GUIDELINES FOR EVALUATION OF PESTICIDE BIO EFFICACY TRIAL REPORTS

PREPARED UNDER THE AUSPICES OF THE WEST AFRICA AGRICULTURE PRODUCTIVITY PROGRAMME

(WAAPP)

FOR USE BY PESTICIDE REGISTRATION EXPERTS

ENVIRONMENTAL PROTECTION AGENCY
CHEMICALS CONTROL AND MANAGEMENET CENTRE
ACCRA

JUNE 2012

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1.0 Introduction

These guidelines describe the general requirements and the format to be used for the assessment of an efficacy trial report submitted in support of registration of pesticides.

In conducting efficacy trials, applicants are expected to demonstrate that when the product is used in accordance with label directions, it is effective for the purposes claimed and that application to the indicated plant or situation will not cause any unintended effect.

Where the data submitted does not adequately support registration, additional data will be required. In some cases, data would be rejected. Efficacy should be demonstrated for every host and pest claimed on the label. Limited extrapolation to other pests and hosts may be accepted with prior approval from the registration authority.

The purpose of the efficacy review is to ensure that the proposed use of a pesticide product is supported by adequate scientific information. For a treatment to be acceptable for registration, the information submitted must prove that the proposed treatment is effective in pest control and safe to the host.

1.1 Purpose of this guide

The intent of these guidelines is to establish procedures and criteria for efficacy data evaluation by regulatory officers authorized to carry out assessment of pesticide efficacy reports. The aim of this guideline is to ensure standardized procedures for the assessment so as to eliminate the potential for uncertainty and confusion of decision regarding the approval process for trials. They also assist the registrants in their understanding of the review process and the basis

for acceptance or rejection of a proposed registration. It should be noted that these guidelines provide general guidance only, rather than a check list or rigid criteria. Scientific judgment should be exercised in using them in assessing a particular efficacy report

1.2 Scope

These guidelines concern efficacy assessment of conventional chemical pesticides only. However, it may be applied in limited extent to biological, microbial or botanical pest control agents. The circumstance must be clearly described.

2.0 Efficacy of a pesticide

For the purpose of this guidelines, the efficacy of a pesticide product in agriculture, forestry, public health and other use situations can be defined as a measure of the overall effect of its application on the intended agricultural, forestry etc system in which it is used. Thus testing for the efficacy of a pesticide product, could result both in a positive effect (that is controlling the target pest or modifying crop growth in order to achieve improvement in the quantity and/or quality of crop yield, premature or delayed ripening), and a negative effect, (such as reduction of quality or quantity of yield/phytotoxicity, damage to beneficial organisms, damage to succeeding or adjacent crops, development of resistance). There are other aspects of efficacy which, depending on the product, can be either positive or negative; these include effects on other non-target pests, length of time in which the product continues to be active, ease of its use, and compatibility with other cultural practices and crop protection measures. The net result of the positive and negative effects should be a sufficient overall benefit in order to justify the use of the product.

In testing for efficacy other parameters such as crop safety, phytotoxicity, resistance, yield quality and quantity of yield should also be assessed and reported.

3.0 Principles for assessing acceptability of efficacy

After a biological dossier has been submitted to the registration authority as part of the request for authorization of the plant protection product, an evaluation has to be made as to the acceptability of the product for the proposed use pattern. This assessment is made by the registration authority.

A number of general principles will always need to be addressed when evaluating a biological dossier and deciding on the acceptability of the product.

3.1 Sources of information

It is the responsibility of the registrant to produce, collect and submit all scientific information required to support the proposed registration. However, the Product Managers may use any relevant data available to them in addition to those submitted by the registrant. They may base their judgement on their own experience and knowledge of the pesticide product under consideration. They may also consult with research scientists and/or other personnel involved in the research being reviewed. It must be remembered, however, that only "scientific evidence" will be used in the assessment of the performance of a product. Testimonials from individuals, without documented evidence, are of no value in efficacy evaluation.

3.2 Scanning of data submissions

The registrant's submission should include all information necessary to provide a complete evaluation of the usefulness of a product. The evaluation expert examines the complete data package and a judgement will be made as to whether any data omissions are significant enough to adversely affect the

review. Those so identified should be communicated back to the registrant for supplemental data submissions before the evaluation can be carried out.

3.3 Assessing the appropriateness and adequacy of the data

If there are no apparent major data gaps which would prevent a meaningful evaluation of the submission, the reviewer will then consider the appropriateness of the submission, i.e., the intended use pattern and adequacy of the data that has been supplied. The following items should be considered in the assessment:

4.0 Test Procedures

Test procedures employed in developing data to support the registration of a control product will vary according to the characteristics of the chemical, the type of formulation, the target pest, the use pattern, the methods and timing of application, and many other factors. However, there are certain basic principles and techniques that should be employed in carrying out the efficacy trials and certain information must be reported in support of registration of a use claim.

4.1 Acceptability of the studies:

The acceptability of a test is evaluated on the basis of whether it is designed and conducted following acceptable test procedures. Elements for consideration may include test material, test species, site of test, method and rate and timing of application, etc.

4.2 Location, duration and number of tests:

For field studies, the geographic distribution of the tests should adequately cover the various climate and soil conditions likely to be encountered. The duration of testing (number of years) should be long enough to reflect fluctuations and variances of conditions that normally occur from year to year. Generally, a minimum of two years is required. The number of tests should be large enough to produce conclusive results with a high degree of confidence. It depends on many factors, such as pest/host combinations, the proposed use situation, and the consistency (reproducibility) of the results.

4.3 Effectiveness:

The data should demonstrate that the pesticide product, when used as directed, will have merit and value such as increases in marketable yields of desirable quality, a reduction of damage, a satisfactorily high degree of repellency or attraction, reduction of injury, or reduction of the pest population to acceptable low levels. The acceptable level of control may vary depending on the purpose of the proposed use.

4.4 Direct efficacy

Various parameters should be taken into account when evaluating the acceptability of the direct efficacy or effectiveness of a plant protection product.

4.5 Comparison with the untreated control

The product will always have to show results (e.g. level, duration and consistency of control of or protection against a pest) that are significantly superior to those recorded in the untreated control.

It is not possible to set generally applicable levels of control that should be achieved. In some cases, relative low efficacy levels (e.g. 50 – 70%) may already provide benefits to the grower. Lower levels of control may also be acceptable if the product has little or no effects on natural enemies of pests and can therefore be incorporated into an IPM approach. In other cases, a high level of control may be required, for instance in the case of epidemic pests that can produce extensive damage or for pests that cause direct damage to the marketable portion of a crop (e.g. extensive blemishing on fruits).

The principal criterion is that the product must produce a clear and meaningful (commercial) benefit to the grower.

If no comparison with a reference product is available, this will be the only criterion that can be used to assess the acceptability of direct efficacy.

4.6 Comparison with a reference product

The efficacy of the product should normally be comparable to or better than that of an appropriate reference product. The reason for this is to prevent products that have a clearly lower efficacy than already available products to come onto the market. Such products are more likely to be overdosed and so increase exposure of humans or the environment.

However, there are various valid reasons for authorizing a product with a lower efficacy for use in a country. This may occur when other characteristics of the product have advantages over the reference product or over other products registered for the same use. This may be justified if the new product:

- Can be used over a wider range of growth stages of the crop;
- Is efficacious against more pest stages;
- Is efficacious against more pest species;
- Is less influenced by climatic factors or soil type;
- Has greater compatibility with cultural practices or other plant protection measures (e.g. IPM);
- Has a lower probability of causing resistance;
- Has fewer undesirable side-effects (e.g. on beneficial organisms, other crops).

4.7 Comparison with other pest management approaches

Whenever possible, the efficacy of a new plant protection product should also be compared with other pest management approaches than the use of chemical plant protection products. This includes, but is not limited to, the use of resistant

varieties, cultural or agronomic pest management measures, biological control or IPM.

While the comparison of efficacy of a plant protection product with an entirely different pest management technique may not always be straightforward, such assessments should be done whenever feasible, to evaluate the overall benefits of registering a new product.

4.8 Crop tolerance

The use of the plant protection product should not result in unacceptable phytotoxic effects on the crop itself. It should not result in an unacceptable reduction in the yield of the crop, and definitely not beyond that what would have occurred without use of the plant protection product (note that in cases of quality improvement, a reduction in yield may sometimes be acceptable). Similarly, there should not be an unacceptable adverse effect on the quality of the crop or its produce, nor on treated plants or plant parts used for propagation.

In certain cases, what are originally unacceptable effects can be mitigated by appropriate measures, and thus become acceptable (e.g. by using specific application equipment, avoiding treatment at particular times during crop growth). In such a case, the registration authority should always appraise to what extent the proposed risk mitigation measures can be realistically applied and respected under the national conditions of use. If realistically the measure cannot be implemented, a decision not to register the product may need to be taken.

5.0 Agronomic sustainability

5.1 Resistance

The (over) use of one single product, or a combination of products, that has a clear risk of resistance development is generally undesirable. A resistance management scheme should then be formulated by the registrant to effectively delay the development of resistance.

The registration authority should always appraise to what extent the proposed resistance management scheme can be realistically applied and respected under the national conditions of use. If realistically the scheme cannot be fully implemented, a decision not to register the product may need to be taken.

5.2 Effects on succeeding crops

Generally, a high risk of adverse effects of the product on succeeding crops, including substitute crops, is not acceptable. In a few cases, label warnings or other mitigation measures may be proposed that can reduce the risk to an acceptable level (e.g. if no alternative plant protection product or pest control measure is available, or if there is only a risk for certain substitute crops that are directly sown after crop failure).

The registration authority should always apprise to what extent the proposed measures to limit the risk to succeeding crops can be realistically applied and respected under the national conditions of use. If realistically they cannot be fully implemented, a decision not to register the product may need to be taken.

5.3 Effects on adjacent crops

The use of the plant protection product should not result in unacceptable effects on adjacent crops unless the risk of such effects can be minimized using

appropriate measures (e.g. use of drift reduction measures, leaving unsprayed barriers).

The registration authority should always appraise to what extent the proposed measures to limit the risk to adjacent crops can be realistically applied and respected under the national conditions of use. If realistically they cannot be implemented, a decision not to register the product may need to be taken.

5.4 Effects on non-target organisms

The evaluation of the acceptability of any risk to non-target organisms is normally taken as part of the evaluation of the environmental dossier. The possible observations of adverse effects encountered in efficacy trials should be taken into consideration during that evaluation.

Products that have a major effect on natural enemies of the crop pest will arguably not contribute to sustainable crop protection and may not be acceptable from an agronomic point of view. In particular, when specific claims are being made with respect to the use of the product in IPM schemes, the product should not have unacceptable effects on the natural enemies of the pests covered in the IPM scheme. Similarly, if the product is to be used on blooming crops, or otherwise in periods when pollinators may be exposed, it should not have unacceptable adverse effects on these pollinators, unless mitigation measures can be realistically applied.

6.0 Conclusion on efficacy evaluation

Appendix I should be used to summarise the review process and the decision of the reviewer. In general, based on the review of all scientific information available, the evaluation officer will decide whether the proposed use of a product is acceptable for registration from the efficacy point of view:

(a) The proposed registration is acceptable if the data demonstrate an adequate level of pest control without unacceptable effect to the host and support all the label claims and statements;
(b) If the proposed registration is not fully supported by available data, changes to the draft label may be made, in consultation with the registrant, to improve use directions and precautions. Acceptance of the registration may then be considered based on the revised draft label; or
(c) If additional data/information are required to support claims and to resolve a particular point or item of concern, the evaluation officer will identify the additional requirements and notify the registrant.

7.0 Appendix I

Environmental Protection Agency

Reporting Form for Pesticide Efficacy Trial Evaluation

Name of Evaluation Expert……Designation……

Department or Organization……Trial reference number……..

Date received ……. Date submitted…….

		For each section please give brief comments. Otherwise indicate acceptability by Y or N as appropriate. (Please refer to guideline)
A	**Background information on test product**	
	Commercial name of product under trial:	
	Product active substance(s)	
	Formulation	
	Product classification	
	Manufacturers/product ownership	
B	**Testing unit**	
	Name of efficacy testing organization/ facility	

	Location where trial was conducted.	
	Soil type	
	Scientist in charge of trial.	
	Number of trials	
	Number of seasons trial was conducted	
	Reference product(s) (justification for use)	
	Plot size and replication	
	Treatments	
	Trial methodology	
	Trial protocol used	
	Date and season of trial	
C	**Trial category**	
	Single product or Mixtures	
	Field trial, laboratory, glasshouse, (please indicate)	
	Storage trials or public health	
D	**Conformity of trial to label claim.(please indicate whether the above parameters conform to label instructions)**	
	Objective of trial	

	Target crop	
	Target pest	
	Application equipment, spray quality/nozzle type, pressure (kPa, bar);	
	The amount (i.e. dose) of the pesticide product ie application rate(l/ha)	
	Crop growth stage at application;	
	The number, frequency and timing of the applications;	
	Method of application	
	If required on the label, the amount of adjuvant added.	
E	**Efficacy parameters. Please indicate the extent to which the underlisted parameters have been addressed**	
	Direct efficacy (effectiveness)	
	Risk of resistance	
	Absence of unacceptable effects on plants or plant products	
	❖ Phytotoxicity	
	❖ Yield	
	❖ Quality	
	❖ Absence of unacceptable effects on production and production systems, in particular on	

	pollinators and natural enemies.	
F	**Assessment of trial**	
	Has trial been conducted under Good Agricultural Practice (GAP)?	
	Was the proposed level of control achieved?	
	Did the product show results that are significantly equal or superior to those recorded in the untreated control?	
	Extent of reduction of pest level or damage (eg below an economic or phytosanitary threshold).	
	Is the performance of the test product comparable to that of the reference product?	
	If an effective minimum dose level has been proposed, is there enough justification to effect a modification of label claims. Please explain the basis for acceptance or otherwise of proposed minimum effective dose from trial	
G	**Conclusion**	
	The acceptability of the trials organizations, test methods and location of testing;	
	The extent, quality and consistency of the data	
	The acceptability of any uses supported by evidence other than trials data	
	-uses recommended for authorization	
	-uses not recommended for authorization	

	Any restrictions on use	
	Any particular comments on the conditions relevant to or limitations on the use of the product in the region and claim for which use is sought.	
	Changes to product label	
	Statistical analysis	
H	**Recommendation for registration. Please indicate reasons for your recommendations and any additional comments on report/label etc(use overleaf)**	
	Approved	
	Suspend	
	Deny	
	Additional data required	