides the justification for a costs-risks-benefits analysis as part of the registration procedure.

In most cases, proof of efficacy establishes the nature of the expected benefits. A more in-depth cost-benefit evaluation is generally more difficult to conduct. Expected benefits of the use of the pesticide will depend on crop yield, its quality and sales value, with the latter in turn depending on the volume of supply of the commodity in the country. A complicating factor is that effects of the pesticide on yield are often only available in comparison with no pest management practices at all (i.e. the untreated control plots in the efficacy trials), but not in comparison to normal farmer pest management practices, a situation which may inflate the beneficial effect of the pesticide.

Costs estimates will include direct and indirect costs to the farmer of using of the pesticide, but also externalities outside the farm, such as environmental effects or adverse effects on other economic activities such as fisheries or honey production.

Due to its complexity, an in-depth cost-benefit evaluation is presently not conducted in Ethiopia as standard practice for registration.

In some cases, however, a cost-benefit evaluation for introducing a new pesticide into the country may be warranted. For instance, in those cases where relatively expensive risk mitigation measures are required, an evaluation of costs and benefits might be needed. This may be the case if the pesticide is intended for the protection of high-value crops, or for migratory pest control, where applying more expensive risk mitigation measures is feasible. Also, cost-benefit evaluations may be called for when it is established that the pesticide is clearly needed by smallholder farmers, who have very limited means to purchase pesticides and are not in a position to assess its benefits in a proper manner.

5 Alternatives assessment

The *Pesticide Registration and Control Proclamation*, in Article 5, stipulates that a pesticide may be registered if it is ascertained that 'the effect of the pesticide on the environment and non-target species is insignificant in comparison with its benefits and the effects of other substitutable alternatives', and that 'other products which may be equally or more effective but less hazardous are not available'.

Furthermore, the *Pesticide Registration and Control Regulation*, in Schedule 2, states that the Ministry may, 'in determining whether the health and environmental risks and the benefits of a pesticide are acceptable, take into account information regarding the risks and benefits of other pesticides that are registered for the same use'.

These provisions in the Proclamation and the Regulation provide the legal basis for an alternative assessment as part of the registration procedure. Alternatives can be other registered chemical or biological pesticides, or they may be other pest control measures (e.g. biological control, agronomic interventions).

When a **pesticide that is to be newly registered, is compared with another chemical or biological pesticide**, the following principles apply to decide whether sufficient pesticides are already available that are equally or more effective, but less hazardous:

- The already available pesticide(s) should be registered in Ethiopia for the same or similar use(s).
- The already available pesticide(s) should be equally or more efficacious against the target pest(s).
- The already available pesticide(s) should pose less risk or require less risk mitigation.
- A minimum number of pesticides with different modes of action that can be used against the same pest should be registered, to ensure that pesticide resistance can be properly managed, if applicable.

The third principle, above, implies that a (similar) risk assessment has been conducted both of the newly to be registered pesticide and of the already available pesticide(s). Since formal risk assessments have only recently been introduced in the Ethiopian pesticide registration procedure, the risks of most presently registered pesticides have not been evaluated yet in much detail. This will be done when the registrations of these pesticides are renewed. Therefore, the alternatives assessment for pesticides, as described above, will be introduced progressively in Ethiopia, when existing registrations are re-evaluated.

When a **pesticide that is to be newly registered, is compared with an alternative pest control measure**, such as biological control or agronomic measures, the following principles apply to decide whether sufficient alternatives are available that are equally or more effective, but less hazardous:

- The already available alternative pest management method(s) should have been tested and/or successfully used for the same or similar use(s) in Ethiopia.
- The already available alternative pest management method(s) should be equally or more efficacious against the target pest(s), alone or as part of IPM.
- The already available alternative pest management method(s) should pose less risk or require less risk mitigation.
- The already available alternative pest management method(s) should be practicable for farmers under local conditions.

No risk assessment methods have yet been adopted in Ethiopia to compare chemical/biological pesticides with non-pesticide pest management methods. Therefore, for the third requirement, a qualitative but well-founded risk assessment of the alternative may be conducted.

Alternatives assessments, such as indicated by the Proclamation and Regulation are not easy to conduct, because few if any formal assessment procedures have been elaborated, even in registration systems with more resources. Therefore, in Ethiopia, alternatives assessments will be conducted primarily for pesticides posing a high risk to the environment (see Chapter 7.3).

6 Risk mitigation

Many measures can be proposed to reduce the risk of a pesticide. However, not all of these may be realistic under the specific use conditions for which the product is to be registered. For risk mitigation measures to be effective, they should preferably meet several criteria:

- The measure should have been demonstrated, or is likely, to be effective under Ethiopian (or comparable) conditions.
- The measure should be practicable for the pesticide user (e.g. the farmer), and should preferably not compromise pesticide product efficacy.
- The expected reduction of risk should outweigh the cost of the measure.
- It should be possible to communicate the measure to the user in a relatively easy and effective manner (e.g. via the product label; through agricultural extension services).
- The measure should have a reasonable possibility of enforcement.
- It should be possible to make a quantitative estimate of the efficacy of the measure so that its effect can be incorporated into the risk assessment.

While some risk mitigation measures may be theoretically plausible, they may not be very effective if they do not meet some of the above criteria. For example:

- It is not feasible to require a reduced dose rate if the efficacy dossier has shown that the recommended dose is the minimum effective dose and cannot be reduced anymore.
- It is not practicable to prescribe untreated buffer zones between the sprayed field and water bodies, if the pesticide will be used in small fields depending on ditch irrigation;
- It may not be feasible to prohibit spraying during flowering of the crop, to protect bees, if the target pest attacks the flowers.

So the feasibility of any risk mitigation measure needs to be carefully assessed by the PHRD before it can be required or recommended as part of the registration of the pesticide.

Furthermore, the level of resources, training and information that a pesticide user (e.g. farmer) has, will influence whether a risk mitigation measure can be applied effectively or not. For example:

- Many small-scale farmers may not be literate, and warnings or precautionary statements on the pesticide label may therefore not be effective. However, these may be effective when the pesticide is used by large-scale farmers who employ specialized staff.
- Certain risk reduction measures will require financial investments (e.g. drift-reducing nozzles, specialized personal protective equipment) which may not be affordable for smallholder farmers, but are feasible for larger commercial farmers

Therefore, whenever a risk mitigation measure is being proposed to ensure that the risk of the pesticide is acceptable, it should be assessed whether this measure can be realistically implemented under the proposed conditions of use in Ethiopia.

A list of risk mitigation measures is provided in Annex 2, with indications of their feasibility under Ethiopian conditions. Examples of precautionary phrases for pesticide labelling are shown in Annex 3.

7 Decision making

7.1 Overall framework

The overall decision-making framework for pesticide registration used by PHRD was given in Figure 1. In principle, all elements of the framework need to be considered when evaluating an application for registration of a pesticide. However, as indicated in chapters 3, 4 and 5, key aspects of decision-making are the efficacy evaluation and the assessment of the risks to human health and the environment, and – to a lesser extent – the evaluation of risks to agronomic sustainability and the availability of appropriate alternatives. Cost-benefit analyses can only be conducted in exceptional cases.

There is no definitive order in which the various aspects of decision-making should be assessed. An indicative flow chart is provided in Figure 2, which provides a logical order of the decision-making steps for pesticide registration that can be used in most cases. Nonetheless, in some cases steps may need to be inverted; in other cases, steps can be omitted or may be assessed several times in an iterative manner. The flow chart in Figure 2 should therefore not be used in an absolute manner; it will, however, apply to many situations.

A presupposition to a positive decision for the registration of a pesticide is that it is efficacious for the intended use (e.g. crop-pest combination), and that a *Good Agricultural Practice* has been established.

The overall principle for decision-making is that no impediment for registration of a pesticide exists if:

- i. the pesticide is efficacious; and
- ii. the pesticide does not pose an unacceptable risk to human health and the environment; and
- iii. the pesticide does not compromise agronomic sustainability.

The overall principle is that registration is denied if:

- i. the pesticide is not efficacious; or
- ii. the pesticide does pose an unacceptable risk to human health and the environment; or
- iii. the pesticide compromises agronomic sustainability; and
- iv. alternatives (pesticide or non-pesticide) are available.

In some situations, where the risks are in principle unacceptable, a pesticide may still need to be registered. This can be the case if no appropriate alternatives are available. In such a case, the pesticide might be registered with the explicit acceptance of the expected risk by the Ministry. As a rule, such a registration should only be issued for specific uses and be temporary to allow further data collection and risk assessment under actual conditions of use in Ethiopia. Monitoring of the use of the pesticide, and possible associated adverse effects, will often be mandatory.

The evaluation of whether the risks of the pesticide to human health and to the environment are acceptable, the second step in the flow chart, may be rather complicated. Decision-making steps for human health and environmental risk assessment are therefore discussed in more detail in the sections below. The outcome of these risk assessments is then introduced again in Figure 2.

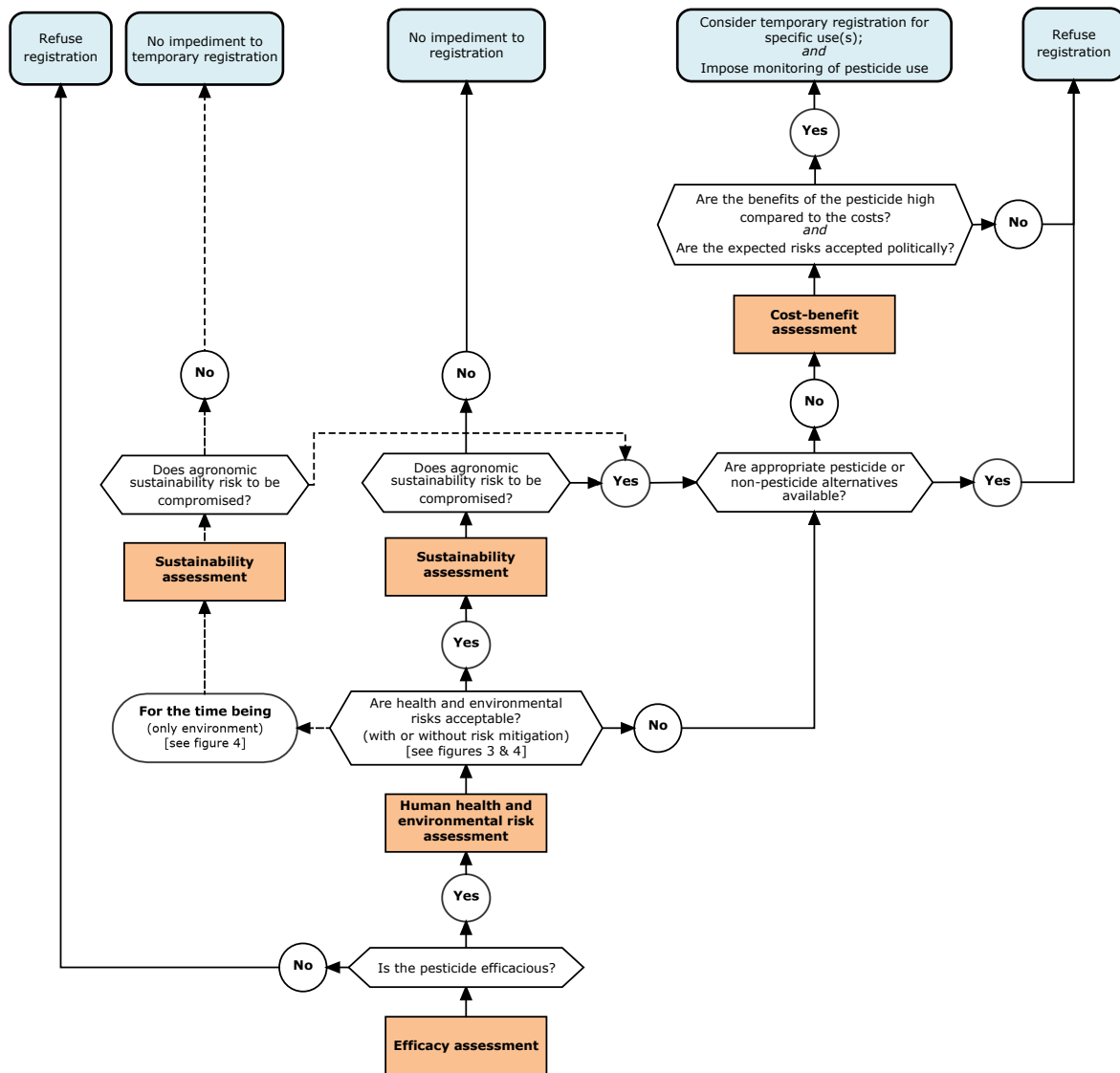


Figure 2 Indicative flow chart of the main decision-making steps for pesticide registration in Ethiopia. Note that the scheme should not be used in an absolute manner, but may need to be adapted to the specific pesticide registration case under evaluation.

7.2 Human health risks

Five human health assessments are being carried out:

- i. A general hazard assessment, identifying highly hazardous pesticides.
- ii. An operator risk assessment, with or without risk mitigation measures.
- iii. A worker risk assessment, with or without risk mitigation measures.
- iv. A consumer risk assessment, with or without locally relevant residue data.
- v. A drinking water risk assessment, both using groundwater and surface water as drinking water source.

The outcome of these assessments is either that the risk is unlikely (i.e. no adverse human health effects are expected; this is represented by a 'green traffic light' in PRIMET) or that risk is present (i.e. adverse human health effects cannot be excluded; represented by a 'red traffic light' in PRIMET). No

'orange', intermediate, risks are being calculated for human health¹. This is because higher tier assessments can be conducted if the outcome of the tier-1 assessment indicates that a risk is present.

Whenever the outcome is 'green' for all aspects of the human health evaluation, there is **no impediment to registration of the pesticide**.

If the outcome is 'red' for one or more human health aspects, a **higher tier risk assessment** will be carried out, taking into account exposure refinements or locally realistic risk mitigation measures. If the higher tier risk assessment still indicates that a risk is present for human health, the pesticide will, in principle, not be registered for the use under evaluation.

Figure 3 shows the decision-making steps for the human health hazard and risk assessments. The decisions resulting from each of the assessments are summarized in Table 1. The outcome of the human health risk assessment is fed back into the overall decision-making scheme in Figure 2.

¹ Intermediate risks are taken into account for the environmental risk assessments (see section 7.3).

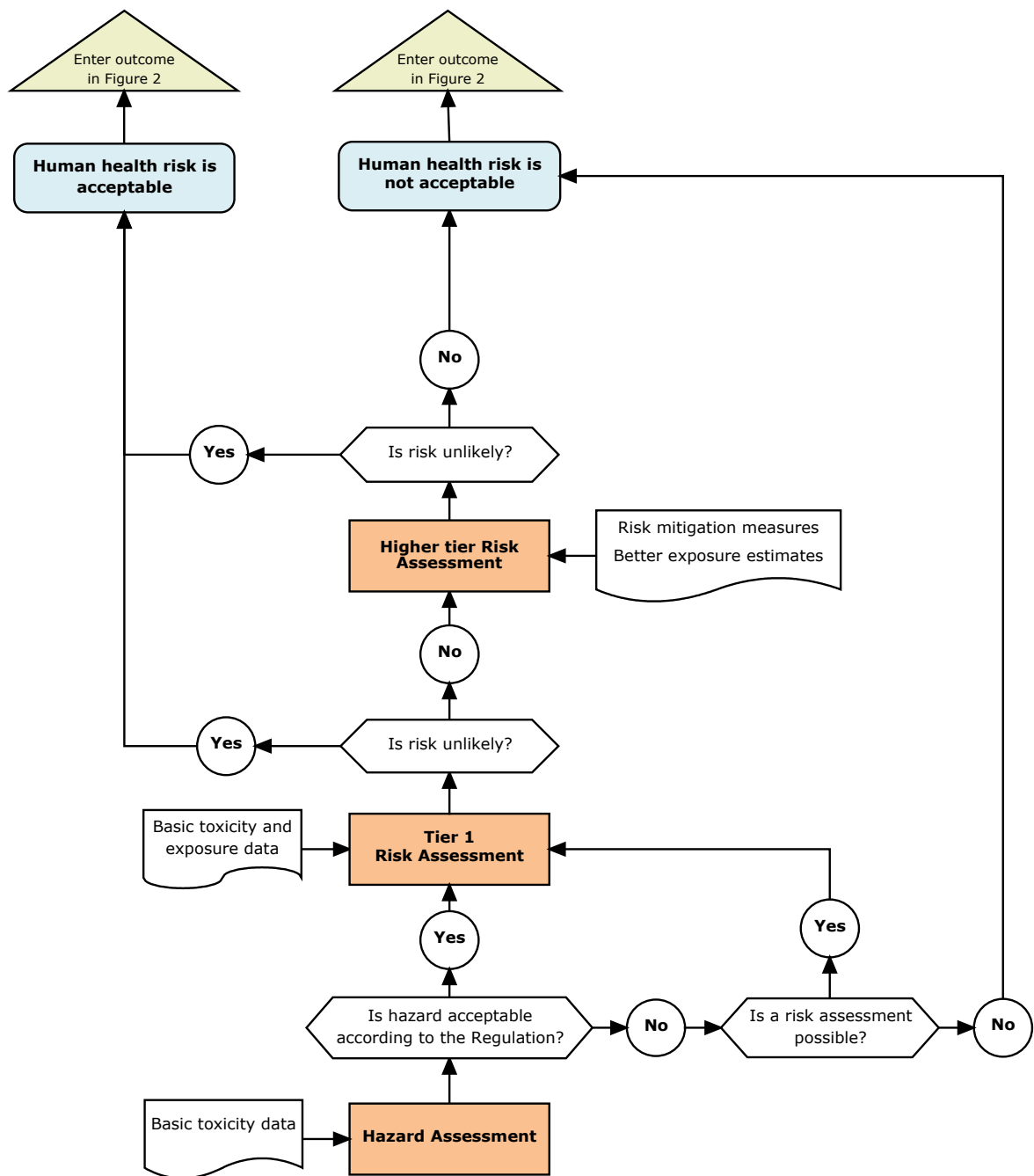


Figure 3 Outline for decision-making in the human health risk assessment. The scheme is followed separately for each of the human health aspects.

Table 1

Summary of decision-making recommendations based on the human health hazard and risk assessments.

Aspect	Outcome of the assessment	Recommended registration decision
General hazard	Not one of these hazards	No impediment to registration
WHO class Ia or Ib; or GHS carcinogenicity 1A or 1B; or GHS mutagenicity 1A or 1B; or GHS reproduction toxicity 1A or 1B	One or more of these hazards	Refuse registration, unless: Operator, worker and consumer risks (see below) are unlikely, with or without realistic risk mitigation measures
Operator and worker risk	Tier 1 – no PPE	
	Risk unlikely	No impediment to registration
	Risk present	Conduct Tier 2 assessment
	Tier 2 – Including PPE	
	Risk unlikely	No impediment to registration
	Risk present	Refuse registration, unless relevant exposure studies show that exposure is below the Acceptable Operator Exposure Level
Consumer risk – agricultural commodities	Tier 1 – Codex MRL	
	Risk unlikely (both acute and chronic)	No impediment to registration
	Risk present (either acute or chronic)	Conduct Tier 2 assessment
	Tier 2 – Locally relevant residue data (STMR, HR)	
	Risk unlikely (both acute and chronic)	No impediment to registration
	Risk present (either acute or chronic)	Refuse registration
Consumer risk – drinking water	Acute risk from surface- or groundwater	
	Risk unlikely (all scenarios)	No impediment to registration
Surface water (3 scenarios) Ground water (3 scenarios)	Risk present (one or more relevant scenarios)	Refuse registration, unless realistic risk mitigation measures reduce the risk to an acceptable level
	Chronic risk from surface- or groundwater	
	Risk unlikely (all scenarios)	No impediment to registration
	Risk present (one or more relevant scenarios)	Refuse registration, unless realistic risk mitigation measures reduce the risk to an acceptable level

7.3 Environmental risks

7.3.1 Introduction

Several environmental risk assessments may be carried out, depending on whether that aspect of the environment is likely to be exposed to the pesticide:

- i. Aquatic ecosystem (3 scenarios)
- ii. Birds
- iii. Earthworms
- iv. Bees
- v. Non-target arthropods (other than bees)
- vi. Non-target terrestrial plants
- vii. Soil micro-organisms

Presently, only tier-1 (conservative) environmental risk assessments have been developed for Ethiopia, and no higher tier assessments are yet available. The environmental risk assessment follows the following principles:

A risk assessment will be performed for those environmental aspects that are exposed to the formulated product. The risk characterization will be expressed as an Exposure-Toxicity-Ratio (ETR), which is defined as the Predicted Exposure Concentration (PEC) divided by the Predicted No Effect Concentration (PNEC). The PNEC is equal to the toxicity value divided by a safety factor. If the ETR is smaller than 1, i.e. the exposure is lower than the PNEC, the risk is low. If the ETR is higher than 1, i.e. the exposure is higher than the PNEC, there is a chance of high risk².

An ETR above 1 will usually result in a higher tier (refined) risk assessment, but due to the limited capacity for risk evaluations and the complexity of higher tier risk assessments, the risk assessment in Ethiopia will for the time being be based on a first tier risk assessment only, as already stated above. For that reason the level of the risk will be classified as low risk, possible risk and high risk:

- Low risk ('green traffic light' in PRIMET): the ETR is lower than 1.
- Possible risk ('orange traffic light' in PRIMET): the ETR is higher than 1 but lower than a certain exceedance factor.
- High risk ('red traffic light' in PRIMET): the ETR is higher than the exceedance factor.

The level of the exceedance factor will be different for different protection goals, and may depend on the type of organism:

- vertebrates (fish, birds) have a higher protection level than non-vertebrates because dead birds and fish are not desired, and a lower exceedance factor is applied;
- organisms that can reproduce fast have a higher ability of recovery after suffering from effects, and therefore a higher exceedance factor can be applied.

The exceedance factor may also depend on how conservative the first tier assessment is. For instance, in case of a strict safety factor (e.g. 100 for invertebrates) or a conservative exposure calculation, the exceedance factor that can be accepted will be higher.

The exceedance factors for each of the protection goals are discussed in the Handbook.

7.3.2 Decision-making recommendations

As a general approach, the following decision-making recommendations for the environmental protection goals apply:

- a. Whenever the outcome is 'green', there is **no impediment to registration** of the pesticide.
- b. Whenever the outcome of the risk assessment is 'orange', **the risk is considered acceptable for the time being**, provided that:
 - all risk mitigation measures which are realistic and effective under Ethiopian conditions are applied;
 - and*
 - the applicant will provide a higher tier risk assessment specifically for use in Ethiopia (either theoretical or based on additional data) within two (2) years of first registration.³

PHRD will review the registration after 2 years and may cancel authorization of the concerned uses if this requirement has not been met.

- c. Whenever the outcome of the risk assessment is 'red', **the risk is considered unacceptably high**, unless:
 - the same active ingredient has been registered for comparable uses by a reputable regulator (e.g. the European Commission or the US Environmental Protection Agency) and its risk assessment (including higher tiers) shows that the pesticide will likely pose an acceptable risk in

² For bees and other non-target arthropods the principle of risk assessment is slightly different from the general principle presented in this section. For these aspects empirically derived trigger values are used. Reference is made to the PHRD/Alterra Evaluation Handbook.

³ In some cases, two years may be insufficient to generate the required data. The applicant may apply for a longer temporary registration with PHRD.

Ethiopia for comparable uses;

and

- risk mitigation measures in the risk assessment under a.) required to reduce the risk of the pesticide to an acceptable level are also realistic and effective under Ethiopian conditions (appropriate risk mitigation measures for Ethiopia have been listed in Annex 2);

and

- [insufficient alternative pesticides or pest management options, which require less risk mitigation, are available in Ethiopia for the propose use(s);]⁴

and

- The applicant will provide a higher tier risk assessment specifically for use in Ethiopia (either theoretical or based on additional data) within two (2) years of first registration.

PHRD will review the registration after 2 years and may cancel authorization of the concerned uses if this requirement has not been met.

Special cases with respect to the above general approach are:

Bees

A separate risk assessment for in-crop and off-crop risks to bees is conducted.

For in-crop risks, the outcome 'possible risk' ('orange') is only acceptable if:

- a. the general criteria above apply;

and

- b. the risk mitigation measures, realistic and effective under Ethiopian conditions, must reduce the risk for bees to an acceptable level (appropriate measures to reduce risks to bees in Ethiopia have been listed in Annex 2);

and

- c. the off-crop risks are low ('green'), with or without risk mitigation measures.

Non-target arthropods

A separate risk assessment for in-crop and off-crop risks to non-target arthropods is conducted.

For in-crop risks, the outcomes 'possible risk' ('orange') and 'high risk' ('red') are acceptable if off-crop risks are low ('green'), with or without risk mitigation measures (recolonization of the in-crop area from the off-crop area is then possible). However, in such cases, the pesticide is marketed with the label statement that the pesticide is toxic to beneficial insects (or to natural enemies of crop pests), so that the user will know that the product is dangerous for these organisms.

Any pesticide intended for use in integrated pest management (IPM) or biological control programmes should have low risk ('green') for both in-crop and off-crop risks, with or without risk mitigation measures.

Figure 4 shows the decision-making steps for the environmental risk assessment. The decisions resulting from each of the assessments are summarized in Table 2. The outcome of the environmental risk assessment is fed back into the overall decision-making scheme in Figure 2.

⁴ The requirement to assess alternatives will progressively be introduced, as an increasing number of risk assessments have been conducted by PHRD. The requirement will become mandatory after all registered pesticides have been evaluated according to the new risk assessment system.

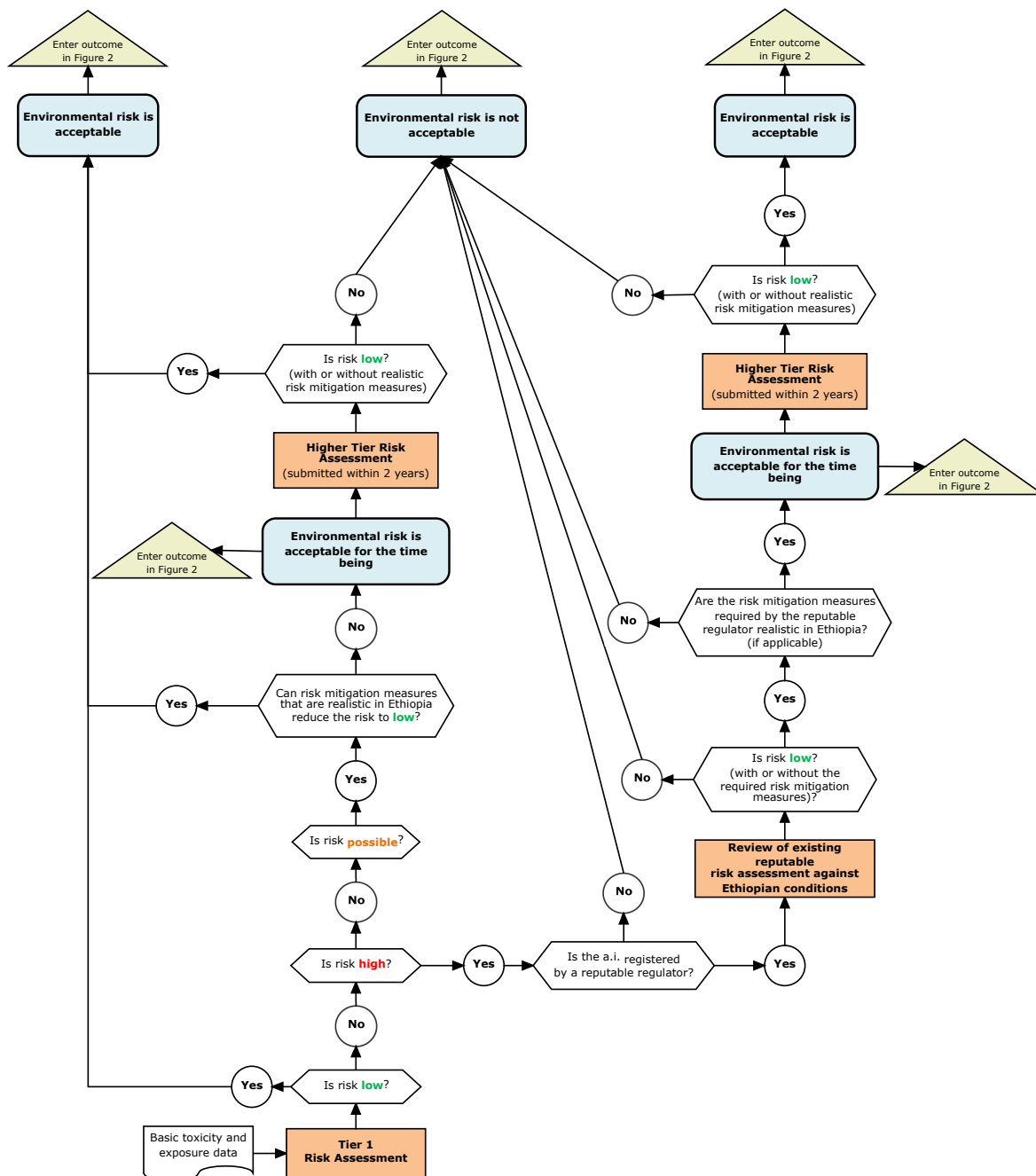


Figure 4 Outline for decision-making in the environmental risk assessment. The scheme is followed separately for each of the environmental aspects.

Table 2

Summary of decision-making recommendations based on the environmental risk assessments.

Aspect	Outcome of the assessment	Recommended registration decision	
Aquatic ecosystems	Acute risk		
	Surface water (3 scenarios)	Risk low (all scenarios)	● No impediment to registration
		Risk possible (one or more relevant scenarios)	● Allow registration, provided that {see criteria in text}
		Risk high (one or more relevant scenarios)	● Refuse registration, unless {see criteria in text}
	Chronic risk		
		Risk low (all scenarios)	● No impediment to registration
	Risk possible (one or more relevant scenarios)	● Allow registration, provided that {see criteria in text}	
	Risk high (one or more relevant scenarios)	● Refuse registration, unless {see criteria in text}	
Birds, Earthworms	Acute risk		
		Risk low	● No impediment to registration
		Risk possible	● Allow registration, provided that {see criteria in text}
		Risk high	● Refuse registration, unless {see criteria in text}
	Chronic risk		
		Risk low	● No impediment to registration
	Risk possible	● Allow registration, provided that {see criteria in text}	
	Risk high	● Refuse registration, unless {see criteria in text}	
Non-target plants		Risk low	● No impediment to registration
		Risk possible	● Allow registration, provided that {see criteria in text}
		Risk high	● Refuse registration, unless {see criteria in text}
Bees	In-crop risk		
		Risk low	● No impediment to registration
		Risk possible	● Allow registration, provided that {see criteria in text}, <u>and</u> off-crop risks are low (with or without realistic risk mitigation measures), <u>and</u> risk mitigation is realistic and effective and sufficient to reduce the risk to an acceptable level.
		Risk high	● Refuse registration, unless {see criteria in text}
	Off-crop risk		
		Risk low	● No impediment to registration
		Risk possible	● Allow registration, provided that {see criteria in text} <u>and</u> the applied risk mitigation measures reduce the risk to an acceptable level
		Risk high	● Refuse registration, unless {see criteria in text}
	Non-target arthropods	In-crop risk	
		Risk low	● No impediment to registration Requirement for IPM/biocontrol
		Risk possible	● Allow registration, provided that off-crop risks are low (with or without realistic risk mitigation measures) Label statement: 'toxic to beneficial insects'
		Risk high	● Allow registration, provided that off-crop risks are low (with or without realistic risk mitigation measures) Label statement: 'toxic to beneficial insects'
Off-crop risk			
		Risk low	● No impediment to registration
		Risk possible	● Allow registration, provided that {see criteria in text} <u>and</u> the applied risk mitigation measures reduce the risk to an acceptable level
		Risk high	● Refuse registration, unless {see criteria in text}
Soil micro-organisms			Risk low
		Risk high	● Refuse registration, unless {see criteria in text}

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Annex 1 Legal basis and protection goals underlying the risk assessment for pesticide registration in Ethiopia

1 Human health

1.1 General criteria for acceptability of a pesticide

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 1.1.1

(The Ministry... shall evaluate...) the overall acute and long-term hazards of the pesticide for humans. The pesticide will not be registered if:

- a. the pesticide formulation is classified as or meets the criteria to be approved as classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard; or
- b. the pesticide meets the criteria of carcinogenicity Categories 1A and 1B of the Globally Harmonized System on Classification and Labelling of Chemicals (GHS); or
- c. the pesticide meets the criteria of mutagenicity Categories 1A and 1B of the Globally Harmonized System on Classification and Labelling of Chemicals (GHS); or
- d. the pesticide meets the criteria of reproductive toxicity Categories 1A and 1B of the Globally Harmonized System on Classification and Labelling of Chemicals (GHS);

unless exposure of humans, either directly or through their diet, is likely to be negligible following the intended uses, and under locally relevant conditions of use.

1.2 Operator exposure

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 1.1.2

(The Ministry... shall evaluate...) operator's exposure to the pesticide, or to relevant metabolites, degradation or reaction products, likely to occur following the intended uses and under locally relevant conditions of use.

- a. The pesticide will not be registered if, based on risk assessment for realistic worst case conditions⁵, the extent of operator exposure in handling and use of the pesticide for the intended uses exceeds the Acceptable Operator Exposure Level (AOEL).
- b. Where the intended use of the pesticide requires the use of personal protective equipment (PPE), the pesticide will not be registered unless:
 - that PPE is effective in reducing exposure to below the AOEL and is readily obtainable by the user; and
 - it is feasible to use the PPE under the conditions of use of the pesticide, taking into account climatic conditions in particular.

⁵ 'Realistic worst case conditions' are the use scenarios of the pesticide which represent a high fraction of all likely environmental and/or agronomic conditions in Ethiopia, i.e. generally representing the 90th to 99th percentile of such conditions in time and/or space. Risk assessment for realistic worst case conditions implies that all uses of the pesticides under less than realistic worst case conditions meet the criteria set in this Annex.

Detailed protection goal

- i. What should be protected?
→ All pesticide operators, i.e. all pesticide applicators, mixers and loaders.
- ii. Where should this be protected?
→ In all field and greenhouse crops where pesticides are applied through spraying, for a maximum of 3 months per year and a maximum of 8 hours per day.
- iii. How strictly should it be protected?
→ No sub-chronic effects on the health of the operators are acceptable, i.e. no exceedance of the Acceptable Operator Exposure Level (AOEL) is allowed.

1.3 Worker exposure

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 1.1.3

(The Ministry... shall evaluate...) the potential exposure of other humans (bystanders, workers or flagmen exposed after the application of the plant protection product) or animals to the pesticide, or to relevant metabolites, degradation or reaction products, following the intended uses and under locally relevant conditions of use, and shall verify that:

- a. Waiting and re-entry safety periods or other precautions be such that the exposure of bystanders, workers or flagmen exposed after the application of the pesticide under realistic worst-case conditions does not exceed the AOEL nor any limit values established for those compounds by the appropriate organ.
- b. Waiting and re-entry safety periods or other precautions be established in such a way that no adverse impact on animals occurs.
- c. Waiting and re-entry safety periods or other precautions mentioned under this sub-Article be realistic and adapted to the locally relevant conditions of use.

Detailed protection goal

- i. What should be protected?
→ All pesticide workers, i.e. all persons entering the sprayed field for e.g. harvesting, weeding
- ii. Where should this be protected?
→ In all field and greenhouse crops where pesticides are applied, for a maximum of 3 months per year and a defined number of hours per day (default is 6 hours per day).
- iii. How strictly should it be protected?
→ No sub-chronic effects on the health of the operators are acceptable, i.e. no exceedance of the Acceptable Operator Exposure Level (AOEL) is allowed.

1.4 Consumer exposure – agricultural commodities

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 1.1.4

(The Ministry... shall evaluate...) the exposure of consumers and animals through their diet following the intended uses and under locally relevant conditions of use, and:

- a. The pesticide shall not be registered if its intended use will lead to residue levels at harvest, slaughter or after storage or processing, as appropriate, which exceed the nationally established maximum residue limit (MRL) or a provisional MRL.
- b. In the absence of a nationally established MRL or provisional MRL, Codex Alimentarius MRLs shall apply, if established for the commodity and pesticide under review.
- c. Taking into account all registered uses of the pesticide, the intended use shall not be authorized if the estimated total dietary exposure exceeds the Acceptable Daily Intake (ADI) or the Acute Reference Dose (ARfD). Where treated plants or plant products are intended to be fed to animals, the residues of the pesticide shall not have an adverse effect on animal health or on the food safety of products from animal origin.

Detailed protection goal

- i. What should be protected?
→ All consumers of agricultural commodities.
- ii. Where should this be protected?
→ Throughout Ethiopia, for all agricultural commodities that have been treated with the pesticide.
- iii. How strictly should it be protected?
→ No acute or chronic effects on the health of the consumer, i.e. no exceedance of the Acceptable Daily Intake (ADI) or the Acute Reference Dose (ARfD) is allowed.

1.5 Consumer exposure – drinking water

Legal basis – Pesticide Registration and Control Regulation*Schedule II – Article 2.1.2*

(The Ministry... shall evaluate...) the contamination of groundwater and surface water, and the risk of using these as sources of drinking water, following the intended uses and under locally relevant conditions of use.

- a. The pesticide will not be registered if the expected concentrations of the pesticide, or of relevant metabolites, degradation or reaction products, in groundwater or in surface water exceed the nationally established drinking water standard under realistic worst-case conditions.
- b. In the absence of a nationally established drinking water standard, the WHO drinking water guidance value shall apply.

Detailed protection goal

- i. What should be protected?
→ All consumers of drinking water originating from non-purified groundwater or surface water.
- ii. Where should this be protected?
→ Throughout Ethiopia. This is represented by three vulnerable scenarios and scenario locations:
Surface water:
 - Small streams, higher than 1500 m elevation
 - Ponds, between 1500 and 2000 m elevation
 - Ponds below 1500 m elevation, but with more than 500 mm rainGroundwater:
 - Alluvial aquifers along small rivers and volcanic aquifers with shallow wells, both above 1500 m elevation
 - Alluvial aquifers in the Rift Valley margins and lowlands in areas below 1500 m elevation
 - Alluvial aquifers in the Rift Valley margins in areas between 1500 and 2000 m elevation
- iii. How strictly should it be protected?
→ No acute effects on the health of the consumer, i.e. no exceedance of the Acute Reference Dose (ADI) after drinking a large portion of surface water, for 99th percentile pesticide concentration in surface water.
→ No chronic effects on the health of the consumer, i.e. no exceedance of the Acceptable Daily Intake (ADI), for 99th percentile pesticide concentration in ground- or surface water.

2 Environment

2.1 Aquatic ecosystems

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 2.1.3

(The Ministry... shall evaluate...) the expected exposure of aquatic organisms to the pesticide, or to relevant metabolites, degradation or reaction products, in aquatic ecosystems relevant to the intended uses of that pesticide and under realistic worst case conditions, considering that.

- a. Where there is a possibility that aquatic organisms be exposed, the pesticide shall not be registered if:
 - the exposure/toxicity ratio for fish or aquatic invertebrates is greater than or equal to 0.01 for acute exposure, or to 0.1 for long-term exposure; or
 - the exposure/toxicity ratio for algae or macrophytes is greater than or equal to 0.1, unless it can be clearly shown through risk assessment that under field conditions no unacceptable effects on aquatic organisms will occur following the intended use of the pesticide.

Detailed protection goal

- i. What should be protected?
 - Aquatic ecosystems existing in surface water
- ii. Where should this be protected?
 - All natural or semi natural water bodies, which can be streams, rivers, ponds, (temporary) lakes, marshland. For Ethiopia this has been operationalized by selecting two types of most vulnerable small surface waters, i.e. small streams only existing in the highlands of Ethiopia (> 1500 m) and temporary ponds existing between 1500-2000 m and below 1500 m, but with at least 500 mm of rain.
- iii. How strictly should it be protected?
 - The sustainability of the aquatic ecosystem should be ensured. Therefore, survival and reproduction of the most sensitive aquatic organisms should not, or only briefly, be affected.

2.2 Birds

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 2.1.7

(The Ministry... shall evaluate...) the expected exposure of birds and other non-target terrestrial vertebrates to the pesticide, or to relevant metabolites, degradation or reaction products, in (agro-) ecosystems relevant to the intended uses of that pesticide and under realistic worst case conditions.

- a. Where there is a possibility that birds and other non-target terrestrial vertebrates are exposed, the pesticide shall not be registered if:
 - the acute exposure/toxicity ratio for birds and other non-target terrestrial vertebrates is greater than or equal to 0.1; or
 - the chronic exposure/toxicity ratio for birds and other non-target terrestrial vertebrates is greater than or equal to 0.2; or
 - if consumption of one treated seed or pesticide granule leads to exposure which exceeds $1/10^{\text{th}}$ of the acute LD_{50} of the pesticide to birds,

unless it can be clearly shown through risk assessment that under field conditions no unacceptable effects on birds and other non-target terrestrial vertebrates will occur following the intended use of the pesticide.

Detailed protection goal

- i. What should be protected?
 - Populations of non-target birds (represented by 3 types of birds relevant to Ethiopia)

-
- ii. Where should this be protected?
 - Treated crop field or other treated locations
 - iii. How strictly should it be protected?
 - No individual mortality or reproduction effects should occur in populations of non-target birds.

2.3 Earthworms

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 2.1.6

(The Ministry... shall evaluate...) the expected exposure of earthworms to the pesticide, or to relevant metabolites, degradation or reaction products, in (agro-) ecosystems relevant to the intended uses of that pesticide and under realistic worst case conditions.

- a. Where there is a possibility that earthworms are exposed, the pesticide shall not be registered if:
 - the acute exposure/toxicity ratio for earthworms is greater than or equal to 0.1; or
 - the chronic exposure/toxicity ratio for earthworms is greater than or equal to 0.2,

unless it can be clearly shown through risk assessment that under field conditions no unacceptable effects on earthworms will occur following the intended use of the pesticide.

Detailed protection goal

- i. What should be protected?
 - Populations of earthworms
- ii. Where should this be protected?
 - In treated fields/locations
- iii. How strictly should it be protected?
 - No long-term effects should occur in populations of earthworms.

2.4 Bees

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 2.1.4

(The Ministry... shall evaluate...) the expected exposure of honey bees and wild bees to the pesticide, or to relevant metabolites, degradation or reaction products, in (agro-) ecosystems relevant to the intended uses of that pesticide and under realistic worst case conditions.

- a. Where there is a possibility that bees are exposed, the pesticide shall not be registered if:
 - the risk quotients for oral and contact exposure of honeybees to sprayed pesticides are greater than 50; or
 - the exposure/toxicity ratio for oral exposure of honeybees following soil or seed treatments is greater than or equal to 0.1; or
 - honeybee larvae or honeybee behaviour are adversely affected,

unless it can be clearly shown through risk assessment that under field conditions no unacceptable effects on colony development and survival will occur following the intended use of the pesticide.

Detailed protection goal

- i. What should be protected?
 - Colonies of honeybees and populations of wild bees
- ii. Where should this be protected?
 - Both inside and outside treated crops
- iii. How strictly should it be protected?
 - No long-term effects should occur on colonies of honeybees and populations of wild bees.

2.5 Non-target arthropods

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 2.1.5

(The Ministry... shall evaluate...) the expected exposure of beneficial arthropods to the pesticide, or to relevant metabolites, degradation or reaction products, in (agro-) ecosystems relevant to the intended uses of that pesticide and under realistic worst case conditions.

- a. Where there is a possibility that beneficial arthropods are exposed, the pesticide shall not be registered if:
 - the exposure/toxicity ratio on artificial substrate for the indicator organisms (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) is greater than or equal to 2; or
 - the exposure/toxicity ratio on natural substrate for relevant organisms is greater than or equal to 1,

unless it can be clearly shown through risk assessment that under field conditions no unacceptable effects on beneficial arthropods will occur following the intended use of the pesticide.
- b. Any claim for selectivity and proposals for use in integrated pest or vector management shall be substantiated by appropriate data ascertaining that the product will not affect beneficial arthropods adversely in the referred integrated pest or vector management system.

Detailed protection goal

- i. What should be protected?
 - Populations of non-target arthropods
- ii. Where should this be protected?
 - Both inside and outside treated crops
- iii. How strictly should it be protected?
 - No long-term effects should occur on populations of non-target arthropods

2.6 Non-target terrestrial plants

Legal basis – Pesticide Registration and Control Regulation

Schedule II – Article 2.1.5

(The Ministry... shall evaluate...) the expected exposure of non-target terrestrial plants to the pesticide, or to relevant metabolites, degradation or reaction products, in (agro-) ecosystems relevant to the intended use of that pesticide and under realistic worst-case conditions.

- a. Where there is a possibility that non-target terrestrial plants are exposed, the pesticide shall not be registered if:
 - the exposure/toxicity ratio for non-target terrestrial plants is greater than or equal to 0.2,

unless it can be clearly shown through risk assessment that under field conditions no unacceptable effects on non-target terrestrial plants will occur following the intended use of the pesticide.

Detailed protection goal

- i. What should be protected?
 - Populations of non-target terrestrial plants
- ii. Where should this be protected?
 - Locations alongside treated crops (off-crop)
- iii. How strictly should it be protected?
 - No long-term effects should occur on populations of non-target terrestrial plants

2.7 Soil micro-organisms

Legal basis – Pesticide Registration and Control Regulation

Not included in the Regulation

Detailed protection goal

- i. What should be protected?
 - Soil processes influenced by soil micro-organisms (e.g. litter break down).
- ii. Where should this be protected?
 - Inside treated fields/locations
- iii. How strictly should it be protected?
 - No long-term effects on soil processes influenced by soil micro-organisms should occur.

Annex 2 Pesticide risk mitigation measures and their feasibility under Ethiopian conditions

Risk mitigation measure	Feasibility in Ethiopia (good, challenging, difficult)		Conditions	Label statement (Annex 3)
	Small-scale (subsistence) farms	Large scale (commercial) farms		
	Human health risks – Limiting occupational exposure			
Do not register the pesticide (or phase-out a registered pesticide)	Challenging	Challenging	For important pests, alternative pesticides or pest management options need to be available	
Severely restrict the use of the pesticide (e.g. only by licensed users)	Difficult	Challenging	Enforcement needs to be effective	
Reduce the application rate or frequency	Good	Good	As long as reduced rate/frequency is efficacious; otherwise impossible	
Require specific personal protective equipment	Challenging	Good		1
Require low-risk pesticide application equipment (e.g. low drift nozzles; closed cabin)	Difficult	Challenging	Equipment needs to be on the market, or relatively easily become available on the market	
Limit to specific formulations (e.g. granules instead of liquids)	Challenging	Challenging	As long as lower risk formulation is efficacious; otherwise impossible May require new registration application	
Require minimum re-entry intervals (for workers, pickers)	Difficult	Challenging		
Require low-risk packaging (e.g. water-soluble sachets)	Challenging	Challenging	As long as the low-risk packaging is compatible with the formulation; otherwise impossible	
Require specific precautionary statements on the label	Difficult	Good	Users should be literate or have access to literate person	2
Human health risks – Limiting consumer exposure				
Do not register the pesticide (or phase-out a registered pesticide)	Challenging	Challenging	For important pests, alternative pesticides or pest management options need to be available	
Severely restrict the use of the pesticide (e.g. only on non-food crops)	Difficult	Challenging	Enforcement needs to be effective	
Reduce the application rate or frequency	Good	Good	As long as reduced rate/frequency is efficacious; otherwise impossible	
Increase pre-harvest intervals	Difficult	Challenging	As long as longer pre-harvest interval allows for efficacious pest management; otherwise impossible	3
Require specific precautionary statements on the label	Difficult	Good	Users should be literate or have access to literate person	4

Risk mitigation measure	Feasibility in Ethiopia (<i>good, challenging, difficult</i>)		Conditions	Label statement (Annex 3)
	Small-scale (subsistence) farms	Large scale (commercial) farms		
	Environmental risks – Limiting groundwater exposure			
Do not register the pesticide (or phase-out a registered pesticide)	Challenging	Challenging	For important pests, alternative pesticides or pest management options need to be available	
Reduce the application rate or frequency	Good	Good	As long as reduced rate/frequency is efficacious; otherwise impossible	5
Restrict use to closed production systems from which there are no emissions or effluents (e.g. glasshouses, containers)	Difficult	Challenging	Enforcement needs to be effective	
Restrict use to formulation types that result in less leaching (e.g. slow-release formulations, seed coatings)	Challenging	Challenging	As long as lower risk formulation is efficacious; otherwise impossible May require new registration application	
Require specific precautionary statements on the label	Difficult	Good	Users should be literate or have access to literate person	6, 7
Environmental risks – Limiting surface water exposure and adverse effects on aquatic organisms				
<i>To reduce pesticide drift</i>				
Apply a no-spray or no-crop buffer zone between the treated area and surface water	Difficult	Challenging	Enforcement needs to be effective	8
Apply drift-reducing techniques (e.g. low drift nozzles)	Difficult	Challenging	Equipment needs to be on the market, or relatively easily become available on the market Enforcement needs to be effective	
Do not authorize aerial applications	Not applicable	Challenging		
Grow wind breaks	Difficult	Challenging		
Require specific precautionary statements on the label	Difficult	Good	Users should be literate or have access to literate person Enforcement needs to be effective	9
<i>To reduce runoff and/or drainflow</i>				
Require a no-spray or vegetated (no-crop) buffer zone between the sprayed area and the surface water	Difficult	Challenging	Enforcement needs to be effective	8
Restrict the application time window to periods when runoff or drainage is likely to be less important (e.g. periods with low rainfall and/or rainstorms are unlikely and/or sufficient vegetation cover)	Difficult	Challenging	Enforcement needs to be effective	10
Require specific precautionary statements on the label	Difficult	Good	Users should be literate or have access to literate person	8, 9, 10
<i>To reduce all types of surface water exposure</i>				
Do not register the pesticide (or phase-out a registered pesticide);	Challenging	Challenging	For important pests, alternative pesticides or pest management options need to be available	
Restrict use to low- or no emission applications (e.g. indoor applications, baiting, dipping, soil incorporation, seed treatment)	Difficult	Challenging	Enforcement needs to be effective	
Reduce the application rate or frequency	Good	Good	As long as reduced rate/frequency is efficacious; otherwise impossible	

Risk mitigation measure	Feasibility in Ethiopia (good, challenging, difficult)		Conditions	Label statement (Annex 3)
	Small-scale (subsistence) farms	Large scale (commercial) farms		
	Require soil incorporation to a certain depth	Difficult		
Restrict use to formulation types that result in less drift/run-off/drainflow (e.g. slow-release formulations, seed coatings, granules)	Challenging	Challenging	As long as lower risk formulation is efficacious; otherwise impossible May require new registration application	
Do not authorize bankside applications	Difficult	Challenging	Enforcement needs to be effective	
Restrict use to drip irrigation/chemigation	Difficult	Challenging	Equipment needs to be available	
Environmental risks – Limiting pesticide exposure and adverse effects on bees (in- and off-crop)				
Do not register the pesticide (or phase-out a registered pesticide);	Challenging	Challenging	For important pests, alternative pesticides or pest management options need to be available	
Reduce the application rate or frequency	Good	Good	As long as reduced rate/frequency is efficacious; otherwise impossible	
Change the timing of application (e.g. only in the evening, when honeybees are not flying)	Difficult	Challenging	Only applicable to rapidly degrading pesticides	11
Change the periods of application (e.g. do not apply during crop flowering or in-crop weed flowering)	Challenging	Good	As long as target pest is not present during flowering	12
Restrict use to greenhouse crops	Difficult	Challenging	Enforcement needs to be effective	
Mulch or mow ground cover before application (if attractive to bees)	Difficult	Challenging		
Require advance notification of beekeepers to allow them to relocate the beehives	Difficult	Challenging	Need effective communication between farmer and beekeeper	13
Restrict use to formulations which pose less risk to bees	Challenging	Challenging	As long as lower risk formulation is efficacious; otherwise impossible May require new registration application	
Apply a no-spray or no-crop buffer zone between the treated area and off-crop areas	Difficult	Challenging	Only for off-crop risks Enforcement needs to be effective	8
Apply drift-reducing techniques (e.g. low drift nozzles)	Difficult	Challenging	Only for off-crop risks Equipment needs to be on the market, or relatively easily become available on the market Enforcement needs to be effective	
Do not authorize aerial applications	Not applicable	Challenging		
Grow wind breaks to avoid exposure of off-crop areas	Difficult	Challenging	Only for off-crop risks	
Require label statement warning about toxicity to bees	Difficult	Good	Users should be literate or have access to literate person	8, 11, 12, 13
Environmental risks – Limiting pesticide exposure and adverse effects on non-target arthropods (in- and off-crop)				
Do not register the pesticide (or phase-out a registered pesticide);	Challenging	Challenging	For important pests, alternative pesticides or pest management options need to be available	
Reduce the application rate or frequency	Good	Good	As long as reduced rate/frequency is efficacious; otherwise impossible	

Risk mitigation measure	Feasibility in Ethiopia (<i>good, challenging, difficult</i>)		Conditions	Label statement (Annex 3)
	Small-scale (subsistence) farms	Large scale (commercial) farms		
	Change the timing of application (e.g. apply only in the evening, so the pesticide deposit dries/degrades before non-targets become active again)	Difficult		
Restrict use to greenhouse crops	Difficult	Challenging	Enforcement needs to be effective	8
Apply a no-spray or no-crop buffer zone between the treated area and off-crop areas	Difficult	Challenging	Only for off-crop risks Enforcement needs to be effective	
Apply drift-reducing techniques (e.g. low drift nozzles)	Difficult	Challenging	Only for off-crop risks Equipment needs to be on the market, or relatively easily become available on the market Enforcement needs to be effective	
Do not authorize aerial applications	Not applicable	Challenging		
Grow wind breaks to avoid exposure of off-crop areas	Difficult	Challenging	Only for off-crop risks	
Restrict use to formulations which are less hazardous to non-target organisms	Challenging	Challenging	As long as lower risk formulation is efficacious; otherwise impossible May require new registration application	
Require label statement warning about toxicity to non-target organisms	Difficult	Good	Users should be literate or have access to literate person	15
Environmental risks – Limiting pesticide exposure and adverse effects on birds and wild mammals				
<i>For all types of formulations</i>				
Do not register the pesticide (or phase-out a registered pesticide);	Challenging	Challenging	For important pests, alternative pesticides or pest management options need to be available	
Reduce the application rate or frequency	Good	Good	As long as reduced rate/frequency is efficacious; otherwise impossible	
Restrict use to formulations which are less hazardous to birds and mammals	Challenging	Challenging	As long as lower risk formulation is efficacious; otherwise impossible May require new registration application	
<i>For seed treatments and granules</i>				
Require seeds and granules to be incorporated into the soil	Difficult	Challenging	Equipment needs to be on the market	16
Require label statement to immediately remove any spills	Difficult	Good	Users should be literate or have access to literate person	17
<i>For rodenticides</i>				
Require of burrow-baiting or bait station	Challenging	Good	Extension service needs to be effective	
If surface spreading needed, apply product on vegetation rather than on bare soil	Challenging	Good	Extension service needs to be effective	
Require removal of dead and moribund rodents, and of bait remains after completion of the control operation	Difficult	Good	Will mainly work for acutely toxic rodenticides; not anti-coagulants. Extension service needs to be effective.	18

Annex 3 Examples of precautionary label statements

Statement reference (see Annex 2 for related risk mitigation measure)	Precautionary statement (examples)	Remarks	
Human health			
1	Wear protective gloves/ protective clothing/ eye protection/ face protection <i>{specify the required type of equipment}</i> Wear respiratory protection	See the <i>Globally Harmonized System of Classification and Labelling of Chemicals</i> for guidance on which elements of these precautionary statements to use, and when.	
2	Do not breathe dust/ fume/ gas/ mist/ vapours/ spray <i>{specify}</i> Do not get in eyes, on skin, or on clothing Avoid contact during pregnancy/while nursing Wash ... <i>{specify body part(s)}</i> thoroughly after handling Do not eat, drink or smoke when using this product Use only outdoors or in a well-ventilated area Wash all protective clothing after use After igniting the product, do not inhale smoke and leave the treated area immediately Ventilate treated areas/ greenhouses thoroughly for ... <i>{specify time}</i> hours/ until spray has dried <i>{specify}</i> before re-entry		
3	Do not apply this product (... <i>{product name}</i>) within ... <i>{specify}</i> days of harvest		
4	<i>Do not apply to food or feed crops</i> <i>Remove or cover food before treatment</i>		
Environment			
5	To protect groundwater: Do not apply this product (... <i>{product name}</i>) more than ... <i>{specify maximum frequency}</i> times		
6	This chemical may leach to groundwater: Do not apply when rain is likely		
7	To protect ground- and surface water: Do not clean application equipment near wells, ditches, rivers and lakes		
8	To protect aquatic organisms/ non-target arthropods/ bees <i>{specify}</i> respect an unsprayed buffer zone of ... m <i>{specify distance}</i> to non-agricultural land/surface waters <i>{specify}</i>		
9	Avoid spray drift: Do not apply in high wind speed		
10	Avoid water contamination: Do not apply when rain is likely		
11	Dangerous to bees: To protect bees, only apply in the evening when bees are not foraging		
12	Dangerous to bees: To protect bees and other pollinating insects do not apply to crop plants when in flower/ <i>{and/or}</i> Do not apply when flowering weeds are present		
13	Dangerous to bees: To protect bees, remove or cover beehives during application and for ... hours <i>{specify time}</i> after treatment		
14	Dangerous to beneficial arthropods: only apply in the evening		
15	Highly toxic to natural enemies of crop pests: Do not use in biological control programmes or IPM		
16	To protect birds and wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.		
17	To protect birds and wild mammals, remove spillages.		
18	Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips, but burn or bury them.		



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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.

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