



Update on EPA's Pesticide Program Activities

**IR-4 Food Use Workshop
September 24, 2019**

**Office of Pesticide Programs (OPP)
Office of Chemical Safety and Pollution Prevention (OCSPP)
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Discussion Topics

- Big News in 2019
- Registration Review Update
- Updates on Specific Chemicals
- Antibiotics
- Registration Division Accomplishments
- Import Tolerance Pilot Project
- Crop Group Proposed Rule
- Hemp

Assistant Administrator (AA) for OCSPP

- Alexandra (Alex) Dapolito Dunn.
- Confirmed January 2, 2019.
- Previously served as the Regional Administrator for EPA Region 1 in Boston, Massachusetts for one year.





PRIA Update

- On March 8, 2019, the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) was signed into law:
 - Reauthorizes PRIA for five years (through FY 2023)
- Category changes
 - Increases number of registration service fee categories from 189 to 212
 - M009: non-FIFRA regulated determinations (e.g., minimum risk, treated articles)
 - Enhances incentives for reduced-risk pesticide submissions by raising fees for the corresponding non-reduced risk categories (new conventional active ingredients and new uses) by 20%



What is Registration Review?

- Statutory Mandate – FIFRA Section 3(g) requires EPA to review each registered pesticide every 15 years
- Scope – ~725 “cases” encompassing over 1,100 pesticide active ingredients (A.I.)
 - Conventional, antimicrobial, and biopesticides
- Statutory Deadline – EPA must complete review of all pesticides by 10/1/2022

Registration review Program: <https://www.epa.gov/pesticide-reevaluation/registration-review-process>

Registration Review Schedule: <https://www.epa.gov/pesticide-reevaluation/registration-review-schedules>



Registration Review Progress (FY19 Q3)

- **Conventionals:**

- 353 draft risk assessments completed (~23% remaining)
- 270 proposed interim decisions complete (~41% remaining)
- 235 final or interim decisions complete (~49% remaining)

- **Antimicrobials:**

- 67 draft risk assessments completed (~51% remaining)
- 57 proposed interim decisions complete (~58% remaining)
- 53 final or interim decisions complete (~61% remaining)

- **Biopesticides:**

- 90 draft risk assessments completed (~29% remaining)
- 90 proposed interim decisions complete (~29% remaining)
- 71 final or interim decisions complete (~42% remaining)



Glyphosate

- On May 6, 2019, EPA opened a 60-day public comment period on a **Glyphosate Proposed Interim Decision**. The comment period has been extended to September 3, 2019.
- The proposed interim decision proposes the following mitigation and label changes to target pesticide sprays on intended pests, protect pollinators, and reduce the problem of weeds becoming resistant to glyphosate:
 - Spray drift management measures (e.g., release height, droplet size, and wind speed restrictions) to reduce off-site exposure to non-target wildlife.
 - Weed resistance management labeling (e.g., information on mode of action, scouting instructions, and reporting instructions for weed resistance).
 - Label consistency measures, including updating maximum application parameters, updating the environmental hazards statement for aquatic use, and clarification on rotational crop timing.
 - Updated label language to raise awareness of potential effects to pollinator habitat and instructions on minimizing spray drift.



Glyphosate

- EPA continues to find that there are no risks to public health when glyphosate is used in accordance with its current label and that glyphosate is not a carcinogen.
- EPA's scientific findings on human health risk are consistent with the conclusions of science reviews by many other countries and other federal agencies.
- After reviewing public comments on the PID, EPA intends to release an interim decision in late 2019.



Pyrethroids

- **2016/2017:** EPA published draft risk assessments for public comment
- **2018:** Consider public comments submitted, revise risk assessments based on new data and comments
- **2019:** Plan to publish proposed interim decisions
- **2020:** Plan to publish interim decisions



Neonicotinoid Update

- **2010-2011:** Imidacloprid, thiamethoxam, clothianidin, and dinotefuran
- **2014:** Published a benefits assessment on the treatment of soybean seeds with neonicotinoids
- **2016-2017:** Published the preliminary pollinator assessments
- **2017:** Published draft human health risk assessment
- **2017:** Published additional benefits assessments on cotton and citrus, along with a revised seed treatment assessment
- **2017-2018:** Received new pollinator toxicity and exposure data



Neonicotinoid Update

- EPA's preliminary pollinator assessments noted the potential for on-field risk from some uses. However, risk was considered to be low for other uses such as seed treatments.
- EPA's draft ecological risk assessments noted potential risk to aquatic invertebrates from drift and run-off, as well as to birds and mammals from potential exposure to treated seed.
- In 2019, EPA anticipates publishing the Proposed Interim Decisions for imidacloprid, thiamethoxam, clothianidin, and dinotefuran.



Sulfoxaflor

- Originally registered in 2013; registration was vacated by the Ninth Circuit Court of Appeals after the court decided that the registration did not have enough data on the effects on bees.
- 2016: EPA approved registrations for some uses (e.g., crops that don't attract bees)
- Registrant submitted additional data on the potential for long-term effects on bees
- EPA conducted a new comprehensive risk assessment
- July 2019: EPA announced decision to restore the remainder of previously approved uses, add new uses and remove some application restrictions from the 2016 registration



Dicamba Over-the-Top Uses

- On October 31, 2018, EPA extended the registration of dicamba for two years for “over-the-top” use to control weeds in fields for cotton and soybean plants genetically engineered to resist dicamba.
- The registration includes label updates that add protective measures to further minimize the potential for offsite damage.
- This action was informed by input from an extensive collaboration between EPA, state regulators, farmers, academic researchers, pesticide manufacturers, and other stakeholders.
- The registration will automatically expire on December 20, 2020, unless EPA further extends it.



Antibiotics as Pesticides

- Antibiotics used on crops for purposes of pest control are pesticides under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act)
- FIFRA requires EPA to determine that any registered pesticide is not expected to cause unreasonable adverse effects on human health or the environment
- For antibiotic pesticides, antibiotic resistance is part of this determination



Assessing for Resistance

- Goal: to reduce the potential for resistance, while allowing availability of antibiotics to protect plant and crop health
- Risk-reduction techniques can be used to mitigate risks
 - More targeted application technique => lower risk
 - Resistance mitigation on a case-by-case basis, depending on crop and antibiotic



Assessing the Risk: A Collaboration

- EPA has conducted federal partner consultations before taking regulatory action on a pesticide used to control a pest of public health importance
 - Initially, used for vector control pesticides
 - First consultations for antibiotics in 2005
- To further protect public health, EPA consults with interested federal partners on antibiotics
 - For antibiotics, includes CDC, FDA, and USDA



Registration Division FY2019

- Registered:
 - 5 new active ingredients
 - 156 new uses for existing chemicals
 - 456 new products (or label amendments)
- Completed:
 - 601 fast track label amendments
 - 1,252 notifications of label changes
 - 177 minor formulation amendments
- Issued:
 - 108 emergency use exemptions (Section 18s)



Minor Use Completions

- EPA completed work on 26 IR-4 petitions in FY 2019, registering 130 minor uses requested by IR-4
 - Includes new tolerances and crop group expansions
- EPA completed over 100 crop group conversions requested by IR-4 in 2019
- Includes 6 workshare projects and 3 joint reviews with Canada and one workshare with California



Section 18 Emergency Exemptions

- Section 18 of FIFRA allows EPA to **exempt State and Federal agencies from any provision of FIFRA** if emergency conditions warrant.
- **Unregistered pesticide uses are temporarily allowed** when urgent and non-routine pest management situations result in emergency conditions.
- **EPA confirms the emergency condition exists** and that the required safety findings can be made for the use.



Four Types of Emergency Exemptions

**Urgent and Non-routine Pest Problem
&
No Effective Controls; and . . .**

poses risk of significant economic loss or risk to the environment	poses significant risks to human health	involves a harmful invasive species
1. Specific Exemption	2. Public Health Exemption	3. Quarantine Exemption

4. Crisis Exemption - any situation with very limited time



2019 Section 18s

- A total of 108 Section 18s were issued in FY 2019
- About half were for uses on minor or specialty crops, including
 - Citrus – Asian citrus psyllid/citrus greening (several chemicals)
 - Pyridate on mint – redroot pigweed
 - Brown marmorated stink bug:
 - Bifenthrin on apple, nectarine & peach
 - Dinotefuran on pome fruit, stone fruit and kiwifruit
 - Fenpropathrin on kiwifruit



Crop Group Updates

- Crop Grouping Phase V proposed rule was published August 27, 2019 with a 60-day comment period

Current Crop Group: §180.41(c)(28)	Proposed Crop Group
Crop Group 19: Herbs and Spices Group <ul style="list-style-type: none">• 68 commodities• Rep crops: basil (fresh & dried); black pepper; chive; celery seed or dill seed	No equivalent
Herb Subgroup 19A <ul style="list-style-type: none">• 36 commodities• Rep crops: basil (fresh & dried); chive	Crop Group 25: Herb Group <ul style="list-style-type: none">• 316 commodities• Rep crops: basil, dried leaves; basil, fresh leaves; mint, dried leaves; mint, fresh leaves
Spice Subgroup 19B <ul style="list-style-type: none">• 32 commodities• Rep crops: black pepper; celery seed or dill seed	Crop Group 26: Spice Group <ul style="list-style-type: none">• 167 commodities• Rep crops: Dill seed or celery seed



Import Tolerance Pilot Project

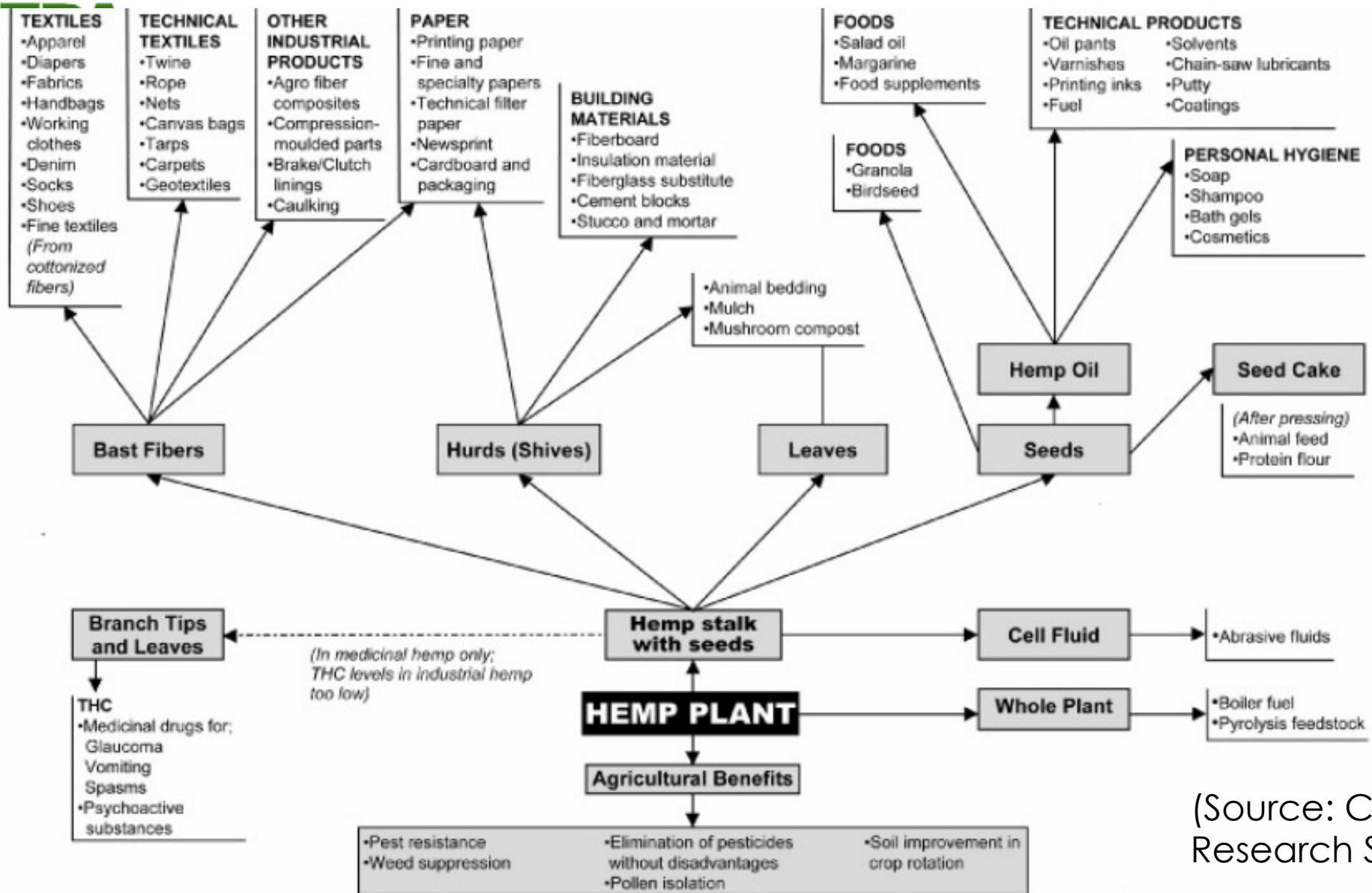
- Rely on data reviews from JMPR, EFSA or National Authority rather than a *de novo* U.S. review
 - In-depth review of report from competent authority
 - Tolerance = MRL from Codex, EU, or exporting country (No “extra” run through the OECD MRL calculator)
 - Compound generally must have food-use registration in the U.S.



Hemp Definition

- Hemp is the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.
- Marijuana has THC >0.3 and remains federally illegal

Uses for Industrial Hemp



(Source: Congressional Research Service, 2018)



2018 Farm Bill - Enacted

- Removes hemp from Schedule I of the controlled Substances Act; no longer a controlled substance.
- Phases out the 2014 Farm Bill industrial hemp pilot
- Amends the Agricultural Marketing Act of 1946 to allow for regulation of hemp
- Contains provisions to ensure the free flow of hemp in interstate commerce



EPA's Position on Hemp

- EPA recognizes hemp as a new and important crop to the U.S. economy
- EPA will apply the best available science to its regulatory decisions and is committed to strong engagement with all stakeholders.



Hemp Pesticides

- There are no pesticides registered by EPA specifically for use on cannabis or marijuana.
- Some pesticide labels do list hemp among listed crops.
- Currently, there are no tolerances established for hemp.
- EPA will use “hemp” on pesticide labels.



Hemp Registrations

- EPA has committed to a timely review of any pesticide registration action for use on hemp
 - As of July 2019, EPA had received 10 applications under FIFRA
 - Seeking comment via Federal Register notice of receipts
 - Most are microbials and biologicals, which tend to have low impact on the environment



HEMP Data Requirements

- EPA is collaborating with industry and USDA's Interregional Research Project #4 (IR-4) to identify and generate data needed to support pesticide registrations.
- EPA and IR-4 are also in active discussions on data generation to support establishing tolerances, which are required for hemp used for food or human ingestion (therapeutic oils)