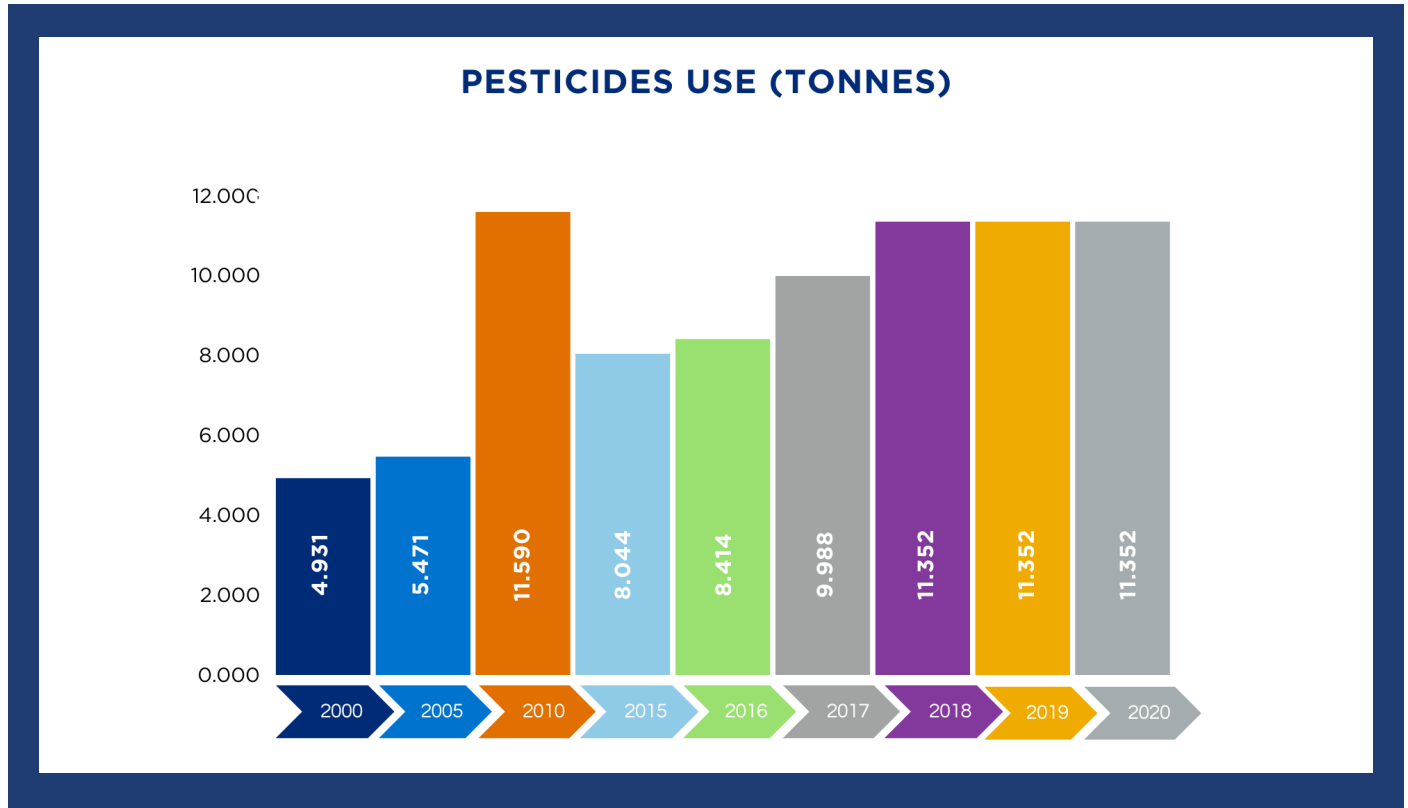


Egypt's Crop Protection Market

Crop protection products play an essential role in Egyptian agriculture, accounting for approximately 6% of total farming inputs. In 2018, Egypt consumed a substantial 11,000 metric tons (MT)⁴ of crop protection products, establishing itself as the leading consumer of these products in North Africa.



Source: FAO 2022 statistical yearbook.

Egypt's crop protection market is fueled by imports from 23 countries worldwide. China leads the pack as Egypt's primary pesticide supplier, exporting 4,502 MT, representing 43.96% of the country's total pesticide imports. India follows with 2,093 MT, while Germany ranks third with 1,171 MT. Japan, France, and Switzerland, also hold significant shares of Egypt's pesticide imports⁵.

The agrochemical markets of North African countries vary widely, and their individual potential, legislation and organization are different. Egypt is the largest market, in terms of consumption, valued at US\$350 million⁶.

The Egyptian crop protection market encompasses a diverse range of registered products, with over 1,870 distinct products derived from 260 active ingredients⁷.

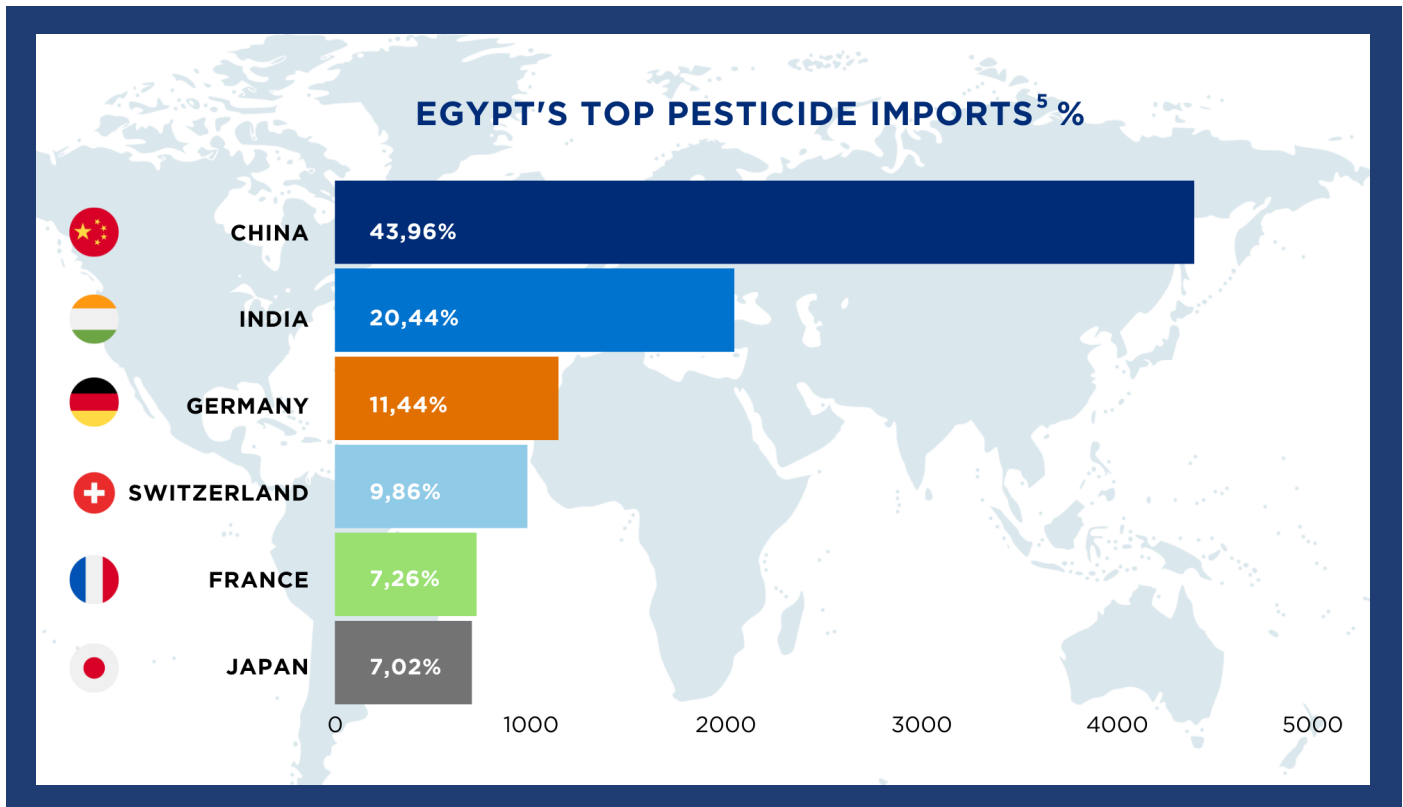


⁴ [AgroPages-A brief journey of the agricultural sector in Egypt-Agricultural news](#)

⁵ TECHNICAL REPORT Under action A1 of the Egyptian Vulture New LIFE project (LIFE16 NAT/BG/000874)

⁶ <https://news.agropages.com/News/NewsDetail---32435.htm>

⁷ [عجائب الدنيا - ليعوض الفشل الرقودا - رصم يف اصن حرم الاعض صم 38 ال جيمم الذي صم 1870 :ة عاززل 7 \(youm7.com\)](http://youm7.com)



Competent Authorities: Roles and Regulations

Egypt's main regulatory bodies for agricultural pesticides are the Ministry of Agriculture (MoA), the Egyptian Environmental Affairs Agency (EEAA), and the Agricultural Pesticide Committee (APC). The Agricultural Pesticide Committee (APC) stands as the sole governing body in Egypt responsible for regulating the registration, handling, and use of agricultural pesticides. As the designated authority, the APC's resolutions hold binding power for all stakeholders and relevant parties, each within their respective jurisdictions, as defined by their assignments, procedures, and directives and ensuring adherence to established guidelines and procedures.

Guided by stringent assessment criteria aligned with the Food and Agriculture Organization's (FAO/UN) International Code of Conduct, the APC meticulously monitors the laboratory and agricultural practices of designated quality assurance agencies. This dedicated commitment to quality assurance safeguards the integrity of agricultural pesticide evaluation and registration processes.

For companies seeking to register crop protection products in Egypt, the APC serves as the gateway to market approval. Navigating the registration process requires a thorough understanding of the APC's requirements, including the submission of comprehensive data on product efficacy, safety, and environmental impact.

To ensure a smooth and successful registration process, companies should engage early with experienced regulatory consultants who possess expertise in Egyptian regulatory requirements, like Battelle's regulatory affairs team. These consultants can provide guidance on preparing the necessary documentation, ensuring compliance with APC guidelines, and navigating the complexities of the registration process.

Stringent regulations govern the registration and trade of pesticides, and Egypt adheres to international standards for maximum residue levels (MRLs).

Registration and Approval Process

The Central Agricultural Pesticide Laboratory (CAPL) and APC review applications for pesticide registration, considering guidelines from Codex Alimentarius, the EU, and the U.S. EPA. Additionally, regulations from countries exporting pesticides are evaluated. Article 29 of Ministerial Decree No. 974 of 2017 sets MRLs for pesticides based on Codex Alimentarius, the

EU, and the U.S. EPA, prioritizing these organizations in that order.

If an MRL is not established by any international body, the APC sets an MRL based on the closest similar crop with an available MRL.

Compliance and Enforcement

Law 10 of 1966 sets penalties for crops exceeding MRLs, but the fines (5 EGP, less than 1 euro) and potential jail time (2 months) are considered extremely light punishments.

Ministerial Decree 622 of 2008 binds Egypt to follow Good Agricultural Practices (GAP) for pesticide trade.

All sellers require licenses according to Law No. 453 of 1954 and Ministerial Decree No. 622 of 2008 which obliges any company that markets or trades pesticides to be registered with APC and inspected regularly.

Environmental Law No. 4 of 1994 prescribes stricter penalties for trading without a license: up to 40,000 EGP (2,000 euros approx.) and 5 years in prison.

Monitoring and Control

All pesticides and agricultural products are inspected by the General Organization for Export and Import Control (GOEIC) of the Ministry of Trade and Industry. GOEIC monitors pesticide levels in commodities at export-import sites.

Regulations and Resources

The MoA and the EEAA maintain a list of allowed and banned pesticides, compliant with Ministerial Decree No. 630 of 2007 and its amendment No. 13 of 2011 which lists all active substances authorized or prohibited for use in agricultural pesticides.

The MoA publishes an annual guidebook containing information about pests, pesticides, and a database of legally allowed pesticides. The guidebook is available in Arabic and only in hard copy. The guidebook includes a full database of all pesticides legally allowed in Egypt with their purposes, registration numbers and different trade names.

The APC maintains an online database where users can search for pesticide information and registration status.

The registration, handling, and use of agricultural pesticides are governed by Ministerial Decree No. 974/2017.

The Egyptian Agricultural Law No. 53/1966 assigns the APC with implementing Ministerial Decree No. 974/2017.

A 2019 document titled "Rules for Registration and Trading of Agricultural Pesticides in Egypt" is available in Arabic.

The Egyptian PPP Registration Process Overview



The Egyptian authorities grant pesticide registration and sales authorization exclusively to local distributors, who serve as the applicants for registration.

Application

After paying the prescribed fees, the stakeholder submits an application to the Agricultural Pesticide Committee (APC) along with the primary technical data sheet for the pesticide.

Review

The APC Rapporteur examines the application and reviews existing data from US-EPA, EU, Canada, Australia, and Japan.

Consistency and Testing

If registration requirements are consistent, the applicant submits the primary technical data sheet along with a proposed experimentation program for testing the pesticide's efficacy against target pests. The committee secretariat and then the main committee review the program, and upon approval, it's distributed for implementation.

Experimentation and Analysis

Upon acceptance from APC of a primary dossier of technical data for a pesticide registration application,

the applicant must provide samples of the active ingredient(s) and their major impurities from accredited sources for use as reference standards.

Additionally, the applicant must submit, at no cost, samples of the pesticide in quantities determined by the APC for further analysis and experimentation. A customs release document for the required samples will be issued free of charge upon presentation of an official letter signed by the APC Rapporteur or an authorized representative

If the program is approved, the stakeholder pays experimentation and analysis fees, and the process begins.

The stakeholder must provide samples of experimentation to the designated administrator of the Institute or the respective laboratory, who assures that they are already required for experimentation, then signs and stamps two samples for sending to the Central Laboratory of Pesticides to confirm chemical and physical specifications.

In case of non-conformity, the stakeholder can request a re-analysis. If the second sample also non-conforms, the program stops, and fees may be reimbursed.

If samples conform, they're sent to agricultural research stations for testing against target pests according to the designed protocol.

Agricultural Seasons and Recommendations

As per Ministerial Decree 974/2017, pesticides undergo testing for two consecutive agricultural seasons, while attractants require only one.

The administrator presents the results to the Institute Council or competent laboratory for discussion and recommendations, which are then presented to the main committee for final decisions.

Final Review and Certificate

The stakeholder provides the complete pesticide file. The APC Secretariat prepares it for review by two specialists chosen by the Committee Chairman. If they disagree, a third reviewer is appointed.

Upon successful completion of all stages and committee approval, a certificate of biological assessment approval is issued.

The reviewers submit their recommendations for committee approval, leading to the issuance of a pesticide registration certificate.



Additional information

Additional Data or Testing Requirements: The APC may request additional data or testing at any stage of the registration process to ensure the pesticide's safety and efficacy.

Pesticide Label Application: Upon issuance of the registration certificate, the stakeholder may apply for a two-year pesticide label after paying the prescribed fees. The pesticide label must be prominently displayed on all pesticide products sold in Egypt.

Pesticide Registration Validity and Renewal: The registration certificate for a technical grade or formulated pesticide remains valid for six years from the date of issuance, with the option for renewal. The efficacy of formulated pesticides shall be reevaluated at the beginning of the third and sixth years following the issuance of the registration certificate. The certificate may be renewed upon request, provided that the conditions stipulated in the decree remain applicable to the technical grade or the formulated pesticide.

Re-evaluation of Formulated Pesticides: To ensure the continued safety and efficacy of formulated pesticides, a re-evaluation is mandated at the beginning of the third year from the registration certificate's issuance date.

Pesticide Importation: Individuals seeking to import registered pesticides must submit an application to the committee, accompanied by a valid recommendation and a license for trading in agricultural pesticides. The APC may approve the importation of a pesticide not included in its registry for use on turfs or in export-oriented crops if it is registered with an internationally recognized reference agency. The APC will determine the importable volume based on the intended treatment area and a technical import permit will be issued for export-oriented crops under the following conditions: Re-importation of the same pesticide or a similar product with the same active ingredient for the same purpose will not be permitted unless the concerned company initiates the registration process according to the established procedures and provisions of Decree No. 974 of 2017.

Biopesticide Registration in Egypt

The Egyptian government is taking steps to promote the adoption of biopesticides, recognizing their potential for reducing the environmental impact of agriculture and promoting sustainable farming practices.

The registration process for biopesticides in Egypt is undoubtedly thorough and rigorous, spanning two years and encompassing field trials across multiple provinces. Each year, a registration pilot project commences in June, subjecting each biopesticide to single-crop, single-pest experiments to meticulously evaluate its efficacy and dosage effects. While the cost per experiment stands at approximately \$2,200, the product analysis costs for each experimental year amount to around \$150. Additionally, every six years, fees for impurity analysis, fingerprint analysis, and registration analysis total approximately \$600⁸.

Cost of the PPP Registration Application in Egypt

The submission fees for PPP registration are around 4000 L.E. (118.87 €). The APC may require other fees:

- Payment of the prescribed fees along with the primary technical data sheet.
- In the case of committee approval on the experimentation program, the stakeholder should pay costs scheduled for experimentation and analysis.
- The pesticide registration certificate is issued in triplicate copies: one of the copies to the concerned person after payment of the prescribed fees.
- After issuing the registration certificate, the stakeholder may apply for the pesticide label (two-year) after payment of the prescribed fees.



⁸ <https://news.agropages.com/News/NewsDetail--9804.htm>

Advantages of Registering Plant Protection Products in Egypt

Egypt offers several advantages for registering plant protection products, making it an attractive destination for companies seeking to expand their market presence in the region. These advantages include:

Alignment with International Standards

Egypt's Agricultural Pesticide Committee (APC) adheres to stringent international standards for pesticide registration, ensuring that only safe and effective products are approved for use in the country. The APC primarily considers pesticides that are officially registered for pesticidal purposes in the United States, European Union, Canada, Japan, and Australia. This alignment with international standards provides a level of assurance for companies seeking to register their products in Egypt, as they can be confident that their products meet global safety and efficacy requirements.

Harmonization with EPA and EU Regulations

The APC strictly follows the regulations of the Environmental Protection Agency (EPA) and the European Union (EU), ensuring that Egyptian pesticide regulations are consistent with international best practices. This harmonization with EPA and EU regulations simplifies the registration process for companies that have already registered their products in these jurisdictions. Additionally, if a product is suspended or banned in Europe, it will also be banned in Egypt, further safeguarding human health and environmental protection in the country.

Recognized Active Ingredient Database

The APC registers the active ingredients of agricultural pesticides based on their "technical grade" or "formulated" forms, according to reference databases of registered pesticides maintained by the European Commission (EC), the U.S. Environmental Protection Agency (U.S.EPA), and other agencies accepted by the APC. This reliance on established reference databases streamlines the registration process and reduces the need for duplicative testing, saving companies time and resources.



Dossier Content

1	Letter of authorization	A letter from the pesticide-producing company to authorize the local company to register and sell the pesticide product imported into the Arab Republic of Egypt "authenticated original".
2	Certificate of registration	Certificate of registration and circulation of the pesticide product imported in the country of origin issued by the official authority responsible for its registration in this country "authenticated original".
3	Certificate of analysis	Certificate of analysis of the components of the pesticide, the names of the additives and associated impurities and their percentages from accredited laboratories with the identification of the sources of these materials for the local preparation "original".
4	Product certificate	Certificate of quality assurance of the product from the producing company in terms of natural and chemical properties "original".
5	Packaging certificate	Certificate of quality assurance of pesticide packages following the standard specifications from the pesticide-producing company "original".
6	Identification card	The identification card of the importer in the country of origin "original".
7	Preliminary file of the technical data	The preliminary file of the technical data of the pesticide according to the model prepared by the Agricultural Pesticides Committee.
8	Acute toxicity studies	Acute toxicity studies of the preparation from internationally accredited laboratories or from the Central Pesticide Laboratory in the case of the local product.
9	Chronic toxicity studies	Chronic toxicity studies of the active substance from internationally accredited laboratories in the case of imported pesticides or from the Central Pesticide Laboratory if it has the possibility of conducting studies.
10	Environmental toxicity studies	Environmental toxicity studies of the preparation from internationally accredited laboratories or the Central Pesticide Laboratory in the case of the local product.
11	Method of analyzing the pesticide	The method of analyzing the pesticide from a globally accredited body such as CIPAC or AOAC, and in the absence of it, it is due to the company's method.
12	Method of analyzing the impurities	The method of analyzing the main impurities associated with the pesticide in detail with the mention of the approved international references.
13	Position of the active substance	The position of the active substance of the pesticide from registration and classification in the European Commission "EC", the US Environmental Protection Agency "EPA" and relevant international organizations and bodies.
14	Maximum residual limit	The maximum residual limit for the pesticide "MRL" proposed by the Codex Alimentarius Commission "CODEX" and the European Commission or the limits allowed for it by the EPA.
15	PHI approval	The pre-harvest period "PHI" of the preparation is approved by the Central Pesticide Laboratory based on its evaluation of field studies under local conditions.
16	Technical specifications certificate	Certificate of technical specifications "natural and chemical" for the analysis of the pesticide and the main associated impurities issued by the Central Pesticide Laboratory when registering or re-evaluating the pesticide.
17	Analysis of the pesticide certificate	A certificate of analysis of the pesticide preparation issued by the Central Pesticide Laboratory for each year of experimentation, or upon re-evaluation.
18	Fees payment receipts	Receipt of delivery of experimentation samples to the institute or research laboratory and proof of payment of experimentation costs for each season.
19	Storage conditions	Conditions of handling and safe storage of the pesticide preparation.
20	Biological assessment test certificate	Certificate of passing the biological assessment test for the pesticide on the target pest.
21	Other	Any other documents that the Committee deems necessary to submit.

Challenges of the Egyptian PPP Market

The Egyptian agricultural sector faces numerous challenges that impact the sustainability of crop cultivation and production. These challenges include the effects of climate change, fluctuating crop acreages, and the absence of clear planting strategies, leading to significant price volatility in agricultural products. Additionally, declining agricultural output values contrast with rising production costs, particularly for agricultural inputs. Labor scarcity, increasing wages, and the loss of farming jobs could necessitate changes in cropping patterns. Moreover, political and economic factors, such as trade agreements, exchange rate fluctuations, and export policies, influence agricultural production and agrochemical trade.

Within this context, the Egyptian crop protection market presents a unique set of challenges for companies seeking to register and commercialize their products. These challenges include:

Complex Regulatory Framework. The process is governed by the Agricultural Law No. 53 of 1966 and the Environmental Law No. 4 of 1994, along with several ministerial decrees. Navigating through this complex regulatory framework poses a challenge for companies seeking registration. Expertise in local procedures is essential to ensure the correct set of data requirements that are considered for a new application.

Collaborative Evaluation Process. The registration process involves cooperation between multiple entities, including the Agricultural Pesticides Committee (APC), the Central Agricultural Pesticides Lab (CAPL), and other agricultural institutes. Coordination and communication among these entities can be challenging without an established network.

Documentation Requirements. The start of the registration process requires the submission of a comprehensive set of documents, including a technical data sheet and administrative paperwork. APC meticulously reviews this submission, determining acceptance or rejection based on specific criteria. Ensuring compliance and meeting documentation requirements poses a demanding task for companies. The completeness of the registration dossier relies heavily on the scientific data as well as the precision of administrative work. Any oversight, including minor details or the absence of legalized paperwork, has the potential to impede the entire process, leading to substantial extensions in timelines.

Language Barrier. Arabic language dominates local guidelines and dossiers. Documents and communication with the Agricultural Pesticide Committee (APC) are exclusively in Arabic. Without fluency, companies lack the ability to defend their submissions or clarify issues during potential challenges. Additionally, necessitating fluency in both English and Arabic to effectively navigate the regulatory process is mandatory. Companies without in-house language proficiency may face delays and difficulties in understanding and complying with regulatory requirements.

Field Testing. Conducting efficacy trials for pesticide registration is a multi-step process. The procedure starts by submitting an application form for open-field experiments to determine the effective application rate on the target crop. The evaluation of efficacy is conducted three times over three consecutive seasons. Timely organization of shipment and customs clearance is crucial to catch the season and expedite the trial evaluation phase. Companies frequently face challenges due to a lack of awareness about the coordination required for field testing, resulting in the negative impact of delayed testing windows.

Counterfeit Product Prevalence. Counterfeit pesticides pose a significant threat to both public health and the environment, accounting for approximately 20% of total pesticide consumption in Egypt. Companies must implement robust measures to protect their intellectual property and ensure the authenticity of their products to maintain consumer trust and market share.



The Battelle Advantage

Battelle’s deep understanding of the Egyptian crop protection market and its regulatory landscape positions us as a trusted partner for companies seeking to register and commercialize their products in this dynamic region. Our global team of experienced regulatory affairs professionals is strategically based in the EU, the U.S., South America, the UK, Switzerland and North Africa, with a presence in key countries like Morocco, Tunisia, and Egypt.

Leveraging our deep expertise and global network, we provide comprehensive support to companies throughout the entire registration process, ensuring timely and successful product approvals.

By partnering with Battelle, companies can effectively navigate the challenges of the Egyptian crop protection market, ensuring timely and successful product registration and commercialization. Our expertise and experience empower companies to establish a strong presence in this strategically important market.

The Battelle Advantage	
BENEFIT	DESCRIPTION
Unmatched Regulatory Expertise	Highly experienced team of multidisciplinary experts with extensive regulatory experience and analytical expertise
Full Regulatory Support	We provide innovative, full-scale registration and re-registration support, along with expert advice in dossier compilation for crop protection products in North Africa
Native Speaker Experts	Our team includes native speakers of Arabic, French, and English, ensuring effective communication
Local and European Expert Support	Our local experts enhance PPP dossier preparation and work closely with local authorities and distributors for submissions
European Technical Expertise	Technical experts with EU-level experience expedite mutual recognition of approved PPPs
In-Depth Regulatory Knowledge	We stay updated on local procedures by continuously monitoring regional regulatory developments
Robust Local Distributor Network	Our extensive local distributor network is cultivated through active conference participation and visits
Tailored Study Design	Customizable study design to meet specific client needs
Compliance with GLP Regulations	All studies are performed according to Good Laboratory Practice regulations, ensuring reliability, consistency, and integrity of the data generated
Study Monitoring	High-quality monitoring of complex regulatory studies
Project Management	Competently managing the scope of projects including quality, proactive communication, timelines, and costs



Contact us today to talk to a Battelle Crop Protection Expert.



+44 1245 450777
+1 800.201.2011
solutions@battelle.org
www.battelle.org

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