Summaries of Chemicals Regulations

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Attached are one-page outlines of four major approaches to managing industrial chemicals: (i) TSCA, (ii) REACH, (iii) Lautenberg's Kid Safe Chemicals Act of 2005 and (iv) the preliminary Framework for Chemicals Policy Reform being worked out by Mark Rossi, Laurie Valeriano and Mike Belliveau.

NOTE: These analyses are very brief and are only intended to provide an overview at the broadest level so that the overall structure of these four approaches can be compared. Full and precise explanations of each approach would contain many exceptions, qualifications, provisos, conditions, elaborations and other complications that are left out here in the attempt to convey the broad outlines.

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U.S. TOXICS SUBSTANCES CONTROL ACT OF 1976 (TSCA)

A. TSCA divides chemicals into two classes

1. Chemicals that were in commerce when TSCA was passed
   a. These chemicals are listed on the "TSCA Inventory"
   b. No safety information is required for these chemicals
      (i) EPA does require periodic information about some of the Inventory chemicals, including approximate annual volume and, starting in 2006, limited manufacturing, processing and use data
      (ii) To order a company to produce safety data, EPA must first prove a chemical "may present an unreasonable risk"
   c. To regulate production or use of a chemical, EPA must prove that:
      (i) the chemical "presents or will present an unreasonable risk";
      (ii) the benefits of regulation outweigh both the costs to industry of the regulation and the lost economic and social value of the product; **and**
      (iii) EPA has chosen the least burdensome way to eliminate only the unreasonable risk

2. Chemicals first manufactured after TSCA was passed
   a. Pre-Manufacturing Notice (PMN) must be filed before new chemical can be manufactured; EPA has 90 days to act or chemical may be marketed
   b. No safety information required in PMN (vast majority contain none)
   c. To require information or restrict production or use during PMN process, EPA must first prove a chemical "may present an unreasonable risk"
   d. Lacking actual safety test data, EPA evaluates new chemicals by computer modeling, and negotiates some restrictions and withdrawals of chemicals
   e. Once marketed, PMN chemicals are listed on the TSCA Inventory, and EPA can regulate them or request data only if it has the same proof required for all Inventory chemicals (see above)
   f. EPA handles 1,500 PMN submissions every year; about 50% of these submissions lead to marketed chemicals

B. Other provisions

1. Though companies are not required by TSCA to create safety information, if companies do create it or become aware of it, they must inform EPA if they believe it reasonably supports a conclusion of substantial risk
2. Much information submitted to EPA (even including chemical identity in PMN submissions) is designated as confidential business information

C. Current TSCA Inventory

1. 82,000 chemicals are on TSCA inventory (9,000 are made/imported at over 10,000 pounds/year/site -- totaling about 15,000 at this level over the years)
2. 62,000 chemicals were on the original Inventory; few have been evaluated; these still constitute large majority of the tonnage of chemicals in commerce
3. 20,000 chemicals have been added to the Inventory through PMN program

REACH (October 29, 2003 Proposal)

I. REGISTRATION

A. All chemicals in commerce over 1 ton/year must be registered to enter or remain on the market. There is no distinction between chemicals already on the market and new chemicals. The dates for registration for chemicals on the market depend on tonnage:

1. 3 years after passage of REACH for CMR's (carcinogens, mutagens, reproductive toxins) and chemicals over 1000 tons/yr;
2. 6 years for chemicals over 100 tons/yr
3. 11 years for chemicals over 1 ton/year

B. Registration includes mandatory data requirements, with the required data increasing at higher tonnages (data tiers are 1, 10, 100, 1000 tons). When a chemical changes categories based on higher use, greater data requirements attach. Data will be publicly available.

C. All chemicals over 10 tons must have publicly available Chemical Safety Reports that specify permitted uses and how the chemical is to be managed for the various uses, including workplace management. These CSRs require communication and transmission of information between manufacturers and downstream users.

II. EVALUATION

All registered chemicals may be evaluated. EU countries must prioritize and coordinate "rolling plans" for conducting these evaluations. New data may be requested by the authorities if they "suspect" a substance of presenting a risk to human health or the environment and "consider that the information is required" to clarify the risk.

III. RESTRICTION

Once "evaluated," any chemical can be regulated ("restricted") where the authorities determine there "is an unacceptable risk to human health or the environment" that is not "adequately controlled."

IV. AUTHORIZATION

A. Highly dangerous chemicals are banned from commerce, unless a manufacturer seeks and obtains "authorization." Highly dangerous chemicals include:

CMRs (carcinogens, mutagens, reproductive toxins);
PBT's (persistent, bioaccumulative and toxic chemicals); and
vPvB's (very persistent, very bioaccumulative chemicals).

B. Such chemicals can stay on the market if a manufacturer applies for a time-limited authorization, maintains that application, and then receives authorization to market the chemical. The manufacturer must prove, for each authorized use, that:

(a) the chemical is "adequately controlled" or
(b) that the socioeconomic benefits of the chemical for that use outweigh the risks and that there are no suitable alternatives.

KID SAFE CHEMICALS ACT OF 2005 (Lautenberg)

I. PRIORITY LIST OF CHEMICALS IN COMMERCE

A. EPA must create a Priority List that must take into account chemicals that are:
   1. Found in human tissues;
   2. Found in food or drinking water;
   3. Made or discharged at over 1,000,000 pounds/year;
   4. Reproductive, neurological or immunological toxicants, carcinogens, mutagens, endocrine disruptors or developmental toxins; or
   5. Persistent or bioaccumulative.

B. 300 chemicals must be placed on the Priority List within 18 months.

C. The Priority List must be updated yearly until all I(A) chemicals are listed.

II. PRIORITY LIST CHEMICALS, AND ALL NEW CHEMICALS BEFORE THEY ENTER COMMERCE, MUST MEET "SAFETY STANDARD"

A. "Safety Standard": The manufacturer must prove that there is a "reasonable certainty that no harm" will be caused by aggregate exposure of a worker, sensitive subgroup or (with 10x safety factor) a child, fetus or infant.

B. In determining whether this Standard is met, EPA shall consider (i) environmental fate and transport, (ii) biological fate and transport, (iii) acute, chronic and subchronic human health effects, (iv) additive or synergistic effects, (v) ecotoxicity, (vi) presence of the chemical in humans, food or drinking water and (vii) releases of the chemical.

C. EPA shall identify a minimum data set for Safety Standard determinations, and can create a tiering process for data submissions. EPA may at its discretion require any of the II(B) information to be submitted.

D. For Priority List chemicals, EPA has 3 years (extendible to 5 years) to make the Safety determination once chemical is placed on the Priority List.

E. All chemicals in commerce must be evaluated for Safety Standard within 15 years. This Safety Standard evaluation must be re-performed for all chemicals every 15 years.

F. If EPA cannot make the required determination, the chemical must be withdrawn from commerce. Exemptions are possible for particular uses that meet the Safety Standard. The President can make a 5-year exemption for national security purposes, but only if there is no feasible alternative.

III. OTHER PROVISIONS

A. CEO's of manufacturers must (a) certify each chemical meets the Safety Standard or (b) assert there is not enough information available to do so. CEO's must make all safety information about the chemical available to EPA and update their submission every 3 years or when new information becomes available.

B. Many manufacturers must do biomonitoring for their chemical and provide methods of detection; EPA shall create an alternatives program and a green chemistry program.

FRAMEWORK FOR CHEMICALS POLICY REFORM
(Rossi, Valeriano, Belliveau 2006)

I. CHEMICALS IN COMMERCE PLACED INTO FOUR CATEGORIES BASED ON HAZARDOUS PROPERTIES

A. Highly Hazardous Chemicals – **to be phased out** based on inherent hazard
   1. Categories of inherently hazardous chemicals:
      Chronic human toxicants;
      PBT's (persistent, bioaccumulative, toxic);
      vPvB's (very persistent, very bioaccumulative); and
      Chemicals of equivalent concern (toxicity, production volume, exposure).
   2. PBT's should be prioritized for earliest phase out.
   3. Hazard warnings required.

B. Hazardous Chemicals – **to be reduced in use and safer alternatives sought**
   1. Categories: inherently hazardous, presence in humans or food, or use and exposure profile.
   2. Substitution planning required of business; government will assist and promote alternatives analysis, with public input; use data will be central to evaluating alternatives.
   3. "Alternatives" defined broadly to include design changes as well as substitute chemicals, and to exclude chemicals have the hazard profile that caused the targeting of the chemical in first place.
   4. Health-based standards will be set, and will trigger mandatory reductions.
   5. Hazard warnings will be required on products.
   6. Exemptions/authorizations/registration systems possible – they should require industry to prove all alternatives are less safe.
   7. Establish green chemistry R&D programs; procurement programs; tax incentives, technical and financial assistance.

C. Chemicals with Insufficient Data – **more information to be provided**
   1. Data gaps must be filled in timely manner, or chemical removed from commerce; Data to be requested at government discretion.

D. Unproblematic Chemicals – **preferred in commerce**

II. OTHER ELEMENTS

This Framework is in development, and will contain other elements, including:

A. Data must be publicly available/strong right-to-know
B. Warnings requirements, modeled on a strengthened Prop. 65
C. Expanded Toxics Release Inventory
D. Labeling requirements
E. U.S., State governments should obtain REACH information from EU