

**OPPORTUNITIES TO REGISTER BIOLOGICAL
PRODUCTS IN SOUTH AFRICA
ABIM MEETING BASEL SWITZERLAND
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SOUTH AFRICA NINE PROVINCES



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STATISTICAL INFORMATION

Population	56 mil
Unemployment	30%
GDP	300 Bill USD
Inflation	5-7%



WEATHER

- **Winter Rainfall climate** (Mediterranean climate – Deciduous fruit, grapes, vegetables and cereals crops)
- **Summer rainfall climate** (subtropical, agronomic crops, cereals and vegetables etc)



MAJOR CROPS PER PRODUCTION AREA

CROP	PRODUCTION AREA (HA)
Maize	2.0 mil
Forestry	1.2 mil
Cereals	Wheat (482 150) + Barley (93 730) = 575 880
Sugarcane	381 707
Grape	Table (18 212) + Wine (93 909) = 112 121
Citrus	68 272
Deciduous fruit	53 064
Potatoes	51 435
Subtropical fruit	41 944

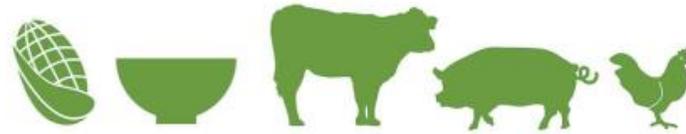


MAIZE PRODUCTION



MAIZE

HARVESTING & PLANTING

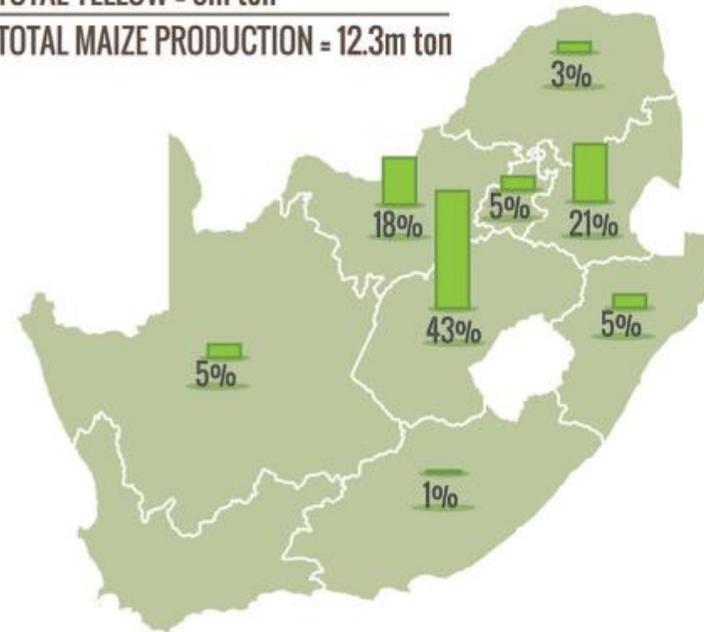


Maize meal • Animal feed

TOTAL WHITE - 7,3m ton

TOTAL YELLOW - 5m ton

TOTAL MAIZE PRODUCTION - 12.3m ton



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WHEAT PRODUCTION



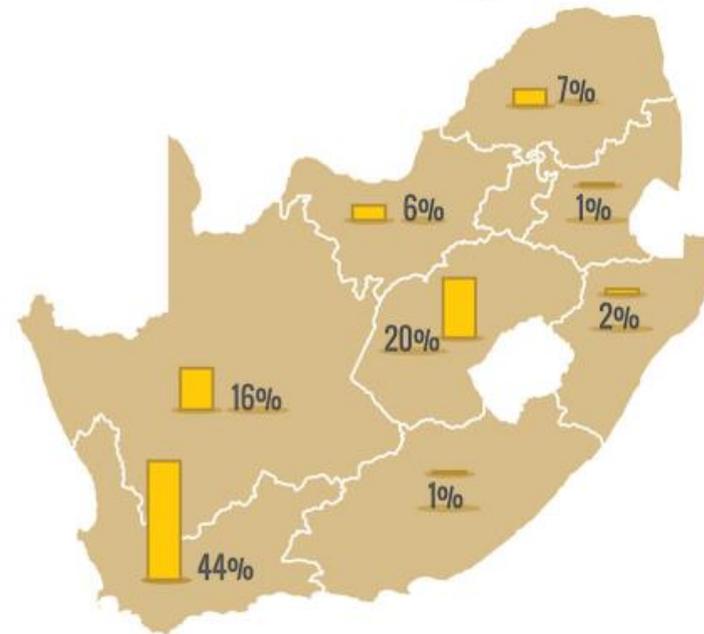
WHEAT

HARVESTING & PLANTING



Bread • Flour • Animal feed

TOTAL PRODUCTION = 1,7M TON

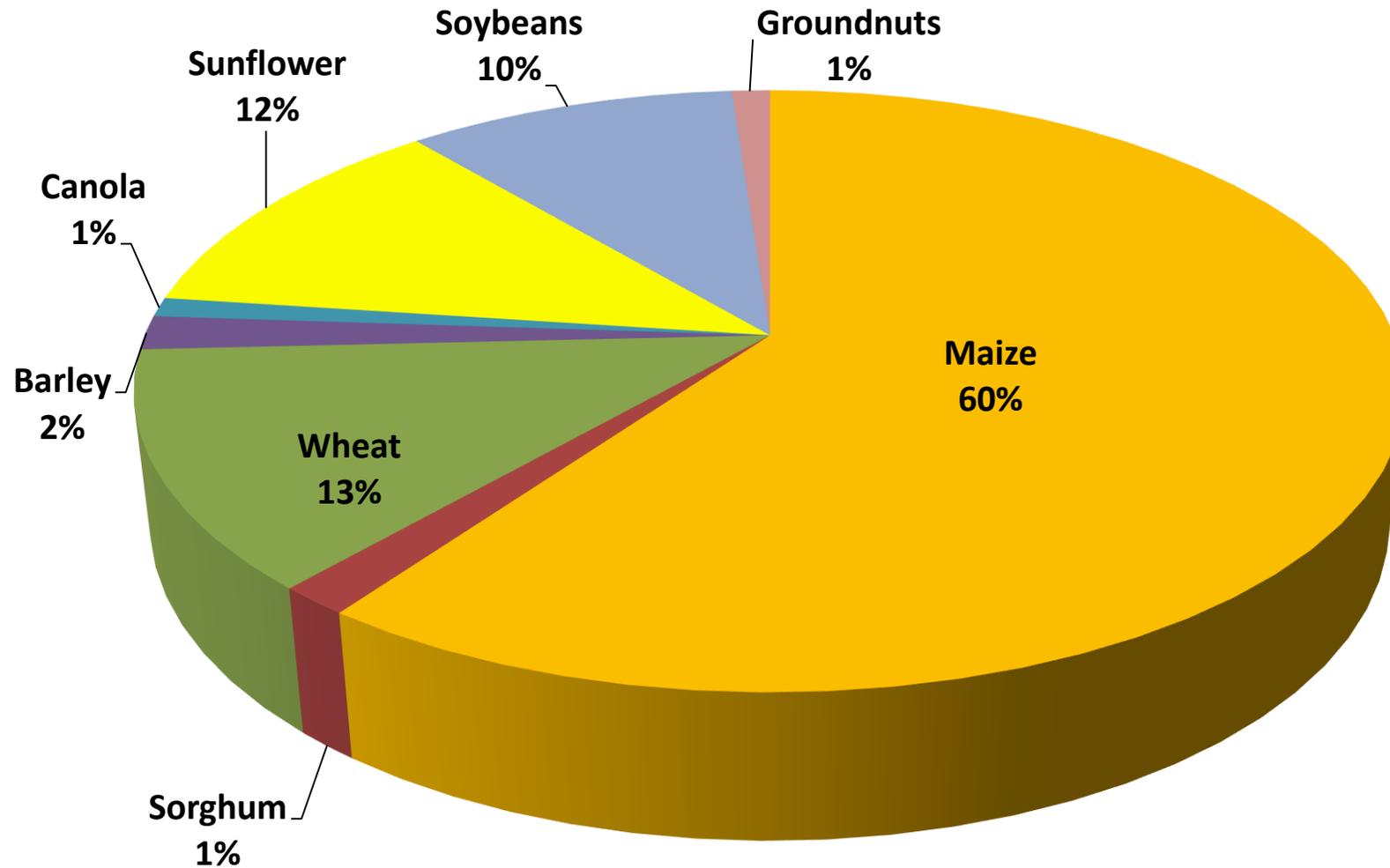


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Grains Hectares % Production



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FORESTRY PRODUCTION AREAS

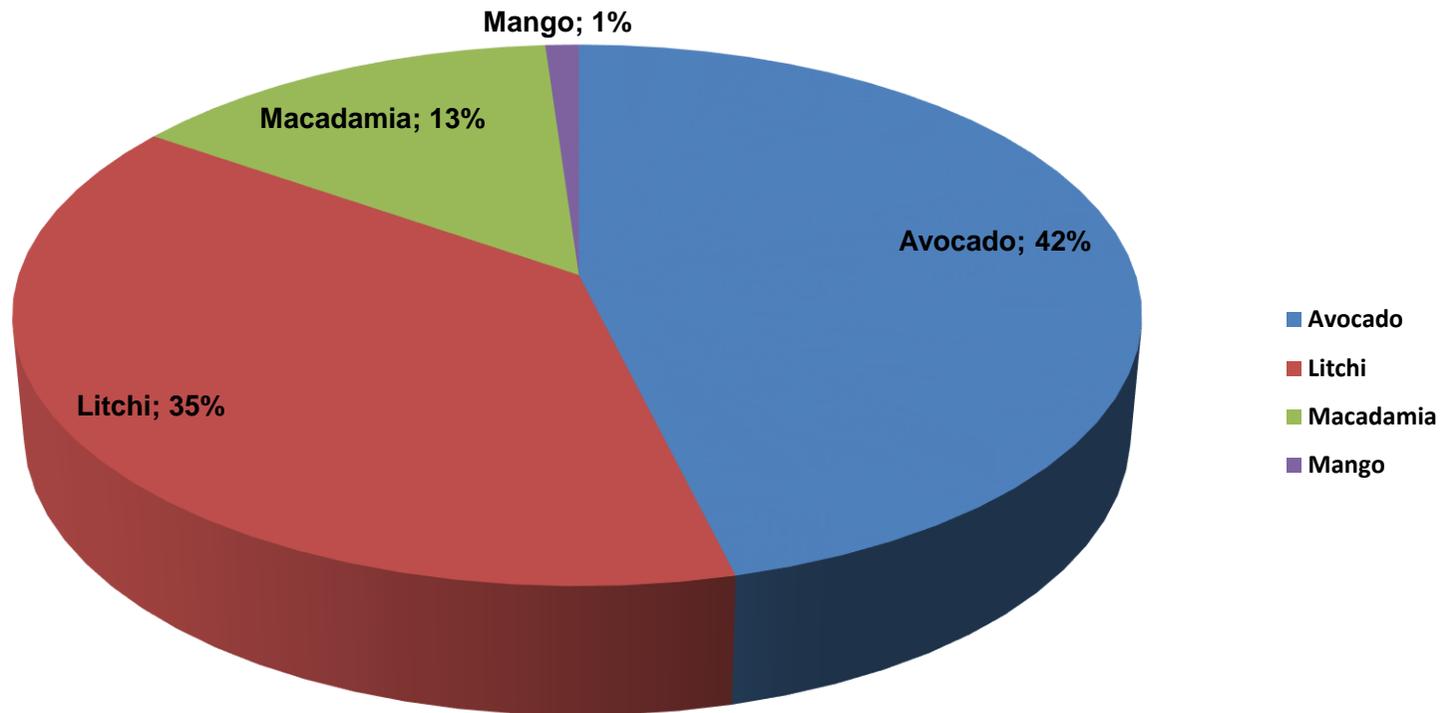


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Subtropicals % Production

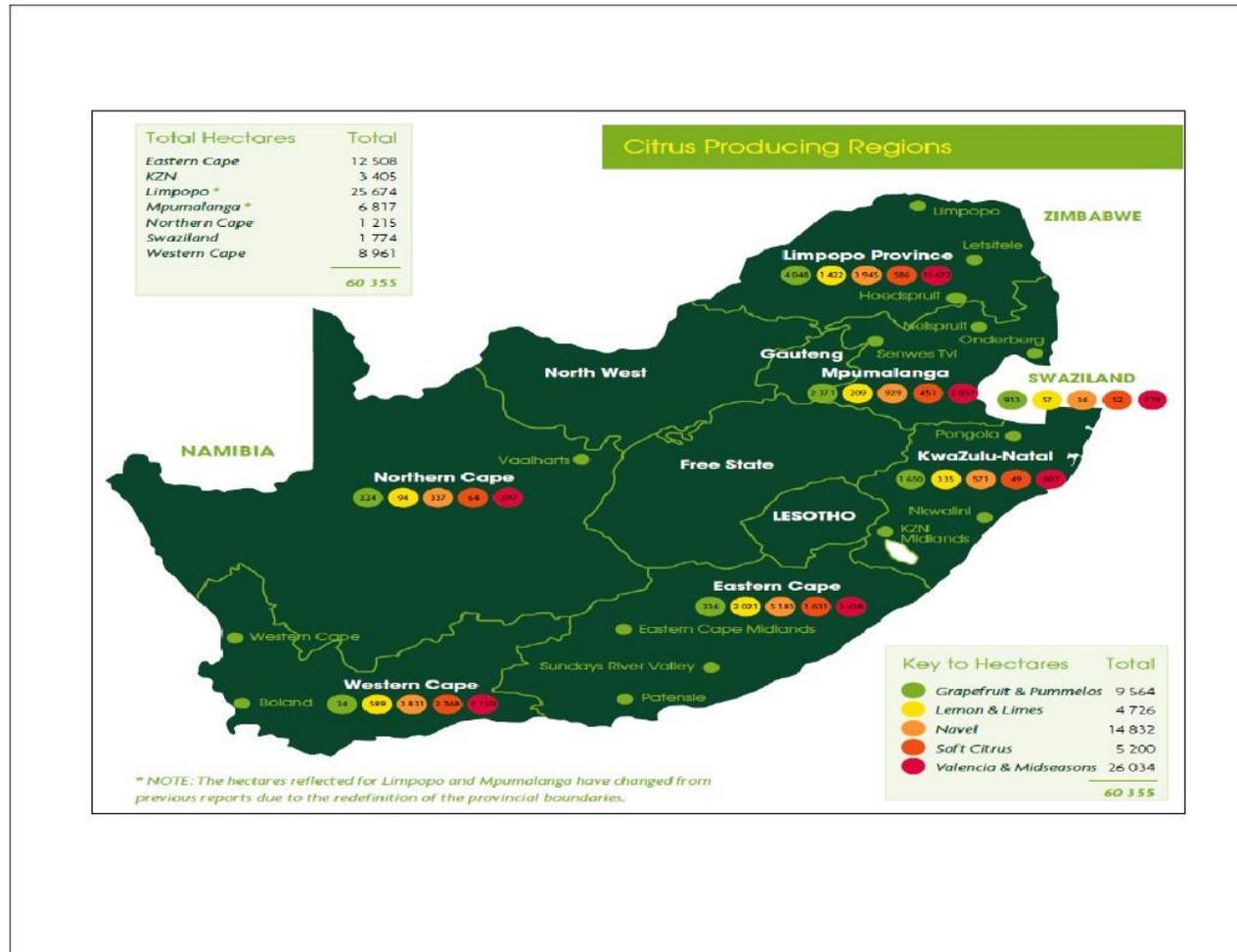


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CITRUS GROWING REGIONS

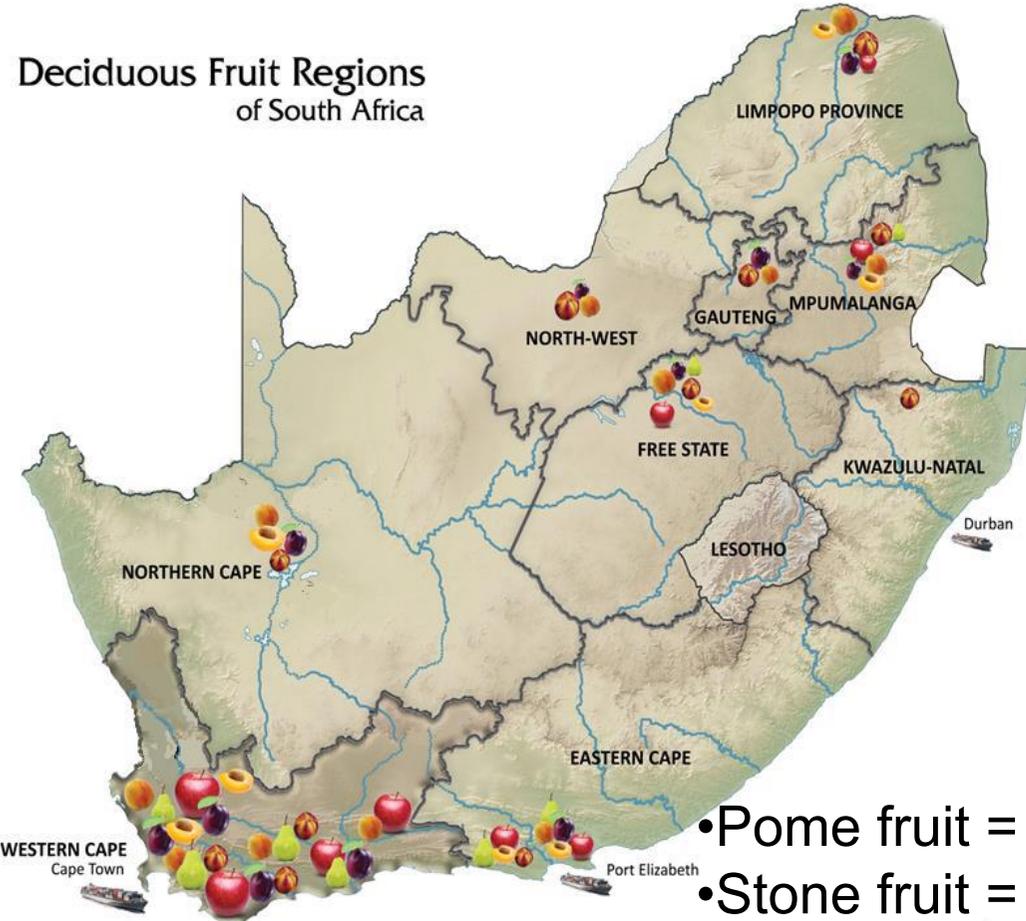


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DECIDUOUS FRUIT GROWING REGIONS



- Pome fruit = 35 136 hectares (66%)
- Stone fruit = 17 928 hectares (34%)



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POTATO GROWING REGIONS

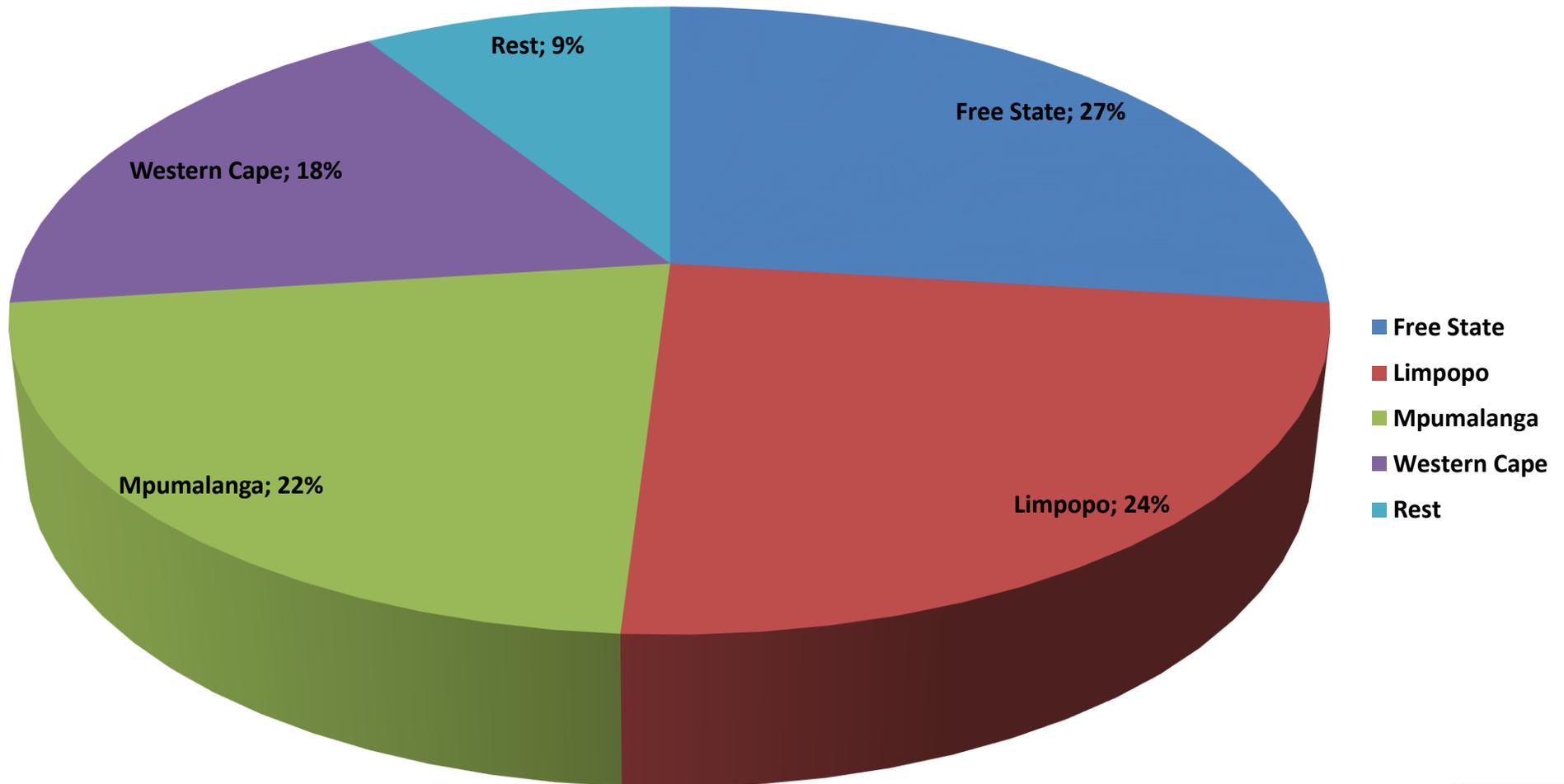
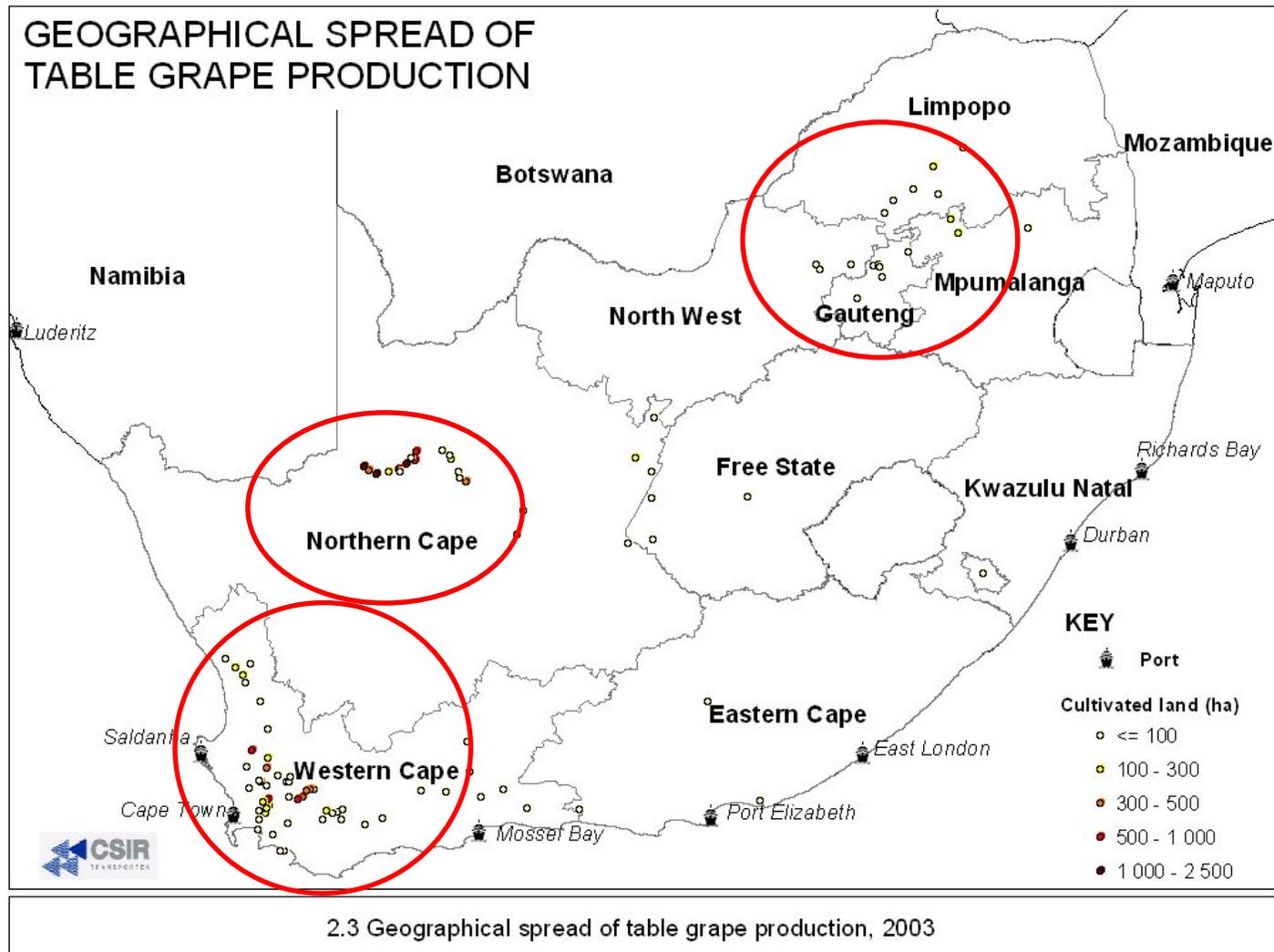


TABLE & WINE GRAPES GROWING REGIONS



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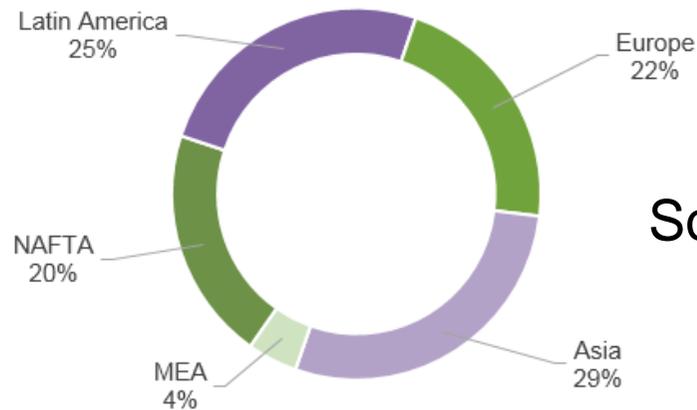
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AGROCHEMICAL GLOBAL MARKET

Agrochemical World Market 2015* by Region** and Indication

South Africa
450-500 m U\$D
Estimated.



Source: Phillips McDougall
CropLife

In \$ m	Crop	Non Crop	Agchem Market	vs. PY in %*
Asia	14040	2326	16366	-4,3
Latin America	14052	430	14482	-13,1
Europe	11604	866	12470	-16,2
NAFTA	9356	2345	11701	-2,9
MEA	2158	354	2512	-0,4

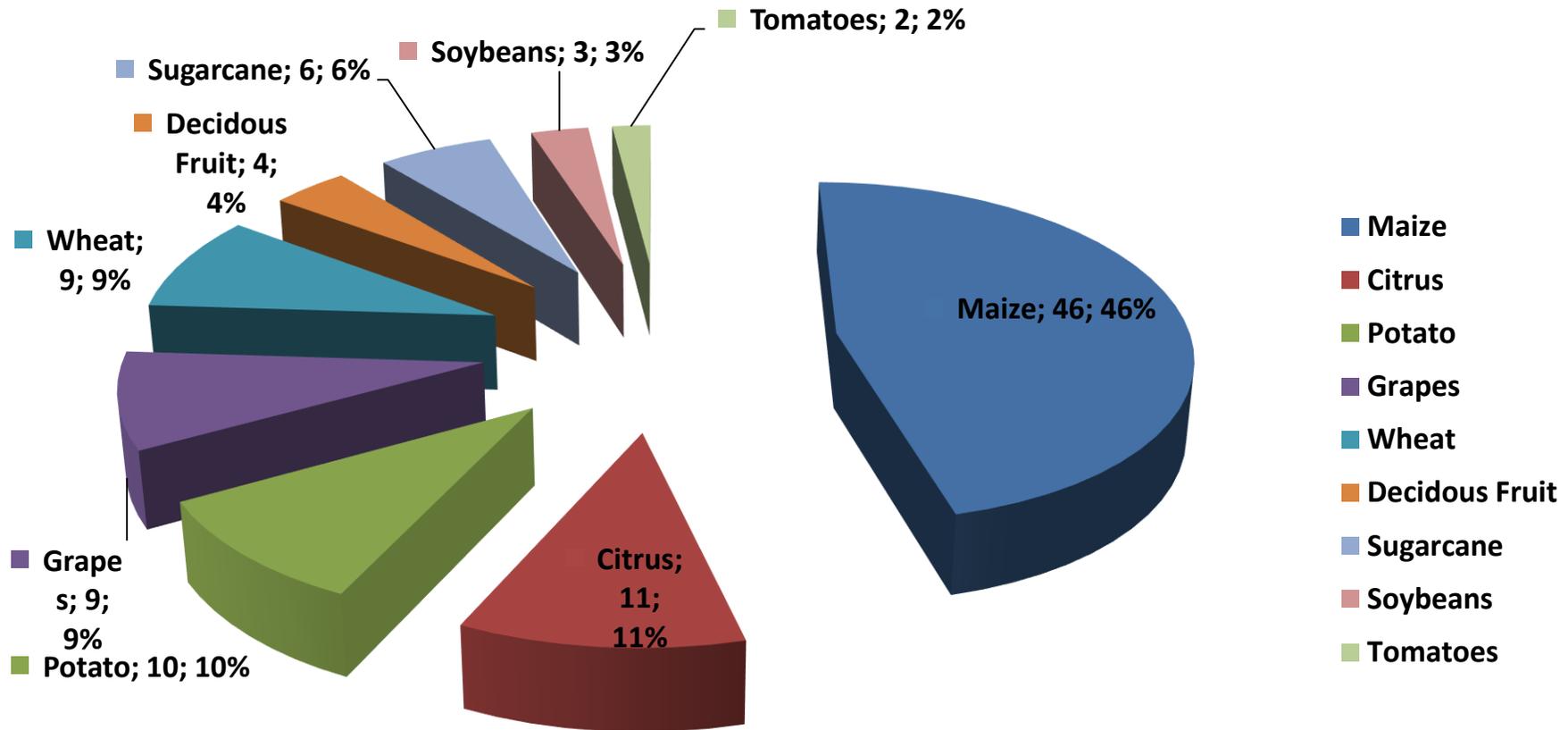


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Top Ten Crops Estimated % Contribution Market Share MARKET SIZE (450-500 M USD)



Vegetables & minor crops?



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Agricultural Remedies? (Fertilizers, Farm Feed, Agricultural Remedies and Stock Remedies Act No. 36 of 1947)

An agricultural remedy: is defined as any chemical substance or biological remedy, or any mixture or combination of any substance or remedy intended or offered to be used for the destruction, control, repelling, attraction or prevention of any undesired microbe, alga, nematode, fungus, insect, plant, vertebrate, invertebrate, or any product thereof.



Scope of Products Regulated Under Act 36 of 1947

- **Agricultural Remedies/Pesticides/biopesticides/legume inoculants/plant growth regulators**
- **Fertilizers/bio-fertilizers/non-legume inoculants**
- **Biostimulants (Depends on the label claims – agricultural remedies/fertilizers)**
- **Farm/animal feeds (e.g. insects used as animal feeds)**
- **Stock Remedies**
- **Pest Control Operators**



OTHER LEGISLATIONS IMPACTING ON IMPORTATION OR REGISTRATION OF BIOLOGICAL ORGANISMS

- **Non Proliferation of Weapons of Mass Destruction Act, 1993 (Biological weapons).**
- **National Environmental Management: Biodiversity Act, 2004 (Alien and invasive species).**
- **Agricultural Pest Act, 1983).**
- **Genetically Modified Organisms Act, 1997.**
- **Animal Disease Act, 1984.**
- **National Health Act, 2003.**
- **Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, Act 36 of 1947.**
- **Medicine and Related Substances Control Act, 1965**
- **Food stuff, cosmetics and disinfectant Act, 1972**



SECTORS USING BIOLOGICAL PRODUCTS

- **Agriculture (bio-fungicides, bio-insecticides, growth regulators etc)**
- **Public health (Bt for vector control)**
- **Forestry (similar to agricultural uses)**
- **Environmental remediation (e.g. odor suppression – does not fall under the scope of Act 36)**



DATA REQUIREMENTS IN GENERAL

- **Locally generated biological (efficacy/phytotoxicity & residues) data**
 - » **Minimum of three trials per crop done in three bioclimatic zones or over two seasons**
 - » **For residues: a minimum of 5 trials done in at least three climatic zones**
- **Toxicology data (OECD GLP accredited lab studies)**
 - » **Department of Health Guidance document is available on request**
 - **Botanical pesticides**
 - **Microbiological pest control agents**
 - **Biochemical pest control agents**
 - » **Scientific publication submitted as supporting data**



REPORTING TOXICOLOGICAL DATA

- **Each report should include a Good Laboratory Practice certificate (OECD)**
- **Summary of test results**
- **Full description of tests results, test procedures and analytical methods**
- **Test method description should be supplied (OECD, US EPA, CIPAC/AOAC etc)**
 - » **Supporting literature studies**
 - **A copy of the journal article/publication**
 - **Motivation for including such information**



BOTANICALS GENERAL DATA REQUIREMENTS

- **Botanical classification of the plant**
- **National occurrence and distribution in South Africa**
- **If synthesized, specify the relationship to the natural form occurring in the plant**
- **Mode of action**
- **Storage stability and method of preparation**
- **Manufacturing process**
- **Reference profile for determination of equivalence**
- **Standardization, the ai must fall within a fixed level of concentration**



MACRO ORGANISMS GENERAL DATA REQUIREMENTS

- **Phytosanitary import permit (Pest Risk Assessment - Agricultural Pest Act, 1983) & National Environmental Management: Biodiversity Act, 2004 (Alien and invasive species).**
 - **The history of the organism and its uses in South Africa (if applicable)**
 - **The biology of the agent (life cycle and growth characteristics of the organism)**
 - **Site of infection/mode of action and of entry into host**
 - **The label must include the state and stage of the organism**
 - **Any known metabolites i.e. primary/secondary must be reported.**



MICRO ORGANISMS GENERAL DATA REQUIREMENTS

- **Shelf life and the active ingredient should be viable at acceptable number for at least six months**
- **If an applicant changes the strain of micro-organism for a registered product, new efficacy data, toxicology must be supplied**
- **Any known metabolites i.e. primary/secondary must be reported**
- **Toxicology studies should be submitted**



SYNTHETIC & SEMI SYNTHETICS TOXICOLOGICAL GENERAL DATA REQUIREMENTS

- **Active ingredient(s) and active constituents**
- **Formulation composition/declaration**
- **Kinetics and metabolism studies**
- **Level one: Toxicological data of active ingredient**
- **Formulation toxicology data**
- **Level 2: Supplemental toxicological studies (chronic studies with the active ingredient)**



IDENTIFICATION OF BIOLOGICALS CONTROL AGENTS

- **Bacteria = (Cultural, microscopic and molecular sequencing technique)**
- **Fungi = (Morphological, Molecular Techniques (ITS gene region) and DNA bar-coding)**
- **Insects = (Morphological and DNA bar-coding)**
- **Nematodes = (Morphological and DNA bar-coding)**
- **Viruses = (Cultural, microscopic and molecular sequencing technique)**
- **Plants extracts/Hormones = (Chemical analysis = 5 batch or Certificates of Analysis - COAs)**



PUSH AND PULL FACTORS STIMULATING BIOLOGICAL MARKET GROWTH

- **UN conventions/protocols.**
 - **Basel convention**
 - **Montreal protocol**
 - **Rotterdam convention**
 - **Stockholm convention**
- **New pests/invasive pests (e.g. *Tuta absoluta*).**
- **Emerging science (e.g. Endocrine disrupters)**
- **Pest resistance to pesticides and chemical residues**
- **Minor crops**

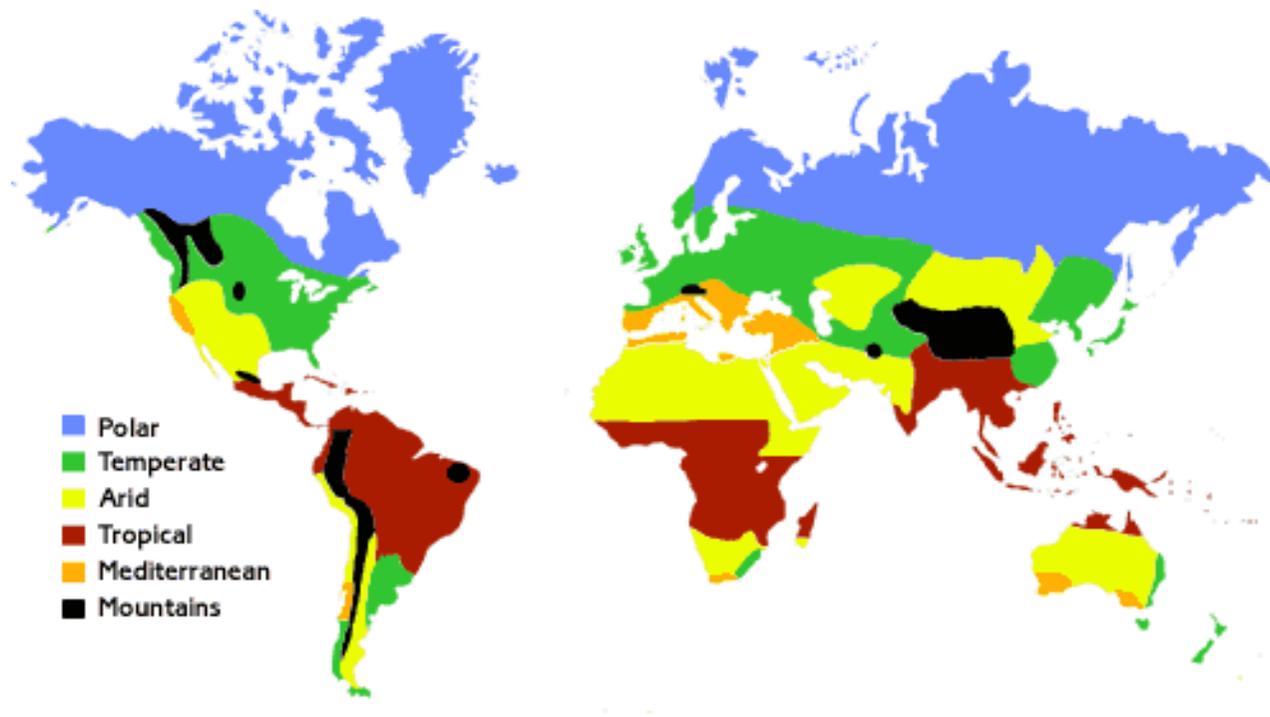


REGISTRATION INCENTIVES DESIGNED FOR MINOR CROPS AND MINOR USE SITUATIONS

- **Efficacy data extrapolation using CODEX crop groups**
- **Pest data extrapolation using a pest e.g. bollworm occurring in different crop groups**
- **OECD Mutual Acceptance of Data Principle (Toxicology/lab studies), GLP laboratory accreditation**
- **Acceptance of international data regarding residue and efficacy (Global climatic zones)**
- **Fast tracking of registration applications where minor crops are listed on the label.**



USE OF GLOBAL CLIMATIC ZONES AS AN INCENTIVE IN A REGULATORY ENVIRONMENT



CROP GROUPS LABELLING APPROACH

Berries (Blueberry group)	Blackberry or Raspberry; Blueberry or Currants, etc	Whole group
Stone fruit (Peaches)	Apricots, Nectarines, Plums, Peaches and Cherries	Whole group



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TIMEFRAMES FOR VARIOUS MAJOR APPLICATIONS

CATEGORY	Total No. of Days
New product	627
Generic products	418
New formulations	418
Label amendments	418



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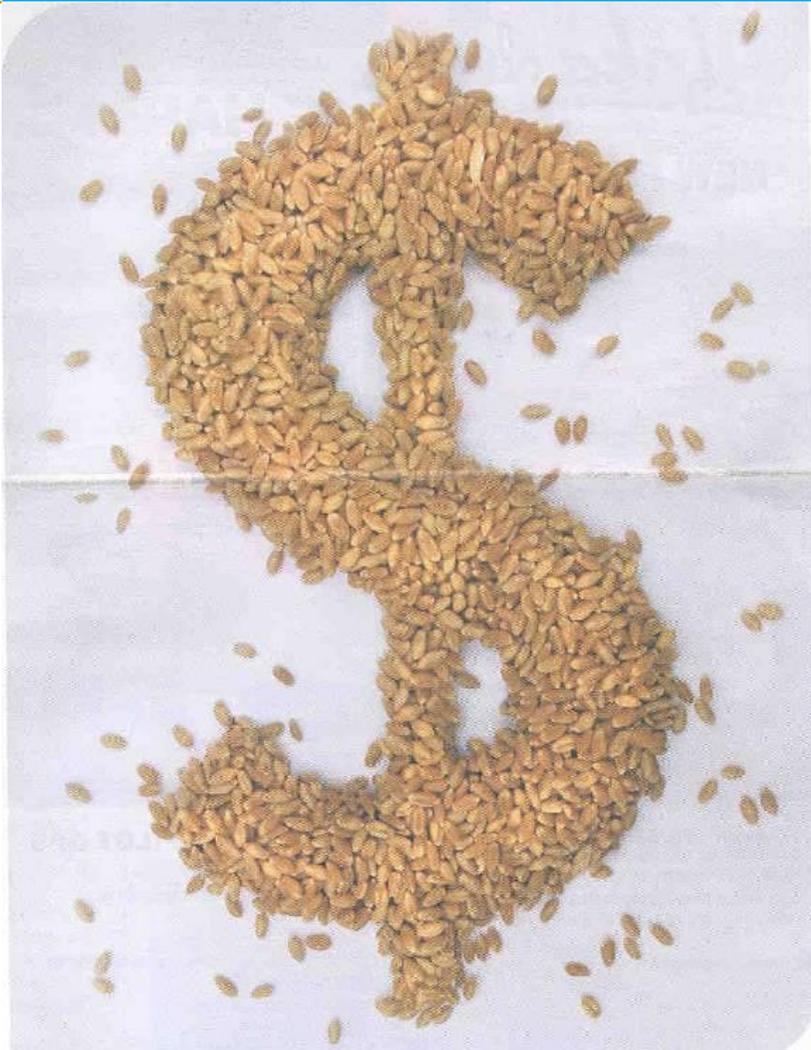


DATA VALIDITY

- **OECD test guidelines**
- **SA guidelines** (<http://www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Agriculture-Inputs-Control>)
- **Scientific publications**
- **Data sourced from the internet?**
- **Legal agreement and authorization to access the data**
- **Laboratory accreditation certificates are required (safety studies)**



ACKNOWLEDGEMENTS



FORESTRY SOUTH AFRICA
Growing Together / Sikhulisa Ndawonye



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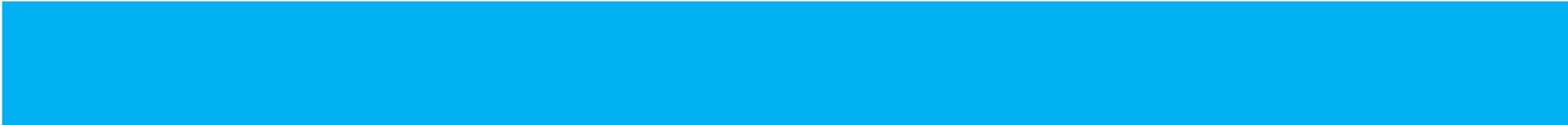
BUSINESS & LEISURE!



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THANK YOU



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