

PEST CONTROL PRODUCTS BOARD

(A Statutory Organization of Government)

Tel: +254-020-8021846/7/8
Mobile: 0720 480 904/0735 778 743



P.O. Box 13794-00800
Loresho, off Waiyaki Way,
NAIROBI, KENYA
Email: info@pcpb.go.ke
md@pcpb.go.ke
Website: www.pcpb.go.ke

Your Ref:

Our Ref:.....PCPB/III/REG/VOL.III/20/143

Date: 15th October, 2020.....

TO ALL LOCAL AGENTS

RE: ELECTRONIC SUBMISSION OF PEST CONTROL PRODUCTS TECHNICAL DOSSIERS (Version 1.0)

Introduction:

This guideline for electronic submission of dossiers has been developed taking cognizance of the prevailing international best practices and in order to scale down on use of bulky paper submissions. This will also prepare the groundwork for future fully fledged online submission of dossiers. The handling of the data provided will be governed by existing laws and regulations.

This guideline **shall be followed** when submitting the application documents and supporting information in electronic format. A well-constructed, named and indexed submission expedites the screening and review process and reduces assessment time. The use of electronic dossier submission will enable the Pest Control Products Board (PCPB) review efficiently, safely and improve the quality of dossier submitted.

It is the responsibility of the local representative to submit the dossier (s) in the format indicated below. Technical Dossiers that do not meet these requirements will not be accepted.

Scope:

This guideline is for the electronic submission of new technical dossiers and resubmission of previously deferred applications.

This guideline does not replace the legal requirements for appointment of the local representative and thus an applicant who is **not a resident** in Kenya must appoint an agent permanently resident in Kenya and duly recognized by the Pest Control Products Board.

Timeline for operationalization:

Due to the current prevailing conditions occasioned by the Covid-19 pandemic, the guideline takes **effect immediately from the date of this circular.**

Other requirements that continue to be in force:

The Applicants are advised to submit dossiers in prescribed Application Forms, abide by all previous circulars i.e. Dossier submission appointment (PCPB/REG/VOL.II/10/03 dated 9th July 2010), Submission of Technical Dossiers for Generic products (Ref: PCPB/III/REG/VOL.I/19/116 dated 27th March 2020), the format of presenting electronic submission of Data Summary (Ref: PCPB/III/REG/VOL.II/20/017 dated 15th April 2020) and electronic submission of Labels (Ref: PCPB/III/REG/VOL.I/20/145 dated 30th March 2020).

Method of electronic dossier submission:

The technical dossier should be provided in encrypted compact disk (CDs) in **.pdf format ONLY**. The PDF should be secure removing features that enables printing, copying, deleting and converting to other formats e.g. word. To allow for preliminary check, the documents provided must not be scanned. Where the submitted documents are password protected, the password must be securely provided to Pest Control Products Board.

i) Submission of the Confidential Business Information:

The Confidential Business Information as indicated in the Circular (ref: PCPB/111/REG/VOL.IV/15/152 dated 11th November 2015) shall be provided in hardcopy accompanied by the hard copy of one Application Form, one hard copy of Form A6, the original letter (s) of appointment, hard copy of contract agreement, letter of access. Applicants are advised to provide the official email address (es) for correspondence.

Documents in hard copy must be sanitized in line with Ministry of Health guidelines.

ii) Submission of the Rest of the Technical Dossier:

The dossier must be submitted in prescribed format (folders & subfolders corresponding to the Annexes in prescribed Application Form). The CD should be enclosed and protected from physical damage.

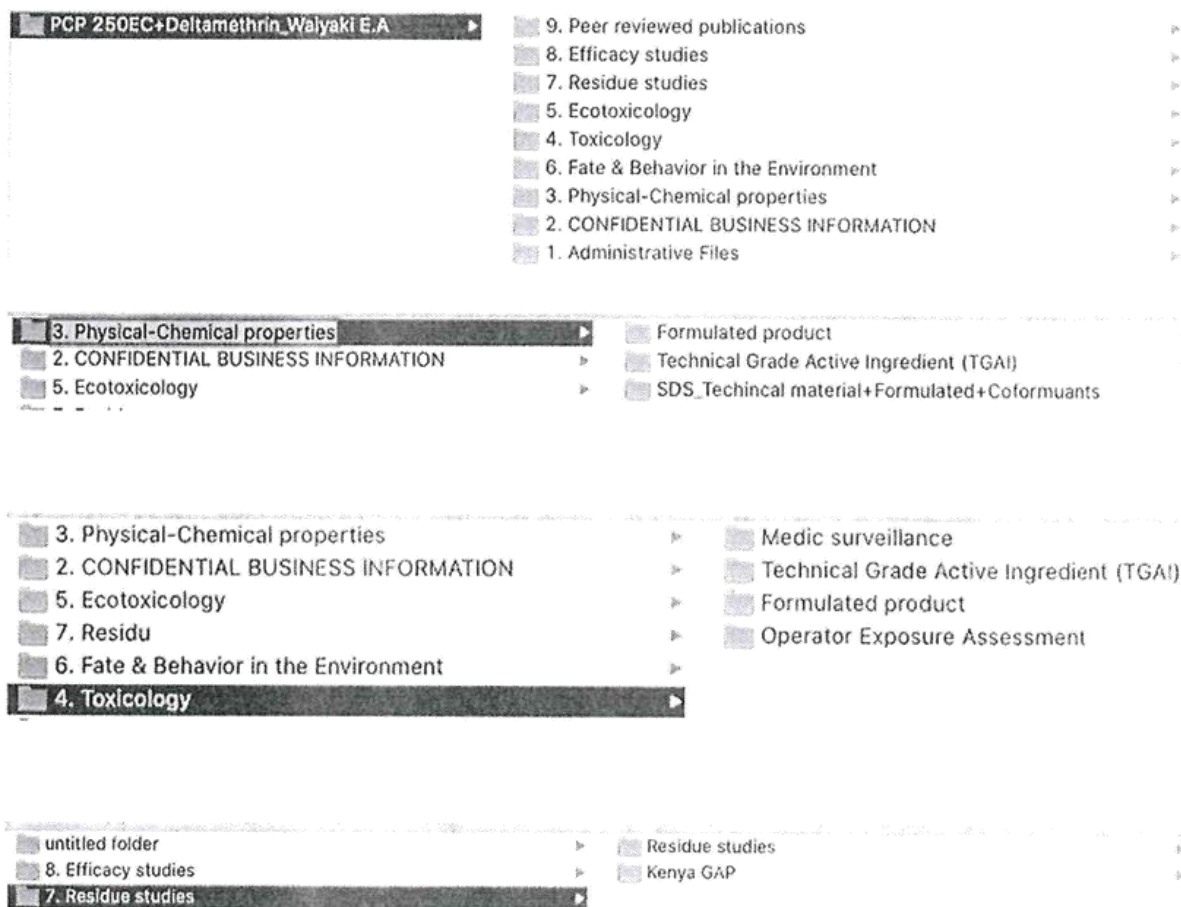
The individual study reports provided **must** be clearly labelled representing the Annexes in the respective Application Form. Please note that each folder **MUST** contain individual study reports e.g. do not provide Acute Oral and acute dermal study in one folder.

Where more than one data sets/ piece of information are presented in a single PDF file (e.g. physical chemical and stability studies present in a single chemistry PDF), the PDF file **must** have all the contents either indexed (table of contents (with automatic link)/index page) or bookmarked to enable navigation of the file and ease of review.

Where the dossier does not conform to these guidelines it will be returned to the Applicant to review accordingly.

Dossier arrangement:

The dossier must be presented using appropriate subfolders (example is given below). The studies should be Annexed as in the Respective Application Form



The study reports **must** be clearly labelled as per the relevant Application Form



Submission of the Administrative Files

The letters e.g. Letters of appointment, letters of access, phytosanitary clearance (where applicable) etc., proof of registration, authentication documents, prescribed Application Forms (relevant Application Form, Application Forms C, A6) provided must be in **.pdf** format (the .jpeg, .pub, .doc, .docx or other versions are not acceptable).

Procedure of e-dossier submission

1. Applicants are encouraged to have an online pre-consultation meeting with a Registration Officer. The applicant should book an appointment to have a skype (regdepartment) virtual consultation with a Registration Officer.
2. Applicant books an appointment through the registration department front desk and is recorded.
3. A registration officer shall be allocated to handle the application in line with PCPB internal procedures.
4. The Registration Officer shall process the Pay Advise for the Applicant to pay prescribed fee as determined by the Board from time to time. The official receipt shall be issued to the applicant a .pdf copy of which must be included in “Administrative folder” of the Dossier.
5. The Registration Officer shall give the date and time for the submission of the dossier.
6. The applicant/local agent shall provide the CBI dossier with the original letter of appointment from the registrant and e-dossier on the day of submission. The CD must be clearly labelled with indelible ink or preferably printed: “Trade name of the product + Active ingredient(s) + Local Agent e.g., *PCP 250EC+Deltamethrin 250_Waiyaki E.A*”
7. The Applicant shall sign the CBI Submission Form (Form C) (available from PCPB website <http://www.pcpb.go.ke/application-forms/>) and included in the CBI file.
8. The dossier shall undergo preliminary check and the applicant informed within two (2) working days of dossier submission of the outcome.
 - a. Where the technical dossier meets the criteria as set out, the Applicant shall be informed that the dossier has been provisionally accepted and await the outcome of the PCPB internal processing.
 - b. Where the technical dossier has not met the criteria as set out, the Applicant shall be informed of the deficiencies.
9. The outcome as prescribed in 8(a) will be communicated to the Applicant not more than ten (10) working days from the day of submission of the technical dossier.
10. Once the dossier is accepted, the Experimental Permit shall be issued within the period stipulated in the PCPB Service Charter (<http://pcpb.go.ke/>).



Dr. Esther Kimani

CHIEF EXECUTIVE OFFICER /SECRETARY

Copy to: CEO, Agrochemicals Association of Kenya
PCPB Registration Officers
PCPB Accounts & Finance
PCPB Research, Strategy, Planning & Performance Management
PCPB ICT
PCPB Compliance & Enforcement
PCPB Analytical Services