agriculture,
forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

GUIDELINES ON THE DATA AND DOCUMENTS REQUIRED FOR THE REGISTRATION OF AGRICULTURAL REMEDIES USED IN NON CROP SITUATIONS IN SOUTH AFRICA

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1. INTRODUCTION

The Department of Agriculture, Forestry and Fisheries (DAFF) through the Directorate Agricultural Inputs Control (DAIC), regulates the manufacturing, distribution, sales, use and advertisement of agricultural remedies through Act No 36 of 1947 “Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies” (1). An 'Agricultural remedy' is defined in this act as “any chemical substance or biological remedy, or any mixture or combination of any substance or remedy intended or offered to be used-

(a) for the destruction, control, repelling, attraction or prevention of any undesired microbe, alga, nematode, fungus, insect, plant, vertebrate, invertebrate, or any product thereof, but excluding any chemical substance, biological remedy or other remedy in so far as it is controlled under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), or the Hazardous Substances Act, 1973 (Act 15 of 1973); or
(b) as plant growth regulator, defoliant, desiccant or legume inoculant,
(c) and anything else which the Minister has by notice in the Gazette declared an agricultural remedy for the purposes of this Act:”

Applicants who wish to manufacture, import, sell and advertise agricultural remedies in South Africa must submit detailed information and data for evaluation to the Registrar of Act No. 36 of 1947, DAIC.

Section 3 of Act 36 of 1947 requires that applicants must submit data generated from scientific studies for evaluation of safety, efficacy and quality of products. Data must be generated from studies carried out according to prescribed standards

The purpose of this document is to outline the data and documentation required by the Registrar of Act No. 36 of 1947 in connection with the registration of non-crop agricultural remedies. The requirements differ according to the type of registration that is being sought. Information normally required for the different categories of registration is set out in this document; however, the Act makes provision for the Registrar to call for any further information in order to determine whether a remedy is acceptable in the context of public interest, suitability and biological efficacy. It is important that only data with a direct bearing on the registration application are presented.
These guidelines do not replace the requirements set out in Act No. 36 of 1947, and the regulations promulgated thereunder, but are complementary to Act No. 36 of 1947 and its associated regulations.

NOTE: If any of the data or documents called for in the paragraphs that follow are deemed by the applicant to be unnecessary or irrelevant, good scientific argument supporting this view should be presented in an application for a waiver of the requirement for such data or documentation. The application for waiver should be submitted before any tests/trials/studies are conducted and prior to the registration application being submitted to the office of the Registrar.

Enquiries to register new human skin applied products not yet classified either as agricultural remedies or a medicine should be referred to the Registrar of Medicines under Act 101 of 1965 at the Department of Health for an initial decision to be made. If a product is not classified as a medicine, then such a product will be registered as an agricultural remedy. This is concerning delousing agents for human use containing recognized medicinal substances intended for application to the skin and insect repellents for human use containing recognized medicinal substances intended to be application to the skin as published on the Government Gazette No. 6087 30th June 1978 by the National Department of Health.

The non-crop agricultural remedies market has traditionally been divided into the following market sectors or use patterns:

- Professional use (pest control companies), including Termiticides use
- Turf (golf courses, sports fields, lawn care operators) & Ornamentals (wholesale production of plants and cut flowers)
- Forestry
- Stored commodities protection (grain, dried fruit, tobacco etc.)
- Wood preservation
- Wool and other fabric/materials preservation
- Vector control of disease carrying organisms (e.g. malaria mosquitoes)
- Control of pests in animal housing and intensive animal husbandry (off-animal use).
- Migratory pest control (e.g. quelea and locust control).
- Amateur/consumer use of agricultural remedies in the home garden
- Amateur/consumer use of agricultural remedies in the home (indoors), including aerosol use
- Industrial vegetation management (including alien vegetation management, aquatic weed control, and bush encroachment control)

All these uses and sectors listed above are not concerned with the production of an agricultural commodity, and therefore fall under the ambit of this guideline.

Some of the sectors referred to above are already covered by guidelines which are available on the Department of Agriculture, Forestry and Fisheries (DAFF) website:

http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control/Guidelines

These will not be covered further in this document.

This document must be read in conjunction with all other relevant guidelines related to agricultural remedies registration requirements under Act No 36 of 1947.

This document is effective as from the 1st January 2018. For the existing labels that may need to be changed based on these new data requirements, manufactures will be allowed a period of five (5) years effective from the implementation date to generate the required studies in order to effect the required changes.

For the test methodologies to be used, applicants can use the latest versions of either SABS or OCED, WHO, FAO, EPPO or any internationally recognized/validated efficacy protocol/guidelines. The applicant should attach or outline the method used when applying for registration in the trials or experimental report.

All field trials must be conducted according to the Guidelines on data requirements for Agriculture Remedies 2015.

For generic claims, the two thirds (2/3) will apply for the claims already appearing on the correct reference standard.

2. PROCESS FLOW OF THE APPLICATIONS

The following section provides a step-by-step description of the submission review process which can be divided into 3 categories; verification, scientific screening and evaluation. The

DAIC will first screen the application (preliminary assessment) to assess whether it is complete. If the DAIC discovers at screening that there is missing information in the application, the DAIC will notify the applicant requesting that information. If the information is not supplied by the applicant within the specified period of approximately 30 days, then the application will be rejected. It should be noted the screening is not a thorough scientific evaluation of the dossier or application but rather a process to check the missing documents or studies. This service may not be done for all the applications submitted if the volumes concerning the number of applications submitted is very high in such a way that it exceeds internally capacity to cope with such a demand.

2.1. The screening process

The screening process is divided into two steps:

- administrative verification
- technical screening

Administrative verification

Administrative screen of applications take place within 14 calendar days after receipt to ensure that non-data elements have been provided. During administrative screening, the following are verified:

- cover letters
- service request form
- applicant details
- approved person details
- product registration number (if available) and if still valid
- application forms in triplicate, fully filled and signed
- legibility of the information and initialization of any corrections made by the applicant
- fees paid
- three copies of the labels, and
- other data specified on the cover letter

If the DAIC administrative section discovers that there is missing information.in the application, the DAIC will notify the applicant, requesting that information. If the information is not supplied by the applicant within the specified period, the application will be rejected.

Scientific screening

Once an application passes the administration verification process, it is allocated to be screened scientifically against the data requirements outline in the:

GUIDELINES ON THE DATA AND DOCUMENTS REQUIRED FOR REGISTRATION OF AGRICULTURAL REMEDIES IN SOUTH AFRICA (2015)

If the DAIC discovers that there is missing information.in the application, the DAIC will notify the applicant, requesting that information. If the information is not supplied by the applicant within the specified period of approximately 30 days, then the application will be rejected.

2.2. Evaluation stage

Once an application passes the screening process, it is allocated for scientific evaluation. During the process of evaluation, the applicant may be contacted for clarity or if data is missing and the information is not supplied by the applicant within the specified period of approximately 30 days, then the application will be rejected.

2.3. Decisions

Once the product evaluation process has been completed, the technical advisor submits an evaluation report and recommendations to the registrar. Registration officers prepare

documents on the application for submission to Registrar. The applicant is informed in writing about the decision of the Registrar, and issued with the relevant documentation. A registration is valid for a term of three years and is subject to renewal.
NB: Registration holders must note any conditions of registration. If these are not adhered to, the registration will be withdrawn or cancelled.

2.4. Appeal process

If the applicant is not satisfied with a decision made by the Registrar, section 6 of the Act provides for an appeal to the Minister against this decision. The Minister will then follow the process available to him/her.

3. REGISTRATION TIME FRAMES

Applications are reviewed according to the dates of submissions and categories of the different applications groups. However, under certain circumstances, an expedited review may be considered if there is a specific critical need identified by the Registrar. The time frames for specific processes and categories can be summarized as followings:

Table1: Estimated time frames for various applications in number of calendar days for major and minor registration applications of agricultural remedies*

Category	Performance Standards (working days)				
Major registration applications					
	Verifications	**Screening**	**Evaluation**	**Decision**	**Total No. of Days**
New molecule	14	30	569	14	627
Generic	14	30	360	14	418
New formulation or major amendment to a registered formulation	14	30	360	14	418
Label extension	14	30	360	14	418
Minor registration applications					
	Verifications	**Screening**	**Evaluation**	**Decision**	**Total No. Days**
New source of active ingredients	14	-	180	14	208
Minor amendment to a registered formulation	14	-	90	14	118
Admin amendments to the application form or label	14	-	90	14	118
Trade name change	14	-	90	14	118
Parallel registrations/ daughter registrations and transfers	14	-	90	14	118
Addition or change of formulator	14	-	180	14	208
Addition or change of packaging material	14	-	90	14	118
Re-instatement	14	-	90	14	118

Advertisements	7	-	21	7	35
Import permits	3	-	8	3	14
Renewals of registrations	90	-	-	-	90
Certificate of Free Sale, or Registration Cancellation	7	-	-	-	7

*Please note these time frames maybe extended, if there is a delayed response from the applicant to a DAIC communication.

4. APPLICANTS and APPROVED PERSONS

4.1. Applicant and registration holder

The applicant is the individual or company who / which will become the registration holder, should be application be successful. In the case where the application is for any changes to be made to an approved current registration, the applicant will be the registration holder.

All individual representative applicants must reside in South Africa or in the case of a company, the company must have a registered office in South Africa. The application form must contain the applicant's full name, street, postal address and contact details. If the applicant is a company then proof of registration in South Africa must be provided. In all cases, the applicant must nominate approved person and their position and title, with whom DAIC can correspond and who will take responsibility for the application.

4.2. Approved person

The approved person is the individual, company representative or third party representative who is resident in South Africa and who will take responsibility for the application. In relation to an application, generally the approved person is responsible for:

- signing the application form
- giving consent to the DAIC to alter the application form
- giving extra information or changing information previously given to the DAIC
- giving the DAIC written notice to withdraw the application.

An applicant may appoint a third party (a company or an individual outside their company but residing in South Africa). A representative from this third party may be appointed as the approved person for the purposes of the application.

When an applicant wishes to make use of a third party representative, they must send a letter of authority to DAIC. The letter of authority must specify:

- Which of the regulatory matters the approved person is authorised to conduct, i.e. all aspects of the application or only specified functions.
- The duration of the agreements, i.e. the same person will also be responsible for only the application process or if they will also be responsible for the post-registration matters.

If an applicant appoints a different approved person for any one or more of the regulatory matters, they must send DAIC a separate letters for each different approved person.

5. APPLICATION REQUIREMENTS

An application can range from only a completed application form to a multi-volume application containing detailed scientific reports and scientifically-based arguments. As a minimum, an application must include the following documents and information

A complete application must:

- Include a service request form;
- the appropriate and fully completed application form signed by an approved person including all relevant information listed in the Active Ingredient Dossier Index (List I) and the Formulated Product Dossier Index (List II) information that application requires (where relevant). See Guideline on the data and documents required for registration of agricultural remedies in South Africa" document of 2015.
- be accompanied by appropriate fee (See document for tariffs adjusted every financial year)

An application will not be accepted by the DAIC and proceed to a full evaluation unless it is complete.

5.1. Service Request Form

- This form must be completed by the applicant / registration holder and submitted with the relevant application form(s) and supporting documentation.
- An additional motivational cover letter may be submitted with the application(s) where necessary.
- A copy of the stamped front page (page1) should be kept by the applicant as acknowledgement of receipt.

5.2. Cover letter

All applications for the registration of a product or the amendment of the registration of a product must include a covering letter.

The covering letter:

- should be addressed to the Registrar for the attention of the Head of the Registration Administration Office.
- should have a subject line which contains the product name (and the existing registration number if it is an amendment application).
- should contain statements as indicated in the attached letter

Note: Providing the registration number can save considerable time in the administration of the application, since the filing systems are all numerically based. Details of the application, that is new application, application for amendment, application for a "daughter" registration, etc., must be outlined briefly. Duplicates of all necessary letters of consent, that is permission for "daughter registration" or permission to use another company's product name on the label, must accompany the covering letter.

Cover letter to include the following:

- Name of product
- Registration number if product is already registered
- Reason for submission
- Identification of the sets of documents enclosed
- Letters of consent if permission from the registration holder is required

5.3. Application forms

Application forms must be submitted for new applications and amendments to an existing registration, including change of formulation.

The following points apply to the application forms:

- The prescribed application forms (SEARCH Form, Active Ingredient: Dossier Index List I and Formulated Product: Dossier Index List II) provided by the Registrar must be used.
- The application forms must be submitted in triplicate. One copy is for the technical adviser, one is for the Registrar's administration office and the other copy is returned to the registration holder when the registration is approved and the registration number of the product is allocated or the registration amendment is approved.
- An overseas company may not apply for registration in RSA. Only a locally registered company, an RSA citizen or a legal body that is registered in RSA may apply for the registration of agricultural or stock remedies.
- The application forms must be signed by the legally appointed person and this should preferably be the company contact person with whom the Registrar's office will communicate.
- The name in which the product will be registered must be identical to the one on the covering letter, application forms and labels. The name is to be used on all labels and correspondence after allocation of the registration number. Any change in this name, however slight, will be regarded as an amendment.
- Application forms must be handed in to the Registration Administration Office, where they will be checked and all the necessary procedures are followed. Handing applications to the Technical Advisers will delay the process and the Registrar's administrative office is not held responsible for such applications.

SEARCH Form

The formatting of the SEARCH form should not be altered in any way.

The required information should be entered into the SEARCH form. Since all the applicable information generally cannot be satisfactorily entered in the relevant sections of the SEARCH form, an attachment with this information, appropriately referenced to the headings of the SEARCH form (see below), should be appended to each copy of the SEARCH form submitted. This attachment should always be included and all sections should be populated even where the information can be accommodated on the SEARCH form. The attachment effectively forms part of the SEARCH Form and should also be submitted in triplicate.

Completion of the SEARCH Form

Identification of nature of application

- The "Pesticide containing a new active ingredient:" option should only be used if a new chemical entity active ingredient is included in the formulation.
- Most commonly, the "Pesticide where source of active ingredient and/or formulation is not identical to that of a registered product:" option should be used.
- For amendments, the "Amendments to an existing registration:" option should be used.
- A brief description of the requested amendment should be inserted in the grey portion of the line.

"Applicant"

- All manufacturing sites, stock depots/warehouses and distribution agents directly controlled by the applicant should be listed an attachment.

"Product"

- The relevant latest Croplife International/FAO Code should be selected from the list provided.
- Use the correct Custom Tariff Code

"Active Ingredient(s)"

- The common name of each active ingredient should be given together with the manufacturer's name and address and either the specified minimum active level or purity range as applicable.

"Formulation"

- The full names and addresses of all sites which may be used to manufacture the product should be entered. Letters, from each company manufacturing the product on their letterhead, signed by an authorised signatory, confirming adherence to the details of the product registration including the specific formulation that is being/has been registered.

"Toxicology"

- Formulation toxicity information: For all formulation types, it is required that formulation toxicity data, generated according to OECD Guidelines using OECD GLP accredited laboratories(2), be submitted for hazard classification as per the latest regulations o/guidelines.

"Packaging"

- The material from which the container is constructed should be declared as well as all pack size in which the product may be intended to be sold.

Note: For the change of packaging material, storage stability tests need to be submitted.

Refer to the **Guideline for Shelf Life Extension of Pesticides in South Africa (2015)**

5.4. Dossier Index List I and List II

5.4.1. Active Ingredient: Dossier Index List I

A separate index should be submitted for each declared active ingredient.

All relevant information listed in the Dossier Index List I should be provided. But, where some information does not fit in the fields provided, an attachment to the index should be provided. This should be divided into sections titled and numbered as per the index list. Where the information cannot be fitted in the field provided on the Active Ingredient: Dossier Index List I, the statement, “See attachment”, should be entered. Where a particular field is not relevant to the product type or format, the statement, “Not applicable”, should be entered.

All information must originate from the supplier of that active ingredient. Where the supplier of the active ingredient is not willing to provide the necessary information directly to the applicant for reasons of confidentiality, they should submit it confidentially directly to the Registration Administration Office in the Registrar’s

office. In addition to a covering letter from the active supplier, the supplier's submission should also include a copy of the applicant's covering letter from the applicant's registration application documentation.

A Letter of Supply from each active ingredient supplier confirming that they will supply the relevant active ingredient(s) should be submitted.

5.4.2. Formulated Product: Dossier Index List II

All relevant information listed in the Dossier Index List II should be provided. But, where some information does not fit in the fields provided, an attachment to the index should be provided. This should be divided into sections titled and numbered as per the index list.

Where the information cannot be fitted in the field provided on the Formulated product: Dossier Index List II, the statement, "See attachment", should be entered. Where a particular field is not relevant to the product type or format, the statement, "Not applicable", should be entered.

Completion of the Formulated Product: Dossier Index List II

Section 1 - "Physical and Chemical Properties":

- Insert as per "physical & Chemical properties" of each product

Section 2 - "Toxicology":

- Formulation toxicity information: For all formulation types, it is required that formulation toxicity data, generated according to OECD Guidelines using OECD GLP accredited laboratories (2be submitted for hazard classification as per the latest regulations or guidelines. discussion.

Sections 3 and 4 - "Emergency Procedures":

- A SDS should be provided in the attachment and reference to SDS need only be made.

Section 5 - "Use":

- "**Household**", "**Home/Garden**", **"Public Health" or "IVM"** as per SEARCH form should be entered for "Crop/ area of use".
- The insects listed on the SEARCH form should be entered for "Target Organism".
- For aerosols, the spray rate should be entered for "Rate". For other formats of product, the dosage rate should be provided.
- The directions for use as they appear on the submitted label should be entered for "Directions for use".
- The Warnings and Precautions which will appear on the label should be entered for "Contra-indications".

Section 6 - "Minimum Label Requirements":

- It is recommended that a list of all claims made on the label for the product is presented and that each claim is specifically substantiated and justified (with data in addition to the primary efficacy test report(s) if necessary in order to ensure as far as possible that they shall be granted by the Registrar. Claims should be supported by a sound technical argument.

Section 7 - "Efficacy Reports":

- Efficacy data should be generated using internationally recognized testing methods (ISO, CEN, SABS, OECD, WHO etc.) because proprietary test methods are subject to copyright issues preventing the full methodology of such methods not being included in efficacy reports. However, applicants wishing to use other test methodologies should submit these methodologies to the Registrar's office in order to ascertain whether these are acceptable to the Registrar. The Registrar's approval shall be obtained prior to use of such methods.

A summary of the results should be provided as well as the original copy of the test report(s).

A formulation change for all applications is regarded as major if more than 10% of the total content of the formulation is changed. A change of less than 10% would also be regarded as major if the classification of the formulation moved to a more hazardous class. Some examples of minor formulation changes (the classification of the formulation must not change to a more hazardous class as a result of the minor change) are:

a. Change in substances added to preserve the formulation in the container or to improve safety to non-target organisms.
b. Substitution of one inert for another with similar properties.
c. Changes in substances used to identify the formulation, e.g. dyes.
d. In general, changes of not more than 10% in the total content of the formulation.
e. Changes in the carrier or water content of GR and SC formulations.

5.5. Labels

- An English copy of the label must be provided in triplicate.
- For all other official languages, the translation must not deviate from the English label.
- For foreign languages, an affidavit from a certified translator must be submitted.

- The labels must be:
  - ✓ submitted in draft form;
  - ✓ clearly legible;
  - ✓ in the correct format (RSA classification); and
  - ✓ all particulars on the label must correspond exactly with those on the application form.
- Registration holders must adhere to the ISO notation, for example in 5 kg where a space is left between the number and the unit of measurement.
- Warnings of all products must include "Keep out of reach of children, uninformed persons and pets"
- Warnings and precautions must not be numbered.

5.6. <u>Efficacy requirements</u>

<u>General requirements for efficacy trials and registration for non-crop agricultural remedies</u>

1) All trials shall be supervised and/or conducted by person(s) qualified and experienced to perform such trials.

2) Efficacy trials may be conducted by external consultants and/or internal personnel of the registrant.
3) All trials shall be replicated, with a minimum of three replicates. A negative control must be included in the trial. Where mortality of the test organism exceeds 10 % in the negative control, the trial will not be considered for a registration application, and the trial would normally have to be repeated.
4) Wherever relevant, all registration applications will be accompanied by results from at least one laboratory trial, unless stipulated otherwise below. Three field trials are mandatory for products with label claims for outdoor use.
5) Trials must include a standard registered (reference) product for comparison purposes. Sometimes no standard product will exist – e.g. when a new formulation type is being tested for the first time for registration in non-crop uses. Under these circumstances it is still possible to include a standard (reference) registered product, the use of which is intended to give the same control result as that planned with the new product/formulation (e.g. 75% control of a specific pest species or application type or combination of both). As an example, say a new residual spray formulation, not covered by any common spray formulation is to be tested for registration, a standard product could include any SC, WG, EC, WP etc. formulation already registered for the intended pest(s) and use pattern (residual spray). The same would apply if the new product was also a new active ingredient, or an active ingredient not registered for a non-crop use before – it is not necessary to compare the same chemistry, but to compare the end result – efficacy against the targeted pest and specific use pattern. For example if the new chemical class was to be tested in a new residual spray formulation, the standard product could be any pyrethroid, organophosphate, phenyl pyrazole etc. chemical class already registered for residual spraying against the intended target pests.
6) Active ingredients listed in Appendix 4: “Generic compounds exempt from the submission of experimental data” of the “Guidelines on the data and documents required for registration of agricultural remedies in South Africa”, are also exempt from the data requirements listed for the purposes of registration in non-crop applications
7) The minimum requirements listed below do not preclude any potential registrant from conducting any additional trials, albeit laboratory simulated field or field trials, and submitting these data for registration purposes.
8) All efficacy data must be generated from trials conducted in South Africa. Additional data from trials in other countries may be submitted as supporting data in a registration application, but will not be assessed to solely support any label claims. Where no capacity exists in South Africa to conduct specific pest/application method trials, then the registration applicant must consult with Act 36 personnel on conducting a trial outside of South Africa, or whether the specified trial/pest/application method claim can be waived for registration.
9) For vector claims on the label, trials should done according to the WHO/WHOPES guidelines and such work should be endorsed by the WHO.
10) As many non-crop pesticide applications are made to various surfaces, certain surface types must be included where relevant. Surface type has a pronounced effect on the performance of a pesticide. The following surface types may be considered for inclusion:
    a. Glazed tiles
    b. Glass or glass tiles
    c. Unpainted wood
    d. Unpainted cement
    e. Enamel painted wood
    f. Emulsion painted cement
    g. Unglazed ceramic tiles
    h. Laminated wooden flooring

i. Stainless steel
j. Various textile surfaces
k. Zinc
l. Clay brick surfaces

11) Formulation toxicity information. For all formulation types, it is required that formulation toxicity data, generated according to OECD Guidelines (2), be submitted for hazard classification (11), or, if test data on Formulation toxicity are not available, formulation toxicity can be calculated from the toxicity of the a.i./s and all relevant inert ingredients, using the GHS Acute Toxicity Estimate Procedure for Classification and Labelling of Chemicals (12). The actual calculation must be submitted. These calculations maybe subject to further discussion.

The efficacy requirements listed below are grouped under application types and/or formulation types. The groupings are as follows:

1) Surface residual sprays
2) Space sprays
3) Cockroach baits
4) Ant baits
5) Fly baits
6) Aerosols
7) Stored grain protectants (Must include residues)
8) Tobacco curing protectants (Must include residues – Refer to Tobacco Guidelines)
9) Termiticides
10) Wood/Furniture/Timber preservatives
11) Wool , skin, hides/leather preservatives
12) Disease vector control: Insecticide-treated mosquito nets
13) Disease vector control: Indoor residual spraying
14) Disease vector control: Space spraying
15) Disease vector control: Aircraft aerosols
16) Insect repellents
    a. Applied to the skin
    b. Applied / impregnated to materials and textiles (tents, clothing etc.)
17) Insect control/killers: impregnated material
18) Dusting powder applications
19) Industrial Vegetation Management: Aquatic weeds & Alien Vegetation Management
20) Rodenticides
21) Molluscicides for home garden use and other uses outside agriculture.
22) Larvicides
    a. Insecticides
    b. Insect growth regulators
23) Adjuvants for non-crop use
24) Home garden use: Vegetables and fruit
25) Home garden use: Ornamentals
26) Home use (indoors): Other products
27) Insecticide/fungicide/algaecide/repellents for paints, , resins, vanishes, coatings and laquer formulations
28) Aircraft products
29) Pests in water (Black fly, mosquito larvae etc.)
30) Smoke generators, fumigants and fogging machines
31) Pheromones
32) Bird repellents

Efficacy testing guidelines per use pattern/formulation type

For all trials for non-crop uses an efficacy threshold of more than 75% mortality, knockdown or control (depending on the trial type and label claim) must be achieved in order for the registration application to be approved, except for rodenticides except where mortality should be greater than 90%. For the test methodologies to be used, applicants can use the latest version of either SABS or OCED or any internationally recognized/validated protocol

1) Surface residual sprays

For surface residual sprays one replicated laboratory trial (minimum three replicates), with a standard reference product, on representative surfaces, will suffice for registration purposes. Where specific surfaces are claimed on the label these surfaces must be tested separately. The length of residuality for regularly cleaned surfaces will generally be accepted to be 4 weeks, but for other surfaces you may claim residuality based on trials done. Where residuality is less than 4 weeks, on certain surfaces or all surfaces, this must be indicated so on the submitted label. Residuality claims for longer than 4 weeks must be tested for and proved with minimum 75 % mortality the requirement. The following surface types can be considered for inclusion in trials:

a. Glazed tiles
b. Glass or glass tiles
c. Unpainted wood
d. Unpainted cement
e. Enamel painted wood
f. Emulsion painted cement
g. Unglazed ceramic tiles
h. Laminated wooden flooring
i. Stainless steel
j. Various textile surfaces
k. Zinc
l. Clay brick surfaces

Residual surface sprays are normally used for indoor applications. Where the label makes mention of exterior use, field trials are required.

See below:

a) Home / urban setting

Indoor use – 1 laboratory trial
Outdoor use – 1 laboratory & 1 field trial

b) Farm or Small holding setting

Three (3) field trials

Target species:

Where target species are not available in the country, then extrapolation of data from other countries is allowed for registration purposes.

Bedbugs: Products that claim control of bedbugs must be tested. A statement on resistance must be added (e.g. “My product will not work on pyrethroid / DDT resistant bedbugs”). If there are no bedbugs in the country, then the above statement on target species applies.

Fishmoth:

Where claims are made for non-staining properties of residual sprays the product must be assessed on the following surfaces/panels for non-staining properties: wood, enamel

painted wood, cement, emulsion painted cement, short fibre carpet, glazed tile, a plastic surface typical of household appliances and furniture, and one additional textile type.

These requirements are relevant for concentrates and ready-to-use surface spray products.

2) Space sprays

Space spray formulations can be tested in aerosol chambers, or free-flying rooms. The trial can be replicated by using caged crawling or flying insects as appropriate. The formulation must be applied with appropriate equipment, either ULV or hot/cold fogging apparatus.

For indoor use: One (1) laboratory trial
For Outdoor use: A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

3) Cockroach baits

One (1) replicated laboratory trial with a standard (reference) product, conducted in an arena type situation is sufficient for registration purposes. German and American cockroaches must be tested separately. To claim Oriental cockroaches, both the American and the German cockroach must be tested in order to allow the extrapolation of data. Any additional label claims (e.g. speed of knockdown, attractiveness, other species etc.) must be tested for separately from efficacy (mortality) studies.

If the product is to be used in a bait station or a specific refillable bait station and is recommended on the proposed label, this bait station must be tested in the trial.

4) Ant baits

Ant baits need to be tested against a minimum of one of the three most important non-crop ant pests in South Africa. The important species are:

- *Pheidole megacephala*: brown house ant, big-headed ant
- *Linepithema humile*: Argentine ant
- *Lepisiota* species: black sugar ant, little black sugar ant

One (1) laboratory trial against one (1) of these species in an artificial nest/arena system which demonstrates efficacy due to high mortality of the workers, and substantial degradation of the ability of the nest to survive, is sufficient to claim a label against all three species. Alternative food sources must be available in this trial.

There are other pest ant species in South Africa. Some of these are listed below:

- *Anoplolepis custodiens* and *A. steingroeveri*: malmiere, pugnacious ant
- *Crematogaster* species: cocktail ants, wipstertmiere
- *Myricaria* species: balbyters

As these other species are mostly found outdoors, three (3) field trials to prove efficacy must be done. Ant activity or trailing is one measure that can be used to assess efficacy in these species. Where a bait product has already been tested against these species in agriculture (and this includes the other 3 ant species above as well), and registered, no additional trial work is required to label the product for non-crop uses.

5) Fly baits

Insecticide-based fly bait trials should be conducted in large aerosol chambers or in a free flight room. An alternative food source and water should form part of the experimental design in a chamber/room. As many fly baits are also used outdoors, and where the label claim makes mention of outdoor use, field trials are also required. Fly populations in the field trial must be monitored pre-baiting and post-baiting and the efficacy measurement should demonstrate a drop in the adult fly population.

Other fly baits (and pheromones) are those that consist of a protein base used to attract flies, and are used in conjunction with a trap design. Field trials should demonstrate efficacy in attracting flies in its vicinity – the trial must be conducted using the proposed trap design. Fly populations in the field trial must be monitored pre-trapping and post-trapping and should demonstrate a drop in the adult fly population. If using an attractant, you must specify the attractant.

For claims tested must be done on species group based on feeding habitats.

For indoor use: One (1) laboratory trial – minimum 3 replicates trial (repeated in the chamber/room)
For Outdoor use: A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

6) Aerosols

Spatial /direct spray aerosols:
One (1) replicated laboratory trial per the chosen protocol.

- For a general claim of “flying insects”, the house fly and a mosquito species must be tested.
- For a general claim of “crawling insects”, the German and American cockroachs, as well as one (1) and species must be tested.
- For a claim against a specific species of insect, data on the efficacy against that species is required.

Aerosols used as surface treatment:

- One (1) replicated laboratory trial for a label claim of a surface aerosol spray is required.
- For a general claim of “flying insects”, the house fly and a mosquito species must be tested.
- For a general claim of “crawling insects”, the German and American cockroachs, as well as one (1) and species must be tested.
- For a claim against a specific species of insect, data on the efficacy against that species is required.

The following surface types can be considered for inclusion in trials:

a. Glazed tiles
b. Glass or glass tiles
c. Unpainted wood
d. Unpainted cement
e. Enamel painted wood
f. Emulsion painted cement
g. Unglazed ceramic tiles

h. Laminated wooden flooring
i. Stainless steel
j. Various textile surfaces
k. Zinc
l. Clay brick surfaces

Where specific label claims referring to surface types not listed above are made, that surface type must also be included. Where labels claims are made regarding non-staining properties, staining must be assessed on all the surface types listed above plus two (2) additional textile types and a plastic surface commonly found in household appliances and furniture.

Metered aerosols:

a) Metered aerosol products utilising standard aerosol valve technology, which has a continuous spray, and an electronic dispenser that controls the spray duration by way of a timer are subject to the same requirements as above for flying insect aerosol products.
b) Metered products utilising metered aerosol valve technology, which sprays fixed amount with each actuation, and an electronic dispenser that controls only the spray interval by way of a timer must be tested according to a test protocol that uses a chamber of at least 30 m^3, an air exchange rate of at least 0, 03 m^3/s and a 24 hour test period.

Label claims for surface control of crawling insects will not be entertained for metered aerosols. Where the label claim for metered aerosols makes reference to duration of activity, this must be proven by submitting data showing the quantity released per metered spray burst of the specific aerosol nozzle/regulator, and the recommended applicator/machine. Where label claims are made regarding non-staining properties the same surfaces as listed above for surface aerosol sprays must be tested.

7) Stored grain protectants

All potential grain protectants applied directly to grain must be tested in the laboratory in a replicated trial, with a standard product as reference, against the species that will be listed on the label. The period of protection must be specified on the label. Beetles and moths should be tested. One (1) laboratory trial is sufficient for registration purposes. For efficacy, there is no need to test the highest rate of 2x.

For direct application products the residue status of the product on the grain must be determined, at the proposed label rate and a 2x rate. An organoleptic test is also required for registration. The following document can be used for guidance: “SANS5957: Pesticides - Organoleptic evaluation of the taste of pesticide-treated edible crops”.

This guideline is meant for grains that are stored for human consumption and feed purposes.

This guideline does not cover the application of grain protectants (including fungicides) to grain seed.

Where grain protectants are used as residual surface sprays or space sprays, these trials should follow the guidelines for those product uses.

8) Tobacco curing protectants

Potential registrants should consult with the tobacco industry re requirements for specific pest and application combinations.

Harvested tobacco, while being dried, stored and processed, is susceptible to a number of insect pests of stored commodities, particularly the cigarette or tobacco beetle, *Lasioderma serricorne* (*Anobiidae*), and *Ephestia elutella* (*Pyralidae*), the tobacco moth. Products claiming to control these two pests in tobacco must provide a replicated trial against the relevant species for registration purposes. Tobacco pest control can be achieved by using residual sprays, fogging and ULV applications, and fumigation products. A single replicated trial is sufficient. A field trial is required, in a facility where tobacco is dried, stored or processed. Where sprays or other applications are applied directly to tobacco, a residue trial at the proposed dosage and a double dosage must be submitted. A taint test (smoking test) must also be submitted for all products submitted for control of tobacco pests.

For additional information refer to the following document: “Guidelines for trials prior to registration of chemical control agents for use on tobacco: 2000”.

9) Termiticides

Termiticides must be tested according to the guideline used for the past 40+ years by the SABS. One (1) replicated field trial at the SABS field testing site, including a standard reference product, is sufficient for registration purposes. The Registrar of Act 36 will approve a provisional registration for a termiticide after the trial has been running for 2 years, with a full registration after 5 years trial data.

Both the 2 year and 5 year registrations will attract a full registration fee and submission.

The field trial is sufficient for registration as a pre- and post-construction label, provided the post-construction label specifies a full perimeter and indoor application of the termiticide. Where the label makes claims to be effective as a partial indoor treatment and perimeter treatment, such efficacy must be demonstrated in field trials at infested houses – three (3) houses are required – the trial must demonstrate that the structures remain free of termites for 3 years.

10) Wood, Furniture and Timber preservatives

A wood preservation guideline exists, and should be adopted into these guidelines for any wood destroying termites, beetles, insects, fungi etc.

See the following document entitled: “Protocol for the approval of industrial wood preservatives in South Africa. Second Edition 2010”.

A method and protocol for wood preservatives protecting timber from termites is contained in “SABS Method 471”. This method/protocol should be followed.

11) Wool , skin, hides/leather preservatives

Moths, beetles, mites, insects, fungi etc. attack wool and other natural fibres/textiles. Where these fibres/textiles are protected by the addition of an insecticide to the fabric/fibre/textile, data should be generated to prove efficacy of the product against the targeted pest. One (1) laboratory trial is sufficient, and all pests claimed on the label above must be tested.

12) Disease vector control: Insecticide-treated mosquito nets

Insecticide treated nets need to be tested in the laboratory against a target species (i.e. *Anopheles* malaria-transmitting species). The resistance status of the mosquito strain must be known, and the test must be on a South African species. The protocol for the laboratory trial and field trials must follow the guidelines of the World Health Organization (WHO) and endorsed by the Pesticide Evaluation Scheme (WHOPES).

13) Disease vector control: Indoor residual spraying

The protocol and format of the laboratory and field trials, as well as evaluation, must follow that of the published method adopted by the WHO.

14) Disease vector control: Space spraying

Where the target vector species is *Aedes* (if yellow fever, dengue, Zika, chikungunya or other viral or other diseases transmitted by *Aedes* ever become established in South Africa), the trial must be carried out with an *Aedes* species. *Aedes* are normally controlled by space spray applications, and where disease transmission is implicated the trial protocols and evaluation should follow published WHO guidelines.

15) Disease vector control: Aircraft aerosols

Aircraft aerosols are used to prevent transport of disease carrying pests by means of human transport, specifically air transport. Trial requirements, protocols and evaluation must follow the published WHO methods.

16) Insect repellents

a) Applied to the skin

See introduction and Notice No R1332 of 30 June 1978 Department of Health text b & c.

For trials where human volunteers are needed, then ethics approval from an ethics committee in South Africa is needed.

For repellents meant to be used on the skin a trial where the repellent is applied to human skin and placed into a free-flying cage with *Aedes* or *Culex* mosquitoes should be submitted. As many less effective products (unregistered) are available on the market the reference standard to be tested against for this trial must be a registered standard product.

Only one (1) laboratory trial is needed for registration.

A WHO method for skin repellent evaluation exists and can be consulted for guidance.

b) Applied to materials and textiles (tents, clothing etc.)

For spatial and other repellents applied to materials and textiles an olfactometer type of laboratory trial must be submitted for registration purposes. All pest species

claimed on the label must be tested for (e.g. flies, mosquitoes etc.). One (1) replicated trial is sufficient for registration purposes.

17) Insect control/killers : impregnated material

The mode of action of an impregnated material provides similar mode of action as provided by surface residual sprays. This provides for an extended period of control. Insecticide impregnated material needs to be tested against the target species by directly exposing the insect to impregnated surface.

For impregnated material, one replicated laboratory trial (minimum three replicates), with a standard reference product will suffice for registration purposes. Impregnated materials are normally used for indoor applications. Where the label makes mention of exterior use, field trials are required.

c) Home / urban setting

Indoor use – 1 laboratory trial

Outdoor use – 1 laboratory & 1 field trial

d) Farm or Small holding setting

A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

18) Dusting powder applications

The application of dusting powders is meant to give similar control results to residual sprays applied to surfaces. Dusting powder efficacy must be conducted in the laboratory, against the pests claimed on the label, and on the appropriate surfaces. One (1) laboratory trial is necessary for registration purposes.

a) Home / urban setting

Indoor use – 1 laboratory trial

Outdoor use – 1 laboratory & 1 field trial

b) Farm or Small holding setting

A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

19) Industrial Vegetation Management: Aquatic weeds & Alien Vegetation Management

Refer to the DAFF Herbicide Guideline 2010

20) Rodenticides

For trials where animal testing is needed, then ethics approval from an ethics committee in South Africa is needed.

For laboratory testing all rodenticide requisitions must follow the recognized trial protocol should be used.

Lab-bred or wild rodents rats can be used for trials.

Field testing and label claims for rodents (gerbils & rate sand mice) in agricultural settings). Refer to the “GUIDELINES ON THE DATA AND DOCUMENTS REQUIRED

FOR REGISTRATION OF AGRICULTURAL REMEDIES IN SOUTH AFRICA, 2015" for additional requirements.

Greater than 90% mortality is required for all rodenticide.

21) Molluscicides for home garden use and other uses outside agriculture

Where the product or formulation to be registered for snail control in non-crop situations is already registered under crop conditions, no additional trials are necessary for a non-crop registration.

Where the product or formulation is different from that used under crop conditions, three (3) field trials must be done. An efficacy trial in an outdoor enclosure in which a suitable crop/ornamental food plant is planted, and from which the snails to be tested cannot escape is needed.

22) Larvicides

Larvicides in non-crop are used (mostly) for the control of immature insects in three situations: in residual sprays on surfaces for the control of the immatures of insects such as cockroaches, fleas etc., in aquatic situations for nuisance mosquitoes, and in manure, rubbish heap and compost situations for fly control.

a) Insecticide

Where a proposed larvicide is a "straight" insecticide (i.e. no claim for IGR effects), one (1) laboratory trial, in the situation or pest combinations that the label proposes, must be submitted for registration.

b) Insect growth regulators

All Insect Growth Regulator (IGR) larvicides must be tested on each insect for which a label claim is desired, as IGR modes of action differ, and different insect species are differently susceptible to different IGR modes of action.

Outdoor applications: Three (3) field trials
Indoor applications (e.g. cockroaches): One (1) laboratory trial.

Where a label for an IGR product claims additional effects over and above those of control of immatures (e.g. fecundity/sterility claims, effects on adults, effects on egg viability etc.) these must be proven in one (1) laboratory trial for the claim/pest combination.

23) Adjuvants for non-crop use

There is more and more interest to use adjuvants in non-crop situations. All adjuvants currently on the market are labelled for crop use. Refer to the Adjuvant Guideline.

24) Home garden use: Vegetables and fruit

For amateur use in the home garden, it is assumed for the purpose of these guidelines that the relevant vegetable/pest/disease and fruit/pest/disease combinations have already been tested and registered for use in agriculture, and the relevant residue and

phytotoxicity trials have been done. Where this is the case no additional testing is required for registration purposes. Where the formulation proposed for use in the home garden differs from that in use in crop, efficacy, phytotoxicity and residue studies must be conducted, similar to those for crop use on the same vegetable/pest/disease and fruit/pest/disease. Plot sizes for such trials may be reduced for home garden use, for fruit trees a single tree plot size is acceptable.

25) Home garden use and Outdoor: (Ornamentals, Proteas and Fynbos)

Efficacy trials on the plant/pest/disease combination for the label claim must be done. Plot sizes can be single plant specimens where the plant is a tree/shrub/rose bush, and small 2 x 2 m plots for other ornamentals/flowers, or single potted plants where the label claim refers to potted plants.

If target pest to be tested is the same for all ornamentals, then indicate “all ornamentals” on label instead of being specific (i.e. Roses).

If the pest is the same (or use pattern is the same) as in a crop situation, then extrapolation is allowed, but phytotoxicity studies must still be conducted.

For species not under commercial / crop (e.g. ferns), then efficacy data must be generated and extrapolation is not allowed for registration purposes.

Phytotoxicity testing: Include the labelled rate (1x) and a double dosage rate (2x).

Indoor & Outdoor use: If claims are already approved in a crop situation, then the data can be extrapolated in Home garden use.

Proteas and Ornamentals: A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

26) Home use (indoors): Other product types

Other household products such as emanators, mosquito coils, mats, liquid vaporisers, repellent candles etc. must be tested in a replicated trial in the laboratory, either in an aerosol chamber or free-flying room, or in an olfactometer for a repellent claim, against the species that will be claimed on the label. One (1) laboratory trial is sufficient for registration purposes. Other products such as insecticide chalks should follow the residual spray guideline.

27) Insecticide/fungicide/algaecide/repellents for paints, , resins, vanishes, coatings and laquer formulations

Products containing insecticides/fungicidal/algaecide that claim to repel or control pests must be tested in a replicated laboratory trial against all the claimed pests. The product must be applied to surfaces to which it will be applied when in use.

Indoor: One (1) laboratory trial
Outdoors: A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

28) Aircraft products

Products containing ingredients that claim to repel or control pests must be tested in a replicated laboratory trial against all the claimed pests. One (1) laboratory test will be

required. For vector control claims, efficacy studies must be done according to the WHO efficacy guidelines and also the product must comply with aviation requirements or specifications.

29) Pest in water (e.g. Black fly, mosquito larvae etc)

Products containing ingredients that claim to repel or control pests must be tested in a replicated laboratory trial against all the claimed pests.

Indoor. One (1) laboratory test will be required. For vector control claims, efficacy studies must be done according to the WHO efficacy guidelines.

Outdoors: A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

30) Smoke generators, fumigants and goging machines

Products containing ingredients that claim to repel or control pests must be tested in a replicated laboratory trial against all the claimed pests.

Indoor. One (1) laboratory test will be required. For vector control claims, efficacy studies must be done according to the WHO efficacy guidelines.

Outdoors: A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

31) Pheromones

Products containing pheromones/attractants that claim to attract pests for monitoring purposes are exempted from efficacy data requirements. However if pheromones/attractants are mixed with an ingredient to control or repel a pest.

Indoor: One (1) laboratory trial
Outdoors: A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines.

32) Bird repellents

Indoor. One (1) laboratory test will be required. For vector control claims, efficacy studies must be done according to the WHO efficacy guidelines.

Outdoors: A minimum of three (3) field trials are required, as per the data requirements for the registration of agricultural remedies guidelines

5.7. Application fee

Proof of payment of the application fee must be submitted with the application. The amount is determined by the application category. The tariffs are published through government gazette at the beginning of each financial year. An application cannot proceed to evaluation until the applicant has paid the application fee in full. If an applicant has submitted an excess amount, the applicant should use the excess amount when making future applications. No refunds will be made to the applicant. The DAIC is able to accept proof of payment for payments made via Electronic Transfers, Cash Deposits or

receipts from payments made at Finance Division of DAFF only. No cash will be accepted by DAIC. Banking details for DAFF can be requested from the office of Registrar (Act 36). These fees are accessible from the Registrar's website.

6. Advertising

Note: Refer to ASA Guidelines

- All advertising or promotional material must be submitted to DAIC for approval.
- Advertisements must be submitted in triplicate and must be accompanied by a covering letter.
- Only refer to a product being new for one (1) year.
- All "natural, organic, environmentally friendly, safe, healthy" statements are not allowed.
- Only adults 16 years and above may be used on advertising.
- No pictures of people are allowed on the labels
- No domestic animals may be shown on the labels.
- Appropriate pictures of domestic animals are allowed on advertising.
- No faxes are accepted.
- Advertisements must be submitted early, not after the advertisement has been published.
- The regulations stipulate that advertisements must be submitted 2 months before publication or the date of broadcasting. Registration numbers, name of the registration holder and the active ingredients must appear in all advertising.
- Approval of advertising or promotional material is valid for 3 years, in line with the registration renewal cycle.

7. Renewal of registrations

This section applies where a product is reaching the end of the 3-year registration cycle and must be renewed.

The following are required:

- Proof of payment of the prescribed application fee.
- Renewal application forms.
- Signed declaration that accompanies the renewal application
- In the case of a Daughter registration being renewed, a newly signed legal agreement.

Note: Agricultural Remedy registrations should be renewed before 31st May. Renewal forms must reach this office within the prescribed period.

The renewal fees are accessible from the Registrar's website.

Late renewals may be done within 30 days of the renewal date, but an additional fine, accessible from the Registrar's website.

After this period of 30 days, application forms and labels must be submitted for re-registration together with the full application fee per product.

Renewal Application Forms

- Form A is the form completed for application of renewal of registered products. It must be completed in triplicate and a sworn declaration under oath must be made on the reverse side of all three copies.
- Form B is to be completed in triplicate when cancelling a registration. The original registration certificate of the product(s) to be cancelled must be returned to the Registrar's office. If the original certificate has been misplaced then an affidavit to that effect should be provided.
- Form C is of utmost importance to regularly update our record of the contact information, for example address, telephone number, contact person, etc.

The applicable forms are accessible from the Registrar's website.

8. Certificates of free sale

The request for a Certificate of Free Sale by the registration holder must be submitted in writing to the administration office of the Registrar. The company must supply the registered name and the registration number of the product(s). These particulars must correspond with those on the registration certificate that was issued when the product was registered.

The applicable fees are accessible from the Registrar's website
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9. Import permits

An import permit granting permission for the import of an unregistered product will only be issued for the following reasons:

- Where the product is to be imported for trial purposes. The trial protocol must be discussed with and approved by the Technical Adviser before the product is imported.
- Where an emergency exists and there is not a currently registered product available in the country. Import permits must be requested in writing. In this case, the request can be faxed to administration. Details on the reason for importing the product, quantities, name of the product and the active ingredient(s) as well as the port of entry must all be provided in the letter.

Import permit requirements

- Motivation letter explaining the purpose of the application.
- The description of the agricultural remedy. This should include the active ingredient content and type of formulation, the registration status of the agricultural remedy in South Africa, the quantity of the agricultural remedy to be imported and the intended use of it.
- Specify the quantity of pesticide imported.
- Specify the pesticide used (active ingredient).
- Indicate the port of entry and exit.
- Country of origin.
- Attach the material safety data sheet.
- If the consignment is to be exported, attach documentation e.g. registration status of the pesticide in the destination country.
- If the pesticide is imported for trial purposes, attach the trial protocol.
- In a case of where the consignment contains living microorganisms, a Permit from Directorate Plant Health, DAFF will be required

10. Conditions attached to different product formats

Certain conditions are applicable to different product formulations.

10.1. Aerosol agricultural remedies

The following definitions of aerosol types have been established:

1. Space spray: An aerosol containing active ingredient(s) without residual action; may be sprayed in the air; must produce a fine spray.

2. Surface spray: An aerosol containing active ingredient(s) with residual action of at least 1 week; may not be sprayed in the air; must produce a coarser spray that does not blow back in a mist, but falls to the ground (stipulations for firms not making use of the Malvern spray pattern); maximum residual action that can be claimed will be "up to four weeks" with appropriate efficacy data.

3. Dual purpose spray: Same as a space spray; can claim “kills flying and crawling insects on contact". The words "on contact” must be of same size lettering as rest of claim.

The toxicity category of an aerosol agricultural remedy must be either II (Yellow Band) or III (Blue Band). The appropriate category is defined by the toxicity of the most toxic active ingredient and not from toxicology studies or the WHO LD_{50} calculation.

10.2. Solid agricultural remedies

The toxicity category of a solid agricultural remedy can be Ia or Ib (Red Band), II (Yellow Band), III (Blue Band) or IV (Green Band). The appropriate category is defined by the acute LD_{50} derived formulation toxicology studies or the WHO LD_{50} calculation.

10.3. Liquid agricultural remedies

The toxicity category of a liquid agricultural remedy can only be Ia or Ib (Red Band), II (Yellow Band), III (Blue Band) or IV (Green Band). The appropriate category is defined by the toxicity of the most toxic active ingredient and not from toxicology studies or the WHO LD_{50} calculation. Formulation toxicity studies are required for new formations/products done under OCED GLP accredited laboratory.

11. ENQUIRIES

General enquires related registration processes, should be directed to Registrations Administrators. Please refer to www.daff.gov.za for the latest contact details.