# Overview of EPA's Pesticide Program

**Farm, Ranch, and Rural Communities Committee Meeting**

**November 13, 2020**

**Edward Messina and Mike Goodis**
**Office of Pesticide Programs**
**U.S. Environmental Protection Agency**

# Presentation Overview

- Background
  - Office of Pesticide Programs Structure and Responsibilities
  - Pesticide Legislation
- Pesticide Registration and Registration Review Process
- Risk Assessment, Risk Characterization, and Risk Management
- Public Involvement
- Collaboration with Domestic & International Partners
- Updates on EPA Issues

# Scope of Pesticide Registrations, Registrants and Users

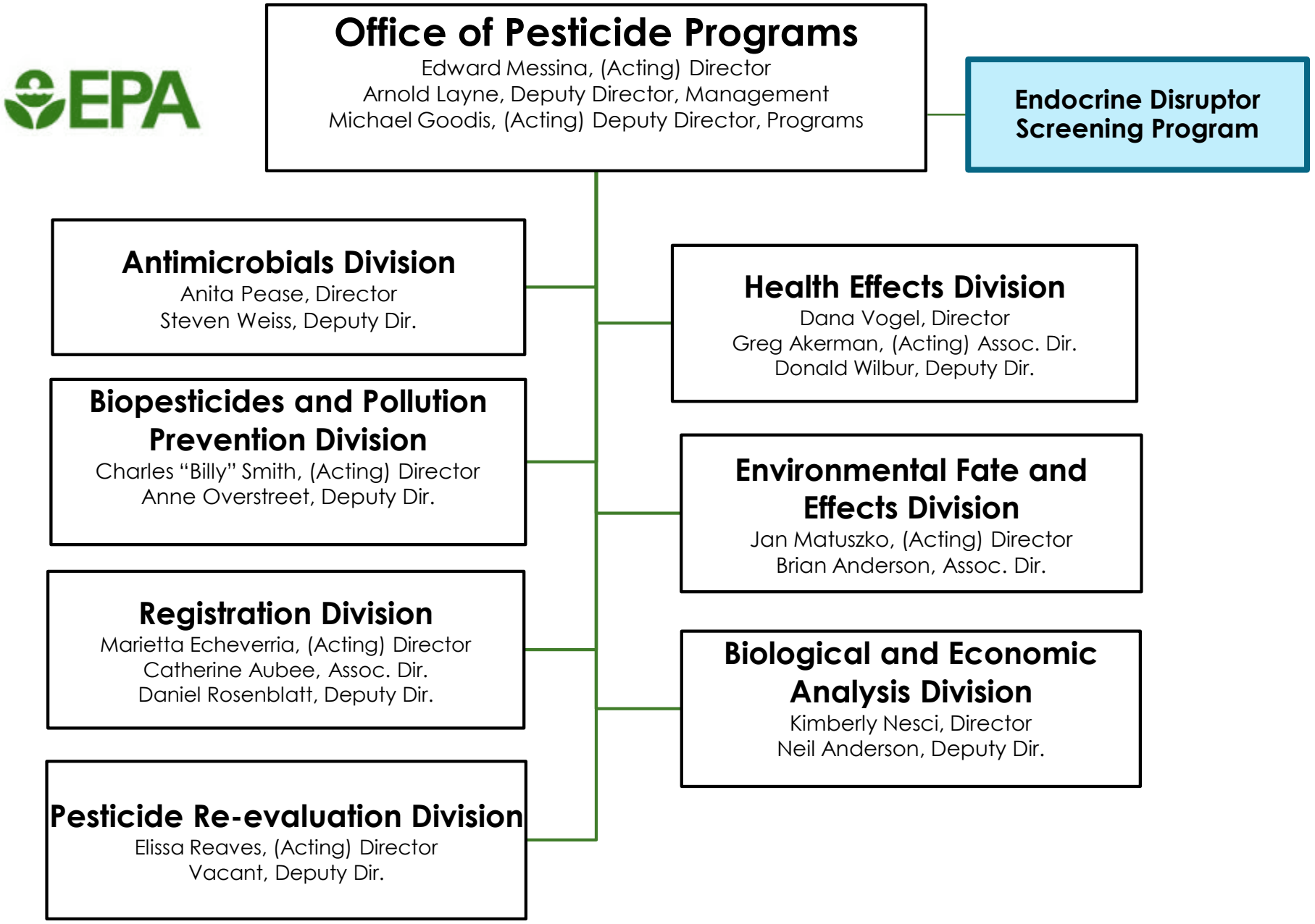
- **Production and Formulation**
  - 18 major producers, 100 other producers, 2,300 formulators, 20,000 distributors
- **Agriculture Use**
  - 2.2 million farms, 1 million certified applicators
- **Residential Use**
  - 105 million households, 33,000 pest control companies
- **US Pesticide Registrations**
  - Over 1,200 active ingredients, over 16,800 pesticide products,
  - Over 16,300 tolerances (maximum allowable pesticide residue on food).
  - >10,000 transactions/year
  - Receive/evaluate scientific information/data for >2,000 pesticide applications/year

# Office of Pesticide Programs (OPP)

- **OPP's Structure and Resources:**
  - One of largest program offices at EPA Headquarters within the Office of Chemical Safety and Pollution Prevention (OCSPP)
  - 7 Divisions containing ~ 600 employees
  - Staff are primarily in Washington, DC area (Arlington, VA) but some pesticide liaisons reside in the 10 regional offices

- **OPP Staff:**
  - Highly educated and technically trained; most have scientific backgrounds including biologists, chemists, toxicologists, geneticists, weed scientists, wildlife biologists, entomologists, plant pathologists, statisticians
  - Support staff include employees with communications, regulatory, financial, information management and computer specialties

# New OPP Org. Structure



# OPP's Responsibilities

- Protect human health and the environment
- Ensure any pesticide residues on food and feed are safe
- Ensure pesticide users have information (*e.g.*, clear label) that allows for proper use
- Ensure decisions reflect the best science and policy judgments
  - Evolving science
  - Endangered species, pollinators, endocrine disruption, human studies are important and challenging science and policy issues
- Meet market needs
  - Industry has timely decisions for their products
  - Farmers and other consumers get products they need
- Meet milestones and statutorily mandated deadlines for regulatory actions

# U.S. Pesticides Legislation

- **Federal Insecticide, Fungicide, and Rodenticide Act** (FIFRA)
  - Registration/Licensing, registration review
- **Federal Food, Drug, and Cosmetic Act** (FFDCA)
  - Tolerances/maximum residue levels (MRLs) for residues in food
- **Food Quality Protection Act** (FQPA)
  - Primarily amended FFDCA by establishing new standard
- **Pesticide Registration Improvement Act** (PRIA 1, 2, 3 & 4)
  - Amended FIFRA by adding registration fees and decision review periods
- **Endangered Species Act**
  - Protect endangered wildlife and plants

# Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Governs the licensing, sale, distribution, and use of pesticides
- Labels ensure safe and proper use of pesticides
- When used according to its label, a pesticide “will not cause unreasonable risk to humans or the environment, considering economic, social, and environmental costs and benefits of the pesticide”
  - Risk-benefit standard: considers **human** and **ecological** risk and requires, for non-dietary risks, the consideration of the **benefits** from the use of the pesticide
- Gives EPA authority to require information (e.g. scientific studies) to be submitted
  - Studies sponsored by and paid for by applicant
  - EPA can require necessary additional data at any time to support registration
- Primary enforcement through the State Lead Agencies

# Federal Food, Drug, and Cosmetic Act (FFDCA)

- Governs allowable pesticide residues in/on food:
  - Referred to as tolerances/maximum residue levels (MRLs)
- "A reasonable certainty of no harm" is the general safety standard:
  - Risk-only standard – does not allow the consideration of benefits



9

# Food Quality Protection Act (FQPA)

- Amended both FIFRA and FFDCA
- Created the risk-based standard for FFDCA
  - “Reasonable certainty of no harm”
- Imposed stricter standards for tolerance setting including:
  - Enhanced children’s protection (FQPA safety factor of 10X)
  - Aggregation of exposures when looking at risk
  - Cumulative assessments
- Required periodic review of pesticides (Registration Review)

# Where FIFRA and FFDCA Meet

- Before EPA can register a pesticide under FIFRA that is used on raw agricultural products, it must grant a tolerance or exemption.
- A tolerance is established to account for the highest pesticide residue level that is expected based on applications in accordance with the use directions listed on the registered product label.
- One of the primary functions of a tolerance is an enforcement tool to ensure compliance with the registered label.

# Pesticide Registration Improvement Act

- The Pesticide Registration Improvement Act and its three reauthorizations provide a fee-for-service structure for EPA review of pesticide applications and set statutory decision time frames for review of those applications.
- PRIA provides two funding sources to EPA's pesticide program:
  - One-time registration service fees (i.e., PRIA fees) for the evaluation of new applications submitted to the EPA; and,
  - Annual FIFRA maintenance fees assessed to products currently in the marketplace, a significant portion of which are used to support the re-evaluation of pesticides in order to meet the statutory deadline of October 1, 2022, for completing the first round of registration review.
- Both PRIA registration service fees and maintenance fees are meant to supplement appropriations in funding these activities, and do not represent the total costs for EPA to conduct these activities.

# Endangered Species Act

- Under Section 7(a)(2) of the ESA, Federal agencies must ensure that the “actions” they authorize will not result in jeopardy or adversely modify designated critical habitat for species listed as endangered or threatened by the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS) (jointly the Services).
- For the Office of Pesticide Programs, the “actions” we authorize are the sale, distribution, and use of pesticides according to the product labeling.

# Overview of Pesticide Registration and Registration Review Process

# Pesticide Registration

- EPA grants license, called registration, to sell or distribute pesticides

- There are several kinds of registrations:
  - New pesticides or new uses (Section 3)
  - Emergency exemptions (Section 18)
  - State special local need registrations (Section 24(c))
  - Experimental use permits (Section 5)

- EPA also establishes pesticide tolerances or “maximum residue levels” for residues in or on food or feed

# Pesticide Registration

- **Registration Process:**
  - Applicant develops a pesticide, generates data and submits an application to the EPA
  - EPA reviews submitted data to assess risk
  - EPA makes its decision based on all available information
    - Typical application for a new active ingredient would include over 100 studies

# Types of Data Required for Registration and Registration Review

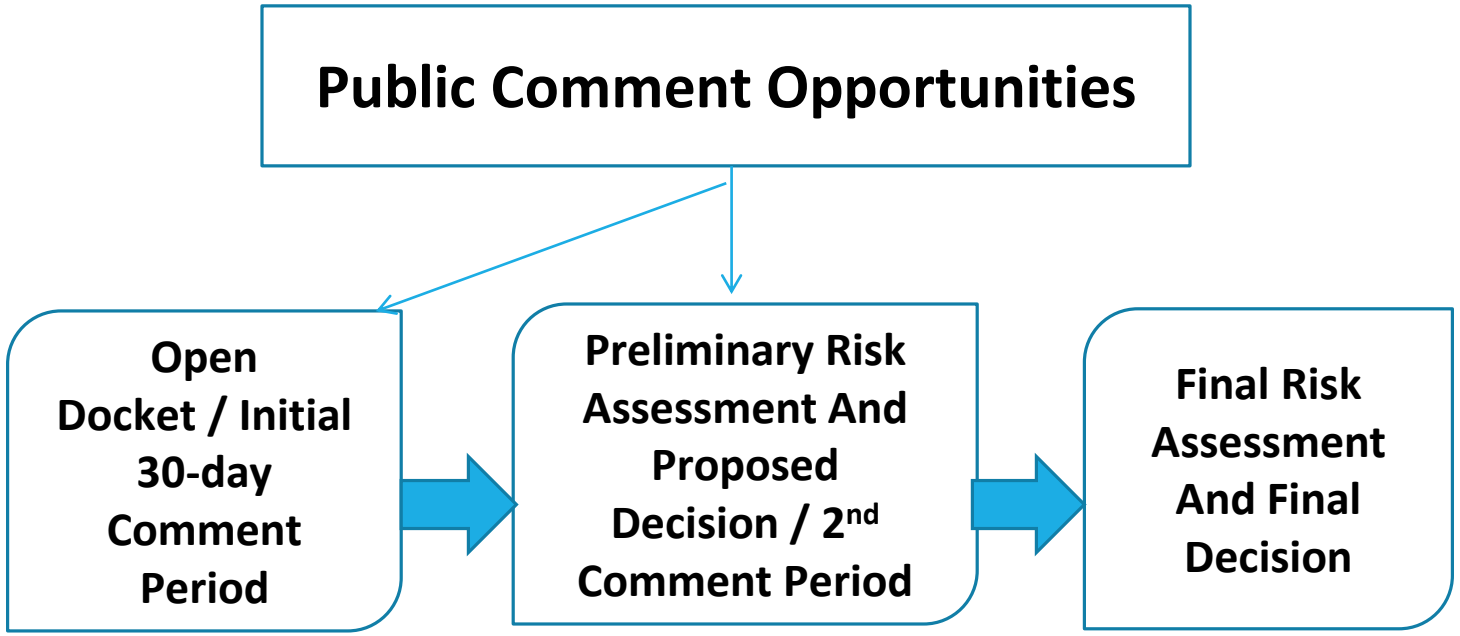
- Product chemistry to assess labelling.
- Product performance data to support labelled pest claims.
- Data from studies to determine hazards to companion animals.
- Toxicity studies that determine hazard to humans.
- Residue chemistry data to determine the nature & magnitude of residues.
- Applicator and post-application exposure studies to determine exposure for workers and homeowners (residential).
- Environmental fate data.
- Data from studies that determine hazard to non-target organisms.

# Pesticide Registration

- Data requirements
  - Used to evaluate risks and make registration decisions
  - Based on regulations
  - Data are provided by the applicant

- EPA may impose conditions for a registration:
  - Use restricted to certified applicators
  - Personal protective equipment
  - Pre-harvest and re-entry intervals
  - Drinking water-well set-backs, buffer zones
  - Follow-up/monitoring requirements

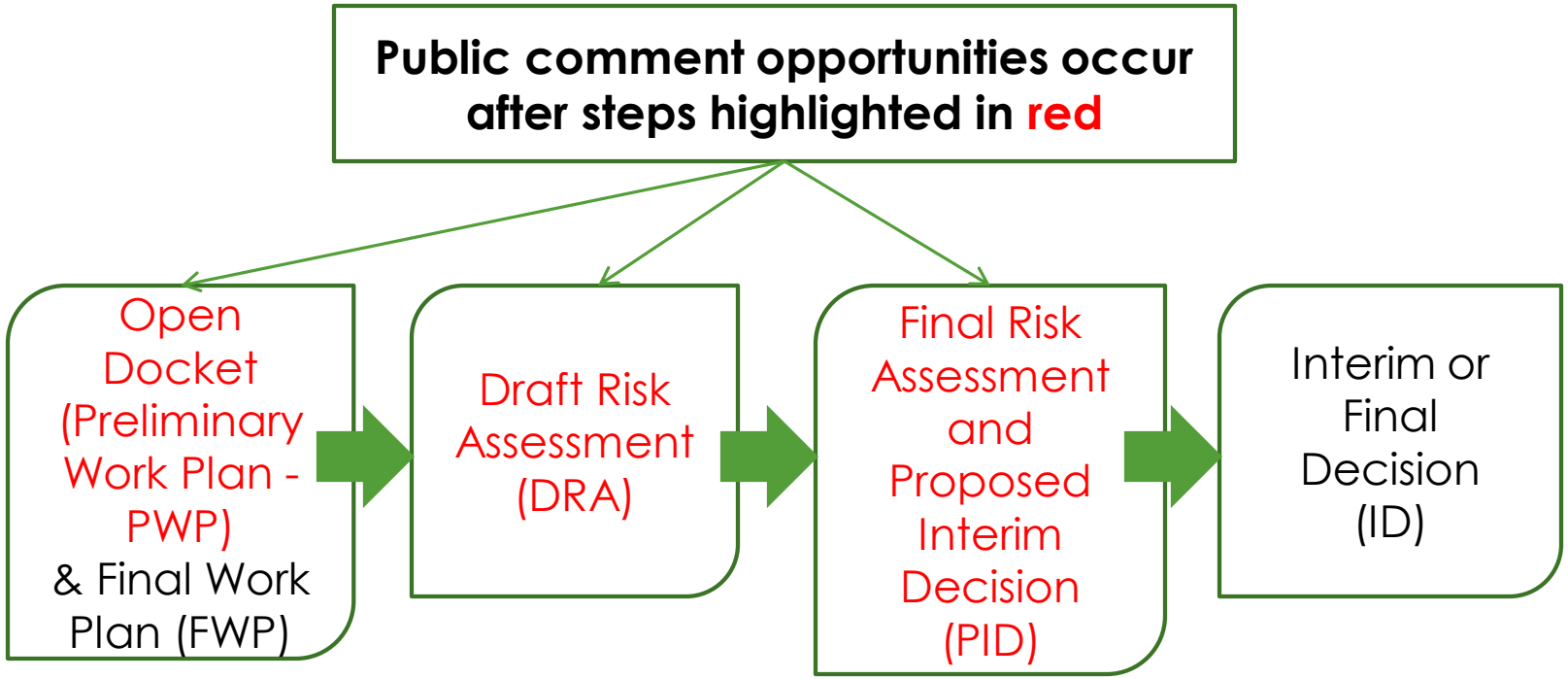
# Registration Process and Public Participation



# Registration Review

- Section 3(g) of FIFRA requires review of each registered pesticide every 15 years to ensure that each pesticide registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment.
- The first round of registration review began in October 2007 and all 726 “cases,” encompassing over 1,100 pesticide active ingredients, must be completed by the statutory deadline of October 1, 2022.
- The future scope of registration review will be revolving, as chemicals need to go through the process again no later than 15 years after the date on which the initial registration review is completed, or the date the chemical was registered.

# Registration Review Process and Public Participation



# Program Accomplishments

## Overall Registration Review Status

- 646 draft risk assessments completed (~11% remaining)
- 551 proposed interim decisions complete (~24% remaining)
- 481 final or interim decisions complete (~34% remaining)

# Enforcement

- “Label is the law” principle - violation of Federal law to use a pesticide not in accordance with the label.
- States in the U.S. are the primary enforcers of the pesticide label
- EPA determines the amount of pesticide residue allowed on foods by establishing enforceable tolerances.
  - Tolerance is the maximum amount of pesticide residue that can remain in or on a particular food.
  - To establish the tolerance, EPA evaluates the potential health risks of the pesticide (from dietary, drinking water and residential uses).
- FDA, USDA, and States work together to monitor food residues & enforce tolerance limits:
  - FDA tests food produced in this country and foods imported from other countries
  - Exception: USDA tests meat and milk

# Risk Assessment, Risk Characterization, and Risk Management

# Human Health and Ecological Risk Assessments

- Once data are submitted, EPA scientists conduct a thorough and careful review of the data and document their findings
- **Human health risk assessment**
  - Identifies potential routes of exposure, identifies hazards, and estimates risk for various groups including U.S. population and potentially sensitive subpopulations including pregnant women, infants, and children.  Assessments also address risk to workers applying pesticides or working in treated fields
- **Environmental fate and ecological risk assessment**
  - Identifies potential routes of exposure, hazard, and estimated risk to taxa which may include plants, birds, invertebrates, fish, and mammals

# Risk Assessment vs. Risk Characterization

- Risk assessment
  - This process evaluates the potential for human health and ecological effects of a pesticide's use based on hazard and exposure
- Risk characterization
  - This is the quantitative and qualitative evaluation of factors that help risk managers understand:
    - Likelihood of occurrence
    - Nature of the effects of pesticide use
    - Level of confidence and uncertainty

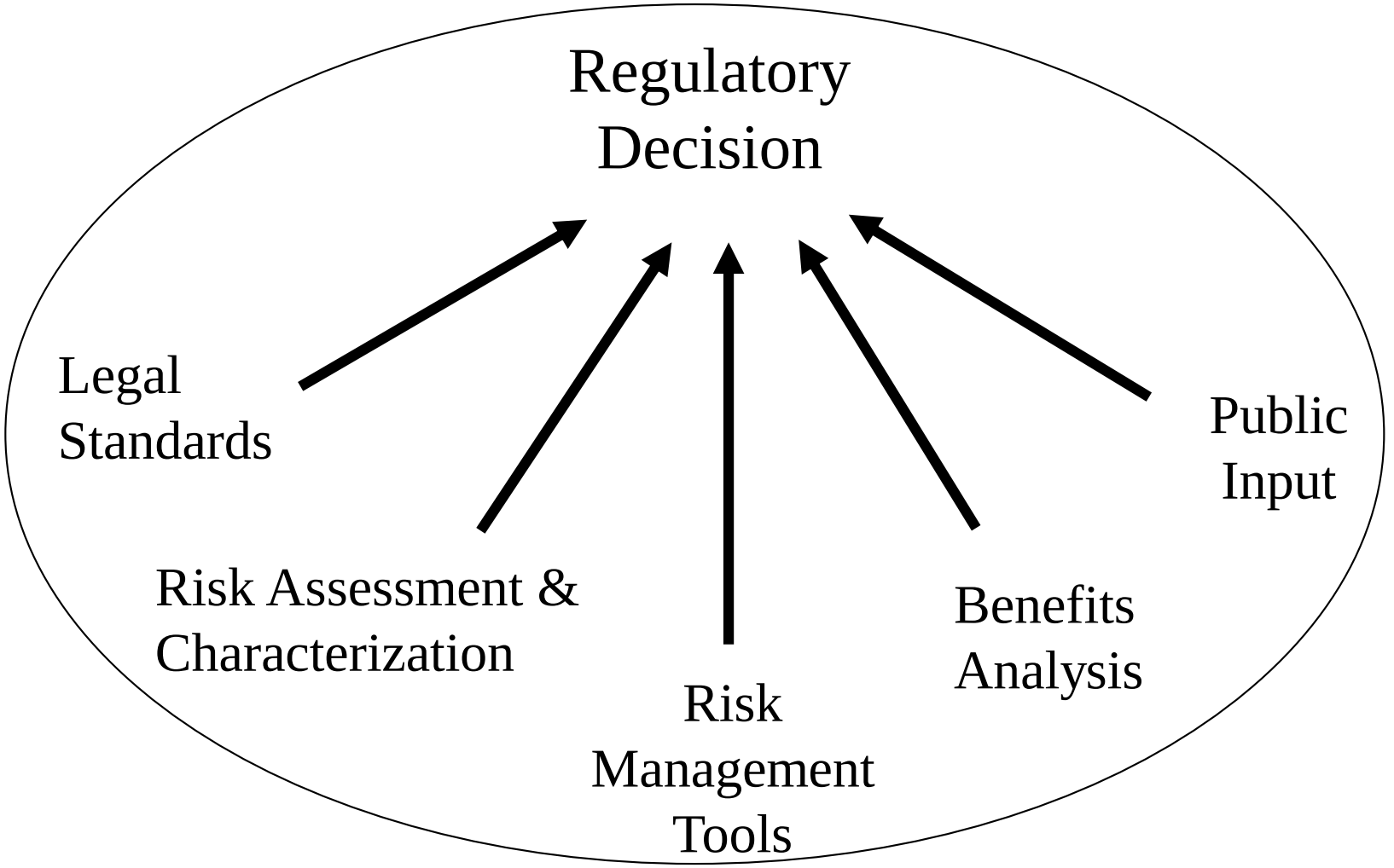
# Benefits, Alternatives and Impact Assessments

- **Benefits -** may change over time as new products come on the market and others are retired.
- **Benefits Assessment** - What value does a given pesticide active ingredient provide (i.e. What crops are they used on? what pest(s) does it control?)
- **Alternatives Assessment** - What are the alternatives to control a pest and their risk profile?  Will be the overall market be impacted by a regulatory change for a given pesticide?
- **Impact Assessment** – What are the potential economic impacts of regulatory options, such as expected effects on crop yields?
- ***Note:*** A pesticide with small sales numbers can still have high benefits (e.g. use on specialty crops, managing noxious weeds, allows for rotation between different chemistries to avoid resistance, public health benefits like bedbug or rodent control)

# Risk Management

- **Risk Management Goals**
  - Ensure that registered pesticides (continue to) meet the statutory standards for protecting human health and the environment
  - Effectively assess, manage and mitigate risks based on best available science and policy, involving stakeholders and the public
- **Risk Managers**
  - Consider the results of the risk assessments
  - Have an understanding of the benefits of a pesticide, as well as alternative pesticides that are already registered
  - Develop measures needed to mitigate any identified risks
  - Negotiate with registrants regarding potential modifications to the product or labeling that must be made to mitigate risk

# Risk Management



# Public Involvement and Collaboration with Partners

# Public Involvement

- OPP actively collaborates with a variety of stakeholders for advice, opinions, ideas to help us with science issues and policy development
  - FIFRA Scientific Advisory Panel
  - Pesticide Program Dialogue Committee
  - Pesticide industry
  - Environmental advocacy organizations
  - Government agencies – all levels
  - International organizations and foreign partners
  - Issue-specific technical experts
  - Public

# Collaboration with Domestic & International Partners

- States
  - Primary enforcement responsibility
  - Applicator certification & training programs
  - May regulate pesticide sales & use within their borders
  - Registration requirements equivalent to or more stringent
- Tribes
  - Assists EPA in ensuring compliance with FIFRA
  - EPA assists in development & implementation of pesticide programs
- International
  - Developing & strengthening international standards & approaches
  - Improving regulatory efficiency
  - Minimizing trade barriers & facilitating fair competition

# Updates on EPA Issues

# Endangered Species Act: Improving Coordination

- In January 2018, EPA, the Department of the Interior and the Department of Commerce signed a Memorandum of Agreement creating a Working Group to provide recommendations for improving the ESA consultation process for pesticide registration and registration review.
  - The Working Group will provide recommendations to EPA, FWS and NMFS leadership on improving the ESA consultation process for pesticide registration and registration review.
- The 2018 Farm Bill established an interagency committee to better coordinate on endangered species work relative to pesticide registration activities under FIFRA.
  - Codified the MOA Group and expanded to include the Council on Environmental Quality
  - Requires regular Reports to Congress on committee's progress

# ESA Obligations

- **Basic Process for ESA Assessments:**
  - EPA makes “effects determination” for individual listed species in a biological evaluation (BE).
  - If EPA concludes:
    - No effect (NE) – no consultation is required
    - Not likely to adversely affect (NLAA) – informal consultation with concurrence from Services is required – and formal consultation may be required if Services do not concur
    - Likely to adversely affect (LAA) – formal consultation is required, and the Services issue a Biological Opinion (BiOp) to determine if there is jeopardy
- Nationwide consultations must consider direct/indirect effects to 1850 listed species and 600+ designated critical habitats.

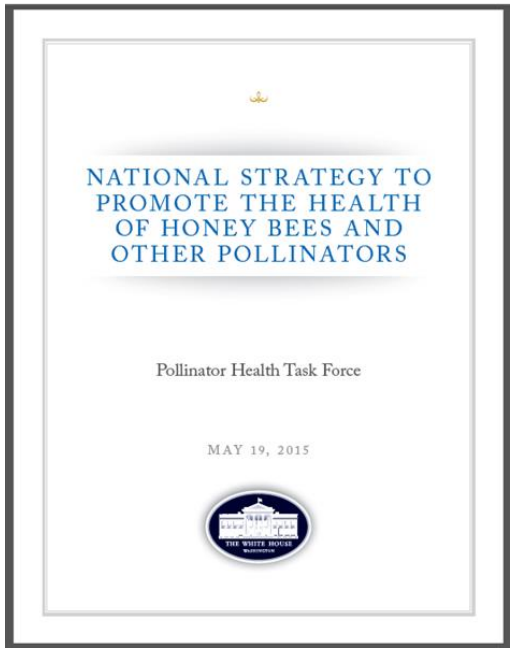
# NAS Report Framework

- EPA's **Biological Evaluation** (BE) determines whether registered pesticides adversely affect one or more individuals of a listed species and/or their designated critical habitats
  - **Step 1** ["No Effect/May Affect" Determination]
  - **Step 2** ["Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA) Determination]
- Services' **Biological Opinion** (BiOp) determines whether the registration of a pesticide is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of its designated critical habitat
  - **Step 3** ["Jeopardy/No Jeopardy" Determination and "Adverse Modification/No Adverse Modification" Determination]

# Presidential Directive to Improve Pollinator Health

- On June 20, 2014, the Administration issued a memorandum calling on federal agencies to increase and coordinate their efforts to improve bee health by developing an integrated strategy

- EPA committed to, among other things:
  - Take appropriate action to reduce risks from the use of products toxic to bees in crops with commercial pollination
  - Engage State and tribal partners in the development of managed pollinator protection plans



# EPA Activities on Pollinator Protection

- Assess the effect of pesticides on bees and other pollinators
- Reduce the risks of products toxic to bees in crops with commercial pollination
- Engage State and tribal partners in the development of managed pollinator protection plans
- Expedite review of registration applications for new products targeting pests (*e.g.*, mites) that are harmful to pollinators
- Encourage the incorporation of pollinator protection and habitat planting activities into green infrastructure and Superfund projects, and
- Enhance pollinator habitat at Federal facilities
- In September, EPA and USDA co-hosted the Pollinator State of Science Workshop webinar.
- Beginning in March 2020, EPA hosted a series of 5 public webinars, highlighting ongoing work to promote pollinator health and habitat.

# Plant-Incorporated Protectants

- PIPs are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the pesticidal substance.
- In October, EPA published a proposed rule in the Federal Register for public comment that will streamline the regulation of certain plant-incorporated protectants (PIPs) that pose no risks of concern to humans or the environment.
- The *existing* regulatory exemption for PIPs is limited to those created through conventional breeding. The *proposed* exemption would allow for PIPs created through biotechnology to also be exempt from existing regulations, so long as they pose no greater risk than PIPs that meet EPA safety requirements and could have been created through conventional breeding.

# New Approach Methods/Animal Testing

- Over the past several years, EPA has made significant progress toward reducing, replacing, and refining animal testing requirements.
- In September 2019, the Administrator set several ambitious new goals for the Agency, including eliminating all mammalian study requests and funding by 2035.
- In October, EPA presented two approaches that utilize these New Approach Methods, or NAMs, which inform uncertainty and safety factors in lieu of reliance on default factors.
- These approaches are a product of collaborative efforts between groups across the Agency, academia, and industry.
- This year, EPA released a comprehensive NAMs Workplan, and issued policies waiving the testing of pesticides on birds, fish and other animals, when the information gained is unnecessary to support a pesticide registration decision.
- EPA's long-term goal is to move towards making decisions with NAMs in order to reduce, refine or replace vertebrate animal testing.

# Thank you

# Questions & Answers