



# Pesticide Synergy

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

NOVEMBER 1, 2017

# Outline

- ▶ Background
- ▶ Patent Focus
- ▶ Proposed Process
- ▶ Next Steps

# Background

- ▶ Definition – Great Than Additive (GTA)
  - ▶ Observed combined effect is greater than the sum of effects of individual chemicals
- ▶ Historical Practice - single active ingredients
- ▶ National Research Council (NRC 2013)
  - ▶ GTA effects are rare across a variety of chemicals
  - ▶ Agency should consider interactions when the best available scientific evidence support the quantitative evaluation.

# Background

- ▶ In 2015, EPA discovered registrants have been granted patents by USPTO for claims of synergy (GTA effects) towards pest species.
- ▶ EPA has been following a process to obtain and analyze patent claims of GTA effects in mixtures of pesticide active ingredients.

# Focus on Patents – Why?

- ▶ There are a large number of US patents making GTA effects claims
- ▶ Patent supporting documents are readily available
- ▶ USPTO process is well understood
- ▶ The mixtures, conditions of testing, effects observed, and organisms evaluated can be readily determined
- ▶ Data likely represent the most compelling evidence to support a GTA effects claim

# Focus on Patents

## To receive a patent

- The invention must be "**non-obvious**"
- GTA must be **unexpected or surprising**
- "USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure."

<https://www.uspto.gov/web/offices/pac/mp/ep/mpep-2100.pdf>

## To use GTA evidence to quantitatively evaluate risk

- Must be subject to the standards for the use of other toxicological data:
  - Relevant to the assessment endpoints
  - Must be supported by empirical data
  - The empirical data must meet Agency standard for data quality

# Focus on Patents

- ▶ So, does the granting of a GTA patent automatically mean the data are appropriate for ecological risk assessment use?
  - ▶ No – patent review is not equivalent to EPA data quality criteria.
- ▶ So, does that mean GTA patents are never pertinent to the ecological risk assessment?
  - ▶ No – experience has shown that some patents have sufficient information to inform risk assessments

# Proposed Process - Goals

- ▶ Document GTA patent claims
- ▶ Establish a data search and reporting approach so efforts are consistent in scope and format
- ▶ Establish criteria to narrow GTA patents to those relevant to Agency ecological risk assessments
- ▶ Provide a data analysis framework for evaluating the statistical significance of any GTA findings

# Proposed Process - Steps

- ▶ Step 1. Search for and identify granted US patents that make claims of GTA effects
- ▶ Step 2. Conduct a review of patent relevance to ecological risk assessment
  - ▶ Patent contains comparison of empirical effects
  - ▶ Effects are relevant to direct effects on tested taxa
  - ▶ Tested taxa are relevant to ecological risk assessment
  - ▶ Test data for chemical considered for regulation
  - ▶ Mixture components tested are registered in the US

# Proposed Process - Steps

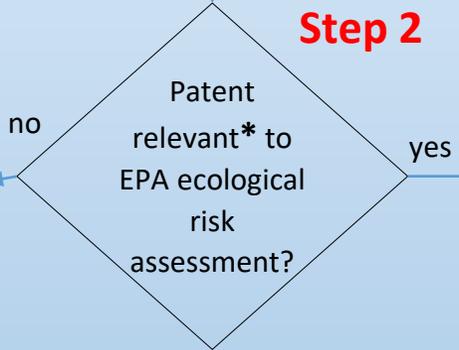
- ▶ Step 3. Effects testing data from relevant patents reported
- ▶ Step 4. Analyze the data to determine if observations of GTA effects are statistically significant
- ▶ Step 5. Evaluate
  - ▶ Do statistically significant observations impact the conclusions of ecological risk assessments?
  - ▶ Can statistically significant observations be used to inform quantitative adjustments to the ecological risk assessment or risk mitigation?
  - ▶ Are additional mixture toxicity data necessary?

Application to following pending registration decisions:  
 1. New chemical  
 2. Other new products or active ingredients for which EPA has specific concerns about potential GTA effects

EPA requests registrant supply information on U.S. patent claims of greater than additive effects.

**Step 1**  
 Registrants search and report chemical combinations for which US PTO granted a patent for an application with a claim of greater than additive effects.

Registrants report patent and relevancy criteria results. Irrelevant patent claims do not require further evaluation.



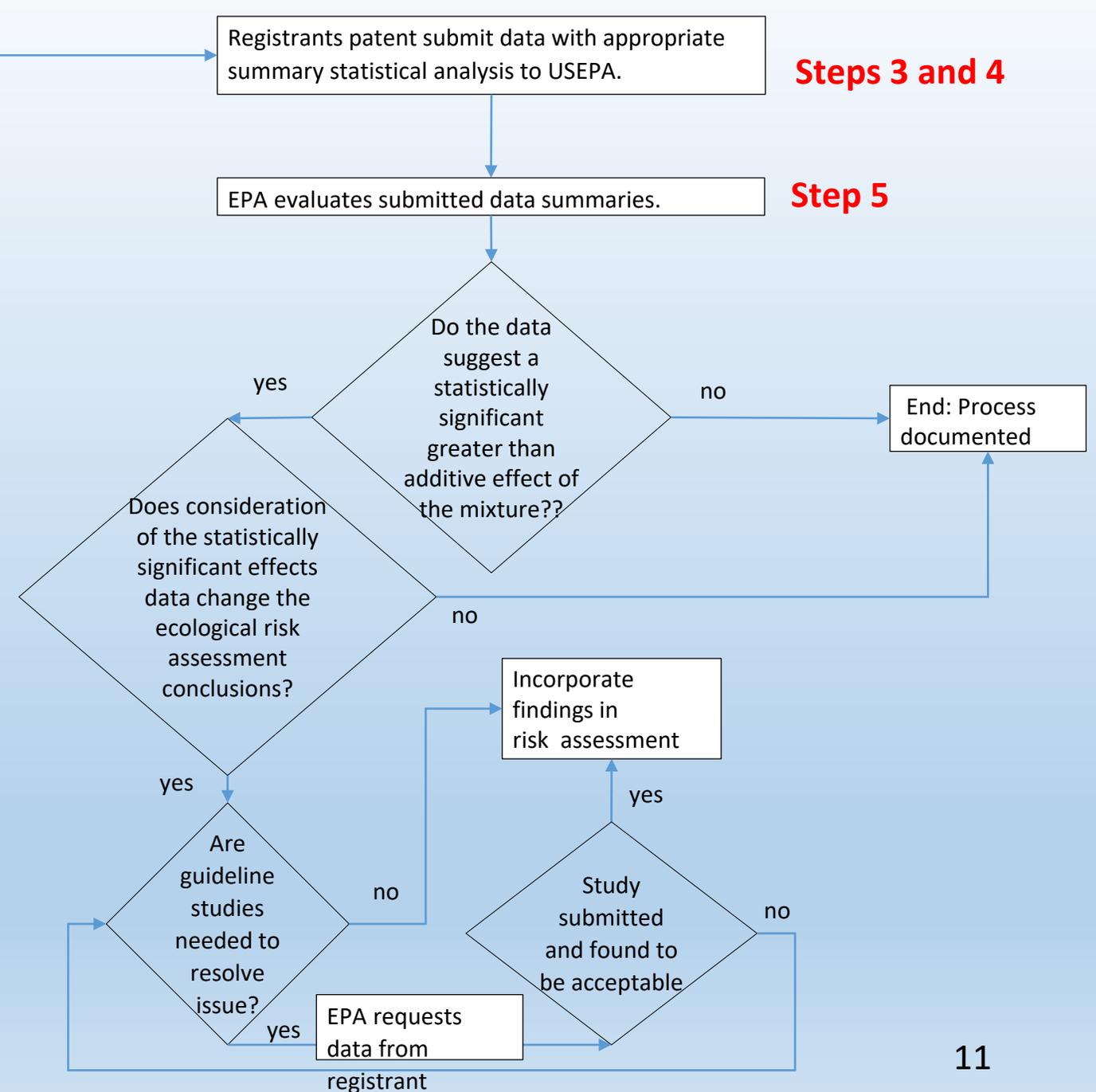
- \* Criteria for relevancy**
1. Patent contains comparison of empirical effects
  2. Effects relevant to direct effects on tested taxa
  3. Tested taxa are relevant to ecological risk assessment
  4. Test data for chemical considered for regulation
  5. Mixture components tested are registered in U.S.

Registrants patent submit data with appropriate summary statistical analysis to USEPA.

**Steps 3 and 4**

EPA evaluates submitted data summaries.

**Step 5**



# Proposed Process – What will we do with what we learn?

- ▶ EPA does not evaluate the USPTO decision on claims.
- ▶ EPA evaluates the data, using evaluation criteria for non-guideline studies, to determine if qualitative or quantitative changes are needed to the ecological risk assessment, or if additional studies are needed.
- ▶ EPA will consider the implications on its regulatory decision, and address this in proposed decision documents as part of the existing public process.

# Next Steps

- ▶ Continue to follow proposed process
- ▶ Publicly release memorandum describing process for public comment
- ▶ Develop a final position, considering:
  - ▶ Public comments
  - ▶ Cases evaluated following this process
- ▶ Release of final position on GTA effects of pesticides

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# Questions?

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