



SUMMARY OF THE GUIDELINES ON DATA REQUIREMENTS FOR THE REGISTRATION OF CONVENTIONAL CHEMICAL PESTICIDES USED IN AGRICULTURE AND FORESTRY IN EAC PARTNER STATES

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PREAMBLE

These summary guidelines are an update of the Agriculture (Farm Input) forms developed by the East African Community in January 2005.

They stipulate that national authorities should ask for the same, or very similar, data from applicants, thus harmonizing the registration process across the EAC region.

The guidelines require that information to be provided by the applicant is sufficient for the national registration authority to assess whether the pesticide is effective for its intended purposes, and does not pose an unacceptable risk to human or animal health, or the environment under the conditions of use in the country or region.

OBJECTIVE

To provide better information to applicants for the registration of a pesticide regarding the data and studies that they should submit to national pesticide registration authorities.

The guidelines provide that data requirements are listed in two parts:

Part I - Data required on the active ingredient(s) - Information to be provided under this category is as below:

1. Designation/Identity of the active ingredient/s
2. Physical and chemical properties
3. Analytical methods
4. Toxicology
5. Ecotoxicology
6. Behavior in environment
7. Mode of action
8. Residues

Part II - Data required on the formulated product - Information to be provided under this category includes:

1. Identity of the product
2. Physical and chemical properties
3. Methods of analysis
4. Toxicology
5. Efficacy
6. Other information e.g. Material Safety Data Sheet (MSDS); Hazard classification; Hazard classification (GHS); emergency measures in case of exposure or poisoning, etc.

The guidelines also contain the application form for registration of a conventional chemical pesticide.

The data requirements are structured as follows:

Number = Data point number. Applicants should follow the numbering in these guidelines when constituting their dossier.

Data = Description of the data or study required

Use pattern = The pesticide use patterns for which the data are required

All: all uses

- Food uses: use of the pesticide on human food, or when food may be exposed to the pesticide (e.g. crops, stored products, livestock)
- Feed uses: use of the pesticide on animal feed, or when feed may be exposed to the pesticide (e.g. grazing land, fodder, feed crops)
- Outdoor uses: all outdoor uses of the pesticide (e.g. terrestrial fields, aquatic use (e.g. irrigated rice), forestry, gardens)
- Indoor uses: all indoor uses of the pesticide (e.g. glasshouse, store)

Conditions = R= always required; CR= Conditionally required

Remarks = Details about the studies to be conducted, conditions under which these are required, etc.

Endpoint of study = The resulting value(s) or outcome(s) of a study. These are specified when relevant.

Level of detail = The level of detail of the information or data to be provided is specified, when needed:

- Endpoint = only the endpoint(s) of the study needs to be provided;
- Summary = a summary of the study needs to be provided, describing – as a minimum – the title page, signed declaration page, materials and methods, main observations and outcomes of the study, the endpoint(s) of the study;
- report = the full report of the study needs to be provided. In ALL CASES, the source /reference of the data or study should be provided, as well as the method used to generate the data. Internationally accepted testing methods should be used, whenever possible (e.g. OECD, CIPAC, ASTM, EC).

Office of the Deputy Secretary General Productive and Social Sectors

East African Community Secretariat

Afrika Mashariki Road

P.O. Box 1096 Arusha

United Republic of Tanzania

Tel: +255 (0)27 216 2100

Fax: +255 (0)27 216 2190

Email: eac@eachq.org