

When Is a Regulation Not a Regulation:
Traditional Government-Initiated Measures
Non-Traditional Initiatives

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Panel Discussion Overview

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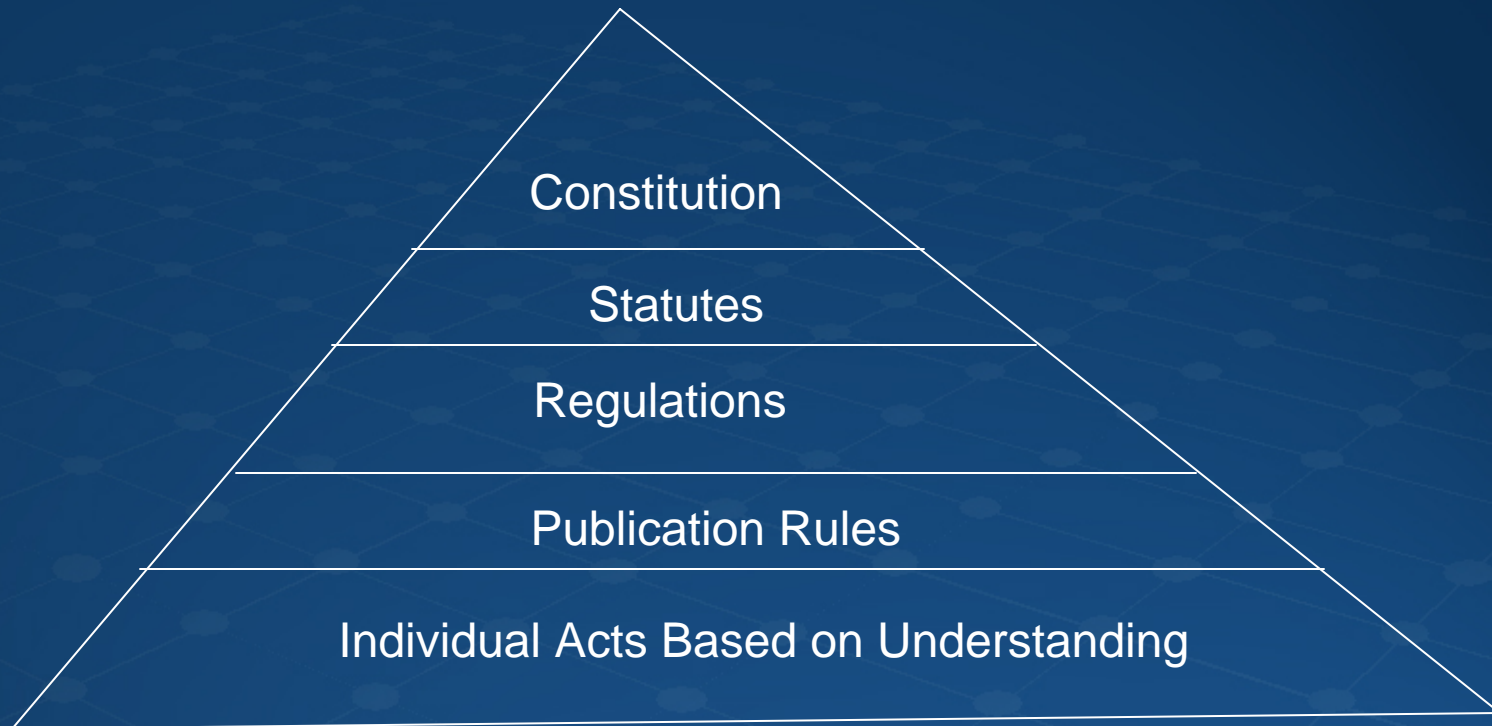
- Traditional Regulations -- Government Initiated
- Governmental Voluntary Programs
- Private-Party Measures and Initiatives
- Non-Traditional Initiatives



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Traditional Regulations -- Background

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Based on Panel Discussion at American Bar Association Administrative Law and Regulatory Process Conference, San Diego, CA (Feb. 2001)



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Traditional Regulations -- Background (cont'd)

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- United States Constitution -- Ultimate Source of Federal Law
 - Statutes -- Issued by Congress -- law of the land
 - Regulations -- Rules that result from formal or informal rulemaking pursuant to the Administrative Procedure Act (APA) Section 553 (notice and comment)



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Traditional Regulations -- Background (cont'd)

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■ APA Regulations

- Status derives from legislative authority to address statutory gaps
- Section 553(b) -- General notice of proposed rulemaking “shall” be published in the *Federal Register*
- Section 553(c) -- After notice is provided, the agency “shall” give interested persons an opportunity to comment



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Traditional Regulations -- Background (cont'd)

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■ Publication Rules

- Interpretations
- Policy statements
- Staff manuals



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Traditional Regulations -- Background (cont'd)

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- Exempt from APA Rulemaking Provisions and May Be Relied On, Used, or Cited As Precedent by an Agency If:
 - Published
 - Indexed
 - Not procedurally defective



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Traditional Regulations -- Background (cont'd)

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- Individual Acts Based on Understanding
 - Issued by individual government representatives
 - Based neither on APA Section 552 nor 553
 - No legal effect on agency or public



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Binding Effect

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■ Regulations vs. Publication Rules

- Regulations -- Binding, enforceable, same effect as statutes
- Publication rules -- Non-binding as a matter of law, but as a matter of practical reality, can have a substantial binding effect as “guidance” and can be “procedurally binding”; if routinely applied, publication rules function like legislative rules unless challenged in court



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Binding Effect (cont'd)

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- Distinguishing publication rules from invalid regulations is critically important in judicial challenges. Criteria:
 - Whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties;
 - Whether the agency has published the rule in the Code of Federal Regulations;
 - Whether the agency has explicitly invoked its general legislative authority; or
 - Whether the rule effectively amends a prior legislative rule

* *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993)



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Role of Enforcement

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- Proven Non-compliance with Legislative Rule = Potential Enforcement Consequences
- Alleged Non-compliance with a Publication Rule (Non-APA Rule) Can and Often Does Result in Enforcement Consequences If Not Judicially Challenged



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Non-Governmental Organization (NGO) Initiatives

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- NGOs Make Use of Innovative and Often High Profile Initiatives That Have Focused Attention on Targeted Issues
- Often Focus on Specific Chemical Products



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Example: Environmental Working Group

Environmental Working Group's
SKIN DEEP
cosmetic safety database

Advanced Search ▶

Search Search

ENVIRONMENTAL WORKING GROUP

WHAT NOT TO BUY

TIPS FAQ RESEARCH ABOUT PRESS

Makeup Skin Care Hair Care Eye Care Nail Care Baby Care Oral Care Fragrance

home > index

45,907,884 searches since 2004



CONTEST: WHAT'S IN YOUR BOTTLED WATER?

Help us study bottled water labels and win a 100% organic cotton shopping bag and a Klean Kanteen water bottle! Entries should be postmarked on or before Friday, March 7.

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Skin Deep is a safety guide to cosmetics and personal care products brought to you by researchers at the [Environmental Working Group](#).

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Example: Environmental Working Group (cont'd)

BROWSE BABY CARE

PRODUCT TYPES

SCORE KEY:  0-2 low hazard  3-6 moderate hazard  7-10 high hazard

[baby bubble bath](#)

[baby lotion](#)

[baby oil](#)

[baby powder](#)

[baby shampoo](#)

[baby soap](#)

[baby sunscreen](#)

[baby toothpaste](#)

[baby wipes](#)

[cradle cap treatment](#)

[diaper cream](#)

[nipple cream \(for moms\)](#)

NGO Initiatives (cont'd)

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- Enhanced State and Local Activism
 - Especially on “toxics”
 - Perception is that federal government lags behind state/local entities



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NGO Initiatives (cont'd)

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- Example: PBDEs -- Bromide Flame Retardants
 - Three key products: penta-, octa-, deca-BDE
 - Classified as PBTs
 - 2003 -- State action on penta-, octa-BDE was limited to one state
 - 2007 -- States with penta-, octa-BDE increased to 13 (enacted/proposed legislative measures)



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Other Chemicals in State Bills

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- Bisphenol A
- Perfluoro (PFOA, etc.)
- Phthalates
- Mercury
- Lead



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Summary

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- Traditional Rulemaking Initiative Will Always Be Important
- Government-Initiated Voluntary Program Will Continue to Proliferate
- Private-party Initiatives Are Expected to Proliferate
- NGO Initiatives Will Continue to Focus Consumer Attention on Targeted Chemicals and Consumer Products in Varied, Innovative, and Effective Ways



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