

Inert Ingredients in Pesticide Products

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Outline of Presentation

- Introduction of staff
- Structure and function
 - Office of Pesticides Programs (OPP)
 - Registration Division (RD)
- Key statutes
- History of Inert Ingredient regulation



IIAB Staff

- P. V. Shah- Chief
- Kerry Leifer- Team Leader
- Lisa Austin- Toxicologist
- Alga Debesai- Chemist
- Mark Dow- Senior Biologist
- Elizabeth Fertich- Biologist
- Karen Samek- Environmental Specialists
- Deirdre Sunderland- Industrial Hygienists





Office of Pesticide Programs

Acting Director—
Steven Bradbury, PH.D.

Health Effects Division

Registration Division
(Director-Lois Rossi)

Environmental Fate & Effects
Division

Special Review &
Reregistration Division

Biological & Economic
Analysis Division

Antimicrobial
Division

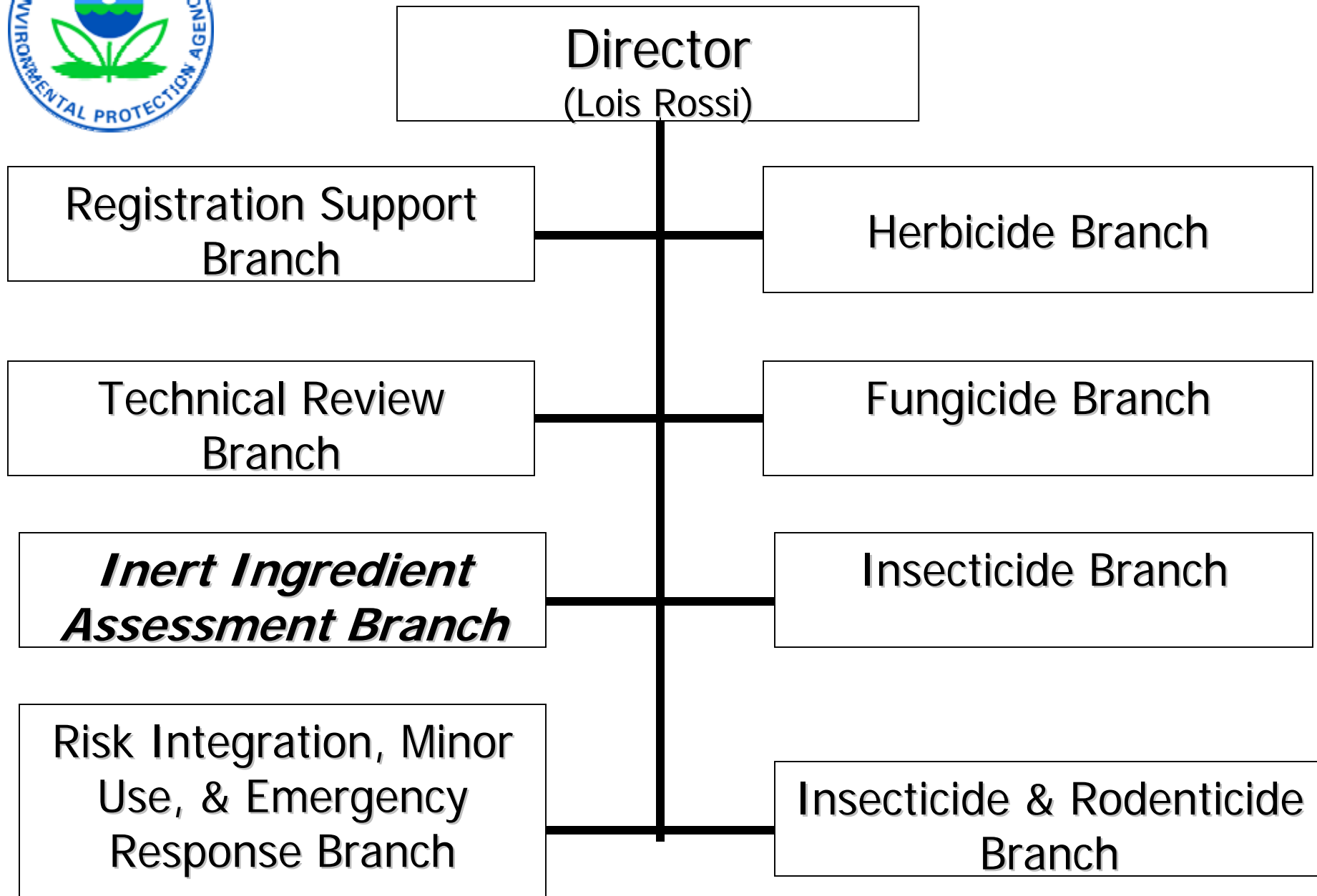
Information Resources &
Services Division

Biopesticides & Pollution
Prevention Division

Field & External Affairs
Division



Registration Division



OPP Registration Process

OPP (RD)
-receives studies from registrant
-Routes studies for interdisciplinary reviews
-Schedules risk assessment

Human health hazard and exposure studies reviewed

Ecological hazard and exposure studies reviewed

Determine endpoints of concern from Toxicity studies

Determine Residential exposure

Determine drinking water exposure

Establish endpoints from toxicity studies

Determine Worker exposure

Determine Dietary exposure

Determine Ecological exposure

Establish RfD by applying safety factors to NOAEL

Determine aggregate human exposure and consider common mechanism

Characterize ecological Risk

Characterize human health Risk

Characterize human health and ecological Risk

Registrant responds; OPP modifies risk assessment if appropriate

OPP formulates risk mitigation and risk management decisions

Tolerance Decision Published

New Active Ingredient Registered





Key Statutes

Food Quality Protection Act
(FQPA 1996)

PRIA
2004
2007

Federal Food Drug
And Cosmetic Act
(FFDCA)

Federal Insecticide Fungicide
And Rodenticide Act
(FIFRA)

EPA establishes MRLs (tolerances)
FDA (Food and Drug Administration) monitors
residues for domestic and imported food and
Enforces against illegal residues

EPA registers pesticide products and
Enforces their correct use according
to the labels

Core Functions of IIAB

- All aspects of the process done in the Inert Ingredient Assessment Branch in the Registration Division
 - Receipt of application
 - Data review
 - Risk assessment for human health and environmental and ecological effects
 - Risk Mitigation
 - Tolerance establishment or exemption from tolerance
 - Clearance for non-food use inert ingredients
 - Screening of inert ingredients in Pesticide Products (Confidential Statement of Formula, CSF)





History of IIAB and its Accomplishments

- Historically IIAB functioned resided in the Registration Division of Office of Pesticide Program
- The Inerts review process has been in place since 1970
 - Limited staff were assigned to review inerts
- Food Quality Protection Act was implemented in 1996
 - This law required EPA to re-evaluate by August 2006 all tolerance exemptions that were established prior to August 3, 1996
 - FQPA mandated special consideration to infants and children and consideration of aggregate and cumulative risk
- OPP management recognized the need for more staff and created IIAB in 2004



History of IIAB and its Accomplishments (continued)

- Of the 826 tolerance exemptions needing reassessment
 - 625 were reassessed as safe
 - 3 were revoked because of risk concerns
 - 75 were revoked because of no use
 - 123 were revoked for insufficient data
- Of the 123 tolerance exemptions that were revoked, 59 of these exemptions were supported by the industry consortia. IIAB developed a data development plan, grouping of these chemicals, and plans for conducting studies. IIAB reviewed submitted data and conducted risk assessments. Based on these new data all the tolerance exemptions were reestablished (with some limitations) except for clusters CST 5 and CST9 which is still under review.



History of IIAB and its Accomplishments (continued)

- Published the list of approved nonfood use inert ingredients on the web
- Reviewed approximately 1530 fragrances on the FIL list
- Responded to petitions filed by several states on inerts disclosure and published an Advance Notice of Proposed Rule Making (ANPRM) for public comments
- Improved inert risk assessment process
- Responded to approximately 800/year email inquiries received in inerts branch box

History of IIAB and its Accomplishments (continued)

- In 2008-
 - Nonfood use- 24 request completed
 - Food Use- 34 petitions completed

 - Approximately 50 petitions for food use received in 2008
 - Approximately 39 nonfood use request received in 2008

- In 2009
 - Nonfood use- 31 request completed
 - Food use- 46 petitions were completed

 - Approximately 48 petitions for food use received in 2009
 - Approximately 32 nonfood use request received in 2009

IIAB Current Workload

- Nonfood use Request- 17
- Food Use Petitions- 59



History of IIAB and its Accomplishments (continued)

Ongoing Projects:

- Currently working on Inerts Data Compensation –Advance Notice of Proposed Rule Making (ANPRM) will be published for public comments
- Improving the web site to include all approved inerts and mixtures at one place and increase the searching capacity to include CAS Number (if applicable), PC Code, Chemical name, CFR exemptions etc.
- Participation on Agency's Endocrine Disruptor Program (EDSP) and handling of Industries response to test orders

