Regulation of Polymers
Exemptions from New Substance Notification and Reduced Notification Requirements

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Outline

Rationale for reduced regulation of polymers vs. chemicals

US TSCA polymer exemption

Other countries – similarities and differences

- Self-actuated exemptions: EU, Philippines, NZ
- Exemptions with notification: China, S. Korea
- Reduced notification: Canada, Australia, Japan

Effect of exemption on resource requirements: US

Summary: Current state, future state

Disclaimer

This presentation is provided only for information purposes and is not a compliance guide. Laws and regulations change frequently. Always consult the original regulatory references that apply to your situation to determine requirements.

Basis for reduced regulation

High molecular weight limits absorption across biological membranes

Human Health

Low acute and chronic mammalian toxicity and irritation potential via oral and dermal exposure

Environment

Low water extractability. Adsorption to sediment removes some polymers from the aquatic compartment

Caveat

Reactivity of certain functional groups can produce toxic effects

US TSCA Polymer Exemption - History

1984 USEPA promulgated the first exemption for polymers modifying notification requirements

From 1979 to 1993 over 12,000 polymer notifications were reviewed by the USEPA

Experience gained in those reviews allowed the Agency to replace the original TSCA polymer exemption with a “self-actuated” exemption in 1995

US TSCA Polymer Exemption - Criteria

1. Substance must meet the OECD polymer definition

- Molecules must be distributed over a range of molecular weights
- > 50 % of the molecules must contain at least three monomer units covalently bound to at least one other monomer unit or other reactant
- No single molecular weight molecule can be > 50 % (w/w) of the total distribution

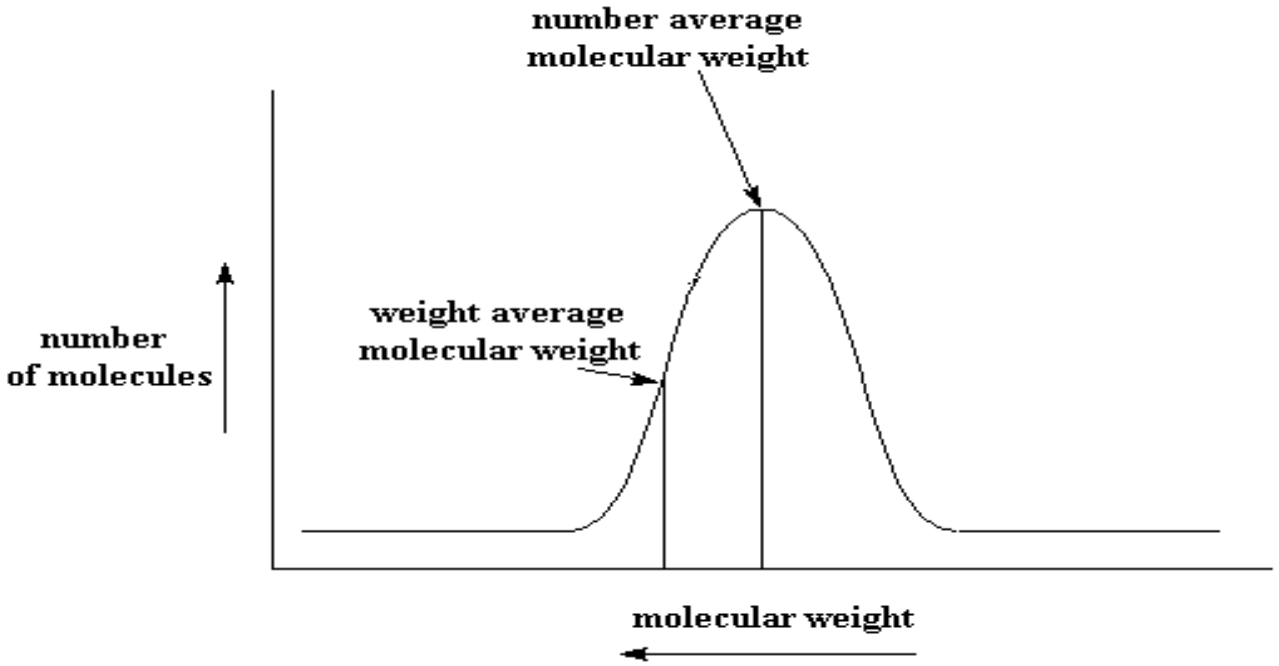
Average Molecular Weight

Mn = number average molecular weight

Total weight of all the polymer molecules in a sample, divided by the total number of polymer molecules in a sample

Mw = weight average molecular weight

Weighted average (accounts for the fact that the higher MW molecules contain more of the total mass)



US TSCA Polymer Exemption - Criteria

2. Average molecular weight and oligomer content

“(e)(1)” Mn > 1000 < 10000

- **< 25% with MW < 1,000**
- **< 10% with MW < 500**

or

“(e)(2)” Mn > 10000

- **< 5 % with MW < 1,000**
- **< 2 % with MW < 500**

(e)(1) exemption includes restrictions on reactive functional groups

US TSCA Polymer Exemption - Criteria

3. The (e)(1) exemption limits the number of reactive functional groups per polymer chain from monomers used at > 2% (Functional Group Equivalent Weight, FGEW)

e.g., Linear polymer with Mn = 10,000, FGEW of X is 5000

Functional Groups of Low Concern (no limit)

Carboxylic acids

Aliphatic hydroxyls

Olefins:

Unconjugated (except those in naturally occurring oils and acids)

Unactivated (part of a larger group such as vinyl ether)

Blocked isocyanates (including ketoximes)

Thiols

Nitriles (unconjugated)

Halogens (except active e.g., benzylic or allylic)

Functional Groups of Moderate Concern: Minimum permissible FGEW is 1000 daltons

Acid halides

Acid anhydrides

Aldehydes

Alkoxysilanes (alkyl > C2)

Allyl ethers

Conjugated olefins

Cyanates

Epoxides

Hemiacetals

Hydroxymethylamides

Imines

Methylolamides

Methylolamines

Methylolureas

Unsubstituted position ortho- or para- to phenolic hydroxyl

Functional Groups of High Concern: Minimum permissible FGEW is 5000 daltons

Acrylates

Alkoxysilanes (alkyl = C1 or C2)

Amines

Aziridines

Carbodiimides

Halosilanes

Halosilanes

Hydrazines

Isocyanates

Isothiocyanates

α and β-Lactones

Methacrylates

Vinyl sulfones

Note: Reactive functional groups that are not specifically identified as low, medium or high concern must be treated as high concern

US TSCA Polymer Exemption - Criteria

4. Polyesters made from a list of specific reactants (“(e)(3)” exemption)

5. Other criteria:

Not designed to degrade

Low cationic density

Elemental limitations

Not water absorbable

Only TSCA listed or exempt reactants at > 2%*

*** Note: All reactants must be listed or exempt to *manufacture* the polymer in the US**

Exemption Requirements

Reporting

Number of substances manufactured or imported for the first time must be reported to the USEPA once a year

Recordkeeping

Chemical Identity

Certification that the substance meets the criteria

Substantiation that it is manufactured for a non-exempt commercial purpose

Production records (first three years) and date of first commercial manufacture

Guidance

USEPA Polymer Exemption Guidance Manual

Questions and Answers for the New Chemicals Program

http://www.epa.gov/oppt/newchems/pubs/guideman.htm

A Practical Understanding of the Polymer Exemption Under the Toxic Substances Control Act

http://www.khlaw.com/admin/pubs/documents/TSCA_PocketGuide_FINAL.pdf

Self-actuated Exemption: EU

Currently, polymers are exempt from REACH registration requirements. Reactants used at > 2% must be registered if > 1000 kg/year

Formerly polymers were exempt from notification requirements when all reactants at > 2% were listed on the EINECS inventory

When notification was required a “Reduced Test Package” category was available for low concern polymers

Mechanism for simultaneous notification of polymer “families” was also available

Self-actuated Exemption: Philippines

Polymers are exempt from notification requirements if:

- All reactants at > 2% are listed on the PICCS inventory, or
- A polymer containing the two highest concentration monomers is listed on the PICCS inventory

If notification is required an abbreviated notification is acceptable if the polymer is listed on at least one other inventory

Self-actuated Exemption: New Zealand

Polymers are exempt from registration requirements if the polymer or formulated product is non-hazardous using HSNO criteria

If the polymer or product is hazardous it may have been previously approved or transferred

Polymer Group Standards have been created for hazardous polymers imported or manufactured as components/raw materials for use in the production of a formulated or manufactured polymer product

Exemption with Notification: China

Polymers are eligible for exemption if:

- All monomers are listed on the IECSC inventory, or
- A polymer containing the two highest concentration monomers is listed on the IECSC inventory and “new” monomer content < 2%, or
- Other criteria (similar to USEPA exemption criteria)

  MW and oligomer requirements

  Functional group requirement: “*This polymer still shall not have an obvious content of active functional groups*”

  Polyester polymers (no reactant limitation given)

Exemption with Notification: S. Korea

1. Nonionic polymer with Mn > 10,000, or

2. Polymer with Mn > 1,000 and

- Reactants are not categorized as Toxic or Observational chemicals
- Reactants are not “new” chemicals or epoxy compounds
- Water solubility is less than 5 mg/g @ pH 2, 7 and 9

If polymer does not meet exemption criteria there are reduced notification requirements

MW, residual monomer, water solubility, and acid and base stability (if the polymer exceeds 50 mg/L solubility @ pH 2, 7 and 9)

Reduced Requirements For Low Concern Polymers: Australia

Criteria for Polymers of Low Concern (PLC) same as TSCA polymer exemption

PLC notification requires molecular weight data, no toxicology data

If not a PLC, limited notification required

Standard notification required if Mn <1000

Reduced Requirements For Low Concern Polymers: Canada

With minimal variation criteria for Reduced Regulatory Requirement (RRR) Polymers same as TSCA polymer exemption

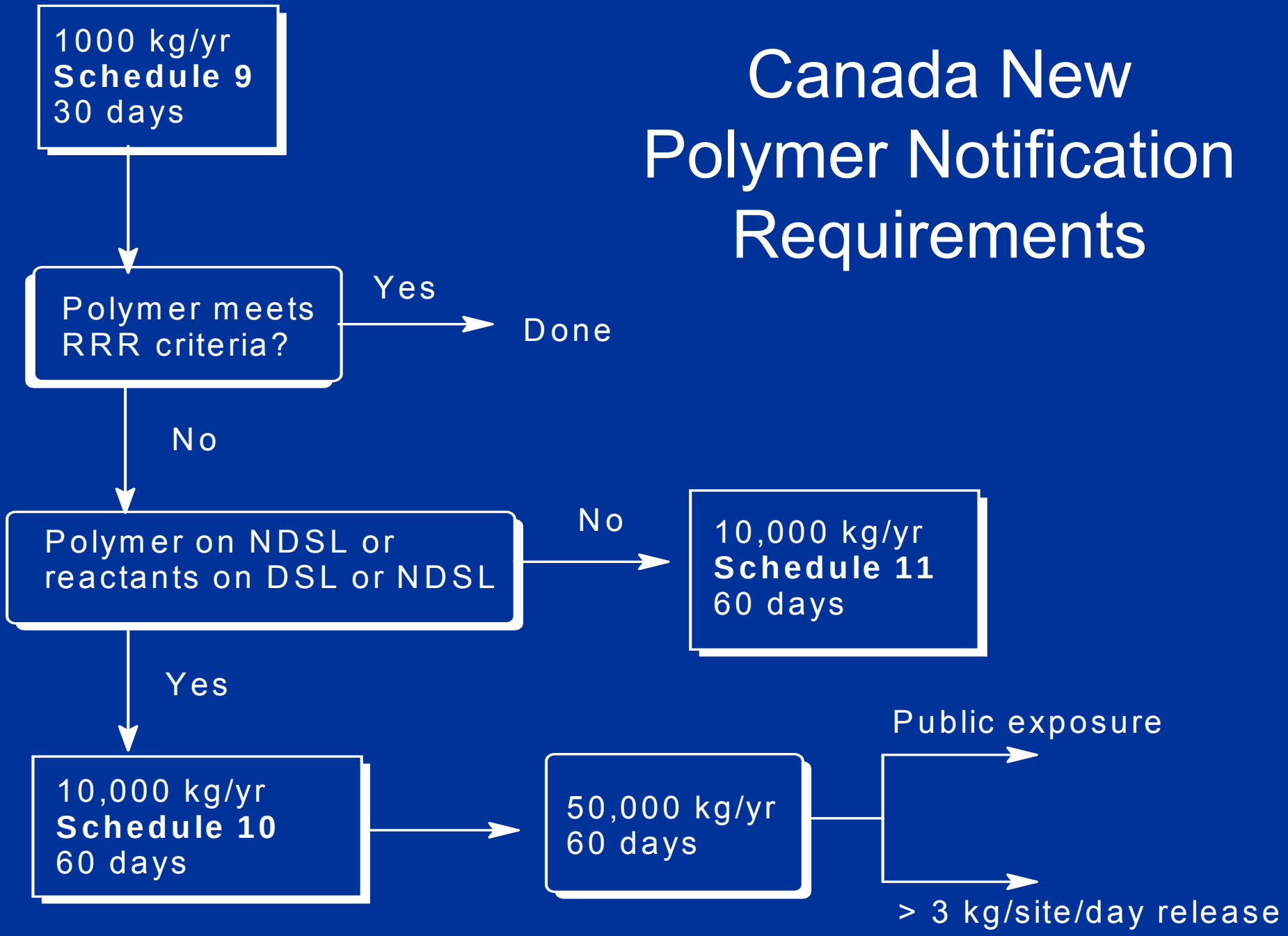
At > 1000 kg/year Schedule 9 submission requires molecular weight data, no toxicology data

Non-RRR polymers require higher Schedules 10 or 11 depending on volume and DSL/NDSL status of polymer and/or reactants.

Physical property and toxicology data requirements increase with higher Schedules

RRR polymers are added to the DSL inventory with a flag

Canada New Polymer Notification Requirements



Japan

Notification required for new polymers

Initial tests designed to establish stability and non-bioavailability for biological activity (low concern)

- < 1% oligomer below 1000 daltons
- Polymer stability established
- Low water solubility; low solubility in certain organic solvents
- No heavy metal content
- Not bioaccumulative

Japan inventory includes many “generic” polymer compositions. This tacitly acknowledges low concern for certain polymer categories and acts as an exemption

Japan – “Generic” Inventory Listings

Section 6 – Addition Polymers

ENCS No. 6-186

Alkyl acrylate-Alkyl methacrylate-Styrene copolymer

ENCS No. 6-257

Methacrylic acid - Alkyl acrylate - Alkyl methacrylate - Styrene copolymer and the light metal salt thereof (Li,Na,K,Mg,Ca,Al)

Section 7 – Condensation polymers

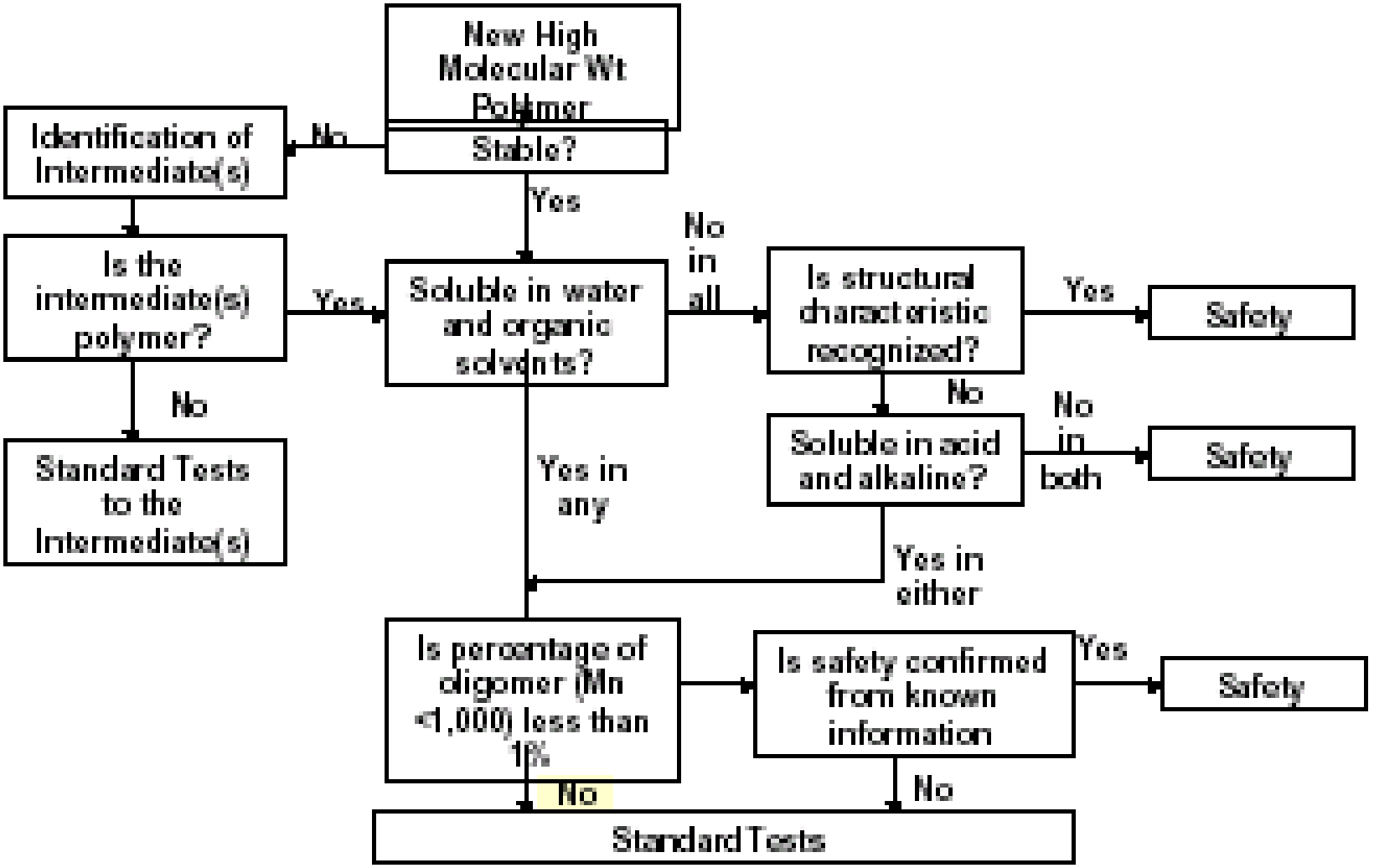
ENCS No. 7-784

Polyester polyol [Aliphatic polybasic acid (C2-12) - Aliphatic polyhydric alcohol (C2-12)]

ENCS No. 7-821

Urethane prepolymer (Organic isocyanate-Polyester polyol)

Japan – Polymer Test Scheme



Benefit of Exemption

Annual Cost Savings ($US Million) From 1995 TSCA Revision*

Annual Submissions	Government	Industry
1000	0.2-0.4	4.7-6.8
2000	0.4-0.8	9.4-13.5
3000	0.6-1.2	14.2-20.3
1500 (2007)**	0.6	11.8

* http://www.epa.gov/fedrgstr/EPA-TOX/1995/March/Day-29/pr-57.html

** Adjusted for inflation using http://data.bls.gov/cgi-bin/cpicalc.pl

Polymer Exemptions - Benefits

New polymers are often developed via incremental changes in compositions generating “new” polymer compositions in one or more countries

Complexity and uncertainty in notification requirements (cost and timing) introduces significant risk to R&D investment. New technology may not be introduced in some countries, or abandoned altogether

Exemptions reduce or eliminate the need for regulatory agency review for substances where there is no concern, allowing resources to focus on substances of concern

Industry can focus on developing new low concern products without regulatory barriers to commercialization

Current State

Exemption types

- Self-actuated: US, EU, Philippines, New Zealand
- Exemptions with notification: China, Korea
- Reduced notification: Canada, Australia, Japan

Low concern polymer criteria aligned in US, Canada, Australia and China. Korea has similar criteria (MW, reactivity)

Japan inventory includes generic polymer “categories”

In NZ registration only required if polymer/product is hazardous

Future State – Issues

Alignment of low concern criteria globally

Conversion of notifications and exemption applications to "self-actuated" exemptions

Importation by customers outside the exempt country (exempt polymers are not listed on chemical inventory)

2% rule for polymer identification

China: No reactant exclusion

Korea: Requires exemption application

Japan: 1% rule (99%)

Exemption criteria are not static