Preamble

This manual is intended as a resource for companies and individuals who wish to have their pesticide products registered for sale in Ghana by the Ghana Environmental Protection Agency (EPA). The manual describes EPA's review and decision-making process for registering a pesticide product and its use. EPA's pesticide review and oversight is conducted by the Chemicals Control and Management Centre (CCMC) of the EPA, made up of scientists, regulatory specialists, and other supporting staff.

Under the Part II of the EPA Act, 1994, (Act 490) the EPA has the mandate to regulate all pesticides that are sold and distributed and use in Ghana. The Act defines pesticides as *(a)* a substance or mixture of substances intended for preventing, destroying, repelling or reducing the destructive effects of a pest, or *(b)* a substance or mixture of substances intended for use as a plant regulator, defoliant, desiccant or wood preservative. A pesticide therefore includes herbicides, insecticides, plant growth regulators, rodenticides, fungicides, biopesticides, and other substances used to control a wide variety of pests and diseases.

In the process of registration, EPA undertakes a rigorous, comprehensive scientific assessment of the product, resulting in a registration decision. This is to ensure that, when the product is used in accordance with label directions, no unreasonable adverse effects on human health or the environment will occur.

This manual is basically organized into 8 chapters (see Table of Contents) that comprehensively discuss issues related to the registration of pesticide products. In addition to describing EPA's registration process, it also provides information about the role of the National Pesticide Technical Committee (PTC) and the EPA Board in the registration process. It also spells out some do's and dont's for applicants/registrants before, during, and after the process of registration. Data requirement for the registration of pesticides are also briefly described. It must be emphasized that a separate document exists to guide applicants in the preparation and organization of product dossiers for submission to the Agency.

Acknowledgments

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Disclaimer

This document has been reviewed in accordance with Environmental Protection Agency's policy and approved for publication.

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Foreword

Pesticides are used to enhance agricultural productivity, protect public health and in various industrial applications including wood and paint preservation. Pesticides therefore play an important role in the sustainable development of Ghana. The use of pesticides in the absence of appropriate management practices pose risks to human health and the environment.

The adverse effects of pesticides on human health and the environment could result from both acute and chronic exposures. For this reason, it is important to ensure that pesticide products used in Ghana are of acceptable quality, highly efficacious for the intended purpose and relatively safe to the user, non-target organisms and do not present unreasonable health and environmental risks to all segments of the environment. This is achieved through a process of registration and other management measures in line with the provisions of Part Two of the Environmental Protection Agency Act, 1994 (Act 490). Registered pesticides are classified under the Act as (1) general use; (2) restricted-use; and (3) suspended / banned.

The objective of regulating pesticides is to protect society from the adverse effects of pesticides without denying access to the benefits of their use. Registration enables authorities to exercise control over quality, use levels, claims, labelling, packaging, advertising, and disposal of pesticides, thus ensuring that the interests of end-users are properly protected.

A scientific approach is adopted in the process of registration of pesticides and this manual provides stepwise guidance to the registration authorities in that regard. It highlights the mission of the Pesticide Department and provides details of the activities of the functional units within the Pesticides Department. It also outlines the timeframe within which the Agency is expected to take decisions on applications submitted.

It is our fervent hope that the use of this manual will help to facilitate the work of the registration experts and contribute to ensuring that Ghana benefits from the use of good quality pesticide products without compromise on safety at all times.

The financial support provided by the West African Agriculture Productivity Programme (WAAPP) of the Ministry of Food and Agriculture (MoFA), through the Council for Scientific and Industrial Research (CSIR), and all those who helped in the preparation of this manual are highly appreciated.

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CHAPTER 1

THE PESTICIDES DEPARTMENT

1.1 Mission Statement

It is the mission of the Pesticide department to ensure the proper registration and licensing (labelling, distribution, storage, transportation, manufacture, use, application, and disposal) of pesticides and dealers within Ghana through fair and equitable implementation and enforcement of the Part II of the Environmental Protection Agency Act, 1994 (Act 490).

1.2 Units of the Pesticide Department

The following constitute the functional units of the pesticide department:

- Pesticides Registration;
- Pesticides Licensing and Inspectorate and Research;
- Occupational Health and Safety; and
- Information, Communication and Technology
- Education, Awareness and Training

1.2.1 Pesticide Registration Unit

The activities of the Pesticides Registration unit include coordination and communication with applicants and scientific evaluation experts regarding the pesticide registration process. Units other than the Pesticides Registration unit may be involved in the evaluation process.

This unit is responsible for processing the initial applications for registration and coordinating the activities of relevant sub-committees involved in the evaluation of scientific data and review of labels. The unit is also involved in communicating with the applicant in all matters relating to the registration of products. The general functions of the unit include but not limited to the following:

- Processing and tracking of new pesticide product applications and renewals
- Processing label and label amendments and other revisions of currently registered products
- Liaising between evaluation sub-committees and applicants
- Carrying out scientific evaluation of submitted data.
- Coordinating and tracking submitted data s and re-evaluations
- Reviewing adverse effects disclosures
- Processing public requests and complaints
- Recording and maintaining a database of registered products and their labels including those amended.
- Reviewing acute and chronic toxicology studies which are submitted in support of obtaining new product registration.
- Preparing, and updating the Pesticides Register.

1.2.2 Pesticides Licensing and Inspectorate Unit

The Pesticide Licensing and Inspectorate unit is responsible for the following activities:

- Processing of pesticide dealers licenses
- Pesticide use enforcement
- Pesticide product compliance inspections
- Monitoring pesticide residues in produce and seizure of produce with unacceptable residue levels.
- Inspecting pesticide licenses to ensure compliance of licensing conditions.
- Coordinating the activities of pesticide inspectors. Organises trainings and awareness campaigns.
- Sampling commodities and products for laboratory analysis of pesticide residues.
- Investigating pesticide poison incidents.
- Collecting and analysing agricultural pesticide use data from relevant institutions.
- Preparing the quarterly and annual Pesticide Use Report, which shall be a listing of the reported amount of each pesticide used on each agricultural commodity and the acreage treated.
- Any other duties as may be necessary for the purpose of enforcing the law

1.2.3 Occupational Health and Safety Unit

The Occupational Health and Safety Unit is responsible for reviewing pesticides and their effects on pesticide applicators and the general public. The Unit's activities include the following:

- Reviewing scientific data relating to exposure of humans to pesticides.
- Identifying health effects of pesticides on persons who mix, load, and apply pesticides or who are otherwise exposed to pesticide applications or residues.
- Developing strategies to reduce excessive exposure to pesticides
- Reviewing reports of accidental pesticide exposure.
- Reviewing and compiling reports of pesticide related incidents.
- Conducting exposure studies of field workers.
- Providing information to physicians, emergency medical care facilities, and poison control centres
- Preparing reports on pesticide exposure incidents, and other related incidents;
- Advising which pesticides should be placed under restricted, banned or suspended use.

1.2.4 Information, Communication and Technology Unit

The Information, Communication and Technology Unit coordinate the following activities:

- Maintaining each pesticide product registration file; EPA documentation; and correspondences from the applicant.
- Maintaining information "Hot Line."
- Providing access to the product label files and databases in response to information requests
- Maintaining the registration refusal filesThe Information Technology Office of the CCMC provides support to the PD in the following areas:
    - Provides information on electronic technology.
    - Supporting department's anti-virus protection.
    - Managing and implementing network security measures.
    - Supporting external Internet server activities
    - Managing the department e-mail system.

1.2.5 Education, Awareness and Training

The Education, Awareness and Training Unit is responsible for:

- Sensitising the stakeholders on the laws and regulations on pesticides
- Sensitising the general public on the health risk of pesticide use.
- Developing awareness materials for dissemination to the general public
- Developing material for training of pesticide applicators

CHAPTER 2

THE PESTICIDE REGISTRATION PROCESS

2.1 Responsibility for Pesticides Registration in Ghana

The Environmental Protection Agency is the lead Agency responsible for Pesticides Control and Management in Ghana as enshrined in Part II of the EPA Act 1994 (Act 490). In that capacity, the EPA has the sole authority and responsibility to register all pesticides imported, exported, manufactured, formulated, distributed, advertised, sold or used within Ghana.

Pesticides registration is the process whereby the responsible national government authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or to the environment.

2.2 Purpose of Registration

The purpose of the registration of pesticides is to ensure that the registered product;

- Is efficacious
- Is used in accordance with label instructions
- Safeguard human health, animal health and the environment
- Meets both national and international standards
- Is properly documented for regulatory purposes

Registration enables authorities to safeguard society from the adverse effects of pesticides without denying access to the benefits of their use. It also enables the authority to exercise control over quality, use levels, claims, labelling, packaging, advertising, and disposal of pesticides, thus ensuring that the interests of end-users are properly protected.

2.3 Definition of Pesticide

The term pesticide is defined under the Part II of the EPA Act, 1994 (Act 490), as:

- a substance or mixtures of substances intended for preventing, destroying, repelling or reducing the destructive effects of any pest: or
- a substance or mixtures of substances intended for use as a plant regulator, defoliant, desiccant or wood preservative.

2.4 Steps in the Pesticides Registration Process

Ghana's pesticide registration is a stepwise process that involves a number of evaluations culminating in a final decision to register or deny registration of a pesticide.

This process is expected to identify potential problems that may arise from the sale and use of pesticides under Ghana's unique conditions and culture. The process of registration determines whether mitigating measures are necessary to assure that effective products will be available which do not present undue hazards to farmers, the public, the consumer and the environment. The process is summarised as follows:

Step 1: *An applicant must submit the appropriate documents and the required scientific data.*

Step 2: *The data undergoes completeness check. If incomplete, the submission may be returned. If complete, the submission undergoes scientific evaluation.*

Step 3: *Data submitted undergo in-depth scientific evaluation by technical sub-committees.*

Step 4: *Evaluation report with recommendations is prepared and submitted to the PTC.*

Step 5: *The PTC deliberates on the reports of the evaluation sub-committee's and tables decisions for consideration by the EPA Board*

Step 6: *The EPA Board decides whether to grant or deny approval for registration.*

After the product is registered, information about the product and its label are computer coded. A paper copy file is also maintained for each pesticide product.

Any changes made to the registered label must be reviewed and approved before the product bearing the amended label can be sold or used in Ghana.

Sub-registrations, additional brand names, changes of product ownership, or changes in company name must also be registered before the product can be sold or offered for sale.

Once a product is registered, it is subject to re-evaluations, and reporting of adverse effects.

The outcome of any of these activities could be suspension or cancellation of the product's registration. In some cases, registrants may amend labels and formulations to mitigate hazards - or may withdraw their registrations. A brief outline of the registration process is presented in box 1 below.

Box 1: Brief outline of the registration process for a new product

Front Desk	Receives submissions, assigns ID numbers and files submitted dossier.
Registration Officers	Review the submissions for completion
	Review the labels
	Return incomplete submissions to the applicant
	Process dossiers for evaluation
Evaluation Sub-committees	Evaluate submitted data Prepares recommendations for attention of PTC
Pesticides Technical Committee (PTC)	Deliberates on reviews of evaluation sub-committee's recommendations and tables decisions for consideration by the EPA Board
Pesticides Registrar	Compiles recommendations of PTC and forward to Executive Director for consideration of the Board
EPA Board	Considers PTC's recommendations and take a decision.
Pesticides Registrar	Communicates decisions of the EPA Board to applicant
Executive Director, EPA	Issue Certificate of Registration and Gazette, right to deny registration

2.5 Classification of Registered Products

- Registered products are classified as follows: General use
- Restricted use or suspended
- Banned

There are other forms of product approvals namely:

1. Experimental/research use
2. Special needs and;
3. Emergency use
4. Transit products

Certain active substances are banned from use in Ghana and products containing these active substances shall not be registered: These include product listed as banned in international conventions that Ghana has signed and ratified. Refer to the current pesticide register for the list of banned products.

2.6 Application Processing Time

Applicants for pesticide registration are entitled to timely decisions on their applications. In accordance with the EPA Act, the following time frame is established:

- The time frame for making a registration decision is 90 days.
- The Registrar must notify the applicant, in writing, of the decision to refuse or register, within the 90-day time frame. If the application is incomplete, the written notification must identify the deficiencies. Registration requests are processed in the order received unless otherwise prioritized by the Registrar. Prioritisation may be a result of the following:
- National emergency situations e.g. epidemics
- Economic importance to Ghana

The 90-day time frame is applicable when all data requirements have been met. Box 2 below outlines the life cycle of pesticide registration

Box 2. Life Cycle of Pesticide Registration

Stages in processing applications for registration of pesticides	ACTOR	DAY
Applicant procures registration form and submits completed application to EPA (completed form + comprehensive dossier on product + efficacy trial report)	Registrant	---
Pre-submission consultation by applicant	Registrant	--
PD opens new file for application. One set of copies is filed and stored at the strong room. Acknowledgement of receipts sent to applicant.	Registration officers	----
Dossier checked for completeness	Registration officers	----
Completeness confirmed or otherwise Evaluation process is initiated if	Registration	0

completeness is confirmed	officers	
Relevant portions of dossier copied and distributed to experts of sub-committees for evaluation	Registration officers	10
Registrar schedules meetings evaluation sub-committees	Registrar	13
Experts evaluate dossiers and prepare reports with recommendations on the following; ❑ Bio-efficacy ❑ Risk to human health and the environment, and ❑ Labels, packaging and advertisement	Sub-committee experts	31
Sub committees (SC) prepare reports with proposals and make presentation to a plenary section of all sub-committees	Sub-committees	34
Registrar collects SC evaluation reports and proposals for consideration of PTC. Registrar convenes a meeting of the PTC	Registrar	40
PTC deliberates on the proposals and makes recommendations.	PTC	60
Registrar summarises the recommendations for the attention of the Executive Director.	Registrar	67
Executive Director presents recommendations to EPA Board for their consideration and approval.	Executive Director/EPA	75
If Board endorses recommendations of PTC, a certificate of registration is issued.	EPA Board	80
Registrar informs applicant about decision and sends invoices to applicants.. If registration is refused, registrant is informed of decision and reasons for refusal. Applicant has a right of appeal in case of a refusal of registration within 14 working days.	Registrar	85
Certificates of registration are issued. Product is **OFFICIALLY REGISTERED**	Registration officers	90

2.7 Description of Stages of the Registration Process

2.7.1 Front Desk Activities

The Front Desk officer receives an application for registration, which must contain the following:

- Two original copies of the completed application form for registration
- All appendices (unless otherwise indicated)
- A dossier of supporting data including efficacy trial report(s)
- Non refundable processing fee payable to the EPA

The Front Desk officer then begins the process by doing the following:

2.7.2 Documenting the Dossier – Framework for Official Use Only

Form 'A' has a first section "For office use only" which is reserved for processing by the Front Desk officer. On receipt of a Dossier, the date of receipt is recorded in the white box. The dossier is then given a Recording Identification Number (ID No). Box 3 below indicates the classes of approval in use:

Box 3: Classes of registration approval

Activity	**Prefix**
Full Registration	FRE
Provisional Clearance	PCL
Experimental Permit	EXP
Registration Renewal	RRE
Banned Products	BAN
Suspended Registration	SUR

Thus, applications for full registration are assigned numbers that begin with the symbol FRE followed by a number in chronological order of five figures. (e.g. FRE- 00008). The other approvals are treated in similar manner. An application for renewal of registration will have the same code as the one for first registration.

2.7.3 General Status Sheet

The status sheet will have information about the product, the applicant, and the category of approval requested. . A sample copy is in Appendix I

2.7.4 Creation of Application Folder

An application folder is created to facilitate routing. The status sheet and tracking ID No. remain with the registration request throughout the process. All accompanying letters are filed. Copies of such letters such as authorization letters are added to the package and remain with the package during evaluation. The package is then forwarded for the attention of the Pesticide Registrar

2.7.5 Indexing

If data are submitted with a registration request, the front desk officer processes the data by doing the following:

- Index the data by entering study information into the database. This information includes the study title, date of the study and the assigned volume numbers
- Generate a letter to the applicant acknowledging receipt of data. The letter includes the assigned
- Tracking ID No. and a report of the indexed data, including test types and assigned volume numbers.

- Forward the registration request to the Registrar of Pesticides.

Applicants must have submitted data in the format outlined in Appendix II

2.8 Review Process

The registrar designates an officer to review the status sheet (also called a Submission Status Record) for accuracy and, if necessary, make corrections. The status sheet is used throughout the evaluation process.

To correct a status sheet, the officer will:

- Make the necessary changes on the original status sheet;
- Make two copies of the corrections highlighted and date it;
- Submit one copy to front desk officer and update the database.

The officer checks the completeness of the application by considering the following items.

2.8.1 Complete Application Form for Pesticide Registration

- Page C, must be completed for each test conducted. Similarly, Page D must be completed for each active substance indicated in the product formulation. Attachments are separated from the documents to facilitate their analysis by the scientific evaluation committees
- The application form must be filled out and signed. The applicant's name and address shown on the application must be the same as will appear on the certificate of registration of the applicant issued by the Registrar General's Department. The trade/brand name on the application form must be the same as the name shown on the label and different from the brand names of pesticide products registered in Ghana
- Each active and inert substance in the product formulation must be listed.
- The composition by weight of the listed substances must total 100 percent
- The application form must be signed and dated by an authorized representative of the applicant making the submission. If an agent signs the application form, a letter from the applicant authorizing the agent to act on the applicant's behalf must be on file.

2.8.2 Application Processing Fee

- Applicant must pay the appropriate processing fee upon submission of application.
- The application form must show the receipt number of the processing fee.
- Provisional Clearance requests require a completed application form and appropriate processing fee.
- Request for experimental permit must be accompanied by a completed application form and appropriate fee.

2.8.3 Proof of Registrations in other jurisdictions

- Certificate of registration of product from country of manufacture where applicable
- Certificate of authorisation from manufacturer of product
- Proof of registration(s) in other country(ies)

2.8.4 Scientific Data

Data are required to obtain product registration and to amend currently registered products. All data submitted to EPA by the applicant in support of registration of their product are to be submitted to the CCMC. The basic data requirements should include the following: mammalian toxicity, ecotoxicity, environmental fate, physical and chemical properties, , five batch analysis, residue chemistry if used on a food or feed crop, fish and wildlife if applicable, phytotoxicity if applicable, and bio-efficacy (refer to registration guide document for details of data requirement).

In lieu of submitting data, an applicant may reference their data previously submitted or may obtain a Letter of Authorization from the owner of the data on file at the secretariat.

2.8.5 Letter of Authorization

A letter of authorization is required if an applicant wishes to use data on file with secretariat owned by a holder. The holder writes a letter addressed to the registrar authorizing use of its data to support the other applicant's registration application. The letter should reference specific data pertinent to the applicant's product. The formulations used in the referenced studies should be identified and the appropriate volumes of data referenced for the scientific review.

A letter of authorization from the holder is needed for products registered as identical to a currently registered product; if there is already an identical product registered in Ghana.

2.8.6 Transfer of Registration Rights

The transfer of registration rights is a procedure allowing the change of ownership of a formulation. The previous owner relinquishes all rights to the formulation to a new registrant, but the formulation keeps the same commercial trade name. Within 21 working days of notification in writing of such transfer by the Registrar, if there is no response from the holder, the transfer is deemed affected.

Important: *The previous and the new registrant shall provide documentary evidence of transfer and acceptance of the formulation rights. The old registrant has to certify under oath that the entire composition of the product is identical in every respect to the last composition communicated to the Registrar. Applicants must separate attachments from the documents to facilitate their analysis by the Evaluation sub-committees.*

Example:

Old registrant (Holder)

We the undersigned, (Name of the holder company, address), requests the transfer of our registration rights. (Trade name and registration number) to the other applicant (Name, address of the new applicant) that will become the new holder.

By the following, we certify under oath that the entire composition of the product that we transfer to the new applicant (Name, address of the new applicant) has undergone no modification and that it corresponds in all aspects to the last composition transferred to the new holder and accepted by EPA..

Name, signature and date.

New holder

We undersigned (Name of the new holder, address) declare to accept the transfer of the registration rights (trade Name and registration number) from the original holder (Name, address of the former proprietor holder) that has transferred to us the entire composition which conforms in all respect to the last composition accepted by the Environmental Protection Agency.

Name, signature and date

2.8.7 Review of the Label

The registrar will determine compliance with the labelling requirements. The required Label elements are outlined in Chapter 7.

2.8.8 Determination of Special Features of the Submission

The majority of submissions may be for full product registrations or label revisions. Some, may however, have features which require special handling. The Registrar determines whether the registration request contains any of the following special features:

- Is the product identical to one currently registered? Identical products are products with an identical composition and identical label claims, with some minor differences allowed. Follow the instructions in Chapter IV Identical Product Registrations.
- Does the label or composition change require the submission and review of data? See Chapter III for procedures
- Are there any special label requirements? (Chapter VII on Label Elements)
- Is the request for a microbial or biochemical product? If so, the request is processed by the designated officer. New microbial or biochemical products may be submitted concurrently to the Secretariat. Does the product contain a new active substance? If so, the application must be accompanied by the relevant data as stipulated in the registration guide.
- Is the request for a major new use? A major new use is a use pattern different from currently registered use patterns and for which there is increased public or worker

exposure or increased environmental exposure. (Chapter 3 Dat*a* requirements). An example is the addition of outdoor use to a product otherwise registered for indoor use, which must be accompanied by appropriate residue, efficacy and exposure data pertinent to the new use pattern

- Is this for use in or around the home? If the active substance is not currently registered for home use, indoor exposure data may be required. See Chapter 3 on Data Requirements
- Is this a request for provisional Clearance allowed by part II of the EPA Act (Act 490)
- Is this a request for an Emergency approval allowed by part II of the EPA Act (Act 490)

2.8.9 Verification for Completeness

The officer verifies the completeness of the registration request and determines whether

- The registration request can be processed by the registrar without Scientific evaluation
- The registration request is deficient and must be returned to the applicant. Or
- The registration request can undergo scientific evaluation

Note: Before a package is processed further, any corrections to the status report must be given to the Front Desk officer.

2.8.10 Processing Packages Not Requiring Scientific Evaluation

The following types of submissions can be processed by the registrar without scientific evaluation:

- *Identical Products*. The registration request is for a product identical to a current registration.
- *Non-substantive changes to the label or the composition.* The applicant submits non - substantive change requests to the Pesticides Registrar for a determination. Each product shall be assigned a designated registration officer who will follow the product till it is registered or otherwise.
- *Label or composition revisions*. The label or composition revisions are minor and can be processed by the Registrar (see Chapter 3 for criteria and procedures)
- First Aid-Statement of Practical Treatment (SOPT) revision: For labels with new revised First Aid - (SOPT), the Registrar determines if it is correct and adequate.

2.8.11 Incomplete Submissions

If any of the required items listed in the preceding sections are lacking, incomplete, or are otherwise unacceptable, the registration requests should not be processed further and should be returned to the applicant. The steps for returning incomplete submissions are as follows:

(a) The Registration Officer

- Prepares an incomplete submission letter to the applicant. The letter should indicate any deficiencies in the submission.
- Makes a copy of only the first page of the original application form. This copy will be sent to the applicant along with the return letter
- Routes the letter, with the copy of the first page of the application form, and the registration request to the Registrar.
- Makes a copy of the letter for the "return package".

(b) The Registrar

- Reviews the deficiencies identified in the letter.
- Routes the letter, copy of the first page of the application form, and the registration request to the Front Desk officer for dispatch to applicant.

(c) The Front Desk Officer

- Enters the tracking ID number and date of incomplete submission letter in the tracking system.
- Mails original letter with copy of first page of application to applicant.
- Attaches copy of letter to data package and place in the "return package" file.
- The applicant has 60 days from the date of the first incomplete submission letter to provide the missing information without an additional fee. All missing information received after 60 days must be accompanied by the appropriate fee.

(d) The Applicant

If the applicant does not provide all of the missing information, the application shall be deemed as still incomplete. The Registrar again returns the request using the appropriate letter. The applicant may provide the missing information within 60 days of the date of the first incomplete submission letter without an additional fee.

2.8.12 Preparing Data Packages for Scientific Evaluation

If the registration request is complete and requires scientific evaluation the Registrar prepares the package for scientific evaluation. The Registrar reviews the label, determines the data requirements, and verifies that all data are present with the package or are referenced in the strong room. Use Chapter 5 to determine the data requirements for most products. The following do not require evaluation by the ecotoxicology sub-committee.

- Most household or home and garden pesticides other than rodenticides and avicides
- Products labelled for manufacturing use only
- Label amendments that have the standard wording 'Do not apply directly to water', to areas where surface water is not present

Note: if the applicant does not believe a required study is applicable to their specific product and use patterns, the applicant can request the data to be waived, and must provide reasons

for the waiver request. If the data waivers are granted, include this documentation when entering the package into evaluation.

2.8.13 Arrangement and Content of package undergoing Scientific Evaluation

The Registrar ensures that the data package undergoing scientific evaluation contains the following:

- The status sheet with correct information
- Any special instructions to the sub-committees
- The printed labels for the products

Write the status sheet ID "tracking Number" on the top right hand corner of one of these labels. For label amendments, applicants are instructed to highlight or identify all changes to labels or applications. If the applicant did not highlight the label, the registration officer should do this. The highlighted copy is submitted to the scientific evaluation process. The second copy of the label is forwarded to the registration officer in a report to the evaluation sub-committee members.

- Copy of the completed Application for Registration Form A.
- Data submitted by the applicant.

If the product contains a new active substance, the data are not routed with the package, but are stored in the strong room with the reference volume. The reference volume contains the cover letter, copy of the application form, label sheet, Material Safety Data Sheet (MSDS), five batch analysis report, and any other correspondence. Also included are:

- Copy of any letter(s) of authorizations referencing data already on file. More than one applicant may authorize use of data on file in support of another application.
- The volume numbers for referenced data specifically listed in the instructions for each evaluation sub-committee
- If a waiver request was submitted, include this documentation when entering the package into evaluation
- If the request is for full registration of a product previously reviewed as EXP, the registration officer attaches a copy of the original evaluation and data

2.8.14 Evaluation sub-committees

The evaluation sub-committees are as follows:

- Ecotoxicology/Human Toxicology
- Bio -efficacy
- Labels and Advertisements

Functions of the evaluation sub-committees are as follows:

- Determining if submitted or referenced data are acceptable and support registration.
- Determining if any required data are not submitted

- Determining if additional testing is required
- Determining if data support information on the label such as signal word and precautionary statements, protective clothing statements, worker and public re-entry intervals, environmental hazard statements, statement of practical treatment, pre-harvest intervals, use directions, and efficacy claims.
- Determining if there is evidence of an adverse effect or potential adverse effect.
- Determining if potential hazards are mitigated by the label

2.8.15 Tracking and Routing of the Data Package

The registration officer indicates the appropriate committee and forwards the registration request for scientific evaluation by the various sub-committees. The registration officer records the information in the folder and enters it into the tracking system database. If deficiencies are noted during scientific evaluation, the Registrar sends the applicant a stop-clock letter. For new products active substances, the designated registration officer will give a copy of the following items to the Registrar who determines if more information is required.

- Status sheet and label
- Detail summary report
- First page of application form

2.9 Decision to Register, refuse registration or provisional clearance

When the scientific evaluation is completed, the Registrar submits a composite evaluation report to the PTC for consideration.

The PTC shall:

- Review the evaluation report and recommendations from the sub-committees
- Communicate any data deficiencies, unmitigated hazards, possible adverse effects, recommendations for conditional registrations, or recommendations for risk assessment to the applicant
- If labels have not been received, notify the applicant that labels must be submitted and found acceptable before registration is granted,

2.9.1 Decision to Register

If the PTC finds the proposal by the sub-committees acceptable, the PTC makes recommendation for the attention of the EPA Board for a decision.

2.9.2 Decision to Refuse Registration

If the PTC finds the proposal of the sub-committees unacceptable, it makes recommendations to the EPA Board for final decision. The proposed decision to refuse registration could be any of the following:

- The evaluators have stated that submitted data indicates a potential hazard not mitigated by the label;

- Label claims are not supported by information/data submitted
- Required data was not submitted

The Registrar communicates in writing to the applicant which includes:

- Reasons for refusal.
- Specific information, data, or description of documentation required to complete the application,
- A copy of the evaluation report may be included

2.9.3 Provisional Clearance Option

If during the scientific evaluation process, provisional registration is recommended, the evaluator(s) should list the types of data or information needed and a time frame for submission.

The Registrar may waive specific data requirements for a period reasonably sufficient for the generation and submission of the required data. Upon registration, the time frame for submission of data is indicated in the letter to the applicant. The time frame will not exceed 2 years. Provisional clearance can be granted only if the following data are submitted and found acceptable.

- Acute oral and dermal LD_{50} data on the product.
- Acute LC_{50} data on products, which produce respirable aerosols or gases.
- Primary eye irritation data on the product.
- Primary skin irritation data on the product.
- First Aid data.
- Foliar and soil residue data sufficient to establish safe re-entry interval when human contact is likely to occur.
- Analytical methods to determine residues of each active substance and toxic metabolite.
- Test methods must allow determination of residues in or on plant tissue, soil and water
- Preliminary efficacy data indicating the effectiveness for the proposed use
- Chronic toxicity data such as reproductive defects, carcinogenicity, mutagenicity, teratogenicity etc

A provisional clearance is converted to a full registration upon acceptance of the required data.

2.9.4 The Pesticides Technical Committee's Decision

The Registrar contacts the Chairman of the PTC who in turn convenes a PTC meeting to deliberate on the proposals of the sub-committees. The recommendations of the PTC is then

processed by the Registrar and forwarded to the Executive Director EPA for presentation to the EPA Board for final approval or otherwise.

2.9.5 Administrative Process for Registering the Product

After approval by the EPA Board, the Registrar issues the certificate of registration. The file data package of the product is finally archived.

2.9.6 Process for Refusal of Product Registration

If the registration is refused by the EPA Board, the Registrar shall within fourteen days of the decision, inform the applicant in writing of the refusal and the grounds for the refusal. The registrar will take the following steps:

- Verify the lacking or deficient items not submitted
- Stamp the first page of the original application form "Refused"
- Attach the final refusal letter (placed on top), a copy of the refused application, a copy of the proposed to refuse letter listing the deficiencies and copies of the evaluation reports and a label. These are stapled together, marked "Refused File" and archived. Mark the route; sheet "Refused " with the date and signature
- File the data package, status sheet, and route sheet for storage on the "Refused Denied Product" shelve in the.
- Record the tracking ID# as final to Deny on the weekly log action.
- After the final denial action has been taken as described above, the applicant may appeal or reapply for registration by submitting a new application for registration.

2.9.7 Issuing a Product Certificate of Registration

The following steps are taken when a product is ready to be registered:

- The Registrar initials the application for registration form and writes the EPA registration number with correct alpha code, and tracking ID# in the upper right hand corner. The first time registration of a product shall be given the alpha code AA. For subsequent renewals, the alpha code is the next one in the sequence AB, AC AD etc.
- Indicate the conditions of registration in a letter.

The registration officer will:

- Prepare the appropriate registration letter for the Registrar to sign. Prepare a certificate for the Registrar to sign.
- For a company name change, issue a new certificate to supersede the old name certificate. The old company name certificate is marked "Amended" in the company certificates file
- Forward a copy of the Certificate of Registration, the copy of the registration letter, and the product file documents listed above to the strong room for filing.

2.9.8 Identical products registration

A product, which is identical to a currently registered product, may be registered without scientific evaluation, and/or submission of data, if the following criteria are met.

- The labels must be identical except the brand name and registration number.
- The formulations must be the same.
- The appropriate documentation and letters of authorization must be submitted.

Identical product registrations involve the issuance of a Certificate of Registration and can be any of the following:

- Product ownership change (with or without a change in firm name).
- Company name change without a change in ownership.

Additionally, some minor differences to a currently registered product can also allow the product to be registered as identical. The formulation can still be considered identical if the only difference is:

- Addition of a fragrance or dye.

The label can still be considered identical if the only difference in the label is:

- Change to water soluble packaging (WSP)
- Storage and disposal statements appropriate to the container type or size.

Identical registration is limited to only one registered product.

2.9.9 Product Ownership Change

For a change in product ownership the following shall be required:

i. An application for change of product ownership.
ii. Appropriate application fee.
iii. Four copies of printed labels indicating the product name, company name and address

A certificate of registration cannot be transferred if there is a change of business ownership.

CHAPTER 3

DATA REQUIREMENTS FOR OBTAINING PRODUCT REGISTRATION AND FOR LABEL AMENDMENTS

3.1 Introduction

Data requirements for obtaining product registrations are the subject of this chapter. In this regard an applicant may be allowed to use data on file if only authorized in writing by the owner of the data. All data must be submitted in full. During scientific evaluation, an evaluator may recommend provisional registration for certain types of data. The adequacy of submitted data is determined during the scientific evaluation process. An applicant who does not believe a required study is applicable to their product use patterns can request the data to be waived indicating reason for the waiver request.

The following are the types of basic data, which are submitted in support of various types of registrations and various types of uses. This section includes only a description of the types of data. Data required for Provisional Clearance, Full Registration Composition, Modification of a pesticide product are presented below. Each data requirement, and the exceptions, is also outlined.

3.2 Acute Toxicology

Acute toxicology studies must be complete; summaries are not acceptable.

- Acute oral LD50 (for rats) on the formulated product, unless the product is a gas or is highly volatile.
- Acute dermal LD50 (for rats) on the formulated product.
- Acute inhalation LC50 on formulated products. This data is applicable only to such pesticides as gases, fumigants, wettable powder (particles < 50 μm) or if label states use of mechanical spray, aerosol, fogger, spray, or indoor. This is not required if the product is applied through course spray that is meant to be applied as a spot spray, through a hand pump, or if a hose-end sprayer is used. The duration of inhalation should be stated.
- Primary eye irritation data (for rabbit) on the formulated product: The applicant indicates if there is irritation of rabbit eye after only one application of the non-diluted commercial product. For these reasons, a product with pH less than 2 or greater than 11.5 or that has shown corrosive properties for the skin will not have to be tested.
- Primary skin (dermal) irritation data (for rabbits) on the formulated product: The applicant indicates if there is irritation of rabbit skin after only one application of the non-diluted commercial product. For these reasons, a product with high pH or that has shown corrosive properties for the skin will not have to be tested.
- Skin sensitisation study if repeated dermal exposure occurs under conditions of use.

- Rodenticide biochemical data describing the metabolic pathway and the mode of action in animal models suitable for assessment of dermal absorption for extrapolation to humans.

Requests for label amendments should be accompanied by applicable acute toxicology study.

The labelling shall be acceptable if all hazards identified by acute toxicology studies are mitigated by precautionary statements and the signal word.

3.3 Chemistry of Formulated Product

- Statement of composition for the formulated product including the chemical name and percent by weight of each active and inert ingredient. If the registrant does not identify the certified limits, Registrar will calculate the amounts.
- Chemical composition and structure of each active substance.
- Discussion of the formation of impurities arising from the manufacturing process.
- The physical and chemical properties can be a summary table. Water solubility, vapour pressure, and octanol/water partition coefficient (Kow) must be available as full studies on the active substances for agricultural use products.
- Analytical method for each active substance.
- For a new active substance, analytical standards shall be sent by the applicant directly to the CCMC.
- Flash point and volatility, if the product contains more than 70 percent petroleum distillates.
- Storage stability conducted at room temperature or under warehouse conditions for a one-year period in the product's commercial packaging.
- Material Safety Data Sheet (MSDS) for each inert ingredient.

3.4 Crop Residues

- Residue chemistry data for new products with food or feed uses on the label or for label amendments adding food or feed uses, except certain crops grown for seed. The residue data is used to determine whether established tolerance levels are likely to be exceeded when the product is used in accordance with its label.
- Studies must be conducted under Ghanaian use conditions allowing determination of residues in or on plants and animals used for food or feed.
- Residue method for determining residues of each new active substance and its metabolite for which a residue tolerance has been established. The method must permit completion of the test within a continuous 24-hour period.

3.5 Ecotoxicology Data Requirements - Active substance(s)

Eco-toxicological data is required for products intended for the following:

- Outdoor uses where the pesticide is likely to come in contact with fish or wildlife.
- Agricultural uses. This includes golf courses, recreation areas, and others.
- Forestry sites.

Eco-toxicological data are however not required for indoor or home use products

Note: Data requirements for each package should be confirmed in advance with the Pesticides Division of the CCMC.

Table 3.1: Basic data requirement for aquatic organisms

Mandatory, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
Ecotoxicology				
Fish – acute			LC_{50}	mg/L
Fish – long-term			NOEC	mg/L
Fish – BCF			BCF	--
Fish – reproduction			NOEC?	mg/L
Water fleas – acute		*Daphnia*	IC_{50}	mg/L
Water fleas – long-term			NOEC	mg/L
Algae – acute	72 hours		IC_{50}	mg/L
Algae – long-term			NOEC	mg/L
Fate & behaviour				
Solubility in water				mg/L
Hydrolysis			$DT_{50\ (hydrolysis)}$	
K_{ow} (or P_{ow})				
DT_{50}			DT_{50}	
Adsorption to field soil				
PEC surface water (long term)	42 days after application			

Table 3.2 Additional data requirements for aquatic organisms

Mandatory, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
Ecotoxicology				
Fish – acute	96-hours	2 species, of which at least 1 warm water species	LC_{50}	mg/L
Fish – chronic	21-day – 3 months	1, preferably warm water, species	NOEC	mg/L
Fish – BCF	[Often part of chronic study]	1, preferably warm water, species	BCF	--
Fish – reproduction		May be combined with the chronic test	NOEC	mg/L
Water fleas – acute	24/48-hours	*Daphnia*	IC_{50}	mg/L
Water fleas – chronic	21-day	*Daphnia*	NOEC	mg/L
Algae – acute	3-5 day	1 species of green algae	EC_{50}	mg/L
Algae – chronic		1 species of green algae	NOEC	mg/L
Fate & behaviour				
Solubility in water				mg/L
Adsorption capacity		To soil	K_{oc} and/or K_d and/or K_{om}	L/kg
Soil aerobic half-life		In field soil	DT_{50} [field]	Days
Hydrolysis half life		In water, at pH 7	DT_{50} [hydrolysis]	Days
Photolysis half life		In water	DT_{50} [photolysis]	Days
Aquatic half-life		Overall field half-life (including hydrolysis)	DT_{50} [aquatic]	Days
Sediment half-life		In (flooded) sediment	DT_{50} [sediment]	Days

Table 3.3 Supplementary data requirements for aquatic organisms

Conditional, upon specific pesticide characteristics or use patterns			
Test	**Duration**	**Species**	**Condition**
Algae and/or aquatic plants	Acute	One or more, not used in the core set	For herbicides
Aquatic invertebrates	48/96-h (E) LC_{50}	One or more insect or crustacean species, not used in the core set	For pesticides to be applied to water
Fish	96-h LC_{50}	One additional warm water species, not used in the core set	For pesticides to be applied to water
Aquatic invertebrates	48/96-h E/LC_{50}	One or more crustacean species (e.g. mysids)	For pesticides that may contaminate estuarine/marine environments
Soil dwelling invertebrates	Chronic	e.g. *Chironomus* sp.	If the pesticide persists in the sediment
Other tests may be required			

Table 3.4: Waiver of data requirements for aquatic organisms

Conditional, upon specific pesticide characteristics or use patterns	
Data requirement to be waived	**Condition**
All aquatic toxicity tests	Products that can solely be used for indoor fumigation
All aquatic toxicity tests	Rodenticidal baits (unless to be used in/around irrigated rice fields)
All aquatic toxicity tests	Household aerosols and mosquito coils (unless to be used in Chinese restaurants)
Chronic fish and invertebrate tests	If pesticide is not applied to water **and** it is only applied once a year **and** it is not persistent in water (suggested: field DT_{50} of parent and major metabolites in the field < 2 days) **and** pesticide has a low bioaccumulation potential (suggested: log K_{ow} < 2)

Table 3.5: Data requirements for groundwater

Mandatory, unless submitter can provide an acceptable reason not to provide certain data.		
Property	**Description**	**Unit**
DT50 [soil]		
K_{oc}	Organic carbon normalized soil/water equilibrium coefficient	L/kg
DT50 [soil, aerobic]	Pesticide aerobic half-life in relevant soil type (laboratory data)	Days

Table 3.6 Data requirements for soil organisms

Condition: always, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
Earthworms			LC_{50}	mg product/kg soil
Soil microorganisms		Soil respiration, nitrogen & carbon mineralization		
DT_{50} [soil]				days
PEC [soil – long term]	50 days after last spray			
Mobility				
Adsorption				
Linked residues	Degree of mobility of metabolites after 100 days			
DT_{50} [photolysis]		On soil surface [?]		Days

Notes:

Specific issues of concern when doing the soil risk assessment are:

- In the humid parts of Ghana, earthworms are an important group of organisms for maintaining soil fertility
- In the semi-arid north of Ghana, earthworms will be less important; termites and dung beetles will probably be more important for soil fertility in these areas

The main objective of the soil organisms' data is to assess the risks posed to soil organisms of economic importance by pesticide products.

Table 3.7: Additional data requirements for soil organisms

Condition: always, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
Ecotoxicology				
Earthworms – acute	14 days	Preferably a species/genus relevant to Ghana (e.g. *Lumbricus*); other species, such as *Eisenia,* are also acceptable though	LC_{50}	mg a.i./kg dry soil
Soil micro-organisms	Up to 100 days	Nitrogen transformation (ammonification and nitrification) & carbon mineralization (respiration)	NOEC	mg a.i./kg dry soil
Fate & behaviour				
Aerobic degradation	Up to 120 days	Laboratory test, preferably at 25 or 30 °C (soils relevant to Ghana)	$DT_{50\ [soil-aerobic]}$ and, if possible $DT_{90\ [soil-aerobic]}$	Days
Soil photolysis	Up to 30 days	Laboratory test, preferably at 25 or 30 °C	$DT_{50\ [photolysis]}$	Days
Field dissipation	At least until 50% dissipation	Field test, preferably carried out at more than one location, under hot tropical conditions	$DT_{50\ [field]}$ and, if possible $DT_{90\ [soil-aerobic]}$	Days
Mobility in soil		Laboratory soil leaching study		
Adsorption/ desorption	Until equilibrium (or 24 hours)	Specify pH and soil types (% organic carbon)	K_d and/or K_{oc}	L/kg

Table 3.8: Supplementary data requirements for soil organisms

Conditional, upon specific pesticide characteristics or use patterns			
Test	**Duration**	**Species**	**Condition**
Earthworms – sub lethal	21 days (or longer)	As in acute test. Endpoints of the test are earthworm growth and cocoon production	If repeated treatments or if the pesticide is moderately persistent in soil (e.g. DT_{50} > 1 month)
Other soil organisms		Springtails, soil mites, termites, dung beetles, tenebrionid beetles	If data are available (e.g. termite/ tenebrionid data may be available for locust control insecticides)
Soil algae			Herbicides, especially if persistent on soil surface
Nitrogen fixation		*Rhizobium* spp.	Pesticides to be applied to leguminous crops
Anaerobic degradation	Up to 120 days	Laboratory test, preferably at 25 or 30 °C	If pesticide is likely to be applied to soils that are flooded (e.g. to irrigated rice)
Non-extractable (bound) residues			If large fraction of residues is "irreversibly" bound to soil (in EU > 70% of initial dose)
Other tests may be required			

Table 3.9: Waiver of data requirements for soil organisms

Conditional, upon specific pesticide characteristics or use patterns	
Data requirement to be waived	***Condition***
All soil toxicity tests and soil fate & behaviour studies	Products that can solely be used for indoor fumigation
All soil toxicity tests	Rodenticidal baits
All soil toxicity tests and soil fate & behaviour studies	Household aerosols and mosquito coils
Others situations may apply	

Table 3.10: Basic data requirements for terrestrial vertebrates

Condition: always, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
Mammals *(from the human toxicology data set)*				
Rat – acute oral			LD_{50}	mg a.i./kg bw
Rat – subchronic				
Rat – chronic				
Birds				
Bird – acute oral			LD_{50}	
Bird – acute dietary			LC_{50}	
Bird – chronic				
Bird – reproduction				

Table 3.11: Additional data requirements for terrestrial vertebrates

Condition: always, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
Mammals *(from the human toxicology data set)*				
Rat – acute oral	Single dose	*Rattus* spp. (+ other species if data available)	LD_{50}	mg a.i./kg bw
Rat – chronic	2 years	*Rattus* spp. (+ mouse, if	NOEL	mg a.i./kg bw/day and

Condition: always, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
dietary		data available)	and NOEC	mg a.i./kg diet
Rat – reproduction and/or teratology study	At least 2 generations	*Rattus* spp. (+ other species if data available)	NOEL and NOEC	mg a.i./kg bw/day and mg a.i./kg diet
Birds				
Bird – acute oral	Single dose	At least 2 species (often bobwhite quail, Japanese quail, mallard duck)	LD_{50}	mg a.i./kg bw
Bird – short term dietary	5 days	At least 2 species (often bobwhite quail, Japanese quail, mallard duck)	LC_{50}	mg a.i./kg diet (also to be expressed as daily dose: mg a.i./kg bw/day)
Bird – reproduction	Until F1 generation is 14 days old	At least 1 species	NOEL and NOEC	mg a.i./kg bw/day and mg a.i./kg diet

Table 3.12: Supplementary data requirements for terrestrial vertebrates

Conditional, upon specific pesticide characteristics or use patterns			
Test	**Duration**	**Species**	**Condition**
Mammals			
Rat – sub acute dietary	Repeated dose (~ 5 days)	*Rattus* spp.	For certain anticoagulant rodenticides
Rat – subchronic dietary	90 days	*Rattus* spp. (+ dog, if data available)	If data are available.
Bird – granule/seed/bait palatability study		1 species of birds	For pesticide granules, treated seeds and broadcasted (small) baits
Reptiles		Lizard species	If data are available.
Amphibians		Frog species	If data are available.
Other tests may be required			

Table 3.13: Waiver of data requirements for terrestrial vertebrates

Conditional, upon specific pesticide characteristics or use patterns	
Data requirement to be waived	***Condition***
All bird toxicity studies	Products that can solely be used for indoor fumigation
All bird toxicity studies	Household aerosols and mosquito coils
Bird – reproduction study	If it can be justified that continued or repeated exposure of bird adults, or exposure of nest sites during the breeding season, is unlikely to occur.
Others situations may apply	

Table 3.14: Basic data requirements for bees

Condition: always, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
Presently				
LD_{50} ingestion				
LD_{50} contact				

Notes:

Specific issues of concern when doing the risk assessment of products on bees are:

- Protection of pollinators in crops that depends much on insect pollination for fruit setting quantity and quality. These include the following crops in Ghana: *[to be further identified]*
- Protection of bees in important honey/wax producing areas in Ghana. These include the following regions: *[to be further identified]*

Table 3.15: Additional data requirements for bees

Condition: always, unless submitter can provide an acceptable reason not to provide certain data.				
Test	**Duration**	**Species**	**Endpoint**	**Unit**
Oral toxicity	Acute	*Apis mellifera,* or another species relevant to Ghana	LD_{50}	µg/bee
Contact toxicity	Acute	*Apis mellifera,* or another species relevant to Ghana	LD_{50}	µg/bee

Table 3.16: Supplementary data requirements for bees

Conditional, upon specific pesticide characteristics or use patterns			
Test	**Duration**	**Species**	**Condition**
Bee brood feeding test	Sub-acute	*Apis mellifera,* or another species relevant to Ghana	If pesticide is an insect growth regulator (IGR)
Other tests may be required			

Table 3.17: Waiver of data requirements for bees

Conditional, upon specific pesticide characteristics or use patterns	
Data requirement to be waived	**Condition**
All bee tests	Products that can solely be used for indoor fumigation
All bee tests	Rodenticidal baits
All bee tests	Household aerosols and mosquito coils
All bee tests	Granular pesticide formulations, unless the pesticide is systemic or may cause indirect effects
All bee tests	Seed treatment formulations, unless the pesticide is systemic or may cause indirect effects
All bee tests	Pre-emergence herbicides, unless the pesticide is systemic or may cause indirect effects
Others situations may apply	

3.5.1 Data requirements - first tier

The following data referred to as first tier studies are required on the active substance.

- Birds oral LD_{50}
- Birds dietary LD_{50}
- Freshwater fish LC_{50} warm water species.
- Freshwater aquatic invertebrate LC_{50} preferably Daphnia magna).

3.5.2 Data requirements - second tier

The second tier studies may not be required depending on the type of use and results of the first tier studies:

3.5.3 Terrestrial Mammalian Toxicity

This requirement is generally waived since the other studies on safety of products to humans and domestic animals generally provide adequate characterization of toxic potential to mammals. However, if other studies demonstrate a wide variation in toxicity between species or if exposure to wild mammals is predicted to be high as a result of the nature of the use, a wild mammal LD50 study may be required.

3.5.4 Reproduction Test - Birds

A test which measures potential reproductive effects of a compound in the diet of birds may be required of a compound which as a result of use, is likely to cause prolonged or repeated exposure to birds; or which is persistent in the environment and therefore may persist in avian feed; or which tends to bioaccumulate in plants or animals as predicted by the octanol-water partition coefficient; or which bears a structural similarity to chemicals known to bioaccumulate.

3.5.5 Acute LC50 Estuarine and Marine

Studies on estuarine and marine organisms are required when direct application to such sites is specified by label direction or when significant concentrations may enter estuarine or marine environments due to the nature of the use or predicted mobility and persistence of the compound.

3.5.6 Fish Early Life Stage and Aquatic Invertebrate Life Cycle Studies

These are required when the compound is to be applied directly to water; or when the compound is expected to be transported to water as a result of use, or if the use is likely to result in continuous or recurrent exposure to water; or if any LC50 or EC50 to an aquatic organism is less than 1.0ppm, or if the estimated environmental concentration is predicted to equal or exceed 0.01 times any LC50 or EC50 for an aquatic organism; or reproductive effects, cumulative effects or persistence in water (half-life more than 4 days) are indicated from any other study.

3.5.7 An Aquatic Organism Accumulation Test

This test may be required if residues are likely to occur in the aquatic environment and if the product or its principal degradation products has a water solubility less than 0.5ppm and an octanol-water partition coefficient greater than 1000; and the product is relatively persistent in water (half-life more than 4 days); or if the compound or its metabolites has demonstrated a tendency to accumulate in organs and tissues of mammals or avian species.

3.5.8 Non-target bee toxicity

Bee toxicity data is required for pesticides, which are likely to contact commercial apiaries or foraging bees.

3.6 Efficacy Data (Reviewed by Bio-efficacy sub-committee)

Each request for product registration must include data supporting efficacy claims. The term efficacy refers to a product's performance.

Efficacy data is not required for Section 5 EUPs, RAs, manufacturing-use only (formulating into pesticides) products, or if selected as a deferred study for an Interim registration.

Tests must address factors normally encountered in the use patterns claimed for the product. These factors depend on the type of pests and site to be treated, and may include the following:

- Pests, sites, use situations.
- Methods of application and application equipment.
- Application rates, timing, and number of applications.
- Nature and level of pest control, duration of pest control.
- Benefits or adverse effects of product use.
- Impact of climate on chemical residues and bait acceptance
- Nature and extent of spray coverage
- Adverse environmental effects such as bioaccumulation and toxicity to beneficial non-target organisms.
- Any other factors which would establish the safe, effective use of the product.
- Increase in population levels of other pests of the target site resulting from control of predatory or competitive microorganisms, or interference with the performance of other pesticides.

Tests may include the following information:

- Comparison tests conducted with various pesticides.
- Tests conducted with various pests, diseases and plants.
- Tests with different application rates.
- Tests for dose response.
- Tests conducted with pre-treatment, post-treatment, untreated control or standard product counts.
- Data on application methods - foliar spray, dust, fumigation, tree injection, irrigation water.
- Effect on beneficial and non-target organisms.

3.7 Phytotoxicity – Reviewed by Bio-efficacy sub-committee

- Data for products applied on or near desirable plants. The data must be obtained under Ghanaian or similar environmental use conditions and indicates that there will be no unacceptable plant injury.
- Phytotoxicity data is not required for Section 5 EUP's or for Research Authorizations (RAs).

3.8 Chronic Toxicology Data

Chronic toxicology data includes the following:

- Results of chronic feeding studies on the active substance in two mammalian species.
- Results of long term feeding studies for oncogenicity on the active substance in two animal species (rat and mouse preferred).
- Results of two teratogenicity studies and a two-generation combined male/female reproductive study with the active substance.
- Results of three mutagenicity studies with the active substance that detect gene mutations (reverse mutation assay, forward mutation assay, and in vivo cytogenetics).
- General metabolism is required if chronic feeding or oncogenicity studies are required.
- Results of acute delayed neurotoxicity study in hens, if active substance is an organophosphate or carbamate or is known or expected to be a neurotoxin.

3.9 Data requirements for renewal of certain registration

The following conditions must be satisfied before renewal of any registrations

- Data available to the registrant, and not previously submitted, pertaining to the general data requirements for product registration.
- For certain types of time-limited registrations, the data required by the terms of the registration as indicated in the following sections.

3.10 Adverse Effect Disclosure with Application for Renewal

Each application for renewal includes a statement that the applicant has complied with the adverse effects disclosure requirements.

If adverse effects disclosure information or data is received with the renewal application, the data or information is forwarded to the designated Registrar for processing.

3.11 Provisional Registration Data for Renewal

The registrant of any conditionally registered pesticide must submit the specified data within the specified time frames. An annual report detailing the progress towards development of each item of data is required for annual renewal of the registration. The conditional registration may not be renewed unless this report is submitted with the renewal application.

3.12 Emergency Registration

An Emergency Registration can be issued for only one year, with a one year renewal allowed if the scientific evaluation process is not yet completed. The registrant must submit evidence that the emergency pest problem continues. This information must be reviewed before the registration can be renewed.

CHAPTER 4

ACCEPTABILITY CRITERIA-HUMAN TOXICOLOGY AND BIOEFFICACY

4.1 Human Toxicology

Human toxicity assessment is undertaken whenever the use pattern of a formulated product is such that human beings are directly or indirectly exposed.

4.1.1 WHO Hazard Class of the Product

End –user pesticide products (formulations) that fall in the WHO hazard class Ia (*extremely hazardous*) will not be registered.

If the end-user product falls in the WHO hazard class Ib (*highly hazardous*), the product may not be registered or, under exceptional circumstances, be severely restricted (if reasonably possible under the proposed use conditions).

Classification of the pesticide will be on the basis of the LD_{50} of the formulated product (as submitted by the company). In the absence of such data, or as a secondary quality check, the LD_{50} of the product shall be calculated using the latest WHO guidelines to classification.

4.1.2 Occular Irritability

If the pesticide product (formulation) causes severe eye irritation, the product will not be registered. Though data will be primarily drawn from submitted dossier, it may be crosschecked against one or more of the following secondary assessments (if available).

- WHO toxicology reviews for the joint Meeting on Pesticide Residues (JMPR).
- Registration reviews carried out by well established registration authorities such as USEPA, NRA-Australia, EU)

4.1.3 Dermal Irritability

Pesticide formulations that cause severe skin irritation, or if they happen to be skin sensitizers will not be registered.

- WHO toxicology reviews for the joint Meeting on Pesticide Residues (JMPR)
- Registration reviews carried out by well established registration authorities such as USEPA, NRA-Australia, EU)

4.1.4 Chronic Toxicity

The end-user product shall not be registered if evidence available indicates that the product is a known or probable mutagen, carcinogen, teratogen and/or has known or probable effects on reproduction. In evaluation for carcinogenicity, products within the following categories will not be registered.

- International Agency for Research on Cancer (IARC): Group 1 (*carcinogenic to humans*) and Group 2A (*probably carcinogenic to humans)*

- US-EPA: [*old classification*] Group B1 and B2 (*probable human carcinogen*); or [*new classification*] Group L2 (*likely carcinogenic to humans*).

In each case data will primarily be drawn from the dossier submitted, but may be cross-checked against one or more of the following secondary assessments (if available and as applicable).

- WHO toxicology reviews for the joint Meeting on Pesticide Residues (JMPR)
- Registration reviews carried out by well established registration authorities such as USEPA, NRA-Australia, EU)

4.2 Obligation to International Conventions

4.2.1 Pesticide Products on PIC List

Pesticides listed in Annex III of the Rotterdam Convention (the PIC) will either not be registered or under exceptional circumstances be severely restricted (if reasonably possible under proposed use conditions)

4.2.2 POP Pesticides

i. POP pesticides that appear in Annex A of the Stockholm Convention shall not be registered.

ii. Products that appear in Annex B of the Stockholm convention shall either not be registered or registered as severely restricted use pesticide.

iii. Pesticides with characteristics defined as follows in Annex D of the Stockholm Convention shall be subjected to proper risk assessment as discussed under Ecotoxicology later in this chapter.

4.3 Problems in Ghana

If any serious problems (health- environmental- efficacy-, or others) should be encountered in the course of usage in Ghana with the end-user product, any registration will be cancelled. Furthermore, if the use of a product would cause problems in international trade of treated commodities, as happens when the MRL for a pesticide has been set to zero in the main importing country, that pesticide shall not be registered on a crop that is destined for export to that country. At best registration may be put on hold pending further developments.

CHAPTER 5:

ACCEPTABILITY CRITERIA - ECOTOXICOLOGY

5.1 Evaluation Procedure for Aquatic Organisms

5.1.1 Likelihood of Aquatic Exposure

The likelihood of (direct or indirect) exposure of the target environment by the pesticide shall be assessed, given the requested (or otherwise likely) use pattern. If exposure is unlikely under Ghanaian conditions, no further risk assessment for the target environment is needed.

5.1.2 Pre-screening - check completeness of the dataset

If the dataset is not complete, no further assessment shall be carried out and the applicant shall be requested to provide the missing data, or justify why these data were not submitted.

5.1.3 Pre-screening - check quality of the dataset

If possible, endpoint values for the different toxicity tests shall be obtained from secondary sources (preferably registration reviews from reputable registration authorities, or from international organizations [e.g. the Environmental Health Criteria]. A comparison table shall be made as well as an assessment of the existence of any major differences between the data submitted by the applicant and the secondary sources.

If large differences exist, the applicant shall be requested for clarifications. If these are not forthcoming, the risk assessment shall be based on a dataset consisting of the most sensitive species in the comparison table.

(a) Pesticides of very low hazard to the aquatic environment ["green zone" pesticides]

If the dataset is complete and of acceptable quality, and if **all** the toxicity endpoints ((E)LC_{50}s and NOECs) are higher than the trigger values listed in the table below, no further aquatic risk assessment shall be carried out.

Criterion	**·Trigger value**
Acute LC_{50} [fish, crustaceans]	> 100 mg/L
Acute EC_{50} [algae]	> 100 mg/L
Chronic NOEC [fish, algae, crustaceans]	> 1 mg/L
Criteria based on FAO (1989) & GHS (2003)	

The above is **not applicable** to pesticides that need to be applied directly to water, or for pesticides that have bioaccumulation potential or are relatively persistent in water.

(b) Pesticides of very high hazard to the aquatic environment ["red zone" pesticides]

If the dataset is complete and of acceptable quality, and if the criterion in the table below is higher than the trigger values listed, registration of the pesticide in Ghana will, in principle, be refused.

Criterion	Trigger value
Persistence in the aquatic environment **as well as** bioconcentration potential	Field-$DT_{50water}$ [of parent compound and main metabolites] > 2 months **and** BCF > 5000 **or** log K_{ow} > 5

(c) "Grey zone" pesticides

All pesticides, which are not clearly in the "green" or the "red zone", will go through a more detailed risk assessment, as outlined below.

5.1.4 Exposure Estimates

(a) Tier I estimate (very worst case)

Assumptions: 100% of AR applied to water; no pesticide degradation; very shallow water body (30 cm deep); static water body (no dilution of pesticide); multiple applications cumulated into one application event. Very worst case PEC shall be calculated as follows:

$$PEC\ (mg/L) = \frac{AR\ (g\ a.i./ha)\ x\ AF}{3000}$$

Where:

PEC = predicted environmental concentration

AR = application rate

AF = application frequency (maximum number of treatments per season)

Tier I risk assessment shall be carried out as above, before continuing to calculate Tier II exposure estimate.

(b) Tier II estimate (realistic worst case)

This shall be carried out if Tier I risk assessment suggest that risk for the aquatic environment exists.

Both the FAO-SEAM model and the EU-FOCUS STEP-1-2 model shall be ran. The assumptions underlying these models, and the physico-chemical input data required to run the models, are given in Annexes 1 & 2 to this section.

Every effort shall be made to ensure that the pesticide application conditions, cropping situation and environmental conditions used in the models are as close as possible to the Ghanaian situation that is evaluated. The likely differences between the two models and the

Ghanaian situation shall be evaluated and an assessment made if this would likely result in an underestimate or an overestimate of surface water exposure in the local situation.

The outputs of the models shall be printed and the results used in the Tier II risk assessment in section 4.1.4.

(c) Tier III estimate (more realistic cases)

If the Tier II risk assessment indicates risk to the aquatic environment, specific PEC calculations for the Ghana situation may be calculated. These will be *ad hoc* estimates, based on knowledge of the local environmental and pesticide application conditions. No locally validated models are available for such estimates as yet.

See the EPPO schemes on Surface Water and on Aquatic Organisms for more guidance.

5.1.5 Risk Assessment

The acceptability triggers that may be used for the risk assessment are indicated in Table 5.1.

Table 5.1 Acceptability criteria for surface water

Assessment	**Trigger**	
	EU	**US-EPA**
Acute risk is not acceptable if:	RQ > 0.01	RQ > 0.05 **or** 0.1 **or** 0.5 [1]
Chronic risk is not acceptable if:	RQ > 0.1	RQ > 1
[1] trigger is 0.05 if endangered species; 0.1 of risk can be mitigated by restricted use; 0.5 for high-risk category. Criteria based on EU (1997) & USEPA (1999)		

If a trigger is passed, either the pesticide is considered of **high risk to the aquatic environment**, **or** the **assessment is refined** (i.e. better exposure estimates and/or better toxicity data).

(a) Tier I (very worst case)

Calculate the acute Risk Quotient (RQ), as follows:

$$Acute\ RQ = \frac{PEC_{\ [peak\ concentration]}\ (mg/L)}{Acute\ (E)LC_{50\ [most\ sensitive\ species]}\ (mg/L)}$$

Where:

PEC = predicted peak environmental concentration, estimated using the "very worst case" scenario (Section 3.3-1).

The (E) LC_{50} of the most sensitive aquatic species from the dataset shall be used.

If pesticide is acceptable, no further exposure estimates are needed. Go to 4.1.5 to assess the risk for bioaccumulation.

(b) Tier II (reasonable worst case)

Calculate the acute Risk Quotient (RQ) as in section 3.4-2 (above), and the chronic RQ as follows:

$$Chronic\ RQ = \frac{PEC_{[chronic]}\ (mg/L)}{NOEC_{[most\ sensitive\ species]}\ (mg/L)}$$

Where:

PEC = predicted environmental concentration, time-averaged over ***t*** days, estimated using the FAO-SEAM and FOCUS STEP-1-2 models.

The ***t*** is chosen to average the PEC over according to the organism and the toxicity test, which is used in the RQ: time ***t*** is roughly the duration of the chronic test, which resulted in the NOEC that is used. If no information on the test duration is available, twenty one (21) days is chosen as a default.

The NOEC of the most sensitive aquatic species from the dataset is used.

If pesticide is acceptable, no further exposure estimates are needed. Go to 4.1.5 to assess the risk for bioaccumulation.

(c) Tier – III (more realistic cases)

To be carried out on an *ad hoc* basis, to be decided by the risk assessor, and if data are available. See the EPPO risk assessment schemes for more information.

5.1.6 Bioconcentration

The octanol-water partition coefficient (K_{ow} or P_{ow}) can be used as an indicator for the potential that the pesticide may bioconcentrate in fish or other aquatic organisms. The triggers below indicate if the pesticide has bioconcentration potential.

Criterion	**Trigger**	
	EU	**GHS**
The pesticide has the potential to bioconcentrate if:	Log K_{ow} > 3	Log K_{ow} > 4

If the trigger is passed, a study determining Bioconcentration Factor (BCF) (normally in fish) should be provided by the applicant. (*Note:* a log K_{ow} > 5 may indicate that the pesticide should be considered as a POP – see section 3.2-4).

The following acceptability criteria for BCFs may be applied:

Criterion	**Trigger**	
	EU	
A pesticide has a high potential for bioconcentration in aquatic organisms if:	BCF > 100 (for not readily biodegradable pesticides)	
	Or	
	BCF > 1000 (for readily biodegradable pesticides)	
Criteria based on EU (1997)		

Note: if rapid depuration of the pesticide from the fish occurs after exposure stops, the risk of bioconcentration will be low if pesticide concentrations in the field do not persist. **If this trigger is passed**, either the pesticide is considered of **high risk to the aquatic environment**, **or** the **assessment is refined** (i.e. better exposure estimates and/or better toxicity data).

5.1.7 Review of existing evaluations

If any registration evaluations are available from reputable sources, for the pesticide under evaluation, the conclusions of the aquatic risk assessment chapter in these evaluations may be reviewed. If major differences in conclusions exist between the evaluation for Ghana and the external reviews, the assessor shall try to determine why these differences exist. Note that often the differences between the Ghana evaluation and one done in a temperate region may be explicable because of differences in climate, application rates and frequencies, or other local factors.

5.1.8 Registration decision

If the pesticide is found to be of high risk to the aquatic environment, the recommendations made to the PTC may include refusal of registration, restriction of the use of the pesticide, or a range of other possible risk reduction measures.

Risk reduction methods shall be decided upon on a case-by-case basis, taking into account the intended application methods, use pattern, ecosystems that may be exposed, technical capacity of the users of the product, and the possibility to enforce any restrictions that may be decided upon. Possible measures to reduce the risk to the aquatic environment include:

- reduction of the application frequency
- reduction of the application rate
- use of low-drift application equipment
- use of low-drift formulations (e.g. granules)
- use of buffer zones between the treated areas and water bodies

- warning statements on the label
- restriction of use of the pesticide by trained/licensed applicators only
- restriction of use of the pesticide to non-sensitive parts of the country

5.1.9 Documentation

The risk assessor shall always document the assessment as thoroughly as possible. Inputs and outputs of exposure models should be saved and printed out. The species and toxicity endpoints reviewed for the assessment should be listed and the toxicity endpoint values used in the calculation of the Risk Quotient should be specified. A short, concise, summary report of the exercise should be prepared for the plenary meeting of the sub-committees. All documentation should be filed in the registration file of the product.

5.2 Evaluation Procedure for Ground Water Contamination

5.2.1 Likelihood of Exposure of Groundwater

The likeliness of exposure of groundwater by the pesticide shall be assessed, given the requested (or otherwise likely) use pattern. If exposure is unlikely under Ghanaian conditions, no further risk assessment for groundwater is needed.

5.2.2 Pre-screening - Check completeness of the dataset

If the dataset is not complete, no further assessment shall be carried out and the applicant requested to provide the missing data, or justify why these data were not submitted.

5.2.3 Pre-screening - Check quality of the dataset

If possible, endpoint values for the required physico-chemical properties shall be obtained from secondary sources (preferably registration reviews from reputable registration authorities). Additional physico-chemical data may be obtained through the USDA Pesticide Properties database. Make a comparison table and assess if major differences exist between the data submitted by the applicant and the secondary sources.

If large differences exist, the applicant shall be requested for clarifications. If these are not forthcoming, the risk assessment shall be based on a dataset for sandy soils.

5.2.4 Exposure Estimates

The FAO-GEAM model shall be ran to obtain an exposure estimate of groundwater to the pesticide (see Annex 1 for the main assumptions of the model).

5.2.5 Risk Assessment

The acceptability triggers that may be used for the risk assessment are summarized in Table 5.2.

Table 5.2: Acceptability criteria for groundwater

Criterion	Trigger	
	WHO	**EU**
Maximum permissible pesticide concentrations	**Drinking water** Guidance Values: see Annex 2 or formula below	**Water intended for human consumption** 0.1 µg a.i./L (for individual pesticides) [1] **or** 0.5 µg a.i./L (for total pesticides)
[1] In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parametric value is 0.03µg/L. Criteria based on WHO (1998 & 2003), EU (1998)		

The WHO calculates its Guideline Values (GV) according to the following equation:

GV = (TDI x bw x P) / C

Where:

TDI = tolerable daily intake (mg/kg bw/day)

bw = body weight (kg) [*WHO default values are 60 kg for adults, 10kg for children and 5 kg for infants*]

P = fraction of the TDI allocated to drinking-water [*WHO default value is 0.1*]

C = daily drinking-water consumption [*WHO default values are 2L for adults, 1L for children and 0.75L for infants*]

Since the WHO has not established drinking water GVs (nor TDIs) for many pesticides, it is suggested that CCMC can estimate provisional indicator GVs for Ghana, to be used in the risk assessment of pesticides for which no GV was fixed by WHO. The following parameters shall be used for Ghana (awaiting more precise values to be proposed by the Ministry of Health):

TDI = use ADI (mg/kg bw/day) for residues in food, as established by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR)

bw = body weight (kg) [*use WHO defaults*]

P = fraction of the TDI allocated to drinking-water [*use default value of 0.2, since ratio drinking water intake/food intake is likely to be higher in hot tropical countries*]

C = daily drinking-water consumption [*use default values of 3L for adults, 1.5L for children and 1L for infants, to take into account higher water intake in hot tropical countries*]

Indicator Guidance Values should be replaced with the drinking water standards to be set by the Ghana Standards Board, as soon as these become available.

5.2.6 Assessment

The estimated long-term groundwater concentration generated by the model shall be compared with both the WHO Guidance Value and the EU limit values (the latter generally tend to be lower).

If the estimated concentration is lower than both the triggers, the pesticide poses low risk of groundwater contamination.

If the estimated concentration is higher than both triggers, the pesticide poses a risk of groundwater contamination above internationally established criteria.

If the estimated concentration is in between the two triggers, the pesticide may pose a risk of groundwater contamination above internationally established criteria. In such a case, the assumptions of the groundwater model should be compared with likely environmental conditions in Ghana to assess if the model likely over- or underestimates risk. K_{oc} and DT_{50} may be modified to correspond better with Ghanaian conditions (e.g. DT_{50}s in registration dossier were often determined at 20-22°C and if so, may be corrected using the Q_{10} principle).

Q_{10} principle: most pesticides will degrade faster in warmer ambient conditions.

Increase in ambient temperature, compared to the temperature at which the DT_{50} was determined	Resultant estimated reduction in DT_{50} [1]	Multiply DT_{50} with the factor below
5 °C	~ 1.5 x	0.69
10 °C	~ 2.1 x	0.48
[1] Arrhenius equation, using an average activation energy of 54000 J/mole (FOCUS, 1997)		

5.2.7 Review of existing evaluations

If any registration evaluations are available from reputable sources, for the pesticide under evaluation, the conclusions of the groundwater risk assessment in these evaluations may be reviewed. If major differences in conclusions exist between the evaluation for Ghana and the external reviews, the assessor should try to determine why these differences exist. Note that often the differences between the Ghana evaluation and one done in a temperate region may be explicable because of differences in application rates and frequencies, soil characteristics and ambient climatic conditions.

5.2.8 Registration Decision

If the pesticide is found to be of high risk to groundwater, the recommendations made to the PTC may include refusal of registration or restriction of the use of the pesticide. This is especially important if the pesticide is to be used in areas where the groundwater table is shallow and/or soils are sandy.

Risk reduction methods need to be decided upon on a case-by-case basis, taking into account the intended application methods, use pattern, ecosystems that may be exposed, technical capacity of the users of the product, and the possibility to enforce any restrictions that may be decided upon. Possible measures to reduce the risk to groundwater include:

- reduction of the application frequency
- restriction of use of the pesticide to non-sensitive regions of the country

5.2.9 Documentation

The risk assessor shall always document the assessment as thoroughly as possible. Inputs and outputs of exposure models should be saved and printed out. If relevant, the values used in the calculation of the indicative Guidance Value should be specified. A short, concise, summary report of the exercise should be prepared for the plenary meeting of the sub-committees. All documentation should be filed in the registration file of the product.

5.3 Evaluation Procedure for Soil Organisms

5.3.1 Likelihood of Soil Exposure

The likeliness of (direct or indirect) exposure of the soil environment by the pesticide shall be assessed, given the requested (or otherwise likely) use pattern. If exposure is unlikely under Ghanaian conditions, no further risk assessment for the soil environment is needed.

5.3.2 Pre-screening - Check completeness of the dataset

If the dataset is not complete, no further assessment shall be carried out and the applicant requested to provide the missing data, or justify why these data were not submitted.

5.3.3 Pre-screening - Check quality of the dataset

If possible, endpoint values for the different toxicity tests shall be obtained from secondary sources (preferably registration reviews from reputable registration authorities, or from international organizations [e.g. the Environmental Health Criteria]. Certain pesticide physico-chemical properties can be obtained from the USDA Pesticide Properties Database; additional toxicity data may be obtained from the USEPA ECOTOX Database.

A comparison table shall be made as well as an assessment of existence of major differences between the data submitted by the applicant and the secondary sources. If large differences exist, the applicant shall be requested for clarifications. If these are not forthcoming, the risk assessment shall be based on a dataset consisting of the most sensitive species in the comparison table.

(a) Pesticides that are highly persistent in the soil ["red zone" pesticides]

If the dataset is complete and of acceptable quality, and if the criterion in the table below is higher than the trigger values listed, registration of the pesticide in Ghana will, in principle, be refused.

Criterion	Trigger value
Persistence in the soil environment	Field-$DT_{50\ [soil]}$ [of parent compound and main metabolites] > 6 months
Criteria of a potential POP, as in the Stockholm Convention (UNEP, 2001)	

All other pesticides will go through a more detailed risk assessment, as outlined below.

5.3.4 Exposure Estimates

(a) Tier I estimates (worst case)

(i) Initial Predicted Environmental Concentration after a single application

Assumptions: only 1 pesticide application; no pesticide degradation; fraction of pesticide may be intercepted by crop

Calculate $PEC_{[initial - single\ application]}$ as follows:

$$PEC_{[1]} = \frac{AR\ x\ (1 - f_{int})}{100\ x\ depth\ x\ bd}$$

Where:

$PEC_{[1]}$ = initial predicted environmental concentration after a single application (mg a.i./kg dry soil)

AR = application rate (g a.i./ha)

f_{int} = fraction of pesticide intercepted by the crop (i.e. not reaching the soil) [defaults = 0 for treatment of bare soil, or 0.5 for treatment of crop]

Depth = mixing depth of the pesticide in the soil (cm) [defaults = 5 cm for surface sprays, or 20 cm for soil incorporated pesticides]

bd = bulk density of the soil (g/cm^3) [default = 1.5]

(ii) Initial Predicted Environmental Concentration after multiple applications

Assumptions: several pesticide applications; pesticide degradation occurs between treatments; fraction of pesticide may be intercepted by crop

Calculate $PEC_{[initial - multiple\ applications]}$ as follows:

$$PEC_{[n]} = PEC_{[1]}\ x\ \frac{(1 - e^{-nki})}{(1 - e^{-ki})}$$

Where:

$PEC_{[n]}$ = initial predicted environmental concentration after n applications (mg a.i./kg dry soil)

$PEC_{[1]}$ = initial predicted environmental concentration after a single application (mg a.i./kg dry soil)

n = number of applications

k = $0.693 / DT_{50\ [soil]}$ ($days^{-1}$)

DT_{50} = pesticide half-life in soil (preferably field derived)

i = time between applications (days)

Tier Ia/b risk assessment in 4.3.4 shall be carried out, before continuing to calculate Tier Ic exposure estimate.

(iii) Time-weighted average predicted environmental concentration

Assumptions: either a single or several pesticide applications; pesticide degradation occurs between treatments and over the averaging period; fraction of pesticide may be intercepted by crop; averaging period set by assessor.

Calculate $PEC_{[time\text{-}weighted\ average]}$ as follows:

$$PEC_{[t]} = PEC_{[1\ or\ n]}\ x\ \frac{(1 - e^{-kt})}{(kt)}$$

Where:

$PEC_{[t]}$ = time-weighted average predicted environmental concentration over t days after the last application (mg a.i./kg dry soil)

$PEC_{[1\ or\ n]}$ = initial predicted environmental concentration after a single or after multiple applications (mg a.i./kg dry soil)

AR = application rate (g a.i./ha)

k = $0.693 / DT_{50\ [soil]}$ ($days^{-1}$)

DT_{50} = pesticide half-life in soil (preferably field derived)

t = averaging time (days)

Note: the averaging time to be used depends on the toxicity data that will be used in the calculation of the Risk Quotients. Roughly use the study time of the relevant toxicity studies as the averaging time.

Tier Ic risk assessment in 4.3.3 is carried out before continuing to calculate Tier Id exposure estimate.

(iv) Long-term plateau concentration

This calculation is only necessary for pesticides that are persistent and are applied frequently.

Assumptions: this calculation assumes that pesticides are applied indefinitely, with a period "i" between applications; pesticide degradation occurs between treatments; fraction of pesticide may be intercepted by crop

Calculate $PEC_{[plateau]}$ as follows:

$$PEC_{[plateau]} = x \frac{PEC_{[1]}}{(ki)}$$

where:

$PEC_{[plateau]}$ = plateau soil concentration reached after indefinite applications with period "i" between treatments (mg a.i./kg dry soil)

$PEC_{[1]}$ = initial predicted environmental concentration after a single application (mg a.i./kg dry soil)

k = $0.693 / DT_{50\ [soil]}$ ($days^{-1}$)

DT_{50} = pesticide half-life in soil (preferably field derived)

i = time between applications (days)

(b) Tier II estimate (more realistic cases)

If the Tier I risk assessment indicates risk to the soil environment, specific PEC calculations for the Ghana situation may be calculated. These will be *ad hoc* estimates, based on knowledge of the local environmental and pesticide application conditions. No locally validated models are available for such estimates as yet.

Soil bulk densities, mixing depths and crop interception fractions may be better defined for Ghana. If applicable, the DT_{50} may be modified to correspond better with Ghanaian conditions (e.g. DT_{50}s in registration dossier are often determined at 20-22°C and if so, may be corrected using the Q_{10} principle).

Q_{10} principle: most pesticides will degrade faster in warmer ambient conditions.

Increase in ambient temperature, compared to the temperature at which the DT_{50} was determined	Resultant estimated reduction in DT_{50} [1]	Multiply DT_{50} with the factor below
5 °C	~ 1.5 x	0.69
10 °C	~ 2.1 x	0.48
[1] Arrhenius equation, using an average activation energy of 54000 J/mole (FOCUS, 1997)		

See the EPPO scheme on soil for more guidance.

5.3.5 Risk Assessment

The acceptability triggers that may be used for the risk assessment are summarized in Tables 5.3 – 5.5.

Table 5.3: Acceptability criteria soil organisms - Persistence

Assessment	**Trigger**	
	EU	**Stockholm**
Pesticide is not acceptable ("red zone" criterion; see section 3.2-3)		$DT_{50\ [soil]}$ > 6 months
Pesticide is not acceptable, unless further (field) studies show that persistence is lower under realistic conditions	field-DT_{50} > 3 months **and** field-DT_{90} > 1 year	
Criteria based on EU (1997) & UNEP (2001)		

Table 5.4: Acceptability triggers soil organisms - Toxicity

Assessment	**Trigger**	
	EU	
Acute risk for earthworms is not acceptable if:	RQ > 0.1	
Sub lethal risk for earthworms is not acceptable if:	RQ > 0.2	
Risk for microbial nitrogen and carbon mineralization is not acceptable if:	> 25% reduced after 100 days (in lab.)	
Criteria based on EU (1997)		

If a trigger is passed, either the pesticide is considered of **high risk to the soil environment**, **or** the **assessment is refined** (i.e. better exposure estimates and/or better toxicity data).

(a) Tier I (worst case - acute)

Calculate the acute Risk Quotient (RQ) for earthworms, as follows:

$$Acute\ RQ_{\ [earthworms]} = \frac{PEC_{\ [1\ or\ n]}}{Acute\ LC_{50\ \ [most\ sensitive\ species]}}$$

Where:

$PEC_{\ [1\ or\ n]}$ = initial predicted environmental concentration after a single, or multiple, applications (mg a.i/kg soil) (section 3.3-Ia or 3.3-Ib)

Use the LC_{50} of the most sensitive species from the dataset.

If acute data are available for other organisms than earthworms, similar RQs can be calculated.

If the pesticide is not persistent and only applied once during the season, and the above RQ acceptable, no further risk assessments are needed.

(b) Tier I (worst case – sub-lethal and chronic)

(i) Calculate the sub-lethal Risk Quotient (RQ) for **earthworms**, as follows:

$$Sublethal\ RQ_{[earthworms]} = \frac{PEC_{[t]}}{NOEC_{[most\ sensitive\ parameter]}}$$

Where:

$PEC_{[t]}$ = time-averaged predicted environmental concentration over the duration of the sub-acute test (often 21 days) (mg a.i/kg soil) (section 3.3-Ic)

NOEC = no observed effect concentration of the most sensitive test parameter (generally earthworm growth or cocoon production).

Use the NOEC of the most sensitive species from the dataset.

If sub-lethal data are available for other organisms than earthworms, similar RQs can be calculated.

ii. Calculate the Risk Quotient (RQ) for **soil microorganisms**, as follows:

$$RQ_{[microorganisms]} = \frac{PEC_{[t]}}{NOEC_{[most\ sensitive\ parameter]}}$$

Where:

$PEC_{[t]}$ = time-averaged predicted environmental concentration over the duration of the soil microorganisms test (often 3 months) (mg a.i/kg soil) (section 3.3-Ic)

NOEC = no observed effect concentration of the most sensitive soil parameter.

If the pesticide is neither highly persistent nor applied repeatedly during the season, and the above RQ acceptable, no further risk assessments are needed.

(c) Tier I (worst case – plateau concentration)

If there is a possibility that the pesticide may accumulate in the soil (i.e. pesticide highly persistent and applied repeatedly during the season, year after year), the RQs of section above shall be recalculated using the $PEC_{plateau}$ as estimated in section 3.3-Id.

If the RQ is acceptable, no further risk assessment is needed.

(d) Tier II (more realistic cases)

If the pesticide is not acceptable in any of the above Tier I assessments, more realistic evaluations may be carried out. They will involve better exposure assessments or additional toxicity data. Such assessments are to be carried out on an *ad hoc* basis, to be decided by the risk assessor, and if data are available.

5.3.6 Review of Existing Evaluations

If any registration evaluations are available from reputable sources, for the pesticide under evaluation, the conclusions of the soil risk assessment in these evaluations may be reviewed. If major differences in conclusions exist between the evaluation for Ghana and the external reviews, the assessor shall try to determine why these differences exist. Note that often the differences between the Ghana evaluation and one done in a temperate region may be explicable because of differences in climate, application rates and frequencies, or other local factors.

5.3.7 Registration Decision

If the pesticide is found to be of high risk to the soil environment, the recommendations made to the PTC may include refusal of registration, restriction of the use of the pesticide, or a range of other possible risk reduction measures.

Risk reduction methods shall be decided upon on a case-by-case basis, taking into account the intended application methods, use pattern, ecosystems that may be exposed, technical capacity of the users of the product, and the possibility to enforce any restrictions that may be decided upon.

Possible measures to reduce the risk to the soil environment include:

- reduction of the application frequency
- reduction of the application rate
- restriction of use of the pesticide by trained/licensed applicators only

5.3.8 Documentation

The risk assessor shall always document the assessment as thoroughly as possible. Inputs and outputs of exposure models should be saved and printed out. The species and toxicity endpoints reviewed for the assessment should be listed and the toxicity endpoint values used in the calculation of the Risk Quotient should be specified. A short, concise, summary report of the exercise should be prepared for the plenary meeting of the sub-committees. All documentation should be filed in the registration file of the product.

5.4 Evaluation Procedure for Terrestrial Vertebrates

5.4.1 Likelihood of Vertebrate Exposure

The likeliness of (direct or indirect) exposure of terrestrial vertebrates by the pesticide shall be assessed, given the requested (or otherwise likely) use pattern. If exposure is unlikely under Ghanaian conditions, no further risk assessment for the soil environment is needed.

5.4.2 Pre-screening - Check completeness of the dataset

If the dataset is not complete, no further assessment shall be carried out and the applicant requested to provide the missing data, or justify why these data were not submitted.

5.4.3 Pre-screening - Check quality of the dataset

If possible, endpoint values for the different toxicity tests shall be obtained from secondary sources (preferably registration reviews from reputable registration authorities, or from international organizations [e.g. the Environmental Health Criteria or the JMPR toxicology review (for mammalian data)]. If required, additional toxicity data may be obtained from the USEPA ECOTOX Database.

A comparison table shall be made as well as an assessment of the existence of major differences between the data submitted by the applicant and the secondary sources. If large differences exist, the applicant shall be requested for clarifications. If these are not forthcoming, the risk assessment shall be based on a dataset consisting of the most sensitive species in the comparison table.

5.4.4 Exposure Estimates

While terrestrial vertebrates can be exposed to pesticides through different routes, it is generally suggested that dietary exposure is the most important one. The estimates below therefore only refer to dietary exposure. Before calculating these dietary exposure estimates, the assessor makes sure that, based on the local pesticide use patterns, no other exposure route is likely to contribute considerably to the intake of pesticides by the vertebrates.
Three "exposure models" are provided below: The FAO-TEAM computer model, and the EU or EPPO lookup tables. The major differences and similarities between these models are given in Annex 1. Note that the EU model and the EPPO reasonable worst-case model are very similar.

The choice which model to choose depends on the type of organisms for which a risk assessment needs to be carried out, and the pesticide use pattern being registered in Ghana.

(a) Identify the type of terrestrial vertebrates to be assessed

The first step is to identify for what types of birds or mammals (no models exist yet for reptiles and amphibians) a risk assessment is needed. This will depend on the type of ecosystem or cropping system that is likely to be treated by the pesticide. The groups of vertebrates covered in the models are all "generic" i.e. small herbivorous mammals, fruit-eating birds, etc., and can be assumed applicable to the Ghana situations as well.

(b) Identify the type of cropping system that will be treated

All models require that one identifies the type of cropping system that will be treated by the pesticide. This will determine the initial pesticide residue levels that are expected to be deposited on the vegetation/crop. The cropping types in the three models are distinctly European and North-American. For the Ghanaian risk assessment it is important to choose a cropping system in the model which comes closes **in vegetation structure** to the Ghanaian one under study (i.e. a cocoa plantation in Ghana may be "represented" by an orchard in the EPPO scheme).

(c) Run the models

It is suggested that the models are run in the following tiered manner:

(d) Tier I (worst case): FAO-TEAM model **and** the EPPO-*reasonable worst-case* lookup table **or** the EU-lookup table. The choice between the EPPO or EU model depends mainly on which one provides the best representation of the Ghana cropping situation combined with a relevant non-target vertebrate group

(e) Tier II (more realistic): EPPO-*most likely case* lookup table.

FAO-TEAM model

A summary of the assumptions underlying the FAO-TEAM model can be found in Annex 1 & 2. A user manual is not yet available for this model.

Notes:

- The model requests an averaging time for the chronic residue estimate, which starts at the first application. For a single application, a 21-day averaging period is convention in the EU system. For multiple applications, use an averaging time, which lasts until 21 days after the last application (i.e. 3 applications at 10-day intervals would result in a residue averaging time of 41 days).
- The model requests a foliar $DT_{50.}$ DT_{50} estimates on vegetation may have been provided in the registration dossier in the residues chapter. If data are absent, one could also check the USDA Pesticide Properties Database or the JMPR residue evaluations on the FAO/Codex web site. If no value is entered in the model, a default DT_{50} of 35 days is used (note: this is considerably longer than the 10 days used as default in the EPPO/EU models!)
- The model can calculate Risk Quotients, if toxicity data are entered as well. Be aware to enter **exactly the toxicity data as the model requests!!** (i.e.: "avian acute LC_{50}" = *bird short term dietary* in the Ghana data requirements [in **mg/kg diet**]; "avian chronic NOAEC" = *bird chronic or reproduction* in the Ghana data requirements [in **mg/kg diet**]; "mammalian acute LD_{50}" = [in **mg/kg body weight**]; and "mammalian chronic NOAEC" = [in **mg/kg diet**].

If toxicity data are only available in other units (e.g. mammalian chronic NOAEC in mg/kg body weight/day) they need to be converted first.

The relevant organism-food item combinations shall be chosen from the output tables, to be further used in the risk assessment.

Outputs are both pesticide residue levels on food items (which can be used to calculate Risk Quotients by the assessor him/herself) and/or pre-calculated Risk Quotients.

(f) EPPO Lookup Tables

A summary of the assumptions underlying the EPPO lookup tables can be found in Annex 1. A detailed description and "user manual" is provided in the *EPPO Risk Assessment Schemes: Chapter 11 – terrestrial vertebrates*.

Exposure of terrestrial vertebrates to pesticides through the diet is called the Daily Dietary Dose (DDD) in the EPPO lookup tables. They are calculated in a slightly different way for acute, short-term and chronic exposure (see Annex 1 or the headings of the lookup tables in EPPO Chapter 11). Outputs are pesticide residue exposure levels expressed as "daily doses", i.e. as mg a.i./kg bw/day.

The relevant organism-food item combinations shall be chosen from the lookup tables, to be further used in the risk assessment.

(g) EU lookup tables

A summary of the assumptions underlying the EU lookup tables can be found in Annex 1. A detailed description and "user manual" is provided in the *EU Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC.*

Exposure of terrestrial vertebrates to pesticides through the diet is called the Estimated Theoretical Exposure (ETE) in the EU lookup tables. They are calculated in a slightly different way for acute, short-term and chronic exposure (see Annex 1 or the headings of the lookup tables in EU Guidance Document). Outputs are pesticide residue exposure levels expressed as "daily doses", i.e. as mg a.i./kg bw/day.

Choose the relevant organism-food item combinations from the lookup tables, to be further used in the risk assessment.

5.4.5 Risk Assessment

The acceptability triggers that may be used for the risk assessment are summarized in Table 5.5.

Table 5.5: Acceptability criteria - Risk for birds and mammals

Assessment	**Trigger**	
	EU	**USEPA**
Acute risk for birds and mammals is not acceptable if:	RQ ≥ 0.1	RQ ≥ 0.5 **or** 0.2
Short-term dietary risk for birds is not acceptable if:	RQ ≥ 0.1	RQ ≥ 0.5 **or** 0.2
Chronic risk for birds and mammals is not acceptable if:	RQ ≥ 0.2	RQ ≥ 1
[1] trigger is 0.2 of risk can be mitigated by restricted use. Criteria based on EU (1997) and USEPA (various)		

If a trigger is passed, either the pesticide is considered of **high risk to terrestrial vertebrates**, **or** the **assessment is refined** (i.e. better exposure estimates and/or better toxicity data).

Note: RQ is defined as **exposure estimate / toxicity estimate!**

(a) Tier I (worst case - acute)

The acute Risk Quotients (RQs) for birds and mammals is calculated separately, as follows:

(i) FAO-TEAM model

For the FAO-TEAM model, acute RQs are already listed in the computer output. Note that the **acute RQ for birds** is based here on the short-term (5-day) dietary LC_{50} (and should thus be compared with the "medium-term" RQs from the EPPO and EU tables).

(ii) EPPO lookup tables

For the Tier I assessment, the *reasonable worst case (rwc)* exposure estimate from the EPPO tables is used (from Table 2).

$$Acute\ RQ_{rwc} = \frac{DDD_{rwc}}{acute\ LD_{50}}$$

Where:

RQ = Risk Quotient (reasonable worst case)

DDD_{rwc} = Daily Dietary Dose [mg a.i./kg bw]

Use the lowest acute LD_{50} for both a bird and a mammal species.

(iii) EU lookup tables

For the Tier I assessment, the exposure estimate from the EU lookup Table 4 is used.

$$Acute\ RQ = \frac{ETE}{acute\ LD_{50}}$$

Where:

RQ = Risk Quotient

ETE = Estimated Theoretical Exposure [mg a.i./kg bw]

Use the lowest acute LD_{50} for both a bird and a mammal species.

(b) Tier I (worst case – short term)

(i) FAO-TEAM model

For the FAO-TEAM model, short-term RQ for birds is already listed in the computer output (see remark above in section 3.4.2a). No short-term data for mammals are provided in this model.

(ii) EPPO lookup tables

For the Tier I assessment, the *reasonable worst case (rwc)* exposure estimate from the EPPO tables is used (from Table 4) (note that exposure in these tables is called "medium term")

$$Short-term\ RQ_{rwc} = \frac{DDD_{rwc}}{short-term\ LD_{50}}$$

Where:

RQ_{rwc} = Risk Quotient (reasonable worst case)

DDD_{rwc} = Daily Dietary Dose [mg a.i./kg bw]

LD_{50} = median lethal dose [mg/kg bw/day]

The lowest short-term dietary LD_5 is used for both a bird and a mammal species. If the LD_{50} is expressed as mg/kg bw/day, one can use the equation above. If only an LC_{50} is available (which will often be the case), expressed in ppm a.i. in diet (or mg a.i/kg diet/day), the equation below is used in which the dietary concentration is converted in a daily dose:

$$Short-term\ RQ_{rwc} = \frac{DDD_{rwc}\ /\ DFI}{short-term\ LC_{50}}$$

Where:

RQ_{rwc} = Risk Quotient (reasonable worst case)

DDD_{rwc} = Daily Dietary Dose [mg a.i./kg bw]

DFI = Daily Food Intake [kg food/kg bw/day] (obtain from Table 4)

LC_{50} = median lethal concentration [ppm a.i. in diet **or** mg a.i/kg diet/day]

(iii) EU lookup tables

For the Tier I assessment, the short-term exposure estimate from the EU Table 6 is used. Note that only estimates for birds are available in the EU table.

$$Short-term\ RQ = \frac{ETE}{short-term\ LD_{50}}$$

Where:

RQ = Risk Quotient

ETE = Estimated Theoretical Exposure [mg a.i./kg bw]

LD_{50} = median lethal dose [mg/kg bw/day]

The lowest short-term dietary LD_{50} available for birds is used. If the LD_{50} is expressed as mg/kg bw/day, one can use the equation above. If only an LC_{50} is available (which will often be the case), expressed in ppm a.i. in diet (or mg a.i/kg diet/day), the equation below is used in which the dietary concentration is converted in a daily dose:

$$Short-term\ RQ = \frac{ETE\ /\ (FIR/bw)}{short-term\ LC_{50}}$$

Where:

RQ = Risk Quotient

ETE = Estimated Theoretical Exposure [mg a.i./kg bw]

FIR/bw = Food Intake Rate per unit body weight [kg food/kg bw/day] (obtain from Table 6)

LC_{50} = median lethal concentration [ppm a.i. in diet **or** mg a.i/kg diet/day]

(c) Tier I (worst case – chronic)

(i) FAO-TEAM model

For the FAO-TEAM model, chronic RQs for birds and mammals are already listed in the computer output.

(ii) EPPO lookup tables

For the Tier I assessment, the *reasonable worst case (rwc)* exposure estimate from the EPPO tables is used (from Table 6) (note that exposure in these tables is called "long term")

$$Chronic\ RQ_{rwc} = \frac{DDD_{rwc}}{NOAEL}$$

Where:

RQ_{rwc} = Risk Quotient (reasonable worst case)

DDD_{rwc} = Daily Dietary Dose [mg a.i./kg bw/day]

NOAEL = No Observed Adverse Effect level [mg a.i./kg b.w./day]

The lowest chronic NOAEL for both a bird and a mammal species is used. Chronic toxicity endpoints related to reproduction and growth are often considered most appropriate for wildlife risk assessment. If the NOAEL is expressed as mg/kg bw/day, one can use the equation above.

If only a NOAEC is available, expressed in ppm a.i. in diet (or mg a.i/kg diet/day), the equation below is used in which the dietary concentration is converted in a daily dose:

$$Chronic\ RQ_{rwc} = \frac{DDD\ /\ DFI}{NOAEC}$$

RQ_{rwc} = Risk Quotient (reasonable worst case)

DDD_{rwc} = Daily Dietary Dose [mg a.i./kg bw/day]

DFI = Daily Food Intake [kg food/kg bw/day] (obtain from Table 6)

NOAEC = No Observed Adverse Effect Concentration [ppm a.i. in diet **or** mg a.i/kg diet/day]

(iii) EU lookup tables

For the Tier I assessment, the chronic exposure estimate from the EU Table 7 is used.

$$Chronic\ RQ = \frac{ETE}{NOAEL}$$

Where:

RQ = Risk Quotient

ETE = Estimated Theoretical Exposure [mg a.i./kg bw/day]

NOAEL = No Observed Adverse Effect Level [mg a.i./kg bw/day]

The lowest chronic NOAEL for both a bird and a mammal species is used. Chronic toxicity endpoints related to reproduction and growth are often considered most appropriate for wildlife risk assessment. If the NOAEL is expressed as mg/kg bw/day, one can use the equation above.

If only a NOAEC is available, expressed in ppm a.i. in diet (or mg a.i/kg diet/day), the equation below is used in which the dietary concentration is converted in a daily dose:

$$Chronic\ RQ = \frac{ETE\ /\ (FIR/bw)}{NOAEC}$$

Where:

RQ = Risk Quotient

ETE = Estimated Theoretical Exposure [mg a.i./kg bw]

FIR/bw = Food Intake Rate per unit body weight [kg food/kg bw/day] (obtain from Table 7)

NOAEC = No Observed Adverse Effect Concentration [ppm a.i. in diet **or** mg a.i/kg diet/day]

(d) Tier I evaluation

If none of the RQs (acute, short-term and chronic) exceed the triggers, for both birds and mammals, the risk of the pesticide to these organisms is likely to be low. No further risk assessment is then necessary.

If one or more of the RQs does exceed the triggers, continue with the Tier II assessment for these organisms/exposure times only.

If RQs appear to be conflicting between the different models, evaluate which of the models that was used represents the Ghana situation best. Base the evaluation decision in such a case on the best model for Ghana.

(e) Special cases

A special case is pesticides with a high bioaccumulation potential (log K_{ow} > 3). These may cause secondary poisoning through the food chain. For these pesticides, refer to chapter 4.3 in the EU Guidance Document, which provides a number of simple models to estimate the risk of secondary poisoning.

Similarly, pesticide granules require a separate risk assessment. This procedure can be found in the EPPO chapter 11.

(f) Tier II (more realistic cases)

The EPPO risk assessment scheme for terrestrial vertebrates also provides lookup tables for *most likely case* exposure scenarios. These are considered more realistic (for European conditions) than the reasonable worst cases scenarios used in Tier I.

- Use Table 3 in the EPPO scheme for acute exposure
- Use Table 5 in the EPPO scheme for short-term exposure
- Use Table 7 in the EPPO scheme for chronic exposure

If none of these Tier II RQs exceed the triggers, the risk of the pesticide to these organisms is likely to be low. No further risk assessment is then necessary.

If one or more of the RQs still does exceed the triggers, a Tier III assessment for these organisms/exposure may be required.

(g) Tier III (better locally representative cases)

If the pesticide is not acceptable in any of the above Tier II assessments, evaluations may need to be carried out that better represent the Ghana situation. They will generally involve better exposure assessments or sometimes additional toxicity data. Such assessments are to be carried out on an *ad hoc* basis, to be decided by the risk assessor, and if data can be made available.

5.4.6 Review of existing evaluations

If any registration evaluations are available from reputable sources, for the pesticide under evaluation, the conclusions of the soil risk assessment in these evaluations may be reviewed. If major differences in conclusions exist between the evaluation for Ghana and the external reviews, the assessor shall try to determine why these differences exist. Note that often the differences between the Ghana evaluation and one done in a temperate region may be explicable because of differences in climate, application rates and frequencies, groups of organisms assessed, or other local factors.

5.4.7 Registration decisions

If the pesticide is found to be of high risk to certain groups of terrestrial vertebrates, the recommendations made to the PTC may include refusal of registration, restriction of the use of the pesticide, or a range of other possible risk reduction measures.

Risk reduction methods shall be decided upon on a case-by-case basis, taking into account the intended application methods, use pattern, ecosystems that may be exposed, technical capacity of the users of the product, and the possibility to enforce any restrictions that may be decided upon.

Possible measures to reduce the risk to the soil environment include:

- reduction of the application frequency
- reduction of the application rate
- restriction of use of to specific crops (e.g. where sensitive species are not prevalent)
- restriction of use to specific seasons (e.g. not the breeding season for sensitive bird species)
- restriction of use in ecologically sensitive or protected areas

5.4.8 Documentation

The risk assessor shall always document the assessment as thoroughly as possible. Inputs and outputs of exposure models should be saved and printed out. The species and toxicity endpoints reviewed for the assessment should be listed and the toxicity endpoint values used in the calculation of the Risk Quotient should be specified. A short, concise, summary report of the exercise should be prepared for the plenary meeting of the sub-committees. All documentation should be filed in the registration file of the product.

5.5 Evaluation Procedure for Bees

5.5.1 Likelihood of Exposure

The likeliness of (direct or indirect) exposure of bees by the pesticide shall be assessed, given the requested (or otherwise likely) use pattern. If exposure is unlikely under Ghanaian conditions, no further risk assessment for bees is needed.

5.5.2 Prescreening - Check completeness of the dataset

If the dataset is not complete, no further assessment is carried out and the applicant requested to provide the missing data, or justify why these data were not submitted.

5.5.3 Prescreening - Check quality of the dataset

If possible, endpoint values for the different toxicity tests shall be obtained from secondary sources (preferably registration reviews from reputable registration authorities). Additional bee toxicity data may be obtained through the US-EPA ECOTOX database or the Koppert database (see Annex 1). A comparison table shall be made as well as an assessment of the existence of major differences between the data submitted by the applicant and the secondary sources.

If large differences exist, the applicant is requested for clarifications. If these are not forthcoming, the risk assessment shall be based on a dataset consisting of the most sensitive species/tests in the comparison table.

The EPPO risk assessment scheme PP 3/10(2) [2002] can be followed as risk assessment procedure.

5.5.4 Exposure Estimates

The principal exposure estimate for the bee risk assessment is the highest recommended application rate [g a.i./ha] of the pesticide. No multiple application factors are normally used.

5.5.5 Risk Assessment

The acceptability triggers that may be used for the risk assessment are summarized in Table 5.6.

Table 5.6 Acceptability criteria for bees

Assessment	**Trigger**
	EPPO
Acute risk is low if:	HQ < 50 **and** pesticide is no IGR **and** indirect effects are unlikely
Acute risk is high if:	HQ > 2500
Criteria based on EPPO (2002)	

(a) Tier I assessment

For **pesticides that are neither IGRs nor acting indirectly**: calculate the Hazard Quotient as:

$$HQ = \frac{highest\ application\ rate\ (g\ a.i./ha)}{lowest\ LD_{50}\ (\mu g\ a.i./bee)}$$

If the HQ > 2500, consider the pesticide high risk to bees; no further evaluation is generally needed (though industry may provide data showing that effects in the field are less than expected based on the laboratory trials).

If the HQ < 50, consider the pesticide low risk to bees. No further evaluation is generally needed.

If 50 < HQ < 2500, the pesticide is moderately hazardous to bees. Tier II tests may be required to get better insight in the actual risk of the pesticide.

For **IGRs or indirectly acting pesticides**, assess the effects of bee brood tests or other more specific tests (see EPPO scheme for further guidance).

(b) Tier II assessments

Tier II risk assessments are generally based on cage, tunnel or field tests. These are often required if the pesticide is considered moderately hazardous after the Tier I evaluation. The results of such studies are assessed on a case by case basis (see EPPO scheme for further guidance).

5.5.6 Review of existing evaluations

If any registration evaluations are available from reputable sources, for the pesticide under evaluation, the conclusions of the bee/pollinator risk assessment in these evaluations may be reviewed. If major differences in conclusions exist between the evaluation for Ghana and the external reviews, the assessor shall try to determine why these differences exist. Note that often the differences between the Ghana evaluation and one done in a temperate region may be explicable because of differences in application rates and frequencies, or to other local factors.

5.5.7 Registration decisions

If the pesticide is found to be of high risk to the bees, the recommendations made to the PTC may include refusal of registration or restriction of the use of the pesticide. This is especially important if the pesticide is to be used in areas where bees are important.

If the pesticide is of moderate risk to bees, risk reduction measures tend to be recommended.

Risk reduction methods shall be decided upon on a case-by-case basis, taking into account the intended application methods, use pattern, ecosystems that may be exposed, technical capacity of the users of the product, and the possibility to enforce any restrictions that may be decided upon.

Possible measures to reduce the risk to bees include:

- not spraying at the time of the day when bees are actively foraging
- not spraying when crops and/or surrounding vegetation are flowering
- do not allow spraying of particular crops
- restriction of use of the pesticide by trained/licensed applicators only
- restriction of use of the pesticide to non-sensitive regions of the country
- warning statements on the label (recommending one or more of the above measures)

5.5.8 Documentation

The risk assessor shall always document the assessment as thoroughly as possible. Inputs and outputs of exposure calculations should be saved. The species and toxicity endpoints reviewed for the assessment should be listed and the toxicity endpoint values used in the calculation of the Hazard Quotient should be specified. A short, concise, summary report of the exercise should be prepared for the plenary meeting of the sub-committees. All documentation should be filed in the registration file of the product.

CHAPTER 6

ACCEPTABILITY CRITERIA – BIO-EFFICACY

6.1 General Requirements for the Design of the Efficacy Trials Programme

Efficacy is the ability of a pesticide to fulfill the claims made for it on the (proposed) label. Through efficacy evaluation the EPA assesses the efficacy and crop safety of new pesticides in order to evaluate the benefits to be obtained from their use. These benefits are then weighed against the potential hazards from the introduction of a new product. This benefit/risk analysis is then incorporated in the decision on granting registration. The efficacy of pesticides used in animal husbandry also goes through similar process.

The term "efficacy evaluation" as used here thus covers the evaluation of pesticides for efficacy and safety to crops, and thus is synonymous with the commonly used term "biological evaluation". In order to assess the benefits of a product, the registrant shall present a report on field trials that has been carried out under practical conditions of use. The test procedure, the design of the experiments, and the reference product should, WHEN FEASIBLE, be discussed with the EPA.

In practice, efficacy should be tested on one or several specific host/pest combinations, for each of which registration is sought. Consideration shall be limited to certain 'key' pests, in which case registration for so-called 'minor uses' may need to be based on efficacy data from similar uses or from other countries

Efficacy may be expressed in terms of:

- the extent of decrease of a pest population occurring on the crop or
- the extent of development of the pest population surviving the treatment, or
- the protection of the yield, quantity and/or quality, against damage caused directly or indirectly by the pest organism concerned.

A list of the elements to be considered in efficacy evaluation is set out below. The evaluation of efficacy is normally based on consideration of the following elements, as appropriate:

i. the effect on the pest organism;

ii. the reliability, duration and consistency of protection or other intended effect(s), appropriate to the desired crop protection objective at the various development stages of the pest and/or of the crop;

iii. effects on quantity or quality of the yield of treated plants or plant products;

iv. safety considerations, to the crop (including different cultivars), to animals or to the substrate to be treated;

v. comparison with reference product or normally accepted practice;

vi. compatibility with different cultural practices and other crop protection measures under the conditions of use envisaged;

vii. effect of variables, such as climate, temperature, humidity, soil, etc. and, in the case of baits, acceptability by the pest organism;

viii. advantages of the product or its manner of use which may compensate for any deficiencies in level, duration or consistency of protection or other intended effects;

ix. undesirable or unintended side effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or other parts of treated plants used for propagating purposes (seeds, cuttings, runners).

Only basic requirements of a general nature shall be required. The designs of any experiment, the required plot size and the methods for the evaluation have to be adapted to the specific pest/crop combination and the agricultural practices concerned. More detailed information on this can be found in Appendix II.

Trials shall, be carried out in the field. The test programme and the documentation should be sufficiently comprehensive to allow a thorough evaluation of the efficacy of a plant protection product under study. The trials in this instance should be designed, the pesticide concerned applied, and results evaluated in such a way that a reliable judgment can be made on the efficacy of the pesticide under the conditions prevailing in these experiments.

The test programme should not only include the application of the pesticide in a typical or an "average" condition prevailing in areas in Ghana in which the use is intended, but the performance of the pesticide should be studied in a range of conditions prevailing in these areas during the periods of the year the pesticide will be used.

Such programmes, including a range of conditions, will enable the evaluation of possible differences in performance of the pesticide applied under various conditions. These differences can arise from:

- variations in climate;
- agricultural practices;
- crops and cultivars of crops grown or
- pests and strains of pests that occur.

The test programme for a pesticide under study should always include supervised trials on main cultivars currently grown in Ghana or areas with similar agro-climatic conditions as Ghana.

Where relevant, the crop safety should be investigated at rates of application higher than recommended, as well as at the recommended rates.

The number of sites in which supervised trials should be carried out with a pesticide used on a specific pest/crop combination, for which an registration is requested, is dependent on the extent of variations as mentioned above (which should be covered) and on the predictability of the occurrence of the pest or disease.

As a general rule, replicated trials on annual crops should be carried out at a minimum of 8 to 10 sites in any one season. Owing to the difficulty of acquiring adequate sites in large perennial crops such as fruits, the number of sites may have to be confined to 3-5.

Where a pest is not generally abundant or the distribution of the pest population is rather uneven, a larger number of sites may be advantageous. With soil-applied chemicals, it is essential to spread the experiments over a range of soil types. This is particularly important if the pesticide may be used on rather "extreme" soil types, e.g. soils with a high organic matter content or very light sandy soil types. If there is any likelihood of use on such soils trail data shall be demanded.

In order to cover to some extent the variation in climatic conditions in different years, the test programme should normally be carried out in at least two successive years.

6.2 Guidance for Designing and Reporting Individual Efficacy Trials

When resources permit, the EPA and other collaboration institutions shall either organize limited additional trials or participate in such trials organized by the applicant. In such cases, the applicant will need to specify fully the conditions in which the trials are to be carried out, consistent with the proposed use of a product and the claims made for it.

An advantage of the active participation of the experts of the agency in the efficacy evaluation is that they become more familiar with the pesticide under study than would be possible from written reports alone. If the results obtained from these additional trials support the predictions derived from the manufacturer's data they can be regarded as a validation under the conditions of the trials. Data from independent sources shall also be accepted as a part of the efficacy evaluation dossier, again provided that these data were obtained with recognized harmonized methods. In any case, the database should be sufficient to enable the EPA evaluate the product's efficacy (including crop safety) and, in particular, to determine whether the level of efficacy is satisfactory.

6.2.1 Background and Design of Individual Trials

The selection of trial sites for Field Trials

The sites should be as level and uniform as possible and representative of the conditions where commercial use is anticipated. Sites with irregular soil conditions should be avoided. The pest, disease or weed, which forms the object of the efficacy test should occur in a

uniform pattern over the site or should be expected to become uniformly present during the trial period.

With soil insects or nematodes in particular, estimates of numbers present and uniformity should be made before the start of the trial. When selecting a site, the preceding crop situation should be known and taken into account: A single preceding crop, on which only uniform treatments were applied, should have been grown over the whole area of the site.

Sites at field edges, or near ditches, trees, hedges or other obstacles should, in general, be avoided, as they are subject to interfering "edge" effects from those obstacles. Edge effects may however sometimes be exploited especially when the pest organism concerned prefers the field-edges rather than the middle of the field, but the trial lay-out should then be specially designed for this situation.

It is usually desirable to site the experiment towards the center of a normal commercial crop. If this crop has to be treated with a pesticide, which may interfere with those under study in the experiment, then a sufficient margin of untreated crop should be left in the immediate vicinity of the experiment. If the trial consists of repeated blocks which follow each other in the direction of drilling, spraying or other treatment of the crop, it may be helpful to have a gap between the blocks to allow for turning the supply of the pesticide on and off and for lining up the apparatus with the next plot or sub-plot.

6.2.2 Biology of Pests, Diseases and Weeds

Experiments for efficacy testing of pesticide products should be designed and treated, taking into account adequate knowledge of the life history and behaviour of the pest, disease or weeds to be controlled. The timings and the mode of application of the plant protection chemical should be determined by the behaviour of the organism in question. Also the mode of action of the pesticide may influence the timing and methods of application. The evaluation methods SHALL BE adapted to the mode of action of the pesticide under study. Especially when a pesticide may show "delayed" effects, the observations and assessments should be designed to reveal such effects. It is also important that the experimental crop should be sown and treated similarly to a commercially grown crop, e.g. late sowings or excessively sheltered sites should be avoided since such conditions may be quite atypical and not representative for prevailing growing conditions.

6.2.3 Lay-out of Individual Trials

The design of a trial intended for efficacy evaluation should permit a statistical evaluation. The design, however, should not be made any more complicated than is compatible with the immediate object of the test. Multi-factorial designs should in general be avoided.

Usually a randomized block design is adequate, comprising in each block the pest control chemical(s) to be evaluated, the reference product(s) and in general a non-treated block, distributed at random in the block, the blocks being repeated as many times as replications (in most cases 4-5).

If it is necessary to introduce into the experiment other factors in addition to the treatments of the pesticide(s) under study at the recommended dosage rate, e.g. various times of application or other dosage rates, this should be accomplished by splitting the main plots into sub-plots, provided that the size of the sub-plots is still sufficient to allow a reliable evaluation.

Although in many cases the inclusion of non-treated control plots is essential, it has to be recognized that in some particular situations the lay-out of non-treated plots within the randomized blocks may give rise to disadvantages due to extensive interference between non-treated and treated plots.

In the case of herbicide trials, efficacy tests (on weed control) and selectivity tests (for crop safety) should be considered on a separate but equal footing. In particular, for selectivity evaluation, it is desirable to test at least one dosage rate higher than the recommended rate, and to use land, which is as free from weeds as possible.

6.2.4 Comparison with Reference Products

In view of the variability of conditions under which pesticides are used, it is necessary to include a reference product in field trials to allow meaningful evaluation of efficacy under the conditions of the trial. Satisfactory levels of efficacy will generally be met when performance is comparable to that of such a reference product, which should preferably be a registered product widely accepted as satisfactory in practice. However, other considerations (e. g manner of use, side effects, etc. as listed in section 1.3h & i below may arise in assessing what is a satisfactory level of efficacy.

Where the type of pesticide product or its use is new, comparison with a reference product may be impossible or inappropriate. In this case, the product under study should show a consistent well-defined benefit. The pesticide to be introduced should be able to bring and/or keep the pest population and the damage to which it gives rise below an economic or phyto-sanitary threshold level, where this is known.

Wherever feasible the reference product chosen should be one which has shown satisfactory results in practice; its mode of action should be the same as or similar to that of the test product.

6.2.5 Plot Size and Shape

No general rules can be given on the most suitable plot size; this depends on the particular combination of crop, pest or disease situation. In orchard trials or trials on similar tree crops, it is desirable to have 4-6 trees per net plot to allow for variability between trees. In agricultural crops the minimum plot size will probably be between 10m (e.g. 5 x 2m) and l00m (e.g. 10 x 10m). The minimum plot size in very uniform vegetable or flower crops may be smaller but only in cases where internal interferences can be avoided.

The mobility of pests and lateral spread of treatments may considerably influence the plot size. Also the available apparatus for spraying or other mode of treatment and for harvesting may require an increased plot size.

6.2.6 Number of Replications

The number of replications to be included in one trial is dependent on the following factors:

(i) the likely magnitude of experimental variance;

(ii) the number of treatments. (The fewer the treatments, the more replications are needed to give an acceptable estimate of variance. In most cases 4-5 replications should be sufficient to give a reasonable estimate of the variation, but in special circumstances three (3) may be acceptable.

An erratic distribution of the pests, diseases or weeds over the experimental area will call for a greater number of replications. When crop yields are to be evaluated, replications should be sufficient in number and the plot size large enough to offset the variability in crop yield due to variation of soil or other environmental factors over the test area.

6.2.7 Application of the Pesticides

The equipment used should give an even distribution of the pesticide product over the plot. The type of equipment used, which should, where possible, be similar to that currently used in practice in Ghana, should be recorded. When relevant, information should also be provided on operating conditions (e.g. type of nozzles, operating pressure in kPa), as well as any deviations in dosage of more than 10 percent.

The type, time and dosage of the pesticide application will generally be as proposed by the applicant. Precautions should be taken to ensure a minimum of interference with other pesticide applications.

6.2.8 Meteorological Data

In the field, weather conditions around the time of application, precipitation (type and daily amount in mm), temperature (daily average, maximum and minimum in degrees) should be

recorded on the trial site. Extreme weather conditions such as severe and prolonged drought, storms, etc.

6.2.9 Assessment of Efficacy

i. Observations should be scored using convenient qualifying methods such as the quantity and quality of yield, percent of control and extent of remaining pest populations, according to the pesticide and pest concerned.

ii. Due considerations shall be paid to "claim (s)" presented on proposed label based on the assumption that with "proper use" of pesticide product, the claim can be met.

iii. The efficacy trial data shall be examined to find out whether it covers the proposed claims with regards to: crops - pests/diseases, dose rates, mode of application, time of application and frequency of application.

iv. Valid grounds for extrapolation must be evident

v. Dose rates in trials should correspond to that of the "claim"

vi. Trial must have been carried out correctly and in accordance with recommended guidelines.

vii. The sufficiency of efficacy is determined by comparing with the performance of a reference product.

viii. In concluding, efficacy data must indicate if claim is acceptable. Reasons should be given if indications are that claims are not acceptable. Changes and limitations that are needed on the label to ensure acceptability of the claims should also be stated.

6.2.10 Assessment of Phyto-Toxicity and other Side Effects

The type and extent of phyto-toxicity should be described and, where appropriate, recorded according to a recognized scale. Any detrimental effects on wildlife and/or beneficial organisms should also be recorded. Phyto-toxicity must be acceptable.

6.2.11 Statistical Analysis of Data

The raw data should be supplied (or held by the applicant for submission on request) and statistically analyzed where appropriate. Where results of statistical analysis of efficacy data are to be submitted, an analysis of variation should be carried out. The information provided must include:

- Mean and range,
- Numbers of degrees of freedom in the trial, and
- Standard error and probability that an effect is due to the treatment.

Providing the F-statistic would also be useful. If another method of statistical analysis is used, an explanation of why this method was used should be provided, together with a reference to the method and a critical appraisal of the results.

6.3 Reporting

The report section of the efficacy evaluation dossier is a very important but often rather neglected part of the presentation. A presentation of assessment data in a summarized form without explanation or clarification of specific methods of assessment shall not be accepted. It must be recognized that the presentation of data without sufficient details or clarification may give rise to loss of essential or valuable information for the expert(s) in the EPA engaged with the evaluation of efficacy data of the pesticide for, which registration is sought.

In essence this means that all data obtained from the analysis of single samples should be recorded and not merely a summary or an average figure. If necessary, explanatory notes for erratic results should be provided. It should always be clearly stated how samples were taken and in which manner assessments were made. It is also essential that the evaluation method used to establish the effectiveness is described together with the way in which the results are interpreted.

It is essential that the presentation of the results should be standardized in order to facilitate understanding of the trial results. Therefore, the data should preferably be presented in the following way:

- name of the experimenter and organization responsible for the trial:
- objective and location of the trial;
- chemical name and formulation;
- pest, disease or weed against which tested;
- crops and cultivars;
- plant growth stage;
- soil type;
- experimental design, size and number of plots treated;
- application dates and rates;
- application method and equipment;
- volume of spray liquid or other carrier (types);
- weather conditions during and after treatment;
- treatment of the plots with other crop protecting materials, fertilizers and other products;

- application dates;
- dates of assessment;
- size and frequency of sampling;
- quantity and quality of the yield of the harvested crop;
- any results on crop safety including intervals to be observed in order to avoid phyto-toxic effects;
- data assessment including significance;
- interpretation and discussion on the results of the experiment in comparison with similar trials.

CHAPTER 7

ACCEPTABILITY CRITERIA – PESTICIDE LABEL

7.1 Label pattern

The law requires that each container of a pesticide offered for sale have a clearly printed label attached to the packaging.

The labels must be in English language and attached in a very conspicuous manner. Only labels prepared according to the following normalized model will be accepted.

<table>
<tr><td rowspan="2">Safety phrase</td><td>Name of the product</td><td rowspan="2">Directions for use</td></tr>
<tr><td>Active substance/composition</td></tr>
<tr><td>Warning</td><td>Summary of the possible uses</td><td></td></tr>
<tr><td rowspan="3">First aid measures
Medical instructions</td><td>Registration number
Batch number and date of Manufacture</td><td>Cultural practices</td></tr>
<tr><td>Liability</td><td>Pre-harvest interval</td></tr>
<tr><td>Name and address of the formulator
Name and Address of Local Agent</td><td>WHO Class</td></tr>
<tr><td colspan="3">Hazard class / colour code
Pictograms</td></tr>
</table>

7.2 Placement on the Container

The label must appear on the immediate container. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also appear on the outside wrapper or container if it is part of the retail package. The label has to adhere by its entire surface to the packaging containing the substance. If the product is dispensed in several packages, the label or the inscription has to appear on each of them.

The applicant has to provide 6 samples of the proposed label. A sample of labelling for the container is also required.

7.3 Prohibited Containers

Under no circumstances should a pesticide be placed or kept in any container of a type commonly used for food, drink, or household products

7.4 Legibility

Label information must be all of the following:

- Clearly legible to a person with normal vision.
- Readable horizontally when the packaging is in normal position
- Set in on a clear contrasting background.
- Not obscured or crowded.
- Correspond to all claims and descriptions, which, the registrant has made about the product in print.
- Reasonably fit for any purpose for which the product is intended, according to any printed statement of the registrant.

7.5 False or misleading label statements

False or misleading label or advertising/literature statements shall not be allowed. Examples of unacceptable wording:

- No claims as to the safety of the product including such statements as "Safe", "Non-poisonous", "Non-toxic", " Non-injurious", "Harmless", "Among the least toxic chemicals known". No false or misleading statement about the product's effectiveness or about a comparison with another company's pesticide product.
- No statement directly or indirectly implying endorsement or recommendation by any government agency.

7.6 Background Colours of the Label

Depending on the target organisms, 4 colours are prescribed for the background of the label. The Committee will reject any colour that does not correspond exactly to the following pantones:

Function of the product	Background colour	Ref. pantone
Insecticide – miticide	Violet	237 C
Fungicide	Yellow	109 C
Herbicide	Green	375 C
Nematicides - Rodenticides - Avicides - Molluscicides – miscellaneous	Blue	325 C

7.7 Items Required on Labels

All packaging or container should provide the following indelible and legible information:

1. The commercial name or the designation of the product;
2. The name and address of the product manufacturer and the proprietor of the approval;
3. The name and the address of the person in charge of the packaging and final labelling;
4. The registration number of the product;
5. The type of formulation (wettable powder, emulsifiable concentrate, etc.);
6. The volume or net weight in SI unit;
7. The function of the product (insecticide, herbicide, etc.);
8. The mode of action of the product (contact, systemic, etc.);
9. The name and the content of each active substance;
10. Uses (crop, harmful organism, dosage, stage of treatment) for which the product is authorized, and particular conditions in which the product can be used or must, on the contrary, be excluded (contraindications) in accordance with the registration decision. Eventually, the mention "For professional use only" is written legibly on the label;
11. Indications about the possibly toxicity for crops, the sensibility of certain varieties of plants, or every other adverse effect direct or indirect, on crops and harvested products;
12. Pre-harvest intervals;
13. Physical and chemical possible incompatibilities with others products;
14. The date of formulation (month and year);
15. The date of expiration in normal conservation conditions, when the duration of conservation of the product is inferior to two years
16. Appropriate information on the storage stability;
17. The indication of the hazard with a coloured stripe on the label;
18. The indication of the risk for human being, animals and environment by risky phrases correctly chosen;
19. Precautions to take for the protection of human being, animals and environment by safety phrases correctly chosen;
20. Precautions to take for the manipulation and use the product, or contraindications indicated on the approval decision;
21. The indications for the safety disposal of the product and its package;
22. Indications on the emergency measures in case of intoxication.

7.7.1 Commercial name

The commercial (brand or trade) name of the pesticide product appearing on the front panel of the label must be the same as that on the certificate. This name must be different from all registered trademarks in Ghana, as well as of any active substance names.

Regulations allow a pesticide to be registered under more than one brand name. However, the same brand name cannot be registered for products of different chemical composition or different physical condition sufficient to affect the pesticidal properties.

- A brand name cannot include the name of only one or more active substances without including all active substances.
- A brand name cannot be false or misleading or conflict with other label statements.
- A brand name cannot contain names that are construed as claims for un- substantiated qualities. For example, a brand name cannot contain a claim of heightened efficacy

7.7.2 Function of the product

The Committee verifies that the function(s) of the product correspond(s) to any of the lists below

• Miticide	• Herbicide	• Chemical mediator (floral induction, growth regulation, maturation regulation, Chemical thinning out)
• Fungicide	• Nematicide	
• Insecticide	• Rodenticide	
• Molluscicide	• Virucide	• Others (to specify)
• Repulsive	• Bactericide	
• Molecide		

7.7.3 Company name and address

The applicant named in this box should be the supplier of the product, or his representative, who is registered to do business in Ghana. He is responsible for the commercialisation of the product when it is registered. If the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by wording such as "Packed for __", "Distributed by __" or "Sold by __". If there are two or more locations, the principal location should be indicated.

The permanent address of the applicant has to be indicated; it must be as much as possible a geographically identifiable address, the only mention of the P.O. Box is not sufficient.

The address on the label may differ from the application form and the certificate.

7.7.4 Active substance statement

The ingredient statement on the label must include the identity and percentage of each active substance and the total percentage of the inert ingredients. If the product is exempt from registration, and the company chose not to register, all ingredients must be listed along with their percentages.

The ingredient statement must be on the front panel of the label unless the package size or form makes this impractical. The text of the statement must run parallel with, and be distinguishable from, other text on the same panel. If there is an outside container or wrapper

and the ingredient statement cannot be clearly read, the ingredient statement must also appear on the outside container or wrapper.

The percentages of ingredients must be stated in terms of percent by weight and must total 100%. All ingredient statements must be expressed as nominal concentration. Nominal concentration is the amount expected to be present in percent by weight. Percentages cannot be expressed by a range on the label such as "22-25 percent.

Regulation requires that the name of each ingredient be the accepted common name, if there is one. If the common name is not well known, it should be followed by the chemical name. If there is no common name, only the chemical name is required

If the rate of application of the product is expressed as weight of active substance per unit area, a statement of the weight of active substance per unit volume of the pesticide formulation must appear in the ingredient statement

If the product is for internal administration to animals, the ingredient statement may be given in terms of dosage in lieu of percentage by weight.

(a) Microbial products

Products containing live organisms must indicate the equivalent number of viable units (spores, cells, colony forming units, etc.) per unit weight of product. Bacillus thuringiensis (Bt) product active substance declaration is based on percent by weight of insecticidal toxin.

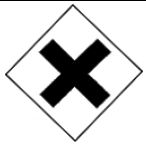
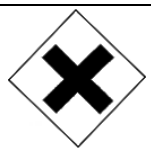
If the product contains Bacillus thuringiensis, the active substance percentage on the label may include all dried fermentation products.

7.7.5 Toxicological stripe and hazard symbols

In accordance with the hazard class established according to the "Classification of pesticides recommended by the WHO", the label has to provide a toxicological coloured stripe. Be certain that this toxicological stripe covers more than 15% of the label surface.

The table below shows the classification of hazard and the corresponding toxicological stripe, colour and the symbol that should appear on the packaging or the container.

WHO hazard class	Hazard indication	Ref. pantone	Hazard symbol
Ia Extremely harmful	VERY TOXIC	Pantone Red 199 - C (magenta 100%, yellow 70%)	
Ib Very harmful	TOXIC	Pantone Red 199 - C (magenta 100%, yellow 70%)	

II Moderately harmful	DANGEROUS	Pantone Yellow C (yellow 100%, magenta 10%)	
III Slightly harmful	ATTENTION	Pantone Yellow C (yellow 100%, magenta 10%)	

7.7.6 Human hazard – signal word

The signal word is required on the front panel of the label and is determined by the toxicity category of the product. The signal word is preferred in all capital letters:

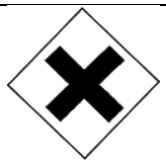
- Category I = DANGER
- Category II = WARNING
- Category III (or IV) = CAUTION

If the product is a Category I pesticide because of its oral, inhalation, or dermal toxicity, the word "POISON" must appear in red on a contrasting background and skull and crossbones must appear in immediate proximity to the word "POISON". This is in addition to the required signal word "DANGER."

7.7.7 Pictograms

Pictograms indicate graphically a message for a safe handling of the products. They must be designed on the label pattern of annex 7. The applicant mentions on the form their number and wording. Pictograms **must** appear on all labels.

A list of pictograms are presented below:

 1 - The product is very toxic/toxic to human beings and to animals	 2 - The product is dangerous to human beings and to animals	 3 - Keep locked away and out of reach of children	 4 - Use the recommended quantity of the product which is a liquid concentrate
 5 - Use the recommended quantity of the	 6 - Precautions to take for the application of the	 7 - Wear gloves	 8 - Wear boots

product which is a solid concentrate	product		
 9 - Wear protection of nose and mouth	 10 - Wear respirator	 11 - Wear eye protection	 12 - Wear protective overalls
 13 - Wear protective apron	 14 - Wash after use	 15 - Harmful to domestic and savage animals	 16 - Harmful to fish and aquatic organisms; do not pour in waterways, lakes, rivers and points of water

7.7.8 Child Hazard warning-Keep out of reach of children

Children protection systems may be required. Every label must bear the statement "Keep Out of Reach of Children" on the front panel unless the product's contact with children is extremely remote such as for a manufacturing-use only product. The statement is not required if the product is registered for use on infants or small children

7.7.9 First Aid

A First Aid statement (Statement of Practical Treatment) is required on all pesticide products, which are toxicity Category I, II, or III due to oral, inhalation, or dermal toxicity. The term "First Aid" is now allowed in lieu of "Statement of Practical Treatment" on the label. A statement is required for each route of exposure where the acute toxicology study is classified as Category I, II, or III. It is permissible to have a referral statement such as "See Statement of Practical Treatment on Back Panel." If the word "Poison" and the skull & crossbones are required, the referral statement must be in close proximity.

7.7.10 Precautionary Statement for Human and Domestic Animals hazard

Precautionary statements indicating hazard to human and domestic animals must be stated under the general heading "Precautionary Statements" and under the subheading "Hazards to Humans and Domestic Animals". These statements must be immediately preceded by the signal word.

Precautionary statements shall be based on results of the acute toxicity studies.

7.7.11 Precautionary environmental hazard statement

Environmental hazards precautionary statements are required if a hazard to non-target organisms exists. These must be stated under the general heading "Precautionary Statements" and under the subheading "Environmental Hazard". Labels, which include the statement "Do not apply directly to water, to areas where surface water is present", are acceptable. If registered only for outdoor residential use, use the statement "Do not apply directly to water." Labels need not be submitted for scientific evaluation of this wording.

7.7.12 Precautionary physical or chemical hazard statement

Products distributed in the market must be kept in their original container or package.

The applicant should indicate transport requirements on the over-packages and large packages in accordance with the international symbols adopted for aerial transportation, maritime, railway and terrestrial.

Physical and chemical hazards statements must be stated under the general heading "Precautionary Statements" and under the subheading "Physical or Chemical Hazards

These statements includes the product's flammability, explosiveness, or other hazardous features or appropriate symbols as shown below

Examples	*Code IMO-IMDG: Class 6.1 - group III - label 6.1 (KEEP AWAY FROM FOOD) mark " p " marine Pollutant*	 N – Harmful for environment			
 F+ - Extremely flammable	 F - Easily flammable	 E - Explosive	 O – Oxidizer	 C - Corrosive	 N – Harmful for environment
 Very toxic	 Toxic	 Harmful	 Irritant	 Warning	

7.7.13 Registration number

The EPA Registration Number must be set in type of a size and style similar to other print and must run parallel to it. These numbers may appear in the following format on labels: For regular products: EPA Reg. No. 000 0000-00000.

The first set of digits is the prefix indicating the type of registration. The first two digits of the second digits is the number assigned to the year of registration. Whilst the next two digits of the same set stands for the code for the registrant The third set of digits is five digits of chronological order indicating the number for the registered product (e. g FRE-0302-00005, for full registration for product registered in the year 2003 by registrant with code number 02 for product registration number 0005).

Activity	Prefix
Registration (Full)	FRE
Registration (Provisional)	PCL
Experimental Clearance	EXP
Registration Renewal	RRE

7.7.14 Direction for Use

Directions for use must be stated in terms easily read and understood by the person likely to use or to supervise use of the pesticide. The directions for use must include:

- Site of application such as crops, animals, areas, or objects to be treated.
- Target pests for each site. If a pest is listed on the label, directions for use must be included for that pest.
- Dosage rate for each site and pest.
- Method of application.
- Dilution instructions, when applicable.
- Frequency and timing of applications (including pre-harvest intervals, PHI, when applicable).
- Re-entry intervals (REI), when applicable. See more complete section on WPS later in this chapter.

7.7.15 Dosage

The dosage of the product shall be expressed per treated unit (ha, m^2, m^3, t, etc.). The unit of the dose has to be written after the value.

Example: 1 l/ha; 100 g/kg of bait.

Units for the expression of use dosages (all other units will be considered as inappropriate by the PTC):

WORN	FORMULATION	ACTIVE SUBSTANCE
Watering and soaking of plants and seeds: - Solid formulations; - Solutions, suspensions and emulsions.	 g/hl g/hl	 g/ha g/ha
Solid baits: - Solid formulations; - Liquid formulations.	 g/kg of bait l/kg of bait	 g/kg of bait g/kg of bait
Fumigants formulated as liquids or gases: - Stocked commodities and seeds; - Premises; - Soil.	 l/q g/m3 l/ha	 g/q g/m3 g/ha
Spraying: - Premises treatments; - Outdoor treatments.	 l/m3 l/ha	 g/m3 g/ha
Powdering and coating of seeds	g/q	g/q
Powdering of stocked commodities.	g/q	g/q
Powdering and flow-dust.	g/ha	g/ha
Pulverization in premises and on packaging: - Solid formulations; - Liquid formulations.	 g/m2 l/m2	 g/m2 g/m2
Pulverization on seeds and stocked commodities.	l/q	g/q
Pulverization at low volume and ultra low volume.	l/ ha	g/ha
Pulverization at normal volume: - Solutions, suspensions and emulsions.	 l/ha	 g/ha

7.7.16 Storage

All product labels must have appropriate storage instructions set apart and clearly distinguishable from other directions for use. Labels for household products should emphasize storage in the original container and placement in locked storage areas.

7.7.17 Pesticide Product Disposal

All product labels must show explicit instructions for pesticide disposal.

Labels for products intended solely for household use must show the statement "*Securely wrap original container in several layers of newspaper and discard in trash*".

All other product labels must have the exact wording *"Do not contaminate water, food or feed by storage or disposal".*

7.7.18 Container Disposal

All product labels must include container disposal instructions appropriate to the type of container.

All products (except those for household use) must bear the following container disposal instructions:

The statement "*Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash*" is used for the following products:

- Liquid household use products in containers of 1 gallon or less.
- Liquid household bleach products up to 1-1/2 gallons.
- Dry household products 5 pounds or less.
- Dry fertilizer-herbicide lawn products up to 25 pounds.

7.7.19 Net weight or measure of content

The contents must be stated in the largest suitable units. Standard weights and volumes must be used; metric measurements may be added.

Dry formulations are expressed as pounds or ounces, liquids as gallons, and pressurized products as avoirdupois pounds and ounces

7.7.20 Risky phrases

A statement of particular risks to human beings, animals and the environment should be made on the label using typical sentences chosen in an appropriate manner from the following list, and should also stated on the form in the white space. R phrases list is as follows:

R1 Explosive when dry
R7 May cause fire
R8 Contact with combustible material may cause fire
R9 Explosive when mixed with combustible material

R10 Flammable

R11 Highly flammable
R12 Extremely flammable
R13 Liquid gas extremely flammable
R14 Reacts violently with water
R15 Contact with water liberates extremely flammable gas
R16 Explosive when mixed with oxidizing substances
R17 Spontaneously flammable in air
R18 In use, may form flammable/explosive vapour-air mixture
R19 May form explosive peroxides
R20 Harmful by inhalation
R21 Harmful in contact with skin
R22 Harmful if swallowed
R23 Toxic by inhalation
R24 Toxic in contact with skin
R25 Toxic if swallowed
R26 Very toxic by inhalation
R27 Very toxic in contact with skin
R28 Very toxic if swallowed
R29 Contact with water liberates toxic gas
R30 Can become highly flammable in use
R31 Contact with acids liberates toxic gas
R32 Contact with water liberates very toxic gas
R33 Danger of cumulative effects
R34 Causes burns
R35 Causes severe burns
R36 Irritating to eyes
R37 Irritating to respiratory system
R38 Irritating to skin
R39 Danger of very serious irreversible effects
R40 Possible risks of irreversible effects
R41 Risks of serious damage to eyes
R42 May cause sensitisation by inhalation
R43 May cause sensitisation by skin contact
R44 Risk of explosion if heated under confinement
R45 May cause cancer
R46 May cause heritable genetic damage
R47 May cause congenital malformations
R48 Danger of serious damage to health by prolonged exposure
R49 may cause cancer by inhalation
R50 Very toxic to aquatic organisms
R51 Toxic to aquatic organisms
R52 Harmful to aquatic organisms
R53 May cause long-term adverse effect in the aquatic environment
R54 Toxic to flora

R55 Toxic to fauna
R56 Toxic to soils organisms
R57 Toxic to bees
R58 May cause long-term adverse effect in the environment
R59 Dangerous for the ozone layer
R60 May impair the fertility
R61 May cause harm to the

R62 Possible risks of impaired fertility
R63 Possible risks of harm to the unborn child
R64 May cause harm to breastfed babies
R39/23/24 Toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/23/25 Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/24/25 Toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/23/24/25 Toxic: danger of very serious irreversible effects by inhalation, in contact with skin and if swallowed
R39/26 Very toxic: danger of very serious irreversible effects through inhalation
R39/27 Very toxic: danger of very serious irreversible effects in contact with skin
R39/28 Very toxic: danger of very serious irreversible effects if swallowed
R39/26/27 Very toxic: danger of very serious irreversible effects by inhalation and in contact with skin
R39/26/28 Very toxic: danger of very serious irreversible effects by inhalation and if swallowed
R39/27/28 Very toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/26/27/28 Very toxic: danger of very serious irreversible effects through inhalation
R40/20 Harmful: possible risks of irreversible effects through inhalation, in contact with skin and if swallowed
R40/21 Harmful: possible risks of irreversible effects in contact with skin
R40/22 Harmful: possible risks of irreversible effects if swallowed
R40/20/21 Harmful: possible risks of irreversible effects through inhalation and in contact with skin
R40/20/22 Harmful: possible risks of irreversible effects through inhalation and if swallowed
R40/21/22 Harmful: possible risks of irreversible effects in contact with skin and if swallowed
R40/20/21/22 Harmful: possible risks of irreversible effects through inhalation, in contact with skin and if swallowed
R42/43 May cause sensitisation by inhalation and by skin contact
R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation
R48/21 Harmful: danger of serious damage to health by prolonged exposure in R48/25 Toxic: danger of serious damage to health by prolonged if swallowed
R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed

R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact

7.8.21 Safety phrases

Precautions to take for the protection of human beings, animals and the environment are mentioned on the label using specific sentences. The applicant chooses them in an appropriate manner in the following list, and writes them on the application form:

S37 Wear suitable gloves

S38 In case of insufficient ventilation, wear suitable respiratory equipment

S39 Wear eye/face protection

S40 To clean the floor and all objects contaminated by this material, use ... (to be specified by the manufacturer)

S41 In case of fire and/or explosion do not breathe fumes

S42 During fumigation/spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer)

S43 In case of fire, use ... (indicate in the space the precise type of fire-fighting equipment. If water increases risk, add: "Never use water")

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

S46 If swallowed, seek medical advice immediately and show this container or label

S47 Keep at temperature not exceeding ...°C (to be specified by the manufacturer)

S48 Keep wet with ... (appropriate material to be specified by the manufacturer)

S49 Keep only in the original container

S50 Do not mix with ... (to be specified by the manufacturer)

S51 Use only in well-ventilated areas

S52 Not recommended for interior use on large surface areas

S53 Avoid exposure - obtain special instructions before use

S56 Dispose of this material and container hazardous or special waste collection point

S57 Use appropriate container to avoid environmental contamination

S59 Refer to manufacturer/supplier for information on recovery/recycling

S60 This material and its container must be disposed of as hazardous waste

S61 Avoid release to the environment. Refer to special instructions/Safety Data Sheets

S62 If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label

S1/2 Keep locked up and out of the reach of children

S3/7 Keep container tightly closed in a cool place

S3/9/14 Keep in a cool, well-ventilated place away from ... (incompatible materials to be indicated by the manufacturer)

S3/9/14/19 Keep only in the original container in a cool, well-ventilated place away from ... (incompatible materials to be indicated by the manufacturer)

S3/9/49 Keep only in the original container in a cool, well-ventilated place

S3/14 Keep in a cool away from ... (incompatible materials to be indicated by the manufacturer)

S7/8 Keep container tightly closed and dry

S7/9 Keep container tightly closed in a well-ventilated place

S7/47 Keep container tightly closed and at a temperature not exceeding ...°C (to be specified by the manufacturer)

S20/21 When using do not eat, drink or smoke

S24/25 Avoid contact with skin and eyes

S29/56 Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point

S36/37 Wear suitable protective clothing and gloves

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection

S36/37 Wear suitable protective clothing and eye/face protection

S36/37/39 Wear suitable gloves and eye/face protection

S47/49 Keep only in the original container at a temperature not exceeding ...°C (to be specified by the manufacturer)

Examples: *S 9 - Keep container in a well ventilated place;*
S 27 - take of immediately all contaminated clothes;
S 30 - Never add water to this product;
S 20/21 - Do not eat, drink and smoke when using.

(a) Choice of the Risk Phrases (R) and Safety Phrases (S) The Most Used

1. All label of a pesticide could usefully carry the following phrases, whatever its toxicological classification: S2, S13, S20/21.
2. For very toxic, toxic and dangerous specialities,: S45 + R phrases appropriated to ways of exposure for which the product has been proven very toxic, toxic or dangerous.
3. For corrosive products: S23, S37, S39.
4. For the organophosphonates: S28.
5. For irritant products: for the skin: R38, S24, S37; for eyes: R36, S25.
6. For very toxic or toxic to fish products: "Very toxic to fish" (or "Toxic to fish"), "Do not treat near waterways and pond surroundings".

For toxic to bees products: R57 + "Do not treat during the blossom

7.7.22 Tank mixes

Tank mix label claims are allowed without supporting compatibility and residue data if the following conditions are met:

- The chemical characteristics of all products to be used in the mix are such that no incompatibility or potentiation is likely to occur.
- The pesticide product to be mixed with the product, which is the subject of the application, does not contain a label prohibition against such mixing.
- The label contains the statement:
- "This product can be mixed with (chemical name, including percentage of active substance and type of formulation, or specific product name, or both) for use on (crops/sites) in accordance with the more (most) restrictive of label limitations and precautions. No label dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing. Where a specific product name is recommended for the tank mix, the label statements shall be more explicit, including such information as specific dilution and application rates."

7.7.23 Local languages

Pesticide labels may contain English language statements and translations. For other products, registrants may choose to translate the label, usually into a local dialect.

7.7.24 Label or Formulation changes

There are times when for one reason or other, a registrant may request for changes in the formulation composition or an amendment to the label. to an already registered pesticide product. Label changes must be submitted to, and found acceptable by, the EPA before the labels are released for sale.

Such requests may fall into the following categories depending on the nature of the request:

- Label amendments requiring data and scientific evaluation.
- Label amendments or formula changes that do not data and scientific evaluation

7.7.25 Label amendments requiring data and scientific evaluation

Examples of label or formula changes requiring the submission of data and a scientific evaluation includes:

- Addition of a crop or a use site.
- Addition of indoors uses.
- Adding pests or types of pests not already on the label.
- Reducing the signal word or the precautionary statements.

7.7.26 Label amendments or formula changes that do not require data and scientific evaluation

Examples of label amendments or formula changes that do not require data and scientific evaluation otherwise known as non-substantive changes include:

- Addition of a pest similar to one already on the label (except antimicrobial products which must be processed as a label amendment).
- Minor revision or restatement of an ingredient in the formula.
- Moving an ingredient listed as active to inert.
- Change of percentage of active substance to the nominal concentration.
- Changes involving similar use patterns or pests. New Registrar should consult with Registrar/Director of CCMC or chairman of Bio-efficacy sub-committee to determine if a changed use pattern or pest is similar to use patterns or pests already on the label.
- First Aid statements amendments
- Change of trade name without change in formulation. Applicant gives a written undertaking on oath that there shall be no changes to the formulation.

Applicant

The applicant to shall submit an application for amended registration with a copy of the first approved, labels, and data, highlighting the proposed label changes.

The EPA

EPA shall stamp the label and send an accompanying letter. For a change in formulation, only a letter of acceptance is sent to the applicant.

For formulation changes

a) If the percent of active substance stated on the label is decreased and the rate of application not adjusted accordingly, the registration package is routed to the Bioefficacy sub-committee to determine if the product is still efficacious.

b) If the percent of active substance stated on the label is increased and the rate of application not adjusted accordingly, the following action can be taken:

- The applicant shall be asked to submit a justification for increasing the amount of active substance, or
- The increase in active substance may require phytotoxicity, residue, or toxicology data.

When the label amendment or formula revision is found acceptable, the Registrar will:

- Write the letter accepting the label amendment or formula change.
- Stamp three labels for distribution to the product file, coding, and the company.
- If a formula revision, include only the top page of the application form. and forward to the product file.
- Compare the submitted label or formula revision to the currently registered label or formula.
- Highlight the revisions, if the applicant has not done so.
- Follow the procedures in Chapter V and, if applicable, Chapter III.
- Record the tracking ID # on the weekly action log.
- Give the letter and label (or formula) designated "company" to the Supervisor of Registration.

The most current EPA approved label or formula becomes the latest registered label or formula.

CHAPTER 8

POST REGISTRATION MONITORING AND SURVEILLANCE

8.1 Procedure for Renewal

A pesticide product certificate of registration expires on December 31st of each due year. By October 15 of each year, each registrant shall be mailed a list of their registered pesticide products that are due to expire.

8.1.1 Initiating the Renewal Process

The Pesticides Registrar shall send each registrant an Application for Renewal, listing the company's registered products. With the renewal request, the Registrar sends a letter outlining general requirements for renewal. The registrant shall:

- Line out the names of any products they wish to discontinue.
- Sign and return the Application for Renewal with renewal fees for the remaining products.
- Submit any required data or adverse effects information not previously submitted.

A product will not be renewed if the registrant has not complied with the conditions of its time-limited registration. With each renewal request, the registrant shall submit the following:

- The signed Application for Renewal. A statement of compliance with the adverse effects disclosure provisions is included on the form.
- $750 per product renewal fee and any applicable penalties.
- Any data the registrant agreed to submit for a provisional clearance.

A progress report must be submitted with the renewal application if the time frame for submission of data is after December 31. When a pesticide registration is renewed without re-evaluation, the Pesticides Registrar makes a written finding that information was not received necessitating re-evaluation. An Emergency Registration cannot be renewed for more than one year. Data not previously submitted by the company should be sent and processed separately from the renewal request.

8.1.2 Processing the renewal request

Applications for Renewal that are complete are processed by the front desk secretary and forwarded to the Information Systems Branch for coding.

If only an address change is made on the renewal request, the Front Desk secretary shall make the change to the certificate and to the computer database. This is confirmed with the designated Officer. If the address change includes an agent's name, this is first verified with the registrar. The Front Desk staff routes any of the following to the Registrar:

- The application for renewal showing a change in firm name, altered brand name, altered registration number, or additional brand name.
- Data or an adverse effects disclosure is received.

An annual progress report is received in accordance with conditional registration or with provisional clearance requirements or any other time-limited registration. The Registrar shall:

- Initial the Application for Renewal and give to the Pesticides registrar.
- Files the progress report in the product file in the Strong Room
- Processes a copy of the report with the route sheet and instructions for presentation t the appropriate Evaluation Sub Committee.

If the Application for Renewal shows a change in a firm name, product name, additional brand name, or new registration number, the Registrar informs the registrant that they must apply for registration. The Registrar requests a new application form, label, and supporting documents.

The Registrar may correct the Application for Renewal to show only those products to be renewed, initial the correction, initial the application, and forward it to the Front Desk secretary.

After the records are updated, the Pesticides registrar issues the Certificate of Registration listing the registrant's products registered for the current year. The registrar groups, checks them for accuracy, distributes copies, and mails the original to the registrant.

8.1.3 Penalties for Late Renewal

If a registrant does not return the Application of Renewal within one calendar month after expiration of the Certificate of Registration, a penalty of $50 per product is charged. An additional penalty of 10% of the original amount is due for each succeeding calendar month. The total penalty cannot exceed 50% of the original amount due.

A penalty is not collected if the Application for Renewal is accompanied by an affidavit that no business was done during the period of non-registration.

8.2 Non Renewal of Product registration

Non-renewal of a product registration can occur for any of the following reasons:

1) The applicant deletes products from their Application of Renewal.
2) The applicant has not submitted the appropriate renewal fees.

3) The applicant has not submitted data required by conditions placed on the product at time of registration. This includes data or information required for any time-limited registrations.

4) The Pesticides Registrar cannot renew a product due to regulatory action, such as cancellation.

In any of the above cases, the Registrar will:

- Line out the brand name.
- Initial the application form and return it to the registrar.
- Inform the registrant by letter that registration of the product will not be renewed and that the renewal fee, if paid, will be refunded.

8.3 Voluntary Cancellation

A registrant may request voluntary cancellation mid-year by sending a written request to the Pesticides Registrar. The written request or form may be submitted by fax, followed by a hard copy.

If received by the Registrar, the Registrar gives the written request to the Registrar, with instructions to issue a Supplemental Certificate of Registration showing deletion of the product.

If the registrant requests no specific date of cancellation, the date of the request letter is used. The registrar will do the following after the Registrar has surnamed the letter:

- Update label file database showing "voluntary cancellation" as the reason for inactivation.
- Line out the brand name and registration number on the main Certificate of Registration,
- Forwards the Supplemental Certificate of Registration and other information to the strong room.
- Forward a copy of Supplemental Certificate of Registration to the Enforcement Branch.

At the Strong room, the registrar

- Marks the product file "inactive" and places into inactive files area.
- Line out the product name and registration number on the main Certificate of Registration.
- File the Supplemental Certificate of Registration and the original letter or form requesting voluntary cancellation in the Certificates file.

8.4 Lapsed Registration

In all of the above cases, the registrant cannot sell the product from the time the registration lapses. A dealer who is in possession of the product with a lapsed registration may sell it for

two years from the date of lapsing. The end user may use the product indefinitely, unless there is a suspension or cancellation of use.

8.5 Changing a Provisional Clearance to Full Registration

When the registrant submits the required data in support of full registration for the provisionally cleared product, the Registrar will review the data package for completeness and correctness.

If the package is complete and correct, the specialist routes the data package to the appropriate evaluation review committee.

If more than one study is required, each study can be submitted and routed separately as it is completed.

A copy of the previous evaluation report or a copy of the letter of conditions and the registered label (label not required for storage stability studies) shall be included.

If all conditions have been met and the data found acceptable, the appropriate letter shall be prepared and sent to the registrant. The letter will state that submitted data supports full registration and the provisional clearance has been changed to a full registration.

A copy of this letter is given to the Registrar who amends the certificate to indicate full registration.

No target date is assigned on the status sheet.

If the submission is incomplete or incorrect, the Registrar will notify the registrant, in writing, of the deficiencies.

If the registrant requests an extension, the Registrar will review the registrant's written request for an extension.

To determine the validity of the extension request, the Registrar consults with the chairperson of the appropriate evaluation sub-committee who recommended the provisional clearance and with the Registrar. When appropriate, the Evaluation Scientist will suggest a reasonable time extension to complete the studies.

The Pesticides Technical Committee shall be consulted before extending the time for the provisional clearance.

If the registrant has not attempted to fulfilled the requirements, and the time frame for submission of data has elapsed, the Registrar will invalidate the registration. The usual procedure for invalidating a provisional clearance is for the Registrar not to renew the product registration.

A letter of intent to invalidate shall be sent to the registrant, followed by a final letter of invalidation.

8.6 Adverse Effects Disclosure

If during the registration process, or anytime after registration, the registrant (or applicant) has evidence of an adverse effect or risk to human health or the environment, the registrant (or applicant) must immediately submit the information to Pesticides Registrar.

If there is reason to believe that use or continued use of the pesticide constitutes an immediate substantial danger to persons or to the environment, the registrar may, after notice to the registrant, suspend the registration.

The Front Desk secretary will in such circumstances determine if the submission is an adverse effects disclosure

If data is submitted, the submission shall be given filed by the registrar in the product file at the strong room.

If no data is submitted, the submission shall be filed and designated as adverse effects disclosure by the Registrar.

The designated Registrar will then determine whether the submission must enter scientific evaluation or whether a letter of acknowledgement to the registrant is sufficient.

If scientific evaluation is needed, the submission shall enter into evaluation.

The Pesticides Technical Committee shall review evaluators' comments after scientific evaluation is completed.

A letter shall be written to the registrant after the scientific evaluation summarizing the results of the evaluation.

If an adverse effect exists, the submission shall be forwarded to the Registrar, who will write to the registrant.

8.7 Archive the submission to the strong room

If the submission contains data, the entire package shall be archived in the strong room. A copy of the letter to the registrant shall be kept on file. If the submission does not contain data, only a copy of the status sheet and evaluator's comments shall be filed and stored in the strong room. The remaining information and documents shall be kept for 2 years.

An annual summary of all adverse effects submissions shall be prepared

8.8 Re-evaluation

The Law requires the Pesticides Division to continuously evaluate registered pesticides. The following factors may result in a registered pesticide product or group of products being re-evaluated:

- Public or worker health hazard.
- Environmental contamination.
- Residue over tolerance.
- Fish or wildlife hazard.
- Lack of efficacy.
- Undesirable phyto-toxicity.
- Hazardous packaging.
- Inadequate labelling.
- Disruption of the implementation/ conduct of pest management.
- Other information suggesting a significant adverse effect.

A re-evaluation may be triggered by ongoing Pesticides Division registration reviews or by national pesticide use surveillance and illness investigations, pesticide residue sample analyses, environmental monitoring activities, and information submitted by other state or private agencies, or other sources.

8.9 Receipt of a request for re-evaluation

Upon receipt of a request for re-evaluation along with the basis and supporting data, the Registrar prepares a "Notice of Proposed Decision to re-evaluate Pesticide Products" and prepares the individual letters to registrants whose products are to be re-evaluated. The Executive Director signs the Notice. The date the notice is signed and shall be the initiation date of the re-evaluation. The Registrar then prepares a reference binder of re-evaluation information. The binder includes:

- All correspondence and memoranda regarding the re-evaluation.
- Copies of letters notifying registrants of the re-evaluation.
- Copy of "Notice of Proposed Decision Concerning Re-evaluation of Pesticide Products."
- Concurrence form and all information relative to the basis of the re-evaluation.
- Copies of labels (unless too numerous to be practical).

During the re-evaluation of a pesticide, data relevant to the focus of the re-evaluation may be required. A reasonable time, not exceeding two years, shall be allowed for the development and submission of data.

The Pesticides Registrar shall inform appropriate stakeholder organisations that the re-evaluation has been initiated and requests a list of data and/or information, if any, to be required from the registrant. Should additional data be required, the Registrar prepares letters notifying registrants of the data requirements. Copies of the letters are routed to the designated Registrar. At this point, the re-evaluation enters an inactive phase until the data are received.

8.10 Processing data submitted during re-evaluation

Once the data are received, the Front Desk secretary prepares a status sheet (the ID number will have RV as a suffix) and routes the data to the strong room for indexing. After indexing, the data are routed to the designated Registrar. The Registrar identifies the appropriate evaluation committee of the data and submits the package into the scientific evaluation process. Upon completion of the reviews, the data package is given to the Registrar. The Registrar writes a letter to the registrant identifying the results of the review, with a copy routed to the Registrar

8.11 Conclusion of the re-evaluation

When the issues that caused the re-evaluation to be initiated have been resolved, the Registrar prepares a summary and recommendation for review by the PTC. The PTC then makes the decision to modify, restrict, suspend, cancel, or continue registration.

There are several possible outcomes of a re-evaluation. The data may demonstrate that the issue is resolved and that no significant adverse effect will occur. The PTC may determined that there is a need to adopt mitigation measures; or PTC may determine that the adverse effect cannot be mitigated in which case the pesticide product(s) must be suspended or cancelled.

The Registrar prepares the "Notice of Final Decision Concerning the Re-evaluation of Pesticide Products" and the individual letters to registrants informing them of the re-evaluation final decision. The PTC chairman signs the final Notice, and routes it for endorsement by the executive Director. The re-evaluation is concluded on the date the notice is signed.

A semi-annual report shall be prepared by the Pesticides Division describing the status of pesticides under re-evaluation, or for which factual or scientific information was received, but no re-evaluation was initiated.

8.12 Risk Assessment

Upon registration of a new active substance product, the active substance shall be prioritized for risk assessment. Risk assessment of currently registered active substances can be triggered by a number of different factors, including the identification of potential adverse

effects. Risk assessments are generally related to chronic human health effects. The PTC shall determine risk assessment prioritization.

The Registration Department is responsible for data distribution and communication with registrants. For any data submitted relating to risk assessment, Front Desk secretary prepares a status sheet using the prefix RA and routes the data to the strong room for indexing. After indexing, the strong room routes the data directly for risk assessment by the appropriate evaluation committee.

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Data on pesticide toxicity to bees can be found at the following web sites.

- **Koppert on-line side-effects database:** Database, run by commercial biocontrol company, on the side-effects of pesticides on natural enemies and bumblebees. Can be accessed at: **http://www.koppert.nl/e0110.html**

  Note that LD_{50}s are provided, but only hazard classes.

- **ECOTOX Database:** Database, run by the US-EPA, on the side-effects of pesticides on non-target organisms. Can be accessed at: **http://www.epa.gov/ecotox/**

  Notes: search on CAS-numbers since pesticide common names are not accepted; check species list for the various bee species in the database.

APPENDICES