

# Recent and Anticipated EHS Requirements Impacting Pharmaceutical Manufacturing and Supply Chains in China

Pharmaceutical EHS Counsel Roundtable

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# Agenda



Overview of Regulatory and Policy Trends

Four Important Environmental Regulations  
Impacting the Pharmaceutical Industry in 2018

Issues to Watch

# Overview of Regulatory and Policy Trends

Central government (e.g. the State Council) sets out specific targets:

- Improve overall air quality
- Slow-down soil and underground water contamination and reduce soil and underground water environmental risks
- Require better waste treatment

# Overview of Regulatory and Policy Trends

- **Environmental Enforcement Actions are Getting More Stringent**

- **National Level**

- ❑ Inspections: Environmental protection law and its implementation measures
- ❑ Inspections: Air pollution prevention and treatment supervision
- ❑ Special inspections: waste processor and waste-using enterprises

- **Local Level**

- ❑ Provinces are launching programs targeting specific improvements
- ❑ Cross-provincial and cross-city audits are now required
- ❑ Past practices have been deemed no longer acceptable

# Overview of Regulatory and Policy Trends

Environmental policies aimed at the pharmaceutical industry continue to be issued at the national and local level

Pharmaceutical industry is one of the key industries for environmental enforcement actions

# Important Environmental Regulations Impacting Pharmaceutical Industries

- **Water Pollution Prevention and Control Law**
  - Revised June 29, 2017 and effective January 1, 2018
  - Setting up the local government accountability and transparency system on the water quality
  - Establishing a total quantity control and discharge permit system



# Important Environmental Regulations Impacting the Pharmaceutical Industry



## Environmental Protection Tax Law

- Issued December 25, 2016 and effective January 1, 2018
- General principle: no additional burden on the enterprises
- Applicable scope: the enterprises, public institutions and other producers and operators that directly discharge pollutants to the environment
- Taxable pollutants: air pollutants, water pollutants, solid waste and noises
- Five tax exemptions and two tax reductions
- The draft of the implementation measures were issued in June, 2017 and final measures are expected to be issued soon

# Important Environmental Regulations Impacting the Pharmaceutical Industry

## Soil Pollution Prevention and Control Law

- Draft was issued in June 2017 for public comments and completed the first commenting period.
- Government accountability
- Soil contamination responsibility system
- Prevention and control of hazardous substances in the soil
- **Looking ahead:** future land related transactions, technical guidance on soil contamination evaluation and restoration and other implementation measures



# Important Environmental Regulations Impacting the Pharmaceutical Industry

- **Administrative Measures on Mandatory Environmental Pollution Liability Insurance**
  - Draft was issued in June, 2017 for public comments and completed the first commenting period
  - Active pharmaceutical ingredients of chemical drugs and chemical drugs formulations industries are subject to the mandatory environmental pollution liability insurance system



# China – Issues to Watch

- **Environmental Enforcement Action**
  - Focused on facility controls
  - Significant uptick
- **Supply chain management**
  - Tied to environmental enforcement
  - Increasing business disruption and reputational risk
  - Some new initiatives in this area



# Questions?

# Thank you!



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