



THE EAST AFRICAN COMMUNITY

Guidelines for the Protection of Confidential Business Information Submitted for Pesticide Registration Actions in the EAC Partner States

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Registration Actions in the EAC Partner States

Introduction

In submitting data or information required by the EAC (and any of its Partner States) for the initial registration or experimental use permit or a temporary/emergency registration or a provisional registration of a pesticide product or any other related regulatory action thereof, applicants (registrants) may claim certain data or information as 'Confidential Business Information' or CBI. This will eventually facilitate trade in the EAC in line with EAC SQMT Act regulations of 2013.

These EAC Guidelines define what constitutes CBI, list the requirements and procedures for submission and designation of CBI, and describe the responsibilities of the Applicant and Regulatory Authorities to protect CBI from unlawful or unintended disclosure.

Definition and Scope of Confidential Business Information

The following data or information required by the Registration Authority in the EAC Partner States and shall be claimed by the applicant (registrant) as CBI:

1. Information that discloses the identity or percentage quantity of deliberately added inert ingredients in the technical grade of the active ingredient or in the formulated products (except those considered to have health and environmental risks/concerns). For example, specifications of the technical grade (active ingredient), composition of the product formulation, the process of formation of impurities.
2. Information that discloses the processes of manufacturing or the formulation process, quality control and testing of batch analysis of a pesticide product. For example, the method of manufacture.
3. Commercial or financial information relating to trade secrets, production, distribution, sales, inventories or other privileged trade information provided for the purposes of registration.
4. There are several other data requirements that do not constitute CBI. For example, the molecular formula of the active ingredient, the characterization or summaries of publicly-available risk evaluations where the risk assessment has been conducted by a governmental organization.
5. As a general rule, CBI shall not be disclosed to the public.
6. In exceptional cases such as in the public interest, an EAC Partner State may disclose CBI to its National Pesticide Committees or in Court Proceedings/Legal Hearings in compliance with other legal authorities or when public health or environmental safety is at risk leading to cancellation or suspension hearings.
7. For a more detailed list of what constitutes CBI, see First Schedule Form A.

General Procedures

The EAC Partner States and the applicant (registrant), and their local representatives shall implement measures to protect CBI.

Responsibilities of the Applicant (Registrant) or its local representative shall be to:

1. Ensure that all CBI is submitted to the EAC Partner State in a secure manner and by a responsible person, authorized by the applicant.
2. Submit the CBI in a separate sealed envelope or a separate electronic storage device clearly marked or identified as "CONFIDENTIAL BUSINESS INFORMATION."
3. Provide justification at the time of submission why additional information may be claimed as CBI. In such case a Form B (Justification for Additional CBI Protection) may be required to be submitted.

Responsibilities of the EAC Partner States shall be to:

1. Designate the regulatory officials that will receive, review, record and store CBI submitted by the applicant(registrant).
2. Establish mechanisms for regular training (minimum of one per year) of the designated regulatory officials in the EAC Protection of CBI Guidelines and its implementation.
3. Institute adequate measures to protect CBI, such as the reception place, the secure storage area (office), and limiting the access to CBI to only authorized personnel.
4. Ensure that the storage area is secured with access to only authorized personnel and contains a locked storage unit (e.g. locked cabinet, or a separate laptop or computer).
5. Maintain a record in the form of a log, that indicates the name of applicant, date of reception, dates of any internal disclosures, the person or committee to whom disclosure was made, and a description of the information disclosed.
6. Designate a regulatory officer who shall receive the CBI, record the list of CBI data or information, and store the CBI in the secure storage area and the secure storage unit.
7. Allow only access to authorized and trained persons.
8. Review and validate the information submitted as CBI and may ask for additional clarification from the applicant to make the determination whether such information constitutes CBI.
9. Make an official notification of CBI determination to the applicant by certified mail, return receipt requested, or by personal delivery. Where there is no response of this official notification, the determination of the CBI shall suffice as the official record of what constitutes CBI.
10. Inform the applicant of disclosure and justification for disclosure in cases when the EAC or its Partner States may be required to disclose CBI by its National Pesticide Committees or in Court Proceedings/Legal Hearings.
11. Not copy any information submitted and marked by the applicant as CBI unless authorized by the Partner States. The authorization to make copies of CBI must contain the following information:

- The name of the recipient of the copy.
- The intended purpose for which the copy is to be used.
- The manner in which the copy is to be disposed of after use.

12. Not disclose CBI in its custody or submitted by the applicant, to other pesticide applicants or other local representatives.

13. Not disclose CBI to a similar authority in a different region or country or jurisdiction for the purposes of facilitating registration for a pesticide product, unless the applicant has consented in writing, in advance, to such disclosure.

14. Domesticate the EAC Guidelines for Protecting CBI into its National Legislation.

15. Implement a sufficiently deterrent penalty or fine system applicable to regulators or other, third parties who intentionally and unlawfully disclose CBI for personal financial or other gains in accordance to their national laws and regulations.

Dispute Resolution

In the event of an unauthorized disclosure of CBI, the EAC Partner State shall conduct an internal investigation to determine the facts of the unauthorized disclosure, to assess culpability for such disclosure, and serve as the basis for any penalty or fine for such disclosure to be assessed under the applicable national law(s).