Pesticide Management in Rwanda

Analysis of the current pest control products administration and management system

Louise Wipfler and Mechteld ter Horst

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PROJECT

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This report describes the assessment of the current pest control products administration and management system in Rwanda. The assessment includes the aspects pesticide registration and evaluation, inspection and control and waste management. Roles, responsibilities and capacities of the public institutions involved are evaluated and current Rwandan legislations, regulations and procedures on pest control products are reviewed based on a series of consults and/or interviews with public and private institutions, actors and stakeholders in Rwanda. Finally, a set of observations and recommendations for improvement is provided based on the assessment.

Keywords: pesticide management, pest control, risk assessment, registration, integrated pest management, Rwanda

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Abbreviations

ADECOR	Rwanda consumers rights and protection organisation
AMDO	Private Sector Pesticide Importers' Obsolete Pesticides Working Group
AGRIFOP	Agribusiness Focused Partnership Organization
EAC	East African Community
EKN	Embassy of the Kingdom of the Netherlands
FAO	UN Food and Agriculture Organization
HGT	Holland Greentech
LD50	The dose required to kill half the members of a tested population after a specified test duration
NAEB	National Agricultural Export Development Board
NOEC	No Observed Effect Concentration - the highest concentration in a test with a mean response not differing significantly from the mean response of the control if compared statistically.
RAB	Rwanda Agriculture Board
RAIDA	Rwanda Agriculture Inputs Dealers Association
RALIS	Rwanda Agriculture Livestock Inspection and Certification Services
REMA	Rwanda Environment Management Authority
RICA	Rwanda Inspectorate, Competition and Consumer Protection Authority
RPSF	Rwanda Private Sector Federation Rwanda
RSB	Rwanda Standards Board
USAID	U.S. Agency for International Development
UTZ	Certification program for coffee and cocoa (https://utz.org)
WHO	World Health Organization

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Preface

This report summarizes our findings on the pesticide management system in Rwanda. It is the result of many discussions on pesticide management we had with Rwandan stakeholders. We would like to thank all of them for their time and their willingness to share their ideas and experiences with us.

In addition, we would like to thank Stefan Engels (SNV HortInvest project leader) and Edwin van der Maden (CDI-WUR HortInvest WUR coordinator) for their support and initiative for this review. We also thank Innocent Matabishi of the Embassy of the Kingdom of the Netherlands for his support and effort to organise all the meetings we had in Kigali.

Louise Wipfler
Mechteld ter Horst

Summary

Background and remit
Following a workshop conducted by Wageningen Environmental Research in Kigali on Sustainable Pesticide Management (September, 2017), from which several priority areas came forward, and subsequently a meeting with EKN (Embassy of the Kingdom of the Netherlands) in Kigali (23 January, 2018), it was decided to assess the pest control products administration and management system in Rwanda as part of the inception phase of HortInvest.

The assessment included the following aspects of the current pest control products administration and management system: 1) registration & evaluation system, 2) control & inspection services, and 3) waste management system. For all three aspects the roles, responsibilities and capacities of the public institutions involved were assessed and recommendations for improvement were provided. The assessment consisted of a review of current Rwandan legislations, regulations and procedures on pest control products and a series of consults and/or interviews with public and private institutions, actors and stakeholders in Rwanda. To this end a visit was being paid to Kigali between 23-27 April 2018. In this week also the HortInvest team as well as EKN was consulted.

Recent developments
Rwanda has adopted the new law on governing of agrochemicals in 2012 and only very recently the corresponding regulations were adopted. Currently, Rwanda is in the process of reestablishment of the pesticide registration system as well as the system on inspection and control of pesticides. Many actors are still in the process of finding/defining their role in this system and most of them indicated that capacity building on all aspects of pesticide management is very much welcomed.

In the meantime the East-African Community (EAC) has developed harmonized guidelines on how to conduct efficacy and residue trials, with the aim to facilitate mutual acceptance of data generated in the region. Data requirements for conventional pesticides were also harmonized, to help initiate joint regional reviews of pesticides. These guidelines will be implemented in the national systems, including that of Rwanda. To domesticate these guidelines Rwanda requested support from the FAO.

Review results
The analysis of the current system can be summarised in the following set of observations and recommendations:

Registration:
- The current pesticide registration system is relatively new. It is recommended to further align the system with international best practices concerning the roles and responsibilities of the different actors in the decision making process.
- The administrative registration system should be reviewed, with the aim to optimize registration procedures which are perceived by stakeholders to be time-consuming and costly.
- Assessment of the risks associated with pesticide use of registered products is currently not part of the registration procedures. It is recommended to implement this as part of the pesticide registration procedures.
- Rwanda would benefit from support and capacity building to implement the EAC guidelines and, in time, to ensure they can fully participate in regional work sharing for pesticide testing and registration.
- It is recommended to review and adapt the regulatory system for biological pest control products as well as to implement specific registration procedures for biological products.

Misuse and overuse:

- Due to ignorance and illiteracy of pesticide users, incorrect pesticide products are used, or they are not used according to label instructions.
- Illegal and counterfeit products at agro-shops are reported to be widely available.
- Easy accessible and updated information for stakeholders, such as agro-dealers, applicants and farmers, on registered products and corresponding labels and dose recommendations, is lacking.
- There is a concern that misuse may result in residue exceedances on agricultural commodities on the local market as well as on export products. Improvement of this situation can be achieved by adopting and enforcing maximum residue limits and associated Good Agricultural Practices.
- Awareness should be raised of farmers, consumers and other stakeholders on the risks associated with pesticide use and possibilities to use low risk alternatives.

Inspection and control:

- The inspection and control system has been developed recently and procedures and work instructions still have to be established. A special Inspection and Control Authority covering all commodities will be established soon (RICA).
- Inspectors would benefit from capacity building on professionalization and borrowing from international practices.
- A number of initiatives by the private sector have been reported, which is in line with the strategy of the government to improve the public-private sector dialogue. E.g. the agro-dealers have organised themselves and aim to professionalize. It is recommended to stimulate and formalize collaboration with the private sector.
- Collection of data on pesticide trade and use along the value chain, and further development of the database on pesticide products registered in Rwanda, is recommended to support the inspection and control services.

Monitoring:

- Health surveillance programmes for occupationally exposed persons are currently not in place.
- Monitoring programs on public health effects of pesticides are not in place, e.g. human health incident reporting and chronic health studies.
- No systematic environmental monitoring systems to measure pesticide concentrations in soil, groundwater and surface water in agricultural areas in Rwanda are currently in place.
- It is recommended to develop monitoring systems mentioned above in order to assess the extent of any possible effects on human and animal health and the environment.

Waste management:

- Empty pesticide containers should be decontaminated (triple rinsing or pressure rinsing) and punctured directly following the use of their contents and inappropriate use of the empty containers should be prevented. It is recommended to set up programs to manage empty pesticide containers. This could include awareness creation, training and setting up a system for users to return their empty containers as part of a pesticide container management scheme.
- Best practices advocated by the government are to collect empty containers, puncture them or destroy them and bring them to a proper disposal area. For expired and obsolete pesticides, they should be collected and incinerated properly. However, in Rwanda there is no collection system of empty containers nor of obsolete pesticides.
- Improved collaboration between the different Rwanda ministries is recommended on waste management, including the ministries of human health, trade and agriculture as well as the Rwanda Environmental Management Authority (REMA) and the private sector.

1 Introduction

1.1 Background

In order to reduce poverty Rwanda has expressed the ambition to increase agricultural production. Currently, the country is in the process of replacing subsistence farming by a fully monetized and commercial agricultural sector (Vision 2020, Economic Development and Poverty Reduction Strategy 2013-2018). The use of high yielding varieties and intensive input use are expected to contribute to substantial growth of the sector.

However, if pesticide use is not managed properly this may have adverse impacts on human health and the environment. Many intensive agricultural practices depend on the use of broad spectrum hazardous pesticides for pest, disease and weed control. Consequences could be adverse effects on the health of the farmers, environmental deterioration and adverse impacts on consumers. Misuse and overuse of pesticides may further lead to reduction of agricultural production (e.g. due to increased resistance against pesticides or reduction of soil fertility) and poor sustainability of agricultural production in general.

Pesticide risk reduction through the registration of less hazardous pesticides and the promotion of non-chemical control measures will therefore be crucial. Also, facilitating the access of innovative products associated with lower risk as well as biological pesticides to the Rwanda market, is needed to enable the transition of the agricultural sector towards sustainable agricultural production and judicious pest control.

Acknowledging the need for sustainable pesticide management, Rwanda collaborates with Kenya, Burundi, Uganda, South Sudan and Tanzania within the East African Community (EAC) to work towards a regionally harmonized system for pesticide registration and pesticide evaluation. Rwanda has a limited market for pest control products with consequently a low incentive for the pesticide industry to register innovative and low risk products. Regionally harmonized registration of pesticides will facilitate the introduction of newer pesticide products, as these products may be registered in Rwanda with relatively less effort by the pesticide industry. Also, the administrative burden can be shared between countries to save resources.

In September 2016 the Dutch ministry of Economic Affairs commissioned a 3-year project on sustainable pesticide management in Kenya, which is coordinated by Wageningen University & Research, i.e. *the Pesticide Management Initiative East African Community-Kenya*. In collaboration with main Kenyan public and private sector stakeholders activities are executed to support the sustainable use of pesticides. Integrated Pest Management (IPM) principles are adopted, based on the vision that sustainable agricultural growth can only be achieved with healthy crops in a healthy environment. It is envisioned to role out similar projects in other East-African countries while in the meantime aligning with developments at EAC level for harmonisation of registration procedures. Project results, procedures and tools developed in Kenya could be applied, with some adjustments, in Rwanda.

1.2 Recent developments

Rwanda has adopted the new law on governing of agrochemicals in 2012 and only very recently the corresponding regulations were adopted. Currenty, Rwanda is in the process of restablishing the pesticide registration system as well as the system on inspection and control of pesticides. Many actors are still in the process of finding/defining their role in this system.

In the meantime the EAC has developed harmonized guidelines on how to conduct efficacy and residue trials, with the aim to facilitate mutual acceptance of data generated in the region. Data requirements for conventional pesticide were also harmonized, to support possible joint regional reviews of pesticides. These guidelines will have to be implemented in the national systems, including that of Rwanda. It will take considerable effort for Rwanda to domesticate these guidelines. The Rwanda Agriculture Livestock Inspection and Certification Services (RALIS) has asked the FAO to support the implementation.

In early 2018, the 'Investing in Horticultural Development in Rwanda' project (HortInvest,) has started. HortInvest is a four year horticultural value chain project in North-Western Rwanda, funded by the Government of the Netherlands through the Embassy of the Kingdom of The Netherlands in Rwanda. The project contributes to the realization of the mission of the Rwandan National Horticulture Policy in terms of fast economic growth and rapid reduction in poverty and malnutrition in the country, and to the objectives of the Rwanda-Netherlands bilateral project aimed at enhanced food security and private sector development. To this aim and as part of the inception phase of the project, Wageningen Environmental Research conducted a review/analysis of the current pesticide administration and management system, including registration of pesticides, inspection and control and waste management. The outcomes of the analysis are summarized in this report and are intended to be used as a basis for a roadmap towards sustainable pesticide management in Rwanda. The review builts further on an earlier workshop held in September 2017 on Sustainable Pesticide Management initiated and commissioned by the Embassy of the Kingdom of The Netherlands in Rwanda.

1.3 Strengthening of the pesticide management system

Strengthening of the pesticide management system is preferably done through working along three pillars, i.e (i) the pesticide registration system, (ii) post-registration of pesticides (the inspection and control system and monitoring activities), (iii) extension services, incl. promotion of Integrated Pest Management (IPM), diagnostics, advice on treatment, judicious pesticide use and awareness raising.

Strengthening the system along these three aspects will safeguard robustness and sustainability of implemented changes. The registration procedures for pesticides are the gateway for pest control products to enter a country; the gate should be closed and only to be opened for efficacious products that pose an acceptable risk to humans and the environment. Once inside the country, the products should be used, stored and disposed of properly. Guidelines and rules for pesticide handling that need to be followed should be in place. Compliance is achieved by enforcement and monitoring but also by informing, training and awareness raising. A lower dependency on conventional products can be achieved by promotion of IPM and the use of products associated with low risks to humans and the environment (Figure 1).

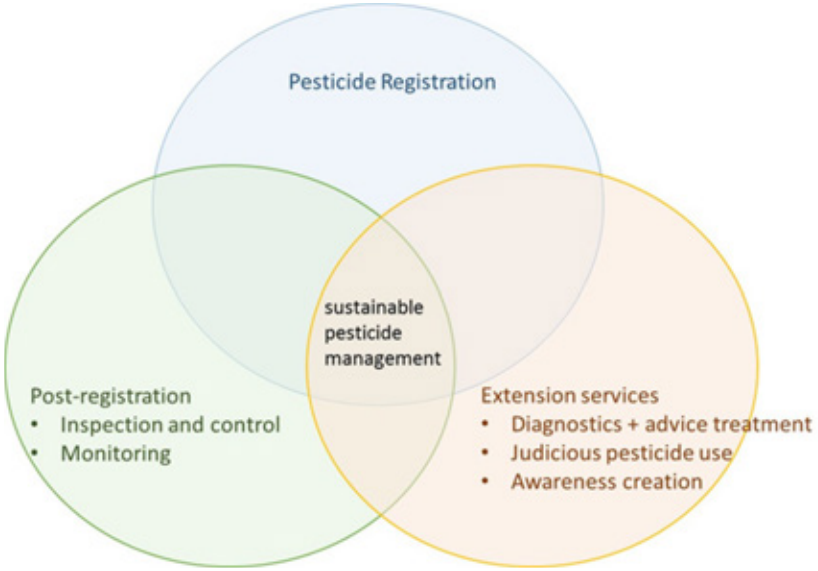

Figure 1 *Interconnection between the three pillars of sustainable pesticide management. Robustness and sustainability of the system is best achieved when working along these three pillars.*

1.4 Report set up

The analysis presented in this report focusses on two of the three aspects of pesticide management: the registration system and the post-registration system. The report contains additionally some remarks on extension services and IPM (training). In Chapter 2 the approach followed and the limitations are described and in Chapter 3 the results of the review of the registration system is described. Chapter 4 provides the results of the review of the post-registration and in Chapter 5 a set of observations and recommendations for improvement is given.

2 Methodology

2.1 Approach

The review of the pesticide administration system was conducted (i) by reviewing current Rwandan legislations, regulations and procedures on pest control products as far as they were available to the authors and (ii) by visiting, consulting and/or interviewing public and private institutions, actors and stakeholders in Rwanda during a visit of the authors to Rwanda which took place in the period 22-27 April 2018.

Representatives of the following organisations were visited and interviewed:
- Ministry of Agriculture and animal resources in Rwanda
- Rwanda Agriculture Livestock Inspection and Certification Services (RALIS)
- Rwanda Environment Management Authority (REMA)
- Rwanda Standards Board (RSB)
- Rwanda Agriculture Board (RAB)
- Rwanda Private Sector Federation Rwanda (RPSF)
- National Agricultural Export Development Board (NAEB)
- Rwanda Agriculture Inputs Dealers Association (RAIDA)
- Agrotech Rwanda (agroshop)
- Balton Rwanda
- Holland Greentech (HGT)
- Rwanda consumers rights and protection organisation (ADECOR)
- Private Sector Pesticide Importers' Obsolete Pesticides Working Group (AMDO)
- Agrifop Rwanda
- UN Food and Agriculture Organization Rwanda (FAO Rwanda)
- U.S. Agency for International Development Rwanda (USAID Rwanda)

In addition SNV Rwanda and the Embassy of the Kingdom of The Netherlands in Rwanda were visited and updated on the visit programme and intermediate findings.

The detailed programme is given in Annex 1.

2.2 Limitations

This review on the pest control product system is based on information gathered within a small timeframe, i.e. the review of the regulation and other background documents was done between February and May 2018 and the discussions and interviews were held in the week of 22-27 April 2018. The review does not aim to be comprehensive. It is limited to those aspects that were considered relevant and for which information was available. If relevant information was lacking, this is indicated by the authors.

The uptake of IPM contributes to sustainable agricultural production in Rwanda for which a broad range of crop protection options and products is needed, in particularly biological ones. Making biological crop protection products available on the Rwanda market and defining specific regulations for biological control products are essential. In absence of a current good and well-defined regulatory system for biological products, the report will however focus on the regulatory system for chemical products. A good management system for biological products is however considered equally important to the authors.

3 Registration and evaluation of pest control products

3.1 Regulatory framework for the registration of agrochemicals in Rwanda

The Rwandan law governing agrochemicals was enacted in August 2012. It governs the manufacture, importation, distribution, use, storage, sale and disposal and burial of agrochemicals, for the protection of human and animal health and the environment, to avoid injury and contamination which may result from their use. This law is the core part of the regulatory framework for the registration of agrochemicals in Rwanda.

The regulatory framework for the registration of agrochemicals encompasses at least the following laws and regulations:

- Law on governing of agrochemicals: N°30/2012 of 01/08/2012.
- Ministerial Order determining regulations governing agrochemicals: N° 002/11.30 of 14/07/2016.
- Organic Law determining the modalities of protection, conservation and promotion of environment in Rwanda N°04/2005 of 08/04/2005.
- Law to establish the Rwanda Agriculture Board (RAB) and determining its responsibilities, organization and functioning N°38/2010 of 25/11/2010.
- Law to determining the mission, organization and functioning of the Rwanda Standards Board to undertake all activities pertaining to the development of Standards, Conformity Assessment and Metrology services in the country N° 50/2013 of 28/06/2013.
- Ministerial order to appoint a registrar of agrochemicals and determining her responsibilities N°003/11.30 of 28/10/2016.
- Ministerial Order determining confidential data that are not recorded and non-confidential data to be recorded in the register of agrochemicals N° 003/11.30 of 15/2/2013.
- Prime Minister's Order determining the members of the Advisory Council on the use of agrochemicals and their responsibilities N° 005/11.30 of 15/02/2013 (in official Gazette nº12 of 25 March 2013).
- Ministerial Order determining fees for registration of agrochemicals N°001/11.30 of 23/11/2011 (in official Gazette nº 12 of 25 March 2013).

Furthermore, Rwanda rectified both the Stockholm convention on persistent organic pollutants (POP) and the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

3.2 Overview main actors, roles, mandate, responsibilities and capacities

3.2.1 Introduction

Implementation of the regulatory framework for pesticide is done by the following bodies: RALIS, RAB, RSB, REMA and the agrochemical Advisory Council.

The general registration process consists of three main steps that must be followed to register a product. These steps, which are depicted in Figure 2, are (i) administration, (ii) dossier evaluation, including efficacy testing, human health evaluation, environmental evaluation and (iii) decision making. In the analyses below these steps will be discussed in consecutive order.

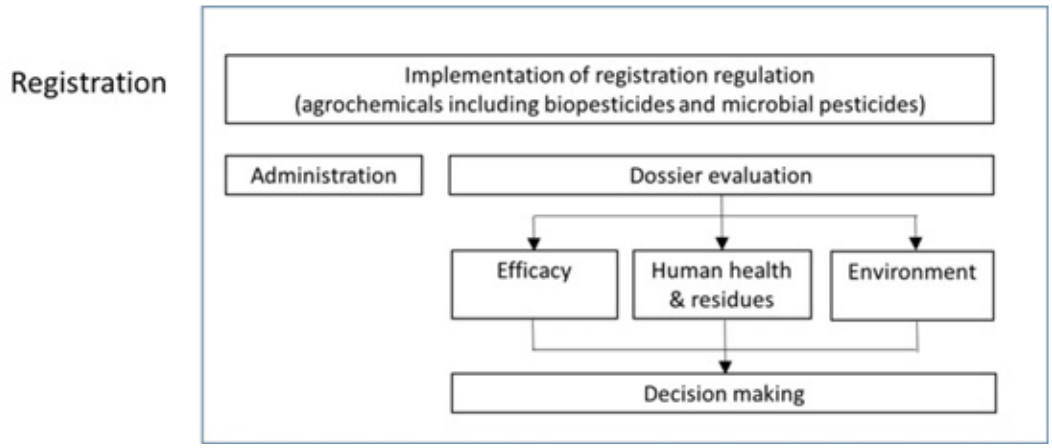

Figure 2 *Basic steps governing the pesticide registration process.*

3.2.2 Administration

The '*Administration*' step in Figure 2 is executed by RALIS and more specifically by the *Registrar of agrochemicals*. Currently, the role of registrar is fulfilled by Eng. Marie Goretti Mujawamariya. The mandate of the *Registrar* considering pesticide registration is to:

- prepare and keep and disseminate the agrochemicals register,
- establish the system of registration of agrochemicals, their quality control and to analyse their residues in accordance with instructions and advice of the Advisory Council on the use of agrochemicals,
- upon authorization by the Advisory Council, register, refuse to register, defer decision, issue and renewal of registration certificates, communicate decisions of the Advisory Council to applicants (source N°30/2012 of 01/08/2012),
- act as the Secretary to the Advisory Council on the use of agrochemicals and to its Committee responsible for approval of agrochemicals (source N°003/11.30 of 28/10/2016)[1].

A more detailed description of the mandate of the registrar is provided in Annex 2.

As Secretary of the Advisory Council, the registrar acts as the manager of the pesticide registration dossier, i.e. she collects all files comprising the dossier and checks whether the dossier complies with the data requirements (i.e. completeness check).

[1] This is the official line as written down in the Law. The establishment of the committee of the Advisory Council has to be verified.

Most of the files (e.g. test reports, summaries of test report, endpoints etc.) are provided by the applicant of the dossier. The file of the efficacy testing is usually prepared by RAB. RAB performs also the efficacy testing and delivers a study report upon commission of the registrar. The costs associated with the efficacy testing are covered by the applicant. Some of the stakeholders reported that efficacy tests are only required in case the pesticide product contains a new active ingredient. An active ingredient is considered as new when it has not yet been specified on the list accompanying the Ministerial Order determining regulations governing agrochemicals: N° 002/11.30 of 14/07/2016[2]. The exact procedure that is followed needs to be verified by the responsible bodies. Also, is not clear to the authors whether bridging is applied for efficacy tests with 'old' molecules. Bridging is a procedure that can be followed for cases were approval of different formulations of the same plant protection ingredient is required. Bridging entails that the direct efficacy and crop safety of the proposed new formulation is compared with an existing formulation of the product for which direct efficacy and safety has been demonstrated (EPPO, 2012).

Upon commission of the registrar, quality control of the pesticide product as part of dossier preparation is managed by RSB. At the time of the review RSB did not have the resources and capacity to perform the quality testing in their laboratory. Until then, testing was done in an accredited laboratory using the standards (i.e. reference chemicals) provided by RSB (usually in Kenya or South Africa). RSB also takes care that the study report reaches the registrant when delivered.

The registrant as Secretary of the Advisory Council calls for a meeting of the Advisory Council to discuss and evaluate a pesticide registration dossier. If a dossier is not complete because the applicant did not provide all requested data, it is the Advisory Council that confirms the incompleteness of the dossiers. Upon request of the Advisory Council the registrar informs the applicant of the incompleteness of the dossier and consequently asks for completing it.

The registrar has additional tasks, i.e. inspection and control, issuing licenses to persons for the importation, manufacture, distribution, sale or disposal of agrochemicals and conducting public awareness campaigns on agrochemicals.

3.2.3 Dossier evaluation

Dossier evaluation is executed by the Advisory council. The council comprises of the registrar in the role of Secretary of the Advisory Council, representatives of the private sector and experts of different Rwandese knowledge institutes. The term of office of the members of the Advisory Council is five (5) years and this is renewable only once (Ministerial order N° 005/11.30 of 15/02/2013).

The current chairman of the Advisory Council is Mr. Evariste Safari. Mr Safari is chairman of the Rwanda Agriculture Inputs Dealers Association (RAIDA) and agricultural manager of Balton Rwanda (importer of agricultural supplies, incl. agrochemicals). Eng. Marie Goretti Mujawamariya is the registrant and secretary of the Council. The private sector is furthermore represented by Ms. Christine Murebwayire (horticultural specialist and chairperson of the Chamber of Agriculture & Livestock). Experts from RAB, RSB and REMA complement the Council.

Evaluation of efficacy
The two members of the Council representing RAB particularly focus on the evaluation on efficacy. They ask for advice from RAB colleagues if needed. The RAB experts also examine the pesticide label (application information) and judge whether the information provided is in line with Rwandese agricultural practises and circumstances. Note that efficacy testing as part of the dossier preparation process is usually also done by RAB.

[2] It was mentioned by stakeholders (e.g. ADECOR) this list is not regularly published or updated, but also not made easy to understand and accessible for farmers.

Evaluation of human health and residues
Hazards for human health are assessed by reviewing the WHO Hazard classification of the pesticide. It is at the time of writing the report not fully clear how hazards/risks for human health are assessed and which members of the Council have expertise in this field.

Although, additional data to characterize the inherent hazard is required, the current data requirements (see Annex 3) are not very specific. For example, it is not clear whether complete toxicity studies, a summary of the study or only the endpoint is required in the dossier. Another example is the data requirements on residues. It is not specified how residues decay curves and proposed maximum residue levels (MRL) for each crops, food, feed or animal should be established. For the authors it is currently unclear whether supervised residue trials are always requested to establish residue decay curves and MRLs or whether a Codex MRL can be used as alternative.

Note that the proposed data requirements as part of the EAC harmonisation on pesticide management guidelines are planned to be implemented in Rwanda. These requirements are specified with a high level of detail.

Evaluation of environmental aspects
According to some of the members of the Advisory Council interviewed, REMA has expertise for the evaluation of environmental aspects. It is at the time of writing the report not clear how hazards/risks for the environment are assessed.

Similar to the human health and residue data, data on environmental aspects is not into detail specified in the data requirements. For instance, there is a request for information on acute toxicity of fish, however it is not specified which endpoint is needed (LD50, NOEC) and/or if a full study report or a summary of the report is required.

3.2.4 Decision making

Next to dossier evaluation, the Advisory Council decides whether the registration is granted for a particular pesticide product. Given the information provided by stakeholders the decision is based on: i) completeness of the dossier, ii) efficacy of the product, iii) quality of the product, iv) WHO hazard classification and v) inspection of the pesticide label.
The characterization of hazards and risks for human health as well as for consumers (residues) and the environment is not clear to the authors and is not documented (WHO hazard classification aside). Also it appears that hazard-based cut-off criteria and criteria to determine whether a risk is acceptable or not are not available or not applied.

Article 7 of the Ministerial Order determining fees for registration of agrochemicals N°001/11.30 of 23/11/2011 (in official Gazette nº 12 of 25 March 2013) states the following considering the Advisory Council's decisions:

The decisions of the Advisory Council shall be taken upon the absolute majority of the members present in a meeting. In case of a tie, the Chairperson's vote shall be decisive.

In the same Ministerial Order it is stipulated that the registrar of agrochemicals does not vote during decision making. He/she can only provide his or her opinions.

The decision taken by the Advisory Council is implemented further by the registrar. He/she informs the applicant of the decision of the Advisory Council, i.e. register, refuse to register or defer decision. Upon deciding to register the registrar is also responsible for issuing and renewing registration certificates.

3.3 Bio-pesticides

The uptake of IPM contributes to sustainable agricultural production in Rwanda for which a broad range of crop protection options and products is needed, in particularly biological ones. Currently, in Rwanda there is no specific regulation for biological control products nor specific procedures. The use of biological control agents (e.g. predators) requires a particular regulation, which in Rwanda could be regulated under the environmental law, regulating introduction of animal and plant species in the country.

4 Post-registration

Post-registration can be sub-divided into a number of separate activities, i.e. Inspection and control, Monitoring, Establishment of a reference laboratory, Waste management, Agricultural extension services and Public awareness raising (Figure 3). These Inspection and control, Monitoring, Establishment of a reference laboratory and Waste management will be discussed in this Chapter. Public awareness raising and Agricultural extension services are not part of this review. Aspects of both activities will touched upon in the discussions though.

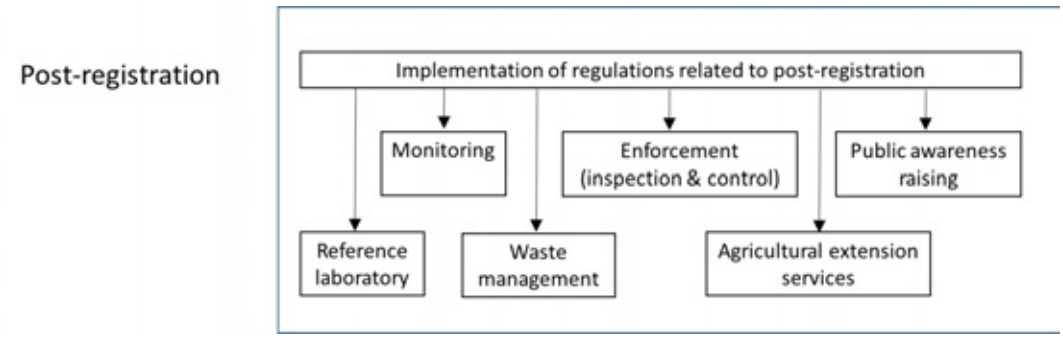

Figure 3 *Main activities in the pesticide post-registration process.*

4.1 Inspection and control

Compliance and enforcement of a pesticide regulatory program is key for good pesticide management to ensure that the benefits from the use of pesticides are derived without adverse effects on humans, animal health and the environment (FAO/WHO, 2008; OECD, 2012). Regulated parties must comply with established requirements to minimise the risks to humans and the environment.

Inspections may include e.g. (not a complete list):

- Inspection of product integrity, ensuring that the product complies with a certain quality at registration and after registration.
- Inspection of proper staff training and certificates of shopkeepers and importers.
- Checks on pesticide storage at premises of the importer, dealers, shops and the farmers. Pesticides should e.g. be inaccessible to the public and pesticides should be stored according to their hazard categories (flammable, corrosive) in order to minimize possible hazards.
- Checks on appropriate product labelling and use instructions.

4.1.1 Law and regulation

In Rwanda regulators conduct compliance and enforcement activities to ensure regulated parties to comply with the regulatory requirements. The Law N 30/2012 on the governing of agrochemicals governs the manufacturing, importing, distribution, use, storage, sale and disposal and burial of agrochemicals for the protection of human and animal health and the environment, to avoid injury and contamination which may result from their use.

Chapter 3 of the Law deals with the powers and responsibility of the inspectors. '*Inspection of agrochemicals shall be carried out by Inspectors appointed by a Ministerial Order which also determines their responsibilities and powers'* (art. 7). *Every customs officer shall have the duty to*

assist in the enforcement of this Law and regulations thereunder, and to prevent the importation into Rwanda of any agrochemical where such importation is contrary to the provisions of this Law.' (art.8) Chapter 7 deals with post-registration control and supervision. '*Under the guidance of the registrar of agrochemicals, inspectors shall control and supervise all that has to do with agrochemicals in order to make sure :*

1. *the conditions for the use of agrochemicals are complied with;*
2. *the agrochemical storage and exhibition conditions are complied with;*
3. *negative impact and other types of effects of agrochemicals are communicated to the Advisory Council so as to improve procedures of registering or refusing agrochemicals.*

Inspection may be carried out upon request by the customer or on the inspector's initiative should there be any conditions that are not complied with. (art 22).

The mandate of the inspector is to take one of the following decisions (after analysis of a sample) (Art. 28):

1. *if the analysis reveals that the samples seized comply with the legal requirements, he/she shall cancel seizure decision within fourteen (14) days;*
2. *if the analysis reveals that the agrochemicals seized do not comply with the legal requirement, the decision for seizure shall remain valid for a period not exceeding six(6) months;*
3. *if the analysis reveals that the agrochemicals seized irreversibly do not comply with the legal requirements, the inspector of agrochemicals shall take the decision of disposing them in accordance with the relevant regulations;*
4. *If agrochemicals seized prove to be harmful to human or animal health, the registrar of agrochemicals shall request the Advisory Council to meet for immediate action.*

Expenses incurred on examining or disposing of agrochemicals seized shall be borne by the owner.'

The Ministerial order N 002/11.30 determines regulations governing agrochemicals, requirements for obtaining business license and fees for registration of agrochemicals. Registration is regulated for agrochemicals, premises, agrochemical dealers, packages and labels, transportation of chemicals, advertising, storage and use of agrochemicals as well as testing and disposal.

The registrar has the power to:

- suspension or cancelation of certification of registered premises (manufacturing, distribution, re-packaging, storage),
- suspension or cancelation of the agro-dealers licence.

The Advisory Council has the power to:

- issue and enforce an instruction stopping or suspending sale of any deficient agrochemical, licences and certifications.

Ministerial order N 001/11.30 (appointing inspectors of agrochemicals and determining their powers and responsibilities) lists the inspectors that are appointed. The following persons are appointed inspectors of agrochemicals in Rwanda: 1° Ms. INGABIRE Jeanne Priscille; 2° Mr. HAKIZAMUNGU Léon; 3° Mr. MUDAHERANWA Joseph; 4° Ms. BERABABYEYI Claudine; 5° Ms. MUJAWAMALIYA Marie Goretti.

Inspectors of agrochemicals have the following administrative powers and responsibilities (Art.2):

1. *to enter, without a warrant, any premises or land other than premises used as an inhabited house, aircraft, vessel or vehicle, at or in which any agrochemical is or may be suspected to be manufactured, stored, transported, sold, distributed or used;*
2. *to require, examine and photocopy licenses, registers of agrochemicals, certificates and seek any other information and documents relating to the application of legal provisions governing agrochemicals;*
3. *to inspect any agrochemical, label or anything related to agrochemicals and take and keep their samples, and submit them for testing and analysis; to carry out periodic inspections of all establishments which manufacture, import, export, store, sell, distribute or use agrochemicals;*

4. *to carry out periodic inspections of all establishments which manufacture, import, export, store, sell, distribute or use agrochemicals;*
5. *to visit and inspect farmers' fields and agricultural premises to ensure that only registered agrochemicals are used appropriately;*
6. *to seize any equipment, product or agrochemical, document, or any other thing which he/she believes has been used in, or which appears as an evidence of non-compliance with legal provisions governing agrochemicals;*
7. *to consult experts of a Committee formed by the Advisory Council on the use of agrochemicals in order to conduct any necessary investigations without prejudice to the powers of officials of the criminal investigation.*

4.1.2 Main Rwandan actors and roles

The main actors for inspection and control is the Rwanda Agricultural and livestock Inspection and Certification Services (RALIS), and particularly the registrar. Inspectors may be part of different institutes, RALIS has the mandate (by Law) to guide the inspectors. Head of the Inspectors is Ms. MUJAWAMALIYA Marie Goretti from RALIS. In total 5 inspectors are currently appointed of which three from RALIS and two from RAB. All inspectors have the same mandate, but they bring in different expertise. RSB has also 30 inspectors. Apart from these inspectors the custom officers of Rwanda aid in the detection and prevention of the importation of illegal imports. The mandate of the RSB inspectors is unknown to the authors.

After seizure of a product, the product is send to RSB for chemical analysis. RSB has no quality assessment lab. However, it does develop the standards (i.e. the reference chemicals) for registered pesticides. Samples are send by RSB to external non-Rwanda labs that are requested to perform the analysis using the reference chemicals (stardards) supplied by the RSB. It is unclear whether RSB is also developing the test protocols (whether or not in cooperation with the external lab).

Also samples of commodities on the market can be taken for residue checks. The samples are send to RSB for analyses.

The inspectors have the mandate to inspect premises and to seize products. The inspectors may call for a meeting of the Advisory Council for consultation as well as decision making on stopping or suspending sale of any deficient agrochemical, licences and certifications. This is the official line in the documents. Whether this line has been implemented and established in the daily practice of the inspectors has not been verified.

Recently the inspection has linked up with police to fight counterfeit products. A special unit of the police is trained and joint inspections with the national police have taken place and several seizures were done. The mandate for inspection and enforcement lays however at the (by ministerial order appointed) inspectors and the Advisory Council. The corresponding ministerial order is relatively young and the implementation of the inspection team has just started. E.g. by September 2017 the ministry announced to enforce regulation of agribusiness (http://www.newtimes.co.rw/section/read/220355). It was reported by the employee of AgriTech that he recently had to reapply for a permit and that inspectors had come to check physically on his remises.

The aim is to merge inspection services of all commodities in Rwanda into one institute: Rwanda Inspectorate, Competition and Consumer Protection Authority, abbreviated as "RICA" (LAW Nº 31/2017 ESTABLISHING RWANDA INSPECTORATE, COMPETITION AND CONSUMER PROTECTION AUTHORITY AND DETERMINING ITS MISSION, ORGANISATION AND FUNCTIONING). RALIS including inspectors from different institutes that work on agrochemicals will become part of the agrochemical department of RICA.

4.1.3 Anecdotal observations

The following anecdotal experiences were reported by the interviewees:

- several stakeholders reported that the number of inspectors is in their view too low to cover all inspections needed.
- the two importers that were interviewed reported control by customs. Inspection was done on the administration as well as on the products;
- the two farmers that were interviewed reported that they were not inspected (storage, correct use);
- several stakeholders reported that agro dealers sell counterfeit and unregistered products. Also shopkeepers would dilute the products. In addition, the sale of both pesticides and food items in the same shop was reported. Shop owners are reported to be not qualified. It was reported that shops in Kigali better comply with the requirements then outside Kigali. Also the agro dealers appear to lack knowledge to advise on which product to use to solve a pest problem;
- The shopkeeper in Kigali that was visited had been inspected physically;
- Inspection and control at the border appears to be unable to stop illegally imported products;
- Also misuse by farmers was mentioned.

4.1.4 Private sector initiatives

Farmers that want to export their produce or that deliver to exporting companies need to comply with (voluntary) standards like GlobalGAP (https://www.globalgap.org/uk_en/) and UTZ (https://utz.org/). In these type of standards good agricultural practice is laid down including judicious use of pesticides, pesticide storage and waste management. Only registered products may be used. Accredited farmers are audited, hence, the privates sector takes responsibility for good practices incl. good pesticide management practices.

The dealer organisation RAIDA aims to organize the Rwanda dealers sector. Currently, 1000-1200 dealers are active in Rwanda. There is a campaign going on to invite dealers to join RAIDA. This action is supported by the Rwanda Government which aims to increase the public private sector dialogue. RAIDA's mandate is to provide advocacy and to professionalize the sector. RAIDA will be able to reach many shop owners and dealers and advocate to take responsibility for good practices and compliance to the regulations. This initiative is supportive to the work of the regulators and inspectors.

4.1.5 Identified needs

The following needs were identified by the stakeholders:

- RALIS maintains a database of importers and imported products to support the inspection process. Also information of dealers, such as sales records, is collected in the database. Such databases are important to follow products along the value chain. If e.g. at a certain point a product is found that does not comply, the owner/source of the product may be identified and measures can be taken to avoid repeated non-compliance. Further elaboration of this database is needed.
- Need for clear instructions for requirements at customs.
- There was a request by some stakeholders to extend partnerships and for joint inspection at district levels with Dutch inspection experts.
- Inspectors should professionalize their inspections.
- A list of registered products including the label instructions should be provided by RALIS. This list must be updated regularly. This list should be used by the inspectors but can also be used by others to check if they comply with the regulations and to check if they use a product that is accepted and if it is used according to the instructions.
- Regular checks on residues on local market commodities are reported to be done very limitedly. A need was identified for a portable test kit to be used by the inspectors as first screening tool.
- The Advisory Council reported problems to send inspectors for certification of importers and agro-dealers in time due to financial limitations.
- There is a request for quality testing lab to check the quality of products in the shops.

4.2 Monitoring

According to the stakeholders no surveillance programmes are in place on pesticides to monitor their risk for humans and the environment. Below the identified needs for human health and the environment are listed.

4.2.1 Human health

Health surveillance programmes are to be executed to monitor the health of occupationally exposed people. It was reported by the stakeholders that this is not done currently, with the exception of farms that apply e.g. GlobalGAP.

Also the monitoring of public health effects of pesticides should be monitored. For pesticide poisoning incidents the FAO code of conduct (FAO, 2014) refers to harmonized tools such as the Rotterdam convention human health incident report forms.

Several stakeholders indicated the importance of the development of both the surveillance program for operators and workers as well as the monitoring on public health for improving the Rwanda pesticide management system. Activities could be developed in collaboration with Rwanda research institutes and Rwanda universities.

4.2.2 Environment

No systematic monitoring systems are currently in place to measure pesticide concentrations in soil, groundwater and surface water in agricultural areas in Rwanda. REMA was not aware of any incidents being reported. It is recommended to put such a monitoring system in place to protect biodiversity, the terrestrial and aquatic ecosystems and also groundwater, which may be used as drinking water for humans and for livestock.

4.3 Reference lab

RSB being responsible for trade facilitation has currently a lab for measuring pesticide residues on commodities in place, however a quality lab or reference lab is still missing. They are in discussion with the ministry of Agriculture to establish such a lab.

The consumer organisation ADECOR advocated for establishment of a food testing laboratory to monitor for ensuring the safety and quality of food products in their compliance with food safety regulations and standards.

4.4 Waste management

4.4.1 FAO/WHO guidelines

The international code of conduct on pesticide management (FAO/WHO, 2014) which aims to establish voluntary standards on pesticide management states the following on waste management:

'*Governments, with the help of pesticide industry and with multilateral cooperation, should inventory obsolete or unusable stocks of pesticides and used containers, establish and implement an action plan for their disposal, or remediation in the case of contaminated sites and record these activities.*' (Art. 10.5)

'*governments should ensure that the treatment of disposal of hazardous pesticide waste are carried out in an environmentally sound manner that complies with national and regional regulations, relevant international standards and multinational environmental agreements, in particular the Basel Convention*.' (Art. 10.6)

'*pesticide industry should, with multilateral cooperation, assist in disposing of any banned or obsolete pesticides and of used containers, including reuse or recycling, with minimal risk where approved and appropriate.*' (Art 10.7)

'*governments, pesticide industry, international organisations, the agricultural community and vector control programmes should implement policies and practices to prevent the accumulation of obsolete pesticides and used containers.*' (Art. 10.8)

More practically, FAO/WHO developed guidelines for three types of pesticide waste:

(i) Bulk quantities of unwanted and obsolete pesticides (FAO, multiple guidelines, http://www.fao.org/agriculture/crops/obsolete-pesticides/resources0/en/). FAO developed many guidelines to deal was bulk quantities of obsolete pesticides. These may have been left behind due to poor stock management or due to banning of specific chemicals. Dealing with historical obsolete pesticides is costly and technically complex.
(ii) Small quantities of unwanted and obsolete pesticides (FAO pesticide disposal series 7). These guidelines advise on what to do with small quantities of unwanted, unusable and obsolete pesticides. The main focus of the document is on preventing the accumulation of pesticide stocks.
(iii) Empty pesticide containers (FAO/WHO, 2008). The guideline provides advice on the development of a containers management scheme and options for covering the costs associated with the implementation of the scheme.

4.4.2 Rwanda Law and Regulations

Although in article one (addressing the purpose of the law) of the Law N 30/2012 on the governing of agrochemicals it states that the Law governs the manufacturing, importing, distribution, use, storage, sale and disposal and burial of agrochemicals for the protection of human and animal health and the environment, it does not mention anything on disposal of empty containers and obsolete pesticides.

Chapter 8 of the Ministerial order N 002/11.30 determining regulations governing agrochemicals however, governs disposal of agrochemicals. It states that dumping of agrochemicals must be away from water courses or lakes: "*No person shall dispose any agrochemical on the land within 10 m of the water course or within 50 m of a lake"* (Art.60). Also, is states that after use, empty containers are collected in a designated place before being taken for safe disposal (Art. 61).

A person should apply for authorisation for disposal of agrochemicals. REMA has the power to issue authorization for disposal.

The collection and disposal of pesticides, which are hazardous, is governed by the Organic Law No 04/2005 of 08/04/2005 determining the modalities of protection, conservation and promotion of environment in Rwanda. In Art.33 it says: "*Any waste, especially from hospitals, dispensaries and clinics, industries and any other dangerous waste, shall be collected, treated and changed in a manner that does not degrade the environment in order to prevent, eliminate or reduce their adverse effects on human health, natural resources, flora and fauna and on the nature of the environment"*.

4.4.3 International recommendations

According to FAO/OECD empty containers should be decontaminated triple rinsing or pressure rinsing and punctured directly following the use of their contents (Croplife, 2014; FAO, 2014)

- inappropriate use of the empty containers should be prevented
- properly rinsed and inspected containers should be classified as non-hazardous waste
- it should be easy for users to return their empty containers to a container management scheme
- Obsolete pesticides should be incinerated at high temperatures or neutralized by using other techniques

4.4.4 Main Rwandan actors and roles

REMA is responsible for management of containers an chemicals (solid waste management) and also for waste water. RALIS is responsible for inspection and control of all entities that import, manufacture, transport, store and use agrochemicals.

There are no regulations in place on hazardous chemicals. A ministerial order is currently being drafted on chemical and hazardous waste. Rwanda has ratified the Basel convention on control of transboundary movements of hazardous wastes and their disposal. This means that this convention is followed; the ministerial order is to domesticate the Basel convention (REMA, 2014). Obsolete pesticides must be reported to REMA and these products must be incinerated at a nearby incineration. REMA reported that each district has its own incinerator, mostly near a local hospital, although some have broken down. The incinerator is then used for pharmaceuticals as well as pesticides. It was also mentioned that the management of the ash of such an incinerator is still a challenge.

The authors understood that best practices advocated by the government is to collect empty containers, pinch them or destroy them and bring them to a proper disposal area. For expired and obsolete pesticides, they should be collected and incinerated properly.

In Rwanda there is no collection system of empty containers nor of obsolete pesticides. MINAGRI noted that there are demarcated areas were empty containers are to be put in some districts.

The consumer organisation ADECOR indicates that there are stocks of non-sold or expired pest control products in the country at dealers and farmers. They request for an action plan to properly dispose these stocks.

Importers. Importers do generally not have empty containers to be disposed of. Expired and obsolete products should be incinerated after notifying REMA. It is unknown whether this is the current practice for importers.

Agro-dealers. Agro-dealers do not have much empty containers to be disposed of, but they do have expired products or obsolete products. A collection system was started a few years ago by AMDO but it was hampered as too high costs were involved for the dealers. De dealers did not provide their waste to the collection system, but disposed the products in another way (e.g. sewage system). An interesting review of the options for a collection system is given by USAID (2015).

Farmers. Large scale farmers (e.g. those that comply with GlobalGAP): the empty containers are incinerated on the farm and the obsolete products are disposed of in a so called soakpit (as reported by one stakeholder). The incinerators were reported to be too far away, for cost efficiency, the soak pits and incineration was used. Small scale farmers are reported be ignorant. They still bury the containers at the farm and even reuse them. Also stocks at farms have been reported too.

There appears to be a code of conduct by RSB on Safety procedure for the disposal of surplus pesticides and associated toxic waste. It is unknown whether this document really exists and whether it is used.

5 Comments/recommendations

Registration

- The current pesticide registration system is very new and needs to be further aligned with international best practices concerning the roles and responsibilities of the different actors in the decision making process. The authors recommend to reconsider the role and the responsibilities of the private sector in the decision making process. There might be a conflict of interest to members of the Council representing the private sector.
- The administrative registration system should be reviewed, with the aim to optimize registration procedures which are perceived by some stakeholders as time-consuming and costly. For instance time could be saved by the members of the Advisory Council if the registrar would do the completeness check and communicate about this with the applicant, without interference of the Advisory Council.
- Assessment of the risks associated with pesticide use of registered products is currently not part of the registration procedures. For proper pesticide management, and following international recommendations, the authors recommend to implement risk assessment in the registration procedure.
- Rwanda would benefit from support and capacity building to implement the EAC guidelines and, in time, ensure they can fully participate in regional work sharing for pesticide testing and registration.
- It is recommended to review and adapt the regulatory system for biological pest control products as well as to implement specific registration procedures for biological products.

Post-registration

Inspection and control:

- Inspectors would benefit from capacity building on professionalization and borrowing from international practices. Before starting to build capacity on inspections, the exact situation needs to be further assessed: what is needed to help the inspectors and the custom officers to improve their work? Which of the stages in the pesticide life cycle would have priority?
- A number of initiatives by the private sector have been reported, which is in line with the strategy of the government to improve the public-private sector dialogue. E.g. the dealers have organised themselves and aim to professionalise. It could be considered to stimulate and formalize collaboration with the private sector.
- Collection of data on pesticide trade and use along the value chain, and further development of a database on pesticide products registered in Rwanda, is recommended to support the inspection and control services.
- There is a concern that misuse may result in residue exceedances on agricultural commodities on the local market as well as on export products. Improvement of this situation can be achieved by adopting and enforcing maximum residue limits and associated Good Agricultural Practices.

Monitoring:

- Health surveillance programmes are currently not in place for occupationally exposed persons.
- Monitoring programs on public health effects of pesticides are not in place, e.g. human health incident reporting and chronic health studies.
- No systematic environmental monitoring systems are currently in place to measure pesticide concentrations in soil, groundwater and surface water in agricultural areas in Rwanda.
- It is recommended to develop these monitoring systems in order to assess the extent of any possible effects on human and animal health and the environment.

Waste management:

- It is recommended to set up programs to manage empty pesticide containers and expired pesticides. This could include awareness creation, training and setting up a system for users to return their empty containers as part of a pesticide container management scheme.

- Improved collaboration between the different Rwanda ministries is recommended on waste management, including the ministries of Human health, Trade and Agriculture as well as the Rwanda Environmental Management Authority (REMA) and the private sector. The NGO AGRIFOP wrote a project proposal for collection of obsolete pesticides and containers at the dealer, including training and awareness raising. It is recommended to follow up on this idea and jointly develop it further.

Training professional stakeholders and awareness creation

- Awareness should be raised of farmers, consumers and other stakeholders on the risks associated with pesticide use and possibilities to use effective low risk alternatives.
- Note that, when raising the awareness of consumers of the risk of pesticides, alternative options/commodities should be available at the local market.
- Farmers lack skills for the use of pesticides. Which type and quality is needed and what is the quantity? Often the farmers are illiterate and cannot read the label on the product. Labels on the products are often not in the local language. There is not systematic training of farmers by extension services of RAB. It is recommended to improve this situation.
- In view of sustainable agricultural production IPM principles should be adopted by farmers. Training of farmers and agricultural extensionists on IPM principles is therefore recommended.

References

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Annex 1 Visit programme

The list of stakeholder organisations and representatives is given below. Innocent Matabishi from EKN and Jean Paul Hakizimana from the HortInvest project accompanied the visits. Additionally, on Monday 23 April an introductory meeting was held at SNV premises with also Stefan Engels (SNV, project manager HortInvest), Klaas de Vries (SNV, advisor), Carian Emeka (EKN, Agricultural attaché of the Netherlands for Rwanda and Uganda), Justine Mucyo (Holland Green Tech). Wednesday afternoon preliminary findings were presented to members of the food safety cluster of EKN and the HortInvest project manager.

Date	representative	Stakeholder organization and role
Monday 23 April 2018	Beatrice Uwumukiza	RALIS, DG
	Mujawamariya Marie Goretti	RALIS, registrar and inspector
	Charles Murekezi	MINAGRI, DG Agricultural development
	Damien NDIZEYE and team	ADECOR, Executive Director
Tuesday 24 April 2018	Antoine Mukunzi	RSB, Divisions manager Chemical Quality Testing Laboratory
	Theodore Asiimwe	RAB, Head of Biotechnology Program
	Otto Muhinda	FAO, assistant FAO representative/ Programme
	Christine Murebwayire	PSF, Chair of the Chamber of Agriculture
	Epimaque Nsanzabaganwa	NAEB, Head of Horticulture Department
Wednesday 25 April 2018	William Macharia	HGT, founder, general manager
	Justine Mucyo	HGT, agronomist
	Evariste Safari	Balton, Agriculture manager; RAIDA, chair
Thursday, 26 April 2018	Jean Bosco Safari	AMDO, chair; AGRIFOP, CEO
	Dr. Spiridio Niyodusenga	AGROTECH, Technical and marketing manager
Friday, 27 April 2018	Jean Damascene Nyamwasa	USAID, Agriculture Productivity Team Leader
	Carol K. Murekezi	Independent consultant for IFC
	Vicky Ruganzu	RAB, Head of Soil Quality and Plant Nutrition Program
	Twiringire Samson	REMA, Chemical and Control Officer

Annex 2 Mandate of the registrar

Registrar of agrochemicals

An officer in charge of drawing and managing a list of agrochemicals

Mandate of the registrar of agrochemicals on pesticide registration according the Law on governing of agrochemicals: N°30/2012 of 01/08/2012 and the Ministerial Order determining regulations governing agrochemicals: N° 002/11.30 of 14/07/2016.

- Provide customs officers with list of all registered agrochemicals (art 8. 2012 Law)
- Prepare and keep the agrochemicals register (art 11. 2012 Law)
- Receives application for authorization of an agrochemical (art. 12. 2012 Law)
- Upon authorization by the Advisory Council, register, refuse to register, defer decision making to require further information or may grant provisional registration.
- Issue and renewal of registration certificates (art 14. 2012 Law + art 12. 2016 regulation)
- Grant authorization or the use of a restricted-use agrochemical (art. 18. 2012 Law): experimental and research use, emergency events, in transit. After consulting the Advisory Council, authorize the importation of unregistered agrochemical (art 3. 2016 Regulation)
- Review list of registered and prohibited agrochemicals when considered necessary (art 4. 2016 Regulation)
- Upon consultation with Advisory Council restrict or prohibit the use of a registered agrochemical (art. 5. 2016 Regulation)
- Acting upon advice of Advisory Council, authorize the manufacture of unregistered agrochemical for export if ... (art. 7. 2016 Regulation)
- After consulting Advisory Council, approve registration and issues certificate if registrar establishes that:
- applicant has sufficient technical knowledge
- the official testing and evaluation have proved that the agrochemical is effective, safe and not a danger to public health
- fees are payed (10 000 Rwf)
- issue certificate of temporary registration (art. 14. 2016 Regulation)
- After consulting Advisory Council issue certificate of provisional registration (art. 14. 2016 Regulation)
- Reject application for registration of agrochemical (art. 15. 2016 Regulation) if among others: *3° use would lead to an unacceptable risk or harm to things for which the agrochemical is intended to be used, public health, plants, animals or to the environment.*
- Communicate decision of Advisory Council as result of analysing/assessing reports on agrochemical testing to applicant (art. 59. 2016 Regulation)

More specific duties of the registrar of agrochemical are given in the ministerial order N°001/11.30 of 15/02/2013.

Annex 3 Data requirements

REPUBLIC OF RWANDA

MINISITERI Y'UBUHINZI N'UBWOROZI

MINISTRYOF AGRICULTUREAND ANIMAL RESOURCES

OFFICE OF AGRICULTURE AND LIVESTOCK INSPECTION AND CERTIFICATION SERVICES

PESTICIDE REGISTRATION DOSSIER COMPONENTS

1. **Details of the Product:**

a) Common name /active ingredient of the agrochemical
b) Trade/brand name
c) Molecular formulae of the active ingredient(s)
d) Molecular of the active ingredient weight
e) Structural formulae of the active ingredient
f) Main (+minor) active ingredient(s), contents by weight/volume. .....
g) List of adjuvant name(s) and their content by weight/volume
h) Type of agrochemical (e.g. insecticide, herbicide, fungicide, fertilizer etc)
i) Type of formulation (e.g. wettable powder, dust, emulsifiable concentrate etc)
j) **Physical properties**
   - Solubility of the agrochemical in aqueous and/or organic solvents (metric units)
   - Emulsifiability / suspensibility (or emulsion stability)
   - Physical description (e.g. colorless crystals)
   - Wettability
   - Stability/comparability (e.g. hydrolyzed by alkali)
   - Spraying/dusting properties
   - Moisture content
   - Melting point
   - Setting point
   - Boiling point
   - Vapour pressure
   - Accelerated storage
   - Flammability, etc
   - Active ingredient by weight/volume.....
   - Acidity/Alkalinity
k) Tolerance limits for the characteristics in (j) above (where applicable)
l) Estimated quantities of the product marketed during last two years and the current year
m) **Storage stability**
   - Solubility in water and solvents
   - Suspensibility / emulsifying characteristics
   - Known capability/ incompability with other pesticide products or active ingredients
   - Flash point and other indicators of flammability
   - pH
   - Methods of destruction or disposal

P.O Box 621, Kigali Website:minagri.gov.rw E-mail: infoinspection@minagri.gov.rw

- Analytical methods for constituents

n) certificate of quality analysis
o)

2. Toxicology and other side effects:

a) Classification (in accordance with the WHO guidelines)
b) Estimation of acute oral LD50
c) Estimation of acute dermal LD50
d) Inhalation LC50
e) Skin irritation / Corrosivity
f) Eye irritation
g) Dermal sensitization
h) Allergic sensitization
i) Subchronic toxicity (21 day, dermal):
j) Subchronic toxicity (90 day, oral)
k) Subchronic toxicity (90 day, dermal)
l) Teratology
m) Reproduction
n) Chronic toxicity
o) Oncogenicity
p) Mutagenicity
q) Acute delayed neurotoxicity:
r) Subchronic neurotoxicity
s) Pharmacokinetics (absorption, storage, metabolism and elimination)

3. Human exposure and Safety:

a) Assessment of applicator exposure
b) Assessment of farm worker exposure
c) Signs and symptoms of acute human poisoning
d) Recommended first aid procedures
e) Recommended medical treatment for poisoning, include antidote if any
f) Proposed acceptable Daily intake
g) Protective equipment
h) Other precautions

4. Analytical methods:

(Supply reprints, photocopies or authenticated texts)
Quantitative determination of the pure active ingredient in technical material formulations and in contaminated biological materials

5. Containers:

a) Type and forms of containers used for storage of the agrochemical
b) Packaging type, sizes and materials
c) QR code

6. Biological Data

a) Description of mode of action or effect on pest for which control is claimed
b) Recommended field of application (mention target pests and crop/animal)
c) Application rate (kg a. I / Ha or % a.i spray dilution for each site/pest listed
d) Suggested methods of applications
e) References of recommended use by authorized bodies in Rwanda
f) Reference of recommended use by authorized bodies outside Rwanda
g) Frequency and timing of application for each site/pest listed
h) Reference where the agrochemical has been used successfully/unsuccessfully showing the dosages applied (metric units)
i) Persistence of the agrochemical in the environment (soil, water, plant and animal products)
j) References of pest resistance to the pesticide product
k) Phytotoxicity
l) Results of laboratory studies, if any
m) Effects on benefial organisms

Environmental effects, fate and transport

a) Avian acute oral toxicity
b) Fish acute toxicity
c) Aquatic acute toxicity
d) Accumulation in fish
e) Avian reproduction
f) Fish reproduction
g) Acute toxicity to honey bees
h) Soil non-target macro / microorganisms
i) Volatility
j) Adsorption / desorption
k) Leaching
l) Degradation in soil
m) Biodegradation
n) Hydrolysis

o) Aqueous photolysis
p) Analytical method – residue in soil / water

Residues in foods

a) Identity of principal residues, metabolites and degradation products in edible crops, foods or feeds
b) Residues decay curves for residues on crops to be treated
c) Residues of active ingredient and principal metabolite in animals fed on treated feeds or grazed on treated fields or pastures
d) Effects of foods processing or home preparation on residues
e) Analytical method for detection of principal residues, metabolites on treated commodities
f) Proposed maximum residue level for each crops, food, feed or animal expected to contain residues

7. Labelling

a) Trade and common name of the agrochemical;
b) Name and address of the manufacturer ;
c) Manufacturing and expiry date;
d) Batch number
e) Net contents
f) Formulation
g) Hazard symbol and precautionary words
h) Instruction for use
i) Percentages of main nutrient elements and grade;
j) Registered source in case of agricultural lime product;
k) Trace elements content in percentage by weight in whole numbers or to one decimal place for agrochemicals containing only one trace element if applicable;
l) Trace elements of the agrochemical both in words and by appropriate chemical symbols.

8. Premises (Attach Sketch):

- Physical address:.....
- Manufacturing room(s).....
- Storage of: Technical materials.....
- Adjutants.....
- Finished products.....
- Standards.....
- Antidotes.....

- Air and other conditioners.....
- Manufacturing equipment.....
- Disposal of wastes.....

9. Manufacturer profile

- Name
- Address
- P.O.box
- Email
- Research and development department

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