

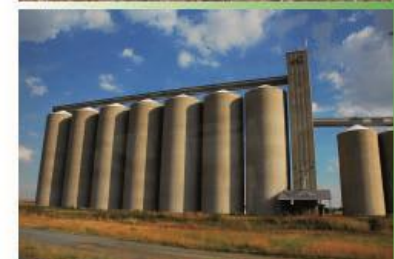
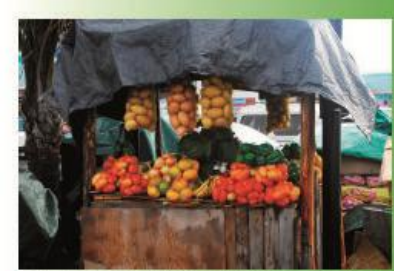
REGISTRATION OF AGRICULTURAL REMEDIES

NP MKULA
DAFF
AGRICULTURAL INPUTS CONTROL
ACT NO. 36 OF 1947



agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA



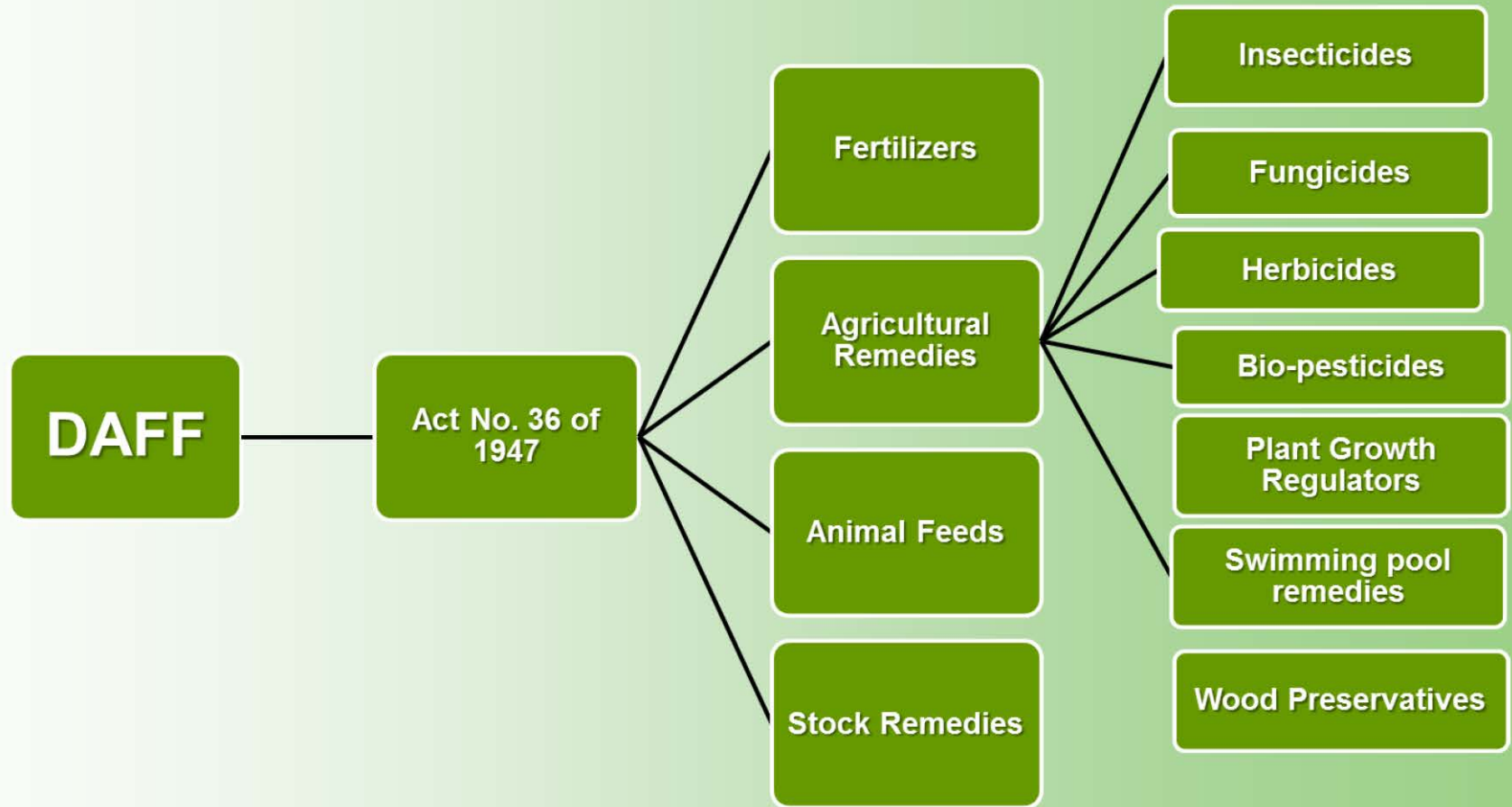
Definition Of An Agricultural Remedy

- Any chemical substance or biological remedy, or any mixture or combinations of any substance intended to be used for:
 - The destruction, control, repelling, attraction or prevention of any undesired microbe, algae, nematodes, fungus, insect, plant, vertebrate, invertebrate, or any product thereof, but excluding any chemical substances, biological remedy or other remedy in so far as it is controlled under the Medicine and Related Substances Control Act or Hazardous Substances Act;
 - As plant growth regulator, defoliant, desiccant or legume inoculant,
 - And anything else which the Minister has by notice in the Gazette declared an agricultural remedy for the purposes of this Act.

DAFF ROLE IN PESTICIDE REGULATION

- The DAFF has the responsibility to ensure that pesticides registered in South Africa are:
 - Safe to the host, user, consumer and the environment
 - Efficacious
 - Properly labelled
 - Do not negatively affect trade

Registration Categories



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WHY DO WE REGISTER AGRICULTURAL REMEDIES/PESTICIDES

- Section 3: 2 (a) of Act 36 of 1947,
- Agricultural remedy in respect of which registration is applied for should be suitable and sufficiently effective for the purposes of which it is applied for.
- Complies with prescribed requirements.
- It should not be contrary to the public interest.
- The establishment where it is manufactured must be suitable.

HOW TO COMPLY WITH SECTION 3 OF THE LAW

➤ MAJOR DATA SETS

- Chemistry data
- Biological data (efficacy/residues)
- Tox data requirements for new ai/new formulations (**OECD guidelines must be followed**)

Development of labels and safety data sheet (MSDS)

LABELLING OF CHEMICALS (RISK MANAGEMENT)

➤ Labels

- Registration number L No
- Active ingredient(s) contents
- Manufacturer details
- Precautions/Warning statements
- Directions for use etc

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PESTICIDE PICTOGRAMS AND COLOR BANDS – RISK COMMUNICATION



**XXXXXXXXXXXXXXXXX¹ 350 WP
LABEL**

Reg No LXXXX Wet/Act 36/1947

A wettable powder contact and stomach insecticide for the control of certain species of insects and mites (as listed) on citrus, deciduous fruit, cotton, potatoes and olives.

'n Benatbare poeier kontak- en maaginsekddoder vir die beheer van sekere insek- en mytpiae (soos aangedui) op sitrus, sagtevrugte, katoen, aartappels en olywe.

AKTIEWE BESTANDEEL / ACTIVE INGREDIENT

XXXX.....350 g/kg.....XXXXXXXXX
(organophosphate) (organofosfaat)
Net Mass kg.....Netto Massa

REGISTRATION HOLDER / REGISTRASIEHOUER

XXXXXXXXXXXXXXXXXXXXXXXXXXXX
REG NO XXXXXXXXXXXX
PRIVATE BAG X
South Africa

Batch Number Lotnommer
Date of Manufacture Vervaardigingsdatum

UN NUMBER: XXX
24 Hour Emergency Tel No: XXX XXXX
Information Hotline Tel No: XXXX XXXXX

VERY TOXIC
UITERS GIFTIG

MATERIAL SAFETY DATA SHEET (RISK MANAGEMENT)

Manufacture contact information	Physical and chemical properties
Composition information on active ingredients	Stability and reaction
Hazard identification	Toxicological information
First aid measures	Ecological information
Fire fighting measures	Disposal
Accidental release	Transport information
Handling and storage	Regulatory information
Exposure control/personal protection	Other information

EXPOSURE ROUTES TO PESTICIDES

- **Oral (food or water) = Food safety**
- **Inhalation = User**
- **Dermal = User**
- **Other (eye or injection) = User**

– **Environmental impact**

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WHO CLASSIFICATION SYSTEM (RISK MANAGEMENT)

➤ WHO TOXICITY CLASS (LD50 for rats (mg/kg b.w))

Class	Oral Solid	Oral Liquid	Dermal Solids	Dermal Liquid
Ia	≤ 5	≤ 20	≤ 10	≤ 40
Ib	5 - 50	20 - 200	10 - 100	40 - 400
II	50 - 500	200 - 2000	100 - 1000	400 - 4000
III	≥ 501	≥ 2001	≥ 1001	≥ 4001
IV	≥ 2000	≥ 3000	-	-

TOXICITY EFFECTS

- **Cancer**
- **Reproductive toxicity (fertility and development)**
- **Central nervous system damage**
- **Chronic respiratory disease**
- **Asthma**
- **Allergy etc**

TOXICITY OCCURRENCE AND REACTION PATHWAY

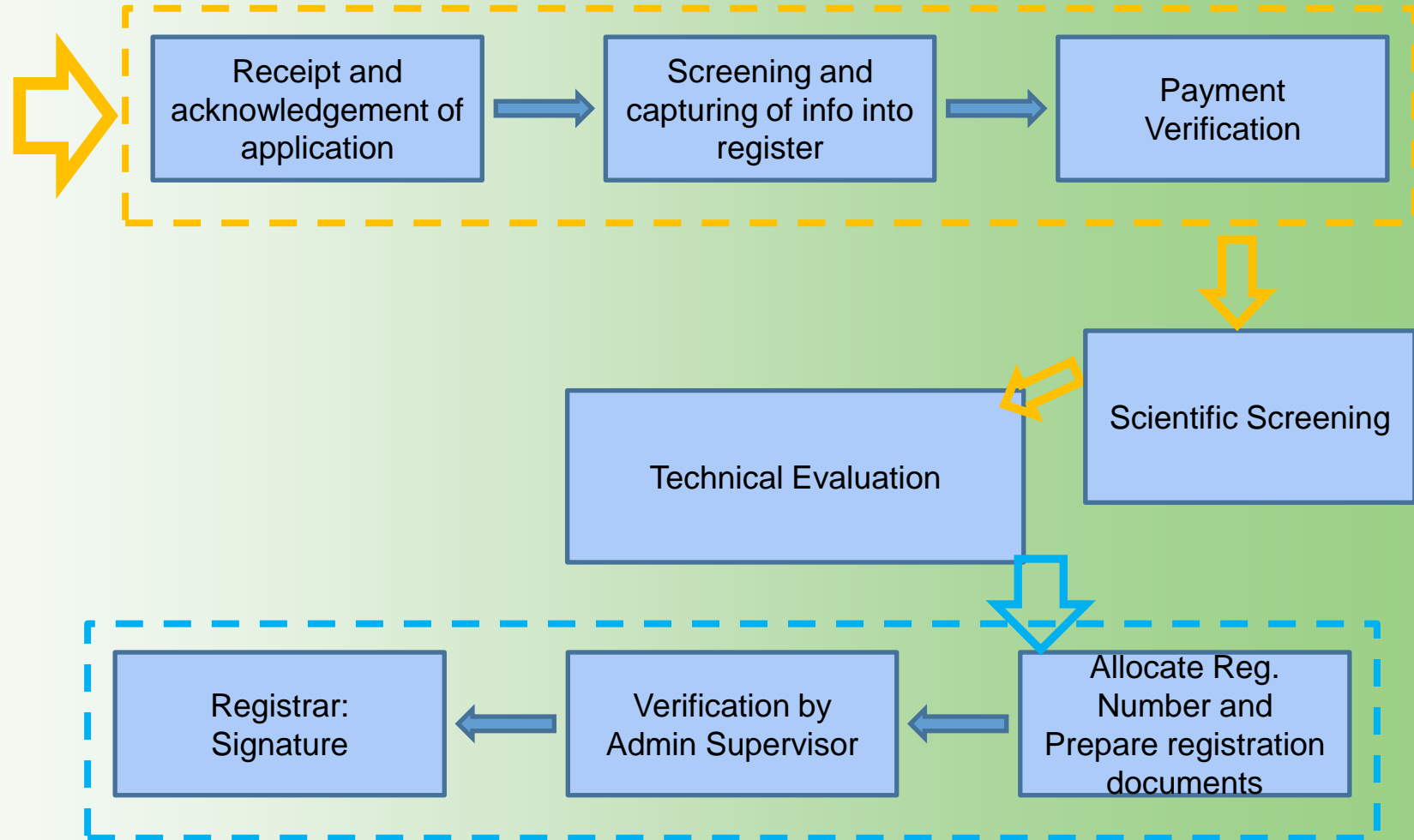
- **Exposure**
- **Clinical symptoms**
- **Medical treatment**
- **Recovery**
- **Death**

Maximum Residue Limit (MRL) Setting Process

- DAFF proposes the MRL to DoH based on residue data submitted by the applicant.
- DoH uses toxicological evaluation values (ADI and ARfD).
- Estimation of consumer intake.
- MRL is then set when ADI/ARfD is not exceeded.
- **The MRL proposed/published should not pose any risk to the consumers.**

Process flow of new applications

Applicant



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Thank You