Central Administration of Pharmaceutical Products
General Administration of Biocides Registration

Guideline

Regulatory Guidelines and Work Rules for the Registration of Pesticides

Year 2025

Code: EDREX:GL.CAPP.033

Version No.: 3

Issue date: February, 2025

Effective date: February, 2025

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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 according to 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 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.

-In case of Pesticides products imported from a reference country, the product should be registered and marketed in the country of origin or in one of the approved reference countries

-In case of Pesticides products imported from a non-reference country and marketed in one of the reference countries, the certificate of free sale of the product in an approved reference country should be presented.

-In case of Pesticides products imported from a non-reference country and not marketed in one of the reference countries, the product shall be evaluated by the specialized committee for registration of household, public health pesticides and antiseptics in order to take a decision to accept or reject.

-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 link of pesticides registration 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. 2. Submitting an incompatible reference with the product or from a non-competent authority or whose data is incomplete. 3. The business activity of the company mentioned in the commercial register approval is not suitable for registering pesticides products 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. 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)	1.Correction or fulfilling data contained in the submitted application. 2.Correcting or clarifying the functions and concentrations of the inactive ingredients in the composition form. 3. fulfilling or correcting Information required on the product label & package according to the reference provided 4. Amending data or results in the certificate of analysis.

- 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 submitting the file on the electronic link of pesticides registration, the registration application is considered invalid according to the decision of the specialized committee for registration of household, public health pesticides and antiseptics on Feb. 11th, 2025.
- The file shall be presented to the specialized committee for registration of household, public health pesticides and antiseptics within 15 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 General 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 Central Administration of Drug Control (Administration of Evaluation and Approval)

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

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

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

- Conduct an analysis for samples at Central Administration of Drug Control (Administration of Evaluation and Approval)

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

N.B. Considering the imported products from reference countries, the applicant company has the option to follow either the normal pathway or the following mentioned pathway which is the possibility to postpone the analysis step and effectiveness & toxicity study conduction step until after the issuance of the final registration license, which is conditional on the analysis of the first incoming consignment by the Administration of Evaluation and Approval in addition to Conducting the effectiveness and toxicity study

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

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

- Conduct an analysis for an R&D batch at the Central Administration of Drug Control (required

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.

- 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)

- If the target pest is Schistosoma snails, effectiveness and toxicity 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 link of pesticides registration. 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 in its session on:

18/2/2020, 29/12/2020, 12/1/2021, 21/5/2024 & 11/2/2025

- Accreditations of the president of Egyptian Drug Authority on:

20/9/2021 & 25/9/2022

7 . Appendixes/supplements:

Checklist for Application of Pesticides Registration

Documents required for all Registration types.

1-Application form with detailed Information with the mail of the company owner (Signed from Chairman and sealed)	نموذج ابليكشن كامل البيانات بختم الشركة و امضاء مدير الشركة موضحا البريد الإلكتروني لصاحب الشركة
2-Submission fees. 3000 L.E for Local products New reg. or Re -reg 4000 L.E for Imported products New or Re –reg + 1000 LE for labeling + 1000 LE for naming (in case of new reg. only)	ايصال الدفع : فى حالة المستحضرات المحلية تسجيل جديد او اعادة التسجيل 3000 جنيه فى حالة المستحضرات المستوردة تسجيل جديد او اعادة تسجيل 4000 جنيه + 1000 مراجعة ماكت او البطاقة الاستدلالية + 1000 مراجعة الاسم التجارى (فى حالة التسجيل الجديد فقط)
3- Syndicate fees 100 LE +7 LE Stamps	إيصال دمغة طبية بقيمة 100 جنيه وطوابع بقيمة 7 جنيهات
4-Letter of Attorney of authorized person-Bank signature Approval.	خطاب تفويض من الشركة للشخص المسئول عن المتابعة - عليه صحة توقيع بنكى لامضاء مدير الشركة
5-Composition sheet on Manufacturer Paper (authenticated in case of imported)	بيان التركيب على ورق المصنع بامضاء مديرالابحاث والتطوير او مدير الانتاج (موثق من الغرفة التجارية والسفارة المصرية ببلد المنشأ فى حالة المستورد)
6-Layout: State product type □ (TC%) □ antidote □ If Public health (not be used in houses except by qualified and licensed labor and not to be used for agricultural purposes) □ □ Active and inactive ingredient □ acute toxicity (Colour band, Hazard symbol & Signal word) according to WHO pictogram -Application rate □ Usage □	بطاقة خارجية للمستحضر موضح بها درجة نقاوة المادة الخام، العقارالمضاد،نوع المبيد، فى حالة المبيدات للصحة العامة كتابة جملة (لا يستخدم فى المنازل الا بواسطة عمالة مؤهلة ومرخصة ولا يستخدم في الاغراض الزراعية) بيان تركيب المستحضر موضح به المواد الفعالة وغير الفعالة درجة سمية المادة باللون المناسب و الكلمة التحذيرية طبقا WHO pictogram و معدل التخفيف و طريقة الاستعمال

7-WHO Reference sheet with Active Ingredients □ - Conc. □ -Target org.□ Pharmaceutical form. & Chronic toxicity Reference.	مرجع WHO موضح به المادة الفعالة و التركيز المستخدم والافة المستهدفة و الشكل الصيدلى مرجع للسمية المزمنة من جهة معتمدة
8- Reference for mixture if present	مرجع للخليط ان وجد
9-Calculation of Application rate-Matched WHO.	طريقة حساب معدل الاستخدام
10-Commercial Register Approval	سجل تجارى للشركة مقدمة طلب التسجيل سارى موضح به نشاط تصنيع مبيدات (لدى الغير فى حالة الtoll) او نشاط استيراد مبيدات فى حالة المستورد فقط
11-Tax Card	بطاقة ضريبية للشركة مقدمة طلب التسجيل
12-Certificate of Analysis of finished products on Manufacture paper Name of Product □ TC % □ Assay of Active ingredients □	شهادة تحليل المنتج النهائى موضح بها الاسم التجارى ودرجة نقاوة المادة الخام وتحليل كمية المادة الفعالة فى المنتج النهائى
13-MSDS of Active ingredient on manufacturer paper (in case of imported products: MSDS of finished product)	شهادة بيانات سلامة المادة الفعالة (شهادة بيانات سلامة المستحضر النهائى فى حالة المستورد)
14- Copy of all papers of last license (For Re-reg only)	نسخة من جميع اوراق اخر اخطار تسجيل للمستحضر (فى حالة اعادة التسجيل فقط)
15- CADC Analysis Approval with the product composition Approved from CADC (For Re-Reg only).	مطابقة المعامل مرفق بها بيان التركيب المعتمد من معامل الادارة المركزية للرقابة الدوائية (فى حالة اعادة التسجيل فقط)
IN CASE OF Local, Toll & F-Toll Products	
1-Letter of Authorization from the supplier of active raw materials to the local company for registration and distribution of active material declaring □(TC) of active ingredient □Manufacturer name □supplier name □raw material name □ Name of local company and its address □ authenticated & legalized □ Original is seen.	خطاب تفويض من الشركة مورد المادة الخام للشركة المحلية بالتسجيل والتداول للمادة الخام موضح بها درجة النقاوة المادة الخام واسم المصنع والمورد واسم المادة الخام واسم الشركة المحلية وعنوانها موثق من الغرفة التجارية والسفارة المصرية ببلد المنشأ □يقدم الأصل للإطلاع

2- Certificate of Impurities of active ingredient Legalized & authenticated □ Original is seen.	شهادة شوائب المادة الخام موثقة من الغرفة التجارية والسفارة المصرية ببلد المنشأ □يقدم الأصل للإطلاع
3- Free sale certificate of active ingredient Legalized & authenticated □ - from Government Authority □ Original is seen.	شهادة التداول الحر للمادة الخام من الجهة الحكومية المسئولة ببلد المنشأ موثقة من الغرفة التجارية والسفارة المصرية ببلد المنشأ □يقدم الأصل للإطلاع
4-Valid ISO Certificate or GMP for Manufacturer of active ingredient □Scope including Active Ingredient	شهادةISO 19001 او GMP لمصنع المادة الخام سارية و لابد أن يغطى نطاق الشهادة المادة الفعالة
5-Industrial Company Register Production line required.	سجل صناعى للمصنع المحلى من الهيئة العامة للتنمية - الصناعية سارى و موضح به خطوط الانتاج.
6-Manufacturing Agreement between Applicant and Manufacturer (Toll &F-Toll only) Valid □ Bank Signature Approval □ Authenticated from EDA legal Affairs	عقد التصنيع بين مقدم طلب التسجيل و المصنع (فى حالات toll and f toll) سارى وعليه صحة توقيع بنكى و موثق من الشئون القانونية بهيئة الدواء المصرية و
7-Manufacturing Agreement Attachment. Trade name of Product □ Authenticated from EDA legal Affairs □	ملحق عقد موضح به الاسماء التجارية موثق من الشئون القانونية بهيئة الدواء المصرية
8-Storage Agreement (Toll &F-Toll only)/If not stated in Man. agreement Valid □ Bank Signature Approval □ Authenticated from EDA legal Affairs	عقد تخزين عليه صحة توقيع بنكى وسارى وموثق من الشئون القانونية بهيئة الدواء المصرية
IN CASE OF Imported & Under license Products	
1-Copy of Free sale certificate of final Product in Exporting Country Valid □ Legalized and authenticated from competent authority	شهادة تداول حر للمستحضر النهائى من بلد المنشأ من جهة حكومية مسئولة سارية و موثقة من الغرفة التجارية والسفارة المصرية ببلد المنشأ
2-Packing Letter from Exporting Country with full pack details.	خطاب تعبئة من الشركة المصدرة موضح بها بيانات العبوة كاملة
3-Agency Agreement (Sole Agency or Product Agency) or authorization letter Valid □ Legalized	عقد وكالة او تفويض من الشركة المالكة المستحضر للشركة مقدمة طلب التسجيل ساري و موثق من الغرفة التجارية و السفارة المصرية ببلد المنشأ

4-Copy of EDA Record Importing Register (If it is not the first product) Valid □ Including Name of Exporting Company	ترخيص قيد سجل المستوردين بهيئة الدواء المصرية او تعهد بأحضاره فور استلام اول اخطار فى حالة التسجيل لاول مرة سارى و موضح به اسم الشركة المصدرة
5- GMP or ISO certificate for the manufacture of finished product	شهادة ايزو او GMP لمصنع المنتج النهائى
6- Local company registration card in the Agent Register (Register 14) from the General Organization for Export & Import Control	بطاقة قيد الشركة المحلية بسجل الوكلاء " س14 " من الهيئة العامة للرقابة على الصادرات والواردات
7-- Local company registration card in the Importers Register (Register 4) from the General Organization for Export & Import Control	بطاقة قيد الشركة المحلية بسجل المستوردين "س4" من الهيئة العامة للرقابة على الصادرات والواردات
IN CASE OF HARD FILE	
1-Preliminary Approval	موافقة السير فى اجراءات التسجيل
2- Stability Approval	موافقة ادارة الثبات
3- CADC Analysis Approval attached to the approved composition with EDA stamp	مطابقة معامل الادارة المركزية للرقابة الدوائية مرفق معها بيان التركيب المعتمد من المعامل
4-Acute toxicity results from RIME	نتائج دراسة السمية الحادة بمعهد بحوث الحشرات الطبية
5- Effectiveness results from RIME indicating Application rate as previously approved in preliminary approval □	نتائج الفعالية بمعهد بحوث الحشرات الطبية موضح بها التخفيف للمنتج كما هو مذكور فى موافقة السير فى اجراءات التسجيل (نتائج الاختبارات المعملية بالاضافة إلى الاختبارات الحقلية فى حالة مبيدات الصحة العامة)
6- Import permit	الموافقة الاستيرادية

Kindly submit your file arranged according to Check list requirements

E-mail: Biocides@edaegypt.gov.eg

Document History

Version number	Release Date	Summary of Change
1	02/2020	----------
2	11/2023	- Accepting the final file after exceeding a maximum of one year from the date of expiry of the deadline for its submission (fulfilling the studies), provided that the prescribed service fee shall be paid - Capability of issuance temporary registration license for a period of one year in case that a production line is not recorded in the industrial registry (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 - Extending the validity period of the preliminary approval from one year to two-year
3	02/2025	- Modifying the time frame for file presentation to the committee from its fulfillment from 14 to 15 working days - Modifying the decision to invalidate registration application if the file isn't fulfilled within one year from the date of the last follow-up into: within one year from the date of file submission on the electronic link of pesticides registration - Requirement for the acceptance of pesticide products imported from reference countries or possessing a free sale certificate from one of the reference countries - Another pathway approval considering the imported products from reference countries, the applicant company has the option to follow either the normal pathway or the following mentioned pathway which is the possibility to postpone the analysis step and effectiveness & toxicity study conduction step until after the issuance of the final registration license, which is conditional on the analysis of the first incoming consignment by the Administration of Evaluation and Approval in addition to Conducting the effectiveness and toxicity study - Checklist update