Central Administration of Pharmaceutical Products
General Administration of biocides registration

Regulatory Guideline

Regulatory Guidelines and Work Rules for the Registration of Pesticides

Year 2023

Code: EDREX:GL.CAPP.033

Version No.: (2)

Issue date: November, 2023

Effective date: November, 2023

Table of Contents

Content includes several topics, as follows:

1. Introduction

This regulatory guideline explains the rules and procedures for registration of pesticides, whether those related to public health or household use. It also explains how to submit registration and re-registration files, starting from the method of submission and the documents required for registration. including all registration or re-registration procedures until the issuance of the final registration license. It also includes decisions related to the registration of pesticides issued by the specialized committee for registration of household, public health pesticides and antiseptics

2. Scope

The regulatory guideline is applied to public health and household pesticide products submitted for registration or re-registration whether they are manufactured locally, manufactured locally by a third party (Toll manufacturing), manufactured locally under license from abroad, or imported products.

3. Abbreviations

GA-Biocide-R: General Administration of Biocides Registration

CAPP: Central Administration of Pharmaceutical Products

CADC: Central Administration of Drug Control

EDA: Egyptian Drug Authority

RIME: Research Institute of Medical Entomology

GOEIC: General Organization for Export and Import Control

WHO: World Health Organization

GMP: Good Manufacturing Practice

TC: Technical Concentration

MSDS: Material Safety Data Sheet

4. Definitions

Pesticides are products containing active substances that kill, repel, or stop the growth of harmful insects or rodents that affect human health and transmit

infectious diseases, whether for household use or public health purposes (Ant killers are excluded because ants do not transmit diseases).

Household pesticides

These are products that kill or repel harmful insects or rodents that transmit infectious diseases and are used in homes or directly on the skin. They are ready for direct use without the need for dilution, and the package cannot be reused. These include aerosols, sprays, mosquito coils, and powders.

Public health pesticides

These are products that kill, repel, or stop the growth of harmful insects or rodents that transmit infectious diseases that affect public health. They are used by specialists only, such as pest control companies and the Pest Control Department at the Ministry of Health. They also include the control of schistosoma snails.

5. Main topic

The requirements, conditions, and procedures of registration at the General Administration of Biocides Registration (GA-biocide-R) are subjected to the decisions of the specialized committee for registration of household, public health pesticides and antiseptics formed by Ministerial Resolution No. 479/2016, which states: “The Scientific Committee for Evaluation of Disinfectants and Sterilizers and the Scientific Committee for Registration of Household and Public Health Pesticides, which were formed by Ministerial Resolution No. 377/2015, shall become one committee named the specialized committee for registration of household, public health pesticides and antiseptics.

General rules for registration of public health and household pesticides

- To register a pesticide product, the active substance must be listed in the WHO scientific reference for the target pest.

- It is not permitted to combine flying insects and crawling insects (multi-insect killers) in locally marketed household pesticides. This regulation is according to the decision of the committee established by Ministerial Resolution No. 8/2018.

-The registration of more than two active ingredients in one product is prohibited for flying insects. However, for crawling insects, the addition of a third active ingredient that acts as a repellent for insects from their hiding places (flushing agent) is allowed.

-Pesticides effectiveness and toxicity studies are being conducted at the Research Institute of Medical Entomology (RIME). If the target pest is schistosoma snails, studies should be conducted at Theodor Schistosoma Institute.

-The validity period of a pesticide registration license is 5 (five) years, according to the Ministerial Resolution No. 93 of 1963.

-Pesticides products undergo re-registration every five years. The product owner is required to submit a re-registration request to the GA-Biocide-R in the last year of the validity of the registration license. The company must fulfil the re-registration requirements within a maximum of 3 (three) years from the preliminary approval. During this period, the product is allowed to be marketed. However, if the re-registration requirements are not met within the specified timeframe, the product registration will be considered expired.

Procedures of submitting the registration file:

The fulfilled registration file should be uploaded to the electronic platform according to the form prepared for reviewing the reception file (checklist) (attached) according to the WHO reference, with a scanned copy of the payment receipt attached. The file will be reviewed within 15 (fifteen) working days, and the applicant will be informed by any required documents via email. In case of the required documents are essential (major), the file shall be rejected and the company shall be informed then the file shall be re-uploaded again after fulfilling the required documents. If the required documents are unessential (minor), the file shall be received and the company shall be informed of the required documents.

Essential requirements (major)	**Non-essential requirements** (minor)
1. Absence of a document from the checklist or the expiration of a document.	1.Correction or fulfilling data contained in the submitted application.
2. Submitting an incompatible reference with the product or from a non-competent authority or whose data is incomplete.	2.Correcting or clarifying the functions and concentrations of the inactive ingredients in the composition form.
3. The business activity of the company mentioned in the commercial register approval is not suitable for registering pesticides products	3. fulfilling or correcting Information required on the product label & package according to the reference provided
4. Not authenticating contracts in the Legal Affairs Department or not authenticating the documents of the imported products by the Chamber of Commerce and the Egyptian Embassy in the country of origin.	4. Amending data or results in the certificate of analysis.
5. Absence of the raw material supplier ISO 9001 certificate or Good Manufacturing Practice GMP of quality manufacturing.	
6. Absence of CADC analysis approval or Acute toxicity or effectiveness study or Stability approval (in the case of final files).	
7. The company submitting the registration application is not registered in the electronic company's registration. (company profile)	

- The file shall be revised initially and technically then the company shall be informed by the requirements, if any, via the e-mail. In case that registration file is not fulfilled for a period exceeding one year from the date of the last follow-up, the registration application is considered invalid according to the decision of the specialized committee for registration of household, public health pesticides and antiseptics on Jan. 14th, 2020.
- The file shall be presented to the specialized committee for registration of household, public health pesticides and antiseptics within 14 working days from the date of file fulfillment. In case that the committee asked to amend some data of the product, the Applicant shall be informed by the decisions of the specialized committee for registration of household, public health pesticides and antiseptics
- In case of rejection by the specialized committee for registration of household, public health pesticides and antiseptics, the applicant may submit an appeal within 3 months from the issuance date of the committee's decision of rejection.
- In case of approval by the specialized committee for registration of household, public health pesticides and antiseptics, the Administration of biocides Registration shall issue a preliminary approval to proceed with the registration procedures. The validity period of the preliminary approval shall be two years (renewable for another year at most in case of the company failure to complete the essential requirements in accordance with the decision of the specialized committee for registration of household, public health pesticides and antiseptics on December 29th, 2020). However, the company is obligated to:

A. In the case of local products, or those manufactured by third part (toll manufacturing products), or products manufactured under license from abroad (new registration), the applicant is obligated to:

- Conduct an analysis for an R&D batch at Egyptian Drug Authority laboratories (Registration Division)

- Submitting an accelerated stability study in accordance with the applied rules by the Stability administration

- Conduct a study on the effectiveness and toxicity of the pesticide product at RIME.

B. In the case of products imported from abroad, the applicant is obligated to:

- Conduct an analysis for samples at Egyptian Drug Authority laboratories (Registration Division)

- Submit a long-term stability study in accordance with the applied rules by the Stability Department,

- Conduct a study on the effectiveness and toxicity of the pesticide at the RIME,

C. In the case of re-registration of products, the applicant is obligated to:

- Conduct an analysis for an R&D batch at the Egyptian Drug Authority laboratories (Registration Division) (required only in case that a variation occurred from the previously registered one).

- Submitting a long-term stability study in accordance with the rules applied by the Stability administration (in addition to accelerated stability study only in case that a variation occurred from the previously registered one)

- Conduct a study on the effectiveness and toxicity of the pesticide at the RIME.

- If the target pest is schistosoma snails, studies should be conducted at the Theodor Schistosoma Institute.
- If the validity period of the preliminary approval to proceed with the registration procedures (two-year) expired before fulfilling the necessary requirements, a request to extend the validity period should be submitted along with the payment for the service fees. The request should include the status of the product regarding the fulfilment of requirements in order for it to be revised and to issue the approval of extending the preliminary approval period for another year.

  In case that the deadline for submitting the final file is exceeded by a maximum of one year from the date of expiry of the deadline for submitting the file, the file is allowed to be accepted (fulfilling the studies), provided that the prescribed service fee shall be paid.
- After fulfilling the requirements required in the preliminary approval of proceeding with the registration/re-registration procedures, the applicant shall upload the final registration file entirely on the electronic platform. The file shall be revised within 15 working days and the applicant shall be informed by any required documents. In case of the requirements are

essential, the file shall be rejected, the company shall be informed and the file shall be re-uploaded after fulfilling the required documents. In case of the requirements are unessential, the file shall be received and the company shall be informed by the requirements via the e-mail.

- I case of fulfilling it, it shall be presented to the specialized committee for registration of household, public health pesticides and antiseptics then the product is given a registration number and a final registration license shall be issued which is valid for 5 (five) years
- In the event that a production line is not recorded in the industrial registry, a temporary registration license will be issued for a period of one year (during which production is not permitted), Provided that a final registration license will be issued after adding and licensing the production line to the industrial registry, in accordance with the decision of the specialized committee for registration of household, public health pesticides and antiseptics on January 12th, 2021.
- Pesticides are re-registered every 5 (five) years based on a request submitted by the product owner to the administration of biocides registration during the last year of the registration license validity, provided that the company shall fulfill the requirements of re-registration. The product is permitted to be marketed during the validity of the preliminary approval to proceed with the procedures of re-registration.

6. References:

- Decisions of the specialized committee for registration of household, public health pesticides and antiseptics.

- Decrees of the Egyptian Drug Authority's President

7. Appendixes/supplements:

Checklist of pesticides registration application

First: Documents submitted for all registration types

1. Application form with detailed information, signed and sealed by company's chairman.
2. Receipt of payment: - EGP 3,000 for local products, new registration or re-registration, - EGP 4,000 for imported products new registration or re-registration, - EGP + 1,000 for labelling, - EGP + 1,000 for reviewing the trade name in case of new registration only.
3. EGP 100 syndicate fees and EGP +7 stamp.
4. Letter of authorization from the company to the person in charge of follow-up, including bank-approved signature of the company's chairman.
5. Composition sheet (4 copies) on manufacturer letterhead, signed by R&D or production manager, authenticated from the Chamber of Commerce and the Egyptian embassy in the country of origin.
6. Product layout (4 copies), indicating: - State product type, - Technical Concentration (TC%) of raw material, - Antidote, - In case of public health pesticide, the note: "Not be used in houses except by qualified and licensed labour" or "For agricultural purposes" should be typed, - product composition including the active and inactive ingredients, - Acute toxicity highlighted in a suitable colour band, hazard symbol & signal word according to WHO pictogram, - Dilution rate, - Usage.
7. WHO reference sheet, indicating active ingredients, concentrations, target

organism, and pharmaceutical form, - Authenticated chronic toxicity reference.
8. Reference for mixture, if any.
9. Way of calculating usage rate.
10. Company's Commercial Register Approval - A valid registration request indicating the activity of manufacturing pesticides (for a third party in the case of toll manufacturing) or the activity of importing pesticides in the case of the importer only.
11. Applicant company's tax card.
12. certificate of analysis for finished products on manufacturer letterhead, indicating: - Product trade name, - TC %, - Assay of active ingredients.
13. Material Safety Data Sheet (MSDS) of active ingredient on manufacturer letterhead, - MSDS of finished products in case of imported products.
14. Copy of last product registration license (for re-registration only).
15. Composition approved from Central Administration of Drug Control (CADC) (for re-registration only).

Second: Documents submitted in case of Local & toll manufacturers:

1. Letter of authorization from the supplier of active raw materials, indicating: - Manufacturer name, - Product name, - TC%, - Name of manufacturer and supplier, authenticated from the Chamber of Commerce and the Egyptian embassy in the country of origin.

2. Certificate of impurities, authenticated from the Chamber of Commerce and the Egyptian embassy in the country of origin.
3. Free sale certificate of active ingredient, authenticated from the Chamber of Commerce and the Egyptian embassy in the country of origin.
4. Valid ISO Certificate for manufacturer of active ingredients, - Appendix including active ingredient.
6. Copy of company's industrial registry from the Generation Administration of Industrial Development, valid and indicating production lines.
7.Manufacturing agreement between applicant and manufacturer (for Toll & F-Toll manufacturing only), valid and showing bank-approved signature and authenticated from EDA Legal Affairs Department.
8. Manufacturing agreement's appendix, indicating the product's trade name, authenticated from EDA Legal Affairs Department.
9. Storage agreement, indicating bank-approved signature, valid and authenticated from the EDA Legal Affairs Department (for Toll & F-Toll manufacturing only), if not stated in the manufacturing agreement.

Third: Documents submitted in case of imported/bulk/under license products.

1. Copy of free sale certificate of final product from the country of origin, valid and issued from a competent authority, authenticated from the Chamber of Commerce and the Egyptian embassy in the country of origin. 2. Packing letter from the exporting country with full pack details.
3. Agency Agreement (sole agency or product agency) or an authorization letter from the product owner to the applicant company, valid and authenticated from the Chamber of Commerce and the Egyptian embassy in the country of origin.
4. Copy of EDA's Record of Importing Register (if it is not the first product to be registered), valid and indicating name of exporting company.
5. Valid GMP or ISO Certificate for manufacturer of finished product.
6. Local company registration card in the Agent Registry ("Reg. 14" form)

from the General Organization for Export and Import Control (GOEIC).
7. Local company registration card in the Importers Registry (“Reg. 4” form) from GOEIC.

Fourth: Documents submitted in case of hard files:

1. Preliminary approval
2. Stability approval
3. GADC analysis approval
5. Acute toxicity results from RIME
5. Effectiveness results from RIME, indicating dilution rate as stated in the preliminary approval and field test results for public health pesticides.
6. Import permit

Kindly submit your file arranged according to the checklist requirements with separators.

Mail for appointments: Biocides@edaegypt.gov.eg