

EPA Pesticide Registration and data compensation in USA

– A Case Study of Prothioconazole



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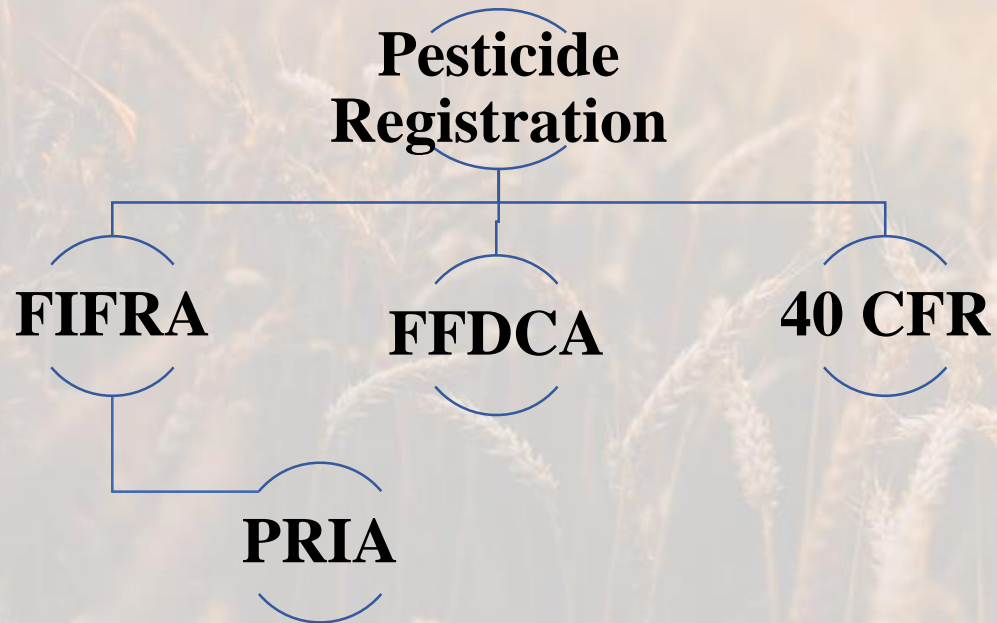
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Pesticide Introduction

- Regulations

- Registration Process

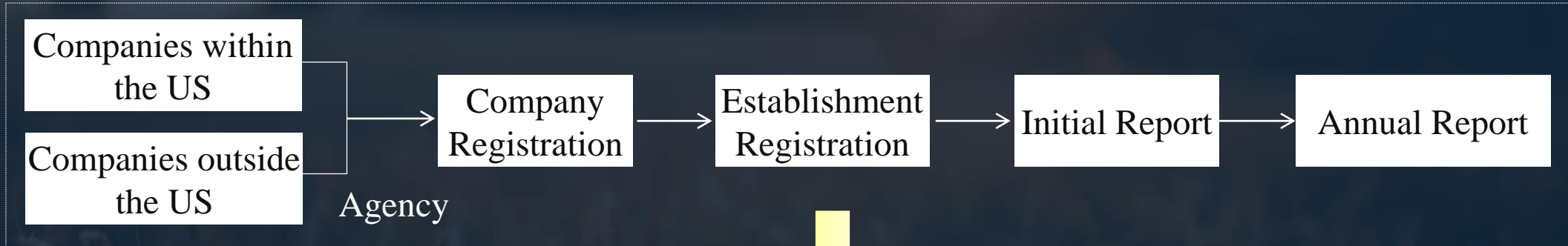
Regulations



- **FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act**
- **PRIA: Pesticide Registration Improvement Act**
- **FFDCA: Federal Food, Drug and Cosmetic Act**
- **Code of Federal Regulations ("40 CFR")**

Registration Process

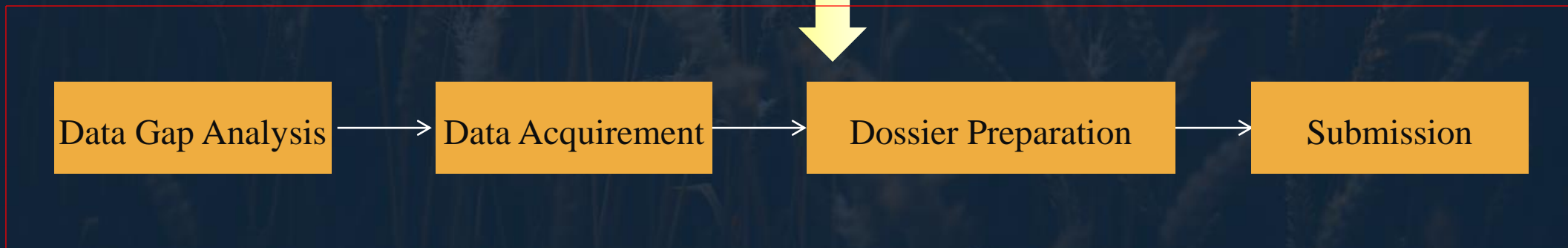
Stage 1



Stage 2



Stage 3



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Registration strategy

—Prothioconazole

- Product Analysis
- EPA Evaluation Process
- Data Analysis
- State Registration

Current Registration Status

Prothioconazole

First Registration

- In 2007
- Fungicide

MP Registration

- 1 approval
- Registrant: Bayer

EPA Registration

- 17 approvals
- Registrant: Bayer, BASF, Loveland Products

Potential Registration

- MP: ADAMA, INMES, SHARDA, LIFE SCIENTIFIC
- EP: BASF, SHARDA, MAKHTESHIM AGAN, ALBAUGH



Usage Analysis

Date: May 11, 2015

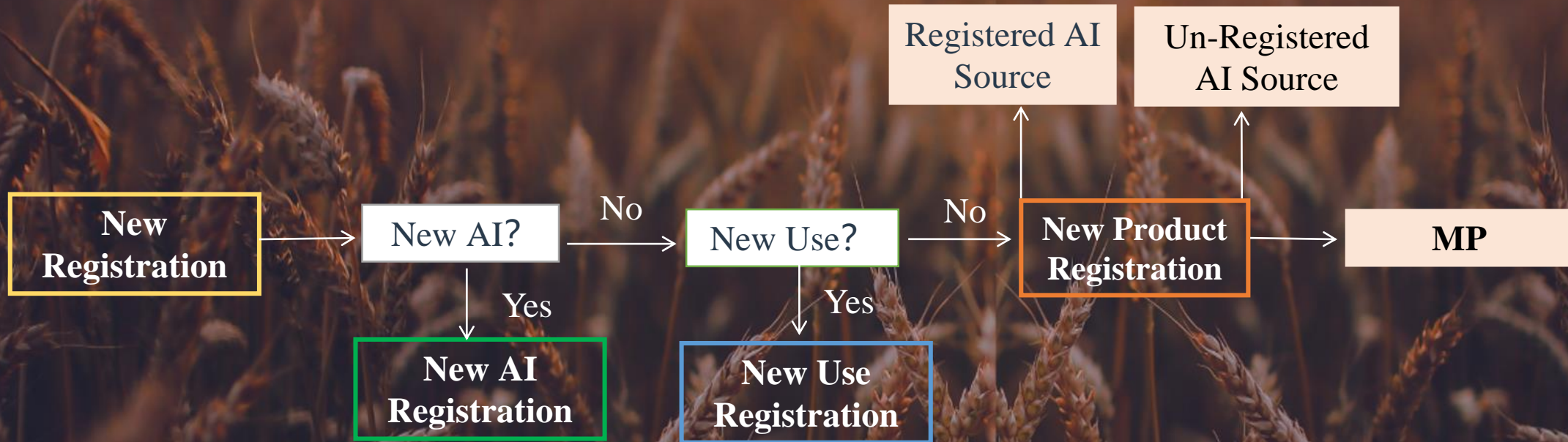
Screening Level Estimates of Agricultural Uses of Prothioconazole (113961)

Sorted Alphabetically

Reporting Years: 2004-2013

	Crop	Average Annual	Percent Crop Treated	
		Lbs. A.I. Applied	Average	Maximum
1.	Barley	3,000	<2.5	<2.5
2.	Beans, Green	<500	<1	<2.5
3.	Corn	40,000	<2.5	<2.5
4.	Dry Beans/Peas	20,000	5	10
5.	Peanuts	30,000	15	20
6.	Soybeans	10,000	<1	<2.5
7.	Sugar Beets	30,000	15	30
8.	Sweet Corn	<500	<2.5	<2.5
9.	Wheat	100,000	5	5
10.	Wheat (Seed Treatment)	1,000	<1	<2.5

Registration Actions for MP



Action Code	Description	Decision Time	FY21 Fee
R332	Un-registered AI source, new generic data package.	24 months	\$297,376
R333	Un-registered AI source. Cite-all or selective data citation where applicant owns all required data	10 months	\$20,830
R334	Un-registered AI source. Selective data citation.	11 months	\$24,255

Data Requirements



- ✓ **New studies**
- ✓ **Data citation & data bridge**
- Existing registration data
- Public data
- ✓ **Data waivers**
- ✓ **Expert assessment**
- Exposure assessment
- Endocrine disruption assessment

Categories of Data

Exclusive-Use Data

- ❖ Initial registration of a new AI, or a new combination of AIs;
- ❖ Amend the original registration to add a new use;
- ❖ Protection of 10 years after the date of the initial registration;
- ❖ Written authorization is needed.

Compensable Data

- ❖ Application data;
- ❖ 15-year compensatory period begins on data submission date;
- ❖ Offer to pay.

Other Data

- ❖ Data out of protection;
- ❖ Public literature;
- ❖ Government-generated studies.

Existing Registration Data

Prothioconazole

➤ Initial Registration

➤ Addition of New Use

➤ Registration Review

- First registered in 2007. Data submitted during 2004-2007.
- No exclusive-use data.
- Most data already out of protection.
- A minor portion of data is compensable.

Data Categories	Product Chemistry	Toxicology	Exposure	Residue	Ecological Effects	Environmental Fate
Exclusive-use Data						
Compensable Data			√	√		
Other Data	√	√	√	√	√	√

Existing Registration Data

Prothioconazole

- Initial Registration
- **Addition of New Use**
- Registration Review

- During 2010-2013, new uses were applied for Prothioconazole containing pesticides.
- New use: low growing berry (except strawberry), bushberry, and cucurbit vegetable subgroups.
- No exclusive-use data.
- All new use data are compensable.

Data Categories	Product Chemistry	Toxicology	Exposure	Residue	Ecological Effects	Environmental Fate
Exclusive-use Data						
Compensable Data			√	√	√	
Other data						

Existing Registration Data

Prothioconazole

- Initial Registration
- Addition of New Use
- **Registration Review**

Reregistration Program

- ❑ Completed in 2008
- ❑ Registered before 1984
- ❑ Reregistration Eligibility Decision (RED)

Not performed

Registration Review

- ❑ Plan to completed in 2022
- ❑ Registered before October 1, 2007
- ❑ Docket: work plan, registration decision, etc.

Existing Registration Data

Prothioconazole

- Initial Registration
- Addition of New Use
- **Registration Review**

- Open Docket in December 2015.
- Conduct comprehensive ecological risk assessment, post-application residential risk assessment.
- Dietary and occupational risk assessment not performed.
- GDCI issued in 2017 for ecological effects and environmental fate data.
- All data support the registration review are compensable.

Data Categories	Product Chemistry	Toxicology	Exposure	Residue	Ecological Effects	Environmental Fate
Exclusive-use Data						
Compensable Data				√	√	
Other Data						

Existing Registration Data

1. Company Name and Address		2. Case # and Name			3. Date and Type of DCI and Number				
BAYER CROPSCIENCE LP 2 T.W. ALEXANDER DRIVE, P.O. Box 12014 RESEARCH TRIANGLE PARK, NC 27709		N/A - Prothioconazole Chemical # and Name: 113961 Prothioconazole			24-Jul-2017 GENERIC ID # GDCI-113961-1613				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Environmental Fate Data Requirements (Conventional Chemical)								
835.4100	Aerobic soil metabolism (14)	N				I,C,A	TGAI	24	
835.4400	Anaerobic aquatic metabolism (17)	N				I,C,A	TGAI	24	
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.2100	Avian acute oral toxicity test (11, 13, 26)	Y				I,C,A	Degr	12	
850.1010	Aquatic invertebrate acute toxicity, test, freshwater daphnids (11)	N				I,C,A	DEGR	12	
850.1025	Oyster acute toxicity test (shell deposition) (10)	N				I,C,A	DEGR	12	
850.1035	Mysid acute toxicity test (10)	N				I,C,A	DEGR	12	
850.1075	Fish acute toxicity test, freshwater and marine (11, 15)	N				I,C,A	DEGR	12	

Data Submitters



Companies

- **Bayer**
- **BASF**



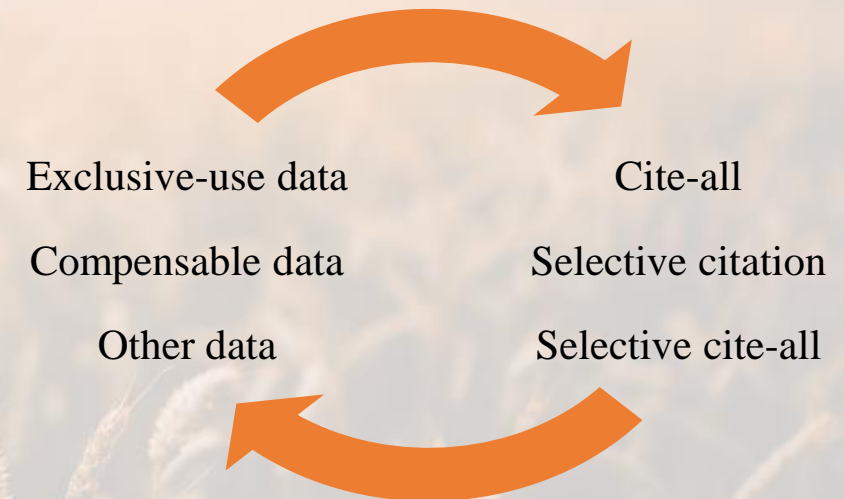
Task Forces

- **U.S. TRIAZOLE TASK FORCE**
- **Spray Drift Task Force**
- **Outdoor Residential Exposure Task Force**
- **Agricultural Reentry Task Force**
- **Agricultural Handler Exposure Task Force**

Data Compensation Strategy

Prothioconazole: Cite-all

- No exclusive-use data
- Most data for initial registration already out of protection
- Only one data submitter other than task forces



- Written authorization is needed for exclusive-use
 - Data compensation to compensable data, no pre-authorization is needed.
- No data compensation agreement is required before registration submission or approval.

Data Compensation Fee Estimation

Data Package



- ❖ Initial registration data
- ❖ New use data
- ❖ Registration review data

Data Package Fee



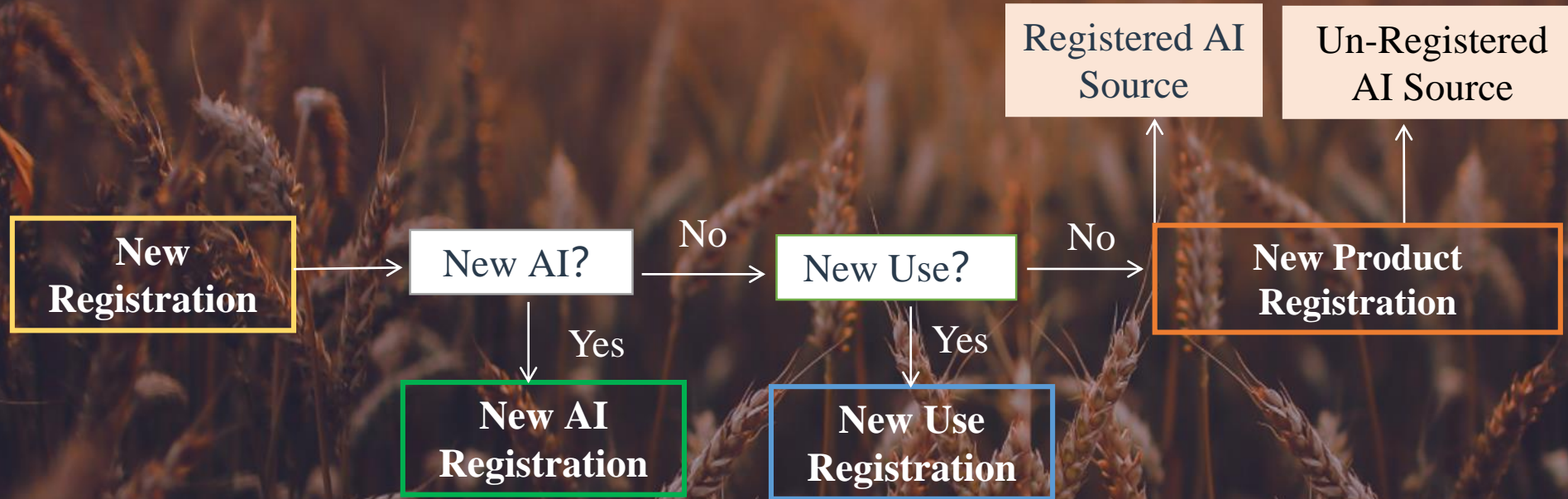
- ❖ Testing fee
- ❖ Testing monitor fee
- ❖ Inflation & interest
- ❖ Cost estimates from EPA

Fee Share



- ❖ Divided per capita (e.g., number of data citers)
- ❖ Protection period remaining
- ❖ One-time vs. multiple use

Registration Actions for EP



Action Code	Description	Decision Time	FY21 Fee
R300/R301	Identical or substantially similar in composition and use to a registered product, cite-all/selective data citation	4 months	\$1,662/\$1,992
R310	New product registration with registered AI source	7 months	\$7,667
R334	New product registration with new physical form	12 months	\$13,888

Data Requirements



MP

❖ Formulator's Exemption

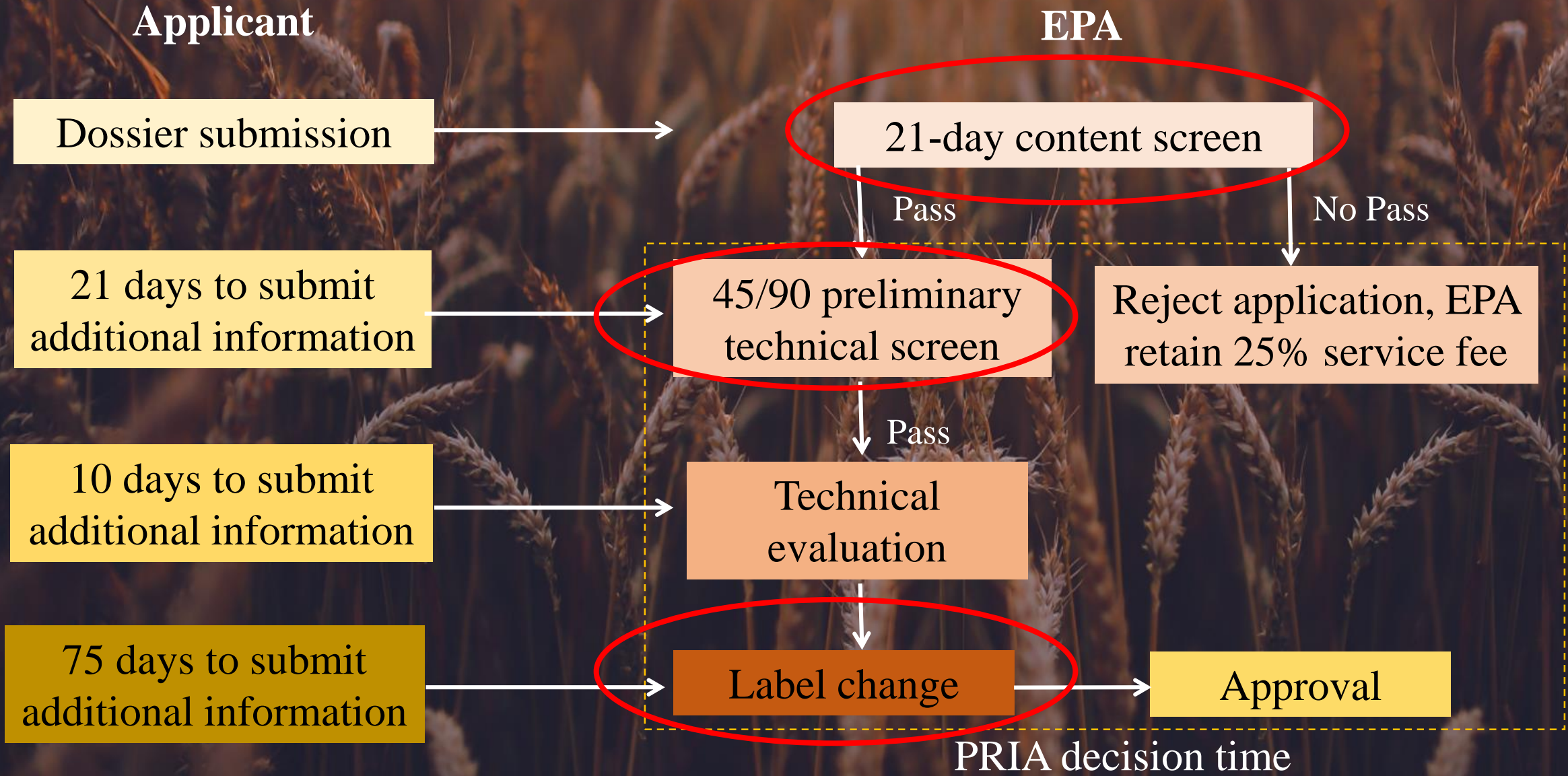


EP

❖ Product Chemistry

❖ Acute Toxicity

EPA Review Procedures



State Registration

- State registration must be done before placing the product in the state market;
- The review period ranges a few days to a few months;
- The review fee ranges from tens of dollars to thousands of dollars;



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Summary

Game of Data

