



# **IR-4 Project & Registration Process: Residues and Good Laboratory Practices**



# THANK YOU!

- Global Minor Use Summit-  
Lucy
- Peter and Ranajit-Aflatoxin
- USDA/FAS- Jason
- Participants!



## IR-4 Mission:

*To provide pest management solutions to growers of fruits, vegetables, and other specialty crops for the benefit of consumers, growers and food processors.*





## Specialty Crops



**Vegetables**

**Fruits**

**Nuts**

**Herbs & Spices**

**Floral**

**Nursery**

**Landscape**

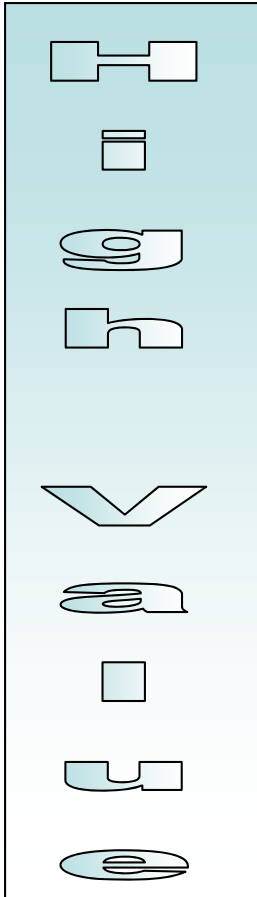
**Turf**

**Christmas trees**





## Specialty Crops



- high value & low acreages
- 40% of U.S. agricultural production  
**= \$45 billion in sales**
- 23 states derive more than 50% of agricultural crop sales from specialty crops

Low Acreage



## IR-4 Funding Sources



Major Funding for IR-4 is Provided By:

- Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the



- State Agricultural Experiment Stations



- USDA-ARS  Agricultural Research Service

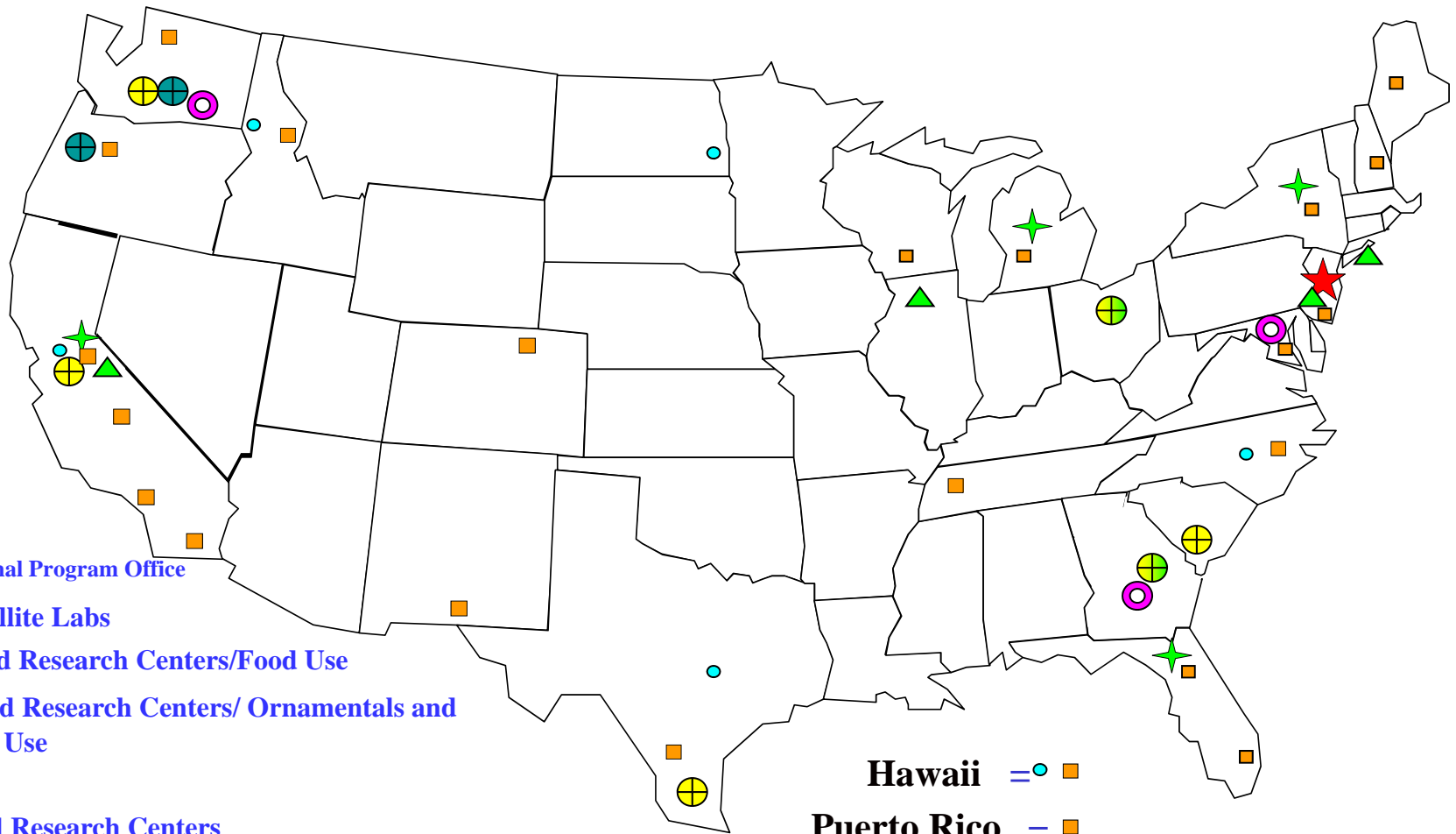
### Additional Support Provided By:

- Commodity & Industry Partners for Special Research Projects





# IR-4 Offices & Research Sites

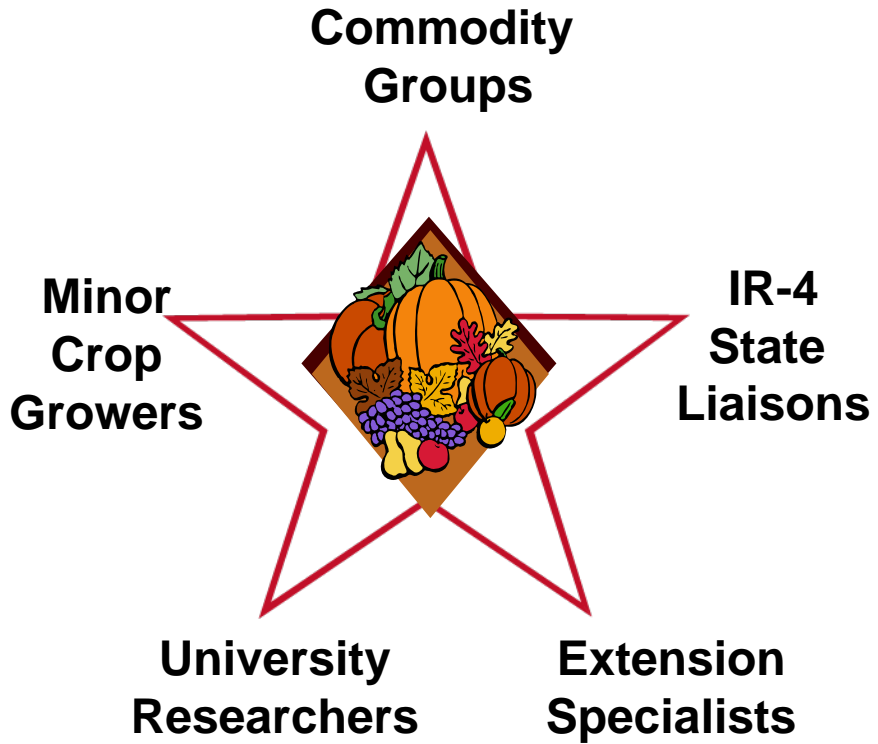


- ★ IR-4 HQ
- ★ IR-4 Regional Program Office
- State Satellite Labs
- State Field Research Centers/Food Use
- ▲ State Field Research Centers/ Ornamentals and Non-food Use
- ARS Labs
- ⊕ ARS Field Research Centers
- ⊕ ARS Field Research Centers

**Hawaii** = ● ■  
**Puerto Rico** = ■



# Project Initiation



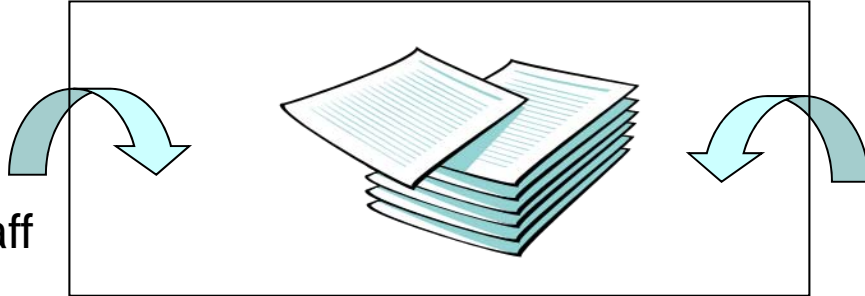
**Project Clearance Request (PCR)**



# Research Planning

Annual Food Use Workshop  
prioritizing active projects

- Growers
- Commodity groups
- University Staff



- EPA
- Crop Protection Industry
- University Staff
- USDA-ARS and CSREES

Regional Field Coordinators/  
Headquarters Coordination



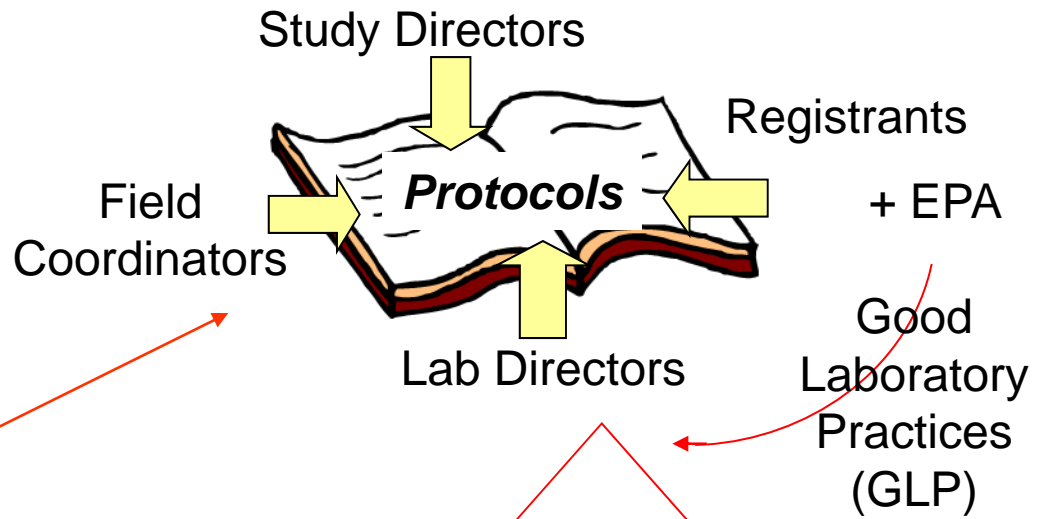
National Research Planning



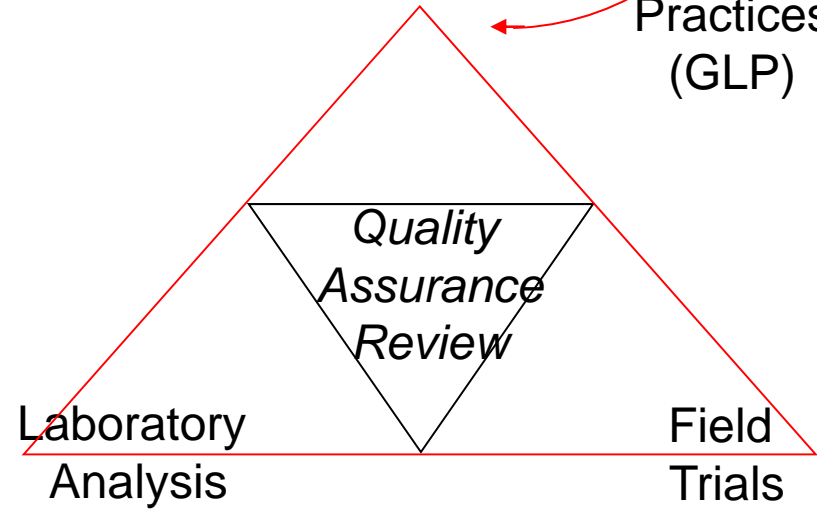
Research projects designated for the coming year



# Data Development

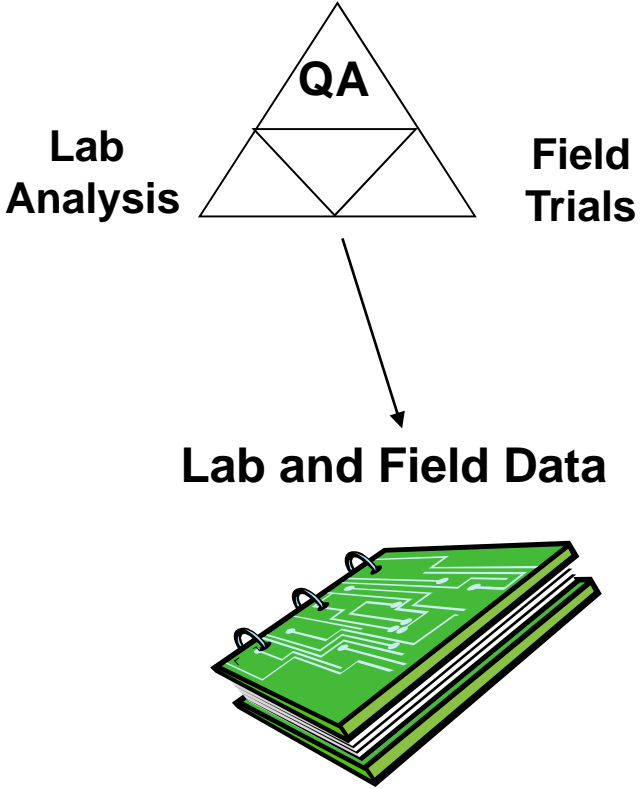


Laboratory and Field Protocols are developed





# Petition Preparation



- Study Directors Review
- QA Review
- Registrant Review

Study Directors Prepare Petition to Submit to EPA





# 30 Month Timeline



Project Initiation

0-month



Analytic Phase

10<sup>th</sup> month



Submission to EPA

30<sup>th</sup> month



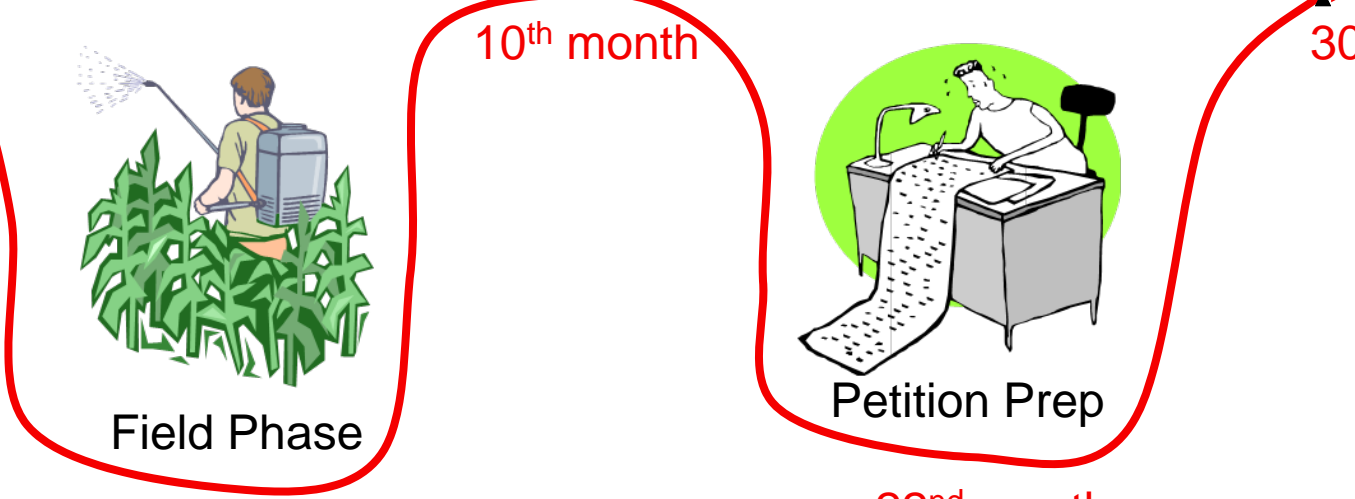
Field Phase

2<sup>nd</sup> month



Petition Prep

22<sup>nd</sup> month





## Product registration



The petition is sent to EPA

where it is reviewed



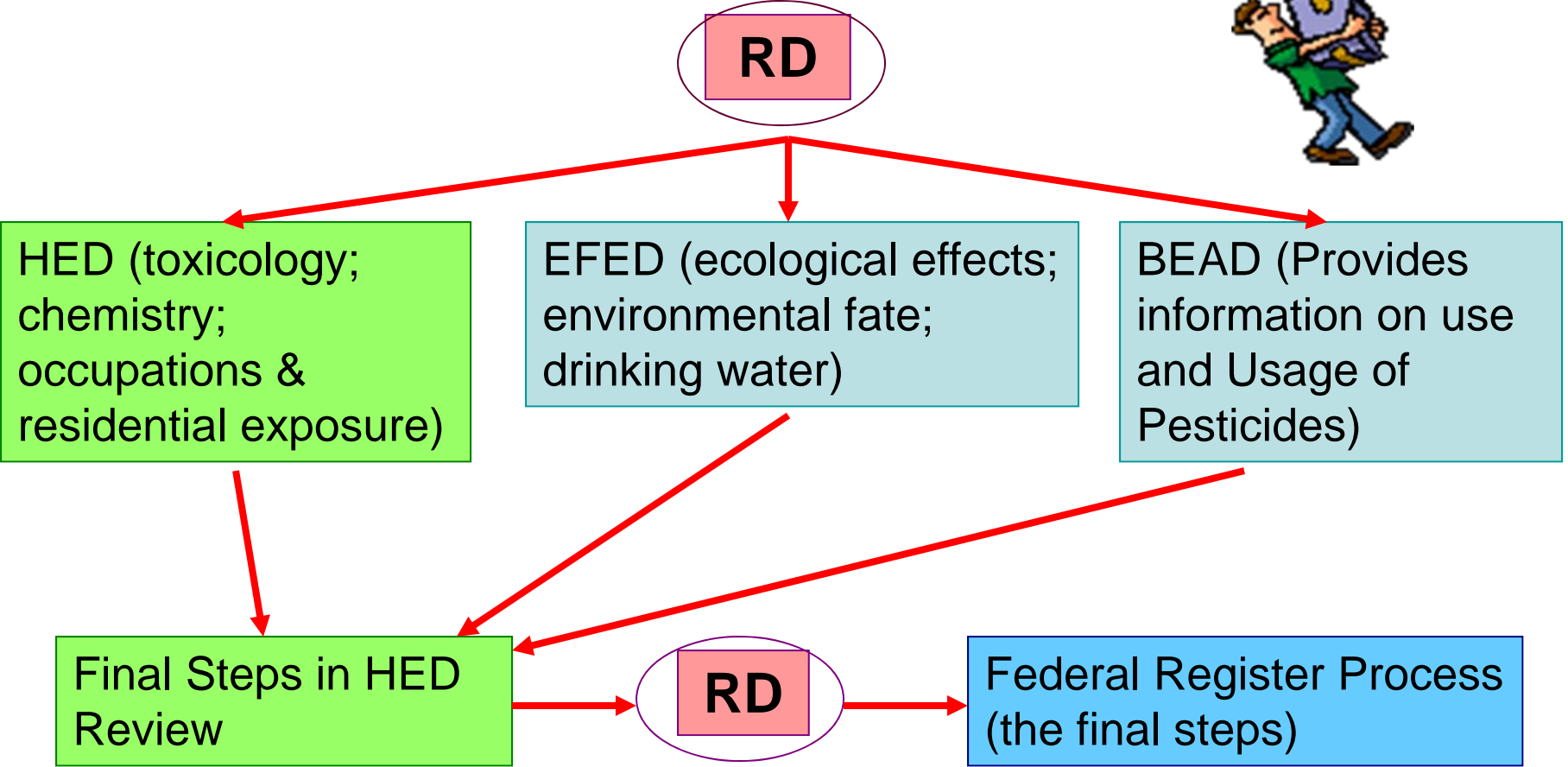
If everything is in order a tolerance is granted (MRL)  
and a registration follows



A new product is now available for minor use



# EPA/OPP Process





# GLPs Terms and Definitions

- Testing Facility Operations
  - Standard Operating Procedures (SOPs)
    - In writing setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data
    - All deviations in a study from SOP shall be authorized by the Study Director and documented in the raw data.
    - Significant changes in SOPs shall be properly authorized in writing by Management
    - A historical file of SOPs and all revisions shall be maintained

# GLPs Terms and Definitions



- Protocol
  - Each study shall have an approved written protocol which clearly indicated the objectives and all methods for the conduct of the study.
    - Title and statement of purpose
    - ID of test and reference substances
    - Name and address of sponsor and name and address of the testing facility
    - Description of test system (specifics described)



# GLPs Terms and Definitions

- Protocol cont.
  - Procedure for ID of test system
  - Description of experimental design
  - Where applicable, solvents, emulsifiers and or other material used in the mixing of the test substance with the carrier

# GLPs Terms and Definitions



- Protocol, cont.
  - Type and frequency of test, analyses and measurements to be made
  - Records to be maintained
  - Date of approval of the protocol by Sponsor and dated signature of the Study Director
  - Statement of proposed statistical analysis
  - All changes in or revisions of an approved protocol and the reasons therefore shall be documented, signed by the SD, dated and maintained with the protocol.



# GLPs Terms and Definitions

- Conduct of Study
  - Raw Data
    - Shall be recorded directly, promptly, and legibly in ink
    - All data shall be dated on the day of entry and signed or initialed by the person entering the data
    - Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change and shall be dated and signed or identified at the time of the change.



- Global Minor Use Summit

Global residue trials to compare residue results across various agro-eco zones

Kenya, Nigeria, Egypt, Morocco, South Africa