

# **New Chemical Notification Under Global Chemical Control Laws**

***.....In Pursuit of Exemptions***

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# Where the Exemptions Are (and Aren't)

- **U.S.→ Toxic Substances Control Act (TSCA)**
- **Canada→ Canadian Environmental Protection Act (CEPA)**
- **Australia→ National Industrial Chemicals Notification and Assessment Scheme (NICNAS)**
- **New Zealand→ Hazardous Substances and New Organisms Act (HSNO)**
- **Philippines→ Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990 (via Republic Act No. 6969=RA 6969)**
- **Korea→ Toxic Chemicals Control Law (TCCL)**
- **Japan→ Chemical Substances Control Law (CSCL)**
- **China→ Provisions on the Environmental Administration of New Chemical Substances (PEANCS)**
- **Europe→ Registration, Evaluation and Authorization of Chemicals (REACH)**

# General Types of Exemptions

- **Articles**
- **Intentionally vs. Unintentionally formed/present (e.g. impurities, byproducts, formed during use of additive, etc.)**
- **Final Use (e.g. Cosmetics, Pesticides, Pharmaceuticals, etc.)**
- **Intermediates (Related to Use of Final Product, Site-limited)**
- **Mixtures (Status of Components, Hydrates)**
- **Naturally Occurring Chemicals**
- **Radioactive Materials**
- **Export Only Chemicals**
- **Transient Chemicals (Just Passing Through)**
- **Biotechnology Products**
- **Activity (e.g. R&D)**
- **Exemptions Unique to Specific CCL's (e.g. "salts exemption")**
- **Certain Classes of Polymers**

# Exemption Warnings

- **Exemption Variability : “Same” Exemption Can Vary Across Spectrum of Global Chemical Control Laws**
- **Missing Exemptions: Not All Exemptions are Present in All Chemical Control Laws**

# Exemption *V*ariability

## Articles

### Elements Common to Most Definitions of “Article”

- Formed to specific shape or design
- End use functions dependent in whole or in part upon shape/design during end use
- No change in chemical composition during end use or changes in composition with no commercial purpose separate from that of the article
- Fluids and particles do not qualify as articles

# Exemption *V*ariability

## Selected Variabilities - Articles

- **TSCA: For the most part, straightforward definition of Article with little room for flexibility in interpretation - releases of chemicals jeopardize status as an article**
- **Toner cartridges and ink pens function through the release of chemicals. The chemicals are not considered “part of an article”**

# Exemption *V*ariability

## Selected Variabilities - Articles

- **CEPA: “Manufactured Items”, fluids and particles that remain within a manufactured item during normal use are “integral part” of the manufactured item and are not notifiable, but fluids and particles released during end use in a controlled and non-dispersive manner related to the end use may still be considered an “integral part” of the manufacture item**
- **Certain types of toner cartridges and ink pens may be considered manufactured items with the chemical components of toner and ink not notifiable despite being released from both**

# Exemption *V*ariability

## Selected Variabilities – Articles

- REACH: Object given special shape, surface or design that determines its function more so than its chemical composition; Can be composed of multiple substances or preparations; Substances in articles must be registered when:

The substance is present in the article in a total weight of > 1 ton per importer per year and the substance is intended to be released during normal and reasonably foreseeable conditions of use

# Exemption *V*ariability

## Selected Variabilities – Articles

- Releases of Chemicals is Intended When:
  1. The release is essential for the end use function of the article or the article would not work sufficiently without the release (e.g. release of ink from pens, release of cleaning agents from wipes) and/or
  2. The release contributes to a quality or minor function of the article, in other words the release provides an added value to the article that is not related directly to the main end use function (e.g. perfume released from a dishwasher tablet)

# Exemption *V*ariability

## Selected Variabilities – Articles

- Other Article Chemical Notifications Under REACH
- Substances of Very High Concern (SVHC) (e.g. PBT's, Very Persistent/Very Bioaccumulative, CMR, etc.) when

The SVHC is present in articles >1 ton per importer per year and the SVHC is present in the articles at a level of >0.1% (w/w)

- If exposure to humans and releases to environment can be excluded the chemical is not notifiable but appropriate instructions must be provided to recipients of articles related to preventing exposure/release

# Exemption *V*ariability

## Selected Variabilities – Articles

- **Other chemicals in articles may be subject to registration if imported > 1 ton in the article and the Agency has reason to believe that the chemical released presents a risk to humans or the environment (NOTE: This may apply to chemicals other than those classified as SVHC)**

# Missing Exemptions

- **Typically covered by other CCL's and authorities prefer to avoid overlap**
- **Common examples include cosmetics, pesticides, pharmaceuticals, veterinary chemicals and food additives**
- **Some categories of chemicals exempt in most but not all CCL's**
  - **Cosmetics**

# Missing Exemptions

## Cosmetics

- **As a general rule, chemicals manufactured for use in cosmetics are covered by separate CCL's**

### For Example:

- **U.S. → Federal Food, Drug and Cosmetic Act**
- **Canada → Food and Drugs Act (Includes Cosmetic Regulations)**
- **Japan → Pharmaceutical Affairs Law**
- **Korea → Cosmetics Act**

# Missing Exemptions

- **Australia does not have a true exemption for cosmetic chemicals under NICNAS**

## Cosmetic Chemical Requirements

- **Based on use level in cosmetic products (e.g. <1%), non-hazardous classification and other criteria, not prohibited/restricted in U.S. or Europe, etc.**
  - **No volume restriction**
  - **Annual Report to NICNAS and 5 years worth of record keeping**
- **Based on annual production volume (e.g.  $\leq 10$  kg), determination of no unreasonable risk, can't be preservative, colorant, or UV-absorber, can't be restricted/prohibited in U.S. or Europe**
  - **Annual Report to NICNAS & 5 years worth or record keeping**

# Missing Exemptions

## Cosmetic Chemical Requirements

- **Based on annual production volume (e.g. >10 kg/<100 kg), can't be produced under <1% use level scheme, no unreasonable risk determination, can't be preservative, colorant, or UV absorber, can't be restricted/prohibited in U.S. or Europe, if used  $\geq 1\%$  in cosmetic product must confirm as safe when used by potentially "high-risk" groups**
  - **Annual Report to NICNAS & 5 years worth of recordkeeping**
- **If none of these 3 "exemptions" applies to the intended manufacture of the cosmetic chemical, the chemical may be subject to full notification requirements under NICNAS**

# Bottom Line Considerations

- **If you are schooled in the exemptions available under TSCA note that a significant number of these exemptions are available in modified form or not at all under other CCL's**
- **In some cases the modifications are advantageous while in other cases the modifications are problematic**