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United States Regulation of Consumer Products and Transparency Initiatives

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Presentation Outline

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- The U.S. Regulatory Framework:
  U.S. Environmental Protection Agency (EPA) vs. Consumer Product Safety Commission (CPSC)
- Transparency Initiatives
- The Evolution of Chemistry

"Consumer Products" are…

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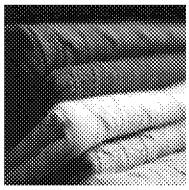
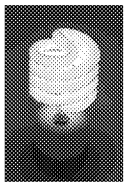
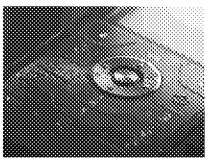
Products sold *to consumers* for use in a household or residence

Products sold or distributed *for consumer use* in home, residence, school or in recreation "or otherwise"

- Components are included







"Consumer Products" do not include…

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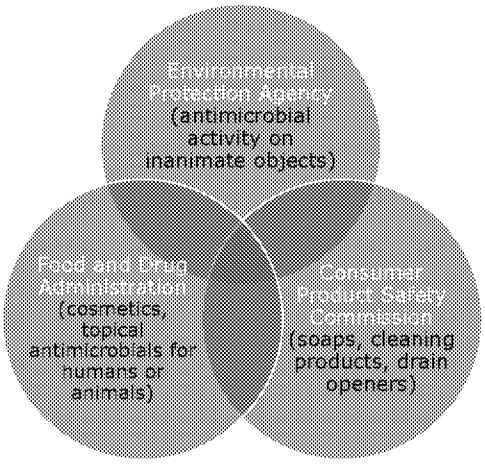
Purely industrial products

- Grey area – industrial type products sold to consumers, e.g. ice cream machine

By statute, products under the jurisdiction of other agencies/statutes:

- Pesticides (including biocides) as defined by U.S. law (FIFRA)

Regulatory Overlap



U.S. Regulatory Framework

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It's all about the Claims!

- Cleans surfaces – CPSC
- Cleans and disinfects surfaces – EPA
- Cleans hands – FDA

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The U.S. Regulatory Framework: EPA vs. CPSC

Consumer Product Safety Commission

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Independent Agency

- Agency not required to comply with Executive Orders (but can choose to comply)
- Agency can vote to override Office of Management and Budget (OMB) disapproval of proposed rule publication, other "collection of information"

Commissioners appointed by the President, confirmed by the Senate

Serve 7 year terms, fixed and independent from the Administration

No more than 3 Commissioners can be from the same political party

Statutes Administered by CPSC

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- Consumer Product Safety Act (CPSA)
- Consumer Product Safety Improvement Act (CPSIA)
- Federal Hazardous Substances Act (FHSA)
- Flammable Fabrics Act
- Poison Prevention Packaging Act
- Refrigerator Safety Act

CPSC Regulatory Tools

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Examples of CPSC Activities

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1977: Banned asbestos-containing consumer patching compounds

1977: Banned lead paint on toys and furniture

1988: Banned butyl nitrite (except as approved under Food, Drug & Cosmetic Act)

1990: Banned isopropyl nitrite and other nitrites (except as approved under Food, Drug & Cosmetic Act)

2008: CPSIA increased stringency of lead paint ban, permanently banned 3 phthalates, interim ban on 3 others

Mandatory Self-Reporting of Product Hazards to CPSC

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Self-reporting is required for:

(1) a “substantial product hazard” or

(2) an “unreasonable risk of injury or death”

Self-Reporting Procedure

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Initial Report
within 24 hours of learning of a substantial product hazard or unreasonable risk of injury or death

Full Report
follows that should contain additional identifying detail relating to the product, nature of the defect and how it came to the attention of the company, total number of products involved, and company response

Failing to report may lead to penalties as high as $16,025,000

CPSC Response to a Self-Report

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Fast Track Recall
Voluntary or government-driven

Public Notice
CPSC requires the manufacturer to provide public notice of the defect, mail notice to all distributors and retailers, and mail a notice to every known purchaser of the product

Temporary Injunction
CPSC or Attorney General restrain adistribution of the product for up to 30 days to allow CPSC to determine whether a hazard exists

The Federal Hazardous Substances Act

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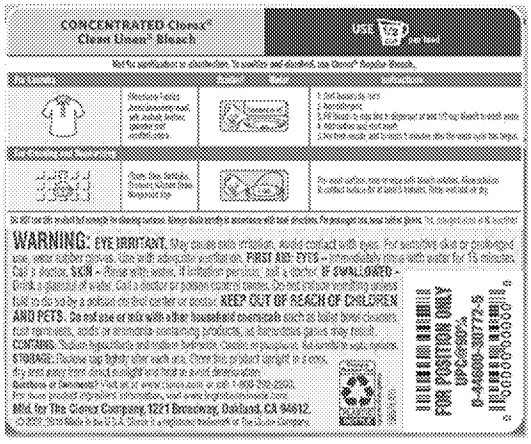
The FHSA requires "hazardous products" to meet warning labeling requirements, including:

(1) Prominent
- Principal Display Panel
- Horizontal placement
- Placed together

(2) Conspicuous
- Type size
- Contrast (color, layout, typography)
- No **interference**, clutter



FHSA Requirements

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Signal Word:

- "CAUTION" or "WARNING"
- "DANGER" for products that are corrosive, extremely flammable, or highly toxic
- If highly toxic, "POISON" and "DANGER"

"Keep out of the reach of children"

Affirmative Statement of Principal Hazards: e.g. "Harmful if Swallowed,"

Precautionary statements, instructions for first aid, storage and care instructions

Common chemical name

Name, business address of manufacturer, packer, distributor or seller

CPSC Regulation of Children's Products

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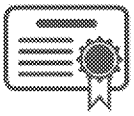
"Children's product": designed or intended primarily for children age 12 and younger

A Children's Product Certificate is required to certify safety, which must be supported by third-party testing. The certificate must include:

- Identification information (product, importer/manufacturer, contact person)
- Citation to each CPSC children's product safety rule to which the product is being certified (e.g. 15 U.S.C. § 1278a, Ban on Total Lead Content in Excess of 100 ppm in Children's Products)
- Third-party testing laboratory and dates/location of testing



CPSC Authority Summary

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Requires Reporting of Product Hazards and can order a range of enforcement/compliance activities

Requires labeling of products for certain hazards

Imposes a regime to ensure children's products meet regulatory requirements

Applies broadly to consumer products with certain exceptions, including pesticides

Statutes Administered by U.S. EPA Related to Biocides

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- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Federal Food, Drug, and Cosmetics Act (FFDCA)
- Pesticide Registration Improvement Act (PRIA)

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

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FIFRA is the principal statute regulating pesticides in the U.S.

"Pesticides" include:

- Antimicrobials/biocides

  Intended to (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or (ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

- Plant Protection Products
- Biopesticides

FIFRA: Requirements for Biocides

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All pesticides require EPA registration prior to marketing or distribution

- EPA must approve each use for the product
- EPA regulates all components of a pesticide product, including active and inert ingredients

EPA requires data before approval

- Data requirements must be satisfied before the product may enter the market
- Data requirements are identified in regulations 40 CFR Part 158W

FIFRA Labels

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The Label is the Law

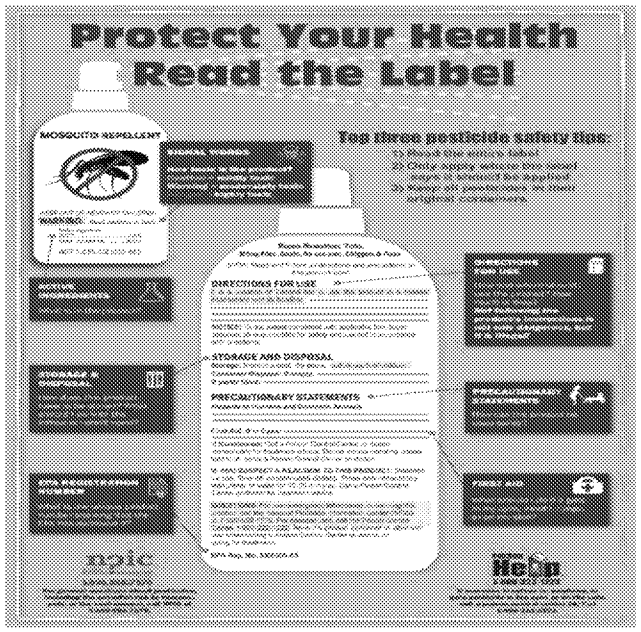
- "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." 40 CFR 156.10(i)(2)(ii).

The label determines how the product can be used

- Who may use a pesticide
- Where can be the product be used (indoor? food?)
- How may the product be used (based on claims)
- How much to use
- How often to apply

Website reference on the label = labeling under FIFRA

FIFRA label requirements are found in 40 CFR 156.10 and EPA's Label Review Manual at https://www.epa.gov/sites/production/files/2018-04/documents/lrm-complete-mar-2018.pdf


Protect Your Health
Read the Label
Top three pesticide safety tips:
MOSQUITO REPELLENT
DIRECTIONS FOR USE
STORAGE AND DISPOSAL
PRECAUTIONARY STATEMENTS
epic
Hello

FIFRA Label Amendments

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Most modifications to the label require approval by EPA

- Application (EPA Form 8570-1)
- EPA review of data may be required – e.g. new use, new application rate, change in precautionary statements, new public health claim, exposure changes
- EPA must approve the amendment and new label before the product can be distributed/sold

Small changes may qualify for a “notification” or “non-notification” (e.g. correction of typographical errors)

PRIA: Fee for Service and Timeframes

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Enacted to provide certainty regarding the timeframes for EPA action on specified types of pesticide applications and amendments.

Establishes a schedule of fees for each specified action and a time frame within which EPA must complete its review

PRIA decision tree sets the appropriate category for particular actions: https://www.epa.gov/pria-fees/pria-3-fee-determination-decision-tree

PRIA schedule of actions, fees and timeframes: https://www.epa.gov/pria-fees/fy-201617-fee-schedule-registration-applications

Federal Food Drug and Cosmetic Act (FFDCA)

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FFDCA Section 408 authorizes EPA to set standards governing pesticide chemical residues in/on food

- Tolerances (the US term for maximum residue levels (MRLs) for pesticide residues in food)
- Exemptions from tolerance (no numeric limit but use conditions)
- A tolerance or exemption must cover all pesticide residues on food in commerce or the food is adulterated under FFDCA

Enforcement Tools

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FIFRA Civil

- Notices of Warning
- Notices of Detention
- Stop Sale, Use, or Removal Orders
- Seizures
- Monetary Penalties

FIFRA Criminal

- Prosecution can be brought for "knowing" violations

FFDCA

- Food containing unauthorized pesticide residues is considered adulterated and can be subject to: warning letters, seizures, injunction, refused entry of imported goods, import alerts, and detention without physical examination

FIFRA Enforcement – Civil Penalties

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Current maximum penalty is $19,446 per violation

5 year statute of limitations

EPA has a penalty policy for each program it administers: https://www.epa.gov/enforcement/enforcement-response-policies-and-guidance

The FIFRA penalty policy is complex, and the penalties assigned in a particular case will depend on several factors https://www.epa.gov/sites/production/files/documents/fifra-erp1209.pdf

FIFRA Adverse Effects Reporting Requirement

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FIFRA § 6(a)(2) requires reporting of "adverse effects" related to registered pesticides. *See,* https://www.epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants

Interpreted to apply to any information relevant to a registration, including information from related compounds

EPA relies on these reports in evaluating continuing approval of registrations

Violations could lead to civil or criminal enforcement

Recent FIFRA Enforcement Example

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(R10) – Amazon Services LLC (February 2018)

Settlement Details

- Settlement Value: $2,739,354
  - $1,215,700 cash penalty
  - $1,523,654 in SEP
- Collaboration with
  - Regions 4, 9, Headquarters

Violations

- *Unregistered and Misbranded pesticide products*
  - *3,792 separate occasions*
  - *Six (6) foreign manufactured pesticides*
    - *3Pos. Cockroach Cockroaches Bugs Ants Roach Kills Chalk;*
    - *Miraculous Insecticide Chalk;*
    - *HUA Highly effective Cockroach killing Bait Powder;*
    - *R.B T.Z. Highly effective Cockroach killing Bait Powder;*
    - *Green Leaf Powder Fly Killing Bait; and*
    - *ARS Mat 12*

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Transparency Initiatives

Greater Transparency

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FIFRA requires disclosure of the active ingredient, but expressly protects the identity of inert ingredients.

Some retailers and one state are requiring product manufacturers to list ingredients on product labels and/or their websites

- Asking for disclosure of ingredients that FIFRA does not require to be require
- All ingredients
- Certain “Chemicals of Concern”

California SB 258

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California is the first U.S. state to require on-pack and online disclosure of ingredients in cleaning products, including online disclosure for cleaning products regulated by FIFRA

Which product categories does the policy cover?

- Air care, automotive, general cleaning, or polish or floor maintenance products used primarily for commercial janitorial, domestic, or institutional cleaning purposes

Who must comply?

- Manufacturers of products sold in California

What needs to be disclosed?

- Full list of intentionally added ingredients, except certain fragrance ingredients and ingredients protected as CBI

Other State Ingredient Disclosure Initiatives

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States consider bills modeled on CA SB 258

- Maryland legislation failed in committee during 2018 session
- Additional legislation expected in 2019 legislative sessions

New York: Governor-driven initiative finalized in 2018 requires online disclosure of all ingredients in cleaning products; exempts FIFRA-regulated products

CA Prop 65: New regulations expand Prop 65 warning requirements. CA and EPA still evaluating how to provide Prop 65 warnings for pesticides

Walmart On-Package Disclosure

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Walmart, the largest U.S. retailer, expects suppliers to list ingredients using one of the following on-pack options:

- Chemicals on California SB 258 designated list
- Full Listing (i.e., all intentionally added ingredients)

Suppliers are expected to begin on-pack listing starting in 2018, but, for registered pesticides, only as registrants update labels

A number of issues remain to be resolved among all stakeholders

Ingredient Disclosure Summary

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- This is an area of substantial activity for both governments and marketplace participants
- It is likely to continue to evolve
- Ingredient disclosure has been accepted by industry which seeks a level playing field to minimize competitive impacts

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The Evolution of Green Chemistry

Multiple Programs Promote Environmentally Preferable Products

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SAFER CHOICE
epa.gov/saferchoice

USDA ORGANIC

MADE WITH SAFE INGREDIENTS
MADE SAFE
WWW.MADESAFE.ORG

OMRI

GREEN SEAL CERTIFIED

Consumer Demand for Green Products

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Growing interest in eco-friendly consumer products:

- A 2016 Nielson Global Survey found that 26% of consumers ranked whether a cleaning product contained organic/all-natural ingredients as “very important” to their purchasing decisions
- 24% of consumers ranked environmentally friendly/sustainable packaging as “very important” to their purchasing decisions

Retailers Are Pressing Suppliers to Move Toward Greener Chemicals

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Walmart	• Disclosure and list of prohibited ingredients
CVS	• More disclosure and elimination of certain ingredients
Whole Foods / Amazon	• Eco-Scale rating system
Multiple Retailers	• Removal of N-methylpyrrolidone (NMP) from paint strippers

Non-Governmental Organization Focus on Safer Chemicals

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NGOs have formed to advocate for environmentally preferable products for homes, schools, institutions

- Some are focused on elimination of particular compounds, others on "green chemistry" generally
- Typically NGO's are seeking to educate consumers so they can influence retailers and up the value chain. *See,* https://saferchemicals.org/mind-the-store/

Focus on Indoor Environments

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Healthy Building Network

- To advance human and environmental health by improving hazardous chemical transparency and inspiring product innovation

LEED (Leadership in Energy and Environmental Design)

- The most widely used green building rating system in the world
- LEED Certification is a label for structures that have been designed, built, and maintained with energy-efficiency and environmental health in mind

Healthy Hospitals Initiative

- Provides hospitals of all sizes with free tools and resources that help focus sustainability efforts (including the use of fewer chemicals)

Governments and Green Procurement

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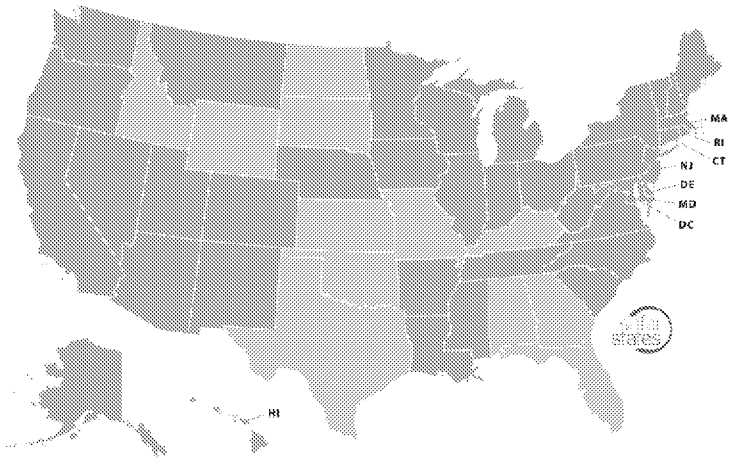
Federal, state and local governments are emphasizing procurement of green products including "environmentally preferable" or "green cleaning products"

Green products in schools

- California Chemical Product Evaluation Program
- New York's Green Cleaning Program
- Chemical Safe Schools in Rhode Island
- Green Universities (e.g. Harvard, University of Virginia, Georgia Tech)

States and Green Chemistry



Source: http://www.saferstates.com/

http://www.saferstates.com/

25 states are considering 132 policies to protect people from toxic chemicals
177 state policies have been adopted in 35 states

Suppliers Support the Evolution toward Greener Chemistries

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Suppliers are interested in developing green products

However, these products are:

- Difficult to formulate using green chemistries while maintaining efficacy
- Require more expensive raw materials and generally do not have large margins
- Communicating information about product benefits to consumers/purchasers is critical to viability of such products

Suppliers Support the Evolution toward Greener Chemistries

To date, cleaning products have been much more broadly introduced than biocides.

Issues hindering development of biocidal products:

- Difficulty and high cost of formulations, as with all green products
- Difficult to describe properties due to regulatory restrictions
  - Use of certain marketing terms is prohibited (e.g., safe, natural, environmental preferable)
  - EPA's "Design for the Environment" program is the **only** indication of environmental preferability allowed on FIFRA-regulated antimicrobial products https://www.epa.gov/saferchoice/design-environment-programs-initiatives-and-projects

Suppliers Support the Evolution toward Greener Chemistries

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Consumer Chemical Product Suppliers support regulatory change to facilitate product evolution:

- Regimes should be flexible to allow truthful, non-misleading claims on all products including biocides
- Third party certification of green biocides should be allowed, as it is for non-biocidal chemical products such as cleaners

Questions

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