WARNING: New Proposition 65 Regulations May Pose a Significant Risk to Your Business

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Agenda

• Overview of Proposition 65
• New Warning Regulations
• Prop. 65 Compliance Program
• Determine if Warning Needed
• Options to Limit Need for Warning
Overview of Proposition 65

• “Person in the course of doing business” must provide a “clear and reasonable” warning to persons prior to exposure to listed chemicals unless it can demonstrate exposure does not pose a “significant risk”. (CA H&S Code §25249.6)

• List of 900+ chemicals
   Carcinogens (DEHP, DINP)
   Reproductive/Developmental Toxicants (BBP, DEHP, DIDP, DBP, DnHP)

• Private plaintiffs enforce

• New warning regulations to replace prior version for products manufactured after 8/30/18
   Sell through provision
Reasons for New Warning Requirements

• Provide Useful Information to the Consumer
  ➢ At least one chemical identified in the warning
  ➢ Symbol to make warning more conspicuous
  ➢ State P65 website to provide additional information

• Discourage Prophylactic Warnings/Over-warning

• Drive the Warning Requirement Up the Supply Chain Away from Retailers Towards Manufacturers & Importers

• Eliminate California Retailer Responsibility
New Consumer Warnings

- Requires at least one chemical to be identified per end point
- Requires use of warning signal
- Long-form warning
- Optional short-form warnings
- Internet and catalogue warnings required
- Products manufactured prior to 8/30/18 grandfathered
New Warning Regulations-Content

• Long-form example for consumer product

WARNING: This product can expose you to chemicals including lead which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

• Short-form example for consumer product

WARNING: Cancer and Reproductive Harm – www.P65Warnings.ca.gov

➢ For consumer products & food warnings, used only on packages, not on signs

• If the product label or sign provides consumer information in a language other than English, the P65 warning must be provided in that language
New Warning Regulations - Transmission

• Warning must be prior to purchase
  ➢ Former regulations allowed warnings before use or sale
    ✓ On-product warnings for products shipped to internet or catalog consumers
    ✓ Warnings on items in package, product manuals, inserts, etc.
    ✓ Warnings on invoices, etc.

• “Brick and mortar” consumer products
  ➢ Label on the exterior of the product/package
    ✓ Long-form and short-form
  ➢ Posted signs, shelf tag, shelf sign at each point of display of the product
    ✓ Long-form only
  ➢ For retroactively applied warning, upstream business must notify and provide warning signs, displays, etc. and instructions to retailers
Direct Responsibility for P65 Warnings

• For Consumer Products & Services
  ➢ Manufacturer, Importer, Distributor, Licensor
  ➢ Retailer – responsible if one in of five circumstances exist
    ✓ Retailer owns the brand (private label)
    ✓ Retailer knowingly introduced the chemical
    ✓ Retailer defaced the warning
    ✓ Retailer was notified by manufacturer and failed to post warning materials provided
    ✓ Retailer has actual knowledge of exposure and
      ▪ Manufacturer has less than 10 employees; or
      ▪ The manufacturer does not have an agent for service of process or place of business in CA
Prop 65 Compliance Program

• Have a Written Procedure
  ➢ Designate a responsible individual – or a team
  ➢ Include all relevant functions - e.g. purchasing, manufacturing, QA/QC, operations, regulatory
  ➢ Integrate Prop 65 compliance into the way you currently do business

• Do a Proposition 65 audit

• Know what products contain listed chemicals
  ➢ Which are found in your ingredients?
  ➢ Which are formed during manufacture/processing?
  ➢ Which may be found in packaging?

• Determine whether you can reformulate or otherwise avoid warning., e.g., exposure assessment & administrative options

• Provide warnings if necessary

• Have a plan for working with others in the stream of commerce
Do I Need to Provide a P65 Warning?

• Listed chemical in my product?
  ➢ Safety Data Sheets
  ➢ Analytical Data
  ➢ Components with P65 chemicals

• Who’s exposed?
  ➢ Consumers?
  ➢ Workers?
  ➢ DIY’ers
  ➢ Others?

• Does it pose a “significant risk” to those exposed?
  ➢ Exposure assessment
  ➢ Compare to “Safe Harbor” values if available
  ➢ Develop “Safe Harbor” value
Potential Mitigation Options

• Proposition 65

  ➢ Administrative Options

    ✓ Safe Use Determination (SUD)
      o Crystalline silica in pet litter & paint
      o DINP in building products & patio furniture

    ✓ Interpretive Guidelines
      o Lead in fishing tackle
      o SO$_2$ in dried fruits
      o Methanol from pectin in fruits & vegetables
      o Chloroanthalonil residues in tomato products

  ✓ Information Letter
    o Fumonisins in corn snacks

  ➢ Internal Options

    ✓ Identify alternatives
    ✓ Monitor & engage regulators
    ✓ Insurance
Thank you....

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