

The background of the slide is a dense, overlapping pattern of various-sized metallic gears. The gears are rendered in a light gray, semi-transparent style, creating a complex mechanical texture. The text is overlaid on this background in a bold, blue font.

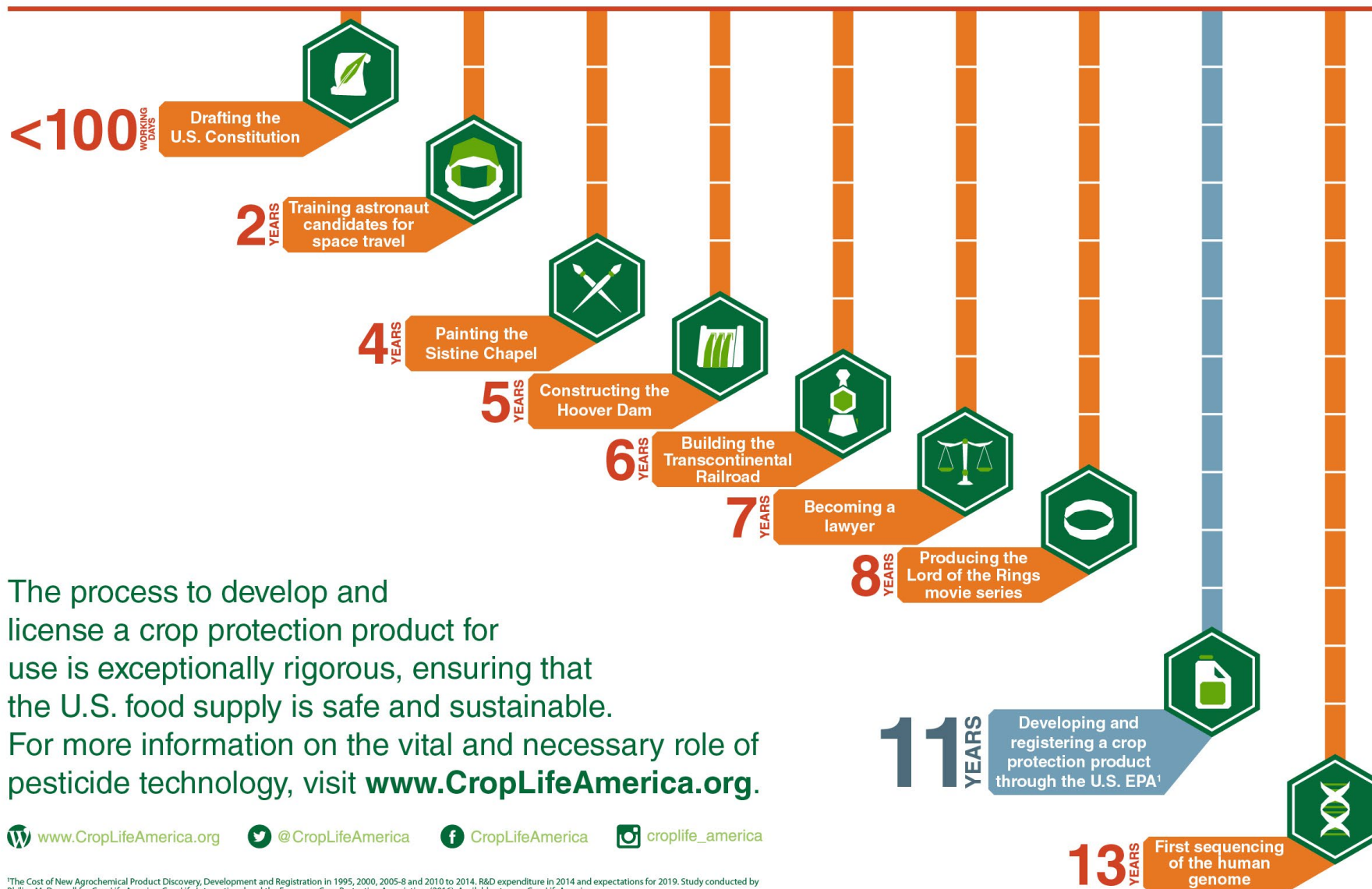
# **Federal and State Pesticide Registrations**

## **The Key Essentials**

**AAPCO Lab Directors Meeting  
March 4, 2025**



# How Long Does it Take for a Crop Protection Product to be Approved for Use?



The process to develop and license a crop protection product for use is exceptionally rigorous, ensuring that the U.S. food supply is safe and sustainable. For more information on the vital and necessary role of pesticide technology, visit [www.CropLifeAmerica.org](http://www.CropLifeAmerica.org).



# How and Why?

## ► The Science

Finding the right compounds and products



## ► The Rules

State and federal regulatory structure and requirements



## ► The Future

Challenges and opportunities in the pesticide regulatory world



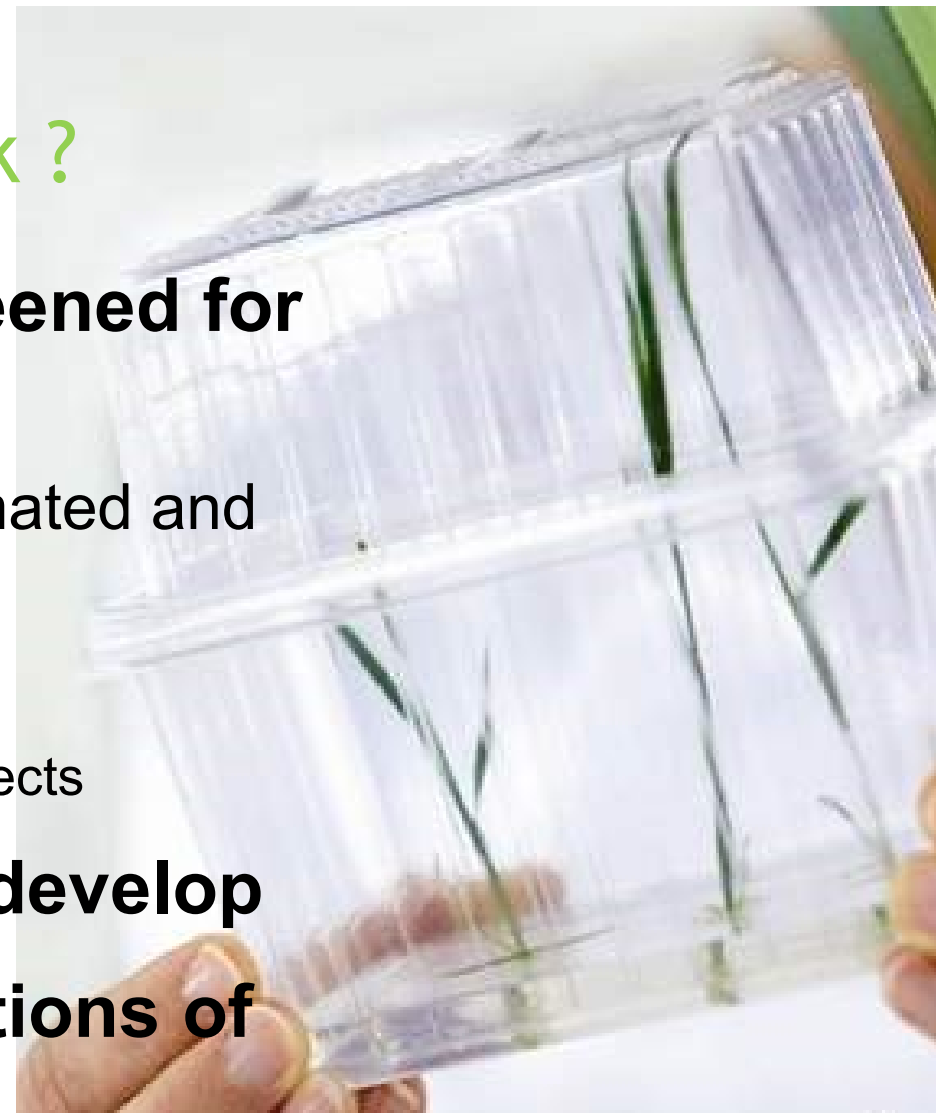


# THE SCIENCE

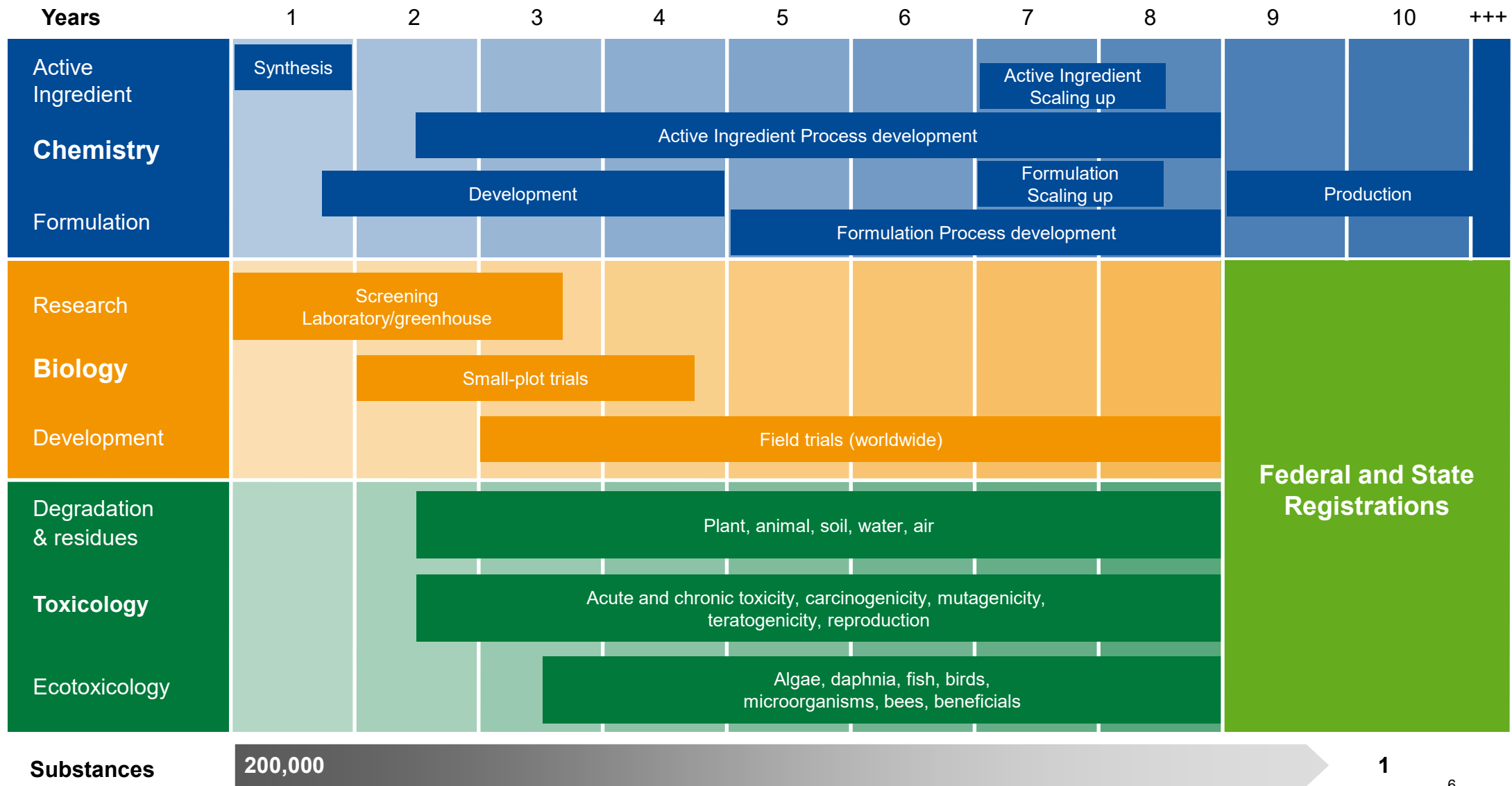
# Discovery Research - Screening

## Where is the needle in the haystack ?

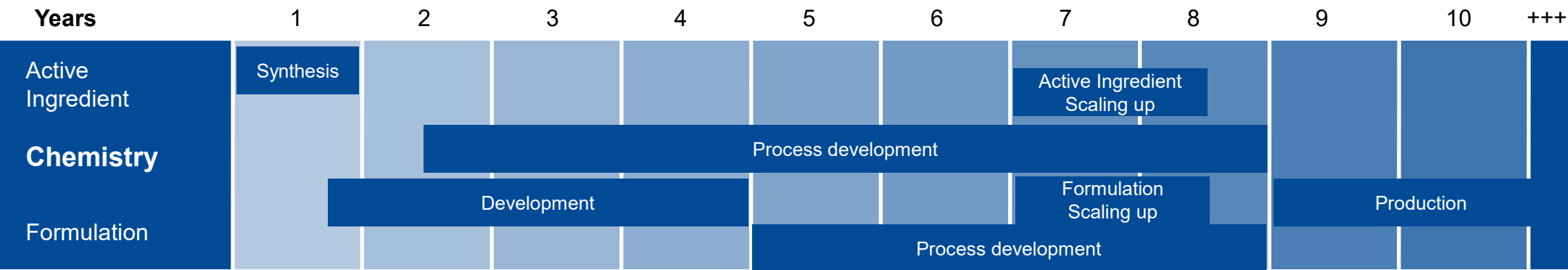
- **More than 200,000 compounds are screened for pesticide activity**
  - Early screening test systems are highly automated and miniaturized
    - Leaf fragments instead of whole plants
    - Insect eggs and larvae as model organisms for insects
- **Partner Companies – acquire rights to develop**
- **Chemical Analogs – chemical modifications of known compounds**



# Development of a crop protection product



# Development of a crop protection product



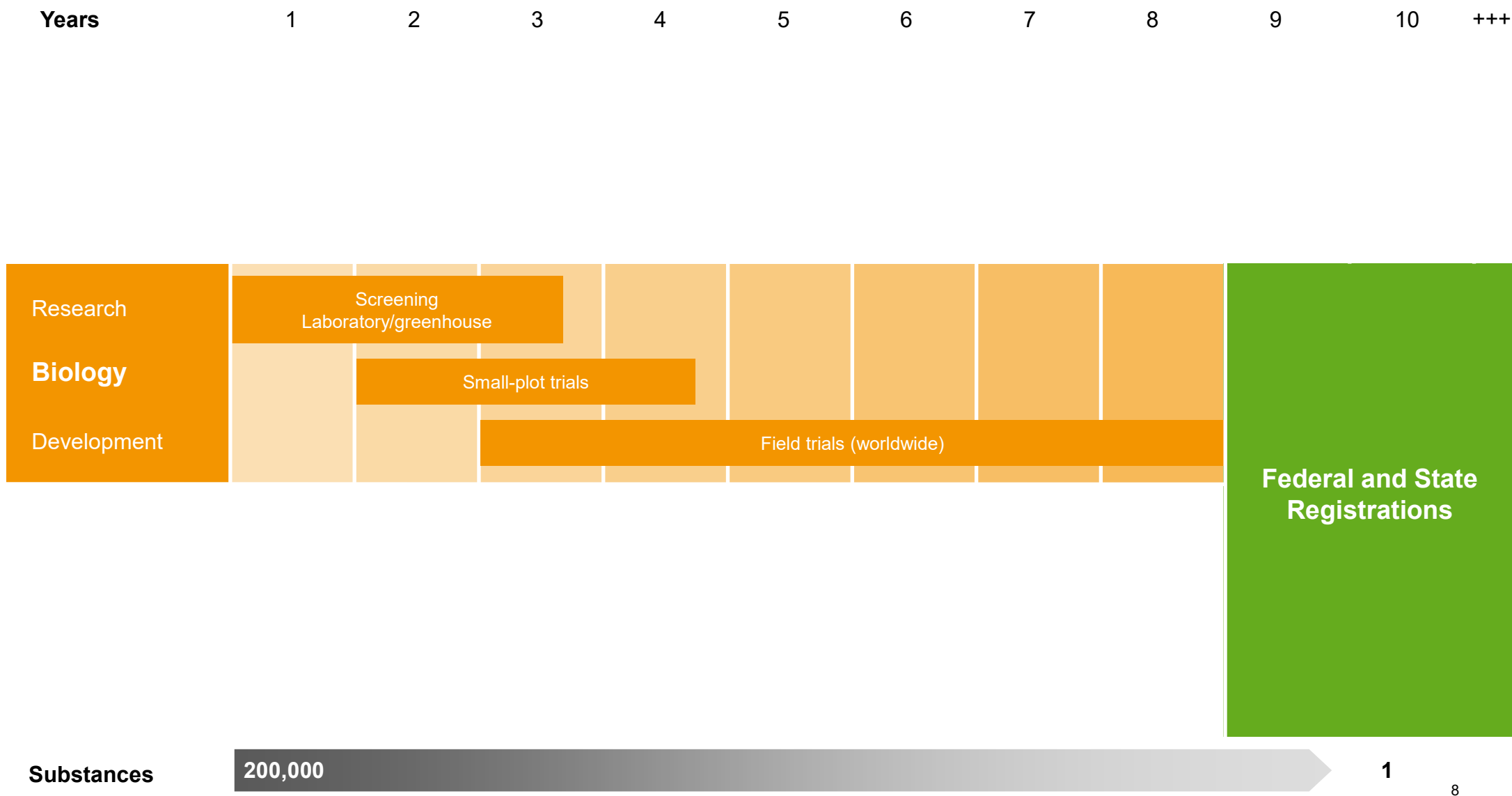
Substances

200,000

1

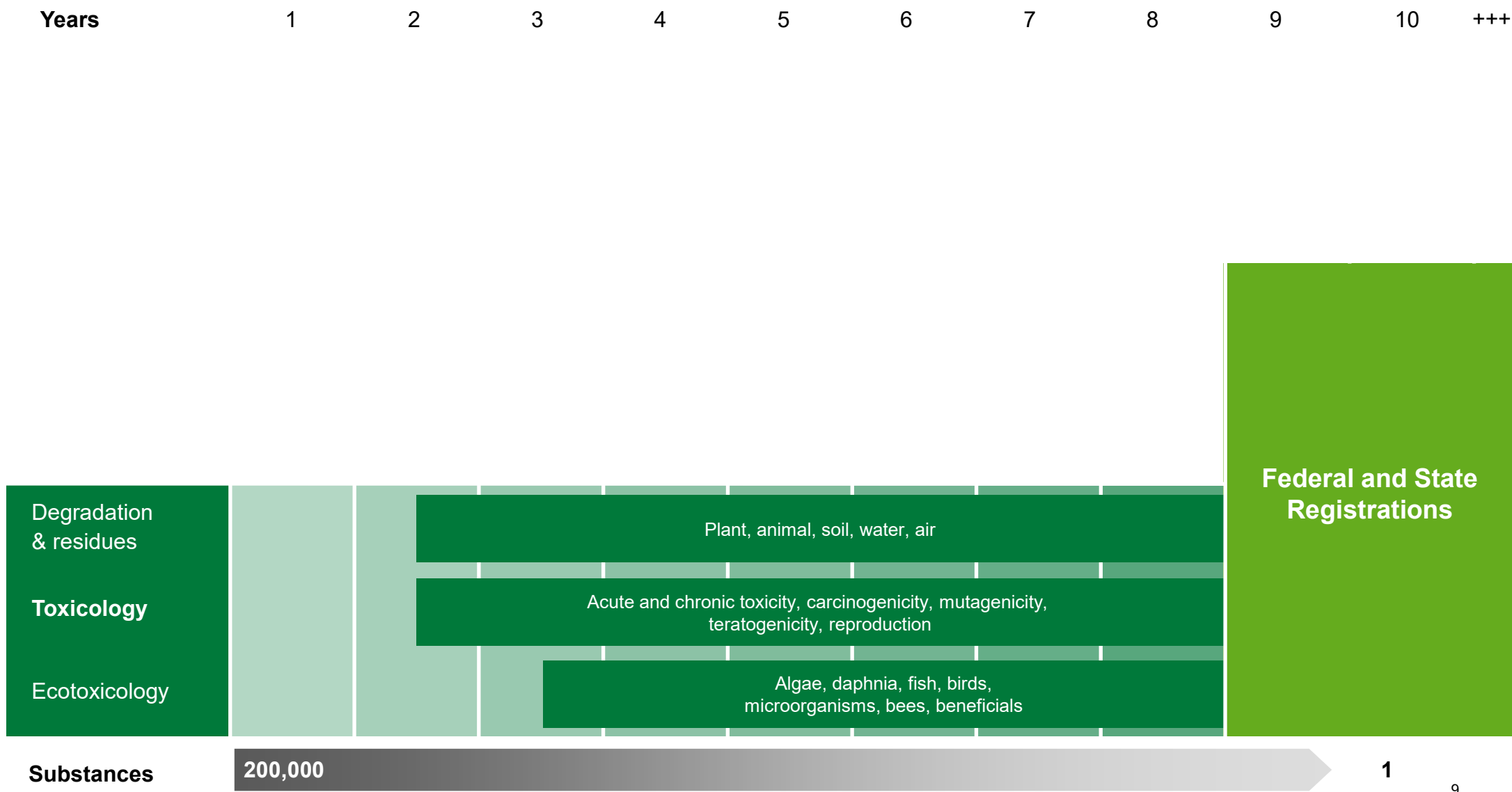
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# Development of a crop protection product

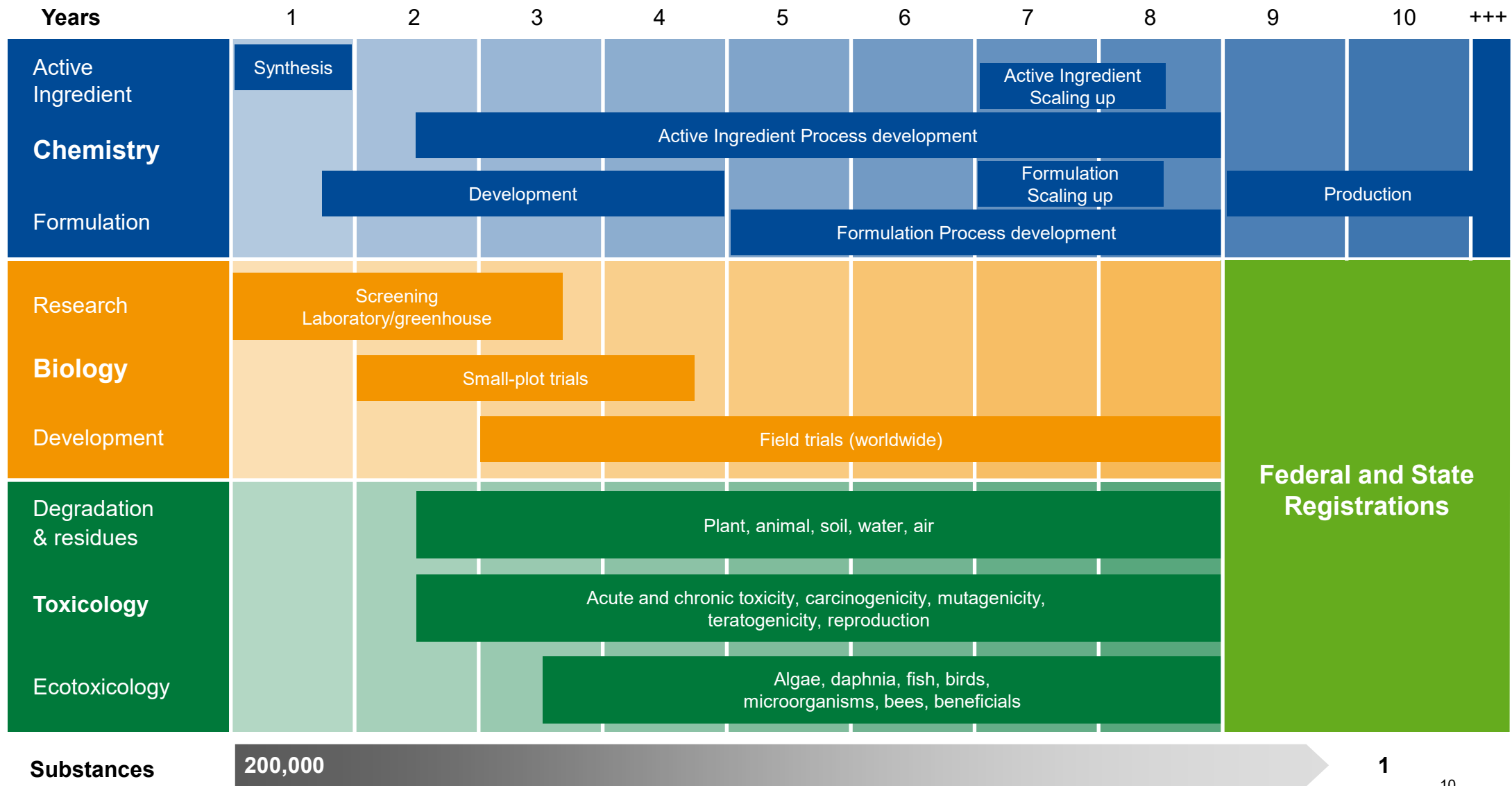




# Development of a crop protection product



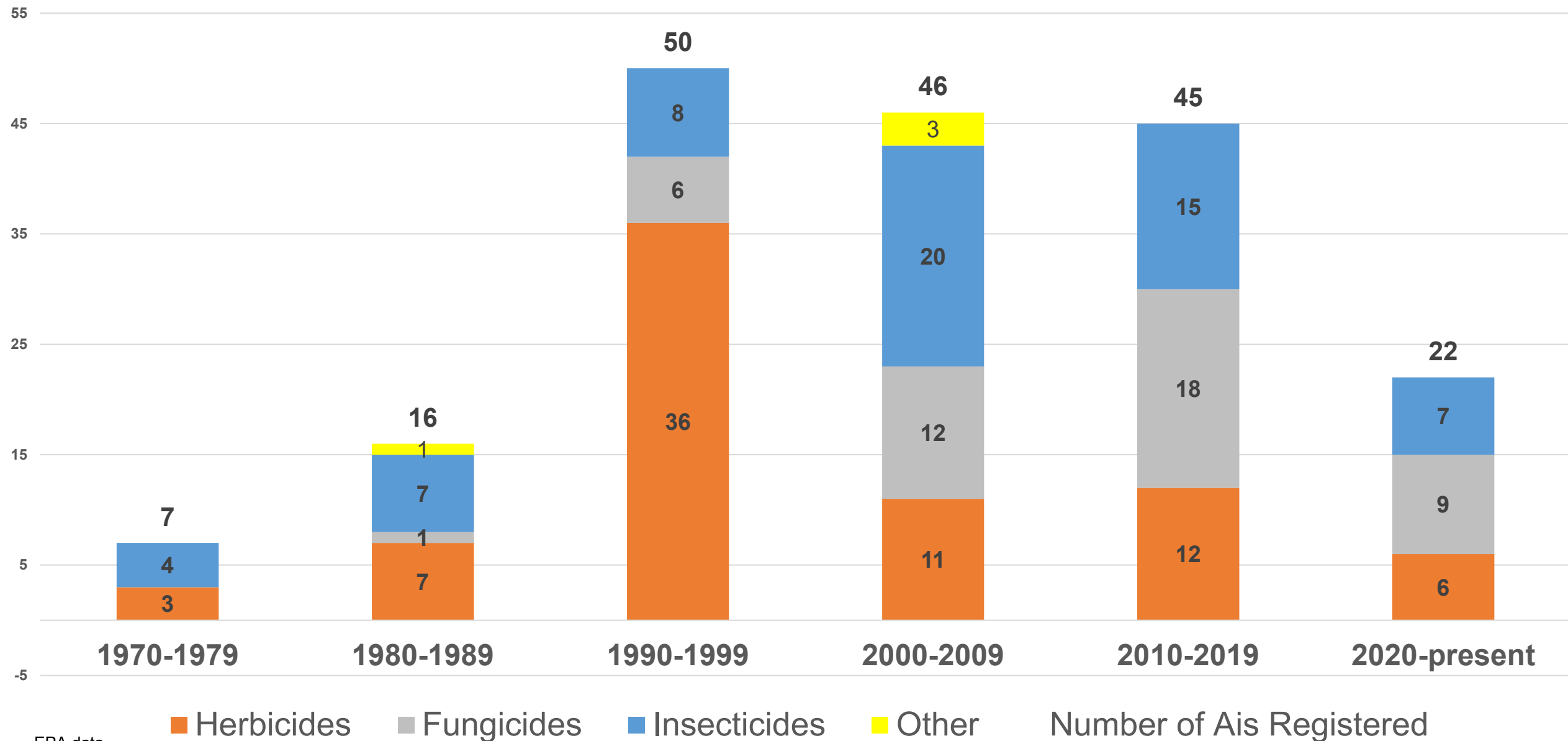
# Development of a crop protection product



# THE RULES



# Total Active Ingredients Registered by US EPA by Decade



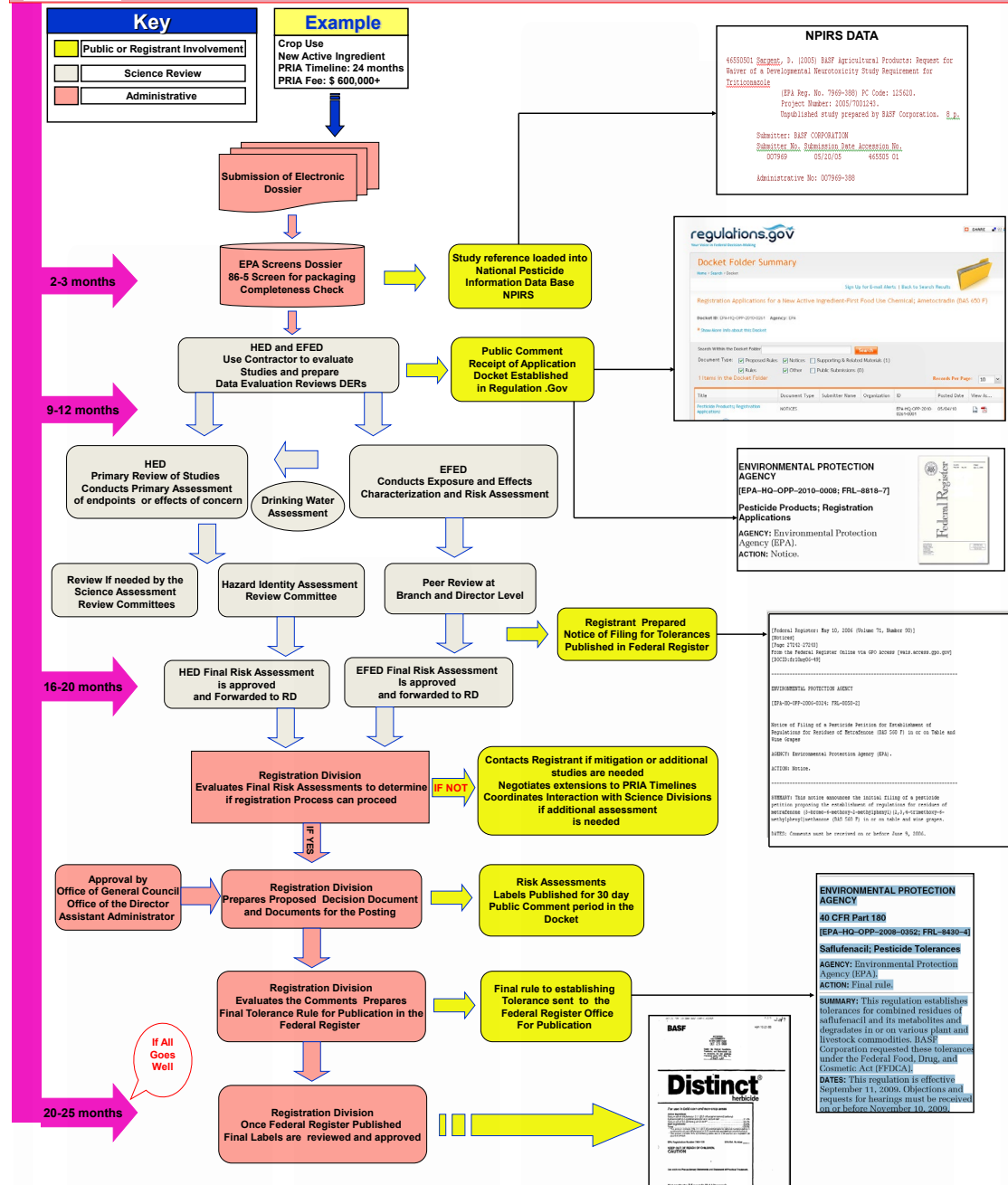
# What does EPA do?

- ▶ Data Requirements for Pesticide Registration
  - ❖ Product Chemistry
  - ❖ Product Performance
  - ❖ Data from Studies that Determine Hazard to Humans and Domestic Animals
  - ❖ Data from Studies that Determine Hazard to Nontarget Organisms
  - ❖ Post-Application Exposure Studies
  - ❖ Applicator/User Exposure Studies
  - ❖ Pesticide Spray Drift Evaluation
  - ❖ Environmental Fate
  - ❖ Residue Chemistry
- ▶ Data Matrix (list of all studies/data fulfilling a data requirement)
- ▶ Benefits Document
- ▶ Reduced Risk Rationale (if appropriate)
- ▶ Application Forms
- ▶ Labels - the label is the law!

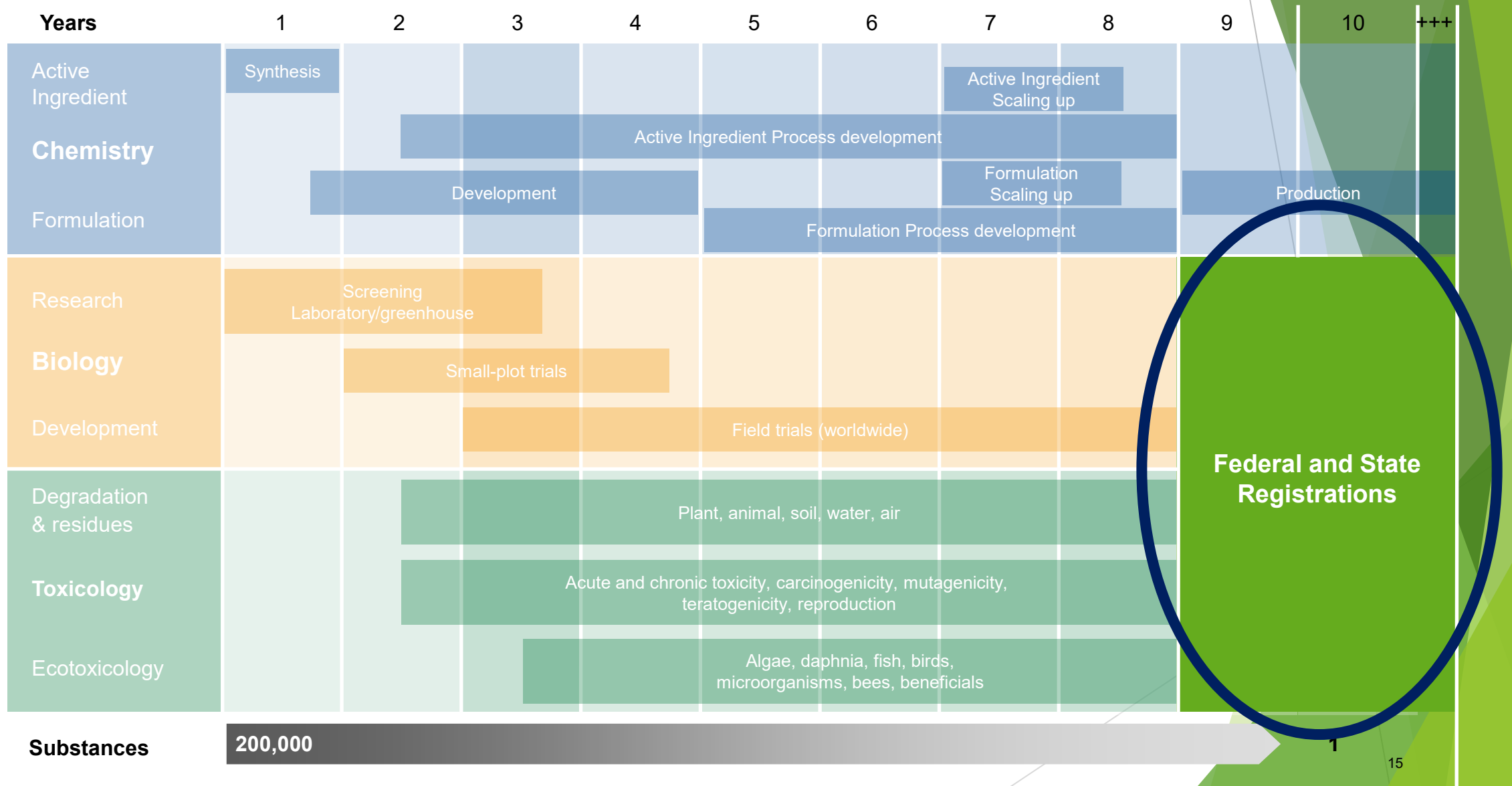




# US EPA Regulatory Process



# Development of a crop protection product



# Master label is approved at EPA

## Now what?

- BASF may make a subset of the Master labels as Container label

TRITICONAZOLE	GROUP	3	FUNGICIDE
PYRACLOSTROBIN	GROUP	11	FUNGICIDE

# Pillar® SC

## Intrinsic® Brand Fungicide



For disease control and plant health in turfgrass

**Active Ingredients\*:**

triticonazole: (1RS)-(E)-5-[[[4-chlorophenyl]methylene]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol]	17.95%
pyraclostrobin: (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester)	15.80%
<b>Other Ingredients:</b>	66.25%
<b>Total:</b>	100.00%

\*Pillar® SC Intrinsic® brand fungicide contains 1.67 lbs triticonazole and 1.47 lbs pyraclostrobin per gallon.

EPA Reg. No. 7969-XXXX EPA Est. No.

**KEEP OUT OF REACH OF CHILDREN**  
**WARNING/AVISO**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand this label, find someone to explain it to you in detail.)

See full label for complete **First Aid, Precautionary Statements, Directions For Use, Conditions of Sale and Warranty**, and state-specific crop and/or use site restrictions.

In case of emergency endangering life or property involving this product, call day or night 1-800-832-HELP (4357).

**ACCEPTED**  
09/27/2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7969-480

Net Contents:

# Pillar® SC

## Intrinsic® Brand Fungicide

TRITICONAZOLE	GROUP	3	FUNGICIDE
PYRACLOSTROBIN	GROUP	11	FUNGICIDE

For disease control and plant health in turfgrass

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EPA Reg. No. 7969-480

EPA Est. No. 51036-GA-001

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Net Contents: **1.36 Quarts**  
(43.5 Fluid Ounces)



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# State Registrations

## ► **Submission to states for registration**

- ❖ Registration required prior to sales and distribution
- ❖ Decision on state priority list, submission in waves vs one time submission to all states
- ❖ Application for registration with supporting documents via State Website, Kelly, ALSTAR etc
- ❖ State registration specialist reviews, seeks clarification and approves the label
- ❖ Timeline varies from 1 to 4 months with a few exceptions (eg: CA, FL, NY)

## ► **Brand New product versus Label revision submissions**

- ❖ Brand New product require the submission of additional data to some states (eg: AZ, FL, NY, HI, CA)
- ❖ More review time
- ❖ Some states require Confidential Statement of Formula (eg: WA), reviews at different branches, submission of analytical standards etc

# Analytical Standards

- ▶ **Technical grade active ingredients (TGAI)**
- ▶ **Regulated metabolites and degradates**
- ▶ **EPA require submission of standards at registration to be kept at National Pesticide Standard Repository**
  - ❖ Volume ~ 100-250 mg
  - ❖ EPA reaches out to registrant when batch expires or low volume
- ▶ **Standards can be used to:**
  - ❖ Test presence of undeclared a.i.s
  - ❖ Test food or feed samples to test if pesticide residue exceed the maximum allowable limit
  - ❖ Analysis of air, water and soil from monitoring or permit enforcement
- ▶ **State-specific information**
  - ❖ Purity of A.I, lot number, expiration data, COA, SDS, storage instructions
  - ❖ MN, OK, WI, FL requires submission from registrant





# State Registration Maintenance

## Renewal, Discontinuance, Cancellations

- ▶ All states require registrants to renew pesticides on a regular basis (75% at year-end)
- ▶ Once production is stopped for a product, we allow enough time for the products to clear the channels of trade
- ▶ Some state require a discontinuation period (~2 years) while others may allow immediate cancellation.
- ▶ Every product is actively supported for stewardship purposes to ensure safe use and handling

# Types of Pesticide Labels

## ■ Section 3

- Most registrations fall under this category, supplemental labeling

## ■ Section 24(c)

- State-specific registration for a special local need (mainly additional uses for a registered pesticide)

## ■ Section 18

- Emergency exemption from registration for emergency pest situations that could cause significant economic impact or public health with no alternatives. Registrants don't make submissions

## ■ Section 2ee

- Exceptions to FIFRA (pest addition, dosage reduction, application with fertilizer, application method unless prohibited by label)

## ■ Section 5

- Experimental use for trials in areas >10 acres

## ■ Section 25(b)

- Minimum risk pesticide products (eg: lemongrass oil)

# Regulatory Challenges in the Pesticide World

## Federal Level

- ▶ Increased workload (registration review, new uses, new sources)
- ▶ Legal challenges to EPA's registration decisions and processes
  - ❖ Endangered Species Act assessments
  - ❖ Treated seed exemption challenges
  - ❖ Endocrine Disruption Screening Program
- ▶ Limited resources
- ▶ Covid-19, federal shutdowns

# Regulatory Challenges in the Pesticide World

## State Level

- ▶ Local ordinances resulting in patchwork regulations across a state
- ▶ Challenges to preemption
- ▶ Legislative pushes for bans, further use/ai restrictions
- ▶ Notification/permission before application



# Opportunities

- ▶ Digital labeling/e-labeling
- ▶ Artificial Intelligence
- ▶ Smart sprayer technology
- ▶ Drones
- ▶ Biologicals
- ▶ Herbicide tolerance
- ▶ Continued pipeline of new active ingredients
- ▶ Continued focus on stewardship

A wide-angle photograph of a two-lane asphalt road stretching into the distance. Three large white arrows are painted on the road, pointing towards the horizon. The sky is bright blue with scattered white clouds, and a soft golden glow emanates from the horizon where the sun is setting or rising.

# THANK YOU!

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