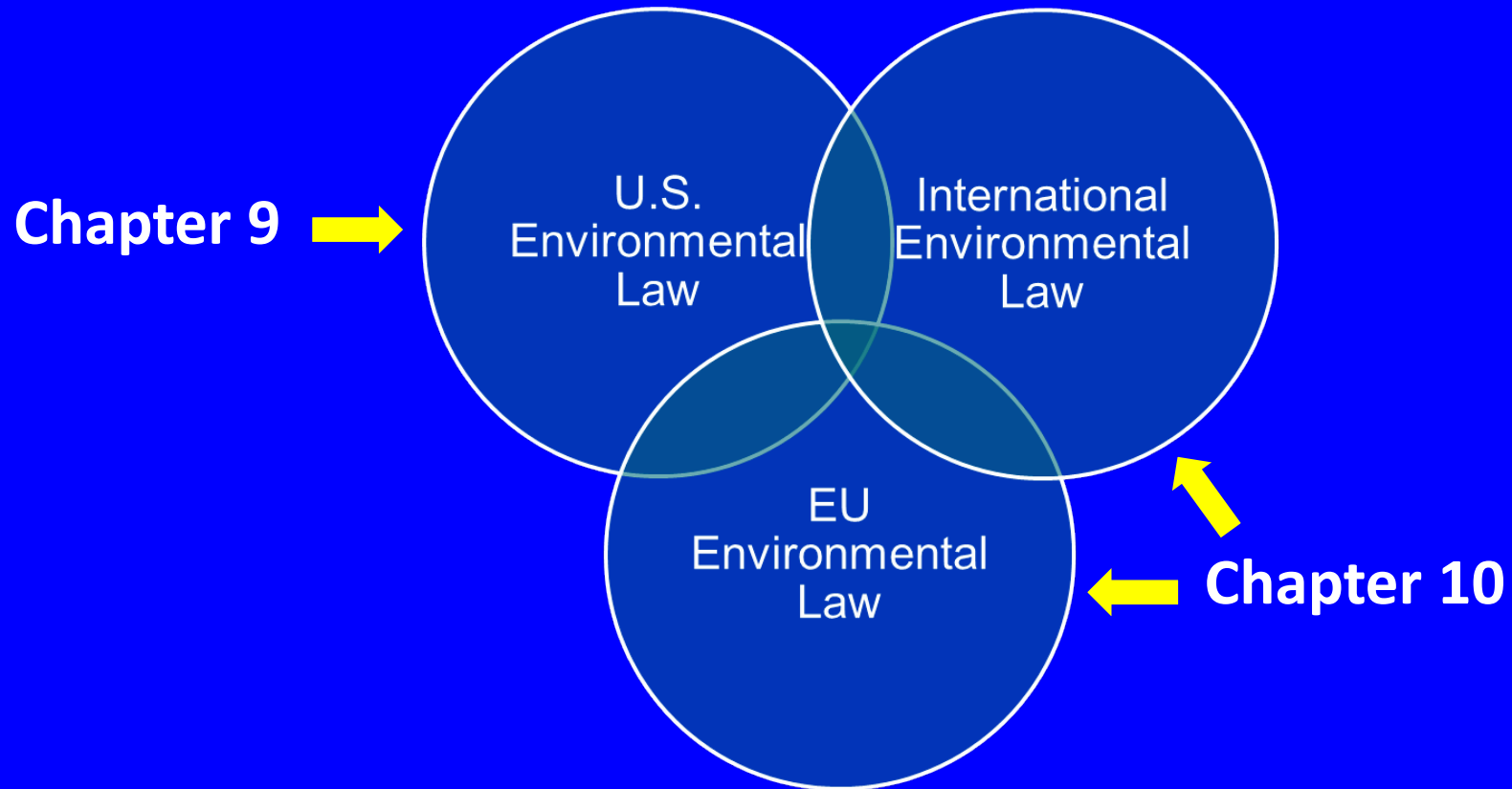


# **GOVERNMENTAL REGULATION OF HEALTH, SAFETY and THE ENVIRONMENT**

**Perspectives from the Nation State  
The US Approach**

**Nicholas A. Ashford  
Massachusetts Institute of Technology**

# Relationship Between US, EU. and International Environmental Law



# Outline of Today's Discussion

- Standard Setting for Chemicals and obligations of the employer, manufacturer, and user.
  - » Exposure limitations, product bans, technology requirements
  - » Duty to generate information
  - » Duty to retain information
  - » Duty to provide access to information
  - » Duty to inform affected parties
- Worker and Community Right-to-Know
- Cleaner and Inherently Safer Technology
- Liability for Contamination of Land and Water
- A Technology-based Strategy for a Sustainable Environment
- The Precautionary Principle
- Trade-off Analysis as an alternative to CBA

# EVOLUTION OF APPROACHES TO HEALTH, SAFETY, AND ENVIRONMENTAL PROBLEMS

- Dispersion of pollution and waste
  - » The “dilution” solution
  - » Often requiring expensive remediation/restoration of land and water
  
- **‘End-of-pipe’ Pollution Control**
  - » *Collecting wastes; workplace ventilation and protective equipment*
  - » *No fundamental changes in inputs, final products, or production technology*
  - » *Media shifting: air and water pollution=> waste and workplace exposures*
  - » *Problem shifting: toxicity => accident potential*
  
- Industrial Ecology: waste & material exchange and consolidation
  - » *No fundamental changes in inputs, final products, or production technology*
  
- **Pollution prevention and cleaner & inherently safer technology**
  - » **Improvements in toxic content, eco-efficiency, and energy efficiency**
  
- H&S and Environmental Management Systems
  - » ISO 8999 and 14,000
  - » Environmental Management Audit System (Europe)
  
- **System changes and Sustainable Development**

# US Standard Setting for Chemicals

- The Occupational Safety and Health Act of 1970
- The Toxic Substances Control Act of 1976 and 2016 (40 years later)
- The Clean Air Act of 1990
- Water Legislation
  - » The Clean Water Act
  - » The Safe Drinking Water Act
- Regulation of Hazardous Waste and Environmental Contamination
- Worker and Community Right to Know
- Consumer Product Safety (food, drugs and other products)
- Chemical Safety
- Pollution Prevention and Inherent Safety Legislation

# The Occupational Safety and Health Act of 1970

- Initially allowed the adoption of ~ 450 Threshold Limit Values (TLVs) of the American Conference of Governmental and Industrial Hygienists (ACGIH) **grandfathering prior industrial standards.**
- The Secretary of Labor (i.e., the Assistant Secretary for OSHA) must **set permanent standards** that ensure that:
  - “no employee suffer material impairment, based on the best available evidence, to the extent feasible”
- The Supreme Court added a requirement for “**significant risk**” bounded between a lifetime risk of  $10^{-3}$  and  $10^{-9}$ .
- Reagan’s OSHA chose the “bright line” of **significant risk at  $10^{-3}$** , Clinton did not change it.

# The OSHA Act (cont'd)

- Upon challenge, courts examine the standards to ensure they are based on “substantial evidence on the record as a whole” (the standard of judicial review) ~ satisfied by legislative policy judgments about issues that are “on the frontiers of scientific knowledge.” Courts endorse the principle of ‘erring on the side of caution’.
- The Secretary of Labor must set *temporary emergency standards* where necessary to protect workers from “grave danger.”
- Employers are also under a “**general duty**” to provide workplaces and work free from “recognized hazards” independent of the existence of standards.

# The 1976 Toxic Substances Control Act

- EPA must set **standards for substances** that:
  - presents “**unreasonable risks** to health or the environment”. In implementing protections EPA must take taking into account costs, effects on health & the environment, technological innovation, and the *availability* of substitutes.
- EPA requires industry to **test chemicals** if:
  - » there are insufficient data and the substance “may present unreasonable risks to health or the environment” or there is a substantial quantity/exposure or exposure is significant.
- EPA must **either regulate or explain** why not if
  - » there may be a reasonable basis to conclude a chemical presents a risk of cancer, birth defects, or mutations
- EPA requires the **reporting of “significant adverse reactions”** and information about of their products’ toxicity.
- Upon challenge, courts examine the standards to ensure they are based on “substantial evidence on the record as a whole” (the standard of judicial review).



# The 2016 Toxic Substances Control Act

- EPA must set standards for substances that:
  - presents “unreasonable risks to health or the environment” **Only risk management decisions can consider costs and “non-risk factors.”** For all new chemicals, an “unreasonable risk” determination must be made.
- Risk assessment is now required in the 2016 TSCA to be **firmly based “on science” and the “weight of the evidence”**. The existence of conflicting studies can defeat EPA’s essentially discretionary finding that a risk is unreasonable.
- 
- The determination of an “unreasonable risk” under 2016 TSCA is **a rejection of the precautionary principle**. Only risks that are attended by **strong, and essentially unequivocal, scientific evidence** are likely to be addressed, with considerable discretion afforded the EPA administrator, but that will no doubt be influenced OMB/OIRA.

# The 2016 Toxic Substances Control Act

- By shifting economic concerns from determination of what constitutes “unreasonable risk” to a risk management decision does nothing in practice to address the reality that **economics will trump public health and environmental protection.**
- With more scientifically-based evidence now needed to support a finding that a risk is unreasonable (discussed above), **fewer chemicals are likely to cross the threshold for implementing mandatory risk management.**
- ***EPA must prioritize chemicals for testing and risk management with deadlines*** and can require industry to test chemicals ***through administrative orders , but see the later discussion.***
- Federal Pre-emption where EPA regulates/decides not to regulate (but not CA Proposition 65 or state green chemistry laws).

# The 2016 Toxic Substances Control Act

- **TSCA Section 6(C): CONSIDERATION OF ALTERNATIVES** -- in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture ... the Administrator shall consider [and identify]... **whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute .... →innovation??**
- While the consideration of alternatives is welcomed, the language implies that a thorough investigation of costs and benefits of the substitutes might well be required, an acknowledged unrealistic burden on EPA, as evidenced by EPA's reluctance to regulate chemicals after the asbestos regulation was struck down in *Corrosion Proof Fittings*.

# The Clean Air Act of 1990

- EPA must set standards for substances that:
  - » for the “criteria pollutants” “protect public health with an adequate margin of safety” through ambient standards without taking costs into account. (examples: CO, SO<sub>2</sub>, NO<sub>x</sub>, particulates, ozone, lead) **enforced as concentration standards and emission limitations**
  - » for “hazardous air pollutants” set technology-based emission standards” of best ‘average’ performance of top 12% of the industry. Eventually carcinogenic chemicals can not present a risk greater than 10<sup>-6</sup>. (examples: benzene, asbestos, formaldehyde) **emissions standards**
  - » EPA has the authority to regulate greenhouse gases (GHGs) from mobile sources after endorsement by the Supreme Court in *Massachusetts v EPA*.
  - » However, regulating stationary sources (e.g., power plants) is no longer authorized under the “major decisions doctrine” according to the Supreme Court.
  
- Upon challenge, courts examine the standards to ensure they are not “**arbitrary or capricious**” (the standard of judicial review).

## The Clean Air Act of 1990 (continued)

In 1980, the DC Circuit Court of Appeals opined in the setting of a new ambient standard for lead dust:

- Congress...directed [the EPA Administrator] to **err on the side of caution** in making these judgments.
- First, Congress made it abundantly clear that **considerations of economic or technological feasibility are to be subordinated to the goal of protecting the public health by prohibiting any consideration of such factors.**
- Second, it specified that the air quality standards must also **protect individuals who are particularly sensitive to the effects of pollution**, requiring those standards be set at a level at which there is "an absence of adverse effect" on these sensitive individuals.
- Finally, it specifically directed the Administrator to **allow an adequate margin of safety** in setting primary air quality standards in order to **provide some protection against effects that research has not yet uncovered.**

# Water Legislation

- The Clean Water Act:

  - sets **limits for discharges (effluents)** into water bodies and publicly-owned treatment works” (POTWs).

- The Safe Drinking Water”

  - sets **water quality standards** (now relaxed in stringency).

- Upon challenge, courts examine the standards to ensure they are not “**arbitrary and capricious**” (the standard of **judicial review**).

# Hazardous Waste

- Resource Conservation and Recovery Act (**RCRA**)  
1970/1976
  - » **Established treatment standards for waste categories**
  - » **Prohibited untreated disposal in landfills**
- Comprehensive Emergency Response, Compensation and Liability Act (**CERCLA**)
  - » **Cleanup of contaminated sites [National Priority List];**  
abandoned sites no longer funded by a tax on chemical industry
  - » Imposition of strict, joint, and several liability on Potentially Responsible Parties (PRPs). Retroactive liability imposed.
  - » Standards for clean-up levels now relaxed (linked to water quality).
  - » States have the option to keep a site off the federal NPL list and address the remediation themselves
  - » “brownfields designation”

## **CERCLA (continued)**

### **Comprehensive Emergency Response, Compensation and Liability Act (CERCLA) 1984/1986 (continued)**

- » Driven by a concern for actual or substantial threat of release of listed 'hazardous substances' to the environment, or actual or threatened releases of pollutants/contaminants which "may present an imminent and substantial danger to public health or welfare"
- » While recovery for personal injury and damage to property is left to the already-existing remedies available in the 50 individual states, CERCLA/SARA did establish the Agency for Toxic Substances & Disease Registry (ATSDR) which:
  - keeps a registry of exposures and diseases attributable to toxic substances
  - constructs toxicological profiles of chemicals
  - performs preliminary health risk assessments at NPL sites

□ The Environmental Protection Agency (EPA) oversees the remediation of the NPL sites and administers the 'Superfund'.

□ **States have the option to keep the site off the federal NPL list and assume responsibility for the remediation themselves.**



# Worker and Community Right-to-Know

- OSHA Act (employers to provide)
  - » Ingredients information (MSDSs)
  - » Health & Safety info (MSDSs)
  - » Exposure information
  - » Medical records
- TSCA (duties of mnfrs)
  - conduct H&S studies
  - report H&S studies
  - report significant adverse reactions
- EPCRA: reporting requirements on:
  - » Emergency planning (§311 – MSDSs) and (§312 – inventory form)
  - » Manufacture or process (§304)
  - » Use (§304)
  - » Storage (§304)
  - » Expected Emissions: Toxics Release Inventory (TRI) (§313)
  - » Sudden and accidental releases: Added to TRI by Clean Air Act (§304)
  - » Source reduction & waste management practices: Added by PPA Act
- Toxics Use Reduction Act (Massachusetts)
  - » Adds materials accounting to reporting requirements
  - » Adds technology options/state-of-art review

# Chemical Safety

- The OSHA Act
  - » **Process Safety Management rule** for workers
  - » Posting of Material Safety Data Sheets (MSDSs)
- The Clean Air Act
  - » **Risk Management Plans** (and “worst case scenarios”)
  - » **General duty** ~ OSHA Act to *identify* hazards, *design* & *maintain* a safe facility, and *minimize* consequences of accidental releases.
  - » Chemical Safety and Hazard Investigation Board
- Additional **reporting requirements and emergency planning** under the Emergency Planning and Community Right-to-Know Act (**EPCRA**)

# Product Safety

- **Consumer Product Safety Act (1972)**
  - » Purpose: to protect the public against unreasonable risks of injury associated with consumer products (not foods/drugs)
  - » Mandatory Consumer Product Safety Standards
  
- **Federal Hazardous Substances Act** took over regulatory authority in the 1980s for hazardous substances and the emphasis shifted to voluntary standards (industry-dominated consensus standards)
  
- **Food Safety and Drug Safety & Efficacy** regulated by the Food, Drug and Cosmetic Act
  
- Incentives for safety result from **the interplay of legislation and tort liability** (stemming from violations of the duty to warn and to provide safe products)
  - » Undercut by de-regulation and tort reform

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# **Pollution Prevention (PP) and Inherently Safer Production (ISP) have common elements**

- **Input Substitution**
- **Final Product Reformulation**
- **Process Changes and Redesign**
- **Organizational Change**
- **Managerial Change**
- **Changes in Work Practices**

**However, technologies that improve PP may not be the same as those required by ISP, and vice versa.**

# US Pollution Prevention & Inherent Safety Legislation

## □ The Pollution Prevention Act of 1990

- » Preferred hierarchy of input substitution, product reformulation, and process redesign over pollution control
- » Gradual pollution
- » Sudden and accidental releases
- » Amends Community Right to Know Act by requiring additional reporting of pollution prevention activities
- » Requires examination of all prior standards to ensure a pollution prevention approach

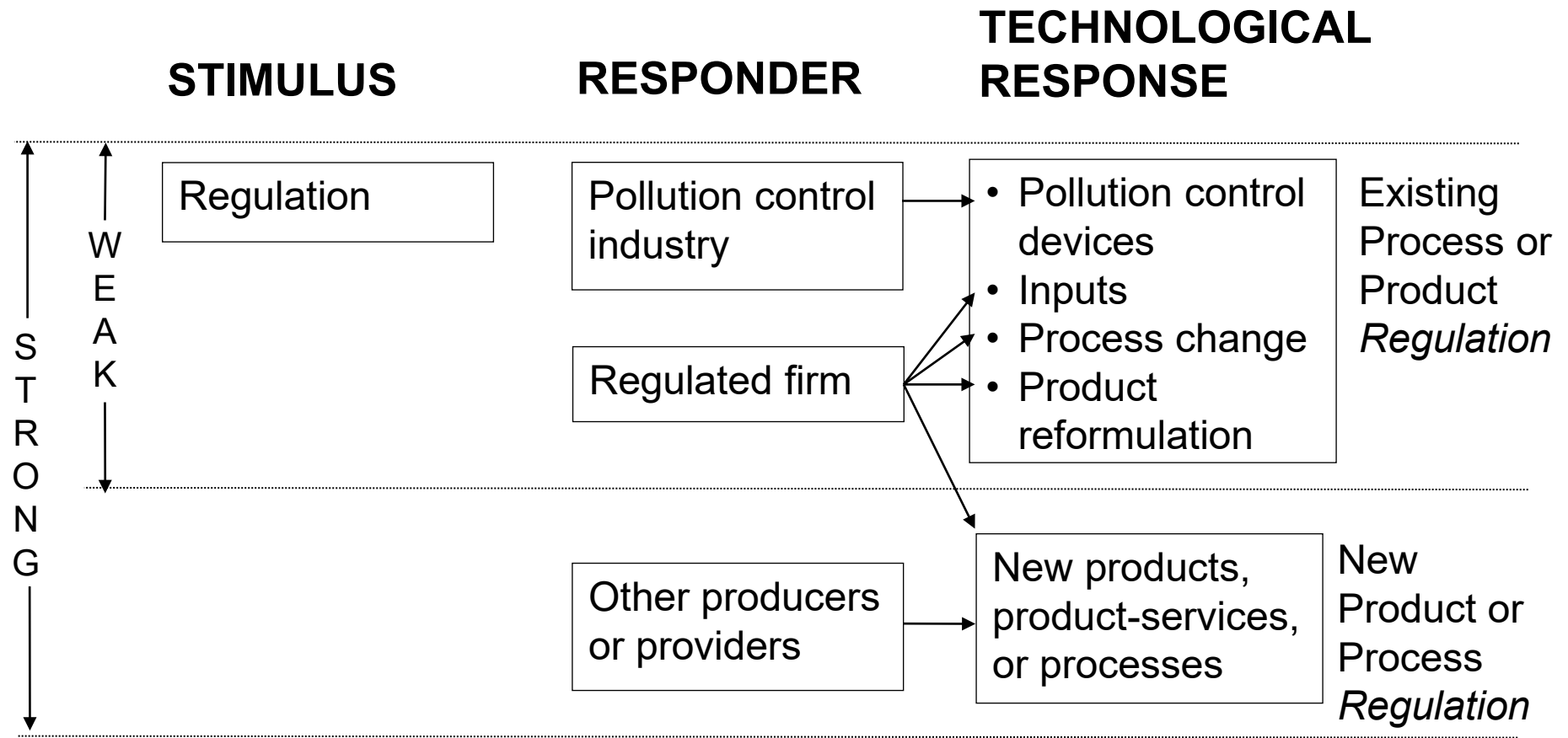
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- » Chemical Safety and Hazard Investigation Board

## □ The OSHA Act

- » Process Safety Management rule for workers
- » Material Safety Data Sheets (MSDSs)

# A Model for 'Weak' (Porter) and 'Strong' (MIT) Forms of the Regulation-induced Innovation Hypothesis



**TABLE 1: CHARACTERISTICS OF SELECTED CLEANER PRODUCTION TECHNOLOGIES**

<b>TECHNOLOGY</b>	<b>Type</b>	<b>External Pollution/ Waste Status</b>	<b>Worker Health Status</b>	<b>Accident Potential Status</b>	<b>Raw Material Use</b>	<b>Water Use</b>	<b>Energy Efficiency</b>
Rapeseed oil extraction by enzymes	adverse for workers	++	--	+	++	-	--
Flame spray zinc	adverse for workers	+	-	(0,-)	n/a	++	(0,+)
Recovery of sulphated mother liquor	adverse for workers	+	-	--	++	++	(0,+)
Recycling of cyanide water	adverse for workers	++	--	--	++	0	(0,+)
Solvent substitution in paint	missed opportunity	+	0	0	+	0	n/a
Production of casting molds	missed opportunity	++	+	+	+	0	0
Hydrocarbon-based dry cleaning	missed opportunity & adverse for workers	++	0	(0,-)	n/a	-	-
Wood & furniture surface treatment	missed opportunity	+	0	0	+	0	0

Legend: ++ significant improvement; + improvement; 0 no change; - deterioration; -- significant deterioration; n/a not available



# Reasons why firms are adopting cleaner production/pollution prevention:

- the costs of waste transport/treatment and pollution control can be high, and
- there is increased liability for environmental damage =>
- there is a ready calculus for risk avoidance; it is economically rationale to avoid gradual pollution and contaminated products
- there is increased transparency of toxic releases (through the TRI) and public awareness
- the Pollution Prevention Act (in the EU the IPPC Directive, EMAS, and ISO 14000) all provide pressure for a search for solutions

# Reasons why firms are not adopting inherently safer technology:

- the costs of [rare] accidents are not apparent until after the event, and
- the probabilities/risk assessments for sudden and accidental releases are problematic (worst-case scenarios are not believed, and perhaps are not believable) =>
  
- there is *no* ready calculus for risk avoidance decisions; it may not seem economically rationale to prevent accidents
- chemical engineers have a simplistic view of 'root causes'.
- Section 112r of the Clean Air Act was minimally implemented; requiring technology options analysis was rejected by the Clinton Administration.
- Inherent safety not given prominence; compare Seveso II
- there has been limited public awareness of the risk ...but 9/11 is changing all that

# Increasing awareness of inherent safety through requiring firms to undertake

- **An *inherent safety opportunity audit* (ISOA)**
  - that identifies *where* in a specific facility inherently safer technology is needed.
- **A *technology options analysis* (TOA)**
  - that identifies *specific inherently safer options* that will advance the primary prevention, i.e., that will alter production systems and final products so that there are less inherently unsafe risks.
  - Both the *adoption*, and the *development*, of inherently safer options need to be considered

# Strategic Questions leading to Technological Change

- What technology is causing the environmental or public health problem?
- What characteristics of the problematic technology are responsible for the hazard?
- What technological response\* is desirable?
- Which industrial sector is most likely to diffuse or to develop the desired technology?
- What kinds of regulation and incentives will most likely elicit the desired response?

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\* Choose, for example, whether a product or a process change; pollution control or prevention? and, further, the diffusion of existing technology, simple adaptation, accelerated development of innovation already in progress, or radical (i.e., disrupting) innovation?

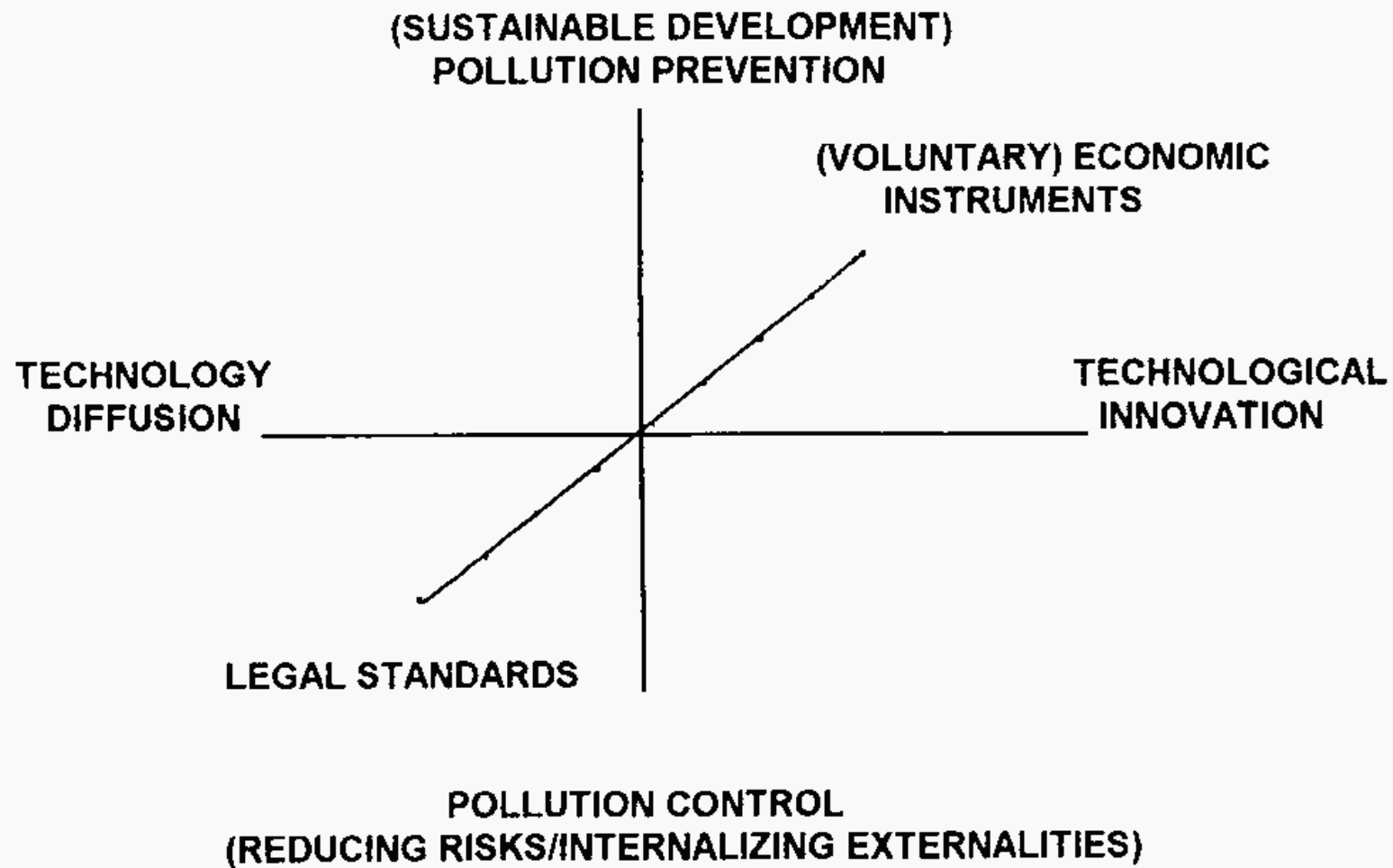


Figure 1. STRATEGIC CHOICES

# Assessing the Effects of Decisions Affecting Health, Safety, and the Environment

EFFECTS Group	Economic Effects	Health/Safety Effects	Environmental Effects
Producers	$C_{\$}$		
Workers	$C_{\$}$	$B_{H/S}$	
Consumers	$C_{\$}$	$B_{H/S}$	
Others	$C_{\$}$	$B_{H/S}$	$B_{ENVIRONMENT}$

# The Precautionary Principle (two formulations)

- Where there are possibilities of large or irreversible serious effects, scientific uncertainty should not prevent preventative actions from being taken (Brundtland).
- Action should (must) be taken where there are possibilities of large or irreversible serious effects (~ risk averseness) e.g., climate disruption, cancer, reproductive system damage

Limiting the reach of the precautionary principle will limit societal protection/environmental restoration because scientific uncertainties can be trumped by potentially large costs for protection and restoration/remediation costs.

# The Precautionary Principle: Essential Elements

- Trade-off analysis vs. CBA
  - » Accountability versus accounting
- Technology Options (Alternatives) Analysis
- *A sliding scale for the burden of proof*, i.e., the strength of data/information needed to justify taking (or stopping) action, depending on the hazard, extent of protection desired, and action taken (notification, regulation, compensation, etc.)
  - ~ *linking causality to level of desired protection*
- Presumptions and shifts in the *burden of persuasion*
- Linked with the Polluter Pays Principle
- Going beyond risk reduction to sustainable development



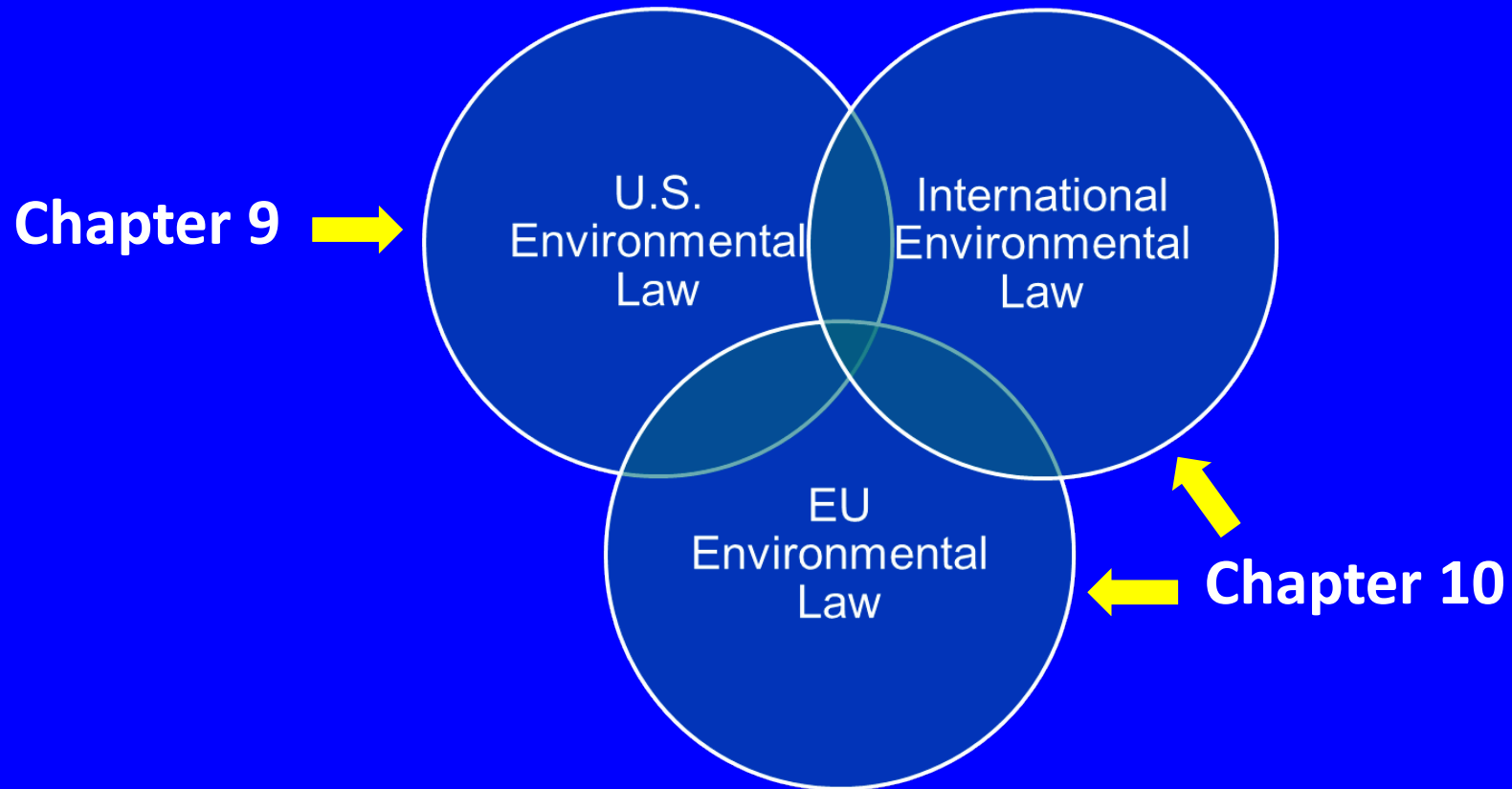
# Elements of the Precautionary Principle, cont'd

- Minimizing Uncertainty
  - » through refinement of (comparative) Risk Analysis
  - » through undertaking (comparative) Technology Options Analysis
    - Safer inputs, production methods, and final products
- Attitudes towards Error Avoidance (*whether and to what extent to intervene*)
  - » Risk avoidance (Type I vs. Type II errors regarding requirements for the reduction of risk)
  - » Cost avoidance (Type I vs. Type II errors regarding requirements for changes in technology)

# **COMPARISON OF ENVIRONMENTAL & OCCUPATIONAL HEALTH & SAFETY REGULATION IN THE US & EU**

**Nicholas A. Ashford, PhD, JD**  
**Professor of Technology and Policy**  
**Director, MIT Technology and Law Program**  
**Massachusetts Institute of Technology**

# Relationship Between US, EU. and International Environmental Law



# Focus of EU Environmental Law

- Transboundary pollution and Extraterritoriality
- Harmonization among member states
- **Worker Health & Safety**
- **Air and Water Framework Directives**
- **Waste Directive (1975) and Waste Electrical & Electronic Equipment (WEEE) Directive**
- **Seveso Directives on chemical accident prevention**
- **Integrated Pollution Prevention & Control Directive (IPPC)**
- **Integrated Product Policy; LifeCycle Anal; Product Liability**
- **Aarhus Directive on participation & access to information**
- **Environmental Management Audit System Directive-EMAS**
- **REACH**
- Food Safety; Pharmaceuticals
- Biotechnology
- **Environmental Liability**
- Financial Assistance and LIFE

# Race to Brussels – Holzinger and Sommerer (2011)

- Analyzed the development of 17 environmental regulations in 24 countries (mostly EU) over a period of 35 years
- Data show not only the absence of a ‘race to the bottom’, but a clear ‘race to the top’
- Some 94 percent of all changes in regulations were *upward moves*, with only 6 percent downward moves
- Upward move of environmental regulation is mostly driven by supranational co-operation at the EU level and the integration of countries into international environmental regimes – i.e., ‘EU harmonization’ explains the upward movement

# US & EU Regulatory Systems

<ul style="list-style-type: none"><li>• The Occupational Safety and Health Act of 1970</li><li>• The Toxic Substances Control Act of 1976 and 2016<ul style="list-style-type: none"><li>– assessment and regulation of chemicals</li></ul></li></ul> <hr/>	<p>OHS Directives REACH</p>
<ul style="list-style-type: none"><li>• The Clean Air Act of 1990</li><li>• Water Legislation<ul style="list-style-type: none"><li>– The Clean Water Act</li><li>– The Safe Drinking Water Act</li></ul></li><li>• Regulation of Hazardous Waste (RCRA)</li><li>• Clean-up of Contamination to Land and Water<ul style="list-style-type: none"><li>– Remediation and Restoration (CERCLA) [Polluter Pays]</li></ul></li></ul> <hr/>	<p>Air Directive Water Directive  Waste/WEEE Liability Directive</p>
<ul style="list-style-type: none"><li>• Pollution Prevention and Inherent Safety</li></ul> <hr/>	<p>IPPC Directive (industrial Emissions)</p>
<ul style="list-style-type: none"><li>• Chemical Safety: workers (OSHA) and community (EPA)</li></ul> <hr/>	<p>Seveso Directives</p>
<ul style="list-style-type: none"><li>• Consumer Products (food, drugs, &amp; other products)</li></ul> <hr/>	<p>Product Safety and Product Liability Directives; Integrated Product Policy</p>
<ul style="list-style-type: none"><li>• Worker and Community Right-to-Know</li></ul>	<p>Aarhus Convention</p>

# US & EU Regulatory Systems

- **The Occupational Safety and Health Act of 1970** **OHS Directives**
- **The Toxic Substances Control Act of 1976** **REACH**
  - » **assessment and regulation of chemicals**

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- **The Clean Air Act of 1990** **Air Directive**
- **Water Legislation** **Water Directive**
  - » **The Clean Water Act**
  - » **The Safe Drinking Water Act**
- **Regulation of Hazardous Waste (RCRA)** **Waste/WEEE**
- **Clean-up of Contamination to Land and Water** **Liability Directive**
  - » **Remediation and Restoration (CERCLA) [Polluter Pays]**

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- **Pollution Prevention and Inherent Safety** **IPPC Directive (IED)**  
**(industrial emissions)**

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- **Chemical Safety: workers (OSHA) and community (EPA)** **Seveso Directives**

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- **Consumer Products (food, drugs, & other products)** **Product Safety and**  
**Product Liability Directives; Integrated Product Policy**

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- **Worker and Community Right-to-Know** **Aarhus Convention**

# REACH (2003)

## Background Problems with Industrial Chemicals

- » Large number of chemicals (~30,000 on the inventory)
- » Toxic risks attended by high uncertainty
- » Complexity
- » The challenge of innovation



# REACH (continued)

Features (REACH influenced by Seveso Directives)

- » “No data, no market” => Continuous supply of data/info
- » Risk Assessment for high volume chemicals (SARs)
- » Substances of very high concern (SVHC) => substitution thru TOA
  - Especially PBT or vPvB chemicals
- » Firms must prove risks are “adequately controlled” or continued use is justified thru socio-economic analysis if no viable alternative exists ~ acceptability of the risks posed (Q’n: is this precautionary?)
- » Responsibility shared by all in the supply chain
- » Shifts in the burden of persuasion ~ on the proponent of use
- » Search for safer alternatives: required 18mths prior to auth’n end
- » Review and monitoring ~ authorization re-examined periodically
- » Administered by ECHA (EU agency) with considerable discretion
- » The Commission puts the proposed restriction forward, while allowing challenges by the Council of Ministers (a qualified majority) or by the Parliament (majority) ~ precautionary??

# IPPC Directive → (Industrial Emissions Directive, 2010)

- **IED** aims to achieve a high level of protection of human health and the environment taken as a whole by reducing harmful industrial emissions across the EU
- ~60,000 large-scale industrial installations required to operate with an integrated permit (air/water/waste)
- IED is based on several pillars:
  - » Integrated approach - permits must take into account the whole environmental performance, energy efficiency, and accident prevention of the plant
  - » Use of best available techniques - permit conditions including emission limit values must be based on the Best Available Techniques (BAT) which can require radical changes
  - » Flexibility - less stringent emission limits can be set in some member states if BAT would result in disproportionately higher costs vs. environmental benefits
  - » Inspections - IED requires mandatory environmental inspections (every 1 to 3 years based on risk-based criteria)
  - » Public participation - the public have access to permit applications, permits and the results of the monitoring of releases
- Prevent, recycle, or dispose of waste in the least polluting way possible (PP>PC)
- Return sites to their original state when the activity is over

# US & EU Regulatory Systems

- The Occupational Safety and Health Act of 1970
  - The Toxic Substances Control Act of 1976
    - » assessment and regulation of chemicals
- 
- **The Clean Air Act of 1990**
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    - » **The Clean Water Act**
    - » **The Safe Drinking Water Act**
  - **Regulation of Hazardous Waste (RCRA)**
  - Clean-up of Contamination to Land and Water
    - » Remediation and Restoration (CERCLA) [Polluter Pays]
- 
- Pollution Prevention and Inherent Safety
- 
- **Chemical Safety: workers (OSHA) and community (EPA)**
- 
- Consumer Products (food, drugs, & other products)
- 
- Worker and Community Right-to-Know
- OHS Directives  
REACH
- Air Directive**  
**Water Directive**
- Waste/WEEE**  
Liability Directive
- IPPC Directive (IED)
- Seveso Directives**
- Product Safety and  
Product Liability Directives; Integrated Product Policy
- Aarhus Convention

# THE AIR DIRECTIVE

- Air pollution: using equipment, concentration, and emission standards (phaseouts/reductions); air framework directives 96/62/EC and 2008/50/EC on Air Quality Assessment and Management
- Reduction of acidification (and reduction of ground level ozone by 2/3rds): SO<sub>2</sub>, NO<sub>x</sub>, VOCs, and NH<sub>3</sub> (emission ceilings by the end of 2010) 2001/81/EC
- Limit values, 'alert thresholds' and monitoring requirements for SO<sub>2</sub>, NO<sub>x</sub>, Pb (1999/30/EC); particulates; O<sub>3</sub> (92/62/EC); benzene and CO (2000/69/EC); Polycyclic aromatic hydrocarbons (PAH), Cd, As, Ni, and Hg (2004/107/EC)
- Air quality standards and emissions limitations (on diesel engines and combustion plants)
- Kyoto (EU programme on climate change)
- Trans-boundary pollution
- Ozone depletion: replacement of HCFCs and methyl bromide more stringent than the amended Montreal Protocol
- Waste incineration (2000/76/EC)
- Clean Air for Europe (CAFE) Programme (2001)

# The Water Framework Directive, 2000

- Eventually replaces 7 older directives to provide a sufficient supply of good quality surface water and groundwater as needed for sustainable, balanced and equitable water use utilizing:
  - » concentration and discharge limits for direct discharges (using best available techniques) and
  - » for diffuse sources (using best environmental practices).
- To be integrated with the Integrated Pollution Prevention and Control Directive (IPPC)/Industrial Emissions Directive and other directives.
- Effluent (emission) limits on “dangerous substances” (76/464/EEC) are established through five daughter directives: mercury, cadmium, hexachlorocyclohexane, etc.

# The Waste Framework Directive and WEEE

- The Waste Framework Directive 75/442/EEC (as amended by Council Directive 91/156/EEC) has as its purposes to prevent/reduce waste production and to recover waste by recycling, re-use, reclamation or any other process, to use waste as energy. **Waste prevention approaches are to be integrated with IPPC/IED and REACH.**
- Waste reduction is to be achieved by prevention or reduction of waste production using clean technology, products designed to reduce waste, and techniques for final disposal of dangerous substances
- Solid waste (75/442/EEC) and hazardous waste (78/319/EEC ) are distinguished
- Hazardous waste (78/319/EEC) must be disposed of safely; there is prohibition of uncontrolled discharges/disposal; the Directive requires the creation of a “competent authority” in the member states.
- **End of life vehicles initiative**
- **The WEEE Directive, 1971 (see below)**
- PCBs/terpehenyls/waste oils
- Limits on **packaging waste** (94/62/EC) as amended by (2004/62/EC)
- Landfill limitations (Directive 1999/31/EC)

**The EU Directive on waste electrical and electronic equipment (WEEE) aims to reduce the amount of electrical and electronic waste disposed in landfills and incinerators. Under the Directive, producers will be responsible for taking back and recycling electrical and electronic equipment.**

**Member States are to draw up a register of producers and keep information on the quantities and categories of electrical and electronic equipment placed on the market, collected, recycled, and recovered in their territory.**

# US & EU Regulatory Systems

- The Occupational Safety and Health Act of 1970 OHS Directives
- The Toxic Substances Control Act of 1976 and 2016 REACH
  - » assessment and regulation of chemicals

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- The Clean Air Act of 1990 Air Directive
- Water Legislation Water Directive
  - » The Clean Water Act
  - » The Safe Drinking Water Act
- Regulation of Hazardous Waste (RCRA) Waste/WEEE
- **Clean-up of Contamination to Land and Water** **Liability Directive**
  - » **Remediation and Restoration (CERCLA) [Polluter Pays]**

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- Pollution Prevention and Inherent Safety IPPC Directive (IED)

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- Chemical Safety: workers (OSHA) and community (EPA) Seveso Directives

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- Consumer Products (food, drugs, & other products) Product Safety and Product Liability Directives; Integrated Product Policy

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- **Worker and Community Right-to-Know** **Aarhus Convention**

# EU ENVIRONMENTAL LIABILITY DIRECTIVE (2004)

- **Areas of Liability**
  - » **Prevention and Restoration (Remediation) of Environmental Damage**
    - **Strict, joint, and several liability**
    - **Not retroactive (unlike US liability under CERCLA)**
  - » **Protection of species, and natural habitats**
    - **At fault liability (negligence)**
- **Operators (private and public) have a duty to:**
  - » **Prevent, notify (report), and manage ‘environmental damage’ to land, water, species, and natural habitats**
  - » **Prevent ‘environmental damage’ associated with “dangerous or potentially dangerous occupational activities” [ANNEX III]\***
  - » **Primary duty is to act in response to any governmental order**
  - » **Secondary duty is to bear the costs, premised on appropriate national law.**
  - » **May be liable, if negligent, for damage to species and natural habitats**
  - » **May be liable for damage (contamination) to land, providing the damage creates a “significant risk“ to human health. (‘significant’ is undefined and creates an opportunity to impose a heavy evidentiary burden, not reflecting a precautionary approach)**

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\* linked with the IPPC/IED Directive permitting



# **EU ENVIRONMENTAL LIABILITY DIRECTIVE (2004)**

## **(continued)**

- **Defenses available to Operators to defeat/reduce cost-bearing:**
  - » **Mandatory**
    - Operators acted in accordance with a compulsory government order
    - Damage was due to the act of an unconnected third party
  - » **Optional (established by each Member State)**
    - State-of-the-art care/practices at the time were followed
    - Operator was allowed to conduct itself in accordance with a permit issued by a Member State in the context of an IPPC requirement,
- **Public Authorities:**
  - » **Must require preventive or remedial action by operators**
    - If damage has not yet occurred, required actions are to be determined by the appropriate Member State
  - » **May, but are not obliged to, take necessary measures in the case that**
    - An operator is not identified, an operator doesn't meet his/her obligations, or is not required to bear the costs (consult available defenses)
    - This is in effect removes an enforceable mandatory state duty to act.
  - » **May recover remediation/restoration costs incurred by the authority.**

# **ENVIRONMENTAL LIABILITY DIRECTIVE (2004)**

## **(continued)**

### **□ Citizens/NGOs:**

- » **Procedural rights marginally expanded (in the nature of the Aarhus Convention).**
- » **Comments of Citizens/NGOs must be supported by evidence and their comments on preventive measures to be taken on land are allowed at the discretion of the Member State.**
- » **They can request public authorities to act, but Member States (MSs) can restrict their access to the courts.**

### **□ Commentary**

- » **Specific targets and benchmarks are lacking.**
- » **Evidentiary burdens are high, vitiating a precautionary approach.**
- » **Prevention is not a driver of this Directive**
- » **The Directive creates weak incentives to change technology at best.**
- » **Financial assurance mechanisms are needed (now optional by MSs)**
- » **Liability with vary significantly among Member States.**
- » **Although technically included, damage from GMOs is hardly included.**
- » **Significant environmental damage may go unabated.**
- » **Enhanced of public participation promised by Aarhus is not achieved.**
- » **The Directive is reminiscent of the weakening of the REACH initiative.**

# The Aarhus Convention

- **Access to environmental information** held by public authorities. This can include information on the state of the environment and policies or measures taken. Citizens are entitled to obtain this information within one month of the request and without having to say why they require it. Public authorities are obliged to actively disseminate environmental information in their possession.
- **Public participation in environmental decision-making** from an early stage in environmental decision-making. Arrangements are to be made by public authorities to enable citizens and environmental organisations to comment on proposals. These comments are to be taken into due account in decision-making, and information on the final decisions and the underlying rationale are to be provided to the public.
- **Access to justice** (EU: left to the member states) challenging, in a court of law, public decisions that have been made without respecting the two aforementioned rights, or in violation of environmental law in general.”

# US & EU Regulatory Systems

- **The Occupational Safety and Health Act of 1970** OHS Directives
- **The Toxic Substances Control Act of 1976 and 2016** REACH
  - » assessment and regulation of chemicals

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- **The Clean Air Act of 1990** Air Directive
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- **Regulation of Hazardous Waste (RCRA)** Waste/WEEE
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- **Pollution Prevention and Inherent Safety** IPPC Directive (IED)

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- **Chemical Safety: workers (OSHA) and community (EPA)** Seveso Directives

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- **Consumer Products (food, drugs, & other products)** Product Safety and Product Liability Directives; Integrated Product Policy

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- **Worker and Community Right-to-Know** Aarhus Convention

# US & EU Regulatory Systems

- The Occupational Safety and Health Act of 1970 OHS Directives
  - The Toxic Substances Control Act 1976, 2016 REACH 2003
    - » assessment and regulation of chemicals
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- The Clean Air Act 1990, 1997, 1990 Air Directives (1996, 2008, and related directives)
  - Water Legislation The Water Framework Directive 2000
    - » The Clean Water Act 1972, 1977, 1987
    - » The Safe Drinking Water Act 1974, 1986, 1996
  - Regulation of Hazardous Waste (RCRA) 1970, 1976, 1984 Hazardous Waste/WEEE 1971
  - Clean-up of Contamination to Land and Water Liability Directive 2004
    - » Remediation & Restoration (CERCLA 1986) [Polluter Pays]
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- Pollution Prevention and Inherent Safety IPPC Directive 1996 as amended by the Industrial Emissions Directive 2010
    - » PPAAct 1990; OSHAAct 1990; CAA 1990 Seveso Directives 1982, 1996, 2012
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- Consumer Products (food, drugs, & other products) Product, drug & food safety directives; Integrated Product Policy
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- Worker and Community Right-to-Know Incorporation of Aarhus Convention into EU Law 2006
  - OSHA Communication std 1983
  - EPCRA Community Right-to Know 1986

# EU Initiatives and Innovation

