



Roundup of Current Issues: Ethylene Oxide, Plastics, COVID-19 Workplace Requirements, Prop 65

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Ethylene Oxide Developments

Key driver of regulatory issues was the development of the seriously flawed 2016 IRIS risk value for EO

- ACC Request for Correction filed in 2018; EPA has yet to respond
- EPA requested comments in the HCL RTR, used the IRIS value in the MON RTR and has stated an intent to use it in an update to the Sterilizers NESHAP rulemaking

IRIS value has substantially increased litigation risk to companies from ENGOs and state regulators

- Referenced in state Attorneys General actions and dozens of suits against medical device sterilizers to support allegations of harm

Ethylene Oxide Developments

Recently, EPA has begun developing community-specific notifications for what it calls high-risk localities

Next steps

- Prepare for compliance with new regulations
- Evaluate litigation risk
- Prepare for litigation

Plastics Regulations

- Biden Administration and new Congress
 - Acknowledgment of plastic pollution problem
 - NGO pressure for executive and legislative action
 - Break Free From Plastic Pollution Act to be reintroduced
- State legislation and regulations
 - Packaging, food serviceware, other single-use products
 - Extended producer responsibility, bans, taxes, ecodesign, labeling, etc.
- International developments
 - National policies
 - Multilateral negotiations

Risks and Opportunities for the Pharmaceutical Sector

- Recyclability of packaging
- Recycled content in packaging
- Related marketing considerations
- EPR legislation
 - Pharmaceutical EPR legislation typically excludes packaging, encourages recycling
 - Packaging EPR legislation occasionally excludes certain pharmaceutical/medical waste
- Microplastics

A microscopic view of several COVID-19 virus particles. The particles are spherical with a textured, greyish surface and numerous red, spike-like protrusions extending from the surface. They are set against a dark blue background with a bokeh effect of light blue and white dots. A solid blue horizontal bar is positioned across the middle of the image, containing the text.

COVID-19 Workplace Requirements

Federal Requirements

OSHA has relied on existing requirements, supplemented by guidance

Existing Requirements:

- General Duty Clause
- Personal Protective Equipment
- Respiratory Protection
- Sanitation
- Protection from Bloodborne Pathogens
- Recordkeeping and Reporting
- Employee Access to Medical and Exposure Records

Guidance:

- Preparing Workplaces
- Returning to Work
- Enforcement
- Recordkeeping
- Industry-Specific Resources
- Most recently, "Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace."

State Requirements

States have moved forward with COVID-19 Standards

States include:

- Virginia
- Michigan
- Oregon
- California

Common features:

- Exposure assessment
- Written control plans
- Prevention measures
- Screening and testing
- Information and training
- Recordkeeping and reporting

What's Next?



Federal Emergency Temporary Standard

- Under President Biden's EO on Protecting Worker Health and Safety, OSHA must issue ETS by March 15 if OSHA determines an ETS to be necessary

Continued development of state requirements


Additional guidance re vaccines

CA Proposition 65 Proposed Amendments

- Notice of Proposed Rulemaking issued Jan. 8, 2021
- Proposal would amend the safe harbor warning regulations that became effective in August 2018
- Safe harbor method and content changes target short form warnings:
 - Short form warnings only permitted if necessary due to size constraints
 - Short form warnings must include at least one Prop 65-listed chemical
 - Short form warnings not permitted for online and catalog purchases

CA Proposition 65 Proposed Amendments

- Example of proposed short-form warning:

 **WARNING:** Cancer Risk From Formaldehyde and Reproductive Risk From Toluene Exposure - www.P65Warnings.ca.gov.

- Proposed amendments include a limited phase-in period

CA Proposition 65 Proposed Amendments Cont.

- Next steps:
 - Public comments accepted through March 29, 2021 (recently extended)
 - Public hearing scheduled for March 11, 2021, at 10 a.m. PT

Thank you

To submit a question, please unmute yourself or use the chat function on the right side of your screen



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