agriculture,
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Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

Registration Guidelines for Minor uses (Minor crops) in South Africa

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1.0 INTRODUCTION

The lack of remedies to control pests on minor crops results in the creation of barriers with international trading partners. Illegal use of pesticides becomes common. Human and environmental health may be adversely affected due to the misuse of pesticides.

In order to approach the problem of minor crops in South Africa, creative solution will have to be established in order to help growers to engage in sustainable businesses. It should be noted that the requirements to register minor crops remedies should be slightly different from that used to register pesticides for major crops. Therefore data extrapolation will be used to circumvent the costs associated the generation efficacy data and by offering incentives in order to encourage applicants to include minor crops on their labels.

The purpose of these guidelines is to overcome registration hurdles encountered when applying for registration of minor crop products/pesticides. These guidelines are aimed at expediting minor use pesticide registrations in situations where there is no or limited pesticide registered for a specific indication in South Africa and they must be read in conjunction with all other registration guidelines published by the department in order to fully comply with registration requirements. These will ultimately afford growers more alternatives in their farming endeavors.

2.0 General Minor Use Definition

Minor use as defined in by CODEX alimentarius commission is the use of chemical pesticides or-non chemical means of crop protection where the potential use is on a scale not sufficiently large to justify registration of that use from applicant's perspective alone. The key driver for minor uses is a lack of economic return to an applicant from registering those uses, in particular the associated costs of generating the data required for obtaining and maintaining regulatory approval and potential liability from those uses once approved. Minor uses involve crops grown on a small scale (minor crops) and often are high value crops. Additionally minor uses can involve uses within major crops in terms of controlling minor pests and diseases. This results in a situation where specialty crop industries are either left without or are lacking sufficient access to pesticides to adequately protect their crops.

In South Africa, minor uses of agricultural remedies are defined as those desired uses of registered agricultural remedies for which the anticipated increase in the volume of sales is not sufficient to persuade the manufacturer or registration holder to carry out the research required for registration. This definition emphasizes that it is the projected increase in annual sales of the remedies that are minor, not necessarily the crop or pest.

In order to simplify the mater, a common sense approach was used in compiling a list of minor crops following a consultative process and such a list together with the extrapolation table can only be expanded or edited by the office of the Registrar after receiving convincing motivation regarding a particular crop to be listed as minor crop. The listed crops below will be used in conjunction with the extrapolation table below. It must be recognized that there will be situations where data extrapolation will not be possible using crop grouping, and therefore data regarding efficacy, phytotoxicity and residue should be generated for the specific crop.

3.0 LIST OF MINOR CROPS

1. Artichokes/Asparagus/Celery/Rhubarb
2. Apricots/Nectarines/Peaches
3. Aubegines
4. Barley/Oats
5. Beetroot
6. Broccoli
7. Broccoli seedlings
8. Brussels sprout
9. Blueberry/currents/Goosebery/Raspbery
10. Butternut/pumpkins/marrows/patty pans/squash
11. Canola
12. Carrots
13. Capsicum
14. Cauliflower
15. Celery
16. Chicory
17. Chillies
18. Cherries/Plums/Prunes
19. Chinese cabbage
20. Chive
21. Clover
22. Courgettes
23. Fennel
24. Figs
25. French endive

26. Fresh dates
27. Garlic
28. Ginger
29. Green beans
30. **Indigenous leafy vegetables** (e.g.Amaranthus spp, Solanum nigrum, Cucurbits, Vigna unguiculata, Cleome monophylla, Chorcorus trilocularis, Bidens pilosa, Citrullus lanatus etc)
31. Indigenous Fruits
32. Kiwi fruit
33. Kumquats
34. Leek
35. Limes/Lemons/Mandarins
36. Lettuce
37. Litchi
38. Lucerne
39. Lupins
40. Macadamia
41. Onions
42. Onion seedlings
43. Okra
44. Olives
45. Papaya
46. Parsley
47. Passion fruit
48. Patty pans
49. Peas
50. Pecan nuts
51. Pepinos
52. Peppers
53. Persimmons
54. Pistachio
55. Plums
56. Pomegranate
57. Prickly pears
58. Quinces
59. Radish/Horseradish
60. Raspberry/Blackberry
61. Rhubarb
62. Ryegrass
63. Spinach
64. Sorghum
65. Sweet corn
66. Sweet pepper seedlings
67. Sweet potato
68. Strawberry
69. Sugar beet

70. Tngerines
71. Turnips
72. Walnut
73. Water melons

4.0 REQUIREMENTS FOR REGISTRATION

- Registration application forms
- Registration fee
- Toxicological data
- Five batch analysis (Technical Material) done by GLP/ISO17025 accredited laboratory
- Efficacy/phytotoxicity data **(VISUAL ASSESSEMNTS)**
- Residue data

4.1 Toxicological data

In case where the product is not registered in South Africa, toxicological data will be required. If a product is already registered in the **EU; USA, JAPAN and AUSTRALIA** locally generated efficacy and phytotoxicity data will suffice in applying for temporary registration, however such registrations must be accompanied by a toxicology report from an independent toxicologist, temporary registration will be given pending the evaluation of the toxicology dossier by the Department of Health. However registration certificates and other documents must be submitted in order to support such applications.

4.2 Efficacy/Phytotoxicity

Locally generated efficacy and phytotoxicity data will suffice in applying for registration. The following must clearly be outlined on the label, crop, pests, rate of application, and number of application timings, pre harvest intervals, and growth stages of both the pest and the crop. Minor crop growers may also generate their own data in order to increase the number of pesticides available in dealing with problems that they may be experiencing. However, good agricultural practices and proper trial methodology have to be followed in order to generate high quality data. As a general rule a minimum of three trials will be required per crop.

4.3 Residue Trials

Local generated residue data have to be submitted depending on whether a product in question is a generic or new active ingredient. Residue trials guidelines must be followed when conducting residue trials.

4.4 REGISTRATION INCENTIVES

The Registrar will offer the applicant incentives as indicated below if the applicant had met or exceeded the requirements in terms of the number of minor crops listed on the label.

- Extending data protection to the original registrant if a minimum of five minor crops are included on the label (5 years).
- Extending data protection on mixtures and formulations, if the registration includes a minimum of five minor crops on the label (5 years).

5.0 DATA EXTRAPOLATION

The CODEX crops groupings will be used to extrapolate data (**efficacy data**) from one crop to another if the crops in question belong to the same group. It should be remembered that data extrapolation will only be used for those crops listed or identified as minor crops. However **residue data extrapolation** will not be considered when extrapolating efficacy data from one crop to another, and therefore residue will have to be generated from a specific crop. It should be noted that there will be situations were crop grouping will not allow data extrapolation as indicated on the Table below, and therefore efficacy data will have to be generated from those specific crops where extrapolation is not possible as indicated on the Table below.

6.0 EXTRAPOLATION TABLE (CODEX CROP GROUPING)

CROP GROUP	**CROP GROUP MEMBERS IN SA**	**DATA EXTRAPOLATION (Discussion is needed)**
1. **Citrus**	**Subgroup 1** Lemons Lime Mandarins **Subgroup2** Grapefruit Oranges Tangerines	Whole group
2.**Pome fruit**	Apple Pear Quince	Whole group
3. **Stone fruit**	**Subgroup 1** Apricot Nectarines Peach **Subgroup 2** Cherries Plums Prunes	Whole group
4.Berries and other small fruit	**Subgroup 1** Blackberry Raspberry **Subgroup 2** Blueberry Currents Gooseberry **Other group**	According to subgroups

	Grapes Strawberry	Not possible.
5&6.Tropical and subtropical fruit	Dates Figs Avocado Banana Guava Kiwifruit Litchi Mango Pawpaw Passion fruit Persimmons Pecan nuts Pineapple Other (indigenous fruit) Marula Prickle pear	Not possible, data need to be generated from each crop
9.Bulb Vegetables	**Subgroup 1** Garlic Onions **Subgroup 2** Chives Spring onions **Subgroup 3** Leeks **Subgroup 4** Fennel bulb	According to subgroups Subgroups 1,2 and 3 possible to extrapolate.
10.Brassica Vegetables	**Subgroup 1** Cauliflower Broccoli **Subgroup 2**	The whole group

	Cabbage **Subgroup 3** Brussels sprout	
11.Fruiting Vegetables Cucurbits	**Subgroup 1** Cucumber Patty pans **Subgroup 2** Melons Marrows Pumpkins Squash	Whole group Melons to be considered separately
12.Fruiting Vegetables	**Subgroup 1** Egg plant Tomato **Subgroup 2** Fungi Mushroom **Other:** Peppers Chilies Cape gooseberry Sweet corn Okra	Not possible for subgroups 1 & other.
13.Leafy Vegetables (including brassica leafy vegetables)	**Subgroup 1** Lettuce Mustard **Subgroup 2** Spinach **Subgroup 3**	According to subgroups and subgroup 4, individual vegetables should be considered on their own.

	Fennel **Subgroup 4** Chinese cabbage Other (Indigenous Vegetables) e.g. Amaranthus spp Bidens pilosa Chenopodium album Solanum nigrum, Vigna unguiculata, Cleome monophylla, Chorcorus trilocularies, Bidens pilosa, Citrullus lanatus etc)	
14.Legume Vegetables (succulent seeds and immature pods)	**Beans (green)** **Peas (green)**	
15.Pulses Dry:	Peas Beans Chickpea Lupin Soybean	Whole group except Lupin
16.Roots and Tuber Vegetables:	**Subgroup 1** Carrots Parsnips Asparagus **Subgroup 2** Beetroot Turnip **Subgroup 3** Potato Sweet potato **Subgroup 4** Radish Horseradish	According to subgroups

	Subgroup 5 Chicory	
17.Stalk and Stem Vegetables:	Artichoke Asparagus Celery Rhubarb	Whole group except Rhubarb
20.Cereal Grains:	**Subgroup 1.** Wheat Triticale **Subgroup 2** Barley Oats **Subgroup 3** Maize Sorghum Millet	Combine subgroup 1 and 2
21. Grasses for sugarcane and syrup production:	Sugarcane	
22. Tree and Nuts	Almonds Cashew Chestnuts Hazelnuts Macadamia Pecan Pistachio Walnuts	Whole group
23.Oiseeds:	**Subgroup 1** Mustard seed **Subgroup 2** Sunflower seed **Subgroup 3** Peanut **Subgroup 4** Soybean **Subgroup 5**	According to subgroups

	Olives	
24.LEAF/Seed for Beverage:	**Coffee** **TEA** **ROOIBOSS**	Not possible to extrapolate.
27. Herbs	Many	
28 .Spices	Many	

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