



United States Department of Agriculture

USDA Irradiation Rules

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United States Department of Agriculture

I will talk about

- **Three rules on irradiation**
- **Requirements for southern facilities**
- **Steps to follow**

Relevance to exports

When it comes to irradiation:

- **Harmonization of requirements required**
- **US import requirements closely followed**
- **Pest-free trade means greater credibility**

Irradiation as a Phytosanitary Treatment

Some unique features/advantages of IR:

- **Commodity non-specific**
- **Wider range of pests covered**
- **Pest mortality not necessary**
- **Relatively less toxic to commodity**

Three Irradiation Rules – Landmark rules

- **October 23, 2002** – Sets the ground work
- **January 27, 2006** – Provides generic doses
- **July 20, 2012** – Allows facilities in southern U.S.

The October 23, 2002 Rule established

- **Treatment requirements**
- **Monitoring**
- **Inspection**
- **Safeguards**
- **Facility certification**
- **Dosages for 12 pests**

The January 27, 2006 Rule expanded pest list

Anastrepha ludens	70	Cryptophlebia illepada	250
Anastrepha obliqua	70	Cylas formicarius	
Anastrepha serpentina	100	elegantulus	150
Anastrepha suspensa	70	Cydia pomonella	200
Bactrocera jarvisi	100	Euscepes postfasciatus	150
Bactrocera tryoni	100	Grapholita molesta	200
Brevipalpus chilensis	300	Omphisa anastomosalis	150
Conotrachelus nenuphar	92	Rhagoletis pomonella	60
Crotophlebia ombrodelta	250	Sternochetus mangiferae	300
ALL Fruit Flies of Tephritidae family not listed above			150
ALL Insects except Lepidoptera pupae and adults			400

Three more pests with specific doses added later

The January 27, 2006 Rule

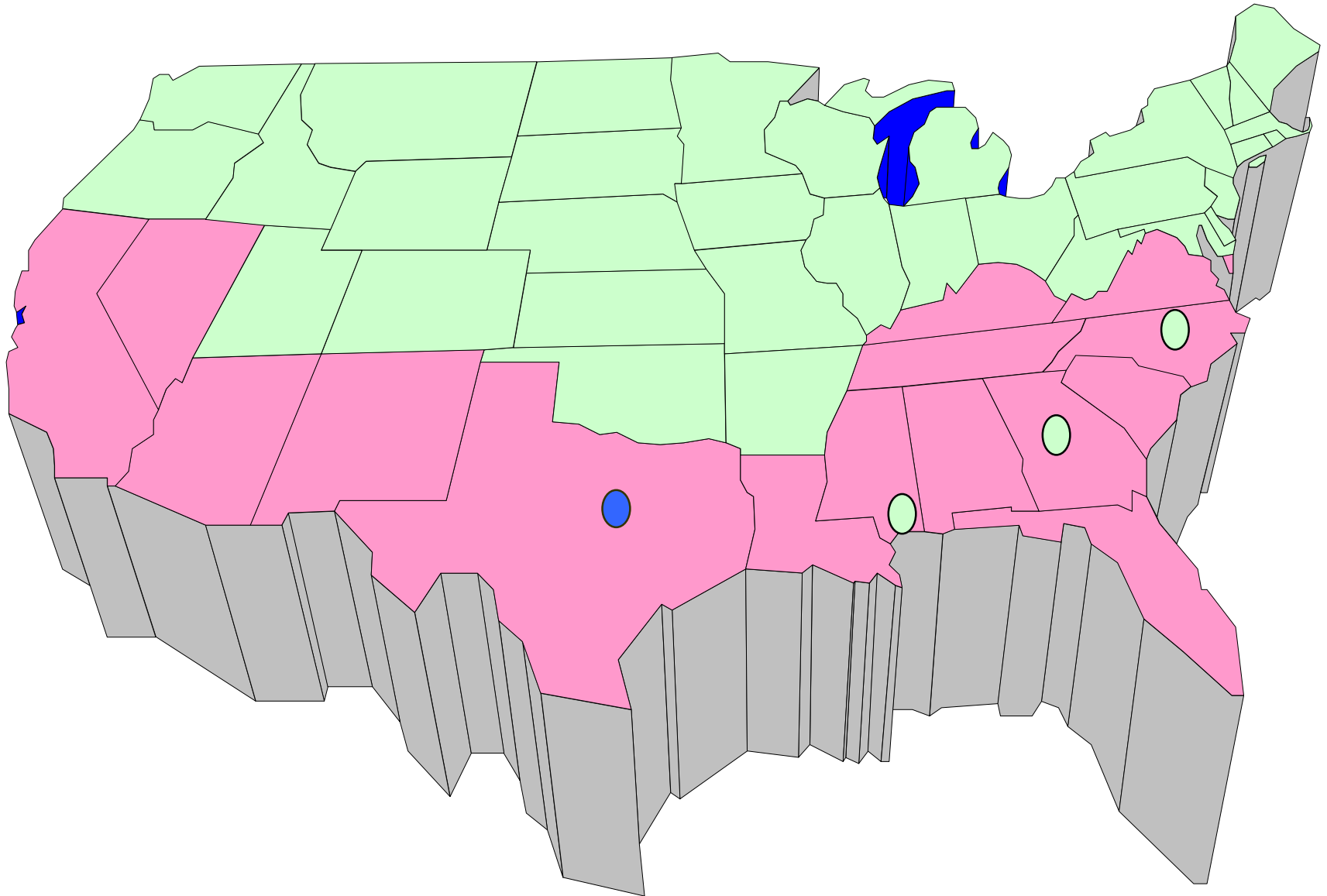
Generic Doses

- **150 Gy** – Neutralizes all fruit flies
- **400 Gy** – Neutralizes all insects
(excluding Lepidoptera adults & pupae)

Irradiation facilities in the southern United States

- **Earlier many States of the U.S. were prohibited to have irradiation facilities**
- **After July 20, 2012, a rule allowed to have facilities in the southern U.S.**

Approved US Locations Prior to July 2012



Irradiation facilities in the southern United States ... cont'd

- **In 1994, APHIS conducted a study that determined areas where fruit flies may or may not overwinter**
- **Thus certain area in northeast was considered safe and movement of FF hosts and facilities were allowed**
- **Certain areas considered unsafe required to have additional measures to allow such movement or have facilities**

Key requirements for southern facilities

- **Location to be operationally feasible**
- **State concurrence in writing**
- **Facility to provide map of crops around**
- **Facility certification required**
- **Pest proof boxes & fruits stay in them until treated**

Key requirements for south ... cont'd

- **Refrigerated or A/C conveyance**
- **Pre-arrangement with the facility
(Time/Route/Conveyance)**
- **Facility under compliance agreement**
- **Pest trapping or monitoring**
- **Secured devanning of fruit ensured**

Key requirements for south ... cont'd

- **Treated commodities kept separated**
- **Facility is locked during non-business hours**
- **Back up CT/MB fumigation required**
- **Contingency destruction plan required**
- **Only pre-approved admissible articles allowed**
- **Other requirements if necessary per CA**

So where you go from here ? (next steps)

Check FAVIR to determine admissibility

<http://www.aphis.usda.gov/>

<https://epermits.aphis.usda.gov/manual/index.cfm?ACTION=pubHome>

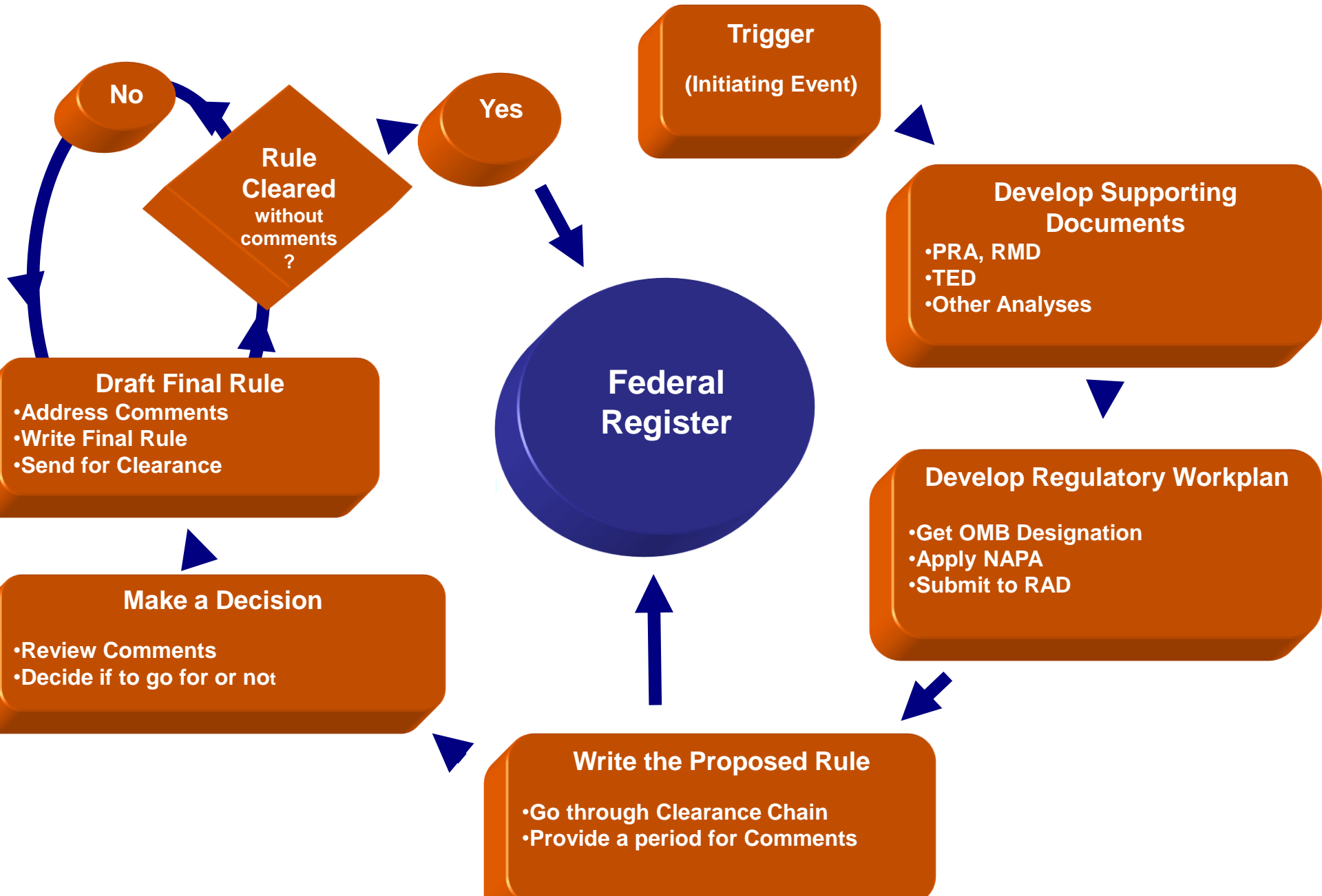
If admissible (work on operational issues):

- Work thru NPPO to finalize agreements (FEWP, OWP, CA, Trust Fund, etc),
- Have facility certified; Apply for import permit, set up funds for preclearance etc

If not admissible – have NPPO initiate the approval process

Commodity Approval – Two ways

- **Rulemaking Process** – to change the regulations (CFR)
- **Notice Based Process** – to change the manual (FAVIR) –



Trigger
(Initiating Event)

Develop Supporting Documents

- PRA, RMD
- TED
- Other Analyses

Develop Regulatory Workplan

- Get OMB Designation
- Apply NAPA
- Submit to RAD

Write the Proposed Rule

- Go through Clearance Chain
- Provide a period for Comments

Make a Decision

- Review Comments
- Decide if to go for or not

Draft Final Rule

- Address Comments
- Write Final Rule
- Send for Clearance

Rule Cleared without comments?

Yes

No

Federal Register

Agreements Required for use of IR

- **FEWP** (Framework Equivalency Work Plan)
- **OWP** or Operational Work Plan
 - Includes:
 - Detailed procedures for IR application
 - Facility Certification
 - Safeguards needed
- **Compliance Agreement** with Facility, Importer
- **Trust Fund** to pay APHIS' preclearance activities abroad

Thank you

Currently 9 countries have signed the FEWP with the U.S.

India

Philippines

Laos

South Africa

Malaysia

Thailand

Mexico

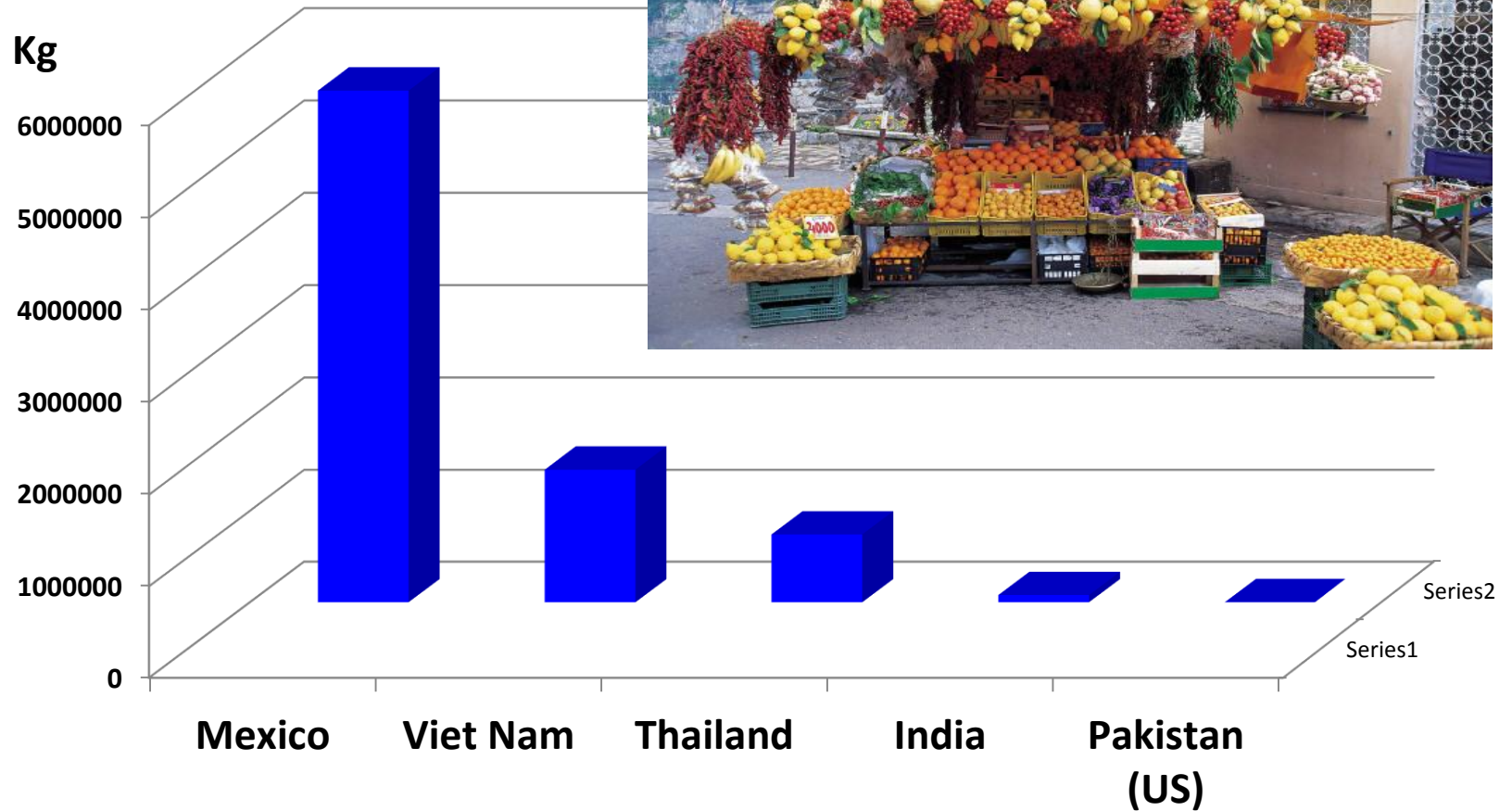
Vietnam

Pakistan

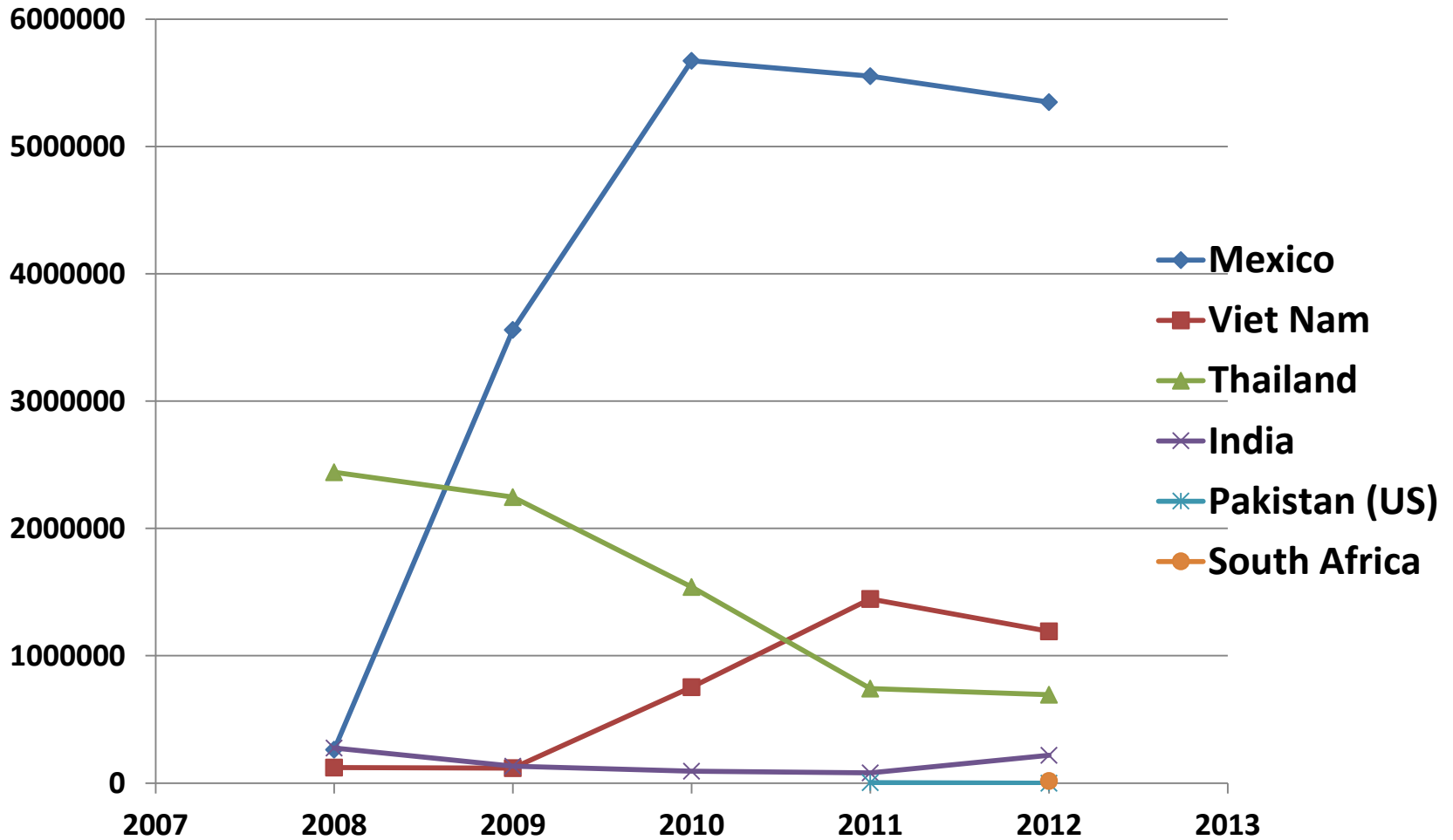
Peru

[United States]

Imports of irradiated fruit into the U.S. in 2011



Imports of irradiated fruits 2008-2012



Pests where irradiation still not approved

- **Mites**
- **Mollusks**
- **Nematodes**
- **Weeds & weed seeds**
- **Lepidoptera adults & pupae**
- **Pathogens**

Code of Federal Regulations (CFR)





Federal Register

Tuesday,
January 26, 2010

Part IV

Department of Agriculture

Animal and Plant Health Inspection
Service

7 CFR Parts 301, 305, 318, et al.
Phytosanitary Treatments; Location of
and Process for Updating Treatment
Schedules; Final Rule

Commodity Approval - Rulemaking (RM) vs. Notice Based Process (NBP)

- **RM is a time consuming process, takes years**
- **In 2007, APHIS approved NBP, a streamlined process**
- **NBP takes only months as opposed to years**
- **NBP applicable to pre-approved Designated Measures only**

Commodity Approval - Notice Based Process ...

Five Designated Measures

- as Conditions of entry
 - **Commercial consignment only**
 - **From Pest free area**
 - **Inspection (External pests)**
 - **PC declares shipment as free of pests**
 - **Treatment (High risk internal pests)**

Treatment Types

- **Chemical Treatment e.g. MB fumigation**
- **Heat Treatments – By Hot Air, Water or Steam**
- **Cold Treatment or Refrigeration**
- **Freezing**
- **Irradiation – potentially an alternative to methyl bromide fumigations**

Relative Tolerance of commodities

- **High tolerance**

Apple, cherry date, guava, longan, cantaloupe, nectarine, papaya, rambutan, raspberry, strawberry, tomato

- **Medium tolerance**

Apricot, banana, cherimoya, fig, grapefruit, kumquat, loquat, litchi, orange, passion fruit, pear, pineapple, plum, tangelo, tangerine

- **Low tolerance**

Avocado, cucumber, grape, green bean, lemon

Some Challenges

- **Public misperception – Education helps**
- **Initial capital required high**
- **Relative costs of treatment an issue**
- **No way to validate treatment at POE**
- **Many pest groups still not mitigated**

Some quarantine significant pathogens

- **Citrus canker**
- **Citrus black spot**
- **Citrus greening**
- **Citrus scab**
- **Karnal Bunt**
- **Fusarium spp**
- **Puccinia rusts**
- **Xanthomonas spp**
- **Ralstonia spp**
- **Chrysanthimum white rust (& others)**

