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**Series V - Other Ingredients and  
Their Roles in Crop Protection**

**Changes in Regulations for Inerts:  
New TSCA, Prop 65, and Ingredient  
Disclosure**

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## Topics

- **New Toxic Substances Control Act (TSCA)**
  - Changes in law
  - Changes in the U.S. Environmental Protection Agency's (EPA) approach
  - What to expect from premanufacture notices (PMN)
- **Prop 65**
  - New warning regulations
  - Compliance strategies
- **Ingredient Disclosure**
  - New York and California

## Changes to TSCA

- Frank R. Lautenberg Chemical Safety for the 21st Century Act enacted on June 22, 2016
- Changes to Section 5 effective immediately
- Section 5(a)(3) requires EPA to make a determination on each new chemical (or significant new use)

## Section 5(a)(3) Determinations

- EPA must determine if each case
  - (A) Will present
  - (B) May present (including insufficient information and exposure-based findings)
  - (C) Not likely to present  
unreasonable risk to health or environment under intended or reasonably foreseeable conditions of use
- If “will present” or “may present,” EPA must issue a consent order regulating “to the extent necessary” and issue a Significant New Use Rule (SNUR)
- New chemicals may not proceed to commercialization until EPA has made its determination and taken any necessary actions

# Changes to TSCA New Chemicals -- Expected and Unexpected

Expected	Unexpected
More regulatory actions	Vast majority regulated
Reviews taking 90-180 days	Substantial delays
Risk-based “not likely” determinations	Hazard-based “not likely” determinations
	Insufficient information determinations for inhalation hazards

## New Chemicals Review and Timing

Old TSCA	New TSCA
<i>ca.</i> 80% not regulated (“drop” cases)	<10% not regulated (“not likely” cases)
Drops and non-5e SNURs: 90 days	Not likely: probably less than 60 days
Standard consent orders: <180 days	Consent orders: at least 90 days, typically >120 days
Exemption notices: 30 days	Non-order SNURs: timeframe unknown
	Exemption notices: 30-60 days

## Why the Changes?

- Regulating except in case of low hazard for health and low hazard for ecotoxicity (“low/lows”)
  - EPA views this as necessary given what it views as “reasonably foreseen”
- Begs the questions:
  - What is “not likely”?
  - How is “reasonably foreseeable” different from “any conceivable”?

## Results of Changes

- Protective conditions commonly include:
  - Required personal protective equipment (PPE)
  - Required hazard communication (that may deviate from the Globally Harmonized System of Classification and Labeling of Chemicals (GHS))
  - Surface water release limits
  - Import only
  - Use as specified in the PMN
- Begs the question:
  - What is the “extent necessary”?



## What Does This Mean for Innovators?

- Much worse new chemical bias
- If not low/lows
  - Plan for substantial delays
  - Be prepared to deal with restrictions
  - Little if any value in pollution prevention statements
- Sustainable Futures/Project XL no longer provides any relief to review time
  - Either “not likely” and shorter than 90 days or much longer than 90 days

## Other Problems

- Errors in hazard, exposure, and risk assessments
  - Misinterpretation of no effect vs. no adverse effect levels in toxicity studies
  - Lack of understanding of substance properties or industry practices
  - Preference for modeled data over measured data
  - Improper use of EPA standard models
- Enormous workload
  - Reviews and re-reviews
- New employees unfamiliar with TSCA or “how things work”

## What Can Submitters Do Pre-Submission?

- Do not over-rely on your company's "good behavior"
- Build a robust PMN, which should include:
  - Detailed descriptions of all potential releases and exposures throughout the supply chain
  - Description of cleanout of equipment used for manufacturing, processing, or use
  - Disposition of empty containers
  - Disposition of rinsate from cleaning operations
  - Data on properties, toxicity
- Identify available measured data
- Identify analogs with measured data

## What Can Submitters Do Post-Submission?

- Request new chemicals reports
  - Review carefully
  - Refute or respond to assumptions
- Be prepared for some restrictions
- Work with EPA to craft restriction to address EPA's concerns while minimizing burden on customer

## TSCA Summary

- New chemicals review taking much longer
  - Unless EPA finds substance is low hazard to health and environment
- Submitters should generally expect EPA to regulate the substance
- Program is still in flux

## Prop 65 -- Background

- Prop 65 prohibits any person, in the course of doing business
  - From knowingly and intentionally exposing any individual
    - To a chemical known to the state to cause cancer or reproductive toxicity
    - Without first providing a clear and reasonable warning
- California's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency responsible for implementing Prop 65

## Effective Date of New Warning Regulations

- OEHHA's warning requirements regulations were significantly amended on August 30, 2016
- The regulations will be operative on **August 30, 2018**
  - For consumer products, from present day to **August 30, 2018**, businesses may comply with the regulation in effect on August 30, 2016, or the provisions of the new regulations
  - After **August 30, 2018**, businesses must comply with provisions of the new regulations

Note: OEHHA is not requiring the difficulties and expense involved for manufacturers and retail sellers to locate all products bearing the old warnings; such warnings will be considered compliant if the product was manufactured prior to the effective date of the new regulations

## Prop 65 Compliance Strategies -- General Background

- Businesses must know if there are listed Prop 65 chemicals in their products
  - Used in the manufacture of the product
  - Are byproducts or impurities of chemical processes (e.g., motor vehicle exhaust)
  - Are not intentionally added (e.g., lead in foods)
- Businesses must know potential routes of exposure
  - Consumer product
  - Occupational
  - Environmental



## Compliance Options

- Update warnings
  - New warnings are more extensive and include a list of substances that trigger the warning
- Update short-form warning (on-product label)
  - Does not require listing a particular chemical, but the business must be able to identify at least one
- Conspicuous non-label methods to transmit warnings
  - Posted sign, shelf tag, or shelf sign at each point of display of the product or warning via electronic device or process for on-line purchases
- Establish Safe Harbor exemption
- Occupational warnings

## Compliance Option -- Occupational Warnings: Background

- 2016 amendments clarify that Prop 65 warning requirements are satisfied if a business “fully complies with all warning information, training, and labeling requirements” of:
  - Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) (29 C.F.R. Section 1910.1200);
  - California Hazard Communication Standard (Title 8, California Code of Regulations Section 5194); and
  - Pesticide and Worker Safety requirements (Title 3, California Code of Regulations Section 6700, *et seq.*) (for pesticides)

Note: Out-of-state manufacturers do not need to address workplace exposures for facilities outside California; such exposures are preempted by OSHA HCS

## Compliance Options -- Next Steps

- Know 100 percent chemical composition -- review Safety Data Sheets (SDS) and consider alternatives if needed
- Have plan in place for **August 30, 2018**, deadline
  - Recordkeeping for products manufactured before this date with old warnings
- Consider industry approach to No Significant Risk Level (NSRL)/Maximum Allowable Dose Level (MADL) development, exposure assessments, Safe Use Determinations (SUD)
- Consider short-form label warnings and Internet warnings
- Work with supply chain and retail sellers regarding method of warning transmission

# Ingredient Disclosure Requirements

## ■ New York

- Excludes pesticide products “as defined in Article 33 of the Environmental Conservation Law”

## ■ California

- Excludes pesticide “as defined in Section 12753 of the Food and Agricultural Code” and exclusive industrial products, including food and beverage processing and packaging
- Includes air care product, automotive product, general cleaning product, or a polish or floor maintenance product used primarily for janitorial, domestic, or institutional cleaning purposes

# Thank You

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# Compliance Option -- Provide Warning: Revisions to Prop 65 Warning Language


- Comparison between pre-2016 and post-2016 warning requirement for consumer products

## Options -- Provide Warning -- Revisions to Its Prop 65 Warning Regulations

### BEFORE

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

### AFTER

 WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm.  
For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

## Compliance Option -- Provide Warning: Short-Form Label

- Section 25603(b) provides a “short form” label (previously called on-product); an example for a chemical listed as known to California to cause cancer would be:



Cancer -- [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

- Advantages
  - Does not require businesses to include in the warning a particular listed chemical that triggers the warning
  - Provides warning for small sized products (but this is not a requirement)
- Businesses still must be able to identify at least one listed chemical that triggers the warning
- If an on-product warning is provided pursuant to Section 25602(a)(4), the warning provided on the website may use the same content as the on-product warning

## Compliance Option -- Provide Warning: Non-Label Methods to Transmit Warning

- Prop 65 regulations set forth methods of transmission for consumer product warnings other than a label
  - Posted sign, shelf tag, shelf sign at each point of display of the product
  - Product-specific warning via electronic device or process (e.g., Internet purchases) that provides warning “prior to or during the purchase of the consumer product, without requiring the purchaser to seek out the warning”
- OEHHA guidance focuses on ensuring that such warnings are prominently displayed, conspicuous, and seen by the consumer prior to purchase/use
- Where a consumer product sign or label used to provide a warning includes consumer information in a language other than English, the warning must also be provided in that language in addition to English



## Compliance Option -- Establish Safe Harbor Exemption: Background

- A business has “safe harbor” from Prop 65 warning requirements or discharge prohibitions if exposure to a chemical occurs at or below:
  - **For Carcinogens:** NSRLs = one excess cancer for every 100,000 people exposed (assuming exposures occur over a 70-year lifetime); and
  - **For Reproductive Toxins:** MADLs = the average user of its product is less than 1/1000th of the lowest level at which reproductive effects are not observed in laboratory animals

## Compliance Option -- Establish Safe Harbor Exemption: Can Companies Develop a NSRL or MADL?

- Companies can develop NSRL/MADL
- OEHHA has adopted regulations (Articles 7 and 8) providing guidance for businesses to calculate their own NSRL/MADL in the absence of an OEHHA-established safe harbor level
- Advantages of an industry approach to develop a NSRL/MADL for any particular listed substance
  - Ensures consistency in approach
  - Cost sharing and efficiencies

## Compliance Option -- Occupational Warnings: Scope of HCS Compliance

- If a substance does not trigger OSHA HCS warning/label requirements (e.g., is not present at a high enough concentration), that does not mean that there are no Prop 65 warning requirements
- In the event that there is an occupational exposure to a Prop 65 listed chemical not covered by HCS, businesses can satisfy warning requirements pursuant to provisions for consumer product and/or environmental warnings