Risk reduction of pesticides in Myanmar

Interim report of the Dutch-Myanmar project on pesticide registration and pesticide risk reduction 2016 – 2018

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Mechteld ter Horst[1], John Deneer[1], Harold van der Valk[2], Aung Kyaw Oo[3], San San Lwin[3], Seng Raw[3] and Janhendrik Krook[4]

1 Wageningen Environmental Research, Wageningen University & Research

2 Falconsult, the Netherlands

3 Plant Protection Division of the Myanmar Ministry of Agriculture, Livestock and Irrigation

4 Linge Agroconsultancy, the Netherlands

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The Dutch-Myanmar project on pesticide registration and pesticide risk reduction aims at reduction of risks of pesticide use through the development of a well-functioning pesticide registration system, and the elimination of high-risk pesticides from the market. To this end an evaluation methodology for the registration of pesticides in Myanmar was developed together with the Plant Protection Division of the Myanmar Ministry of Agriculture, Livestock and Irrigation. Risk reduction of high-risk pesticides was taken up by adopting the three-step approach developed by the FAO/WHO for risk reduction of so-called Highly Hazardous Pesticides (HHPs). The first step of this approach was performed: guidance was written and applied to identify HHPs within the package of pesticide products registered in Myanmar by May 2017.

Keywords: pesticide, risk reduction, registration, decision support, Myanmar, Highly Hazardous Pesticides, evaluation, human health

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Contents

Summary **5**

1 Introduction and reading guidance **7**

1.1 Introduction 7
1.2 Reading guidance 8

2 Pesticide registration and pesticide risk reduction; project results 2016-2017 **9**

2.1 Bodies responsible for pesticide registration in Myanmar 9
2.1.1 Current situation 9
2.1.2 Discussion and recommendations 9
2.2 Overview of the current process of pesticide registration in Myanmar 10
2.2.1 Introduction 10
2.2.2 Steps taken during the registration phase 10
2.3 Considerations when changing the process of pesticide registration 12
2.3.1 Introduction 12
2.3.2 Formalised evaluation methodology for the registration of pesticides in Myanmar 12
2.3.3 Pesticide labelling: Good Agricultural Practice (GAP) table 13
2.3.4 Risk mitigation measures 13
2.3.5 Requirements for implementing the developed decision support system 14
2.4 Risk reduction of Highly Hazardous Pesticides 16
2.5 Legislation 19
2.6 Linkage to agricultural advisory services 22
2.7 Communication with stakeholders 22

3 Preliminary protocol for pesticide registration evaluation **25**

3.1 Introduction 25
3.2 Decision supporting flow chart for pesticide registration and the accompanying decision supporting summary 25
3.2.1 Decision supporting flow chart 25
3.2.2 Decision supporting summary 28
3.3 Efficacy assessment and GAP table 28
3.4 Identification of low risk pesticides 28
3.4.1 Introduction 28
3.4.2 Decision making on low risk pesticides 29
3.5 Hazard assessment 29
3.5.1 Introduction 29
3.5.2 Hazard assessment for labelling purposes 29
3.5.3 Hazard assessment for identification of highly hazardous pesticides for use in the decision supporting scheme for registration 31
3.5.4 Emergency need for a HHP 40
3.5.5 Alternatives for a HHP 40
3.5.6 Decision making on HHP 41
3.6 Registration by analogy 41
3.6.1 Introduction 41
3.6.2 Guidance for registration by analogy 42
3.6.3 Decision making based on registration by analogy 42

3.7 Human health risk assessments 43
3.7.1 Introduction 43
3.7.2 Myanmar specific guidance for occupational risk assessment (operators and workers in the field) 46
3.7.3 Myanmar specific guidance for the risk assessment for consumers (dietary) 48
3.7.4 Mitigation measures feasible in Myanmar 52
3.7.5 Decision making based on human health risk assessments 52

4 Recommendations 54

References 55

Annex 1 Pesticide registration process in Myanmar – April 2016 57

Annex 2 Table of Intended Uses *or* Good Agricultural Practice (GAP) table 59

Annex 3 Review of the feasibility of risk mitigation measures for pesticide registration in Myanmar 62

Annex 4 Details of the discussion of the stakeholder meetings in February 2018 68

Annex 5 Notes for the decision supporting flow chart for pesticide registration in Myanmar (version: 6 October 2017) 77

Annex 6 Prioritisation of protection goals in Myanmar 80

Annex 7 Format of decision supporting summary for the registration of a pesticide in Myanmar (version of 3 November 2017) 81

Annex 8 Guidance on using the EU "low risk active substance" list and the US-EPA "minimum risk pesticides" list 85

Annex 9 Registration by analogy check-list and guidance (source: FAO Pesticide Registration Toolkit) 87

Annex 10 Information on human health toxicity studies 97

Annex 11 No Observed Adverse Effect Level (NOAEL) 100

Annex 12 Exposure and Hazard for Operators and Workers 102

Annex 13 Instruction for downloading the EFSA AOEM model 105

Annex 14 Step by Step guidance for performing risk assessment of operators in the field 107

Annex 15 Step by Step guidance for performing risk assessment of workers in the field 111

Annex 16 Background information on terms relevant for the consumer/dietary risk assessment 113

Annex 17 Details of the principles of the first tier acute consumer exposure assessment as performed in the EU 119

Annex 18 Myanmar specific manual of the tool used for the (first tier) chronic risk assessment of consumers 121

Annex 19 Myanmar specific guidance for higher tier chronic consumer risk assessments for consumers and for assessing residue levels for crop export 125

Annex 20 Details of the 8 criteria used in the FAO assessment of Highly Hazardous Pesticides 127

Annex 21 Details of PBT criteria 133

Summary

As a result of a Memorandum of Understanding (MoU) on Agriculture, Livestock, Fisheries, Farmers Organisations' and Food Quality signed by the governments of Myanmar and the Netherlands, a project on pesticide registration and pesticide risk reduction was initiated by the Dutch embassy in Yangon in 2016. The project aims at reduction of risks of pesticide use through the development of a well-functioning pesticide registration system, and the elimination of high-risk pesticides from the market.

Wageningen University and Research (WUR) and the Plant Protection Division (PPD) of the Myanmar Ministry of Agriculture, Livestock and Irrigation (MoALI) developed an evaluation methodology for the registration of pesticides in Myanmar. Moreover, guidance was written and applied to identify Highly Hazardous Pesticides (HHP) within the package of pesticide products registered in Myanmar. Currently, the first phase of the project (roughly covering the period March 2016 – March 2018) is about to be concluded and plans are being developed for the second phase.

This document summarizes the work done during the first phase of the project and provides a brief outlook of the continuation of the work in the subsequent phase (2018 – 2020), i.e. an active support of the PPD in applying the newly developed evaluation system and a continuation of the work on risk reduction of Highly Hazardous Pesticides by further assessing the risks, needs and alternatives for all identified HHPs (Step 2), and by discussing, adopting and implementing risk mitigation measures (Step 3).

1 Introduction and reading guidance

1.1 Introduction

In May 2015 a Memorandum of Understanding (MoU) on co-operation in the field of Agriculture, Food safety, Livestock, Fisheries and Farmers' organisations was signed between the Ministry of National Planning and Economic Development of the Republic of the Union of Myanmar and the Ministry of Economic Affairs of the Kingdom of the Netherlands. In the MoU, the two parties express their wish to collaborate on several sub-sectors and bring different regulatory frameworks in line with international standards, including judicious use of inputs and technologies for crop protection.

The MoU builds on an agenda developed and endorsed in the Roundtable Meeting (RTM) hosted by the Myanmar Ministry of Agriculture and Irrigation and the Netherlands Embassy to Myanmar on 20th November 2014, in cooperation with Mercy Corps and East – West Seed.

The Netherlands is committed to contribute to the realisation of the endorsed agenda on judicious and effective use of plant protection products. To this end, a scoping mission was carried out in November 2014. The mission included consultations and discussions with stakeholders, and its results, conclusions and recommendations are reported in the document "Crop protection and pesticide risk assessment Myanmar, towards sustainable agricultural production and export of high value crops" (Peeters *et al.*, 2015).

This report was endorsed by the Plant Protection Division (PPD) of the Ministry of Agriculture Livestock and Irrigation (MoALI) in Myanmar. In June 2015, based on a jointly developed Terms of Reference (ToR), a mission was organised by Wageningen UR and the Netherlands Food and Consumer Product Safety Authority (NVWA) to develop a proposal for a multi-annual plan for implementing the recommendations for pesticide registration and phytosanitary services of the above mentioned report.

Based on the mission in June 2015, a work plan was developed with regard to the work package dealing with pesticide registration and pesticide risk reduction for a period of two years (March 2016 – March 2018). A number of activities were identified that i) support the agricultural sector by providing a procedure which stimulates marketing of new pesticide products, ii) will result in a quick decrease of risks for human health and the environment and iii) consider the number and level of expertise of staff at the PPD and the absorptive capacity of the PPD.

The explicit goal of this pesticide registration project is to contribute to sustainable agricultural production in Myanmar, through the development of a well-functioning pesticide registration system and elimination of high-risk pesticides from the market.

In the time frame of the project described here the FAO also initiated activities in Myanmar considering pesticide registration. The FAO made an overview of several instruments and procedures potentially useful for pesticide registration via a website called 'the FAO Pesticide Registration Toolkit' (FAO, 2017). Alignment was sought with their activities and where relevant instruments, information and procedures from the FAO Pesticide Registration Toolkit were used.

1.2 Reading guidance

The results of the first phase (March 2016 – March 2018) of the Dutch-Myanmar project on pesticide registration and pesticide risk reduction are described in three chapters.

Chapter 2 provides a general introduction to the current situation with regard to pesticide registration in Myanmar. It briefly describes the administrative bodies involved, schematically outlines the current procedure of pesticide registration, and mentions some aspects that may be of importance when considering to change the procedure of pesticide registration. The outcome of a scan for 'highly hazardous pesticides' among currently registered pesticide products and an proposal for follow-up steps are briefly discussed. A summary of the review of the Pesticide Law and recommendations and comments as result of the review are given in Chapter 2. Furthermore, the linkage between initiatives on improving agricultural advisory services and communication with stakeholders are described.

Part of the project was dedicated to improving the pesticide registration procedures with regard to dossier evaluation. Therefore, a decision support system including detailed guidance was developed together with the Myanmar project partners. The results of this work are described in Chapter 3. Parts of the text of sections 3.5.2 and 3.7 are from the evaluation manual of Ethiopia (Deneer *et al.*, 2014) and where necessary adapted for Myanmar. We consider the guidance developed to be a preliminary evaluation protocol and therefore decided to describe it in a separate chapter.

Finally, the main recommendations as result of the project are given in Chapter 4.

2 Pesticide registration and pesticide risk reduction; project results 2016-2017

2.1 Bodies responsible for pesticide registration in Myanmar

2.1.1 Current situation

In Myanmar, the Ministry of Agriculture, Livestock and Irrigation is responsible for implementing the Pesticide Law (The Pyidaungsu Hluttaw Law No. 14, 2016). This law covers the registration, production, distribution and use of pesticides. Decisions on whether plant protection products can be sold and used in Myanmar are taken by the Pesticide Registration Board (PRB). The PRB has been formed by the Ministry of Agriculture, Livestock and Irrigation, with approval of the Union Government. The PRB comprises the Deputy Minister of the Ministry as a chairman, the Director General as a secretary, the Director of the Plant Protection Division (PPD) as a joint secretary, and experts of relevant departments as members. The PPD together with the Technical Committee (TC; comprising the Director General as a chairman, the Director of the PPD as a secretary and experts of relevant departments as members) are responsible for the pesticide registration dossier evaluation. In actual practice, the PPD does the evaluation and the TC completes the dossier evaluation where necessary and has a supervisory task. The PPD is also responsible for the administrative organization of pesticide registration in Myanmar.

The PPD is one of the divisions of the Department of Agriculture that is part of the Ministry of Agriculture, Livestock and Irrigation. The PPD is the National Plant Protection Organization (NPPO) in Myanmar and its major tasks are in the field of phytosanitary services, pesticide registration and management (including agricultural extension, i.e. agricultural advisory services to farmers). The PPD is comprised of nine sections, one of which deals with pesticide registration. Of the hundreds of employees of the PPD located at Yangon headquarters and regional bureaus, less than 20 are engaged in pesticide registration. The PPD is the main project partner on the Myanmar side.

2.1.2 Discussion and recommendations

During the project responsibilities of the different bodies in Myanmar dealing with pesticide registration were discussed several times. It was noted that membership of the TC often changed, hampering continuity. Also, TC members from outside the PPD generally do not have sufficient time to review pesticide dossiers in detail. It was therefore recommended to MoALI to ensure that members of the TC are nominated for a prolonged period, to ensure that national technical capacity can be built for pesticide evaluation. In the course of the project the PPD requested the relevant departments to nominate experts for membership of the Technical Committee for a prolonged period. Also, it was recommended that the technical review of pesticides should be included as an official task in the terms of reference of TC members. Furthermore, it was recommended to specify the responsibilities of the different bodies involved in pesticide registration in Myanmar in legislation, i.e.:

- PPD – performs the evaluations
- TC – supervisory task only – formally gives advice on decision to the PRB
- PRB – decision making on whether to allow or refuse registration of a pesticide product.

2.2 Overview of the current process of pesticide registration in Myanmar

2.2.1 Introduction

The scope of pesticide registration is determined by its main objective: to demonstrate that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment under the conditions of use in the country or region (WHO, 2010).

The registration of pesticides involves actions from the applicant as well as the registration authorities, covering the entire range from application to post-registration activities by either entity, and may take considerable time and effort. However, a minimum number of steps will typically have to be taken to ensure that applications are handled effectively and correctly, and that the evaluation is conducted in a standard manner and that decisions are taken in a transparent way.

There are typically four phases: pre-registration, registration, post-registration and review of existing registrations. The overall structure of the process generally follows the chart below (Figure 1), but the exact steps may differ from country to country. This depends, among others, on the legal and administrative organization of pesticide registration in the country, and the human and financial resources available (FAO Pesticide Registration Toolkit; FAO, 2017).

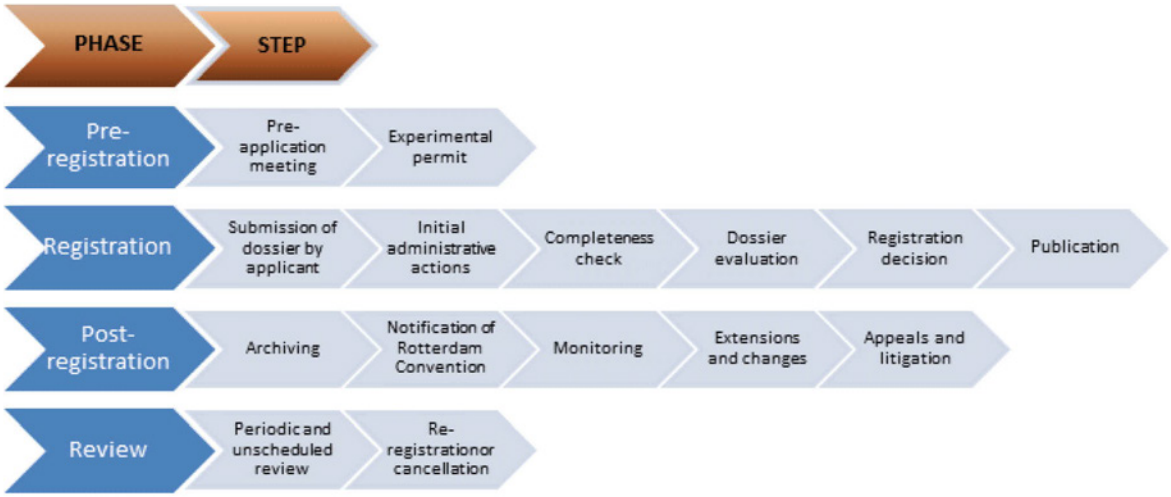

Figure 1 *Steps in the pesticide registration process, from the point of view of the registration authority (taken from the FAO Pesticide Registration Toolkit (FAO, 2017).*

The various steps in the pesticide registration process have been described in more detail in the FAO/WHO Guidelines for the registration of pesticides (WHO, 2010).

2.2.2 Steps taken during the registration phase

In collaboration with the PPD and some members of the TC, FAO mapped the Myanmar pesticide registration process in April 2016. Based on the scheme given in Figure 1 the different steps in the implementation in Myanmar at that time were identified. The result is given in Annex 1. More details on the steps during the 'Registration' phase are described in Peeters *et al.* (2015) and are reproduced in this report for completeness (Note: status at the start of the project in spring 2016).

2.2.2.1 Submission of the dossier by the applicant

The applicant should submit the registration according to the data requirements (which can be downloaded from the website of the PPD: http://www.ppdmyanmar.org/prb.html):

- Completed application form
- Letter of consent from the manufacturers
- Technical supporting document
- Proposed pesticide label incl. translation into Myanmar language
- Formulated product in sufficient amount for carrying out supervised efficacy trials and quality control of the product.
- 25 Grams of technical active ingredient for the Pesticide Analytical Laboratory.

The type of registration is approved by the PRB. The validity period of registration certificates varies with the type of registration (Table 1). Most applications concern provisional registrations.

Table 1

Registration Type	Validity	Development/Marketing Stage
Experimental Registration	2 years	Registration that is permitted for experimental use during two years to determine the efficacy of a pesticide within a specified area, and to determine whether the method of use is suitable for agricultural practice.
Provisional Registration	5 years	Pesticides that have been marketed in the country prior to the enactment of the Pesticide Law and already undergone more practical and detailed bio-efficacy and toxicological evaluation may obtain Provisional Registration and reach marketable stage. Efficacy trails are requested for new active ingredients only.
Full Registration	10 years	If the studies during provisional periods are satisfying, full registration will be granted for use in the respective crop in accordance with the instruction pertaining to the pesticide.
Special use permit	1 year	For emergency use for the specified pesticide to prevent from outbreak of unexpected pests.

2.2.2.2 Initial administrative actions

The pesticide registration team of the PPD under the supervision of the joint-secretary of the PRB (i.e. the director of the PPD) is responsible for the administrative process.

2.2.2.3 Completeness check

The pesticide registration team of the PPD checks whether the dossier is complete; this task is performed under the supervision of the secretary of the PRB (i.e. the director of the PPD).

2.2.2.4 Dossier evaluation

The pesticide laboratory of the PPD will analyse the samples to verify the product quality. In practice the pesticide registration team of the PPD will evaluate the technical documents (internal TC meetings). Next to analytical lab expertise, the PPD expertise consists of pathology, entomology, integrated pest management, weed, pesticide analytical laboratory and rodent control. Only a basic level of expertise is available on human health, residues and environment. Registration decisions considering human health and environment are mainly based on Stockholm (Annexes A and B) and Rotterdam convention (Annex III) and WHO classification 1a and 1b. Only for new active ingredients efficacy trials will be conducted by the PPD together with a governmental research station for limited crop/pest combinations. For example, if a pesticide registration application is made for use on 10 pests for 10 crops, only 2 or 3 crop/pest combinations will be required. For each combination, a series of trials should be carried out in different places with different environmental conditions for at least 2 seasons (6-8 trials for major pest/crop and 2-6 trials for minor use). Based on the analytical results and the findings of the technical committee, an external TC meeting is organized for further review and completing the evaluation. The TC formulates a recommendation for decision making by the PRB.

2.2.2.5 Registration decision

After evaluation of the application for registration of formulated pesticides or active ingredients to be imported into Myanmar, the PRB has the right either to accept or to reject the application. Its decision is based on the recommendation by the TC. The PRB meets about two times per year. Applications can be rejected or postponed because of missing data (analytical data). It is not allowed to apply for registration of a banned pesticide (the list of banned pesticides in Myanmar can be found on the website of the PPD); all other pesticides will be registered. About 3353 pesticide products were registered by May 2017.

Applicants pay the registration fee upon registration of the pesticide. The fee depends on the type of registration.

2.2.2.6 Publication

Decisions are circulated to the relevant departments and the list of pesticides registered in Myanmar can be downloaded from the website of the PPD (http://www.ppdmyanmar.org/prb.html; last entered January 18, 2018).

2.2.2.7 Conclusion

An important finding was that dossier evaluation is done by both the PPD and the TC. The PPD performs the evaluation and the TC completes the evaluation where necessary and has a supervisory task. The TC formulates a recommendation for use in the decision made by the PRB. Time needed for dossier evaluation varies. Evaluation procedures especially on human health, residues and environment are not formalised. The latter means that in practice evaluations are partly based on expert judgement of the registration team of the PPD and the TC members which makes the decision making process less transparent.

2.3 Considerations when changing the process of pesticide registration

2.3.1 Introduction

Agricultural production is often prone to pests and diseases. Reduction of such pests can be achieved through the use of pesticides, marketed by industry. However, the use of any pesticide is bound to introduce risks, both to humans as well as to the environment. Registration of pesticides aims at reducing risks, using a transparent procedure. Registration procedures are devised such that industry provides a sufficient set of data, enabling authorities to evaluate both efficacy and risk, allowing them to decide whether risks are sufficiently low to grant registration. The pesticide is then allowed to be marketed and used. Registration of a pesticide results upon the request of a manufacturer, who is responsible for supplying data needed for evaluation (this is the procedure in most countries with a high registration standard). The registration procedure should preferable be science-based and tailored to the country of intended use and should be transparent to all involved stakeholders such as industry, government, non-governmental organisations and farmers.

As concluded in section 2.2, dossier evaluation is not completely formalised in Myanmar. As a consequence Myanmar specific guidance is not available and thus an evaluation manual (as used by many reputable registration authorities) for pesticide registration does not exist in Myanmar. Currently, evaluations are partly based on expert judgement of the registration team of the PPD and the TC members. Transparency of the reasoning behind a decision is not ensured in this way.

2.3.2 Formalised evaluation methodology for the registration of pesticides in Myanmar

The project described here particularly aimed at formalising dossier evaluation, by developing an evaluation methodology for the registration of pesticides in Myanmar taking the present capacity of the PPD into account as much as possible. The methodology involves a decision support system that

enables registration authorities to make sound and transparent decisions on authorizing or rejecting pesticide products. The system has been designed in such a way that it can be tailored to the capacities of registration authorities in different countries. It consists of a flow chart and a format for an accompanying decision supporting summary. The flowchart includes elements like human health risk assessments, guidance based upon FAO/WHO criteria to identify highly hazardous pesticides (HHPs) and a fast-track evaluation procedure for low risk pesticides. In the project, the different elements of the flow chart were discussed, tested using existing examples and, where necessary, adjusted to the requirements and/or capacity of the PPD.

For the element "risk assessments" in the flow chart it is needed to define protection goals (what to protect, where to protect over what time period). In the framework of the project it is not feasible to develop risk assessment methods for many different protection goals. Therefore, the prioritisation of protection goals was discussed several times (Annex 6). Human health was considered to be the highest priority and therefore risk assessments for consumers (food consumption) and operators and workers (occupational) in the field were developed in the project.

The decision support system and its methods are described in more detail in Chapter 3. Chapter 3 can be regarded as a preliminary evaluation protocol for pesticide registration in Myanmar. It is called a preliminary protocol, because it is envisaged that the PPD will first gain experience in its use for pesticide registration in a follow-up project. Based on this experience the guidance can then be amended/improved, resulting in a final version of the evaluation protocol for pesticide registration in Myanmar (i.e. a handbook/evaluation manual) at the end of the follow-up project.

2.3.3 Pesticide labelling: Good Agricultural Practice (GAP) table

The Table of Intended Uses, or Good Agricultural Practice (GAP) table provides a description of the intended uses of a pesticide when it is submitted for registration. The GAP table is based on the outcome of the efficacy evaluation and should be part of the registration dossier. The GAP table is reviewed by the PPD, and may be amended depending on the evaluation of efficacy and risks.

The GAP table is the basis of the instructions for use on the pesticide label. It is also the starting point for the human health and environmental risk assessments, as it determines to a large extent the levels of exposure resulting from agricultural use.

In the project the format and contents of a GAP table were discussed with the PPD and several TC members. In principle, all information required on a GAP table is requested by the PPD as part of the registration dossier.

A generic format for a Table of Intended Uses or GAP table, proposed for Myanmar, is presented in Annex 2. The format of this GAP table is slightly adapted from the international standard of the Organization for Economic Co-operation and Development (OECD, 2017) and the EU Data requirements for efficacy guidance (SANCO, 2013).

2.3.4 Risk mitigation measures

Risk mitigation measures are applied to ensure that the risks of a pesticide are acceptable under local conditions of use. A pesticide may be registered with or without risk mitigation measures. If such risk mitigation measures are prescribed on the label, pesticide users should in principle comply with them.

However, a number of pre-conditions should generally be met before a risk mitigation measure is likely to be effective under local conditions of use. These include that:

- the measure should have been demonstrated, or should be likely, to be effective in reducing the risk of the pesticide in the local situation;
- the measure should be feasible for the pesticide user (*e.g.* the farmer) and preferably not compromise pesticide product efficacy;
- the measure should be affordable to the pesticide user;
- it should be possible to communicate the measure to the user in a relatively easy and effective way;
- the measure should have a reasonable possibility of enforcement.

Implementation of risk mitigation measures is a shared responsibility of pesticide users, the registrant and regulators. However, the pesticide registration authority has a special responsibility to assess whether a risk mitigation measure, necessary to reduce risk to acceptable levels, can be realistically implemented under local conditions of use. If this is not the case, the registration authority should review whether the pesticide can be registered at all.

During the project a long list of possible risk mitigation measures for the reduction of human health and environmental risks, compiled from other regulators in different parts of the world was presented to the PPD and several TC members. It was evaluated which of these measures could be realistically implemented in Myanmar and under which circumstances. The outcome of this evaluation is summarized in Annex 3.

Participants to the discussion concluded that a few risk mitigation measures can be implemented in Myanmar.

Risk mitigation measures that were considered feasible in Myanmar included:
- refusing the registration of a pesticide;
- encouraging registration to low risk formulation types;
- encouraging registration to low risk packaging;
- requiring precautionary statements on the label;
- prohibiting the cleaning of spray equipment close to water.

Risk mitigation measures that were considered feasible in Myanmar, but only in certain situations, included:
- severely restricting the use of a pesticide;
- requiring Personal Protection Equipment (PPE);
- requiring technical measures (e.g. low drift nozzles);
- restricting the use of the pesticide to no- or low-emission applications (e.g. glasshouses, stores);
- changing the period or timing of the application;
- requiring advance notification of beekeepers;
- requiring bait stations or burrow-baiting for rodenticides.

2.3.5 Requirements for implementing the developed decision support system

In the project, discussions were initiated at different governmental levels on requirements for implementing the developed decision support system. A major issue proved to be the huge number of applications for pesticide registration (~1000/year). This problem and possible solutions (including recommendations for adjusting the pesticide law) were discussed during a stakeholder meeting with representatives of different governmental bodies in February 2018.

Since the Pesticide Registration Board meeting of May 2017 the PPD already received applications for the registration of about 500 pesticide products (status October 2017). It needs to be noted that most of these applications concern provisional registrations (only efficacy trials needed for new active ingredient; registration valid for 5 years). This number of applications will be too high for conducting a proper evaluation of the dossier according to the procedure developed for Myanmar and described in this report (see Chapter 3). It is therefore of the utmost importance that both the PPD, as well as the Pesticide Registration Board acknowledge the need for applying incentives to reduce the number of applications.

Together with the PPD and several members of the TC, possible incentives for reducing the number of applications for pesticide registration were discussed and a summary is given below:
1. Increase the registration fee.
   - Increase of the registration fee may limit the applications for registration to products for which the applicant sees a market.
   - Legal basis exists under the 2016 Pesticides Law.

2. Establish a registration maintenance fee.
   - Establishment of a maintenance fee (e.g. annual) to maintain the registration of a pesticide in the Register, will likely reduce the number of pesticides that are registered; companies that do not sell their product in Myanmar may pull their product off the register.
   - Legal basis does not exist under the 2016 Pesticides Law.

3. Make the registration fee due for payment before the start of the dossier evaluation by the PPD, *i.e.* the fee should be paid when submitting the application.
   - Currently a fee is paid upon a successful registration (so after dossier evaluation and only for products receiving a registration). Paying the application fee simultaneously with the submission of the application may limit the applications for registration to products for which the applicant sees a market.
   - Legal basis does not exist under the 2016 Pesticides Law. The 2016 Pesticide Law (article 14c) states that the registration fee should be payed if the permission of registration is obtained, implying payment only after conclusion of a successful registration.

4. Abolish the provisional registration, or reduce the period of provisional registration to 1 year, or grant provisional registration only once, requiring full registration thereafter.
   - Currently most applications are for provisional registration. Provisional registration is granted for a relatively long period (5 years) and less data is required than for full registration. Setting limits for provisional registration may limit the applications for registration to products for which the applicant sees a real market.
   - Legal basis does not exist under the 2016 Pesticides Law

5. Stricter evaluation of efficacy.
   - For provisional registration, the application does not need to hand in efficacy studies performed in Myanmar (efficacy studies are only needed in case of a new active ingredient). Reports of efficacy studies performed in other countries can be used. The evaluation of these studies can be done in a more strict way, *e.g.* i) by requesting that crops specified in the GAP for Myanmar match the crops used in the efficacy trials, ii) requesting that growth/climatic situations of the efficacy trials match those of Myanmar (*e.g.* efficacy trials from North EU may not be representative for the Myanmar situation). By using stricter requirements for the evaluation of efficacy, the applicant is forced to put more effort into gathering suitable efficacy data. This may limit the applications for registration to products for which the applicant sees a market.

6. Stricter completeness check.
   - It was noticed that pesticide registration dossiers at the PPD do not always contain all data required (data requirements). By being stricter on the completeness check, the applicant is forced to put more effort into fulfilling the data requirements. This may limit the applications for registration to products for which the applicant sees a real market.

7. Stricter consideration of acute toxicity data.
   - Request that the company always delivers toxicity studies for the formulated product ("6-pack" or part of "6-pack").

Alternative for option above:
- The company should provide the "recipe" of the formulated product, enabling extrapolation of active ingredient toxicity data to toxicity for the formulated product. Companies often do not like to provide their "recipe", which is considered to be a part of their intellectual property. Sharing the "recipe" enables production of the same formulated product.

8. At the moment it is common practice in Myanmar that product "b" with active ingredient "x" automatically obtains a registration if there is already a registration in place for a product "a" using the same active ingredient "x".
   - Consider to maintain this rule only for those products for which the formulation is comparable.

As result of a discussion on whether it is a welcome development to have many products with exactly the same active ingredient, in the same concentration and formulation type on the market, the PRB decided to use the following rule: *if there are already more than 50 products with a specific active ingredient, a new product with this active ingredient will not receive a registration for the next three PRB meetings*.

2.4 Risk reduction of Highly Hazardous Pesticides

One of the aims of the project is to take steps in the elimination of high-risk pesticides from the market.

To this end the three-step approach developed by the FAO/WHO for risk reduction of Highly Hazardous Pesticides (HHP) was adopted (FAO, 2017b).

According to the International Code of Conduct on Pesticide Management, HHPs are defined as: *Pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as the World Health Organization (WHO) or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous.*

The FAO/WHO three-step approach for reducing the risks of HHPs comprises: 1) identification of HHPs, 2) assessing the risks, needs and possible alternatives and 3) discuss, adopt and implement risk mitigation measures.

The PPD and WUR conducted an evaluation of > 3000 pesticide products registered in Myanmar by May 2017 with the objective to identify Highly Hazardous Pesticides (HHPs) (Step 1). The pesticide products were assessed using the guidance based on FAO/WHO criteria to identify HPPs.

Detailed guidance (a 'cookbook') was developed by the WUR for conducting the HHP scan for Myanmar, using the spreadsheet available in the FAO Toolkit (FAO, 2017b) for documentation of the HHP assessment. More details on the method for identification of HHPs is given in Chapter 3.

Results of the HHP scan were presented to the PPD and several members of the TC. A total of 181 pesticide products were identified as HHPs (5.5% of the total number of registered products). These contain 19 different active ingredients (*Table 2*).

In Table 2 several reasons are given for identifying a pesticide products as a HHP: i.e.
- Pesticide active ingredients and formulation by the Rotterdam Convention in its Annex III
- Pesticide active ingredients and their formulations that meet the criteria of carcinogenicity, mutagenicity & reproductive toxicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (indicated in Table 2 as respectively carc 1A/1B, muta 1A/1B and repr 1A/1B).
- Pesticide formulations that meet the criteria of Classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard.
- Pesticide active ingredients meeting the criteria on persistence, bioaccumulation and toxicity given in paragraph 1 of the Stockholm Convention (indicated in Table 2 as PBT).

Table 2 *Results of the HHP scan for pesticide products registered in Myanmar by May 2017.*

Active ingredient(s) of HHP	Why considered to be a HHP?	Number of products
carbendazim (F)	muta 1A/1B, repr 1A/1B,	78
carbofuran (I[1])	Rotterdam Annex III, WHO 1a/1b (≥48% formulation)	44
benomyl (F[2])	muta 1A/1B, repr 1A/1B	20
aluminium phosphate (I)	WHO Ia/Ib (≥56% formulation - Tablets)	14
brodifacoum (R[3])	repr 1A/1B, WHO 1a/1b (≥2.5% formulation)	2
bromadiolone (R)	repr 1A/1B	4
glufosinate-ammonium (H[4])	repr 1A/1B	3
trichlorfon (I)	Rotterdam Annex III	3
diafenthiuron (I, A[5])	PBT (Persistent, Bioaccumulative and Toxic)	2
terbufos (I, N[6])	WHO Ia/Ib (10% GR)	2
borax decahydrate (I, F, H)	repr 1A/1B	1
tridemorph (F)	repr 1A/1B	1
hydramethylnon (I (HH[7]))	repr 1A/1B	1
metaflumizone (I)	PBT (Persistent, Bioaccumulative and Toxic)	1
mineral oil (I,A)	carc. 1A/1B	1
triflumizole (F)	repr 1A/1B	1
boric acid (I)	repr 1A/1B	1
magnesium phosphide (R, I)	WHO Ia/Ib (≥56% formulation)	1
methamidophos + cypermethrin(I)	Rotterdam Annex III (methamidophos)	1

The International Code of Conduct stipulates that: *Prohibition of the importation, distribution, sale and purchase of highly hazardous pesticides may be considered if, based on risk assessment, risk mitigation measures or good marketing practices are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment.*

After establishing the short-list of HHPs, further assessment of risks, needs and alternatives should be conducted for all identified HHPs (Step 2), and risk mitigation measures should be discussed, adopted and implemented (Step 3).

It was concluded that a further review of the short-list of HHPs needs to be conducted by the PPD and WUR in a follow-up phase of the project. This review should in particular assess:

- The present use and future needs of the pesticides
- Available alternatives, both less hazardous pesticides as well as non-chemical control options (e.g. biological control, IPM)
- Risks associated with the use of the HHPs under local conditions of use

Based on this review, the Pesticide Registration Board can decide on which risk mitigation options to apply for the HHPs, to reduce their risks to acceptable levels (note that the results of the discussion of risk mitigation options feasible in Myanmar described in section 2.3.4 might be used as input). These may include the cancellation of registration of these pesticides, restriction of their uses, or other risk reduction measures. A decision making scheme for reducing risks of those HHPs that are on the HHP short list to acceptable levels was drafted and discussed with the PPD and several members of the TC (Figure 2).

[1] I: insecticide
[2] F: fungicide
[3] R: rodenticide
[4] H: herbicide
[5] A: acaricide
[6] N: nematicide
[7] HH: household

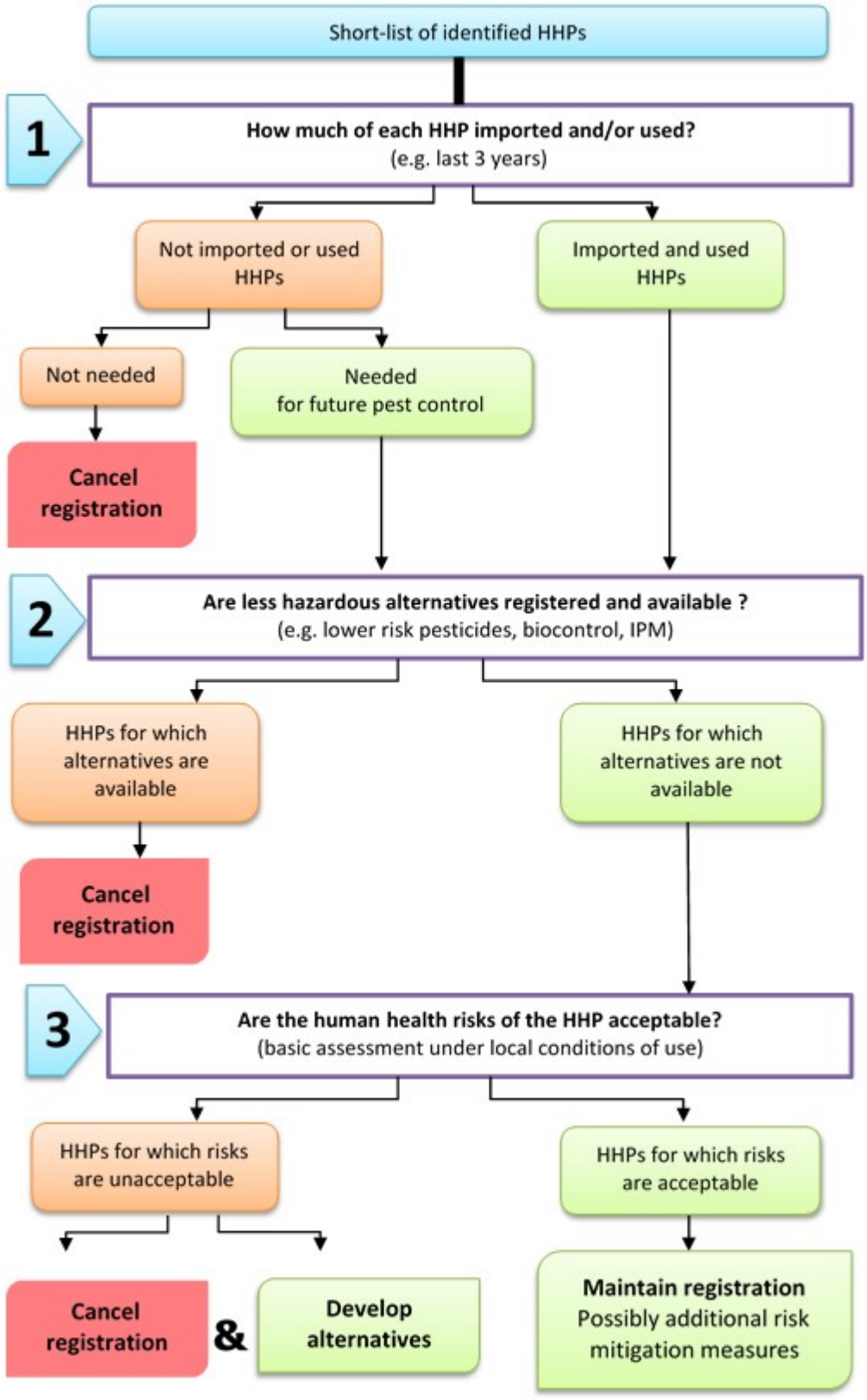

Figure 2 *Decision making scheme for reducing risks of HHPs on the HHP short list to acceptable levels by the cancellation of registration of these pesticides, restriction of their uses or other risk reduction measures.*

2.5 Legislation

As part of the project, the Myanmar Pesticide Law (version: The Pyidaungsu Hluttaw Law No. 14, 2016 The 11th Waxing of Pyatho, 1377 M.E. 20th January, 2016) was reviewed by the project in autumn of 2017. At that point the secondary law (Regulation of Ministerial Decision) was not translated into English and could not be reviewed.

A summary of the review is given below. Detailed comments and recommendations on the Pesticide Law resulting from the review performed as part of the project are given in Table 3.

Overall, the Law has many good provisions that will allow Myanmar to properly regulate pesticides in Myanmar.

At the same time, however, there are certain activities/aspects of pesticide management that are not regulated at all by the Law. These are:

- Storage
- Transport
- Disposal of obsolete pesticides
- Empty container management
- Advertising

It is recommended to check if these activities/aspects are regulated elsewhere. Labelling is not addressed in the 2016 Pesticide Law but is covered by the Regulation (source PPD).

With respect to the pesticide registration process, the project made some remarks and suggestions on how to make this process more effective; there are a number of gaps in the text of the law that could be misused by applicants.

Recommendations and outlook

The English version of the 2016 Myanmar Pesticide Law is at the time of writing of this report (February-March 2018) at the attorneys office for approval and is expected to be concluded within three months. However, the PPD is of the opinion that it is useful to start a process for improving this 2016 Pesticide Law.

If this process is not started, it is recommended that much care is taken in the elaboration of the Regulation. It may be possible to cover a number of gaps in the Law by carefully addressing them in the Regulation (but it is always a legal difficulty to include new activities in the Regulation which were not regulated in the Law – unless the Law allows this).

Given that considerable effort is needed to update the law to regulate the aspects/activities specified and that a review of the secondary law (Regulation) it is recommended as a next step to contact development partners experienced in pesticide legislation. At the end of 2017 discussions were started with the FAO and KemI (the Swedish Chemical Agency), to investigate whether there would be scope for legal support to develop the Myanmar pesticide legislation in consultation with these development partners. In February 2018 representatives of PPD, FAO, KemI and WUR met to discuss legal support. KemI indicated that they can make resources available to assist the PPD, with help of the FAO, to make amendments and improvements to the Pesticide law and the regulations. To this aim it was agreed that the PPD will send an official request for legal assistance to the FAO.

Table 3 *Results of the review of the Myanmar Pesticide Law (version: The Pyidaungsu Hluttaw Law No. 14, 2016 The 11th Waxing of Pyatho, 1377 M.E. 20th January, 2016).*

Myanmar Pesticide Law	Recommendation/comment
Chapter I, article 2	Consider to use the Code of Conduct definition as much as possible, because they are internationally accepted. E.g. for pest, pesticide, active ingredient, label, etc.
Chapter I, article 2 (h)	Five years is quite a long period for provisional registration. In particular since the Law does not specify when a provisional registration is allowed instead of a full registration. In order to lower the number of applications for registration, it is recommended to shorten the period for provisional registration or to abolish provisional registration.
Chapter I, article 2 (j)	There is no provision for "restricted use" pesticides in the law. That would be very useful if you would like to restrict the use of a product to certain (licensed) users or specific use situations (e.g. for Highly Hazardous Pesticides; HHPs). Consider to include this in the Regulation, as a "subcategory" of a full/special use registration.
Chapter I, article 2 (r)	Typo: Licen**c**e should be Licen**s**e
Chapter II, article 3 (b)	A fixed period for appointment of Board members (e.g. 4 years) is not specified. This is the case in many countries. Consider to specify a fixed period for appointment of Board members.
Chapter III, article 6	It seems that the only requirements to obtain a registration certificate are i) the correct concentration of the active ingredient, and ii) acceptable efficacy. That is very limited and does not take into account the health and environmental risks or the quality of the pesticide product (formulation) It is recommended to add requirements on risks for human health and environment and requirements on the quality of the pesticide product.
Chapter III, article 7	Is this only for already registered pesticides, or can the PRB also refuse the registration of a new application? It would be logical that a registration can be refused if the pesticide poses a high risk. It is recommended to add requirements on risks for human health and environment for both pesticides that are already registered as pesticides for which a registration is asked (new applications).
Chapter III, article 11	In most countries, only part of the data are confidential business data (CBI), mostly information about the manufacturing process and specifications of the pesticide. But data on human health and environmental risks, or the identity of the product, are never confidential! In principle the Law should distinguish between: Confidential business information (never to be made public) And Exclusive use of data: this means that the data can be public, but they can only be used by the owner of the data to support an application for registration; they cannot be used by other applicants (e.g. competitors) Consider to change the law on this issue.
Chapter III, article 9	Text in English of this article is not very clear; especially 'systematic destruction' and 'systematic disposal' Please consider to improve this.
Chapter IV, article 13	In this article registration is linked to the import of pesticides only. However, it should be linked to the distribution, sales and use in the country. The law should ensure that a locally formulated pesticide should also be registered. Consider to change the article text such that the registration is linked to the distribution, sales and use in Myanmar.

Myanmar Pesticide Law	Recommendation/comment
Chapter IV, article 14 (a)	These are very limited data requirements (much less than you already require in Myanmar). It is not necessary to specify all the details in the Pesticide Law, but then it is necessary that the Regulation of Ministerial Decision specifies in detail the data required for an application.
Chapter IV, article 14 (c)	Paying the registration fee after successful registration is not a good system. Now there is no incentive for the applicant to provide a good application/dossier; PPD staff may have a lot of extra work on their hands for completing the dossiers. It is our recommendation to modify the text of this article such that applicants should always pay the registration fee, even if they do not get a registration.
Chapter IV, article 16 (reference to Chapter IV, article 14 (a))	It is strange that the requirements for export are the same as the requirements for local registration! E.g. why ask for instruction for use, if the product is not used in Myanmar but exported? The same applies to the methods of analysis.
Chapter V, article 17 (d)	The impression is given that a license is not needed to import pesticides into Myanmar. This is highly relevant for Myanmar since almost all the pesticides used in Myanmar are imported. Improving the law on this point would provide additional legal means to the government to regulate the import (and use) of pesticides through the importers. The impression is given that a license is not needed for disposal of pesticides or for storage/transport of (large quantities) of pesticides. Please check whether this is regulated under the environment legislation. If not consider to improve the Pesticide Law on this point.
Chapter V, article 17 (f)	Text in English of this article is not very clear. Please consider to improve this.
Chapter VIII	Typo in title of chapter: Registra**r** should be Registra**nt**.
Chapter VIII	Many countries specify in law that manufactures have a legal representative in their country. Who else to give a fine/sue if a pesticide product does not comply with the requirements? An article specifying this is missing in Chapter VIII. Consider to add an article on this.
Chapter VIII, article 23 (a)	Text in English of this article is not very clear. Please consider to improve this.
Chapter VIII, article 24 (d)	Text in English of this article is not very clear. Please consider to improve this.
Chapter VIII, article 24 (h)	Text in English of this article is not very clear. Please consider to improve this.
Chapter XIV	Consider to include the following text as article 32: *'No one shall distribute, sell or use a pesticide that has not been registered according to the provisions of this Law.'*
Chapter XVI, article 45	Text in English of this article is not very clear. Please consider to improve this.

2.6 Linkage to agricultural advisory services

Parallel to the project on pesticide registration and pesticide risk reduction, Wageningen University & Research (Wageningen Plant Research) collaborates in a project with the PPD on improving the agricultural extension services of the PPD, and in Myanmar in general. Where relevant, proper linkage is sought between the results of both projects.

In the project on improving agricultural advisory services, training modules addressing improved crop varieties, quality seeds, nursery systems, crop protection, crop nutrition and integrated crop management are developed. Judicious pesticide use and thus selecting favourable pesticides (*i.e.* pesticides that are on the market and that do control a certain pest/disease and are associated with less hazards for human health and environment and/or fit into a resistance strategy compared to other candidates) is part of the Integrated Pest Management (IPM) approach. To this end WUR developed a decision support system: the Pesticide Selection Tool (PST). The PST contains a database of all pesticide products in Myanmar registered by May 2017. The tool can be used by advisory officers and/or farmers and will assist them to select the most favourable pesticide on the market.

Linkage between the work of the pesticide registration project and the projects on improving agricultural extension services is achieved through the use of the PST. Linkage is important considering the HHPs. Next to risk reduction of the use of HHPs through measures like cancellation of registration of these pesticides, restriction of their uses or other, pesticide label specified, risk reduction measures (PRB decisions), the risks of the use of HHPs can also be reduced via extension services. Through agricultural advisory, farmers can be stimulated to avoid the use of HHPs and instead use less hazardous pesticides or other alternatives that are part of integrated crop management (like good strategies on crop nutrition or water management). As the PST is a key tool in the PPD-WUR projects on improving advisory services to farmers, it was decided, as a first step, to explicitly label HHPs in the database of the PST for Myanmar.

In the second phase of the project the HHP risk reduction process will continue with further assessment of risks, needs and alternatives. Experts of the PPD-WUR projects on improving advisory services to farmers will be involved in the development of alternatives for the HHPs (other pesticides and/or Integrated Pest Management strategies). In this way alternatives developed will become part of the advisory services to farmers.

2.7 Communication with stakeholders

The first occasion to meet and discuss with stakeholders was during a Netherlands – Myanmar Vegetables information session in Yangon on February 16th, 2016. The intention of the meeting was to provide the stakeholders with the latest information about new and on-going vegetable related Dutch projects in Myanmar. Furthermore, the occasion was also used to share information on each-others projects and initiatives to inspire and, where applicable, to avoid duplication of activities. The meeting was organised by the Embassy of the Kingdom of the Netherlands in Myanmar. Stakeholders from industry (pesticide and seed companies), other development donors (Mercy Corps, GIZ, CABI), Myanmar government (MoALI, Ministry of Commerce) and research (WUR, ACIAR, New Zealand Plant & Food Research) were present.

The Government of the Netherlands contributes to the development of the Myanmar vegetable sector through several parallel initiatives. It supports the international competitiveness by a further development of the resilience and sustainability of the sector. Also the public sector is supported through capacity-building at particularly, although not exclusively, the Plant Protection Division to bring the regulatory systems and capacities for phytosanitary services more in line with SPS and IPPC-standards and in general by investing in pesticide managerial skills.

The second occasion to inform and discuss with stakeholders was in February 2018. Two stakeholder meetings were organised by WUR, the PPD and the Embassy of the Kingdom of the Netherlands in

Myanmar. One meeting was organised for the members of the Pesticide Registration Board (PRB) and Technical Committee members in Nay Pyi Taw on February 5th, 2018. A second meeting was organized for all other stakeholders in Yangon on February 7th, 2018. The meetings aimed to present the work, results and future initiatives of the project and get feedback on requirements for implementing the developed decision support system and the work done on and further plans for the risk reduction process of Highly Hazardous Pesticides.

In Nay Pyi Taw next to relevant staff from the PPD, representatives of the following Myanmar governmental bodies attended the meeting: Department of Agricultural Research, Forest Research Institute, Livestock Breeding and Veterinary Department (LVBD), Department of Trade, Department of Health of the Yangon City Development Committee, OEHD Department of Public Health MOHS, Food and Drug Administration (FDA), Department of Consumer Affairs (DOCA), Environmental Conservation Department. In total 20 participants attended the meeting in Nay Pyi Taw. In the Nay Pyi Taw meeting the discussion focussed on measures for reducing the number of applications for pesticide registration (i.e. the measures discussed in section 2.3.5 of this report). Details of the discussion are provided in Annex 4. Most measures were found to be effective for lowering the number of applications of pesticide registrations and are generally supported, although for some options amendment of the Pesticide Law will be needed. The option for a stricter completeness check is currently under discussion in the PRB. A stricter evaluation of efficacy for provisional registration will not be feasible according several participants, because of a lack of human resources at the PPD. Generally there were concerns that implementation of some of the options lead to higher prices for pesticide products and lower availability of some cost-effective products. There is anxiety that this might consequently lead to an increase of illegal products in the country. An important recommendation was that the results of the discussion on options to reduce the number of applications for pesticide registration should be taken forward to the higher (ministry) level.

The Yangon meeting was attended by forty-eight participants. Next to relevant staff of the PPD, the following Myanmar governmental bodies were represented: Department of Agriculture, OEHD Department of Health, Department of Medical Research and National Health Laboratory. Furthermore, representatives of the private sector (pesticide producers, distributers, import- export agricultural commodities, consultancy agencies) attended the meeting as well as a few network organisations (Agriterra, Myanmar Agricultural Network) and the following development partners: GIZ, JICA, KemI (Swedisch Chemical Agency), CABI and FAO.

The discussion focussed on two issues: 1) risk reduction of Highly Hazardous Pesticides and 2) current registration practices in Myanmar and the newly developed evaluation methodology. Participants were divided into four breakout groups and asked to discuss along several questions related to one of the two issues. In each group a rapporteur took notes and presented a summary of the groups' discussion to all participants of the meeting.

Two groups were asked to give their feedback on the plans for risk reduction of Highly Hazardous Pesticides. In particular on Step 2 of the risk reduction plan because in this step the input of the different stakeholders could be valuable. Step 2 in the development of the risk reduction plan of each individual HHP product is i) to assess of risks of the product identified as HHP in Step 1 and ii) to assess to what extent current uses of the product are actually needed and whether alternatives are available (this is also referred to as needs and alternatives assessment).

The other two break-out groups focussed on discussing current registration practices in Myanmar and the newly developed evaluation methodology. Details of the results of both discussions are provided in Annex 4. A summary of the recommendations and remarks made by the participants is given below.

The following recommendations and remarks were made by the participants of the meeting in Yangon.

- The decision making flow chart and its complementary decision making summary is in principle applicable to pesticide registration in Myanmar. However, the PPD needs to practice more to get enough experience and confidence to apply the flow chart successfully.
- Data protection is an issue in Myanmar. Data protection cannot be guaranteed and this is a major constraint for companies to apply for registration of newer products.

  - Data protection by the PPD (filing of dossiers)
  - Data protection should be anchored in the law
- If the HHP risk reduction process leads to cancellation of registration of some products, alternatives are needed. These can be mixture products (several active ingredients in one product). At the moment the Pesticide Registration Board uses a rule that if there are already more than 50 products with a specific active ingredient, a new product with this active ingredient will not receive a registration for the next three PRB meetings. This rule might become counterproductive if you need new mixture products on the market to serve as alternatives for HHPs banned.
- Provisions are needed in the Pesticide Law, to base a registration decision on the outcome of risk assessments.
- Discussion on counterfeit products/illegal products – What if the new evaluation methodology and/or HHP risk reduction process lead to higher prices for pesticide products and lower availability of some cost-effective products? There is anxiety that this might consequently lead to an increase of illegal products in the country.
- Myanmar needs laboratories with well-trained staff to test the quality of pesticide products and to measure pesticide residues.

3 Preliminary protocol for pesticide registration evaluation

3.1 Introduction

To improve transparency and take a first step to bring the registration procedures in Myanmar in line with international standards, Wageningen University and Research (WUR) and the Plant Protection Division of the MoALI (PPD) developed an evaluation methodology for the registration of pesticides in Myanmar. The basis for the methodology is a decision supporting flow chart and the accompanying decision supporting summary.

This support scheme fits in the pesticide registration procedure at the 'dossier evaluation' step.

The flow chart considers several assessment elements, including efficacy, human health risks and identification of low risk and highly hazardous pesticides. The flow chart guides the registrar through various pathways along which a pesticide may be registered, and which result in different registration advices (captured in the decision supporting summary) that are handed over to the Pesticide Registration Board (PRB) for consideration.

3.2 Decision supporting flow chart for pesticide registration and the accompanying decision supporting summary

3.2.1 Decision supporting flow chart

WUR and the PPD jointly developed a decision support system that enables registration authorities to make sound and transparent decisions on authorizing or rejecting pesticide products. The system consists of a decision supporting flow chart and a format for an accompanying decision supporting summary.

In this section the flow chart is explained (Figure 3; more detailed notes about each of the steps in the flow chart are provided in Annex 5). The aim was to design a flow chart in such a way that it can be tailored to the needs and capacities of registration authorities in different countries. The guidance developed for the different elements in the flow chart and described in this report is however tailored to the situation in Myanmar.

The use of the flow chart assumes that the pesticide has passed efficacy testing, and that one or more agricultural uses have been established in a table of intended uses, or GAP (Good Agricultural Practice) table. See sections 2.3.3 and 3.3 for more details.

The decision support includes pathways for quickly identifying low risk pesticides (box [3] in Figure 3) and highly hazardous pesticides (box [5] in Figure 3); i.e. so called "fast-track" evaluations. For low risk pesticides the advice to the PRB would be to authorise them without further in-depth evaluation. For highly hazardous pesticides (HHPs) it is advised to the PRB not to authorise them or to authorise them only for restricted use, IF there is an emergency need for the pesticide (box [6] in Figure 3) AND if no appropriate alternatives are available (box [7] in Figure 3). Note that the element of 'conduct a hazard classification' (box [4] in Figure 3) was added to ensure that the flow chart was in line with the format of the complementary decision supporting summary (section 3.2.2).

Furthermore, for the remaining products (*i.e.*, not low risk or HHP) assessment methods at different levels of complexity are available. Basic evaluation approaches are included in the decision support system, ensuring that assessments can be done with limited resources. These evaluation approaches use

basic assumptions and information which results in a, from a regulatory point of view, conservative estimate of the risk. It was decided to use the FAO methodology 'Registration by Analogy' (box [9] in Figure 3) as the basic assessment that can be used by registration authorities with limited resources.

If the pesticide product is not registered in a country with a reputable registration system, the 'Registration by Analogy' method cannot be used (box [8] in Figure 3). Also, the conclusion of the 'Registration by Analogy' method may be that risks are likely to be higher than in a country with a reputable registration system (*i.e.* reference countries; box [10] in Figure 3). For these situations the registration authority can decide to perform more in-depth risk assessments (box [11] in Figure 3). These risk assessment use more complex methods, with a higher level of reality and will lead to more accurate estimates of risks associated with pesticide use. If in such a case the registration authority does not have the resources/capacity to perform more in-depth risk assessment, it might consider not to authorise the pesticide product.

The more in-depth risk assessments consist of a human health risk assessment and an environmental risk assessment. If risks to human health and/or the environment under the conditions of use in the country or region are considered unacceptable, a pesticide will not be registered.

What risks are considered (un)acceptable is defined in the national legal framework. The priority of protection goals may vary between countries, depending on local conditions and national policy and regulations. Protection goals define what needs to be protected from the potential adverse effects of a pesticide (*e.g.* which species; what type of person; which component of the environment, where to protect and how strict – no risks at all or 90% protected).

Preferably risk assessments should be location specific, *i.e*. based on location specific exposure and effect assessments. Exposure (occupational and environmental) is influenced by local conditions like climate, soil type, crops, geology, hydrology, agricultural practices and other factors. Dietary exposure assessments need local food consumption data. Part of the effect assessment is based on outcomes of toxicity testing. Human health toxicity data determined in one country (*e.g*. a resource rich country in the northern hemisphere) can be used in another country (*e.g*. a resource poor country in the southern hemisphere). However, this might not be the case for ecotoxicity studies. For instance, Myanmar may have aquatic species that are more sensitive to a particular pesticide than the test species used in the dossier prepared for the reference country.

Developing location specific environmental risk assessments is time consuming and costly and preferably involves high resolution spatial and temporal data. Moreover, performing these risk assessments is time consuming, data-intensive and requires specialized expertise.

Within the constraints of the project and considering the capacity of the PPD it was decided to develop only risk assessments for consumers (dietary) and operators and workers in the field (*i.e.* the top three prioritised protection goals; see Annex 6). As a next step and when more resources become available for developing location specific environmental risk assessments, PPD staff resources increase, and (access to) scientific capacity is improved, environmental risk assessments methodologies may be developed and included in the evaluation of pesticide registration dossiers. Alternatively, environmental risk assessment methodology development might be taken up at a regional level (e.g. ASEAN; Association of Southeast Asian Nations).

A complete assessment of the pesticide risk in theory comprises the evaluation of its risks to human health and the environment, the value of the pesticide (i.e. sustainability assessment: box [13] in Figure 3), as well as possible alternatives (box [14] in Figure 3). 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 it may have high value. Risks and values could be also assessed against existing or possible alternatives, with the aim to decide the need for registration of the pesticide (FAO Pesticide Toolkit; FAO, 2017). For Myanmar the elements 'sustainability assessment' and an assessment on alternatives are not applied.

Elements in the flowchart that are at present not feasible in Myanmar are: location specific environmental risk assessments, sustainability assessment and an assessment on alternatives.

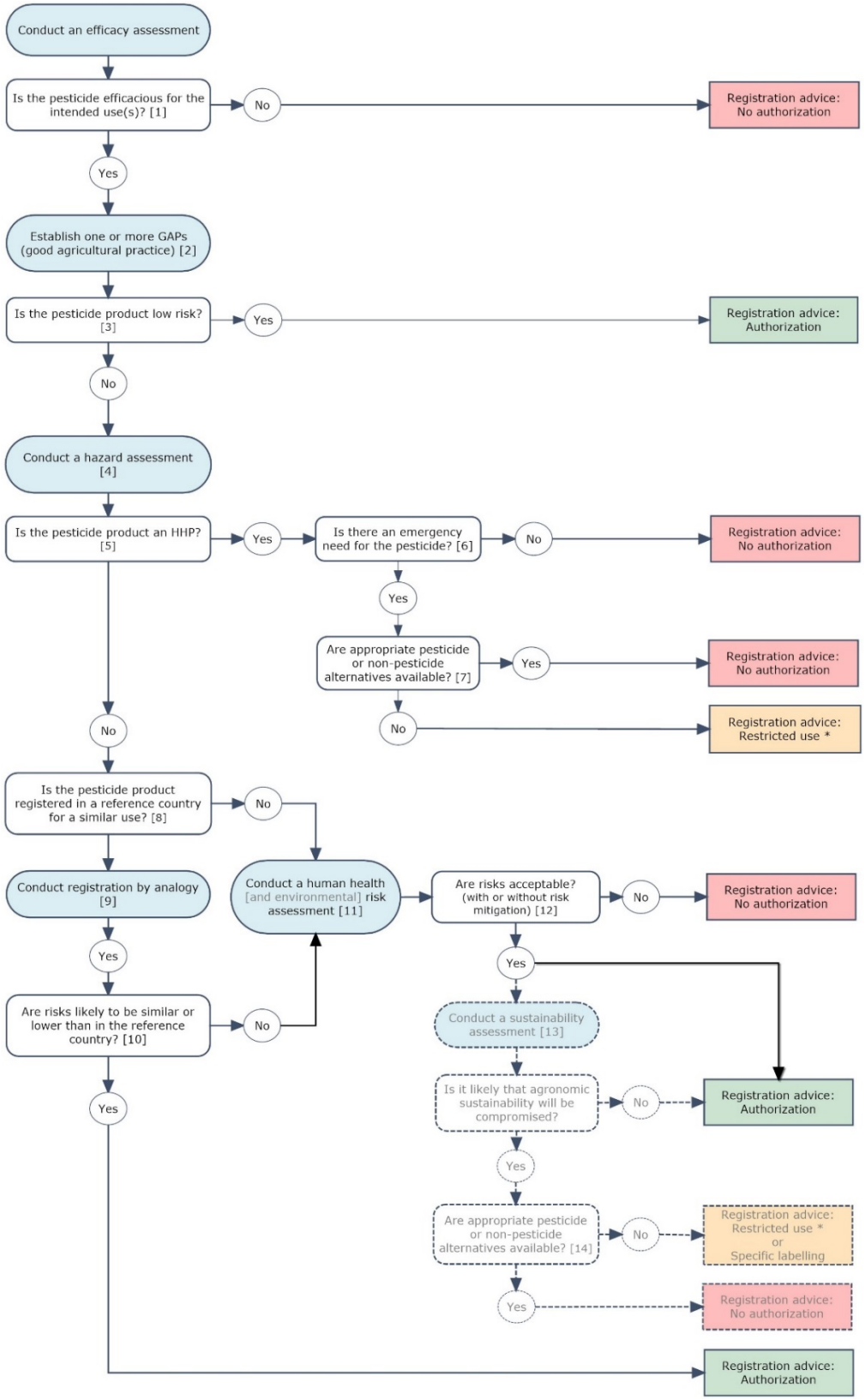

Figure 3 *Decision supporting flow chart for pesticide registration in Myanmar (v. 6 October 2017). Elements in the flowchart of Figure 3 that are at present not feasible for the pesticide registration process in Myanmar are indicated by text in grey, or by dashed lines for flow chart symbols.*
** Registration for restricted use is not yet included in the Myanmar legislation, but was proposed by the project to be included.*

3.2.2 Decision supporting summary

As part of the dossier evaluation step in the registration procedure, the PPD prepares a summary of chemical, toxicological and environmental information for each new active ingredient that has to be reviewed by the Pesticide Registration Board (PRB). This summary is partly based on information in the registration dossier and partly on publicly available data (mainly endpoints from the Pesticide Manual or an internet database). In addition, basic information about each pesticide product to be evaluated is provided to the PRB in the format of a table.

While such summaries provide useful data for the PRB on the pesticides they need to evaluate, they do not give any outcomes of efficacy or risk assessments conducted by the PPD or the TC. Thus, the guidance that is provided to the PRB to take a decision whether to authorize the use of a pesticide for use in Myanmar should be extended at this point.

A decision supporting summary was therefore developed together with the PPD which contains relevant endpoints on efficacy, toxicity and environmental effects, as well as outcomes of classifications and assessments performed for the pesticide. A requirement was that the summary is concise (2-3 pages), provides key elements of importance for decision making by the PRB, and adheres to the decision supporting flow chart of Figure 3.

The format of the decision supporting summary is shown in Annex 7.

3.3 Efficacy assessment and GAP table

The PPD already had procedures in place for assessing efficacy. On the basis of the efficacy data one or more GAPs (Good Agricultural Practice) should be established (box [2] in Figure 3). For each crop/pest combination, a GAP should be established. These are summarized in a GAP table. The use of GAP tables as part of the registration procedure is common e.g. European countries. A GAP table consolidates the intended uses and is the basis for the further risk assessments done by the registration authorities. In the project the format and contents of a GAP table were discussed with the PPD and several TC members (section 2.3.3) and a generic format for a Table of Intended Uses or GAP table, proposed for Myanmar, is presented in Annex 2.

3.4 Identification of low risk pesticides

3.4.1 Introduction

If a pesticide is "low risk", it is not expected to pose human health or environmental risks even under relatively high exposure situations. Low risk pesticides include many microbial pest control products, pheromones, but also some chemical pesticides.

For low risk pesticides, in principle, no further risk assessment is required and these products may be registered.

Two sources are presently used to verify whether a pesticide active ingredient has been identified as low risk:
- EU Pesticide Database (EU, 2017; see list of references for link to website);
- US-EPA list of "minimum risk pesticides" (EPA, 2017; see list of references for link to website).

The EU is currently working on a guidance document which aims at specifying new criteria for the approval of low-risk active substances and which will also provide guidance for implementation of those criteria in the approval of active substances as "low-risk active substances". The latest draft of this EU guidance document was assessed by the project and it was concluded that the proposed guidance is too elaborated and complicated for implementation in Myanmar. It was therefore recommended that the PPD checks the lists of low risk pesticides from the EU and the US-EPA. The two lists are described in more detail in Annex 8.

3.4.2 Decision making on low risk pesticides

Pesticide products are considered low-risk if all active ingredients they contain are considered low-risk according to either the EU or the US-EPA list.

3.5 Hazard assessment

3.5.1 Introduction

A hazard assessment is conducted as a first step to evaluate the potential risks of a pesticide. A hazard assessment differs from a risk assessment, since only toxicity/effects information is considered without taking into consideration the level of exposure that may occur. At present, this assessment focusses on human health hazards.

Highly hazardous pesticides (HHPs) are expected to cause unacceptable risks under most, if not all, use situations in the country. Therefore, in principle, HHPs should not be registered, unless: i.) there is an emergency need for the product and, ii.) no alternatives are available.

The identification of HHPs for Myanmar is performed in two distinctive and separate steps, which partly overlap in the criteria they use. The first step (which includes the WHO Classification of Pesticides by Hazard, and classification according to the Globally Harmonised System of Classification and Labelling of Chemicals, GHS) is performed with the purpose of labelling the product accurately. These classifications (WHO and GHS) are therefore discussed first, in section 3.5.2. More information on labelling of pesticide products in Myanmar can be found in the 'Guideline for Pesticide Labelling' on the PPD website (PPD, 2017, for a link to the website see list of references).

The second step in the identification of HHPs, which is performed in the context of the decision supporting procedure for registration of pesticides, is more elaborate. Section 3.5.3 gives practical guidance on the procedure for identification of Highly Hazardous Pesticides in the context of the decision supporting procedure and summary.

Part of the text in the following sections was taken from Deneer *et al.* (2014).

3.5.2 Hazard assessment for labelling purposes

For labelling purposes, the pesticide is classified according to two different schemes: both the WHO classification of pesticides by hazard, and the Globally Harmonised System of Classification and Labelling of Chemicals, GHS, result in a classification indicating whether (and which) hazards may be attributed to a given pesticide. Details of these classification schemes are given in sections 3.5.2.1 and 3.5.2.2 respectively.

3.5.2.1 WHO classification of pesticides by hazard

The pesticide formulation is classified according to the latest version of the *WHO Classification of pesticides by hazard* (WHO, 2017).

In the decision supporting summary the regulator should indicate the WHO class according to Table 4 (WHO, 2010). WHO uses the Acute Toxicity Hazard Categories from the GHS as the starting point for classification.

It is highly desirable that, whenever practicable, toxicological data for each formulation should be made available by the manufacturer. However, if such data are not obtainable, the classification may be based on proportionate calculations from the LD50 values of the technical ingredient or ingredients, according to the following formula:

LD50 formulation = (LD50 active ingredient×100) / Percentage of active ingredient in formulation Eq. 1

LD50 is the dose required to kill half the members of a tested population.

Table 4 *WHO-Classification Scheme*

WHO class		LD50 for the rat (mg/kg body weight)	
		Oral	Dermal
Ia	Extremely hazardous	< 5	< 50
Ib	Highly hazardous	5-50	50-200
II	Moderately hazardous	50-2000	200-2000
III	Slightly hazardous	2000 - 5000	2000 - 5000
U	Unlikely to present acute hazard	> 5000	

3.5.2.2 Globally harmonized system of classification and labelling of chemicals (GHS)

The pesticide active ingredient is also classified according to the latest revision of the *Globally harmonized system of classification and labelling of chemicals* (GHS, Part 3 - Health hazards) (UNECE, 2017).
The regulator should specify the GHS health hazard classification of the pesticide active ingredient in the decision supporting summary (Annex 7).

Skin irritation:
The hazard statement "**H315**: Causes skin irritation" is assigned, however, no use of additional personal protective equipment (PPE) is recommended.

Eye irritation (reversible effects):
The hazard statement "**H319**: Causes serious eye irritation" is assigned, however, no additional PPE are recommended.

Skin corrosion:
The hazard statement "**H314** Causes severe skin burns and eye damage" is assigned, additional PPE are recommended: Wear protective gloves/protective clothing and eye protection/face protection.

Eye damage (irreversible effects):
The hazard statement "**H318**: Causes serious eye damage" is assigned, additional PPE are recommended: Wear eye protection.

Skin sensitisation:
The hazard statement "**H317**: May cause an allergic skin reaction" is assigned, additional PPE are recommended: Wear protective gloves/protective clothing.

Pesticide active ingredients and their formulations that meet the criteria of **carcinogenicity, mutagenicity & reproductive toxicity** Categories 1A and 1B of the GHS (the CMR criteria) are classified as a Highly Hazardous Pesticide (HHP).

The hazard statement "**H350**" is assigned to **carcinogenicity** Category 1A (Substances known to have carcinogenic potential for humans; the placing of a substance is largely based on human evidence) or Category 1B (Substances presumed to have carcinogenic potential for humans; the placing of a substance is largely based on animal evidence)

The hazard statement "**H340**" is assigned to **mutagenicity** Category 1A (Substances known to induce heritable mutations in germ cells of humans) or Category 1B (Substances which should be regarded as if they induce heritable mutations in the germ cells of humans)

The hazard statement "**H360**" is assigned **reproductive toxicity** Category 1A (Known human reproductive toxicant) or Category 1B (Presumed human reproductive toxicant)

For the CMR criteria, pesticide formulations are classified based on their active ingredient(s), irrespective of its concentration. However, very diluted formulations, with A.I. concentrations < 0.1%, do not need to be classified for CMR. This is rarely the case for pesticides, but may occur for certain rodenticide formulations or aerosols.

The GHS does not classify individual chemicals; this has to be done by national or regional regulatory authorities on the basis of the GHS criteria. To assess whether a pesticide is a category 1A or 1B for CMR, regulators will need to classify the product themselves. A single authoritative international database of GHS classifications does not exist for pesticides. However, certain intergovernmental or national databases can be used to check the CMR classification of a pesticide. Which source to use is the choice of the regulator. The PPD decided to use the ECHA C&L inventory (ECHA, 2017).

Note that it is our experience that websites are often changed and that paths to particular sites are quickly outdated. In case paths specified above are outdated we advise to check the FAO Pesticide Registration toolkit website (Information sources – Hazard classifications): http://www.fao.org/pesticide-registration-toolkit/tool/page/pret/hhp/hazard-classifications. The website regularly updates paths to the different websites and the FAO indicated that the pesticide registration toolkit website will be maintained for years to come.

3.5.3 Hazard assessment for identification of highly hazardous pesticides for use in the decision supporting scheme for registration

A Highly Hazardous Pesticide (HHP) scan is part of the decision supporting flow chart for the pesticide registration process in Myanmar. The HHP scan is based on the FAO/WHO HHP guidance which specifies 8 criteria for assessing a pesticide. If one of the criteria is met, the pesticide product is identified as a HHP. The FAO/WHO Guidelines on highly hazardous pesticides (HHPs) (FAO, 2017b) provide international criteria and outline the risk reduction process for HHPs. On the basis of these guidelines, a guidance document has been elaborated for the identification of HHPs in Myanmar. The FAO/WHO HHP guidance is tailored to Myanmar by prescribing the use of certain databases and specifying those issues that are left to the regulator in the generic FAO/WHO guidance (see sections 3.5.3.1 and 3.5.3.2, Annex 20 (details 8 criteria used in the FAO assessment) and Annex 21 (Details PBT criteria).

It should be noted that one of the criteria used in the identification of HHPs (specifically the Persistence, Bioaccumulation and Toxicity, or PBT criterion) is considered to be of a somewhat arbitrary nature, since the cut-off values used in the assessment are not scientifically underpinned, but among others based on the properties of a number of compounds (Solomon *et al.*, 2013). Criteria for the identification of substances classified as PBT are established in several regulations/frameworks, among others in Annex XIII of the REACH Regulation (EG) 1907/200 and in the Stockholm convention (Stockholm Convention 2001). PBT substances can give rise to specific concerns due to i) their potential to accumulate in parts of the environment, ii) accumulation that is difficult to reverse under practical conditions, and iii) the effects of such accumulation being unpredictable in the long-term (ECHA, 2014). That PBT criteria are used in the assessment nevertheless, is mainly due to practical reasons, i.e. they are used in many (regulatory) frameworks.

If a pesticide is identified as a PBT chemical, this implies that it may possibly, but not necessarily, be considered a HHP according to the FAO/WHO guidance on HHP. The general recommendation of most frameworks is not to use the PBT criteria as a final step in the process of risk management but rather that decisions be made 'after rigorous scientific assessment' (Solomon *et al.*, 2013). For pesticide registration in Myanmar it is advised to perform a more detailed risk analysis for aquatic ecosystems, soil organisms, consumers drinking surface water, *etc* for pesticides that are considered to be PBTs. Note that currently for Myanmar such risk assessments are not available. It is therefore advised to use the registration by analogy methodology to further assess the risk of substances that are based upon the PBT criteria classified as possibly a HHP.

3.5.3.1 Guidance for the identification of Highly Hazardous Pesticides (HHPs)

The FAO developed the HHP identification spreadsheet for performing the HHP scan. The original FAO spreadsheet and a detailed instruction for its use can be obtained from the FAO website (FAO, 2017b).

The spreadsheet facilitates the identification of HHPs by assessment of eight criteria used for identification of HHPs. These criteria are discussed in more detail in Annex 20.

A modified version of this HHP spreadsheet is used to perform the HHP scan for Myanmar. The Myanmar specific version of the spreadsheet can handle a much larger number of pesticide products and the guidance for identification of PBTs (Annex 21) was implemented in this modified spreadsheet. It was also decided to use different spreadsheets for products with respectively one, two or three active ingredients.

Each spreadsheet contains 4 sheets:

- One data entry sheet.
- One data summary sheet
- A sheet called "Notes" – containing explanations of the terms/topics/parameters in the various columns of the data entry sheets.
- A sheet called "Lists" – containing lists with options for several fields the data entry sheets (e.g. active ingredients listed under the Rotterdam convention etc, cutoff values for the Stockholm Annex D parameters).

This document contains guidance on how to fill in the data entry sheet in the HHP identification spreadsheet.

The data entry sheet is divided into two parts (A, B) each part containing a set of columns:

- Part A (columns A – H) deals with information considering the pesticide product (see Figure 4)
- Part B (columns I – AH) deals with information needed considering the eight HHP criteria (indicated as B1, B2, etc) (see Figure 5).

Part A is self-explanatory and does not require further instructions.
Regarding Part B, each of the 8 HHP criteria are discussed in a separate section, reproducing information specified on the FAO toolkit website (FAO, 2017, 2017b).

A more detailed instruction on how to apply this guidance for using the HHP spreadsheet is given in section 3.5.3.2. Note that the order of checking the criteria is different from the order as given in the WHO/FAO HHP guidance and spreadsheet.

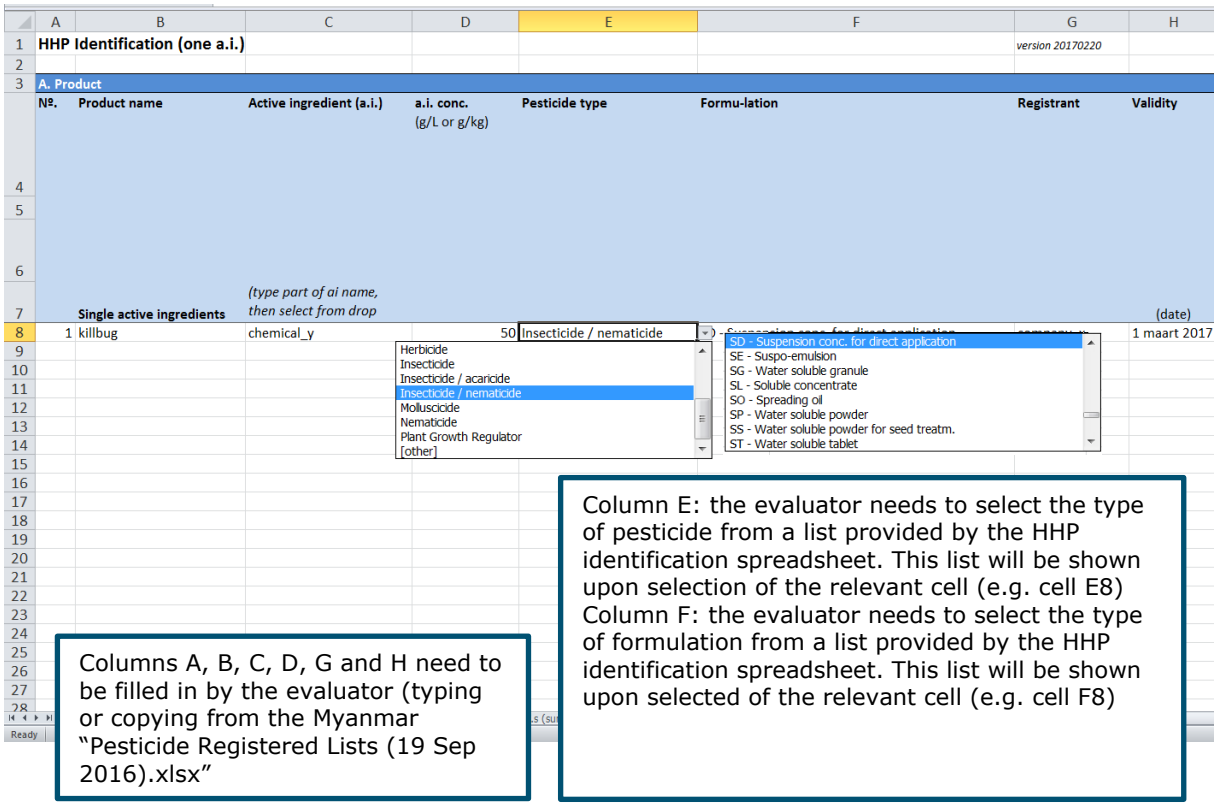

Figure 4 *Section A. Part of the data entry sheet for products containing only one active ingredient of the HHP identification spreadsheet.*

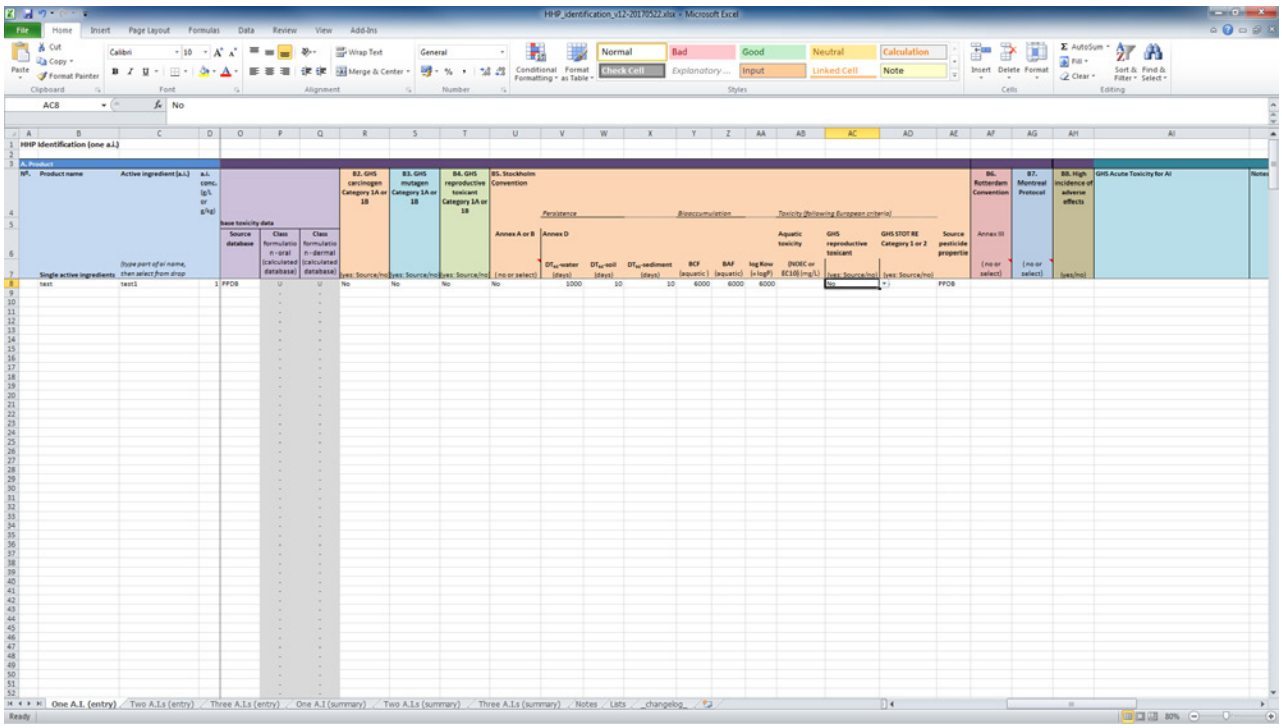

Figure 5 *Section B. Part of the data entry sheet for products containing only one active ingredient of the HHP identification spreadsheet.*

3.5.3.2 Order of steps in the assessment of HHPs

Note that the order of checking against the criteria in this instruction (Figure 6) differs from what is specified in the WHO/FAO HHP guidance and spreadsheet (FAO, 2017b). Moreover, since only a HHP scan is performed instead of a full HHP identification, not all checks have to be performed. If during one of the steps a pesticide is identified as a HHP, all subsequent checks do not have to be performed.

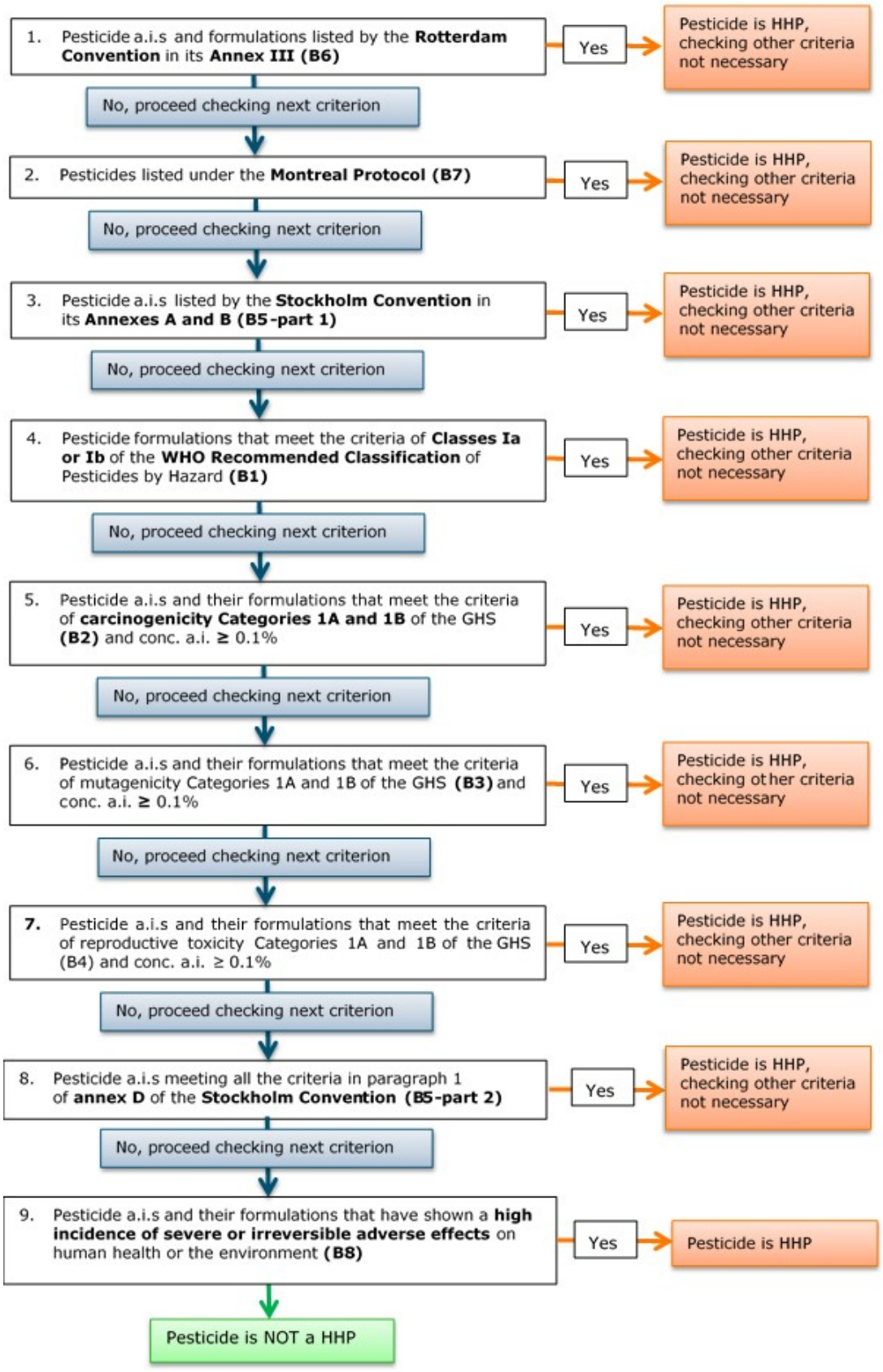

Figure 6 *Order of steps in the assessment of Highly Hazardous Pesticides as proposed for Myanmar.*

Step 1. Identify pesticide active ingredients and formulations listed by the Rotterdam Convention in its Annex III (B6)
HHP spreadsheet **Column AF** (B6. Rotterdam Convention, Annex III) – Select from the picklist of the relevant cell either 'No' or the relevant a.i.

Step 2. Identify pesticides listed under the Montreal Protocol (B7)
HHP spreadsheet **Column AE** (B7. Montreal Protocol) – Select from the picklist of the relevant cell either 'No' or the relevant a.i.

Step 3. Identify pesticide active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention (B5-part 1)
HHP spreadsheet **Column U** (B5 Stockholm Convention, Annex A or B) – Select from the picklist of the relevant cell either 'No' or the relevant a.i.

Step 4. Identify pesticide formulations that meet the criteria of Classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard (B1)
Take the value of LD50 of the formulated product ("6-pack") from the pesticide registration dossier and compare this value with the LD50 of the active ingredient found in the WHO Recommended Classification of Pesticides by Hazard (document downloadable from WHO, 2017).

If the active ingredient is not listed in the WHO Recommended Classification of Pesticides by Hazard, retrieve the LD50 of the active ingredient of the Pesticide Properties Database (PPDB) (University of Hertfordshire, 2017).

- Search the active ingredient in Tables 1-5 of the WHO Recommended Classification of Pesticides by Hazard (WHO, 2017).
- Identify from the information on the active ingredient in Tables 1-5 of the WHO Recommended Classification of Pesticides by Hazard whether the route op application used for the classification is oral or dermal. In principle the route is oral, unless specified otherwise.
- If the route is 'oral', fill in the value of the LD50 of the active ingredient found in Tables 1-5 of the WHO Recommended Classification of Pesticides by Hazard in **column I** in the HPP spreadsheet (Oral LD50 formulation (dossier))
- If the route is 'dermal', fill in the value of the LD50 of the active ingredient found in Tables 1-5 of the WHO Recommended Classification of Pesticides by Hazard in **column J** in the HPP spreadsheet (Dermal LD50 formulation (dossier))
  - If the active ingredient is not found in the WHO Recommended Classification of Pesticides by Hazard, search the active ingredient in the PPDB
  - Fill in the value of 'Mammals - Acute oral LD50 (mg kg-1)' found in the PPDB in **column M** (Oral LD50 a.i. (database))
  - Fill in the value of 'Mammals - Dermal LD50 (mg kg-1 body weight)' found in the PPDB **in column L** (dermal LD50 a.i. (database))

Step 5. Identify pesticide active ingredients and their formulations that meet the criteria of carcinogenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (B2)

Step 6. Identify pesticide active ingredients and their formulations that meet the criteria of mutagenicity Categories 1A and 1B of the GHS (B3)

Step 7. Identify pesticide active ingredients and their formulations that meet the criteria of reproductive toxicity Categories 1A and 1B of the GHS (B4)
- Go the website of the ECHA – C&L Inventory (ECHA, 2017).
- To consult the inventory:
  1. Access the C&L Inventory – Click on the "CL inventory" link to display the search fields
  2. Tick the legal disclaimer

3. Enter the pesticide common name in the "substance name" field or use another identifier such as the CAS number. Experienced learned us that searching by substance name often fails. Therefore better to use the CAS number (can e.g. be found via Pesticide Manual of Tomlin)
4. Click on the Search button
5. On the results page, scroll down a bit and click on the *"view" icon* of the relevant substance
6. The subsequent results page shows the official EU classification of the pesticide active ingredient: hazard classes and category codes, hazard statement and hazard symbols. Inspect the first section, on harmonized classification, which is in line with the GHS.
7. Check whether the following Hazard Class and Category Code(s) are found in the overview
   i. Carc. 1A or Carc. 1B (**H350**)
   ii. Muta. 1A or Muta 1B (**H340**)
   iii. Repr. 1 A or Repr. 1B (**H360**)

- Go to HHP spreadsheet

Carc. 1A or Carc. 1B (H350) - **column R** (B2. GHS carcinogen Category 1A or 1B) in HHP spreadsheet

- If Carc. 1A or Carc. 1B (H350) in C&L found in inventory of ECHA **AND** conc. a.i ≥0.1%

  - select from column R (B2. GHS carcinogen Category 1A or 1B) in HHP spreadsheet '*Yes: ECHA*' from picklist

- If Carc. 1A or Carc. 1B (H350) in C&L **NOT** found in inventory of ECHA **OR** conc. a.i. < 0.1%

  - select from column R (B2. GHS carcinogen Category 1A or 1B) in HHP spreadsheet *'No'* from picklist

Muta. 1A or Muta 1B (H340) - **column S** (B3. GHS mutagen Category 1A or 1B) in HHP spreadsheet

- If Muta. 1A or Muta. 1B (H340) in C&L found in inventory of ECHA **AND** conc. a.i ≥0.1%

  - select from column S (B3. GHS mutagen Category 1A or 1B) in HHP spreadsheet '*Yes: ECHA*' from picklist

- If Muta. 1A or Muta. 1B (H340) in C&L **NOT** found in inventory of ECHA **OR** conc. a.i. < 0.1%

  - select from column S (B3. GHS mutagen Category 1A or 1B) in HHP spreadsheet *'No'* from picklist

Repr. 1 A or Repr. 1B (H360) - **column T** (B4. GHS reproductive toxicant Category 1A or 1B) in HHP spreadsheet

- If Repr. 1A or Repr. 1B (H360) in C&L found in inventory of ECHA **AND** conc. a.i ≥0.1%

  - select from column R (B4. GHS reproductive toxicant Category 1A or 1B) in HHP spreadsheet '*Yes: ECHA*' from picklist

- If Repr. 1A or Repr. 1B (H360) in C&L **NOT** found in inventory of ECHA **OR** conc. a.i. < 0.1%

  - select from column R (B4. GHS reproductive toxicant Category 1A or 1B) in HHP spreadsheet *'No'* from picklist

Step 8. Identify pesticide active ingredients meeting all the criteria in paragraph 1 of Annex D of the Stockholm Convention (B5-part 2)

Column V, W, X, Y, Z, AA, AB, AC, AD and AE - Use the Pesticide Properties Database (University of Hertfordshire, 2017) and the step-by-step guidance given below.

Order of entering the criteria:
It is in theory not necessary to fill in *all* the Stockholm Annex D criteria in the HHP spreadsheet. A pesticide is only indicated as a PBT if it is persistent *and* bio-accumulative *and* potentially toxic. So if evaluation of the bio-accumulation criteria indicates that the substance is NOT bio-accumulative, it is not necessary to assess the toxicity and persistence criteria because the substance will not be a PBT. This gives scope for a more efficient strategy for using the spreadsheet, which is depicted in Figure 7. It is advised to fill in the HHP spreadsheet in the order given in Figure 7. In case the user ends up in a green box, the evaluation can be finished, since there is no need to assess the remaining criteria.

A discussion that needs to be continued in the follow up project is on what to decide if data on P, B or T criteria cannot be found in databases.

Figure 7 shows the order in which the criteria in the HHP spreadsheet should be addressed.

First fill in columns Y or Z or AA – if one (or more) of these bio-accumulation criteria are fulfilled proceed with column AB, else stop. If column AB (EC10 or NOEC aquatic organisms) needs to be filled in, check if the criterion is fulfilled. If so, proceed with columns V,W,X; if NOT then fill in column AC and AD. If the criteria of AC and/or AD are fulfilled proceed with columns V,W,X; if NOT then stop.

If columns V,W,X need to be filled in, start with column W ($DT50_{soil}$), if the criterion is fulfilled ($DT50_{soil}$ > 180 d, so persistent in soil), there is no need to fill in columns V and X. If the criterion is not fulfilled proceed with column X ($DT50_{sediment}$), if the criteria is fulfilled ($DT50_{sediment}$ > 180 d, so persistent in sediment), there is no need to fill in column V. If the substance is not persistent in sediment fill in column V ($DT50_{water}$). Use therefore the instruction in Annex 21.

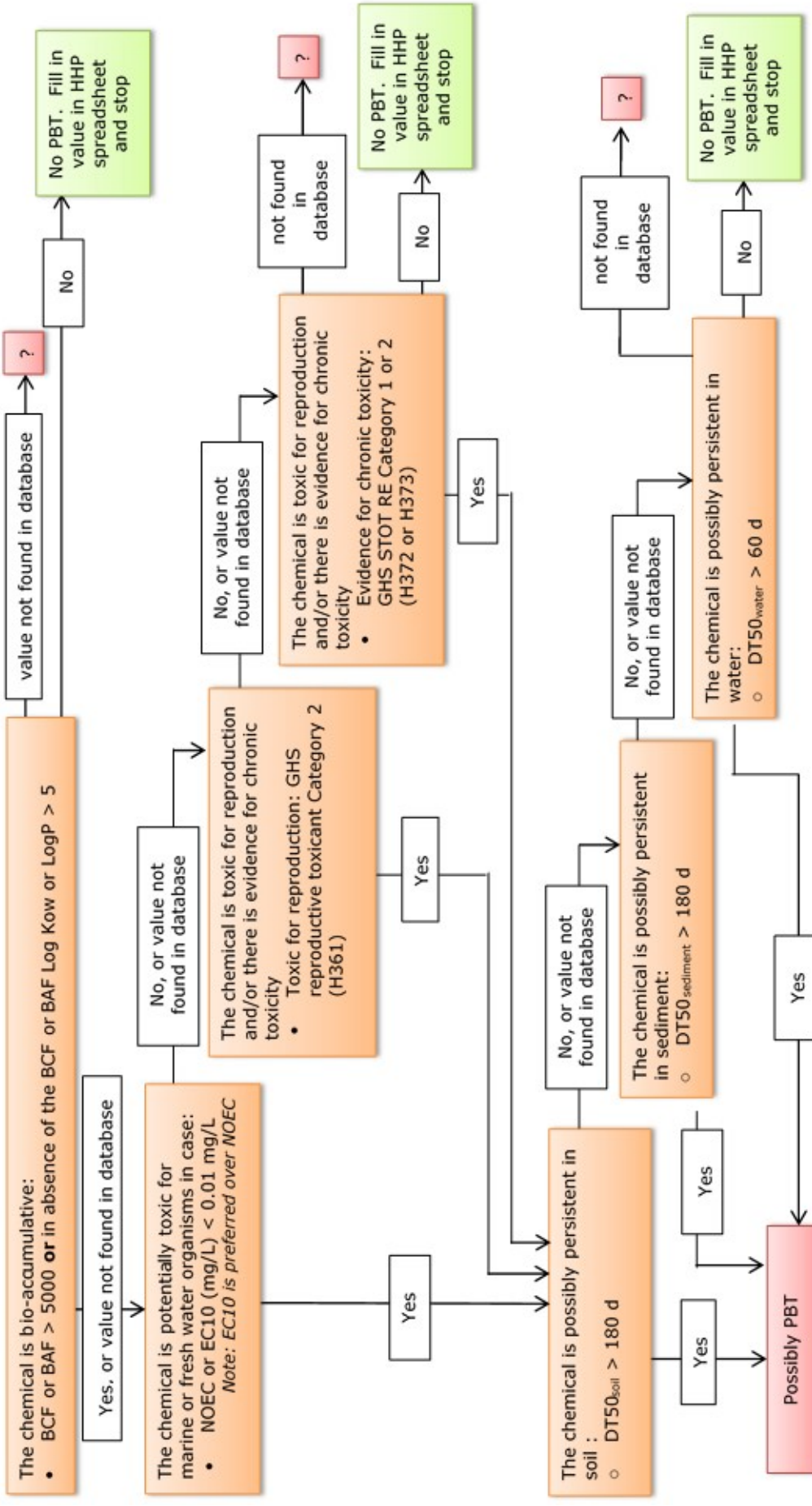

Figure 7 *Efficient strategy for checking the PBT criteria as part of a Highly Hazardous Pesticides scan in Myanmar.*

Bioaccumulation - **Column Y** - BCF (aquatic) or **Column Z** - BAF (aquatic) **Column AA** - log Kow (= logP)

Proposal: Use the BCF or the BAF given in the PPDB and in absence of the BCF or the BAF use the Log P given in the PPDB. The chemical is bio-accumulative if BCF or the BAF > 5000 L/kg and/or Log P > 5

Step by step guidance bioaccumulation (note that the checks specified below need to be followed in the order they are given in order to reach the conclusion on bioaccumulation)

Step 1: Select from the PPDB the BCF (or BAF), and enter this value (in L/kg) in **column Y** of the HHP identification spreadsheet. If the BCF (or BAF) is not available proceed to Step 2 else proceed to the 'toxicity citeria' (Column AB and/or Column AC and/or Column AD in HHP spreadsheet).

Step 2: Select from the PPDB the Log P at pH 7, 20°C and enter this value in column AA of the HHP identification spreadsheet.

Toxicity - Column AB and/or Column AC and/or Column AD

EC10 or NOEC aquatic organisms (fish, Aquatic invertebrates, Aquatic crustaceans) < 0.01 mg/L - **column AB**

- If NOEC or EC10 of one of the aquatic organisms (select lowest value) < 0.01 mg/L
  - Enter value in **column AB** in HHP spreadsheet
- If NOEC or EC10 of one of the aquatic organisms (select lowest value) > 0.01 mg/L
  - Proceed with the persistence criteria (DT50soil, column W)

If the NOEC or EC10 is not found in the spreadsheet, but an LC50 of fish, aquatic invertebrates, or aquatic crustaceans is available, you may conclude that the substance is toxic if this value is < 0.01 mg/L AND if it is absolutely clear that the LC50 is determined in a chronic (21 d or 28 d) study.

- If LC50 of one of the aquatic organisms determined in 21 or 28 d study (select lowest value) < 0.01 mg/L
  - Enter the value in **column AB** in HHP spreadsheet

Repr. 2 (H361) - **column AC** (GHS reproductive toxicant Category 2) in HHP spreadsheet

- If Repr. 2 (H361) found in C&L inventory of ECHA
  - select from column AC in HHP spreadsheet '*Yes: ECHA*' from picklist
- If Repr. 2 (H361) **NOT** found in C&L inventory of ECHA
  - select from column AC in HHP spreadsheet '*No'* from picklist

STOT RE 1 (H322) or STOT RE 2 (H373) - **column AD** (GHS STOT RE Category 1 or 2) in HHP spreadsheet

- STOT RE 1 (H372) or STOT RE 2 (H373) in C&L found in inventory of ECHA
  - select from column AD in HHP spreadsheet '*Yes: ECHA*' from picklist
- If STOT RE 1 (H372) or STOT RE 2 (H373) in C&L **NOT** found in inventory of ECHA
  - select from column AD in HHP spreadsheet '*No'* from picklist

Persistence in soil – **Column W** -DT50-soil (day)

Proposal: Use the DT50 lab at 20°C given in the PPDB (see Table 7 for justification)
A chemical is considered to be persistent in soil if the DT50 $lab_{,soil}$ at 20°C >180 d

Step by step guidance persistence in soil (note that the checks specified below need to be followed in the order they are given to reach the conclusion on persistence in soil)

Step 1: Select from the PPDB the DT50 lab at 20°C

Step 2: Enter the value of the DT50 lab at 20°C in the HHP identification spreadsheet

Persistence in sediment – **Column X** -DT50-sediment (days)

Proposal: Use the DT50 of total water-sediment system given in the PPDB (see Table 7 for justification). A chemical is considered to be persistent in the sediment if the DT50 of total water-sediment system > 180 d

Step by step guidance persistence in sediment (note that the checks specified below need to be followed in the order they are given to reach the conclusion on persistence in sediment)

Step 1: Select from the PPDB the water-sediment DT50 (DT50 of total water-sediment system)

Step 2: Enter the value of the DT50 of total water-sediment system in the HHP identification spreadsheet

Persistence in water - **Column V** -DT50-water (days)

Proposal: Use the guidance given in Annex 21

Column AE: – Select from the picklist of the relevant cell the database used (PPDB is first choice)

Step 9. Identify pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment (B8).

- Check monitoring or surveillance reports generated in Myanmar and the SE Asia region
- Check Myanmar Poison Centre reports

3.5.4 Emergency need for a HHP

In principle, HHPs should not be registered in Myanmar. However, certain specific emergency situations can occur (e.g. appearance of a new important pest, disease or human disease vector) which would justify a restricted use registration of a highly hazardous pesticide.

What is considered an "emergency situation" will need to be defined by the Pesticides Registration Board. This question will be addressed when a further review of the short-list of HHPs is conducted by the PPD and WUR, in a follow-up project (see section 2.4).

3.5.5 Alternatives for a HHP

If effective alternatives for an HHP are available, or can be made available on short notice, the HHP may not be registered, even if there is an emergency situation. Alternatives are lower risk chemical or biological pesticides, or the use of other pest control measures (e.g. biological control, agronomic interventions). If no effective alternatives are available, the HHP may be registered, but for restricted use only.

Development of alternatives for HHPs will be addressed upon a further review of the short-list of HHPs by the PPD and WUR, in a follow-up project (see section 2.4).

3.5.6 Decision making on HHP

Using the guidance provided in this report, the PPD is able to identify a pesticide as being i) a HHP, ii) possibly a HHP (if the PBT criterion is met), or iii) not a HHP. If the pesticide is classified as 'not a HHP' the regulator will proceed with Registration by Analogy (next step in the decision supporting flow chart of Figure 3). Registration by Analogy is for the present also advised if a pesticide is classified as a possible HHP.

If the pesticide is identified as a HHP, the decision supporting flow chart of Figure 3 requires an assessment for emergency needs, and an assessment whether alternatives are available as the next steps. However as indicated in the previous sections, guidance for these assessments is not yet developed.

3.6 Registration by analogy

3.6.1 Introduction

Most of the text below describing registration by analogy is taken directly from the website on the FAO toolkit for registration of pesticides (FAO, 2017).

Registration by analogy uses a limited comparison between a pesticide product submitted for authorization in a resource-limited country, and a similar product in **one or more reference countries.** Registration by analogy is based on the assumption that pesticide quality, efficacy and risks are considered/found acceptable in the reference country, where the product is registered. The registration authority subsequently evaluates whether the efficacy and risk of the same pesticide are also likely to be acceptable in its own country.

This approach applies bridging methods for the evaluation of efficacy and risk of the pesticide and is less complex, uses fewer data and requires less human resources than a complete evaluation. However, registration by analogy is also less precise and may leave considerable uncertainties about efficacy and risk under the local conditions of use (FAO, 2017). Therefore, whenever the registration authority is in a position to conduct a more comprehensive evaluation, it is recommended that these progressively replace registration by analogy.

Registration by analogy is possible if a pesticide product has already been registered for identical or similar uses in a country considered as a reference for Myanmar.

Reference countries/regions proposed for Myanmar are:
- Europe
- USA
- Australia
- New Zealand

If no similar use exists in the reference country, a location specific assessment of human health will be conducted in Myanmar.

Using the FAO Pesticide Registration Toolkit, it is easy to get access to the registration status of active ingredients or formulated products in other countries or regions (FAO Toolkit website: Information Sources – Registrations elsewhere) (FAO, 2017).

3.6.2 Guidance for registration by analogy

The main steps in assessing whether registration by analogy is feasible are schematically shown in Figure 8.

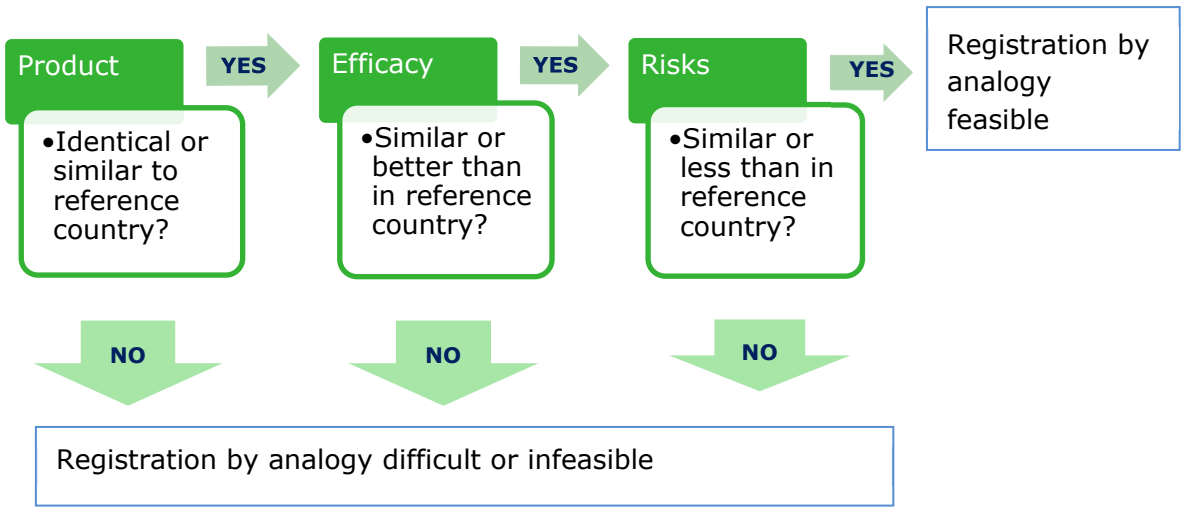

Figure 8 *Registration by analogy: compare local situation with situation in reference country (source: FAO Pesticide Registration Toolkit; FAO, 2017).*

For evaluation by analogy, ideally a comparison is made between identical pesticide products, from the same manufacturer. Registrars should therefore first look for reference countries where identical products have been registered. However, similar products may also qualify for registration by analogy.

Thereafter, the pesticide use pattern is compared between the reference country and the local situation. This includes the crop or use situation, pest, application rate and frequency, and withholding periods, if any. The comparison of use patterns helps to evaluate whether the efficacy in the local situation can be expected to be similar – or better – than in the reference country.

Subsequently, the potential for human health and environmental impact is compared between the reference country and the local situation. This is done by comparing use patterns again, but now the aim is to assess the likelihood of human or environmental exposure. Any use restrictions, personal protective equipment and environmental conditions are also taken into account. This leads to a conclusion whether the risks in the local situation can be expected to be similar, higher or less than in the reference country.

To facilitate the registration by analogy evaluation, the FAO Pesticide Registration toolkit provides a check-list and an associated guidance document (both are given in in Annex 9, note that they might be updated by the FAO. It is advised to check the FAO Pesticide Registration toolkit website to retrieve the latest versions).

3.6.3 Decision making based on registration by analogy

In registration by analogy, a comparison is made between:

A. the registered application rate and frequency of application of the pesticide, and its use restrictions or precautions, in the reference country; and
B. the proposed application rate and frequency of application of the pesticide, and use conditions, in Myanmar.

The likelihood that the risk in Myanmar will be acceptable or not will then be assessed. Based on the assessment the regulator needs to indicate whether the product can be registered in Myanmar or not

(Conclusion/last entry in the 'registration by analogy' section of the decision supporting summary, Annex 7). It may be difficult to decide whether to register or not based on registration by analogy. For instance a proper comparison might not be possible, because there is not enough information in the dossier of the reference country. In such cases the conclusion on whether the product can be registered based on the registration by analogy approach in Myanmar should be 'No'. Consequently the decision supporting flow chart will guide the regulator towards the next step: more in-depth risk assessment.

3.7 Human health risk assessments

3.7.1 Introduction

This section provides guidance on the assessment of the risk of a pesticide on human health (occupational and consumer). Myanmar specific guidance for the estimation of the risk for operators, workers and consumers of treated crops is described in sections 3.7.2 and 3.7.3.

Parts of the text of section 3.7 are taken from the evaluation manual of Ethiopia (Deneer *et al.*, 2014) and where necessary adapted for Myanmar.

3.7.1.1 General theory on risk assessment

Toxicity is an inherent property of all substances. All chemical substances can produce health effects at some level of exposure. Risk is the likelihood that an adverse health effect will result from an exposure to a particular amount (dose) of a chemical. Therefore, risk is a function of both toxicity and exposure.

The risk assessment process can best be described as a 3 step procedure: hazard assessment, exposure assessment, and risk characterisation.

- **Step 1 - Hazard assessment**
  Examines whether a substance has the potential to cause harm to humans, and identifies the dose-response and the lowest relevant No Observed (Adverse) Effect Level (NO(A)EL)
- **Step 2 - Exposure Assessment**
  Examines what is known about the frequency, timing, and levels of exposure to a substance
- **Step 3 - Risk Characterization**
  Examines how well the data support conclusions about the nature and extent of the risk from exposure to pesticides.

Risk characterization is the final step in assessing human health risks resulting from exposure to pesticides. It is the process of combining the hazard, dose-response and exposure assessments to describe the overall risk posed by a pesticide (Figure 9). It explains the assumptions used in assessing exposure as well as the uncertainties that are built into the dose-response assessment. The strength of the overall assessment is considered, and generalized conclusions are drawn.

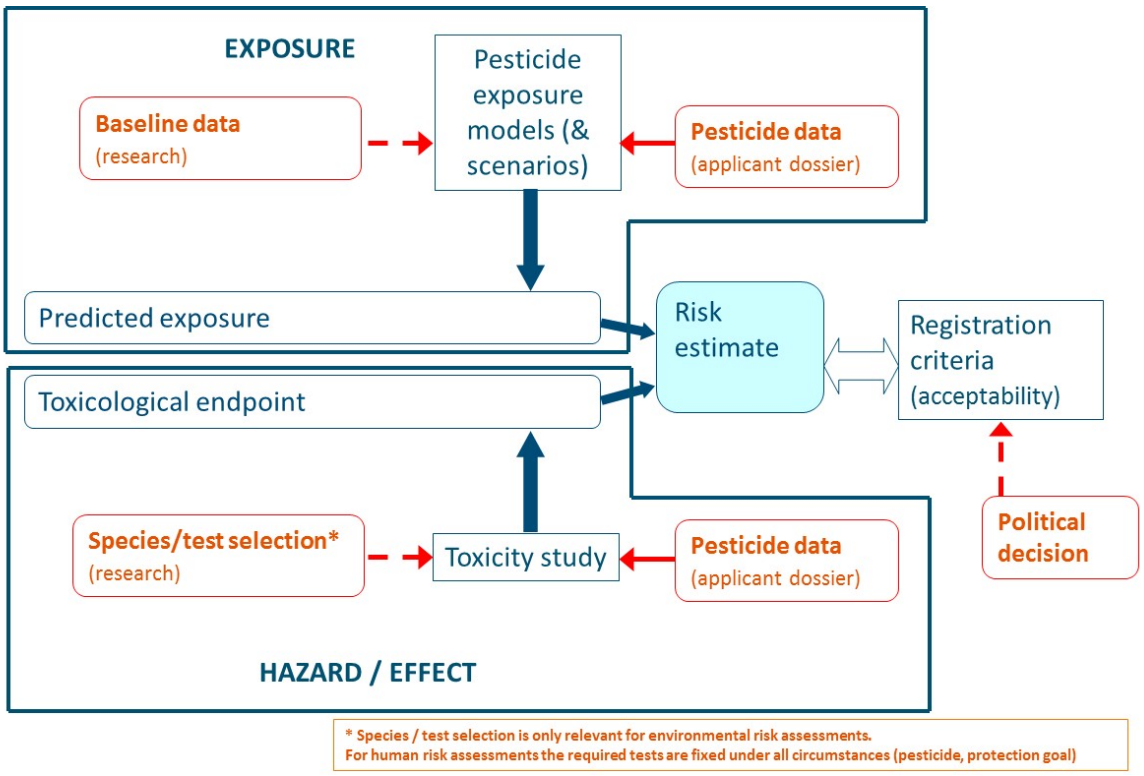

Figure 9 *Risk assessment procedure.*

This means that the risk to human health resulting from pesticide exposure depends on both the hazard (toxicity of the pesticide) and the likelihood of humans being exposed. At least some exposure and some toxicity are required to result in a risk. For example, if the pesticide is very poisonous but no people are exposed, there is no risk. Likewise, if there is ample exposure but the chemical is non-toxic, there is no risk. However, usually when pesticides are used, there is some toxicity and exposure, which results in potential risk.

Effects may vary between individuals. To account for this variability, uncertainty factors are built into the risk assessment. These uncertainty factors create an additional margin of safety for protecting individuals possibly exposed.

3.7.1.2 Human health protection goals elaborated in this project

Protection goals are often specified in quite general terms, e.g. stating that 'the environment' or 'human health' should be protected from risks resulting from the use of pesticides. Implementing such goals requires the specification of more precise goals for protection, usually called specific protection goals (EFSA Scientific Committee, 2016). Each specific protection goal requires definition of what should be protected, where it should be protected and how strict it should be protected.

Environmental risks are not yet considered in the pesticide registration process of Myanmar. The focus for the time being is on protection of the population through human health risk assessments. A distinction is made between protection of users of pesticides (operators, workers) and the protection of consumers of agricultural products that have been treated with pesticides (consumers).
The following protection goals are selected for the situation in Myanmar:

- operators
- workers
- consumers (dietary)

The exposure of operators and workers is expected to be higher than what is expected for bystanders/flag men and residents, and the latter are therefore not yet explicitly included in the risk assessment.

The detailed protection goal for operator exposure is defined as follows:

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 crops where pesticides are applied through spraying.

iii. **How strict 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.

The detailed protection goal for worker exposure is defined as follows:

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 crops where pesticides are applied.

iii. **How strict should it be protected?**

   → No sub-chronic effects on the health of the workers are acceptable, i.e. no exceedance of the Acceptable Operator Exposure Level (AOEL) is allowed.

The detailed protection goal for consumer exposure through food is defined as follows:

1. **What should be protected?**

   → All consumers of agricultural commodities.

2. **Where should this be protected?**

   → Throughout Myanmar, for all agricultural commodities that have been treated with the pesticide.

3. **How strict should it be protected?**

   → No acute or chronic effects on the health of the consumer, i.e. no exceedance of the Acute Reference Dose (ARfD) or the Acceptable Daily Intake (ADI) is allowed.

3.7.1.3 Data requirements

The WHO (2010) indicates that responsible authorities should, whenever possible, make use of data that have been released publicly, and that preferably have been peer-reviewed, when considering an application for registration. In this way, duplication of work and inefficient use of resources can be minimized. Mutual acceptance of data by several regulatory authorities on topics such as efficacy and residues, among others, is recommended whenever a sound basis can be established to ensure that the data is relevant to the situation being considered.

In addition, hazard assessments are generally applicable globally and are available from published sources, including the peer-reviewed assessments of the FAO/WHO Joint Meeting on Pesticide

Residues (JMPR) or other reputable national or regional registration authorities. These may be used in the evaluation of a dossier, as long as data propriety is adequately taken into account.

For Myanmar the data requirements can be downloaded from the website of the PPD specifying Myanmar data requirements (PPD, 2017b).

Data requirements for toxicology are indicated in section 6 of the Myanmar data requirements document (PPD, 2017b). These requirements refer to both the active ingredient and the formulated product. In several countries it is common practice to compare the endpoints required for both active ingredient and formulated product. Differences in the values of these endpoints indicate a difference in toxicity between the active ingredient and the formulated product. In cases where the toxicity of the formulated product is significantly higher than that of the active ingredient, pesticide registration authorities might require additional toxicity studies with the formulated product and use the toxicity endpoints derived from these studies for the human health risk assessments.

In many countries, the applicant has to provide the full study reports and a summary of each study including the relevant endpoints such as e.g. the 'No Observed (Adverse) Effect Level' (NO(A)EL), LD50, irritating yes/no, etc. The data requirements of Myanmar are less clear in this respect. Section 6 of the Myanmar data requirements document states that *"it is sufficient to enclose the brief description of experiments including essential of execution and the evaluation of results"* and that *"it is the responsibility of the application to submit the results of appropriate toxicological examinations, together with their evaluation which allows consideration of the following:*

- *The possible short and long term hazards to field workers handling a product and appropriate precautionary measures necessary to allow safe working condition*
- *The diagnosis and most effective methods for treatment of accidental poisoning*
- *The estimate of an Acceptable Daily Intake for men (ADI) in food commodities*
- *The hazard classification of the formulated products for sale"*

A good evaluation of the data requirements results for each study and for each toxicological sub-aspect (e.g. irritation potency, acute toxicity, carcinogenicity etc.) in a toxicology based endpoint, and in a toxicological profile of a substance. The toxicological endpoints derived from the submitted research are the basis for the risk evaluation for operator, worker and for consumers.

With respect to the near future, the Myanmar PPD decided to use the reference values needed for the risk assessments for consumers, workers and operators from international databases. Reference values ADI and ARfD are used in the consumer risk assessment; reference value AOEL is used for the occupational (workers and operators) risk assessment.

A short explanation of the different types of toxicity endpoints and studies are given in Annex 10 and Annex 11.

3.7.2 Myanmar specific guidance for occupational risk assessment (operators and workers in the field)

3.7.2.1 Theory occupational risk assessment

Occupational risk assessment is performed to assess whether the application of a pesticide product has no adverse consequences for operator and worker. Operators may be exposed to the pesticide during spraying, mixing and loading. Persons working in the field after the pesticide has been applied may be exposed to the pesticide during activities like harvesting, cutting, irrigation, weeding etc. A pesticide can have adverse consequences for operators and workers when it passes the barriers of the body and enters the blood circulation, thus reaching all organs and tissues.

To assess whether the application of a pesticide product has no adverse consequences for operator and worker, the endpoints from the toxicological dossier and the corresponding reference value (e.g.

AOEL: Acceptable Operator Exposure Level) must be compared with the expected exposure (Predicted Exposure) (Figure 10).

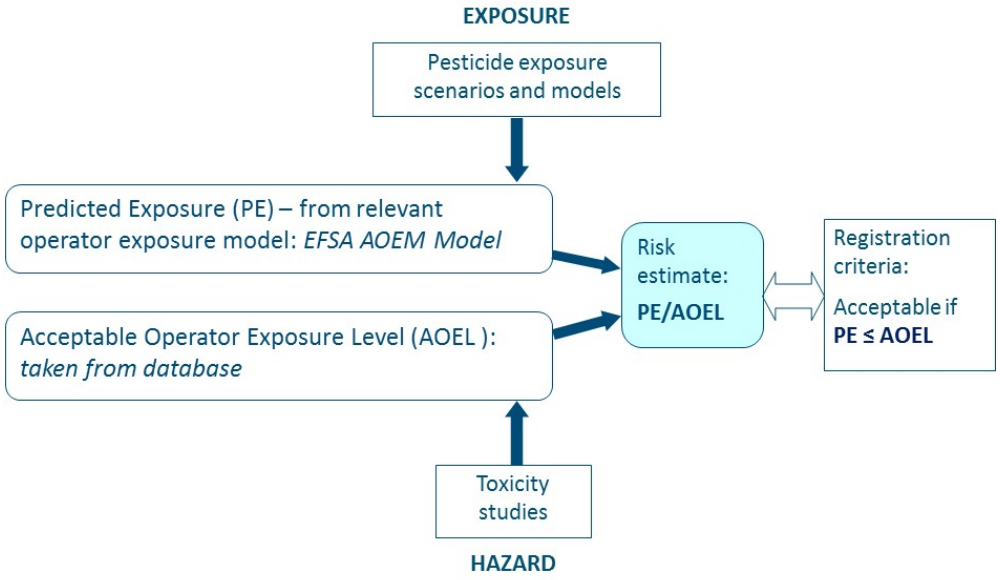

Figure 10 *Operator risk assessment as proposed for Myanmar.*

Ideally operator and worker exposure is assessed on the basis of exposure studies. As such studies are usually missing, a first exposure estimation is performed using generic or more specific models. Supplementary data on actual exposure can be requested, if necessary, based on this risk assessment.

There are several models available for estimation of the exposure of workers and operators to pesticide products. EFSA AOEM assists with the assessment of exposure of operators, workers, residents and bystanders to pesticides, and is proposed for pesticide registration purposes in Myanmar. Reasoning for selecting EFSA AOEM is as follows:

- The model contains up-to-date occupational exposure data (based on a better and bigger dataset than other models)
- According to the developers of the tool, it is reasonably well applicable in non-European situations (personal communication Harold van der Valk). It is recommended not to modify any of the input parameters, because differences between different situations probably compensate each other. E.g. low quality spraying equipment gives a higher exposure, but this is compensated by the actual lower work load per day in the non-European country.

Exposure is calculated based on, among others, data on applications (dose, timing, frequency etc.) Applicants for registration of pesticides should provide a Table of Intended Uses (also called a GAP table; see Annex 2) containing the data needed.

At present the reference value (AOEL) is not a data requirement in Myanmar and the PPD does not have the capacity to evaluate dermal absorption studies. It was therefore decided to take the AOEL values from international databases.

In the models, the total systemic exposure and % of AOEL is given. The risk assessment is performed by combining the exposure estimations and the reference value (AOEL).

In the first tier the risk assessment assumes that no Personal Protective Equipment (PPE) is used.

No adverse effects on humans expected (acceptable risks) if:

Total systemic exposure is ≤ 100% of AOEL.

Adverse effects on humans cannot be excluded (unacceptable risks) if:
Total systemic exposure >100% of AOEL,

If adverse effects on humans cannot be excluded (unacceptable without PPE), a refinement of the risk assessment should be considered including risk mitigation measures. Currently, the only risk mitigation measure considered feasible in Myanmar, but only in certain situations is using PPE (Personal Protection Equipment). This option can only be chosen in consultation with the applicant.

Possible mitigation measures for the future could be:
- Lowering of the application rate and/or increasing the interval between applications in case of multiple applications (note: it has to be checked whether the pesticide product is still effective). The PPD and several members of the TC were of the opinion that these measures are currently not feasible in Myanmar.

Possible higher tier options are:
- The use of better dermal and oral absorption data (if default values are used in the first tier); should be done in consultation with the applicant.
- The use of exposure studies, in which the actual exposure is measured for that particular use.

The last two options become feasible once the PPD has the capacity to evaluate dermal absorption studies and exposure studies.

It should be noted that this risk assessment contains a margin of safety.
1. The AOEL is based on a NOAEL in animals, the dose at which no adverse effects are observed. The next higher dose (the LOAEL) is the dose at which adverse effects are observed in the animals. Usually this LOAEL is a 3-10 times higher dose than the NOAEL.
2. The AOEL includes an uncertainty factor of 100, assuming that a sensitive person, e.g. a child or elderly person, may be up to 100 times more susceptible than the test animals in the study.
3. The exposure estimations are based on models, which usually will overestimate the actual exposure.

A margin of safety is necessary to make sure that operators will not experience adverse effects if (incidentally) the product is not used entirely according to the GAP. In considering the need for a pesticide, the responsible authority should weigh the benefits against the risks the pesticide would pose if it were to be used under local conditions.

More details on exposure and hazard estimation for use with operator risk assessments are given in Annex 12. An instruction for downloading the EFSA AOEM model is given in Annex 13. Guidance on using the EFSA AOEM model for assessing the risks for operators and workers is given in respectively Annex 14 and Annex 15.

3.7.3 Myanmar specific guidance for the risk assessment for consumers (dietary)

3.7.3.1 Theory consumer risk assessment

People can be exposed to pesticide products by consuming treated food and drinking water that has been contaminated with (residues of) pesticides (Figure 11). In this chapter the assessment of residues in consumable crops and the assessment of consumer risk will be described in detail.

Consumer exposure is assessed by establishing which consumers will be exposed and comparing the magnitude of exposure to a toxicological reference value.

Figure 11 *Consumer exposure: from the farm to the fork.*

To assess whether the residues resulting from the application of a plant protection product have no adverse consequences for the health of consumers, the endpoints from the toxicological dossier and the corresponding reference value (ADI and ARfD) must be compared to the expected exposure (Figure 12).

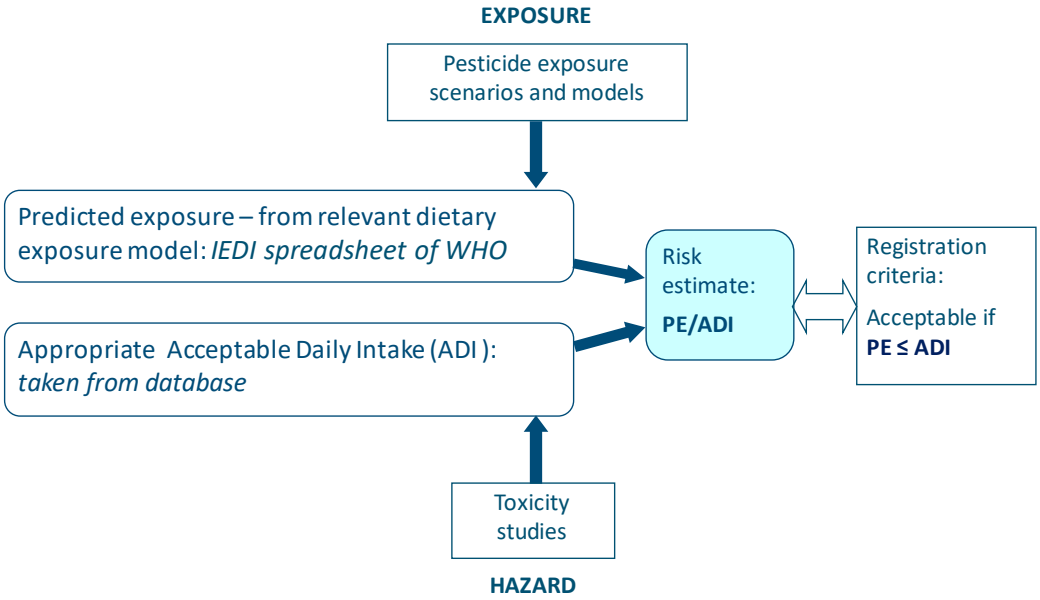

Figure 12 *Chronic consumers (dietary) risk assessment proposed for Myanmar.*

The expected exposure is calculated using the expected residue levels in the treated crops and contaminated water, consumption patterns, bodyweight of consumers and a number of other parameters. Expected residue levels and the MRL (legal value, Maximum Residue Level) are obtained from studies with the active substance. Furthermore, MRLs are needed for crop export to assess whether the instructions for use were adhered to during cultivation of the crop.

In countries that have sophisticated systems to evaluate the risks of pesticides, the process of assessing a residue profile and assessing the risk for consumers is usually as described below.

Before the exposure can be assessed, the residues relevant for consumer exposure should be identified by means of metabolism studies, since the applied parent compound may be partly or completely degraded to metabolites.

When the residues relevant for consumer exposure have been established, supervised residue trials are performed in accordance with the intended use(s), analysing the relevant residues. These residue trials are the basis for deriving the levels of exposure of the consumer, since levels found in these studies are used for the derivation of the magnitude of residues. For assessment of consumer risk, the outcomes of supervised residue trials are used in dietary assessment models, comparing the results against toxicological reference values.

There is currently not enough capacity at the PPD to evaluate or perform metabolism studies and studies on supervised residue trials. Some background information on terms relevant in consumer exposure and risk assessment (Acceptable Daily Intake, residue definition, supervised residue trials, maximum residue levels, definition of endpoints) is given in Annex 16.

Guidance for the PPD on the assessment of consumer exposure is discussed in section 3.7.3.3 and MRLs for export of crops are discussed in Annex 19.

3.7.3.2 Principles of consumer exposure assessment

This section describes the principles of consumer exposure assessments as proposed for Myanmar. They are based on the exposure assessment as performed in the EU.

Risk assessment concerning consumer exposure needs to be performed to exclude a risk for consumers eating treated crops. Consumer risk is assessed for chronic (lifelong) as well as acute (one time and coincidentally high) exposure.

The endpoints from the toxicological dossier and the corresponding limit values (ADI, ARfD) of a certain active substance must be compared to the expected exposure to assess whether the application of a plant protection product has no adverse consequences for public health. Exposure estimation is based on data from the residue dossier.

Consumer risk assessment uses a tiered approach. The first tier is based on a worst-case situation with regard to the estimated exposure (all crops treated according to critical GAP, all products are assumed to have residue levels equal to MRL, no processing such as peel-pulp distribution, boiling etc. is assumed). If the first-tier criteria are not met, supplementary data can be provided and a refined risk assessment could be carried out (called 'higher tier').

In the assessment of risk to consumers, both chronic intake and acute intake are calculated. For each crop a Supervised Trial Median Residue level (STMR), a Highest Residue (HR) and a Maximum Residue Limit (MRL) are derived from the residue trials, as explained in Annex 16. Consumer exposure to residues of pesticides is determined on the basis of the residue data provided, in combination with dietary data from a relevant region (region with the same dietary habits). The first tier chronic consumer risk assessment (see Eq. 2) uses MRL values which can be obtained from a relevant database, e.g. the FAO/WHO compiled Codex Alimentarius (Codex, 2017).

The intake calculations indicate how much residue is ingested by consumers as a result of the use of a specific active substance under Good Agricultural Practice (GAP). This intake may not exceed the value of the ADI (life-long exposure) and ARfD (one time and coincidentally high exposure).

At present for Myanmar we propose to perform only the first tier of the chronic consumer exposure assessment. Once Myanmar gained further capacity for performing first tier chronic consumer risk assessments, the acute risk assessment and the more refined (i.e. higher tier) risk assessments can be performed.

Chronic risk assessment for consumers as proposed for Myanmar
A 'worst case scenario' is tested as a first tier. It is assumed that all crops from which the consumed products were derived have been treated, and residues will be present at the level of the MRL. Products can be consumed raw or processed. As a first tier risk assessment, it is assumed that all consumed products are raw which is reflected by the top line of each crop[8]. Dietary data relevant for Myanmar can be found in WHO GEMS[9] Cluster Diet 09 (WHO, 2012, 2017b).

This worst case scenario is also called the International Theoretical Maximum Daily Intake (ITMDI) calculation:

$$ITMDI = \Sigma (MRLi \times Fi) \qquad \text{Eq. 2}$$

MRLi = Maximum Residue Level of a product (mg/kg)
Fi = corresponding national consumption of the product per person (kg/day)

If the ITMDI of cluster 09, which represents Myanmar, is found to exceed the ADI, a second tier calculation may be performed: an IEDI (International Estimated Daily Intake) calculation, in which processing data are included and the STMR (median residue level) instead of the MRL is used as residue level.

$$IEDI = \Sigma (STMRi \times Ei \times Pi \times Fi) \qquad \text{Eq. 3}$$

STMRi = Supervised trial median residue level of a certain product (mg/kg)
E = factor for the edible part of the particular product
P = processing factor of the particular product
F = corresponding national consumption of the particular product per person (kg/day).

Principles of the acute risk assessment for consumers as performed in the EU are given in Annex 17.

Relevant references
http://www.who.int/foodsafety/publications/chem/en/pesticide_en.pdf
http://www.who.int/foodsafety/databases/en/
http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

3.7.3.3 Guidance specifically for Myanmar

National risk assessment for food products
In consultation with the PPD it was recommended to perform only a first tier chronic risk assessment in Myanmar and for the time being, not to perform an acute dietary risk assessment. Arguments are that:
- Currently, no adequate data are available for performing an acute dietary exposure assessment, and the capacity available at the PPD for performing risk assessments is limited
- The chronic dietary exposure assessment can be considered rather worst case, since the MRL is used as input.

The cases presented in section 3.7.3.2 are included in the WHO-GEMS spreadsheet for IEDI (Excel spreadsheet). Hence, the formulas are also included in this model. The only input parameters needed for the first tier chronic evaluation in Myanmar are the ADI and MRL. In the future, more refined higher tier risk assessments might be performed. For these higher tier risk assessment the STMR and processing data are needed.

[8] The top line of each crop in the WHO-GEMS spreadsheet is the total crop consumed, expressed as raw commodity. The processed products like juice are converted to raw fruit and added to fruits eaten raw. Since MRL and STMR values are derived for raw commodities, the diets or these commodities (g/persons per day) are most appropriate for the first tier risk assessment (personal communication Janhendrik Krook of Linge Agroconsultancy).
[9] Global Environment Monitoring System (for monitoring and assessment of food contamination).

As currently no diet information is present for the Myanmar people, a model designed to fit specifically to the population of Myanmar is not available. Instead, the WHO-GEMS regional C09 diet will be used as a best approximation to the Myanmar diet.

In the model, the results of the chronic calculations are expressed as **a percentage of the ADI**. A proposal for decision making using the outcome of the model in given in the section below. A short Myanmar specific manual of the tool used for the (first tier) chronic risk assessment of consumers is given in Annex 18.

First tier chronic risk assessment for consumers
In the first tier, the risk assessment is performed by using the established Codex Alimentarius MRLs. Note that MRLs calculated from the submitted residue trials using the OECD MRL calculator could also be used. However at present Myanmar lacks capacity to perform or evaluate residue trails.

Proposed decision making on the outcome of the first tier calculation:
a. Total dietary exposure (ITMDI) is ≤ 100% of ADI: no adverse effects on consumers are expected (acceptable risks) and authorisation can be granted.
b. Total dietary exposure (ITMDI) > 100% of ADI: Adverse effects on consumers cannot be excluded (unacceptable risks) and the risk assessment should be refined.

Myanmar specific guidance for higher tier chronic consumer risk assessments for consumers and for assessing residue levels for crop export are given in Annex 19. The guidance given in this annex is of interest only at a later stage, when Myanmar has gained experience and the capacity to perform residue analysis of treated crops and to perform residue trials.

3.7.4 Mitigation measures feasible in Myanmar

In the project it was assessed which mitigation measures could be realistically implemented in Myanmar and under which circumstances (Annex 3).

For the occupational risk assessment, mitigation measures by way of personal protection equipment is an integral part of the assessment. For the operator risk assessments, risks will be calculated for three different options of personal protection equipment: for 1) application without PRE/PPE, 2) with full PPE (incl. head and respiratory protection FP2) and 3) a combination of PRE/PPE that is most appropriate according the regulator. For the worker risk assessment risks will also be calculated for three different options of personal protection equipment: for 1) without PPE, 2) PPE: work wear (arms, body and legs covered) and 3) full PPE: work wear + gloves.

Mitigation measures are not an integral part of the consumer risk assessment. Mitigation options which could be considered by the PRB are: grant no registration, restrict the use of the pesticide, and increasing the pre-harvest interval (see also Annex 3). In case of the latter option it should be evaluated whether the pesticide still provides efficacious pest/disease control given its instruction of use.

3.7.5 Decision making based on human health risk assessments

Results of the occupational and consumer risk assessments are reported by the PPD in the decision supporting summary (Annex 7). Based on the information provided in the decision supporting summary the PRB can decide which risks, and in case of the occupations risk assessments which mitigation options, are acceptable for Myanmar.

The occupational risk assessment is performed by comparing the exposure estimates to the reference value (AOEL). Therefore, exposure is expressed as a percentage of the AOEL. Deciding whether risk are acceptable or not is based on the established percentage:

- No adverse effects on humans are expected (acceptable risks) if:
  Total systemic exposure is ≤ 100% of AOEL.

- Adverse effects on humans cannot be excluded (unacceptable risks) if:
  Total systemic exposure >100% of AOEL,

The risk assessment for consumers in Myanmar is performed by comparing the exposure estimates (result of the WHO IEDI spreadsheet; which is the total dietary exposure as percentage of the ADI) to the reference value (ADI). Deciding whether risk are acceptable or not is based on the established percentage:

- No adverse effects on humans expected (acceptable risks) if:
  Total dietary exposure (TMDI) is ≤ 100% of ADI

- Adverse effects on humans cannot be excluded (unacceptable risks) if:
  Total dietary exposure (TMDI) is >100% of ADI

4 Recommendations

During the first phase of the project, described in the current report, a decision supporting system for evaluation of pesticide registration dossiers was developed together with the PPD and several members of the Technical Committee. The system comprises a decision supporting flowchart and a corresponding decision supporting summary. For the elements in the flowchart that are currently judged to be feasible for the pesticide registration process in Myanmar, detailed guidance was written and tested by the PPD. We consider this guidance to be a preliminary evaluation protocol. The second phase of the project foresees in more training of the PPD staff in applying this guidance. This was highly recommended by the PPD and other stakeholders. Based on experiences with applying the guidance to recent pesticide registration dossiers, improvements in the description of the guidance may be proposed. The updated guidance will be delivered as 'evaluation manual for the registration of pesticides in Myanmar' at the end of the second phase of the project. It is recommended to translate this evaluation manual into Myanmar language to facilitate its use by PPD staff. The intention of all parties involved is that the manual will be applied in the near future in the pesticide registration in Myanmar.

One of the main constraints for using the newly developed evaluation methodology described in this report proved to be the huge number of applications for pesticide registration (~1000/year). This problem was discussed during the first phase of the project and possible solutions (including recommendations for adjusting the Pesticide Law) were identified. It is advised that this discussion is transferred to the higher (ministry) level and that incentives are implemented to reduce the number of annual applications for registration of a pesticide.

Several stakeholders recommended to start initiatives to improve inspection and enforcement and awareness raising of the risk of pesticides among farmers and consumers.

In the project the English translation of the Pesticide Law (The Pyidaungsu Hluttaw Law No. 14, 2016) was reviewed. Although, overall, the Law has many good provisions that will allow the Myanmar administration to properly regulate pesticides in Myanmar, several gaps were identified and these were discussed with the PPD. Myanmar could benefit from international expertise on establishing and improving pesticide legislation. KemI (the Swedish Chemical Agency) and FAO offered their assistance on this topic and it is recommended that the PPD makes an official request for legal assistance to the FAO.

One of the aims of the project is to achieve progress in the elimination of high-risk pesticides from the market. To this end the three-step approach developed by the FAO/WHO for risk reduction of Highly Hazardous Pesticides (HHP) was adopted. In the first phase of the project we performed an assessment whether any of the pesticide products registered in Myanmar (situation May 2017) might qualify as a Highly Hazardous Pesticide (Step 1). After establishing the short-list of HHPs, further assessment of risks, needs and alternatives should be conducted for all identified HHPs (Step 2), and risk mitigation measures should be discussed, adopted and implemented (Step 3). It is advised to continue the work on this subject during the second phase of the project.

Several stakeholders recommended that the PPD, TC and PRB discuss counterfeit products and illegal products. There are concerns that the new evaluation methodology and/or the HHP risk reduction process lead to higher prices for pesticide products and lower availability of some cost-effective products and that his consequently might lead to an increase of illegal products in the country. Problems with counterfeit products are increasing worldwide, also in industrialized countries.

Data protection is not well organised in Myanmar and this is a major constraint for companies to apply for registration of newer products. It is recommended that the PPD guarantees data protection by adopting adequate archiving systems and that data protection is anchored in the Myanmar Law.

References

Note that for many of the references a link to the website is given; it is our experience that websites are often changed and that paths to particular sites are quickly outdated. The data that the path was checked last is given as part of the information on the link. If a link is outdated it is probably best to search for the title given, using a search engine like e.g. Google or Bing. Another option is to check the FAO Pesticide Registration toolkit website (Information sources – Hazard classifications): http://www.fao.org/pesticide-registration-toolkit/tool/page/pret/hhp/hazard-classifications. The website regularly updates paths to the different websites and the FAO indicated that the pesticide registration toolkit website will be maintained for years to come.

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Annex 1 Pesticide registration process in Myanmar – April 2016

Phase	Steps																	
Pre-registration	**Pre-application meeting**	>	**Experimental permit**															
Yes/No	**Informal Discussion**		**YES, as part of Reg Proc**		no official permit but import endorsement for trial													
Who?	**PPD - Reg Sect**		**PPD**															
How long?			**< 1 week**															
Formalized?	**NO**		**NO**															
Constraints?	**none**		**none**															
																Extra steps		
Registration	**Submission of the dossier by the applicant**	>	**Initial administrative actions by the registration authority**	>	**Completeness check**	>	**Dossier evaluation**	>	**Registration decision and risk management**	>	**Publication and dissemination of the registration decision**					Supervision of trials	Quality control step
Yes/No	**YES**		**YES**		**YES**		**YES**		**YES**		**YES**							
Who?	**PPD**		**PPD**		**PPD, Internal TC**		**RS pre-evaluates; TC, internal and external**		**PRB, follows TC**		**PPD through PP officers**							
How long?	**n.a.**		**1/2 hr**		**1-2 hrs**		**1 wk - 1 month**		**1 day (max 6 months wait)**		**1 month**							
Formalized?	**YES**		**YES**		**YES**		**????**		**Yes, becaused basd on recomm TC**		**YES, but no central publication**							
Constraints?	**none**		**none**		**none**				**none**									

Phase		Steps											
Post registration		**Archiving**	**>**	**Notification of the Rotterdam Convention**	**>**	**Monitoring and evaluation**	**>**	**Extensions and changes**	**>**	**Appeals and litigation**			
Yes/No		**YES; 3 copies**		**NO**		**YES**		**YES**		**NO**		1 dossier = 1 binder of ~200 p	R'dam never notified
Who?		**At PPD**				**PPD, Public Health, inspectors at states and divisions**		**PPD**				market surveys	
How long?													
Formalized?		**YES**											
Constraints?		**Space**				**resources for sampling; limited staff**							
Review		**Periodic or unscheduled review**	**>**	**Re-registration or cancellation of registration**									
Yes/No		**YES**		**YES**									
Who?		**PRB**		**PRB**									
How long?													
Formalized?		**Yes (limited review)**											
Constraints?													

Annex 2 Table of Intended Uses *or* Good Agricultural Practice (GAP) table [10]

Product name:		**Active ingredient name:**		**Concentration of active ingredient:** (g/kg or g/L)		**Formulation type:**	

Use no.	**Crop and/or situation**	**Use** (F, G or I)	**Pests or group of pests controlled**	**Application**				**Application rate**			**PHI** (days)	**Remarks**
				Method / kind	Timing / Growth stage of crop & season	Number (min. – max.)	Interval between applications (min.)	g or L product/ha (min – max. per application)	g or kg a.i./ha (min – max. per application)	Water L/ha (min – max.)		
1												
2												
3												
4												

[10] Table of Intended Uses is modified from OECD Dossier Guidance (rev. 2, 2005) and EU Data Requirements for Efficacy Guidance (rev. 3, 2013)

EXPLANATIONS

General remarks: All abbreviations must be explained.

Product name: Indicate as proposed to be placed on the market. If additional components have to be added to the applied product (tank mixtures; e.g. safeners, synergists), all relevant information must be provided in the column remarks.

Active ingredient name: Use pesticide common names. In case the product contains more than one active substance, provide all names.

Formulation type: Use CropLife International codes, if available. *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) [https://croplife.org/wp-content/uploads/pdf_files/Technical-Monograph-2-Revised-May-2008.pdf]

Crop and/or situation: For crops, Codex classifications should be used, if available. For other uses, the use situation should be described (*e.g.* fumigation of a store, indoor residual spraying against mosquitos, …).

Use: Outdoor or field use (F), glasshouse application (G) or indoor application (I).

Pests or group of pests controlled: Scientific and common names should be provided, and (if relevant) names of pest groups (*e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds, mosquitos); indicate developmental stage of the pest at the moment of application.

Application – Method/kind: ***Method:*** *e.g.* high volume spraying, low volume spraying, spreading, dusting drench. ***Kind:*** *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants – type of equipment used must be indicated.

Application – Timing/growth stage of crop & season: Time(s), period, first and last treatment. Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants – 2001 [https://ojs.openagrar.de/index.php/BBCH/article/view/515]), including where relevant, information on season at time of application.

Application – Number: The minimum and maximum number of application possible under practical conditions of use must be provided. It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Application – Interval between applications: Minimum interval between subsequent applications should be provided

Application rate – g or L product/ha: Minimum and maximum rate per application (in g or L of product per ha) should be provided.

For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or boxes used for storage of fruits, roots). For seed treatment, also the load of product (L or g or kg) per kg or 100 kg or unit treated seed should be stated, beside the application rate per hectare.

See also EPPO-Guideline PP 1/239 Dose expression for plant protection products [https://pp1.eppo.int/list.php]

Application rate – g or kg a.i/ha: Minimum and maximum rate per application (in g or kg of active ingredient per ha) should be provided. For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or boxes used for storage of fruits, roots).

In case the plant protection product contains more than one active ingredient the application rate for each active ingredient should be indicated in the same order as the a.i.'s are mentioned in the heading.

Application rate – Water L/ha: If relevant, minimum and maximum quantities of water, with which the product is to be diluted, should be provided

PHI: Minimum pre-harvest interval (or other withholding periods), in days

Annex 3 Review of the feasibility of risk mitigation measures for pesticide registration in Myanmar

Outcome of the assessment of feasibility of risk mitigation, conducted by PPD and TC members in March 2017. Assessment was done by four working groups; an "X" in the table refers to the view of one working group.

A: Human health (operator and consumer exposure)

Risk mitigation measure	Limiting occupational exposure	Limiting consumer exposure	Conditions	Feasibility in Myanmar (outcomes of 4 working groups)			Remarks
				Well feasible	Feasible, but only in certain situations	Not feasible	
Do not register the pesticide (or phase-out a registered pesticide)	■	■	Alternative pesticides or pest management options may need to be available	XX	X	X	Consensus: feasible, but if alternatives are available.
Severely restrict the use of the pesticide (e.g. only by licensed users)	■	■	Enforcement should be effective	X	XX	X	Consensus: may be feasible. Special use permit not explicitly in the law; legal basis stronger may need to be stringer. Licensing operators is not common and enforcement is limited
Reduce the application rate	■	■	Reduced rate should be efficacious			XXXX	Not feasible: No information available at registration to allow lower rates.
Reduce the application frequency and/or increase of re-treatment interval	■	■	Reduced frequency or increased re-treatment interval should be efficacious			XXXX	Not feasible: No information available at registration to allow lower frequencies
Require specific personal protective equipment (PPE)	■		PPE should be available and affordable to users	X	XXX		Consensus: may be feasible. However, depends much on farmer awareness and climatic conditions (regions in the country). Commercial applicators or farmers may implement this more easily.

Risk mitigation measure	Limiting occupational exposure	Limiting consumer exposure	Conditions	Feasibility in Myanmar (outcomes of 4 working groups)			Remarks
				Well feasible	Feasible, but only in certain situations	Not feasible	
Require engineering measures to reduce exposure (e.g. low drift nozzles, closed cabin on tractor, close-circuit pesticide pumping system)	■		Equipment should be on the market (or can readily be made available) and is affordable to users	X	XXX		Consensus: may be feasible for commercial farmers (nozzles on the market); not feasible for smallholder farmers.
Limit the authorization to lower risk pesticide formulations (e.g. water-soluble granules instead of liquids)	■		Lower risk formulation should be efficacious. (may require new registration application)	XXXX			Measure is controlled by registrar
Require low-risk packaging (e.g. water-soluble sachets)	■		Low-risk packaging should be compatible with the formulation	XXXX			Measure is controlled by registrar
Require minimum re-entry intervals (for workers, pickers)	■		Work in the field should resume when agronomically required (e.g. harvest time)		X	XXX	Consensus: not feasible. Requires much information/extension. Lack of observance by farmers.
Increase pre-harvest intervals		■	Longer pre-harvest interval should allow for efficacious pest management			XXXX	
Require specific precautionary statements on the label	■	■	Users should be literate or have access to a literate person	XXXX			Feasible. Farmers communicate label information among them, so also reaching illiterate pesticide users.

B: Environmental exposure

Risk mitigation measure	Limiting groundwater exposure	Limiting surface water exposure and adverse effects on aquatic organisms	Limiting pesticide exposure and adverse effects on bees (in- and off-crop)	Limiting pesticide exposure and adverse effects on non-target arthropods (in and off-crop)	Limiting pesticide exposure and adverse effects on birds and wild mammals	Conditions	Feasibility in Myanmar (outcomes of 4 working groups)			Remarks
							Well feasible	Feasible, but only in certain situations	Not feasible	
Registration measures										
Do not register the pesticide (or phase-out a registered pesticide)	■	■	■	■	■	Alternative pesticides or pest management options may need to be available	X			See human health
Reduce the application rate	■	■	■	■	■	Reduced rate should be efficacious		X		See human health
Reduce the application frequency and/or increase of re-treatment interval	■	■	■	■	■	Reduced frequency or increased re-treatment interval should be efficacious			X	See human health
Restrict use to formulation types that result in less drift/run-off/drainflow (e.g. slow-release formulations, seed coatings, granules)		■				Lower risk formulation should be efficacious (may require new registration application)			X	See human health
Restrict use to formulations which pose less risk to the non-target organisms			■	■	■	Lower risk formulation should be efficacious. (may require new registration application)	X			
Restriction in space										
Restrict use to low- or no emission applications (e.g. glasshouses, containers, baiting, dipping, soil incorporation, seed treatment)	■	■	■	■	■	Effectiveness of the measure depends on the pesticide and the non-target organism		XXX	X	Consensus: may be feasible. But Farmers often do not follow label instructions
Restrict use to soil types that are less vulnerable to leaching or not subject to excessive crack-flow	■	■				Geographical restriction of pesticide use should be feasible and enforceable			XXXX	Lowlands have more clay soils and highlands more sand; but patchy, not generalized.

Risk mitigation measure	Limiting groundwater exposure	Limiting surface water exposure and adverse effects on aquatic organisms	Limiting pesticide exposure and adverse effects on bees (in- and off-crop)	Limiting pesticide exposure and adverse effects on non-target arthropods (in and off-crop)	Limiting pesticide exposure and adverse effects on birds and wild mammals	Conditions	Feasibility in Myanmar (outcomes of 4 working groups)			Remarks
							Well feasible	Feasible, but only in certain situations	Not feasible	
Restrict use to areas with low annual rainfall, to reduce leaching	■					Geographical restriction of pesticide use should be feasible and enforceable			XXXX	Geographical restrictions not possible nor enforceable
Restrict use to regions with deep groundwater level	■					Geographical restriction of pesticide use should be feasible and enforceable			XXXX	Geographical restrictions not possible nor enforceable
Restrict use to non-drained fields and/or require holding times to release water		■				Geographical restriction of pesticide use should be feasible and enforceable			XXXX	Geographical restrictions not possible nor enforceable
Do not authorize bankside applications or applications in or on water		■					XX		XX	
Do not apply close to vulnerable habitats for birds (e.g. nature reserves; bird sanctuaries)					■	Geographical restriction of pesticide use should be feasible and enforceable			XXXX	No legal restrictions on pesticide use in protected areas and nature reserves.
Restrictions in time										
Apply a no-spray or no-crop buffer zone between the treated area and the off-crop area	■	■	■	■	■	Will only protect non-target organisms that live off-crop			XXXX	Small plots; will not be respected by farmers
Restrict use to certain periods in the year when leaching, run-off or drainage is likely to be less important (i.e. periods with low rainfall and/or sufficient vegetation cover)	■	■				Temporal restriction of pesticide use should be feasible and enforceable			XXXX	No clear distinctions between dry season and wet season crops in large parts of the country.

Risk mitigation measure	Limiting groundwater exposure	Limiting surface water exposure and adverse effects on aquatic organisms	Limiting pesticide exposure and adverse effects on bees (in- and off-crop)	Limiting pesticide exposure and adverse effects on non-target arthropods (in and off-crop)	Limiting pesticide exposure and adverse effects on birds and wild mammals	Conditions	Feasibility in Myanmar (outcomes of 4 working groups)			Remarks
							Well feasible	Feasible, but only in certain situations	Not feasible	
Change the periods of application (e.g. do not apply during crop flowering or in-crop weed flowering)			■			Target pest should not be present during flowering		XXXX		Requires awareness; but some farmers already avoid spraying during crop flowering.
Change the timing of application (e.g. only in the evening, when honeybees are not flying, or to allow the pesticide deposit to degrade)			■	■		Only applicable to rapidly degrading pesticides		XXXX		Some knowledge about importance of bees. Some farmers already spray in evening, but mainly because of lower temperature.
Restrict time of application to periods when birds or mammals are not breeding					■	If the pesticide poses a reproductive risk		XXXX		Might be possible for pesticides used on livestock; farmers are aware.
Engineering controls										
Apply drift-reducing techniques (e.g. low drift nozzles)		■	■	■		Equipment should be on the market (or can readily be made available) and is affordable to users				See human health
Do not authorize aerial applications		■	■	■						No aerial applications are conducted in Myanmar
Restrict use to drip irrigation/chemigation		■				Equipment should be on the market				Drip irrigation not common in Myanmar
Cultivation controls										
Grow wind breaks to avoid exposure of off-crop areas		■	■	■		Land should be available to the farmer for this purpose			XXXX	Not the responsibility (or influence) of the PPD
Require soil incorporation of the pesticide (granules) to a certain depth		■			■	Appropriate equipment should be available			XXXX	Granular pesticides are mainly broadcasted

Risk mitigation measure	Limiting groundwater exposure	Limiting surface water exposure and adverse effects on aquatic organisms	Limiting pesticide exposure and adverse effects on bees (in- and off-crop)	Limiting pesticide exposure and adverse effects on non-target arthropods (in and off-crop)	Limiting pesticide exposure and adverse effects on birds and wild mammals	Conditions	Feasibility in Myanmar (outcomes of 4 working groups)			Remarks
							Well feasible	Feasible, but only in certain situations	Not feasible	
Mulch or mow ground cover before application (if attractive to bees)			■							Muclhing not applied in Myanamr; could become part of IPM at later stage.
Limit application to spot or row treatments only					■	Efficacy against the target pest should not be affected		XXXX		Could become part of IPM at later stage.
Labelling										
Require specific precautionary statements on the label	■	■	■	■	■	Will often refer to one or more of the other measures in this list. Users should be literate or have access to literate person.	XXXX			
Other risk reduction measures										
Prohibit cleaning of equipment near well heads or bank sides	■	■					XXXX			Farmers can observe this measure relatively easily
Require advance notification of beekeepers to allow them to relocate the beehives			■			Communication between farmer and beekeeper should be effective		XXXX		Requires improvement in the communication between farmers and beekeepers. Requires pesticides with low toxicity to bees.
Require immediate removal of any spills (of granules)					■					May need to be included on the label
Require of burrow-baiting or bait station (for rodenticides)					■			XXXX		Bait stations already required/recommended for some rodenticides
Require removal of dead and moribund rodents, and of bait remains after completion of the control operation (for rodenticides)					■	Effective mainly for acutely toxic rodenticides		XXXX		Not common practice.

Annex 4 Details of the discussion of the stakeholder meetings in February 2018

Stakeholder meeting in Nay Pyi Taw, February 5th 2018

Figure 13 *Group photo of the participants of the stakeholder meeting in Nay Pyi Taw.*

Feedback of the participants of the stakeholder meeting on possible options for reducing the number of applications for pesticide registration is given in the tables below.

	Proposed option	Feasibility?	Do you support this option?	Reason for support or no support
1.	Increase the registration fee. Increase of the registration fee may limit the applications for registration to products for which the applicant sees a real market. Legal basis exists under the 2016 Pesticides Law.	3x yes	2x yes 1x no	Support: Found to be effective for lowering the number of applications for pesticide registration No support: Increasing transaction costs Disadvantage for end user: product gets more expensive Concerns that it will lead to an increase of illegal products in the country.
2.	Establish a registration maintenance fee. Establishment of a maintenance fee (e.g. annual) to maintain the registration of a pesticide in the Register, will likely reduce the number of pesticides that are registered; companies that do not sell their product in Myanmar may pull their product off the register. Legal basis under the 2016 Pesticides Law is unclear.	3x yes	3x yes	Support: Makes it possible to analyse the active importers Provides scope for excluding inactive importers
3.	Make the registration fee due for payment before the start of the dossier evaluation by the PPD, *i.e.* the fee should be paid when submitting the application. Currently a fee is paid upon a successful registration (so after dossier evaluation and only for products receiving a registration). Paying the application fee simultaneously with the submission of the application may limit the applications for registration to products for which the applicant sees a real market. Legal basis does not exist under the 2016 Pesticides Law. The 2016 Pesticide Law (article 14c) states that the registration fee should be payed if the permission of registration is obtained, implying payment only after conclusion of a successful registration.	3x yes	3x yes	Note: amendment of law is needed Support: Will lead to more qualified products in the market Scope for differentiating between active and in active importers Suggestion participants: Consider to install three type of fees: Registration fee Administration fee Laboratory fee
4.	Abolish the provisional registration, or reduce the period of provisional registration to 1 year, or grant provisional registration only once, requiring full registration thereafter. Currently most applications are for provisional registration. Provisional registration is granted for a relatively long period (5 years) and less data is required than for full registration. Setting limits for provisional registration may limit the applications for registration to products for which the applicant sees a real market. Legal basis does not exist under the 2016 Pesticides Law	3x yes	3x yes	Suggestions for periods of 1 year (check the qualified product in the market during 1 yr), 2-3 years and period should be based on the shelf-life of the product.

	Proposed option	Feasibility?	Do you support this option?	Reason for support or no support
5.	Stricter evaluation of efficacy. For provisional registration, the application does not need to hand in efficacy studies performed in Myanmar (efficacy studies are only needed in case of a new active ingredient). Reports of efficacy studies performed in other countries can be used. The evaluation of these studies can be done in a more strict way, *e.g.* i) by requesting that crops specified in the GAP for Myanmar match the crops used in the efficacy trials, ii) requesting that growth/climatic situations of the efficacy trials match those of Myanmar (*e.g.* efficacy trials from North EU may not be representative for the Myanmar situation). By using stricter requirements for the evaluation of efficacy, the applicant is forced to put more effort into gathering suitable efficacy data. This may limit the applications for registration to products for which the applicant sees a real market.	2x no 1x yes	2x no 1x yes	Support: Might be considered for relatively new products No support: Not enough resources at PPD to evaluate the efficacy reports Difficult to implement
6.	Stricter completeness check. It was noticed that pesticide registration dossiers at the PPD do not always contain all data required (data requirements). By being stricter on the completeness check, the applicant is forced to put more effort into fulfilling the data requirements. This may limit the applications for registration to products for which the applicant sees a real market.	3x yes	3x yes	This options is currently under discussion in the PRB. The proposal is that the applicant gets one chance to hand in a complete dossier. The PPD checks the dossier once on completeness. If it is not complete there will be no further evaluation and the application will be discarded. Completeness check is considered to be not very time-consuming.
7.	*The following issue concerns the question: "what is the toxicity of the product in the bottle (what ends up on the shelf of the shop)?* Stricter consideration of acute toxicity data. Request that the company always delivers toxicity studies for the formulated product ("6-pack" or part of "6-pack"). Alternative for option above: The company should provide the "recipe" of the formulated product, enabling extrapolation of active ingredient toxicity data to toxicity for the formulated product. Companies often do not like to provide their "recipe", which is considered to be a part of their intellectual property. Sharing the "recipe" enables production of the same formulated product.	3x yes	3x yes considered to be very important by some participants	<u>Remarks:</u> Should be made very clear in data requirements that the "6-pack" is required for the formulated product. Experience of PPD that some companies do not want to provide this information.

	Proposed option	Feasibility?	Do you support this option?	Reason for support or no support
8.	At the moment it is common practice in Myanmar that product "b" with active ingredient "x" automatically obtains a registration if there is already a registration in place for a product "a" using the same active ingredient "x". Consider to maintain this rule only for those products for which the formulation is comparable.	3x yes	2x yes 1x no	Remarks: Quality control of all products needed No support: Current practise is preferred because this results in a higher number of different products for the end user Will result in more expensive products, thus more illegal products More likely that one importer sets the standard considering the formulation (i.e. first importer asks registration for a certain formulation; all others follow with the same formulation). Fear of only getting only limited formulation types on the market.

Stakeholder meeting in Yangon, February 7th 2018

Figure 14 *Group photo of the participants of the stakeholder meeting in Yangon.*

Discussion on risk reduction of Highly Hazardous Pesticides

One of the aims of the project is to take steps in the elimination of high-risk pesticides from the market. To this end the three-step approach developed by the FAO/WHO for risk reduction of Highly Hazardous Pesticides (HHP) was adopted (http://www.fao.org/3/a-i5566e.pdf).

According to the International Code of Conduct on Pesticide Management, HHPs are defined as: *Pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as the World Health Organization (WHO) or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous.*

The FAO/WHO three-step approach for reducing the risks of HHPs comprises: 1) identification of HHPs, 2) assessing the risks, needs and possible alternatives and 3) discuss, adopt and implement risk mitigation measures. The final aim of the risk reduction process is to ban or restrict HHPs or limit in permitted uses, but with a sound underpinning.

The PPD and WUR conducted an evaluation of all pesticide products registered in Myanmar by May 2017 with the objective to identify Highly Hazardous Pesticides (HHPs) (Step 1) (see Table 2). The pesticide products were assessed using the guidance based on FAO/WHO criteria to identify HPPs. Now the short-list of HHPs has been established, further assessment of risks, needs and alternatives should be conducted for all identified HHPs, and risk mitigation measures should be discussed, adopted and implemented. This work is foreseen for the second phase of the project.

We asked the participants of the stakeholder meeting to give their feedback on the plans for risk reduction of Highly Hazardous Pesticides. In particular on Step 2 of the risk reduction plan because in this step the input of the different stakeholders could be valuable.

Step 2 in the development of the risk reduction plan of each individual HHP product is i) to assess of risks of the product identified as HHP in Step 1 and ii) to assess to what extent current uses of the product are actually needed and whether alternatives are available (this is also referred to as needs and alternatives assessment).

Two of the four break-out groups gave their feedback on i) the risk assessment phase and ii) the needs and alternatives assessment phase, by discussion the questions provided below.

i) Risk assessment

Risk assessment could be based on studies about actual impact, available models to assess risk, exposure monitoring data, field observations or surveys of use, bridging to risk assessments which were done in other countries or regions.

Discussion point 1a

*What type of information could be made available by stakeholders, that may be of use for the **risk assessment** of the individual HHP products?*

Discussion point 1a – summary discussion

- Poisoning data – ministry of Health.
- Field observations Inle lake – one campaign, 10 years ago – Ministry of Health, Ministry of Environment.
- Full pesticide residue studies– could be provided by applicant
- Government side needs to guarantee data confidentiality and possibility to countercheck the study package provided.
- Research institutes could also conduct pesticide residues studies in order to deliver data for the consumer risk assessment.
- Consider to refer to risk assessments done in neighbouring or ASEAN countries.

ii) Needs and alternatives assessment

It is foreseen to possibly use stakeholder fora to advise on:

- For what purpose is the specific pesticide identified as HHP being used?
- What chemical and non-chemical alternatives are registered/available, or can be made available?
- How effective are the alternatives?
- What are the limitations of the alternatives ?

Discussion point 1b

What type of expertise would be needed in such a stakeholder meeting?

Discussion point 1b – summary discussion

- Plant pathologists
- IPM specialists
- Product specialists/ supplier of products
- Entomologists
- Weed specialists
- Rodent specialists
- Chemists (lab: PAL)
- Medical doctors (poisoning)
- Environmental experts/environmental health specialists
- Practical experience (farmers)

Discussion point 1c

What type of information could be made available by stakeholders (applicants, governmental organisations, research organisations), that may be of use for the discussions.

Discussion point 1c – summary discussion

- Import data – from government/PPD
- Effectivity of product – from farmer association and universities
- Spatial data on pests & diseases – from PPD (extension services) and companies
- Which product is sold where? – companies
- Alternatives for HHP – PPD, companies, CropLife, experts from donor project on improving agricultural extension services
- Alternative solutions from other countries.
- Usage of product and hazardous situations – farmers
- Detailed information on risk of product – private sector/companies
- Detail product registration status up-to-date – PPD

Discussion point 1d

Which stakeholders should be involved in the needs and alternatives assessment fora (e.g. plant protection and extension services, plant protection research institutes, suppliers of pesticides and biological alternatives, farmers organizations, etc.).

Discussion point 1d – summary discussion

- PPD
- Pesticide companies/distributers
- CropLife
- Farmers/Farmer associations/Farmers cooperation's
- Local research organisations
- Registration authorities of other (neighbouring) countries
- Exporters/traders (of agricultural commodities)
- Organisations working on agricultural extension services
- Consumer organisations
- Women organisations
- Government (Environment/Public Health)

General remarks during the discussion on Highly Hazardous Pesticides

- Current HHP products are effective to control pest/disease but risk assessment for human and animal has not been conducted.
- Raising awareness among farmers considering the risks when using these products is very important.
- Currently, carbofuran (identified as HHP) is the only available solution for nematodes and soil borne diseases. There are other alternatives but none can compete the cost-effectiveness of carbofuran. Concerns for illegal import if products with carbofuran are taken of the market.
- For benomyl (identified as HHP) there are many other alternatives, but the market situation will need to be considered.
- GIZ can provide assistance considering food safety issues – technical cooperation, no hardware.

Discussion on current practices in pesticide registration in Myanmar

During the discussion session two of the four break-out groups focussed on discussing current registration practices in Myanmar and the newly developed evaluation methodology. Considering discussing current registration practices in Myanmar the discussion was structured around the question below:

Discussion point 2a

If you could change anything considering the current (administrative) pesticide registration process, what would this be?

Consider issues like: transparency of procedure, availability of information on process and data requirements, availability of PPD staff for consultation, fees, time needed for the registration process by PPD and Pesticide Registration Board.

Discussion point 2a – summary discussion

- Consider to improve transparency:
  - Improve website – password secured for confidential data
  - Adequate info on registration status of products
  - Establish e-office (database)
- Preferably fixed time-frames for registration procedure.
- PRB meeting 2 times a year.
- Fees should be paid at the time of application, not upon registration of product
- Increase the registration fees.
- Registration should be supported by inspection and enforcement:
  - If fake products are found on the market consider punishment for distributer and farmer. Example Vietnam: distributer pays fine of 100 times the value of the product.

Discussion on: newly developed evaluation methodology for pesticide registration in Myanmar

WUR and the PPD jointly developed an evaluation methodology for pesticide registration in Myanmar. The methodology is basically a decision support system that enables registration authorities to make sound and transparent decisions on authorizing or rejecting pesticide products. The system consists of a decision supporting flow chart and a format for an accompanying decision supporting summary (more detailed information is given in Annex 1). For the different elements in de decision supporting flow chart detailed guidance is developed. During the meeting the basic ideas of the decision supporting flow chart were explained.

During the discussion session two of the four break-out groups focussed on discussing current registration practices in Myanmar and the newly developed evaluation methodology. The interaction between the participants was guided by providing discussion points. The discussion points on the newly developed evaluation methodology and a summary of the discussion for each discussion point is given below.

Discussion point 3a

Do you support the proposed approach so far? Do you have any recommendations how to improve the process and the focus of the work.

Discussion point 3a – summary discussion

- Concerns that the human health risk assessment takes a substantial amount of time and that specialized skills are needed. Does the PPD have enough capacity to perform these risk assessments?
- The assessment methods registration by analogy and the human health risk assessments do take into account the use pattern (dose, frequency, spraying interval etc). This is supported by the participants.
- The hazard assessment is among others needed for labelling purposes – WHO and GHS classifications systems are currently used (the PPD published in 2012 the bilingual guidance 'Guideline for Pesticide Labelling'). During the project the Myanmar 'Guideline for Pesticide Labelling' was reviewed and it was concluded that the GHS classification is preferred. This is supported by the participants. GHS labels should be put on the pesticide labels in order to communicate the hazards of the product to the user.

Discussion point 3b

How can we make this work?
The support of stakeholders is an important prerequisite to make the implementation of the methodology a success (e.g. by providing adequate and complete pesticide registration dossiers, farmers following the use instruction on the label of the pesticide product).

What could you and your organisation do to make this work and do you have any suggestions for your colleague-stakeholders?

Consider representatives from pesticide industry, farmers, NGOs, research organisations, governmental institution other than PPD.

Discussion point 3b – summary discussion

- Pesticide industry should provide adequate and complete registration dossiers
- Industry should reconsider the way they advertise for products (informative for farmers instead of nice ladies running in fields)
- Support of extension services needed
  - Instructing farmers on judicious pesticide use (use according pesticide label, use of personal protection equipment)
  - Instructing farmers to use registered products only
  - Instructing famers to use warning posts in the field when spraying (warning bystanders to keep distance)
  - Awareness raising to the farmers and the general public on the risks of pesticides
  - Further develop PPD-CABI pest/disease diagnostic app.

Discussion point 3c

What would you and your organisation need from the project or from the PPD to make this work (e.g. more information, practical training on ...., other)?

Discussion point 3c – summary discussion

- Training on the risk assessment for applicants or PPD staff should give special consultation on how to perform the evaluations (incl. risk assessments).
- Improve capacity of the PPD (number of staff, knowledge level)
- System for announcement of public on pesticides that received registration is not adequate
  - Improve database (database on products registered in Myanmar is not up to date) and the PPD website.
  - Consider announcements via newspaper or Facebook
  - Also announcements to public on pesticides that did NOT receive an authorization (incl. reason why).

Annex 5 Notes for the decision supporting flow chart for pesticide registration in Myanmar (version: 6 October 2017)

[1] Is the pesticide efficacious for the intended use(s)?

The starting point for any registration of a pesticide is the efficacy of the product. If the pesticide is not efficacious, registration is not justified. Efficacy data may be generated locally, or it may be possible to extrapolate from similar situations (climate, pest, disease, agronomic practice) in other countries.

Note that effectiveness of the pesticide may be either "control" or "suppression" of the pest. Where other pest management methods are applied simultaneously with the pesticide, such as in IPM, suppression of the development of a target pest/disease/weed may be acceptable effectiveness, even if there is no complete control.

[2] Establish one or more GAPs (good agricultural practice)

On the basis of the efficacy data, Good Agricultural Practices (GAPs) will be established. These are basically the directions for use of the product: crop, pest/disease/weed, application rate and frequency, type of equipment/application, pre-harvest interval. For each crop/pest combination, or specific pesticide use, a GAP should be established. These are normally summarized in a GAP table.

[3] Is the pesticide product low risk?

If a pesticide is "low risk", it is not expected to pose human health or environmental risks even under relatively high exposure situations. Low risk pesticides include many microbial pest control products, pheromones, but also some chemical pesticides.

For low risk pesticides, in principle, no further risk assessment is required and these products may be registered.

Two sources are presently used to verify whether a pesticide active ingredient has been identified as low risk:

- EU "low risk active substances": http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN
- US-EPA "minimum risk pesticides": https://www.epa.gov/minimum-risk-pesticides/active-ingredients-eligible-minimum-risk-pesticide-products

[4] Conduct a hazard assessment

A hazard assessment is conducted as a first step to evaluate the potential risks of a pesticide. At present, this assessment focusses on human health hazards.

The pesticide formulation is classified according to the latest version of the *WHO Classification of pesticides by hazard*: http://www.who.int/ipcs/publications/pesticides_hazard/en/

Furthermore, the pesticide active ingredient is also classified according to the latest revision of the *Globally harmonized system of classification and labelling of chemicals* (GHS): https://www.unece.org/trans/danger/publi/ghs/ghs_rev07/07files_e0.html (Part 3 - Health hazards).

The ECHA C&L Inventory can be used to obtain classifications:
https://echa.europa.eu/information-on-chemicals/cl-inventory-database

[5] Is the pesticide product an HHP (Highly Hazardous Pesticide)?

Highly hazardous pesticides (HHPs) are expected to cause unacceptable risks under most, if not all, use situations in the country. Therefore, in principle, HHPs should not be registered, unless: i.) there is an emergency need for the product and, ii.) no alternatives are available.

The *FAO/WHO Guidelines on highly hazardous pesticides* (HHPs) (2016) provide international criteria and outline the risk reduction process for HHPs. A specific guidance document has been elaborated in the project for the identification of HHPs in Myanmar.

[6] Is there an emergency need for the pesticide?

In principle, HHPs should not be registered in Myanmar. However, certain specific emergency situations can occur (e.g. appearance of a new important pest, disease or human disease vector) which would justify a *restricted use registration* of a highly hazardous pesticide.

What is considered an "emergency situation" will need to be defined by the Pesticides Registration Board.

[7] Are appropriate pesticide or non-pesticide alternatives available?

If effective alternatives to an HHP are available in the country or can be made available on short notice, the HHP may not be registered, even if there is an emergency situation. Alternatives are lower risk chemical or biological pesticides, or they may be other pest control measures (e.g. biological control, agronomic interventions).

If no effective alternatives are available, the HHP may be registered, but for *restricted use* only (see note 5).

[8] Is the pesticide product registered in a reference country for a similar use?

If the same pesticide product has been registered for identical or similar uses in a country considered as a reference for Myanmar, registration by analogy may be possible (see below).

If no reference country and use exists, a locally specific assessment of human health and environmental risks will have to be conducted.

[9] Conduct registration by analogy

Registration by analogy comprises of a limited comparison of the product, its efficacy and risks between the reference country registration and the proposed registration in Myanmar.

The FAO Pesticide Registration Toolkit provides guidance on the application of this approach. See: http://www.fao.org/pesticide-registration-toolkit/tool/page/pret/registration-by-analogy

[10] Are risks likely to be similar or lower than in the reference country?

In registration by analogy, a comparison is made between:

A: the registered application rate and frequency of the pesticide, and its use restrictions or precautions, in the reference country; and

B: the proposed application rate and frequency of the pesticide, and use conditions, in Myanmar.

The likelihood that the risk in Myanmar will be acceptable or not will then be assessed.

[11] Conduct a human health and environmental risk assessment

If registration by analogy is not possible, a basic risk assessment for human health and environment will need to be conducted.

At present, methods for occupational risks assessment (EFSA operator and worker exposure model) as well as consumer risk assessment (WHO GEMS dietary risk assessment spreadsheet) can be adapted to the Myanmar conditions of use of the pesticide.

Basic methods for environmental risk assessment will be developed in the future.

[12] Are risks acceptable?

If risks are not acceptable, even when realistic risk mitigation measures are proposed, the Registration Board should not register the pesticide.

[13] Conduct a sustainability assessment

If risk human health and environmental risks are acceptable, a sustainability assessment is conducted.

In principle, the registration of the pesticide should strengthen the sustainability of agricultural systems, i.e. 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 agricultural sustainability in various ways, including: development of pest resistance, adverse effects on pollinators, adverse effects on natural enemies, adverse effects on succeeding (rotational) crop, or on adjacent crops, adverse effects on soil organisms and fertility. If it is unlikely that sustainability will be compromised by authorizing the pesticide, the product may be registered.

Methods for a sustainability assessment still need to be worked out for the Myanmar situation. Therefore, for now, this step in the process is skipped.

[14] Are appropriate pesticide or non-pesticide alternatives available?

If sustainability is likely to be compromised, it should be assessed whether alternative pest management options are available (see [6]). If no alternatives are available, but the pesticide is absolutely needed, the Board may decide to register the pesticide *for special use*, applying specific risk mitigation measures.

If alternatives are available, the Registration Board should consider not to authorize the use of the product.

Annex 6 Prioritisation of protection goals in Myanmar

Based upon discussions with the PPD and several TC members protection goals for Myanmar are prioritised. The list of prioritised protection goals that is given below was endorsed by the PPD director and communicated to the ministry level.

1. Dietary (food consumption, residues)
2. Operators
3. Workers (field)
4. Dietary – drinking water consumption
    - from surface water
5. Aquatic ecosystem
6. Others (e.g. bees, birds, drinking water from groundwater, non-target plants, on-target arthropods)

Highest priority for Myanmar

Lowest priority for Myanmar

Annex 7 Format of decision supporting summary for the registration of a pesticide in Myanmar

(version of 3 November 2017)

Data should in principle be based on the dossier; other sources can be used as comparison/quality check

Identity

Product name:			
Active ingredient name:			
Formulation type:		Concentration:	
Chemical class:			
Applicant name:		Applicant address:	
Manufacturer name:		Manufacturer address:	

Efficacy

Have local efficacy trials been conducted?			☐ Yes ☐ No
Pest/crop or use:	1.	2.	3.
Are efficacy data available from other relevant locations?			☐ Yes ☐ No
Pest/crop or use:	1.	2.	3.
Effective dose rates established?			☐ Yes ☐ No
Pest/crop or use:	1.	2.	3.
			Attach GAP table or proposed label

Low risk pesticide

Is the product a low risk pesticide?	☐ Yes ☐ No	Source:	

Hazard classification – human health

WHO hazard class of the formulated product:		☐ Ia	☐ Ib	☐ II	☐ III	☐ U
GHS health hazard classification of the a.i. *(only classified hazards are listed)*	*Category*	*Hazard statement*			Source:	
	. . . .	. . . .				
Is the pesticide listed in Annex III of the Rotterdam Convention?					☐ Yes ☐ No	
Is the pesticide listed in Annex A or B of the Stockholm Convention?					☐ Yes ☐ No	
Is the pesticide listed in the Montreal Protocol?					☐ Yes ☐ No	
Has the pesticide shown a high incidence of severe or irreversible effects or human health or the environment in Myanmar, or under similar use conditions? *If yes,* indicate source(s):					☐ Yes ☐ No	
Is the pesticide a highly hazardous pesticide (HHP)?					☐ Yes ☐ No	

Registration by Analogy

Has registration by analogy been conducted?			☐ Yes ☐ No
Reference country:		Reference product:	
Is product in Myanmar identical/similar to the product in the reference country?			☐ Yes ☐ No
Can efficacy in Myanmar be expect to be similar or better than in the reference country?			☐ Yes ☐ No
Remarks:			
Can risks in Myanmar be expected to be similar or less than in the reference country?			☐ Yes ☐ No
Remarks – human health:			
Remarks – environment:			
Conclusion: Can the product be registered in Myanmar?			☐ Yes ☐ No

Human health risk assessment

Relevant toxicological endpoints:

	Reference value	*Source*
AOEL (mg/kg body weight per day)		
ADI (mg/kg body weight per day)		

Risk assessments for operators and workers:

Is risk assessment for operators and/or workers done (EFSA model)?			☐ Yes ☐ No
Crop type:		Application rate of a.i. (kg a.i./ha):	
Application method:		Application equipment:	
Dermal absorption product:	☐ 10%	☐ 100%	Other: …
Dermal absorption in-use dilution:	☐ 10%	☐ 100%	Other: …

Results of the risk assessment for operators (exposure from mixing, loading and application):			
	Without PPE	*With full PPE (= gloves, work wear, head and respiratory protection (FP2)*	*Defined by PPD:* *-.....* *-.....* *-.....*
Exposure as percentage of AOEL (%):			
Operator risk acceptable?	☐ Yes ☐ No		

Results of the risk assessment for workers (exposure from harvesting, pruning, cutting, etc.)			
	Without PPE (= "potential exposure")	*PPE: work wear (= arms, body and legs covered)*	*With full PPE (= work wear + gloves)*
Exposure as percentage of AOEL (%):			
Worker risk acceptable?	☐ Yes ☐ No		

Risk assessment consumers:

Has a chronic dietary risk assessment been conducted (WHO GEMS2 Cluster Diet 09) ?	☐ Yes ☐ No

Maximum Residue Limits:		
Commodities - this registration request:	*MRL (mg/kg)*	*Source*
Additional commodities – already registered pesticides with the same active ingredient	*MRL (mg/kg)*	*Source*

Results of the chronic dietary risk assessment - Total dietary exposure as percentage of ADI (%):	
Based on commodities in this registration request	…. %
Based on all commodities for which the a.i. is proposed to be used	…. %
Dietary risk acceptable?	☐ Yes ☐ No

Environmental assessment

Risk assessments (*to be filled in later*)

Registration advice

☐ Experimental use registration	
☐ Provisional registration	
☐ Full registration	
☐ Special use permit	
☐ Refuse registration	Justification for refusal:
Risk mitigation measures required:	

Annex 8 Guidance on using the EU "low risk active substance" list and the US-EPA "minimum risk pesticides" list

Source: EU "low risk active substance"

The European Union identifies low risk active substances. These are pesticides which have been evaluated in the standard manner (standard EU evaluation methods), but were identified as posing a low risk to human health and the environment.

At present active substances identified as "low risk" by the EU can be found via the EU pesticide database (EU, 2017).

In order to get the list of low risk active substances, on the website the button "Advanced Search" should be clicked (Step 1 in Figure 15). Upon clicking this button a filter function appears at the left hand side of the screen. In this filter function select "Low risk active substances" from the picklist of the "Type" field (click the small arrow behind the white coloured field to visualize the picklist) (Step 2 in Figure 15). Next in the table at the right hand side of the screen the list with low risk actives ingredients appears (Step 3 in Figure 15). To view details of the active substance click on the '+' next to the active substance name.

At this moment only approx. 10 low risk pesticide active ingredients may be found in the EU list, and they are registered in the EU for a duration of 15 years instead of the 10 years for other pesticide active ingredients. Currently, the EU (Standing Committee on Plants, Animals, Food and Feed Section) is re-evaluating according Regulation EC 1107/2009 about 50 active substances that were identified as low-risk substances under Directive 91/414/EEC.

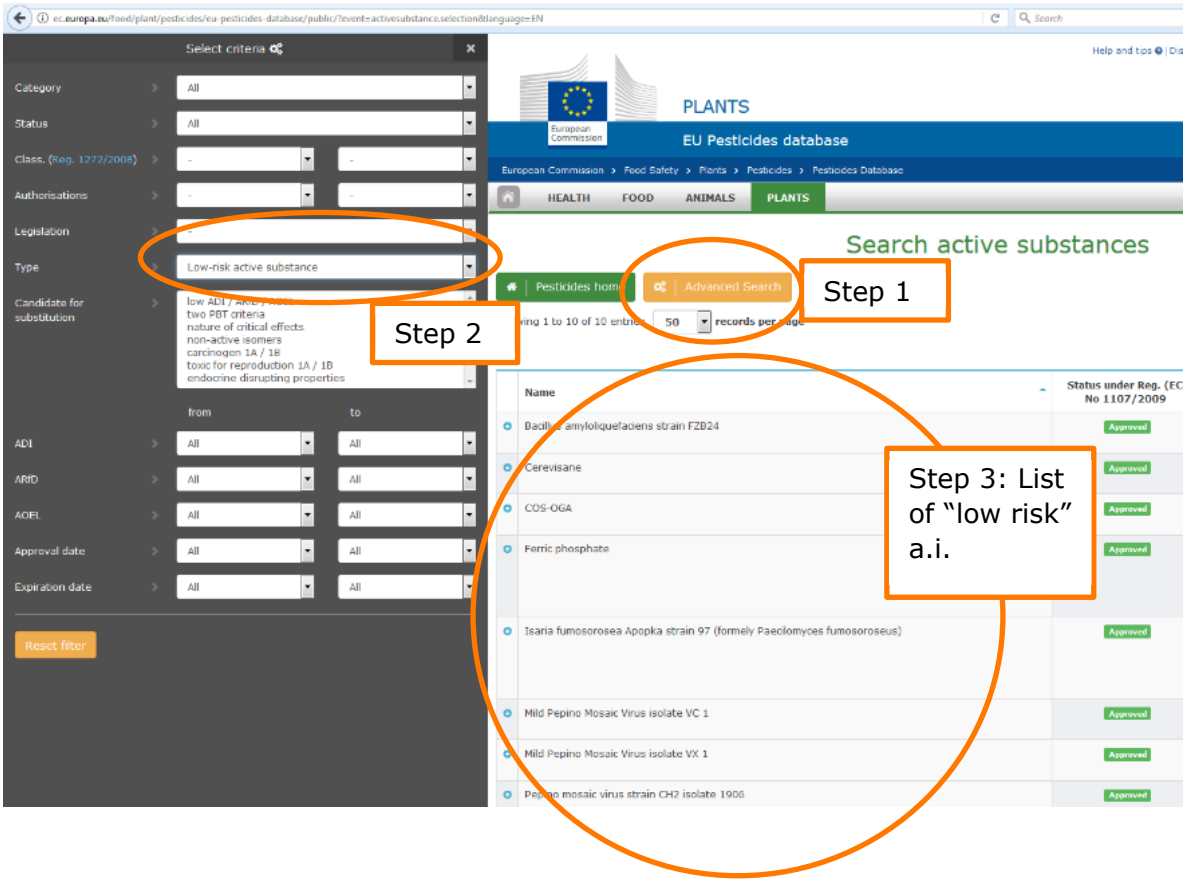

Figure 15 *Instruction for obtaining the list of low risk active substances on the EU Pesticides database website.*

Source: US-EPA "minimum risk pesticides"

The United States Environmental Protection Agency (US-EPA) publishes a list of active substances currently considered as "minimum risk pesticides". These are pesticides that pose little or no risk to human health and the environment and therefore do not need to be registered in the USA. The list of present active substances allowed in "minimum risk pesticides" is published on the US-EPA web site (EPA, 2017).

Annex 9 Registration by analogy check-list and guidance (source: FAO Pesticide Registration Toolkit)

Registration by analogy – check-list	
Product name:	**Registration file number:**
Name of the assessor:	**Date of the assessment:**

Parameter		*Comparison of parameters for the local situation under review and a reference country* **Describe/quantify the parameter for:**		**Remarks**
		Local situation *(application)*	***Reference country*** *(registration)*	
	Country			
1	Country			
	Applicant/registrant			
2	Name and address of applicant/registrant			
3	Name of manufacturer			
4	Registration status in reference country			
	Pesticide product			
5	Product name			
6	Active ingredient common name			
7	Formulation type			

Parameter		*Comparison of parameters for the local situation under review and a reference country* **Describe/quantify the parameter for:** ***Local situation*** *(application)*	***Reference country*** *(registration)*	**Remarks**
8	Active ingredient concentration in the product (g a.i./L or g a.i./kg)			
9	Declaration by applicant that the product is identical or equivalent to the one in the reference country			
	If not:			
10	Active ingredient manufacturing source			
11	Impurities			
12	Co-formulants triggering a hazard classification			
13	*Conclusion with respect to the pesticide product:*			
	Use			
14	Crop or use situation			
15	Pest			
16	Dose rate (g a.i./ha)			
17	Number of applications per growing season			
18	Withholding period			
19	*Conclusion with respect to the use:*			
	Human health risks			
20	Use restrictions (human health)			
21	Required/recommended PPE			

Parameter		*Comparison of parameters for the local situation under review and a reference country* **Describe/quantify the parameter for:** ***Local situation*** *(application)*	***Reference country*** *(registration)*	**Remarks**
22	Level of training/experience of operator			
23	*Conclusion with respect to the human health risks: Risks similar or less when compared to the reference country*			
	Environmental risks			
24	Use restrictions (environment)			
25	Rainfall, temperature, soil			
26	Sensitive ecosystems/organisms			
27	*Conclusion with respect to the environmental risks:*			
28	***Overall conclusions***			

Registration by analogy – Guidance for completing the check-list

(Version 26.05.2015)

Registration by analogy is a basic registration approach where a limited comparison is made between a pesticide product submitted for authorization in a resource-limited country and similar products in one or more reference countries. The registration authority may decide to register a pesticide which has already been authorized for use in a reference country, if it judges that its efficacy and risk are also likely to be acceptable in its own country.

This document provides guidance for completion of the check-list used to compare the registration of a pesticide product in the reference country with the application for registration in the local situation.

If more than one reference country is considered, the check-list should be filled out for each one of them.

1. Country

   Name of the country in which the application for registration is done, and name of the reference country.

   Reference countries can be selected for various reasons, such as: i) similar agronomic conditions or pesticide use practices; ii) environmental and ecological similarities; iii) reliable pesticide evaluation procedures; iv) same countries of origin of the imported pesticides; v) good working contacts with the registration authority

   One or more reference countries will often be chosen because several of the above reasons are met.

APPLICANT/REGISTRANT

2. Name and address of applicant/registrant

   An identical name (and address) of the applicant may support the claim that the pesticide product is identical or similar.

3. Name of manufacturer

   Name of the manufacturer of the active ingredient and, if different, also the manufacturer of the commercial product.

   An identical name of the manufacturer may support the claim that the pesticide product is identical or similar. However, even for the same manufacturer, the pesticide active ingredient and/or product may have been produced in different locations/factories. As a result, the pesticide product may not be identical.

4. Registration status in reference country

   Note if the pesticide is registered with or without any restrictions, and what possible restrictions are. Of particular interest are any restrictions on the use in the reference country which may be difficult to implement in the local situation.

Document compiled as part of FAO Pesticide Registration Toolkit (*v1, 26/05/2015*)

PESTICIDE PRODUCT

5. Product name

Complete product name, including formulation type and concentration indication, when available. E.g.: Killtox forte 40 SC

6. Active ingredient common name

In principle, pure active ingredients (PAI) with the same common name are identical. However, for the production of commercial products, technical grade active ingredients (TGAI) are used, which can contain various manufacturing impurities, some of which may be toxic. Thus, TGAIs with the same common name, but produced by different manufacturing processes or locations, are not necessarily identical.

Some active ingredients consist of a combination of isomers, some of which are more active than others. For such compounds to be identical, the isomer ratios in the active ingredient should also be identical.

7. Formulation type

Similar formulation types can be expected to result in similar efficacy and risks (but see points 9 & 10, below). Standardized coding of different formulation types is provided by CropLife International.

For registration by analogy, the following formulation types are considered similar:

- For residues: i) formulation types which are diluted in water prior to application including EC, WP, WG, SC, SL. Experience demonstrates that these formulations lead to similar residues.
- For occupational and bystander risks: i) all solid formulations to be applied as a spray; ii) all liquid formulations to be applied as a spray; iii.) formulations applied as granules
- For environmental risk assessment: i) all formulations applied as sprays; ii) formulations applied as granules; iii) formulations for seed treatments

8. Active ingredient concentration

For a pesticide product to be considered similar, the active ingredient content should not exceed the following variation:

Declared active ingredient content (in g/kg or g/L)	Acceptable variation
up to 25	± 15% of the declared content for homogeneous formulations (EC, SC, SL, etc.), *or* ± 25% for heterogeneous formulations (GR, WG, etc.)
above 25 up to 100	± 10% of the declared content
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
above 500	± 25 g/kg or g/L
Source: Manual on the development and use of FAO and WHO specifications for pesticides (2010)	

9. Declaration by applicant on equivalence of products

The applicant may provide a declaration to the registration authority that the product is identical or equivalent to the one in the reference country.

Document compiled as part of FAO Pesticide Registration Toolkit (*v1, 26/05/2015*)

If the applicant is identical to the registrant in the reference country, and the products are indeed identical or equivalent, the applicant is in a position to provide such a declaration. It should include details about the manufacturing source of both products. If these sources are different, the specifications of both products, preferably those published by the FAO/WHO Joint Meeting on Pesticide Specifications, should be supplied to show equivalence.

If the applicant is not identical to the registrant in the reference country, the applicant will generally not have access to the manufacturing details of the product in the reference country. However, if both products have been evaluated by the FAO/WHO Joint Meeting on Pesticide Specifications, the applicant can use these specifications to show equivalence.

Otherwise, it will normally not be possible for an applicant to provide a justified declaration that his product is equivalent to one registered in the reference country. In such a case, the applicant should provide the information listed under points 10 – 12.

10. Active ingredient manufacturing source

The applicant should provide the manufacturing source (name and address) of the TGAI and product. The registration authority may contact the registrar in the reference country to check whether these sources are the same. If the manufacturing source is the same, this fact may support similarity of the pesticide product with the one registered in the reference country (provided that formulation type and active ingredient concentration are the same).

If the manufacturing source and/or process is different, different impurities may be formed when producing the active ingredient (see point 11 below).

11. Impurities

If the manufacturing source and/or process is different, different impurities may be formed when producing the active ingredient. Either the type of the impurity or its concentration may affect the toxicity of the product.

The registration authority can check whether the FAO/WHO Specification for the technical grade active ingredient lists any toxic impurities. (See Specifications new procedure or Specifications old procedure). If toxic impurities are listed in the specification, any difference in manufacturing process may well result in difference in toxicity of the active ingredient. If no toxic impurities are listed, a difference in manufacturing process may still result in a difference in toxicity of the active ingredient, but its likelihood is less great.

12. Co-formulants triggering a hazard classification

In addition to the active ingredient, pesticides generally consist of various co-formulants, added to improve the performance of the product or reduce risks. These co-formulants may thus have considerable influence on the efficacy and risks of the formulated pesticide product. In principle, the type and concentrations of co-formulants should be similar in the pesticide submitted for registration and the one registered in a reference country. Very often, this will not be the case.

Equivalence of co-formulants can be checked by comparing the CAS numbers of the substances in the application dossier or the Safety Data Sheet of the product. The same CAS numbers indicate the same co-formulant; however, different CAS numbers do not necessarily means chemical non-equivalence of the co-formulants.

Alternatively, equivalence of co-formulants can be evaluated by comparing the hazard classification on the Safety Data Sheet: co-formulants with the same hazard classification can be considered equivalent with respect to hazard.

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Changes in the contents of the same co-formulant in a pesticide product can be considered similar if they do not exceed the following variation:

Initial concentration range of the compound (in g/kg or g/L)	Acceptable variation
up to 5	± 100%
above 5 up to 10	± 50%
above 10 up to 25	± 30%
above 25 up to 100	± 20% of the declared content
above 100 up to 250	± 10% of the declared content
above 250	± 5% of the declared content

Source: European Commission – Guidance document on significant and non-significant changes of the chemical composition of authorized plant protection products (2012)

13. *Conclusion with respect to the pesticide product*

Based on parameters 2 – 12, evaluate whether the pesticide product submitted for registration is identical, equivalent or sufficiently similar to allow comparison with the pesticide in the reference country.

If parameters 2, 3, 5, 6 & 7 are the same when compared to the reference country, the product submitted for registration can be considered identical to the reference country.

In other cases, the registration authority will need to make an expert assessment whether the differences between the products are so large that registration by analogy to the reference country is not justified anymore.

Use

14. Crop or use situation

If the crop or use situation is identical between the local situation and the reference country, registration by analogy is facilitated.

However, often (minor) differences between countries will occur. Evaluate whether the crop or use pattern in the reference country compares well enough with the proposed use in the country. The following aspects will generally have to be taken into account: efficacy, residues, occupational & bystander risk, environmental risk (various types). Unfortunately, similarity for one aspect (e.g. operator risk) does not necessarily indicate similarity for another (e.g. residues), so these will have to be assessed separately.

The Codex Alimentarius has defined commodity groupings within which residue data can be extrapolated (Codex classification of foods and animal feeds – click on CAC/MISC 4). As an approximation, the same commodity groups can be used for extrapolation of efficacy data. Thus, crops falling within the same commodity group would aid registration by analogy.

For occupational and bystander risks, a distinction is generally made between high crops and low crops, with the former posing a higher exposure risk than the latter.

For environmental risk assessment, similar crop structure at the moment of pesticide application tends to indicate similar risks for groundwater and surface water exposure. Spraying on flowering compared to non-flowering crops is a main indicator of pollinator exposure.

15. Pest

If the pest is identical between the local situation and the reference country, and occurs on the same crop, pesticide efficacy is likely to be similar, and registration by analogy is facilitated.

However, pests will often be (slightly) different; or pests may be the same, but attacking different crops. If it can be expected that the pests in the two situations show similar susceptibility to the pesticide, registration by analogy is facilitated. Presently, no global "pest groupings" exist that can be used for extrapolation of efficacy data. However, certain groups of pests, often of similar taxonomy, can be expected to have similar susceptibility to, at least chemical, pesticides (e.g. aphids, thrips, whiteflies, powdery mildews; but many other cases exist).

16. Dose rate

The dose rate, or application rate, of the pesticide expressed as g a.i./ha or g a.i /unit, directly influences efficacy and risks.

If dose rates in the reference country and the local situation are identical, registration by analogy is facilitated.

If dose rates are similar, then efficacy, residue levels and risks can be expected to be similar too. For the purpose of this guidance document, an increase or decrease of less than 25% of the (active ingredient) application rate – under otherwise identical conditions – will be considered similar.

Note that an increase or decrease in the dose rate will have a different impact on efficacy on the one hand, and residues and risks on the other. An increase in dose rate in the local situation when compared to the reference country will tend to confirm the efficacy in the local situation, and encourage registration by analogy. However, the same increase in dose rate in the local situation will also increase residue levels and human health and environmental risks when compared to the reference country, which discourages registration by analogy.

17. Number of applications per growing season

Similarly to point 16, the frequency of application influences both efficacy and risks. If frequency of application in the reference country and the local situation are the same, registration by analogy is facilitated.

If the number of applications are similar, then efficacy, residue levels and risks can be expected to be similar too. For the purpose of this guidance document, an increase or decrease of less than 25% of the application frequency – under otherwise identical conditions – will be considered similar.

18. Withholding period

Withholding, such as pre-harvest intervals, pre-slaughter intervals, and re-entry intervals for livestock or humans may influence consumer and occupational risks.

If the withholding periods in the reference country and the local situation are the same, registration by analogy is facilitated.

If the withholding periods in the local situation are similar or longer, then residue levels and risks can be expected to be similar or less too. For the purpose of this guidance document, an increase or decrease of less than 25% in the withholding period – under otherwise identical conditions – will be considered similar.

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Conclusion with respect to use

Based on parameters 14 – 18, evaluate whether the use of the pesticide product submitted for registration is identical or sufficiently similar to allow comparison with the pesticide in the reference country.

If parameters 14 – 18 are the same when compared to the reference country, the use of the pesticide can be considered identical to the reference country.

Alternatively, evaluate whether the efficacy of the pesticide can be expected to be similar, or better, in the local situation than in the reference country. In such a case, registration by analogy may be possible.

HUMAN HEALTH RISKS

19. Use restrictions

Note any use restrictions or risk reduction measures for the pesticide and its use which have been defined by the registration authority of the reference country. Assess whether these restrictions can and should be imposed, and will be effective, in the local situation.

20. Required/recommended PPE

Note any personal protective equipment and clothing that is required for use of the pesticide in the reference country. Assess whether this PPE can and should be imposed, and will be effective, in the local situation.

21. Level of training/experience of operators

Estimate the likely level of training and experience that operators will have when handling and applying the pesticide in the reference country. Assess whether operators in the local situation are likely to have similar levels of training and experience.

22. *Conclusion with respect to human health risks*

Evaluate if human health risks (occupational, bystander, consumer) as a result from the proposed use of the pesticide in the local situation will be similar or less than in the reference country. If this is the case, registration by analogy may be possible.

Take into account the pesticide product composition (which may have an effect on toxicity of the product), the use details of the pesticide, and the human health section (which may have an effect on exposure).

ENVIRONMENTAL RISKS

23. Use restrictions

Note any use restrictions or environmental risk reduction measures for the pesticide and its use which have been defined by the registration authority of the reference country. Assess whether these restrictions can and should be imposed, and will be effective, in the local situation.

24. Rainfall, temperature, soil

Climatic and soil conditions can have an impact on the persistence and mobility of the pesticide. Definite rules cannot be given but, indicatively, higher rainfall may increase leaching to groundwater and runoff/drainage to surface water; higher temperatures may increase the degradation of the pesticide in soil and water; and lower soil organic matter and/or a higher sand fraction (or lower clay fraction) in the soil may increase leaching to groundwater.

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25. Sensitive ecosystems/organisms

Certain ecosystems and non-target organisms may be particularly sensitive to pesticides. If the pesticide is to be used in a sensitive ecosystem in the local situation, but this is not the case in the reference country, environmental risks may be greater. Some examples of sensitive ecosystems for pesticides are: pollinated crops (in particular for insecticides); irrigated agriculture (for all types of pesticides); organic agriculture or livestock breeding (for all types if pesticides); agro-ecosystems under biocontrol or integrated pest management (for all types if pesticides); agriculture in/close to protected areas and nature reserves (in particular for insecticides and herbicides); areas with surface waters or delta-estuary areas (for all types if pesticides).

26. Conclusion with respect to environmental risks

Evaluate if environmental risks as a result from the proposed use of the pesticide in the local situation will be similar or less than in the reference country. If this is the case, registration by analogy may be possible.

Take into account the pesticide product composition (which may have an effect on toxicity of the product), the use details of the pesticide, and the environmental section (which may have an effect on exposure and resulting adverse effects).

28 Overall conclusion

Evaluate whether registration by analogy is feasible and describe the main uncertainties. Judge whether the pesticide product can be registered for use in the local situation. Determine whether any risk mitigation measures or use restrictions are required.

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Annex 10 Information on human health toxicity studies

Large parts of the information given in this Annex are taken from Deneer *et al.* (2014).

Data requirements for the active ingredient

Acute toxicity studies (oral, dermal, inhalation)
These studies provide an estimate of the relative toxicity of a substance by the different routes of exposure and they may serve as a basis for classification and labeling. It is an initial step in establishing a dosage regimen in subchronic and other studies and may provide information on the mode of toxic action of a substance by these routes.

Skin and eye irritation studies
These studies provide information on health hazard (e.g. irritation, corrosion) likely to arise from exposure to the test substance by application to the skin or on the eye. They may serve as a basis for classification and labelling.

Skin sensitisation
There are several methods: Buehler test, Guinea Pig Maximisation Test (GPMT) and the mouse Local Lymph Node Assay (LLNA). They all assess the potential of a substance to cause skin sensitisation, an immunologically mediated cutaneous reaction to a substance. The studies may serve as a basis for classification and labelling.

Reproduction multi-generation study
This study is designed to provide general information concerning the effects of a test substance on the integrity and performance of the male and female reproductive systems, and on the growth and development of the offspring. The test substance is administered daily in graduated doses to several groups of males and females. A properly conducted reproductive toxicity test should provide a satisfactory estimation of a no-effect level and an understanding of adverse effects on reproduction, parturition, lactation, postnatal development including growth and sexual development.

Subchronic toxicity 90 day
This study provides information on health hazards likely to arise from repeated oral exposure over a prolonged period of time covering post-weaning maturation and growth well into adulthood. The study will provide information on the major toxic effects, indicate target organs and the possibility of accumulation, and can provide an estimate of a no-observed-adverse-effect level (NOAEL) of exposure which can be used in selecting dose levels for chronic studies and for establishing reference values, such as the AOEL.

Chronic toxicity
The objective of chronic toxicity studies is to characterize the profile of a substance in a mammalian species (primarily rodents) following prolonged and repeated exposure of at least 1 year. The study will provide information on the major toxic effects, indicate target organs and the possibility of accumulation, and can provide an estimate of a no-observed-adverse-effect level (NOAEL) of exposure which can be used for establishing reference values, such as the ADI. The test is often combined with carcinogenicity testing.

Carcinogenicity
The objective of a long-term carcinogenicity study is to observe test animals during a major portion of their life span for the development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration. This Test Guideline is intended primarily for use with rats and mice, and for oral administration. The duration of the study will normally be

24 months for rodents. For specific strains of mice, duration of 18 months may be more appropriate. The test is often combined with chronic toxicity testing.

Neurotoxicity
These studies provide the information necessary to confirm or to further characterise the potential neurotoxicity of chemicals in adult animals (rats). The dosing regimen may be acute (1 day), subacute (28 days), subchronic (90 days) or chronic (1 year or longer). For organophosphates, specific tests are designed to detect delayed neurotoxicity in hens.
The study can be used for establishing reference values, and is often the basis for the ARfD.

Teratogenicity
This study is designed to provide general information concerning the effects of prenatal exposure on the pregnant test animal and on the developing organism; this may include assessment of maternal effects as well as death, structural abnormalities, or altered growth in the foetus. The study can be used for establishing reference values, and is often the basis for the ARfD.

Mutagenicity / Genotoxicity
The primary function of genetic toxicity testing is to investigate, using test cells or organism, the potential of chemical substances to induce mutation in man that may be transmitted via the germ cells to future generations. Scientific data generally support the hypothesis that DNA damage in somatic cells is a critical event in the initiation of cancer. Such damage can result in mutations, and tests to detect mutagenic activity may also identify chemicals that have the potential to lead to carcinogenesis.

Metabolism
These in vivo studies provide information on mass balance, absorption, bioavailability, tissue distribution, metabolism, excretion, and basic toxicokinetic parameters [e.g. AUC], as well as supplemental approaches that may provide useful information on toxicokinetics. Information from toxicokinetic studies helps to relate concentration or dose to the observed toxicity and to understand its mechanism of toxicity. The test substance ("unlabelled" or "radiolabelled" forms) is normally administered by an oral route, but other routes of administration may be applicable. The study/studies can provide the oral absorption value of the test substance, which is necessary for the setting of the AOEL. If no oral absorption is indicated in the dossier, a default of 100% should be used.

Data requirements for the formulated product

The present data requirements for toxicology (section 6 of the Myanmar data requirements document) refer to both the active ingredient and the formulated product. Common practice in several countries is that human health risk assessments are performed using endpoints derived from toxicity studies with the active ingredient, unless there are indications that toxicity of the formulated product is significantly larger. In such a case, pesticide registration authorities might require additional toxicity studies with the formulated product and use the toxicity endpoints derived from these studies for the human health risk assessments.

For the behaviour of residues of active substances in formulations, the formulation type used is considered to be of minor importance. Residue studies are commonly performed with a formulated product, and not with 100% technical active substance. Hence, studies with the specific product for which authorisation is sought, are not required. The application regime used in the studies, should reflect the intended use.

For operators and workers the dermal and inhalation routes are the most important routes of exposure. Insight in the extent to which the skin or lung absorbs a substance and/or formulation after exposure to a relevant level is important for calculation of systemic (internal) human exposure.

In many countries, if appropriate, dermal absorption data with a relevant product should be provided. If the study is not performed with the product for which authorisation is requested, the application

should provide a scientific justification why the tested products is equivalent to the product for which authorisation is requested.

Studies on dermal absorption with a relevant product is at present not a data requirement in Myanmar.

Annex 11 No Observed Adverse Effect Level (NOAEL)

For each human health toxicity study, if possible, the No Observed Adverse Effect Level (NOAEL) is derived. The NOAEL is the highest dose at which the most relevant critical effect (the adverse health effect that occurs first) is not yet observed (Figure 16). The Lowest Observed Adverse Effect Level (LOAEL) is the lowest dose at which there was an observed toxic or adverse effect.

Sometimes the terms No Observed Effect Level (NOEL) and Lowest Observed Effect Level (LOEL) may also be found in the literature. NOELs and LOELs do not necessarily imply toxic or harmful effects and may be used to describe beneficial effects of chemicals as well.

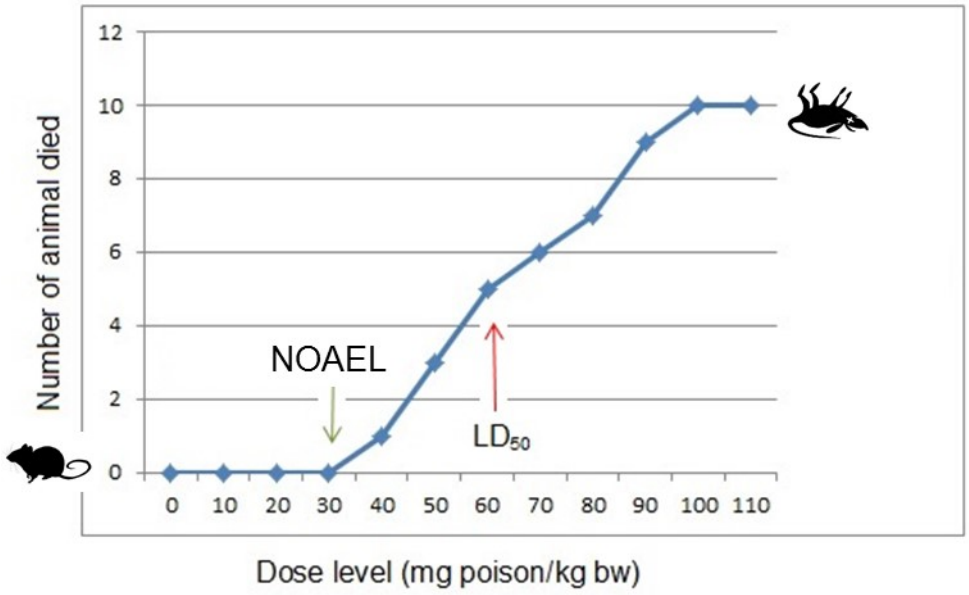


Figure 16 *Illustrating the No Observed Adverse Effect Level (NOAEL) using an imaginary experiment with 10 animals.*

For most end-points it is generally recognized that there is a dose or concentration below which adverse effects do not occur; for these, an NOAEL and/or LOAEL can be identified. For genotoxicity and carcinogenicity mediated by genotoxic mechanisms, dose–response is considered to be linear, meaning that risk cannot be excluded at any exposure level. A pesticide containing such an active ingredient can therefore not be authorized.

The lowest relevant NOAEL/LOAEL value should normally be used for risk characterization and the setting of acceptable exposure levels.

If the critical NOAEL/LOAEL is derived from an animal study, a default Uncertainty Factor (UF) of 10 is usually recommended to account for interspecies differences (WHO, 1994; WHO, 1999). In addition a default UF of 10 is used to account for inter-individual differences in the general population (WHO, 1994; WHO, 1999). Contributors to the overall UF are normally multiplied because they are considered to be independent factors; the most commonly used default UF for the setting of reference values for the general population is therefore 10 x 10 = 100 (WHO, 1994; WHO, 1999).
In some cases, the use of additional UFs is justified. Situations in which additional UFs should be considered include the following:

- When LOAEL is used instead of NOAEL, an additional UF (e.g. 3 or 10) is usually incorporated,

- When an NOAEL from a sub-chronic study (in the absence of chronic study) is used to derive a reference value for long-term exposure, an additional UF (often 10) is usually incorporated to take account of the attendant uncertainties,
- If the critical NOAEL relates to serious, irreversible toxicity, such as developmental abnormalities or cancer induced by a non-genotoxic mechanism (WHO, 1999),
- When there are exposed subgroups, which may be extra-sensitive to the effects of the compound (e.g. neonates because of the incompletely developed metabolism),
- If the database is limited.

Relevant references are given below:
WHO (1994). Environmental Health Criteria no. 170. Assessing Human Health Risks of Chemicals: Derivation of Guidance values for Health-Based Exposure Limits.

WHO (1999). Principles for Assessment of Risk to Human Health from Exposure to Chemicals. Environmental Health Criteria no. 210. World Health Organization, Geneva.

Annex 12 Exposure and Hazard for Operators and Workers

Exposure of operators and workers

For operators and workers the dermal and inhalation routes are the most important routes of exposure. Since Good Agricultural Practice is that operators and workers should not be eating during handling the plant protection product or treated crops, the oral route is not considered a relevant route of exposure for these two groups.

The exposure model used will estimate the exposure on the outside of the human body, the external exposure. To compare this exposure to the AOEL, it is adjusted for route-specific absorption to calculate systemic, internal, exposure.

Uptake after dermal exposure

Insight in the extent to which the skin absorbs a substance and/or formulation after exposure to a relevant level is important for calculation of systemic exposure. There is an OECD Guidance note on dermal absorption (2011)
http://www.oecd.org/chemicalsafety/testingofchemicals/48532204.pdf
and a WHO report on dermal absorption (EHC no 235, 2006)
http://www.inchem.org/documents/ehc/ehc/ehc235.pdf

Since studies on dermal absorption are at present not a data requirement in Myanmar, for the time-being default values can be used for the risk assessment.

If no suitable (animal) experimental data are available, a default value of 100% for dermal absorption has to be assumed as a first step in the exposure calculations. The physicochemical properties of a substance have a major impact on its dermal penetration. Thus, for example, it is widely assumed that for large molecules and those with either a very low or a very high octanol-water partition coefficient (log Pow), the skin is much less permeable than it would be for other, smaller molecules. Many authorities, particularly in Europe, consider this factor by reducing the 100% default value to 10% if the molecular weight (MW) is greater than 500 g/mol and log Pow is either below -1 or above 4. In addition to the use of the 100% and 10% default values, it can be argued that dermal absorption cannot exceed the oral absorption rate. Although the validity of using the physicochemical properties to obtain the default criteria is unclear, at this stage it is a pragmatic way to lower the rather extreme default of 100% in particular cases.
In summary:

- Dermal absorption value < oral absorption value,
- 10% default dermal absorption value: log Pow < -1 or > 4 and MW > 500 g/mol,
- 100% default dermal absorption value: all other cases.

Uptake after inhalation exposure

The level of systemic exposure requires insight in the extent to which a substance and/or formulation is taken up in the body via inhalation after exposure to a relevant level.
A default value of 100% is applied where no suitable data on respiratory absorption at the respiratory NOAEL are available.

National default values

Myanmar operators and workers are considered to weigh 60 kg. The duration of a working day is assumed to be 8 hours.

Hazard for operators and workers

Acceptable Operator Exposure Level (AOEL)

The reference value against which non-dietary exposures to pesticides are currently assessed. It is intended to define a level of daily exposure throughout a spraying season, year on year, below which no adverse systemic health effects would be expected. The AOEL is normally derived by applying an assessment factor (most often 100) to a No Observed Adverse Effect Level (NOAEL) (corrected if appropriate for incomplete absorption) from a toxicological study in which animals were dosed daily for 90 days or longer. Less often, the critical NOAEL comes from a study with a shorter dosing period (e.g. a developmental study).

Source: EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874

Operator exposure considered acceptable from a health point of view is in the EU referred to as AOEL (Acceptable Operator Exposure Level). The AOEL is defined as the maximum amount of a substance to which the operator (including workers in treated crops or treated spaces) can be exposed at which no adverse effects on health are expected.

The following formula is used:

AOELsystemic [mg/kg bw/day] = (NOAEL x Absorption) / 100 Eq. 4

The NOAEL is the highest dose at which the most relevant critical effect (the adverse health effect that occurs first) is not yet observed (see Annex 11 for a more elaborated explanation of the NOAEL).

Absorption is given as the fraction of the substance absorbed by the body after oral administration, e.g. if the absorption is 60%, then the numerical factor Absorption = 0.6).

In Europe there is a Guidance Document on the setting of the AOEL.
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_tox_accpt-exp-levs-2006.pdf

Where relevant, different AOELs can be established for acute, short-term (semi-chronic) or long-term (chronic) exposure. The AOEL is expressed in mg/kg bw/day.

Systemic AOEL/AEL
In principle, a systemic AOEL is derived. Systemic effects of active substances are caused by the amount of active substance actually absorbed into the body. In practice, exposure to these substances occurs mainly via the dermal and –to a lesser extent- via the respiratory route. For most active substances in plant protection products that are to be evaluated, however, only suitable studies with repeated exposure via the oral route are available. In practice, an AOEL is therefore usually derived on the basis of an oral study. The choice of the systemic AOEL used in the risk assessment should be justified in the decision making.

Choice of data for calculation of the systemic AOEL/AEL
The suitable studies with repeated exposure to the substance are selected from the toxicological dossier for calculation of the systemic AOEL. In addition, the kinetic data on the substance are used to establish the systemic availability (via the oral, dermal or inhalatory route) of the substance.
In principle it is assumed that the period during which exposure takes place is shorter than or equal to 3 months per year. This means that the AOEL calculation is preferably based on a short-term, i.e., semi-chronic toxicity study.
If exposure during a period longer than 3 months per year cannot be excluded based on the application scenario, a chronic toxicity study is preferred.

Besides duration and frequency of exposure, the choice of the most relevant study can also be determined by the excretion rate of the active substance and its metabolites, and by the rate at which the effects that may be caused by exposure to a substance are reversible.
The most relevant studies are selected from the dossier on the basis of these considerations. The selection must be justified in the decision making.
The study with the most relevant NOAEL, obtained with the most relevant test animal,
is selected. This does not necessarily always have to be the lowest NOAEL found in the most sensitive test animal. The choice of the NOAEL as starting point depends on the total package of available toxicity studies and the mutual relationships in dose regimes. The most suitable NOAEL on which the AOEL is based should be selected on a case-by-case basis, for which expert judgement is required.

Safety factor for calculation of the AOEL/AEL
A systemic AOEL is derived from the selected NOAEL by applying an uncertainty factor.
In accordance with the ADI principle the uncertainty factor applied is usually 100. The basis for this approach is a factor of 10 for differences within the animal species (intraspecies differences) and a factor of 10 for differences between animal species (interspecies differences). This latter factor compensates for the wider variation in sensitivity in the population of exposed workers in comparison with the relatively small (and relatively homogeneous) group of exposed laboratory animals.
Additional uncertainty factors may be used, as indicated for the ADI.

Absorption after oral exposure
Determination of the level of the systemic AOEL after oral exposure requires insight into the extent to which a substance is absorbed by the body after oral administration.
The value for absorption after oral exposure to a relevant amount of substance is the sum of the amounts of substance and metabolites that are subsequently excreted in the urine and that remain in tissues and carcass. If the absorbed dose is significantly lower (<80%) than the administered dose, this is adjusted by a correction factor equal to the percentage absorption. Because absorption may be dose-dependent, absorption data are required of a dose in the range of the NOAEL.

Annex 13 Instruction for downloading the EFSA AOEM model

EFSA AOEM is a tool assisting in the assessment of exposure of operators, workers, residents and bystanders to pesticides. This tool is proposed for pesticide registration purposes in Myanmar to be used as part of the decision support scheme, box "Conduct a human health risk assessment.

EFSA AOEM is part of a guidance document that sets out a (EU) harmonised methodology for calculating exposure to pesticides for four major population groups - operators, workers, residents and bystanders (EFSA, 2014). The user-friendly software tool consists of data spread sheets to quantify potential non-dietary, systemic exposure to pesticides. The tool can be downloaded as follows:

Go to the website for downloading the EFSA guidance (EFSA, 2014).

1. Scroll down and click on the section ' Supporting information'

2. A drop down menu (Figure 17) appears from which a zip file containing the model can be downloaded.

The EFSA AOEM model is not suitable for some types of applications, such as dusting of crops before storage, seed treatment, spraying via airplane, fumigation of greenhouses.

Figure 17 *Screen dump showing where to download the EFSA calculator assisting the assessment of exposure of operators, workers, residents and bystanders to pesticides.*

Annex 14 Step by Step guidance for performing risk assessment of operators in the field

Short manual for using EFSA AOEM for exposure assessment of operators in the field

Once the zip file containing EFSA AOEM is downloaded (instructions are given in Annex 13) the spreadsheet can be extracted from the zip file.

The spreadsheet contains several data sheets with different functions: instructions, data entry, results, default values and fixed input for the different exposure assessments.

For the assessment of exposure of operators of outdoor spray applications the data sheet: "Data entry" needs to be filled in and results of the assessment can be found in the data sheet: "Operator Outdoor Spray AOEM". Note that in the data sheet: "Operator Outdoor Spray AOEM" some input from the user is needed as well. For the assessment of granular applications results of the assessment can be found in the data sheet: "Operator Granules".

The information required for the exposure assessment needs to be entered in the worksheet "Data entry". Note that the data entered here serves as input for all exposure assessments (operator, worker, residents and bystanders) in the spreadsheet.

The data entries of the "Data entry" sheet (Figure 18) are discussed below in sequential order (from top to bottom of the sheet).

- The user may specify the substance name and the product name.
- The user needs to specify the RVNAS (Reference Value Non acutely toxic Active Substance); this term corresponds to the AOEL.
- The user may also specify the RVAAS (Reference Value Acutely toxic Active Substance). This term corresponds to the AAOEL (Acute Acceptable Operator Exposure Level) and is necessary for an acute risk assessment. However, at present we propose for Myanmar to only perform a semi-chronic risk assessment for operators and workers. Therefore the RVAAS does not need to be specified.
- The user needs to select a crop type from the picklist. It is highly recommended that the PPD drafts a list which specifies for each single crop to which crop group it belongs (e.g. the single crop broccoli belongs to the crop group brassica). This is necessary to prevent that user-subjectivity introduces variability into the results of the exposure assessment (i.e. different evaluators get different results due to the selection of a different crop group for the same crop).
- Considering the formulation type the user needs to select one of the four specified formulation groups. The formulation type is specified in the Table of Intended Uses/GAP table.
- The user needs to enter the minimum volume of water for application in L/ha (i.e. the minimum quantity of water, with which the pesticide product is to be applied). This corresponds to the entry "Application rate – Water L/ha" specified in the Table of Intended Uses/GAP table.
- The user needs to enter the maximum application rate of the active substance in kg a.s./ha. This corresponds to the entry "Application rate – g or kg a.i./ha" specified in the Table of Intended Uses/GAP table.

- The half-life for dissipation of the active substance on foliage needs to specified. For Myanmar we propose to use the default value of 30 days for organic chemicals, for which there is evidence of breakdown e.g. by photolysis or hydrolysis in soil or water.

- The amount of residue on foliage just after application (assuming no dissipation and assuming that everything is dislodgeable) should be specified. For Myanmar we propose to use the conservative value of 3 µg active substance/cm^2 of foliage/kg a.s. applied/ha. For dermal absorption for the time being we propose to use the following for Myanmar[11]:
  – 10% default dermal absorption value: log Pow < -1 or > 4 **and** MW > 500 g/mol
  – 100% default dermal absorption value: all other cases.
  It is advised to evaluate and discuss this approach for dermal absorption in the follow-up project.

- In general, the percentage dermal absorption from a less concentrated product is in many cases higher than from a concentrated product (the more diluted the formulation, the higher the dermal absorption percentage). For Myanmar we therefore propose to always use a value of 100% for dermal absorption of in-use dilution.

- For oral absorption we propose to use a default value of 100% for Myanmar

- For inhalation absorption we propose to use a default value of 100% for Myanmar

- The vapour pressure of the active ingredient is a data requirement in Myanmar. The user should select from the picklist if the vapour pressure is below $5 \cdot 10^{-3}$ Pa or between $5 \cdot 10^{-3}$ Pa and $1 \cdot 10^{-2}$ Pa. For active substances with vapour pressures ≥ 10^{-2} Pa, an ad hoc approach may be required. It is advised to address the latter in the follow up project.

- Outdoor application should be selected

- The user should select the application method from the picklist. At the moment manual application methods are most common in Myanmar. Two types of manual application methods are available: 1) manual hand held and 2) knapsack. The manual hand held poses the highest risks for the operator and will give more conservative results from a registration point of view. It is up to the regulator to decide which of the application method is most appropriate.

- Buffer strips are not common practice in Myanmar. Therefore the lowest values possible (2-3m) should be selected from the picklist.

- The user needs to enter the number of applications. This is specified in the Table of Intended Uses/GAP table.

- The user needs to enter the interval between multiple applications. This is specified in the Table of Intended Uses/GAP table.

- Specifying the season is not relevant for downward directed spraying applications, thus "not relevant" should be selected from the picklist.

[11] Note that currently the EFSA advises the following approach:
- 10% default dermal absorption value: log Pow > 3 and MW > 500 g/mol
- 25% default dermal absorption value: concentration of active substance > 5% (formulations)
- 75% default dermal absorption value: concentration of active substance < 5% (spray dilutions)

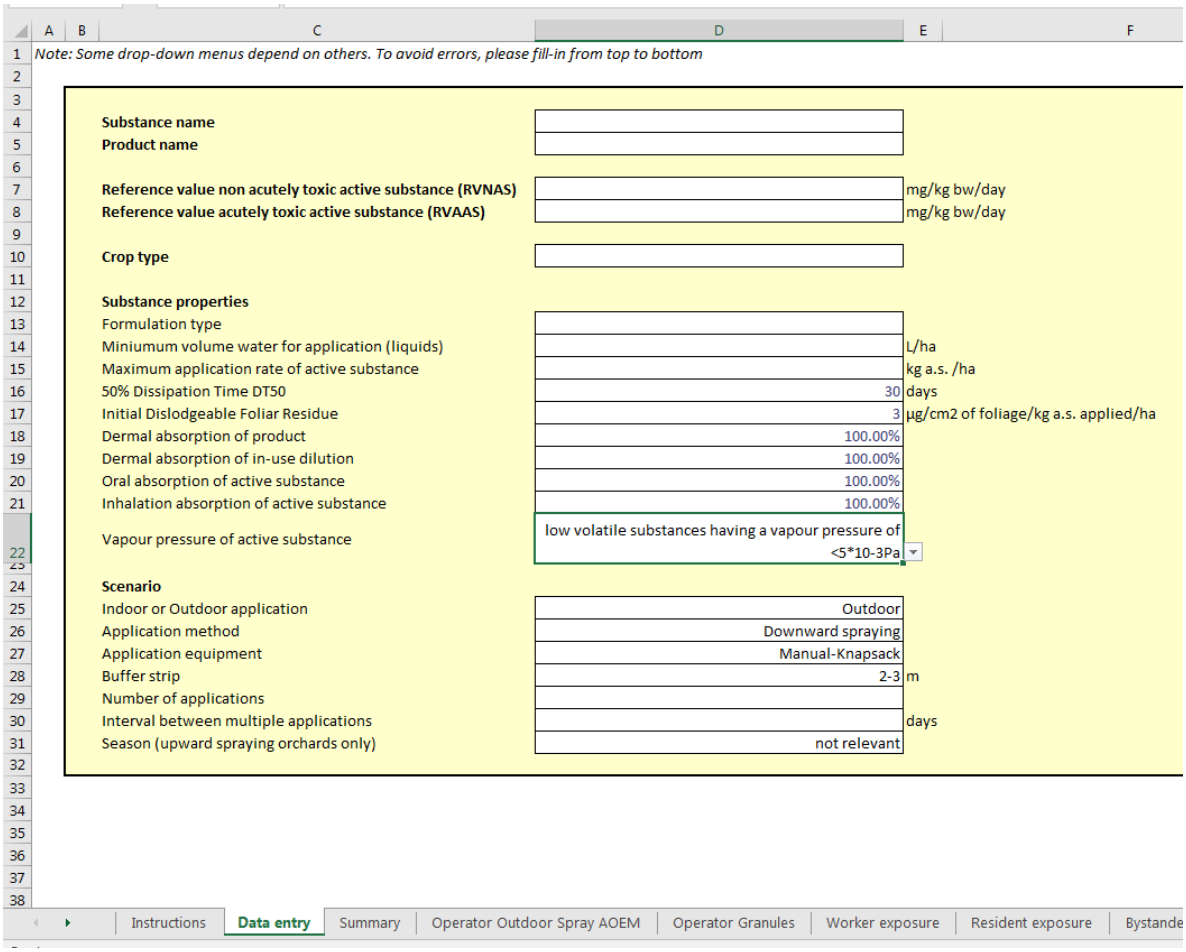


Figure 18 *Screen dump of the Data entry sheet of the EFSA spreadsheet based calculator, part of its Guidance document on the assessment of exposure of operators and workers to pesticides.*

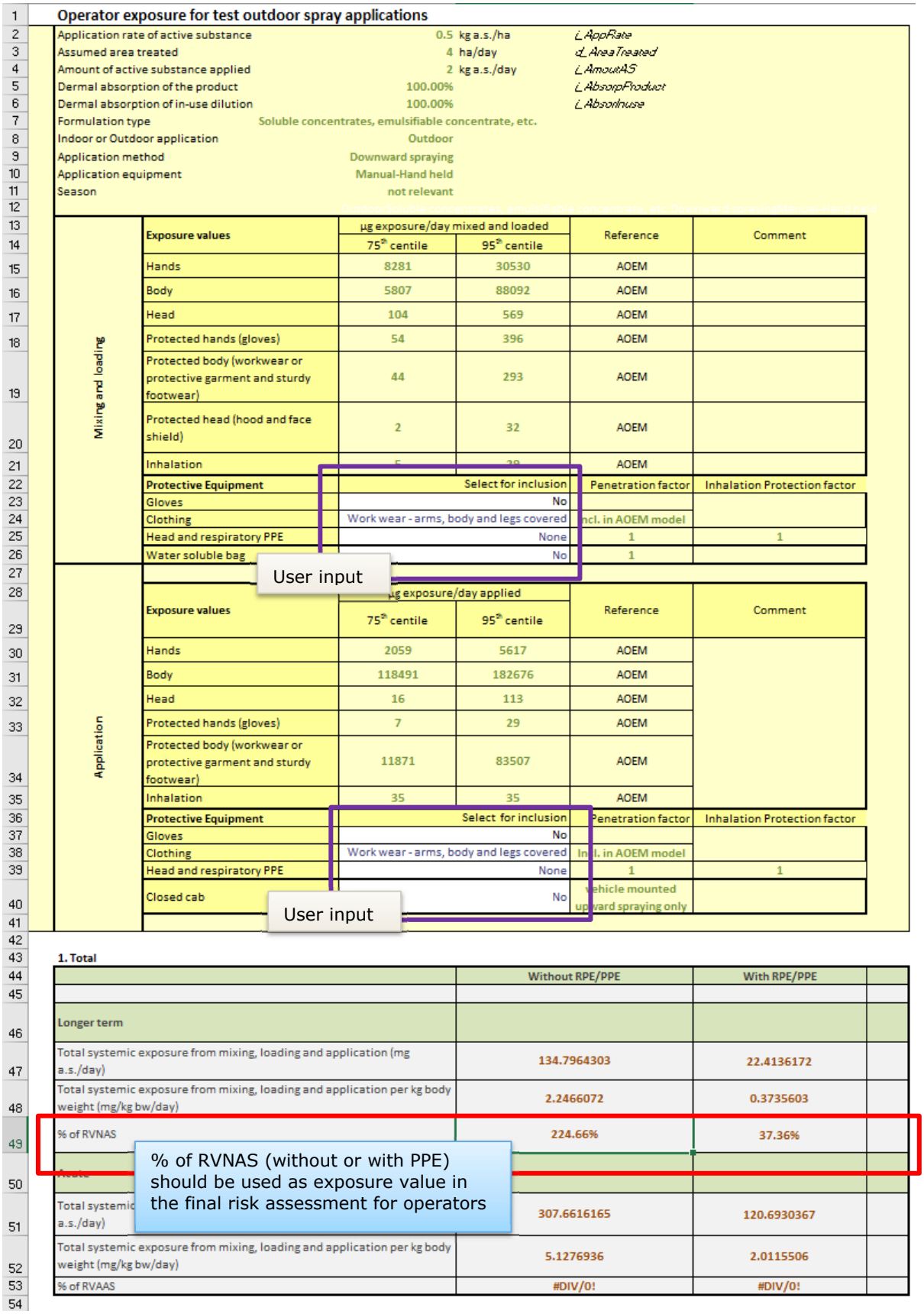
The results of the semi-chronic risk assessment for operators is found on the sheet "Operator Outdoor Spray AOEM" (Figure 19).

Results of exposure from mixing, loading and application are given for i) situations without any use of protective equipment (*without RPE/PPE*) and ii) situations with use of protective equipment (*with RPE/PPE*). For the latter, the user needs to select for both activities of the operator: 1) mixing and loading and 2) application the options for protective equipment:

- gloves: Yes/No;
- clothing: potential exposure/work wear – arms, body and legs covered;
- head and respiratory PPE: none or 4 different PPE options
- water soluble bag (mixing and loading only): Yes/No
- closed cap (application only + only relevant for tractor mounted spraying): Yes/No

As discussed with the PPD, the PPD will perform the risk assessment, for 1) application without PRE/PPE, 2) with full PPE (incl. head and respiratory protection FP2) and 3) a combination of PRE/PPE that is most appropriate according to the regulator. Results of the risk assessment are subsequently reported in the decision supporting summary (Annex 7) which will be used by the PRB for decision making.

For the final risk assessment for operators the total exposure (with or without PPE) as % of RVNAS (which corresponds to the total exposure as % of the AOEL) should be compared to AOEL from the hazard assessment (which is either extracted from a database or derived from the studies in the dossier).



Operator exposure for test outdoor spray applications

Application rate of active substance	0.5 kg a.s./ha	*i_AppRate*	
Assumed area treated	4 ha/day	*i_AreaTreated*	
Amount of active substance applied	2 kg a.s./day	*i_AmountAS*	
Dermal absorption of the product	100.00%	*i_AbsorpProduct*	
Dermal absorption of in-use dilution	100.00%	*i_AbsorpInuse*	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Manual-Hand held		
Season	not relevant		

Mixing and loading

Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Hands	8281	30530	AOEM	
Body	5807	88092	AOEM	
Head	104	569	AOEM	
Protected hands (gloves)	54	396	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	44	293	AOEM	
Protected head (hood and face shield)	2	32	AOEM	
Inhalation	5	29	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Water soluble bag	No		1	

User input

Application

Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Hands	2059	5617	AOEM	
Body	118491	182676	AOEM	
Head	16	113	AOEM	
Protected hands (gloves)	7	29	AOEM	
Protected body (workwear or protective garment and sturdy footwear)	11871	83507	AOEM	
Inhalation	35	35	AOEM	
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	No			
Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
Head and respiratory PPE	None		1	1
Closed cab	No		Vehicle mounted upward spraying only	

User input

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	134.7964303	22.4136172
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	2.2466072	0.3735603
% of RVNAS	224.66%	37.36%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	307.6616165	120.6930367
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	5.1276936	2.0115506
% of RVAAS	#DIV/0!	#DIV/0!

% of RVNAS (without or with PPE) should be used as exposure value in the final risk assessment for operators

Figure 19 *Screen dump of the Operator Outdoor Spray AOEM sheet of the EFSA spreadsheet based calculator, part of its Guidance document on the assessment of exposure of operators and workers to pesticides.*

Annex 15 Step by Step guidance for performing risk assessment of workers in the field

Short manual for using EFSAO AOEM for exposure assessment of workers in the field

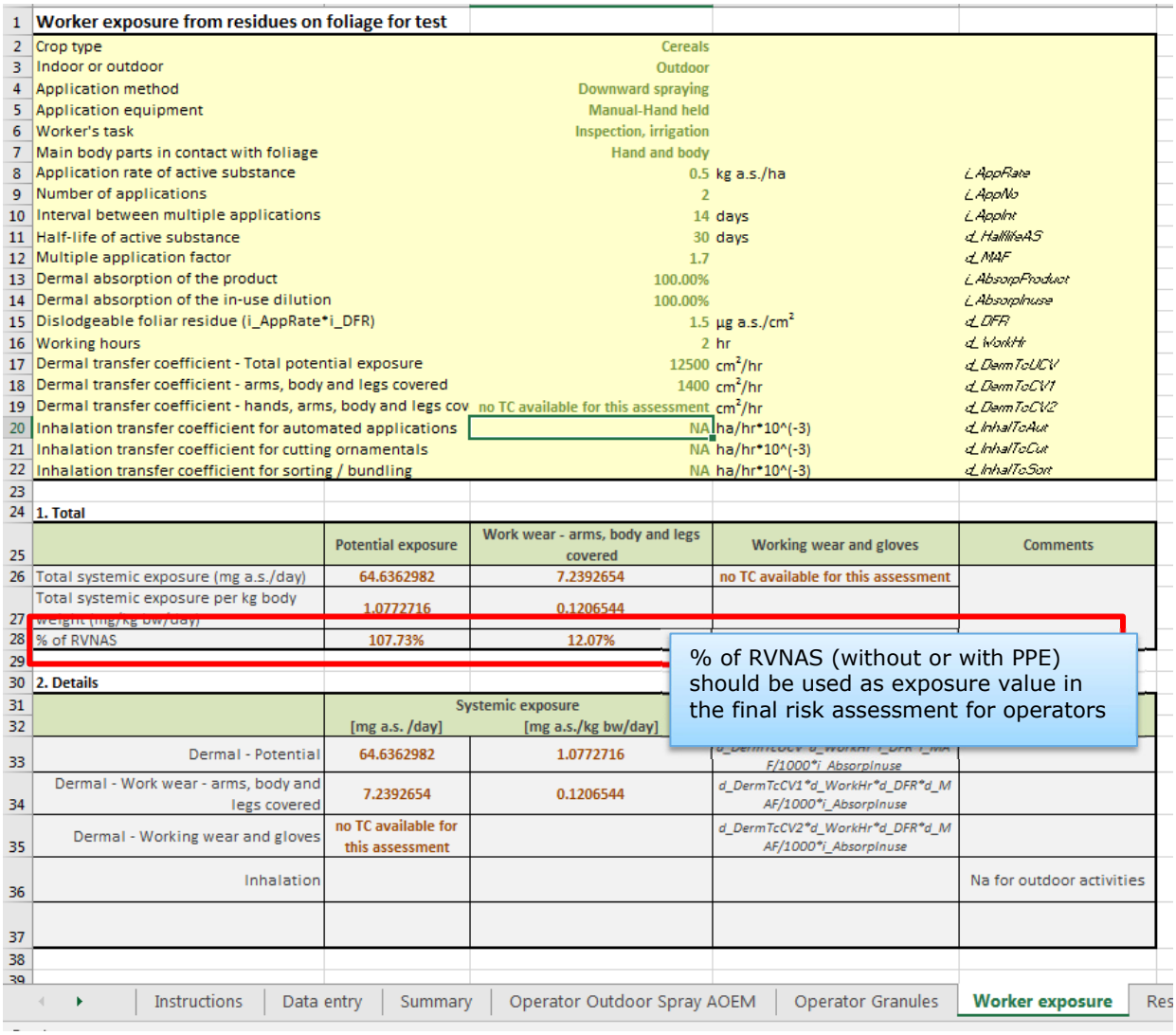
Worker exposure is defined as the exposure of a person who enters an area or handles crop previously treated with a plant protection product. In the first tier, exposure is estimated for the unprotected worker in working clothes common in Myanmar.

As explained in Annex 14, EFSA AOEM for exposure assessment of operators, workers, residents and bystanders contains several data sheets with different functions: instructions, data entry, results, default values and fixed input for the different exposure assessments. Note that the data entered here serves as input for all exposure assessments (operator, worker, residents and bystanders) in the spreadsheet.

For the assessment of exposure of workers in Myanmar the data sheet: "Data entry" needs to be filled in. The results of the assessment are found in the datasheet: "Worker exposure".

The data entries of the "Data entry" sheet (Figure 18) are discussed in Annex 14.

The results of the semi-chronic risk assessment for workers is found on the sheet "Worker exposure" (Figure 20).



1	**Worker exposure from residues on foliage for test**			
2	Crop type	Cereals		
3	Indoor or outdoor	Outdoor		
4	Application method	Downward spraying		
5	Application equipment	Manual-Hand held		
6	Worker's task	Inspection, irrigation		
7	Main body parts in contact with foliage	Hand and body		
8	Application rate of active substance	0.5	kg a.s./ha	i_AppRate
9	Number of applications	2		i_AppNo
10	Interval between multiple applications	14	days	i_AppInt
11	Half-life of active substance	30	days	d_HalfLifeAS
12	Multiple application factor	1.7		d_MAF
13	Dermal absorption of the product	100.00%		i_AbsorpProduct
14	Dermal absorption of the in-use dilution	100.00%		i_Absorpinuse
15	Dislodgeable foliar residue (i_AppRate*i_DFR)	1.5	µg a.s./cm²	d_DFR
16	Working hours	2	hr	d_WorkHr
17	Dermal transfer coefficient - Total potential exposure	12500	cm²/hr	d_DermTcUCV
18	Dermal transfer coefficient - arms, body and legs covered	1400	cm²/hr	d_DermTcCV1
19	Dermal transfer coefficient - hands, arms, body and legs cov	no TC available for this assessment	cm²/hr	d_DermTcCV2
20	Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	d_InhalTcAut
21	Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	d_InhalTcCut
22	Inhalation transfer coefficient for sorting / bundling	NA	ha/hr*10^(-3)	d_InhalTcSort
23				
24	**1. Total**			

25		Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
26	Total systemic exposure (mg a.s./day)	64.6362982	7.2392654	no TC available for this assessment	
27	Total systemic exposure per kg body weight (mg/kg bw/day)	1.0772716	0.1206544		
28	% of RVNAS	107.73%	12.07%		
29					
30	**2. Details**				

31		Systemic exposure			
32		[mg a.s. /day]	[mg a.s./kg bw/day]		
33	Dermal - Potential	64.6362982	1.0772716	d_DermTcUCV*d_WorkHr*d_DFR*i_MAF/1000*i_Absorpinuse	
34	Dermal - Work wear - arms, body and legs covered	7.2392654	0.1206544	d_DermTcCV1*d_WorkHr*d_DFR*d_MAF/1000*i_Absorpinuse	
35	Dermal - Working wear and gloves	no TC available for this assessment		d_DermTcCV2*d_WorkHr*d_DFR*d_MAF/1000*i_Absorpinuse	
36	Inhalation				Na for outdoor activities
37					
38					

% of RVNAS (without or with PPE) should be used as exposure value in the final risk assessment for operators

Instructions | Data entry | Summary | Operator Outdoor Spray AOEM | Operator Granules | **Worker exposure** | Res

Figure 20 *Screen dump of the Worker exposure sheet of the EFSA spreadsheet based calculator, part of its Guidance document on the assessment of exposure of operators and workers to pesticides.*

A 'Transfer Coefficient' (TC) is a theoretical estimate of the amount of contact (*i.e.* area of foliage) that occurs with a pesticide-treated crop during the conduct of a specific work activity. Dermal transfer coefficients are fixed and filled in automatically. The values for the dermal transfer coefficients are crop specific and can be found in the datasheet: "Small tables". Note that for the most protective option (hands, arms, body and legs covered) for several crops no values for transfer coefficients are available. Inhalation exposure may be due to vapour and/or airborne aerosols (including dust). For outdoor activities the inhalation potential is generally low and the inhalation route might only be of importance in exceptional cases. Therefore, the values for transfer coefficients are not given (i.e. default Not Applicable; NA – see sheet "Default values") in the EFSA model.

For the final risk assessment for workers the total exposure (with or without PPE) as % of RVNAS (which corresponds to the total exposure as % of the AOEL) should be compared with AOEL from the hazard assessment (which is either extracted from a database or derived from the studies in the dossier).

Annex 16 Background information on terms relevant for the consumer/dietary risk assessment

ADI

Consumers may be exposed to residues of plant protection products via food, throughout their life. The corresponding reference value (Acceptable daily intake, ADI) must therefore represent the dose that can be ingested over a lifetime via food without adverse health effects. The JECFA (Joint FAO/WHO Expert Committee on Food Additives) has defined the ADI as follows: "the estimated amount of active substance, expressed per kg body weight, that can be consumed daily over a lifetime without appreciable health risks".

Note that the US EPA refers to the chronic reference dose (chronic RfD or RfD) instead of ADI.

The ADI is usually derived from laboratory animal research in which the effect of prolonged exposure to the test substance has been studied, *i.e.* chronic toxicity research.

The following formula is used to set the ADI:

ADI (human dose) = NO(A)EL(experimental dose) / 100 (default uncertainty factor)

The ADI is based on the most sensitive, or most critical effect. 'Effect' is defined as: an effect that is considered adverse. Usually, data on several species are available (rat and mouse and sometimes also dog). The data of the most relevant animal species for the most critical effect form the basis for derivation of the ADI. The relevance of the observed effect for man is also important.

Plant metabolism and residue definition

Crops

To assess the fate of residues of active substances, metabolism studies need to be performed in plants representative of crops in which use of the active is intended, under conditions corresponding to the intended GAP and, using a radiolabelled form of the active substance.

OECD guideline 501 (OECD guideline for the testing of chemicals, Section 5 Other Test Guidelines; http://dx.doi.org/10.1787/9789264061835-en) describe how to correctly perform metabolism studies.

Metabolisms studies do not need to be performed for every crop in which use of the active is intended. A distinction is made between five different crop groups:

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

For the classification of crops, reference is made to OECD guideline 501. The method of application, e.g. foliar spray, soil or seed treatment, should be representative of the intended use. If the metabolism of the active substance is similar in three different plant groups investigated, metabolism is assumed similar in all crop groups and further study is not required.

A residue definition for plant products is derived from the data from plant metabolism studies, performed with an appropriate crop group and according to a GAP similar as applied for, using radiolabelled pesticide. The residue definition is established by taking the following principal points into account:

- the residue definition (for enforcement/ monitoring) must be suitable for routine monitoring, and should preferably be as reliable and as simple as possible in order not to hinder robust monitoring (*i.e.* the use of multi residue methods)
- the residue definition (for risk assessment) should include the toxicologically relevant metabolite(s) and/or the active substance and the components that constitute the largest part of the residue.

In principle all residues >0.05 mg/kg and/or >10% of total residue (TRR, total radioactive residue) will be included in the residue definition for risk assessment unless proven toxicologically irrelevant. The dose rate applied in the metabolism study should not be too low, as this could result in too small fractions to identify the metabolites. Applying too high dose rates can alter metabolic pathways due to saturation of enzymatic processes, and may therefore cause results which are not representative for the intended use.
Whether a metabolite needs to be included in the residue definition, depends on its toxicity. EFSA provides guidance on the establishment of the residue definition to be used for dietary risk assessment (doi:10.2903/j.efsa.2016.4549; http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4549/pdf)

Supervised residue trials
To determine the amount of residues expected after the use of a pesticide product, trials are performed that represent the commercial and agricultural use of the pesticide product. The trials should be performed in accordance with the proposed worst-case use on the label.

The worst-case use can be determined by taking the prescribed highest dose rate, maximum number of applications, the shortest spray interval and the shortest pre-harvest interval. The trials are not performed with radiolabelled material, but with a formulated product.

The crop residue trials that serve for derivation of MRLs in plant products must be carried out in accordance with the requested directions for use, in accordance with the most critical use where several directions for use are concerned and under GLP. It is also required that the relevant residue components are analysed at the time of harvest, *i.e.* the residues in the residue definition for risk assessment. Where the products contain residues above the limit of quantification, consisting of an edible and a non-edible part, these must be analysed separately to be able to derive a processing factor, which can be used for refinement of the consumer risk assessment, e.g. citrus analysis in both peel and pulp, stone fruits in both stone and flesh.

A quick scan can be performed on the supervised residue trials by taking into account the following check points:

- Application rates, interval and PHI (pre-harvest interval, time between (last) application and harvest) in accordance with the critical use;
- Weather details – large amounts of precipitation on the day of application can negatively influence residue levels;
- Indoor/outdoor – is the use applied for indoor or outdoor and are the trials performed accordingly;
- Varieties used – using different varieties of a crop can result in different results;
- Sample size – is the sample size taken large enough to represent a reliable sample? This varies per crop. A very detailed list of sample sizes is presented in EU guideline 7029/VI/95 rev.5 of July 22nd, 1997, appendix B: General recommendations for the design, preparation and realization of residue trials;
- Storage of samples – were the samples taken stored frozen shortly after sampling, during transport and at testing facility. Not freezing samples can result in underestimated levels due to degradation of residues after sampling;
- Analytical method used – is the method used acceptable for the pesticide concerned and are recovery rates acceptable in accordance with guidelines.

Were the requested use concerns a group of comparable products, determination of the residues in one or more representatives of the group is sometimes sufficient and results may then be extrapolated to related crops. The EU provides guidelines on comparability, extrapolation, group tolerances and data requirements for pesticides residues in food and raw agricultural commodities: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-d.pdf

Samples taken from metabolism studies and from supervised residue trials will deteriorate in quality and residues can decline when samples are not stored appropriately. OECD 506 is the guideline on "Stability of Pesticide Residues in Stored Commodities" (http://dx.doi.org/10.1787/9789264061927-en).

Maximum Residue Levels

Definition and legislation
Maximum Residue Levels or Maximum Residue Limits (MRLs) are the legal limits for pesticide residues in food commodities. MRLs are established worldwide, with different legislation for countries/regions.

Europe, US and Japan for example all have their own legislation and consequently, their own limits.

There is also a global forum that established MRLs: Codex Alimentarius Commission. The Codex Alimentarius Commission was established by FAO and WHO in 1963. It develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade.

One organisation (EU) and 189 countries, including Myanmar, are members of Codex.
As Myanmar is a member of Codex Alimentarius, the Codex MRLs (CXLs) are used as a basis for risk assessment. Where Codex MRLs do not cover the use of a pesticide product in Myanmar, no national MRL will be set as appropriate national Myanmar legislation is currently not in place.

MRL databases
MRLs can either be obtained from databases or they can be calculated using results from supervised residue trials or analytical measurements.

The MRL can subsequently be used for a national risk assessment or to compare analysed residue levels with the MRLs set in the country to which crops are exported. A single analytical measurement cannot be used to establish an MRL since multiple results are needed to form a dataset, but it can be used to check whether a batch of a crop complies with the MRL in the importing country. The flow chart in Figure 21 shows how MRL setting for national risk assessment and export is done in many countries. For Myanmar we propose for the short term to use MRLs from databases only. When in the future Myanmar gained capacity to perform and/or evaluate supervised residue trails and/or single analytical measurements Myanmar specific MRLs might be established.

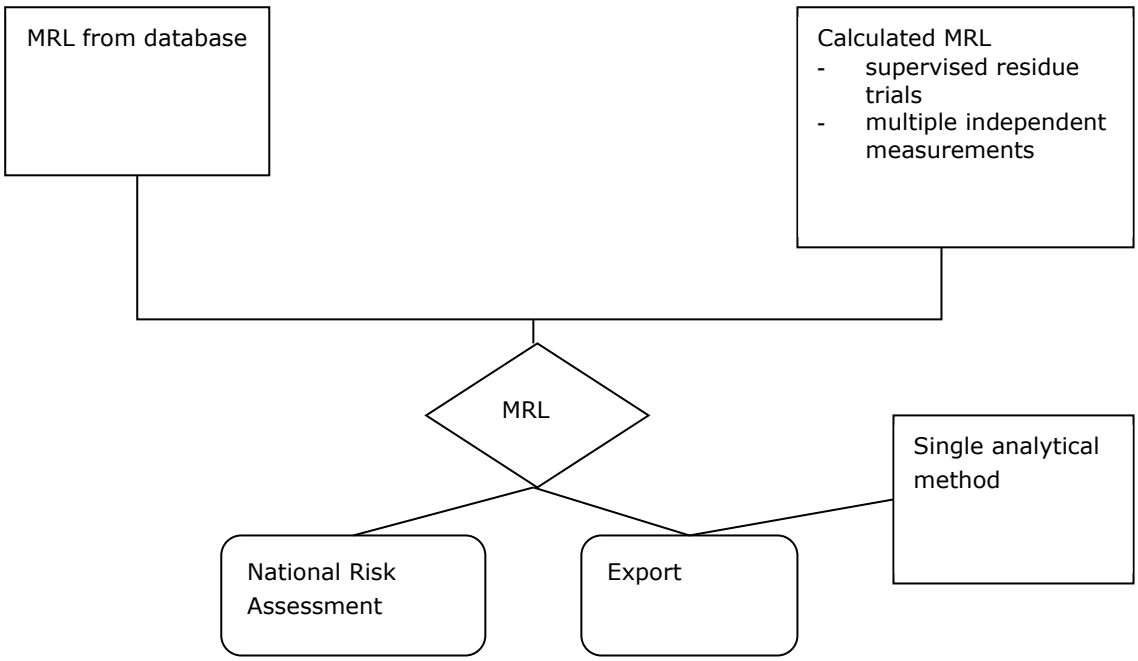


Figure 21 *Flow chart for MRL setting for national risk assessment and export – as used by many countries. For Myanmar we propose for the short term to use MRLs from databases only.*

The most relevant databases for MRLs are listed in the FAO toolkit (http://www.fao.org/pesticide-registration-toolkit/tool/page/pret/maximum-residue-limits) and repeated below:

International sources

Codex Alimentarius
The main principal international source of MRLs is the Codex Alimentarius. MRLs are set by the Codex Committee on Pesticide Residues (CCPR), based on recommendations made by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR).

MRLs can be found in the Codex pesticides in food online database (Codex, 2017). The database can be searched by pesticide common name or class as well as by commodity name of code.

Global MRL database
The United States Department of Agriculture (USDA) used to maintain an international database of MRLs. This database is now managed by Bryant Christie Inc., as the Global MRL database: https://www.globalmrl.com/. A (free) registration is required to access this database. The free subscription only provides access to the U.S. MRLs.

In the ASEAN context work was done on the harmonization of maximum residue limits (MRLs) of pesticides for vegetables. MRLs established can be found here: www.asean.org/storage/images/archive/agr_pub/crops1.doc.

New Zealand MRL web page
The New Zealand Ministry of Primary Industries maintains a web page on pesticide maximum residue limit (MRL) legislation around the world: http://www.foodsafety.govt.nz/industry/sectors/plant-products/pesticide-mrl/worldwide.htm. Links are provides to a large number of national authorities that set MRLs, as well as to their MRL databases if available.

National/regional sources of MRL data

European Union
The European Commission sets its MRLs applicable in the EU (referred to as maximum residue levels), which are not always the same as Codex MRLs: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

The EU MRL database can be searched by pesticide common name or by commodity or commodity groups. For the products and the part of the product to which EU-MRL's apply, see Annex 1 of Regulation (EU) No 396/2005 (most recent updated by Regulation (EU) No 752/2014) (http://eur-lex.europa.eu/homepage.html).

United States of America
The US Environmental Protection Agency (USEPA) sets pesticide residue tolerances applicable in the USA. The official publication of pesticide tolerances for the USA is in the e-Code of Federal Regulations (e-CFR). The USEPA provides guidance on how to obtain MRLs for specific commodities through the e-CFR (https://www.epa.gov/pesticide-tolerances/how-search-tolerances-pesticide-ingredients-code-federal-regulations).

US tolerances can also be accessed through the *Global MRL database*, mentioned under international sources.

Australia
Australian MRLs are published in the Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard). The MRL Standard can be accessed through the Australian Pesticides and Veterinary Medicines Authority (https://apvma.gov.au/node/10806 : click on the link to the ComLaw website).

New Zealand
The MRLs applicable in New Zealand are published in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards (http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm). Click on the link on this page to obtain the most recent version of the standards.

Derivation of endpoints and reference values for consumer risk: MRL, STMR and HR for plant products

Three mathematical values can be derived from supervised residue trials which are needed for consumer risk assessment.

- STMR (Supervised Trial Median Residue) is the median residue value from the residue trials, which can be used for refined chronic and acute intake calculations and feeding studies;
- HR (Highest Residue) value is the highest value measured in a residue trial and can be used for acute intake calculations;
- MRL (Maximal Residue Level) is the maximum concentration of residue, calculated by using a statistical formula and results from supervised residue trials, which can be used for chronic and acute diet calculations for man, as a first tier. Derivation of the MRL is described below.

MRL calculation has been harmonised by the use of the OECD calculator, developed in 2011. As input parameters the results of the acceptable supervised residue trials at the prescribed pre-harvest intervals are used:

The spreadsheet and a guide can be found at:
http://www.oecd.org/env/chemicalsafetyandbiosafety/agriculturalpesticidesandbiocides/oecdmaximumresiduelimitcalculator.htm

Where no residues at all are found above the LOQ (Limit of Quantification), the STMR (Supervised Trial Mean Residue), HR (Highest Residue) and MRL are based on the LOQ. Where there are indications that residue levels are really zero (because the residue levels in the overdosed trials are also < LOQ) the STMR and HR are set at 0 and the MRL at the LOQ.

Annex 17 Details of the principles of the first tier acute consumer exposure assessment as performed in the EU

Acute risk assessment for consumers in the EU

The internationally developed methodology (WHO, JMPR) for point estimation is used; acute risk of consumption of a crop is calculated by using the large portion (LP) from the dietary data and considering that one of the units consumed coincidentally contains a higher residue level than the composite sample from a residue trial from which STMR, HR and MRL values are derived. The variability between units is expressed by the variability factor (v).

Currently, four different cases are distinguished for the calculation of the International Estimated Short-Term Intake (IESTI), each with a specific mathematical method. The different cases reflect the differences in crop weight, amount consumed and unit specific variability thereby influencing the number of units consumed at one time. Summarised the idea is that there is a change that 1 unit (e.g. large fruit like apple) has a higher residue level than the composite sample used for MRL setting (which in general is composed from >2 kg/>10 fruits). To compensate for this effect, a variability factor applies for the risk assessment (3, 5, 7 or 10). For products with small units present in large, mixed lots like grains, no variability is expected since always a mixed portion (equal to a composite sample) will be consumed (v = 1).

The following parameters are used:

- U = unit weight (g) of a commodity, calculated allowing for the edible fraction
- LP = highest 'large portion' (97.5th percentile from consumption data) (kg/day)
- v = variability factor, representing the ratio of the 97.5th percentile residue to the mean residue in single units. Default factors for various commodities apply.
- HR = highest residue level in composite samples of the edible portion, found in the residue trials (mg/kg)
- HR-P = highest residue level, where processing of the crop (mg/kg) is taken into account
- STMR = Supervised Trial Median Residue (mg/kg), median value of a residue data set
- STMR-P = Supervised Trial Median Residue, where processing of the crop (mg/kg) is taken into account
- bw = body weight (kg) provided by the country for which the large portion (LP) was used.

Note, that as a first tier, the MRL is used in the calculations, even though the MRL is not mentioned in the cases given below. In the cases below, where HR(-P) or STMR(-P) are used in the equations, the MRL should be used as the input value for the first tier and the HR(-P) or STMR(-P) for second tier calculations. Only when the calculations result in >100% of the ARfD, a refinement (second tier) needs to be performed by using the appropriate STMR and HR values.

Case 1:

The residue concentration in composite (combined) samples from residue trials (raw or processed) more or less corresponds with the residue in a portion (meal size) of the product; a portion consists of several units. The unit weight is < 25 g:

$$IESTI = [LP \times (HR \text{ or } HR\text{-}P)] / bw \qquad \text{Eq. 5}$$

Cases 2a and 2b:

The portion (meal size), e.g. a piece of fruit or vegetable, may contain a higher residue than composite samples from residue trials. The unit weight > 25 g.

A variability factor is therefore introduced (a default factor or, alternatively, based on available residue data in separate pieces of fruit or vegetable).

Depending on the properties of a product, the standard variability factors given in Table 5 are applied.

Table 5 *Variability factors used by 2002 JMPR.*

Product property	v
Unit weight of head lettuce	3
Unit weight of the whole portion > 250 g	5
Unit weight of the whole portion ≤ 250 g	7
Unit weight of the whole portion ≤ 250 g, and the pesticide is granule for soil treatment	10
Leafy vegetables where the unit weight of the whole portion ≤ 250 g	10

Specific for case 2a:
This concerns the unit weights that are smaller than the large portion (LP):

$$IESTI = [\{IESTI =[\{U \times (HR \text{ or } HR\text{-}P) \times v\} + \{(LP\text{-}U) \times (HR \text{ or } HR\text{-}P)\}] / bw \quad \text{Eq. 6}$$

The Case 2a equation is based on the assumption that the first unit contains residues at the HR x v level and the next ones contain residues at the HR level, which represents the residue in the composite from the same lot as the first one.

Specific for case 2b:
Concerns unit weights larger than the large portion:

$$IESTI = LP \times (HR \text{ or } HR\text{-}P) \times v / bw \quad \text{Eq. 7}$$

Where sufficient residue data in separate units are available to derive a HR for separate units, this value should be entered into the equation, without variability factor.

Case 3:
Concerns processed products that have been combined or mixed; the STMR-P value represents the highest residue concentration:

$$IESTI = LP \times STMR\text{-}P / bw \quad \text{Eq. 8}$$

The mentioned variability factors (v) are standard factors. Generally, these are conservative values, i.e., they are overestimates. Variability can therefore also be calculated from field measurements of a large number of samples taken of the crop in question which has been treated with the pesticide in accordance with GAP. The mathematical procedure for calculating the variability factor is still under debate but a draft proposal has been made by the IUPAC Advisory Committee on Crop Protection Chemistry.

Annex 18 Myanmar specific manual of the tool used for the (first tier) chronic risk assessment of consumers

Chronic risk assessment for consumers using the IEDI spreadsheet

The Microsoft Excel spreadsheet "IEDIcalculation0217clustersfinal.xlsm" is used for the chronic risk assessment for consumers.

The spreadsheet can be downloaded from the WHO GEMS website (WHO, 2017b).

This spreadsheet should be adapted for use in Myanmar according to specifications given on the sheet "Manual" for situations where only MRLs are available:

> If you have only MRLs, change the column titles (in GEMS_Food_diet and Final_table) into MRL and change "International Estimated Daily Intake" into International Theoretical Maximum Daily Intake (ITMDI) (in GEMS_Food_diet). Further proceed as for STMR.

After adapting the spreadsheet, it is good practice to rename the spreadsheet to for instance: "IEDIcalculation0217clustersfinal_Myanmar.xlsm"

The spreadsheet contains four worksheet tabs with background information and default values: "Clusters", "GEMSfood data conversions", "Rounded values" and "Manual". These tabs can be inspected. However, take care that you do not inadvertently change the values in the sheets (the tabs are not protected).

The tabs "IEDI calculation" and "Final_table" respectively are used to provide data and also display results.

Worksheet tab "IEDI calculation" for use in Myanmar

In the worksheet tab "IEDI calculation" the user needs to provide the compound name, the compound number, the ADI (in yellow cells) and the MRLs for relevant commodities (in yellow columns). Note that for Myanmar we use the MRLs as input instead of the STMRs or STMR-Ps. This means that we are not calculating an IEDI, but an ITMDI.

MRLs can be found in the Codex alimentarius database on pesticides in food compiled by FAO/WHO for online use (Codex, 2017). The database can be searched by pesticide common name or class as well as by commodity name of code.

It is the responsibility of the assessor to link the crop in the table of intended uses (or GAP table) to relevant commodities in the sheet "IEDI calculation".

The spreadsheet contains the food category system of the Codex Alimentarius (Codex, 2017b).

This food category system is hierarchical and classifies foods into groups and/or sub-groups. For instance Group 006 "assorted tropical and subtropical fruits-inedible peel" was divided into six subgroups which included the subgroup 006B smooth peel-large. Subgroup 006B smooth peel-large contains different agricultural crops each with an unique code (for instance the fruit mango with code

FI 0345). Different commodities of mango are listed i.e. Mango, raw (incl. canned mango, incl. mango juice), Mango, raw (incl. canned mango, excl. mango juice), Mango, raw (incl. mango juice, excl. canned mango), Mango, juice, Mango, canned. It is up to the assessor to judge which of these different commodities are relevant for his/her country.

For Myanmar, for the sake of simplicity, we propose to always (and only) use the top commodity of such a list of commodities of one particular agricultural product. The top commodity includes all commodities: i.e. the raw commodity and the semi-processed and processed commodities.

A suggestion for future use of the IEDI spreadsheet in Myanmar is to differentiate between commodities relevant and not relevant for Myanmar by marking the commodities irrelevant for Myanmar in red.

Once the user provides the compound name, the compound number, the ADI and the MRLs for relevant commodities, the "make IEDI table" needs to be clicked.
Results of the assessment can be viewed in the worksheet tab "Final_table".

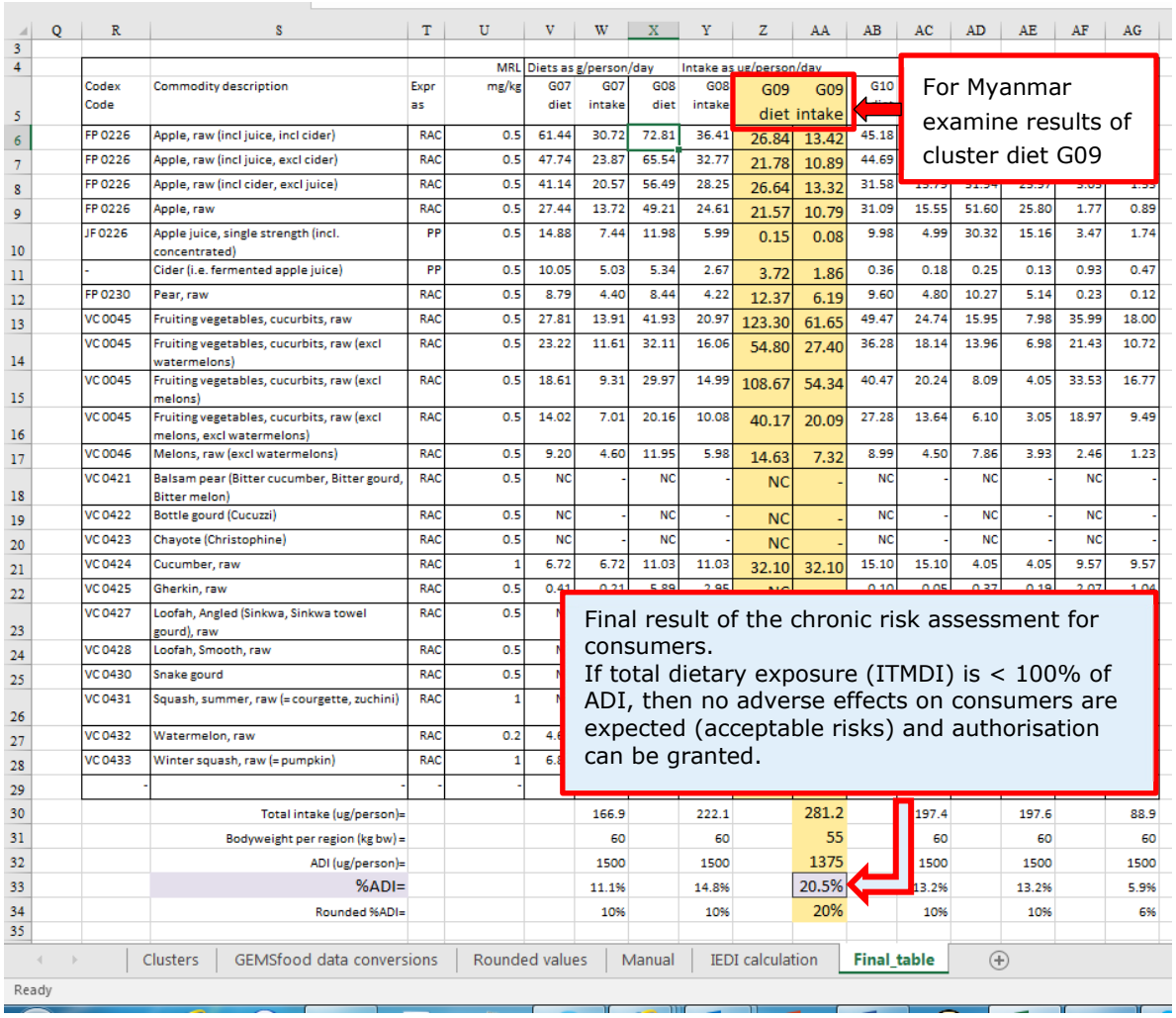
Summarizing, the steps are as follows:
1. Select tab "IEDI calculation"
2. Provide compound name, compound number and ADI (in yellow cells)
3. Provide the MRL (from databases) for relevant commodities (in yellow columns)
4. Start calculations by clicking on the button "Make IEDI table"
5. Select tab "Final_table" to examine the result of the assessment

Worksheet tab "Final_table" for use in Myanmar
As long as Myanmar has not established a national food consumption pattern, it is proposed to use the dietary data of the WHO GEMS12 Cluster Diet 09 (WHO, 2012) as a best approximation.

In the tab Final_table the results of the G09 diet needs to be examined. The number in the cell indicating the total dietary exposure (ITMDI) as percentage of ADI is the final result of the chronic risk assessment for consumers (Figure 22).

If this percentage is above 100%, then adverse effects on consumers cannot be excluded (unacceptable risks) and authorisation should not be granted.

[12] Global Environment Monitoring System (for monitoring and assessment of food contamination).



Codex Code	Commodity description	Expr as	MRL mg/kg	Diets as g/person/day G07 diet	G07 intake	G08 diet	G08 intake	Intake as ug/person/day G09 diet	G09 intake	G10 diet	G10 intake
FP 0226	Apple, raw (incl juice, incl cider)	RAC	0.5	61.44	30.72	72.81	36.41	26.84	13.42	45.18	
FP 0226	Apple, raw (incl juice, excl cider)	RAC	0.5	47.74	23.87	65.54	32.77	21.78	10.89	44.69	
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.5	41.14	20.57	56.49	28.25	26.64	13.32	31.58	
FP 0226	Apple, raw	RAC	0.5	27.44	13.72	49.21	24.61	21.57	10.79	31.09	15.55
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.5	14.88	7.44	11.98	5.99	0.15	0.08	9.98	4.99
-	Cider (i.e. fermented apple juice)	PP	0.5	10.05	5.03	5.34	2.67	3.72	1.86	0.36	0.18
FP 0230	Pear, raw	RAC	0.5	8.79	4.40	8.44	4.22	12.37	6.19	9.60	4.80
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.5	27.81	13.91	41.93	20.97	123.30	61.65	49.47	24.74
VC 0045	Fruiting vegetables, cucurbits, raw (excl watermelons)	RAC	0.5	23.22	11.61	32.11	16.06	54.80	27.40	36.28	18.14
VC 0045	Fruiting vegetables, cucurbits, raw (excl melons)	RAC	0.5	18.61	9.31	29.97	14.99	108.67	54.34	40.47	20.24
VC 0045	Fruiting vegetables, cucurbits, raw (excl melons, excl watermelons)	RAC	0.5	14.02	7.01	20.16	10.08	40.17	20.09	27.28	13.64
VC 0046	Melons, raw (excl watermelons)	RAC	0.5	9.20	4.60	11.95	5.98	14.63	7.32	8.99	4.50
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon)	RAC	0.5	NC	-	NC	-	NC	-	NC	-
VC 0422	Bottle gourd (Cucuzzi)	RAC	0.5	NC	-	NC	-	NC	-	NC	-
VC 0423	Chayote (Christophine)	RAC	0.5	NC	-	NC	-	NC	-	NC	-
VC 0424	Cucumber, raw	RAC	1	6.72	6.72	11.03	11.03	32.10	32.10	15.10	15.10
VC 0425	Gherkin, raw	RAC	0.5	0.41	0.21	5.89	2.85	NC		0.10	0.05
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd), raw	RAC	0.5								
VC 0428	Loofah, Smooth, raw	RAC	0.5								
VC 0430	Snake gourd	RAC	0.5								
VC 0431	Squash, summer, raw (= courgette, zuchini)	RAC	1								
VC 0432	Watermelon, raw	RAC	0.2	4.6							
VC 0433	Winter squash, raw (= pumpkin)	RAC	1	6.8							
-	-	-	-								
	Total intake (ug/person)=				166.9		222.1		281.2		197.4
	Bodyweight per region (kg bw) =				60		60		55		60
	ADI (ug/person)=				1500		1500		1375		1500
	%ADI=				11.1%		14.8%		20.5%		13.2%
	Rounded %ADI=				10%		10%		20%		10%

Figure 22 *Screen dump of the tab Final_table of the spreadsheet IEDIcalculation0217clustersfinal_Myanmar.xlsm.*

In the IEDI spreadsheet, the dietary intake of any particular pesticide residue is obtained by multiplying the residue level in the food (for Myanmar MRL is used) by the amount of commodity consumed from the WHO GEMS[13] Cluster Diet 09. Total intake of the pesticide residue is consequently obtained by summing the intakes from all commodities containing the residue concerned. Note that dietary data relevant for Myanmar is found in WHO GEMS Cluster Diet 09 (WHO, 2012).

Decisions regarding the use of the IEDI spreadsheet in Myanmar:

- Calculate the worst-case situation with regard to the estimated exposure (all crops treated according to critical GAP, all products have residue at MRL, no processing).

- By using the MRL as input, the Theoretical Maximum Daily Intake (TMDI) will be calculated instead of the International Estimated Daily Intake (IEDI). The column titles need to be changed accordingly in the spreadsheet. By using the MRL as input the results of the risk assessment will be more worst case (from a regulatory point of view) than when using the mean residues from supervised trails.

- It is assumed that all crops from which the consumed products were derived have been treated, and residues will be present at the level of the MRL. Products can be consumed raw or processed. As a

[13] Global Environment Monitoring System (for monitoring and assessment of food contamination).

first tier risk assessment, it is assumed that all consumed products are raw which is reflected by the top line of each crop in the spreadsheet[14].

- If registration is asked for product X containing active ingredient Y. GAP tables of all pesticide products containing active ingredient Y should be retrieved from the dossiers. Using this information a list should be made of all crops which potentially can contain residues of active ingredient Y due to the registration of pesticide products containing active ingredient Y.

The risk assessment for consumers in Myanmar will be done by comparing the exposure (result of the WHO IEDI spreadsheet; which is the total dietary exposure as percentage of the ADI) to the hazard (ADI).

Deciding whether risk are acceptable or not is done according:

- No adverse effects on humans expected (acceptable risks) if:
  Total dietary exposure (ITMDI) is ≤ 100% of ADI
- Adverse effects on humans cannot be excluded (unacceptable risks) if:
  Total dietary exposure (ITMDI) is >100% of ADI

[14] The top line of each crop in the WHO-GEMS spreadsheet is the total crop consumed, expressed as raw commodity. The processed products like juice are converted to raw fruit and added to fruits eaten raw. Since MRL and STMR values are derived for raw commodities, the raw commodities (gram per person per day) are most appropriate for the first tier risk assessment (personal communication Janhendrik Krook of Linge Agroconsultancy)

Annex 19 Myanmar specific guidance for higher tier chronic consumer risk assessments for consumers and for assessing residue levels for crop export

Higher tier chronic risk assessment for consumers

If adverse effects on consumers cannot be excluded (unacceptable risks when MRLs are used), a refinement of the risk assessment should be considered by performing a second tier calculation using the IEDI spreadsheet:

1. By using STMR instead of the MRL
2. If an STMR is not available, e.g. because original study data are not available, the general rule of thumb may be applied that the STMR is one third of the MRL.
3. By including processing data, such as peel-pulp distribution, boiling etc. in the intake calculations. The processing factor needs to be multiplied with the MRL or STMR resulting in MRL-P or STMR-P which can be entered in the spreadsheet.

Decision making on the outcome of the second tier calculation:

a. Total dietary exposure (IEDI) is ≤ 100% of ADI: no adverse effects on consumers are expected (acceptable risks) and authorisation can be granted.
b. Total dietary exposure (IEDI) >100% of ADI: adverse effects on consumers cannot be excluded (unacceptable risks) and authorisation should not be granted.

Note that at present, there is no capacity in Myanmar to perform and/or evaluate (supervised) residue trails. The STMR is therefore not available. Options 1 and 3 are therefore currently not possible.

For the time being, it is also strongly advised NOT to apply the second option in Myanmar.

The rule of thumb that STMR is one third of the MRL is derived from a statistical calculation of the MRL from a standard normal distributed dataset (personal communication Janhendrik Krook Linge Agroconsultancy); i.e. the ratio STMR:MRL ~ 1:3 is derived from a standard normal distribution of residues upon which the MRL is based. This ratio is not known when in residue trials residue values < 0.01 mg/kg (LOQ) are measured (there is additional uncertainty because in older studies the LOQ is often 0.05 mg/kg, which means it is sometimes not possible to judge whether a MRL is above or at LOQ).

EU member states and EFSA used the rule STMR = 0.5MRL during the EU MRL harmonisation in 2005 (also then, it was problematic to judge whether it was appropriate to use this rule for those cases where old national MRLs were available, but it was unknown how they were established).

To our opinion, the rule of thumb that the STMR is one third of the MRL should only be applied if regulators have a clear understanding of how MRLs are established and of corresponding variances and uncertainties. Even then for precautionary reasons it should be considered to use a factor of 2 instead of 3 (as done in the EU during the EU MRL harmonisation in 2005) and to use the rule of thumb only for MRL values above LOQ.

Assessing residue levels for crop export

In view of export of crops grown and treated in Myanmar, there is a need to assess whether the residue levels in products are in accordance with international (Codex) MRLs. Countries have their own MRLs with which the residues on the Myanmar products should comply. Various sources for obtaining MRLs are given in Annex 16.

Residue levels resulting from analytical measurements in commercial crops or established in residue trials are compared to MRLs to assess whether products/crops comply with internationally accepted values. At present, Myanmar lacks the capacity to perform residue analysis of treated crops, nor does Myanmar have the ability to perform residue trials. Hence, the guidance given below is of interest only at a later stage, where these abilities have been developed.

The results of analytical measurements of treated crops can be used to derive an MRL. Alternatively, results from residue trials, if available, may be used to calculate a 'virtual MRL'. The term 'virtual MRL' is used, since no risk assessment needs to be performed and no MRL will be set. The 'virtual MRL' is solely used to determine trade compatibility for a certain country and is calculated using the OECD calculator (http://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm).

If the 'virtual MRL' is lower or at the level of the MRL of the importing country, there is no objection against exporting the product. When the 'virtual MRL' is higher than the MRL set in the importing country, export will be hindered, as the country can refuse the product. If the latter is the case, an import tolerance (an MRL based on residue data in an exporting country) can be set. This procedure is different for different countries, and therefore no description is given here. Please consult the relevant country.

Annex 20 Details of the 8 criteria used in the FAO assessment of Highly Hazardous Pesticides

The information provided in this Annex is taken from the 'the FAO Pesticide Registration Toolkit' (http://www.fao.org/pesticide-registration-toolkit/tool/home/).

B.1 Pesticide formulations that meet the criteria of Classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard

- **Definition**

Pesticide formulations that meet the criteria of **Classes Ia or Ib** of the WHO Recommended Classification of Pesticides by Hazard are identified as a HHP

Ia = extremely hazardous
Ib = highly hazardous

The WHO classification is primarily based on the acute oral and dermal toxicity of the pesticide. In rare cases, chronic toxicity has also been taken into account.

- **Identification procedure**

	Hazard classification (2009)				
	Class Ia *Extremely hazardous*	**Class Ib** *Highly hazardous*	**Class II** *Moderately hazardous*	**Class III** *Slightly hazardous*	**Class U** *Unlikely to present acute hazard in normal use*
Oral toxicity (LD_{50} – mg/kg bw)	<5	5 – 50	50 -2000	2000 – 5000	> 5000
Dermal toxicity (LD_{50} – mg/kg bw)	< 50	50 – 200	200 – 2000	2000 – 5000	> 5000

It is **the formulated pesticide product** that should be classified. If acute LD50 values are available for the formulated product (e.g. in the registration dossier), classification can be done directly based on these values.

Alternatively, the product is classified based on the LD50 values of the active ingredient (A.I.) and the concentration of the A.I. in the product (Equations are provided in the WHO classification guidance – the HHP Identification Tool will conduct these calculations).

Both oral and dermal toxicity of the pesticide formulation should be classified; the strictest classification of these two will prevail for HHP identification.

It is often useful to cross-check the LD50 values provided in the dossier with those provided in reputable pesticide property databases. Small differences would be normal; large differences may require clarifications by the applicant.

- **Reference**

WHO Recommended Classification of Pesticides by Hazard

Website: http://www.who.int/ipcs/publications/pesticides_hazard/en/

- **Data sources**

LD50 values - Formulated product

B.2 Pesticide active ingredients and their formulations that meet the criteria of carcinogenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

+

B.3 Pesticide active ingredients and their formulations that meet the criteria of mutagenicity Categories 1A and 1B of the GHS

+

B.4 Pesticide active ingredients and their formulations that meet the criteria of reproductive toxicity Categories 1A and 1B of the GHS

- **Definition**

Pesticide active ingredients and their formulations that meet the criteria of **carcinogenicity, mutagenicity & reproductive toxicity** Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are classified as a HHP.

- **Criteria 2 Carcinogenicity**
  - Category 1A = Substances known to have carcinogenic potential for humans; the placing of a substance is largely based on human evidence
  - Category 1B = Substances presumed to have carcinogenic potential for humans; the placing of a substance is largely based on animal evidence

- **Criteria 3 Germ cell mutagenicity**
  - Category 1A = Substances known to induce heritable mutations in germ cells of humans
  - Category 1B = Substances which should be regarded as if they induce heritable mutations in the germ cells of humans

- **Criteria 4 Reproductive toxicity**
  - Category 1A = Known human reproductive toxicant
  - Category 1B = Presumed human reproductive toxicant

- **Reference**

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). 6th revised edition 2015 - Part 3, Health Hazards

Website: http://www.unece.org/trans/danger/publi/ghs/ghs_rev06/06files_e.html#c38156

- **Identification procedure**

For the CMR criteria, pesticide formulations are classified based on their active ingredient(s), irrespective of its concentration.

However, very diluted formulations, with A.I. concentrations < 0.1%, do not need to be classified for CMR. This is rarely the case for pesticides, but may occur for certain rodenticide formulations or aerosols.

Pesticide active ingredients are not individually classified by the GHS; it only provides the classification criteria. To assess whether a pesticide is a category 1A or 1B for CMR, regulators will need to classify the product themselves.

A single authoritative international database GHS classifications of pesticides does not exist. However, certain intergovernmental or national databases can be used to check the CMR classification of a pesticide. Which source to use is the choice of the regulator.

- **Data sources**

Classification of CMR according to the GHS.

B.5 Pesticide active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention

- **Definition**

Pesticide active ingredients listed by the Stockholm Convention in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention are identified as HHP

- **Reference**

The Stockholm Convention on Persistent Organic Pollutants (POPs) identifies pesticides which have been categorized as POPs. These possess a particular combination of physical and chemical properties such that, once released into the environment, they:

- remain intact for exceptionally long periods of time (many years);
- become widely distributed throughout the environment as a result of natural processes involving soil, water and, most notably, air;
- accumulate in the fatty tissue of living organisms including humans, and are found at higher concentrations at higher levels in the food chain; and
- are toxic to both humans and wildlife. Parties to the Convention commit themselves either to eliminate or restrict production and use of these chemicals, or reduce their unintential release.

If your country is a Party to the Stockholm Convention, registration of pesticides listed as POPs will not be possible or will need to be restricted. If they have been reviewed by the POPs Review Committee, risk profiles will have been elaborated. Pesticides under review for listing under the Convention may also need special attention in the registration process:

- The list of POPs under the Stockholm Convention (http://chm.pops.int/TheConvention/ThePOPs/tabid/673/Default.aspx)
- Chemicals (including pesticides) that have been reviewed for listing under the Convention, and for which a risk profile and risk management evaluation are available (http://chm.pops.int/Convention/POPsReviewCommittee/Chemicals/tabid/243/Default.aspx).
- Chemicals (including pesticides) under review for possible future listing under the Convention (http://chm.pops.int/Convention/POPsReviewCommittee/Chemicals/tabid/243/Default.aspx)

Website Stockholm Convention: http://chm.pops.int/

- **Identification procedure**

Pesticides listed on Annex A and B can easily be found on the Stockholm Convention web site.

Whether pesticides meet the screening criteria for POPs, as defined in Annex D of the Convention, will need to be assessed by Regulators. Such pesticides may not (yet) be listed in Annex A or B.

The HHP Identification Tool presently only includes the parameters describing the criteria for Persistence and for Bioaccumulation. No explicit parameters for Long-range transport and Adverse effects are mentioned in Annex D; these are to some extent subjective. Therefore, the latter two criteria have not been included in the HHP Identification Tool. Regulators will need to assess these criteria themselves.

Annex D Screening criteria for POPs:

Persistence AND	Bioaccumulation AND
• DT50-water > 2 months • DT50-soil > 6 months • DT50-sediment > 6 months • Otherwise sufficiently persistent	• BCF/BAF-aquat. species > 5000 • Log Kow > 5 • High bioaccumulation in other species • Monitoring showing bioaccumulation potential

Potential for long-range environmental transport	AND Adverse effects
• Measured residues of concern distant from sources • Monitoring data showing potential for long-range transport • Fate properties indicate potential for long-range transport	• Evidence of adverse effects to human health or environment • Toxicity/ecotoxicity data showing potential for damage to human health or environment

- **Data sources**

Annex A & B
Stockholm Convention web site: http://chm.pops.int/

Annex D
Use the Pesticide Properties Database (PPDB : http://sitem.herts.ac.uk/aeru/ppdb/en/) and the step-by-step guidance given in this report.

B.6 Pesticide active ingredients and formulations listed by the Rotterdam Convention in its Annex III

- **Definition**

Pesticide active ingredients and formulations listed by the **Rotterdam Convention** in its **Annex III** are identified as HHP

- **Reference**

Annex III: Chemicals subject to the prior informed consent procedure
Website:
http://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals/tabid/1132/language/en-US/Default.aspx

- **Identification procedure**

Pesticides listed on Annex III can easily be found on the Rotterdam Convention web site.

B.7 Pesticides listed under the Montreal Protocol

- **Definition and reference**

Pesticides listed under the Montreal Protocol

- **Identification procedure**

Pesticides listed on under the Montreal Protocol can easily be found on its web site. Presently, the only pesticide listed is methyl-bromide

- **Data source**

UNEP Ozone Secretariat web site: http://ozone.unep.org/en/treaties-and-decisions/montreal-protocol-substances-deplete-ozone-layer

B.8 Pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment

- **Definition**

Pesticide active ingredients and formulations that have shown a **high incidence of severe or Irreversible adverse effects** on human health or the environment.

- **Identification procedure**

No international databases/lists exist of pesticides meeting HHP criteria 8. Assessment is at the discretion of national regulatory authorities. Whether or not a pesticide shows a high incidence of severe or irreversible adverse effects depends on **local use circumstances and availability of reliable data.**

- **Possible indicators that can be used by regulators are:**
  - Surveillance indicates high incidence of poisoning or environmental impact
  - Surveillance indicates high exposure risks
  - Regulatory measures taken by countries with comparable pesticide use situations
  - Surveillance from comparable countries indicating high incidence of poisoning or environmental impact

More information can be found in the FAO/WHO Guidelines on developing a reporting system for health and environmental incidents resulting from exposure to pesticides [2009].

- **Data sources**

Usually country/region specific

Annex 21 Details of PBT criteria

Persistence in water - Column V -DT50-water (days)

Proposal: use the decision making flow chart of Figure 23.

WATER

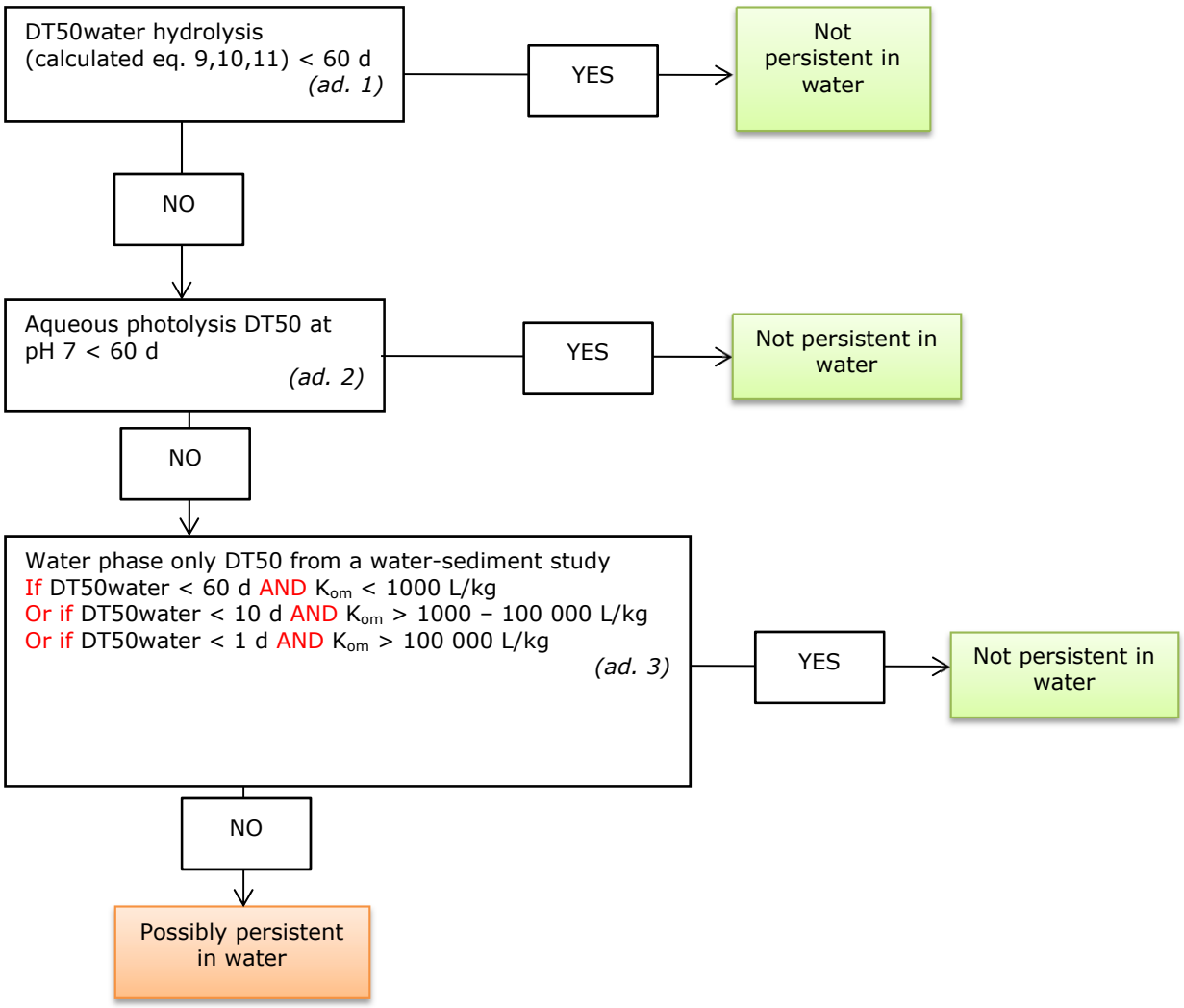


Figure 23 *Decision supporting flowchart to check the persistence of the pesticide in water.*

Step by step guidance persistence in water (note that the checks and steps specified below need to be followed in the order they are given in order to reach the conclusion on persistence in water)

Check 1: DT50water hydrolysis < 60 d?

Step 1: select from the PPDB the aqueous hydrolysis half-life at pH 7 and the aqueous hydrolysis half-life at pH 9 and check if they are measured at temperatures at 20 °C. If both half-lives are measured at 20 °C proceed to Step 3; if not proceed with Step 2. If values of hydrolysis half-lives are not given in de PPDB proceed to Check 2.

*Step 2: C*alculate the half-lives back to half-lives at 20 °C:

Step 2a: Calculate the degradation rate, *k*, from the DegT50 as follows:

$$k = \frac{\ln 2}{DegT50} \qquad \text{Eq. 9}$$

where:

DegT50 =	Degradation half-life (d)
k =	Transformation rate (d^{-1})

Step 2b: Calculate the degradation rate, *k*, at 20 °C (293.15 K):

$$k(T) = k(T_{ref})exp\left[\frac{75000}{8.3144}\left(\frac{1}{T} - \frac{1}{T_{ref}}\right)\right] \qquad \text{Eq. 10}$$

where:

T =	Temperature (K)
T_{ref} =	Reference temperature (K)
k =	Transformation rate (d^{-1})
E =	75000 J mol^{-1} = recommended value for the molar Arrhenius activation energy
R =	8.3144 J mol^{-1} K^{-1} = recommended value for the universal gas constant

Step 2c: Calculate the degrdation half-life (DegT50) at 20 °C:

$$DegT50 = \frac{Ln\,2}{k} \qquad \text{Eq. 11}$$

Step 3: Select the maximum from the two DegT50 values at pH 7 and pH 9 and both at 20 °C

Step 4: Is the maximum value < 60 days?

NO: proceed to Check 2

Yes: chemical is NOT persistent in water – fill in this DegT50 value in the spreadsheet

Check 2: Aqueous photolysis DT50 at pH 7 < 60 d?

Step 1: select from the PPDB the aqueous photolysis half-life at pH 7. If values of hydrolysis half-lives are not given in de PPDB proceed to Check 3.

Step 2: Is the aqueous photolysis half-life at pH 7 < 60 days?

NO: proceed to Check 3

Yes: chemical is NOT persistent in water – fill in this DegT50 value in the spreadsheet

Step 3: Check public literature: Is active ingredient reported to be persistent in water (note water phase only, not water-sediment system)

NO: proceed to Check 3

Yes: chemical is very likely NOT persistent in water – fill in the value of the aqueous photolysis half-life at pH 7 in the spreadsheet

Check 3: is the water phase only half-live from a water-sediment study < 60 d?

Step 1: select from the PPDB the water phase only half-live from a water-sediment study.

Step 2: select from the PPDB the value for the KOC of soil (in L/kg)

Step 3: Calculate the Kom in L/kg using the value of the KOC of soil (in L/kg) using Eq. 12.

Kom = KOC/1.724 Eq. 12

Step 4: DT50water < 60 d AND K_{om} < 1000 L/kg?

NO: proceed to *Step 4b*

Yes: chemical is NOT persistent in water – fill in the value of the DT50water in the spreadsheet

Step 4b: DT50water < 10 d AND K_{om} > 1000 – 100 000 L/kg?

NO: proceed to *Step 4c*

Yes: chemical is NOT persistent in water – fill in the value of the DT50water in the spreadsheet

Step 4c: DT50water < 1 d AND K_{om} > 100 000 L/kg

NO: chemical is very likely persistent in water: fill in the value of the DT50water in the spreadsheet; in case this value is < 60 days, fill in a value of 100 days.

Yes: chemical is NOT persistent in water – fill in the value of the DT50water in the spreadsheet (value should be < 60 days)

Choices available in the PPDB for each of the three POP screening criteria and proposal for property to choose from the PPDB and justification of this choice

Table 6 *Choices available in the PPDB for each of the three POP screening criteria.*

Property for screening criteria POP	Choices in PPDB	
DT50soil	DT50 typical (d)	'Typical values' quoted are those given in the general literature and are often a mean of all studies field and laboratory. This is the value normally used in the regulatory modelling studies and is for aerobic conditions.
	DT50 lab at 20°C (d)	DegT50 values of plant protection products in soil at 20°C obtained from laboratory studies
	DT50 field (d)	DegT50 values of plant protection products in soil obtained from field dissipation studies
DT50water	Aqueous hydrolysis pH 5 (d)	DT50water for the process of hydrolysis obtained from an aqueous hydrolysis study at pH 5
	Aqueous hydrolysis pH 7(d)	DT50water for the process of hydrolysis obtained from an aqueous hydrolysis study at pH 7
	Aqueous hydrolysis pH 9 (d)	DT50water for the process of hydrolysis obtained from an aqueous hydrolysis study at pH 9
	Aqueous photolysis (d)	DT50water for the process of photolysis obtained from an aqueous photolysis study
	Water phase only DT50 (d)	The DT50 of the water phase only obtained from a water-sediment study in the dark (processes of hydrolysis and microbial degradation in the water phase of the water-sediment study only). PDDB
	Water-sediment DT50 (d)	The DT50 of the total water-sediment system obtained from a water-sediment study in the dark (so including processes transformation in water and sediment due to hydrolysis and microbial degradation).
DT50sediment	Water-sediment DT50 (d)	The DT50 of the total water-sediment system obtained from a water-sediment study in the dark (so including processes transformation in water and sediment due to hydrolysis and microbial degradation).
BCF	BCF (l/kg)	Bio concentration factor (values up to 5000 l/kg can be obtained with sufficient certainty)
Log Kow	Log P (-)	Log of the Octanol-water partition coefficient at pH 7, 20°C. (can be established with sufficient certainly until values of 6, above 6 is more difficult).

Note that the BAF (Bio accumulation factor is not given in the PPDB)

Table 7 *Proposal for property to choose from the PPDB and justification of this choice (in case necessary).*

Property for screening criteria PBT	Chosen property from PPDB	Justification
DT50soil	DT50 lab at 20°C (d)	DT50 lab data are the more precise and repeatable of the various options in the PPDB database, and therefore chosen. DT50field values are very likely not determined according the latest EFSA guidance (EFSA, 2010) and therefore not adequate. This EFSA guidance proposes a procedure that ensures that the DegT50 derived from field dissipation studies reflects the degradation rate within in the soil matrix between 1 – 30 cm depth with sufficient accuracy. This procedure aims at diminishing the influence of other loss processes like volatilisation, photochemical degradation runoff etc. which are significant processes in the top millimetres of the soil matrix. Therefore the estimated DegT50 should not be influenced by these loss processes. This can be reached by a proper design of the field study: i.e. by applying irrigation shortly after pesticide application (EFSA advises 10 mm) of by using the proposed method for kinetic evaluation of the field dissipation study for determining the DegT50field. Most field dissipation studies in the dossiers used for the PPDB are performed before the outcome of the EFSA opinion and it is not very likely that the kinetic evaluations are done according the method advised by EFSA (2010). For the same reason the DT50 typical is not suitable as this is often a mean of all studies both field and laboratory, so based upon inaccurate DegT50field values. EFSA Panel on Plant Protection Products; *Guidance for evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil. EFSA Journal 2010;8(12):1936 [67 p]. doi:10.2903/j.efsa.2010.1936*
DT50water (hydrolysis)	Aqueous hydrolysis half-life pH 7 (d) Aqueous hydrolysis half-life pH 9 (d)	ad 1. Figure 23 Select the longest DegT50 in the pH range from 7 to 9.5 from the available data in the PPDB and calculate this back to a temperature of 20°C using Eq. 10. It is recommended to assume an Arrhenius activation energy of 75 kJ/mol = 75000 J/mol (Deneer *et al.*, 2010). Calculating the degradation rate, *k*, from the DegT50 is done as follows: $k = \frac{\ln 2}{DegT50}$ Eq. 9 where: *DegT50* = Degradation half-life (d) *k* = Transformation rate (d^{-1}) $k(T) = k(T_{ref}) exp\left[\frac{E}{R}\left(\frac{1}{T} - \frac{1}{T_{ref}}\right)\right]$ Eq. 10 where: *T* = Temperature (K) T_{ref} = Reference temperature (K) *k* = Transformation rate (d^{-1}) *E* = Molar Arrhenius activation energy ($J\ mol^{-1}$) *R* = Universal gas constant (≈ 8.3144 $J\ mol^{-1}\ K^{-1}$) *Deneer, J.W., W.H.J. Beltman, P.I. Adriaanse. 2010. Transformation reactions in TOXSWA; transformation reactions of plant protection products in surface water. Wageningen, Alterra. Alterra-report 2074. 94 pp.*

Property for screening criteria PBT	Chosen property from PPDB	Justification
DT50water (photolysis)	Aqueous photolysis DT50 at pH 7 (d)	ad 2. Figure 23 DT50water for the process of photolysis obtained from an aqueous photolysis study (often in a laboratory). It should be noted that the DT50 aquatic photolysis is often obtained under specific conditions (e.g. light, dissolved and suspended matter) and these conditions are often not representative for field conditions. Photolysis is a very complex process, whose rate is very much dependent upon the wavelength of the light reaching a molecule in the water column in relation to the absorption spectrum of that molecule (Deneer *et al.*, 2010). In lab studies the conditions are probably more favourable for fast degradation due to photolysis than in the field (in case of NW EU; for Myanmar this might be different). For Myanmar we need a practical approach as the PPD is not in the position to evaluate the data given in the PPDB. We therefore use the DegT50 of aqueous photolysis given in the PPDB. In case this proves to be not strict enough (i.e. active ingredients not classified as PBT, while it is known from literature that they are persistent in water in the field) it is an option to discard box 2 of Figure 23 in a second stage. *Deneer, J.W., W.H.J. Beltman, P.I. Adriaanse. 2010. Transformation reactions in TOXSWA; transformation reactions of plant protection products in surface water. Wageningen, Alterra. Alterra-report 2074. 94 pp.*

Property for screening criteria PBT	Chosen property from PPDB	Justification
DT50water (from water-sediment study; DT50 water phase only)	Water phase only DT50 (d)	ad 3. Figure 23 The DT50 of the water phase only obtained from a water-sediment study in the dark (processes of hydrolysis and microbial degradation in the water phase of the water-sediment study only) – according OECD 308. It is not very clear whether a dissipation half-life (i.e. including the process of diffusion to the water layer) is requested or whether a degradation half-life, DegT50 (excluding the process of diffusion to the water layer and only including degradation processes of hydrolysis and microbial degradation in the sediment) is requested. The latest ECHA guidance (https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f) gives the following guidance. If the DegT50water from OECD 309 < 60 d, other compartments should be taken into account. OECD 309 data is not given in Footprint. The DegT50water from OECD 309 is the lumped sum of biodegradation and hydrolysis. The PPDB suggests that the DegT50 water phase only is obtained from water sediment studies (i.e. OECD 308). DegT50 values from the water phase only are obtained from water-sediment study data using inverse modelling. The estimated DT50water is surrounded by uncertainties (Ter Horst and Koelmans, 2016, Honti *et al.*, 2015). Ter Horst and Koelmans, 2016 mapped the uncertainty of the estimated DegT50water using artificial experimental datasets. They found that at increasing Koc/Kom values the estimated DegT50water is less reliable for increasing values of the DegT50water. The guidance in box 3 of Figure 23 is based on their results. However, this is a rather rough method based on two types of sediment and a dummy chemical of which parameters DegT50water, DegT50sediment and Kom were varied. However, for Myanmar we need a pragmatic approach but do wish to take in to account the uncertainties surrounding the DegT50water derived from water-sediment studies. *Honti, M.; Fenner, K. Deriving Persistence Indicators from Regulatory Water-Sediment Studies – Opportunities and Limitations in OECD 308 Data. Environ. Sci. Technol. 2015, 49, 5879-5886. DOI:10.1021/acs.est.5b00788* *ter Horst, M. M., & Koelmans, A. A. Analyzing the Limitations and the Applicability Domain of Water–Sediment Transformation Tests like OECD 308. Environ. Sci. Technol. 2016, 50(19), 10335-10342.*

Property for screening criteria PBT	Chosen property from PPDB	Justification
DT50sediment	Water-sediment DT50 (DT50 of the total water-sediment system) (d)	It is not very clear whether a dissipation half-life (i.e. including the process of diffusion to the water layer) is requested or whether a degradation half-life, DegT50 (excluding the process of diffusion to the water layer and only including degradation processes of hydrolysis and microbial degradation in the sediment) is requested. We assume that the DegT50sediment (excluding the process of diffusion to the water layer but including degradation processes of hydrolysis and microbial degradation in the sediment) is requested. It is difficult to separately estimate the DegT50 in the sediment compartment from a water-sediment study (e.g. Ter Horst and Koelmans, 2016, Honti *et al.*, 2015). The DegT50 sediment is not found in the PPDB (there is no adequate test to determine the value of this parameter). The DT50 of total water-sediment system is the only information available and this property can in theory be estimated with sufficient certainty. If the DT50 of the total water-sediment system > 180d it is possible that the pesticide is either rather persistent in water or in the sediment. However, it is also possible that in reality the DegT50water of a chemical is smaller than 60 d and that the DegT50sediment of the same chemical is smaller than 180 d, but that the lumped sum of dissipation half-life in the water-sediment system is larger than 180 d. In the latter case using the criterion DT50system > 180 d is actually too strict. However, given the lack of alternatives, for Myanmar we adopt the criterion that if the DT50 of the total water-sediment system of a chemical > 180 d, the chemical is considered persistent in the sediment. *Honti, M.; Fenner, K. Deriving Persistence Indicators from Regulatory Water-Sediment Studies – Opportunities and Limitations in OECD 308 Data. Environ. Sci. Technol. 2015, 49, 5879-5886. DOI:10.1021/acs.est.5b00788* *ter Horst, M. M., & Koelmans, A. A. Analyzing the Limitations and the Applicability Domain of Water–Sediment Transformation Tests like OECD 308. Environ. Sci. Technol. 2016, 50(19), 10335-10342.*

Property for screening criteria PBT	Chosen property from PPDB	Justification
Koc	KOC (L/kg)	ad 3. Figure 23

A value of the sorption coefficient is needed. In this case the Koc of soil (sediment Koc are generally not available in pesticide registration dossiers and thus not given in the PPDB database) is selected.

Kom is needed and can be calculated as follows:

Kom = KOC/1.724 Eq. 12

KOC in the PPDB is very likely the most reliable parameter. Below an explanation is given why we consider Kfoc data from the PPDB to be less reliable.

Problems with the use of $K_{F,oc}$ data

The definition of the K_{oc} is based on a linear sorption isotherm:

$$X = m_{oc}\ K_{oc}\ C \qquad \text{Eq. 13}$$

where
X is mass of pesticide sorbed per mass of dry soil (mg kg^{-1}),
m_{oc} is mass fraction of organic carbon of the soil (kg kg^{-1}),
K_{oc} is the organic-carbon/water distribution coefficient (L kg^{-1}) and C is the mass concentration in the liquid phase (mg L^{-1}).

The definition of the $K_{F,oc}$ is based on the Freundlich isotherm:

$$X = m_{oc}\ K_{F,oc}\ C^{N} \qquad \text{Eq. 14}$$

where $K_{F,oc}$ is the Freundlich coefficient for distribution over organic carbon and water (L^N kg^{-1} mg^{1-N}) and N is the Freundlich exponent (-).

So whereas the unit of K_{oc} depends only on the unit used for the mass of dry soil (kg) and the volume of liquid (L), the unit of $K_{F,oc}$ is also a function of the unit used for the mass of pesticide (mg) and also of N. This has the consequence that the value of $K_{F,oc}$ depends on the unit used for the mass of pesticide. E.g. the $K_{F,oc}$ value obtained by fitting of data with X expressed in mg kg^{-1} and C expressed in mg L^{-1} will differ from the $K_{F,oc}$ value obtained by fitting of the same data with X expressed in µg kg^{-1} and C expressed in µg L^{-1}. Let us consider the following example to illustrate this.

C (mg L^{-1})	X (mg kg^{-1})
0.001	0.0020
0.01	0.0158
0.1	0.1259
1	1
10	7.4943

These numbers are calculated with Eq. 14 using m_{oc} = 0.01, $K_{F,oc}$ = 100 and N =0.9. So if these values would be fitted back to Eq. 14, a $K_{F,oc}$ value of 100 would have been obtained. Let us now consider a researcher that expresses the same data in µg instead of mg.

C (µg L^{-1})	X (µg kg^{-1})
1	2.0
10	15.8
100	125.9
1000	1000.0
10000	7494.3

	Fitting these data to Eq. 14 will give a $K_{F,oc}$ value of 200 instead of 100. This can be easily checked by putting the concentrations of the second table in a spreadsheet and calculating X with Eq. 14 (using $K_{F,oc}$ = 199.526 to get exactly the same result). Sometimes researchers use also mmol instead of mg (1 mmol is usually about 200 mg). So if a $K_{F,oc}$ value is provided, it is necessary to know in which unit the mass of pesticide is expressed. However, this is not done in the PPDB. (pers.comm. Dr. J.J.T.I. Boesten, WUR)

Property for screening criteria PBT	Chosen property from PPDB	Justification
BCF	BCF (L/kg)	Bio concentration factor Values up to 5000 L/kg can be obtained with sufficient certainty. The cut off is 5000 (i.e. establishing that the chemical does not accumulate is fish can be done with sufficient certainty).
Log Kow	Log P (-)	Log of the Octanol-water partition coefficient at pH 7, 20°C. Values up to 6 can be established with sufficient certainty, above 6 is more difficult. The cut off is 5 (i.e. establishing that the chemical does not accumulate is fish can be done with sufficient certainty).

Wageningen Environmental Research
P.O. Box 47
6700 AA Wageningen
The Netherlands
T +31 (0)317 48 07 00
www.wur.nl/environmental-research

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Wageningen Environmental Research
P.O. Box 47
6700 AB Wageningen
The Netherlands
T +31 (0) 317 48 07 00
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