agriculture,
forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

GUIDELINES ON THE DESIGN ON FLUE-CURED TOBBACO SMOKE TRIALS

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1. INTRODUCTION

Apart from the standard toxicology, effectiveness and residue data requirements to comply with registration of agricultural remedies and fertilizers under Act No 36 of 1947, the tobacco industry, together with the office of the Registrar of Act 36 of 1947 will be responsible for defining additional requirements related to the registration of chemical products for use in tobacco production. These guidelines should be read in conjunction with other guidelines published by the office of the Registrar and it precedes all other guidelines published before. These guidelines replace all other smoke tests guidelines published by the Registrar before and are effective for implementation from the 01st of April 2018.

2. PRODUCTS ON WHICH SMOKE TRIALS NEED TO BE CONDUCTED

2.1. All new active ingredients products which are applied to tobacco plants or to the soil in tobacco lands.

2.2. All generic products not yet approved on tobacco which are applied to tobacco plants or volatile or systemic products that are applied to the soil in tobacco lands This will also apply to all generic products already approved on tobacco where the PHI is 7 days or less.

2.3. Biological/biopesticides/biofertilizer products where the product is applied to the leaf in the field.

2.4. Plant nutrients and Adjuvants, if the ingredients in such product have Maximum Residue Limits set or are similar to products registered under the definition of an agricultural remedy.

3. PRODUCTS ON WHICH SMOKING TRIALS DO NOT NEED TO BE CONDUCTED. The discretion of the Registrar of Pesticides applies:

3.1. Products registered abroad for use on tobacco but already approved in South Africa on other crops provided the formulations are the same.

3.2. Generic chemical products
A generic of a known formulation, which is already registered with Act 36 of 1947 or if the formulation is already registered.

4. RESIDUE DATA

Residue data for all new formulation and new molecules must be available before any smoke trials are conducted.
For more information on residue data requirements, refer to the relevant guidelines published by the office of the Registrar.

5. PROCEDURE FOR THE REGISTERING OF PRODUCTS FOR USE ON TOBACCO

5.1. Tobacco Institute of Southern Africa (TISA) should be approached or contacted before any trials work is undertaken in South Africa.

5.2. TISA will present the request to the Research Committee at one of its two annual meetings in May or September/ October.

5.3. The TISA Research Committee will take a decision regarding the merits of the product

5.4. Should the product be acceptable to the tobacco industry, TISA will inform the Registrar accordingly. The Registrar will require that all the required tests are done as per the prescribed requirements.

5.6. The recommendation from the meeting will be sent through to the TISA office for booking of a smoke panel to conduct the sensory trials.

5.7. TISA will forward the request to an accredited research institution.

6. CONDUCTING OF TRIALS AND MANAGEMENT OF SMOKE SAMPLES

6.1. Trials will be planned in conjunction with accredited research institutions as agreed between the applicant and TISA.

6.2. The trials will be handled by an accredited research institution either on contract or in conjunction with a consultancy which officially requests smoke trials to be conducted.

6.3. A standard treatment or control (no treatment) will be tested against the recommended test treatment.

6.4. The smoking material can be obtained from efficacy or residue trials where the highest recommended label rate has been used.

6.5. Adequate material needs to be gathered to ensure a dried/ cured leaf sample of 2 kg.

6.6 .The dried sample needs to be compiled as follows:
20% - lugs
30% - cutters
50% - top leaves

6.7. The same grade tobacco leaf needs to be used for the compilation of the dry/ cured sample.

6.8. The dry/ cured sample needs to proceed through a standard factory re-drying process and should be packed at 12 to 13% moisture.

6.9. Samples need to be sealed in food grade quality packaging material such as “Glad Wrap”.

6.10. Samples need to be clearly and correctly coded and this data needs to be sent to the TISA office. A report on the residue status must accompany the samples.

6.11. The accredited institution will be responsible for the production of cigarettes. All cigarettes will be handmade and include filters.

6.12. The samples are smoked “blind” and the resulting data is provided to the TISA office which will manage the distribution of the information to the relevant parties.

REFERENCES AND LIST OF REGULATORY DOCUMENTS

Guidelines on Residue Study Requirements for Registration of Agricultural Remedies and Setting of Maximum Residue Limits (MRLs) in South Africa (Registrar, Act No. 36 of 1947).