

## COMPARISON OF INTERNATIONAL NEW CHEMICAL NOTIFICATION/CONTROL LAWS

PLEASE CONSULT NATIONAL LAWS FOR DEFINITIVE COMPLIANCE INFORMATION

Country	US	CANADA	AUSTRALIA	PHILIPPINES	CHINA	JAPAN	NEW ZEALAND	KOREA
Law (acronym)	TSCA <sup>1</sup>	CEPA <sup>7</sup>	NICNAS <sup>21</sup>	RA 6969 <sup>36</sup>	PEANCS <sup>43</sup>	CSCCL <sup>56</sup>	HSNO <sup>64</sup>	TCCL <sup>67</sup>
INVENTORY FEATURES								
Common name (acronym)	TSCA <sup>1</sup>	DSL <sup>8</sup>	AICS <sup>22</sup>	PICCS <sup>37</sup>	IECSC <sup>44</sup>	ENCS <sup>57</sup>	NZIoC <sup>65</sup>	KECI <sup>68</sup>
Type	Dynamic	Dynamic	Dynamic	Dynamic	Dynamic	Dynamic	Dynamic	Dynamic
Timing, premarket or import/manufacture	Import and/or Manufacture	Import and/or Manufacture	Import and/or Manufacture	Import and/or Manufacture	Import and/or Manufacture	Import and/or Manufacture	Import and/or Manufacture	Import and/or Manufacture
Polymers listed	Yes –unless made under polymer exemption	Yes	Yes	Yes	Yes –unless made under polymer exemption	Yes	Yes	Yes
Exclusions From Definition Of Substance Or Exempt From Notification								
Articles	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biocide active ingredients	Yes	No	Yes	Yes	Yes	No	No	Yes
Biocide intermediates	No					Yes		Yes
Biotech chemicals	No	No	No			No		Yes
Cosmetics	Yes	No	No	Yes	Yes	Yes	No	Yes
Drugs	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Drug intermediates	Yes	No		Yes		Yes	No	Yes
Foods/food additives	Yes	No	Yes	Yes	Yes	Yes	Yes (foods)	No
Hydrates	Yes	Yes	No	Yes (informal)	Yes	Yes		No
Impurities	Yes	Yes	Yes	Yes	Yes	Yes (< 1%)	No	Yes
Microorganisms	No	No				Yes	No	
Mixtures	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Natural substances	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Nonisolated intermediates	Yes	Yes	Yes	Yes	Yes	Yes		No
Pesticide active ingredients	Yes <sup>2</sup>	Yes <sup>2</sup>	Yes	Yes	Yes	No	No	Yes
Pesticide Intermediates	No	No				Yes		Yes
Radioactive materials	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Site-limited intermediates	No	No	No	No	No	Yes	No	No
Wastes/By-Products	Yes	Yes	Yes	Yes	Yes	Yes	Wastes (No) By-Products (Yes)	No
Chemicals deemed elsewhere to be harmless	No	No	No	No	No	No	No	Yes
Veterinary Chemicals	Yes		Yes	Yes	Yes		No	Yes

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NEW CHEMICALS NOTIFICATION								
Exemptions from Full Notification Requirements	Yes	Yes	Yes	Yes <sup>38</sup>	Yes <sup>45</sup>	Yes	Yes	Yes
R&D	Yes	Yes	Yes	Yes	Yes <sup>45</sup>	Yes	Yes	Yes
• Max vol., kg /yr.	Unlimited	1,000 or 10,000 <sup>9</sup>	100		≤100 (renewable) or ≤1000 (1 year, not renewable) <sup>46</sup>	Unlimited	No volume specified	Unlimited initial volume; unlimited cumulative volume
• Notification required	No <sup>3</sup>	Yes <sup>10</sup>	No		Yes	No	No	No
• Test data required	N/A	Existing only	No		No	No	No	No
Low volume	Yes <sup>4</sup>	Yes	Yes <sup>23</sup>	Yes	Pending Development	Yes	No	Yes
• Max volume, kg /yr	>0/10,000	100 or 1,000 <sup>11</sup>	100 <sup>24</sup>	1000		1000 <sup>58</sup> or 10000 <sup>59</sup>		100/company
• Notification required	Yes	Yes <sup>10</sup>	Yes <sup>25</sup>	Yes		Yes		No
• Test data required	Existing Only	Existing only	No			No <sup>60</sup>		No
Test Market	Yes		Yes <sup>26</sup>	No	No	No	No	No
• Max volume, kg	Qty requested		4000 <sup>27</sup>					No
• Notification required	Yes <sup>4</sup>		Yes <sup>28</sup>					No
• Test data required	Existing Only		No					No
Site limited intermediates	No	Yes <sup>12</sup>	Yes	Yes	No	Yes		No
• Max volume, kg	None	1,000 or 10,000 <sup>9</sup>	10,000	5,000		None		None
• Notification required	Yes	Yes	No	Yes		No		Yes
• Test data required	Existing Only	No <sup>13</sup>	Yes			No <sup>61</sup>		No
Export only	Yes	1,000 to 10,000 <sup>9</sup>	Yes <sup>29</sup>	Yes - 5,000 kg	No	Yes	No	No
Polymers							No	
• "2% rule"	Yes	Yes	Yes	Yes	Yes <sup>45</sup>	No (1%)		No/Yes
• New polymer from existing monomers	Yes <sup>4,5</sup>	No <sup>14</sup>	No	Yes	Yes <sup>45</sup>	No		No
• New polymers from new monomer	No	No	No	No	No	No		No
• Polymers of "low concern"	Yes <sup>4,5</sup>	Yes <sup>15</sup>	Yes <sup>30</sup>	No	Yes <sup>45</sup>	Yes <sup>62</sup>		No/Yes <sup>69</sup>

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Notice of commencement required	Yes	Yes <sup>16</sup>	Yes	Yes	Yes <sup>47,48</sup>	No	No	No
Positive approval required?	No (except for exemptions noted above)	No <sup>17</sup>	Yes	Yes	Yes	Yes		Yes
Notice of exceeding trigger volume	N/A	Yes <sup>18</sup>		No <sup>39</sup>	Not Stipulated	No	No	N/A
Confidentiality Mechanism	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Protection limit, year	Unlim	Unlim	5 <sup>31</sup>		Unlimited <sup>49</sup>	1.5 <sup>63</sup>	5 (guidance)	3 <sup>70</sup>
Testing								
Required with notification	Existing information	Higher tier notices	Yes		Yes <sup>50,51,52</sup>	Yes	No	Yes
Additional may be required (e.g. with volume increases)	Yes	Yes	Yes		Yes	Yes	Yes	Yes
Tox and environ data needed for new polymers, >1000 MW	No	Yes <sup>19</sup>	Yes if not Polymer of Low Concern (PLC)		Yes <sup>53</sup>	Yes if not low concern	Yes (if hazardous)	No
Time Estimates (min)								
Time for approval, days	90 minimum	30 – 140 <sup>20</sup>	90 for certificates 14-20 days for permits <sup>32</sup>	180 <sup>40</sup>	120 days	90	85 (depends on notification type)	45
Assessment Reports from other schemes			Yes <sup>33</sup>	No	No	No	Optional	
FEES AND PENALTIES								
Fees			None <sup>34</sup>		Yes <sup>54</sup>			
• Full notification	\$2,500 <sup>10</sup>	\$C 875 – 3,500	\$15,554 A	3,750.00 <sup>41</sup>		¥ 30,000K	Varies depending on notification type	52,000W
• Limited notification	N/A	\$C 50 – 2,000	\$13,028 A	2,150.00 <sup>41</sup>			\$562.50NZ (rapid assessment or containment)	

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• Polymers of low concern	\$2,500	\$C 125 – 500	\$4,388 A			¥ 3,000K	N/A	
• Commercial evaluation	N/A	\$C 50 – 3,500	\$3,457 A				N/A	
• Low-volume chemicals	N/A		\$3,457 A				N/A	2,000W
• Confidential claim	N/A	\$C 150 - 600	\$1,367 A				N/A	30,000W
• Test variation	N/A		\$1,230 A				N/A	
• Existing Chemicals Assessments	N/A							
Penalties								
• Individual	jail, up to one year – criminal	jail, up to 5 years -	\$33,000A <sup>35</sup>		10,000 to 30,000 RMB <sup>55</sup>	jail, up to one year and/or up to ¥ 500K	Up to 3 months imprisonment and \$500,000NZ (additional fines of \$50,000NZ/day for continuing offenses)	5,000,000W
• Company	\$32,500/day	\$1,000,000 - criminal	\$165,000A <sup>35</sup>	Yes <sup>42</sup>	10,000 to 30,000 RMB <sup>55</sup>	Up to ¥ 50,000K	Yes <sup>66</sup>	5,000,000W/violation

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NOTES:

1. TSCA: Toxic Substances Control Act
2. Excluded only when manufactured, processed or distributed in commerce for use as a pesticide.
3. Notification to EPA not required; Recipients of R&D exempt substances must be notified of R&D status.
4. Eligible substances are not added to the inventory
5. If meet polymer exemption criteria. The EPA requires a one-time notification of the number of new polymer exemptions annually the January after commencement.
6. Consolidated notices (up to six substances) can be made for \$2,500. A fee of \$1,000 is required for intermediate PMNs when filed with the PMN for the final product. There are other fees for specialized notifications
7. CEPA - Canadian Environmental Protection Act
8. Domestic Substances List (Canada also has an NDSL, Non-Domestic Substances List, consisting of substances not on the DSL which have been on TSCA for at least five years, with reduced reporting requirements)
9. 1,000 kg/yr for non-polymer substances (Sched 1); 10,000 kg/yr for polymer substances (Sched. 3)
10. if above threshold
11. 100 kg/yr for non-polymer substances not on NDSL (Sched. 4); 1,000 kg/yr for polymer substances (Sched. 9)
12. Exemption is for "contained" and "transient" only
13. If contained or transient only
14. New polymers from existing monomers are subject to reduced information requirements.
15. Reduced Regulatory Requirements Polymer (RRRP) - Sched. 9
16. Annual notice of manu/ import.; Notice of exceedance
17. Positive approval not required following statutory deadline, but Agency will follow up with a "no suspicion of toxics letter" following assessment
18. (1) can file NOMI at any time to place substance on DSL or (2) must file after exceeding highest trigger volume
19. If not Reduced Regulatory Requirement Polymer. In principle, required testing may be waived, such that "...the (average) costs of CEPA tests are comparable to those under TSCA..." (Socio-Economic Impact report, Apogee Int'l; Jan '93). Requirements will vary. Must consult regulations.
20. All required schedules
21. NICNAS - National Industrial Chemicals Notification and Assessment Scheme
22. AICS - Australian Inventory of Chemical Substances
23. Can be renewed any number of times.
24. Limit of 100 kg/yr in the country.
25. No formal assessment - Permit may be granted based on specific use and summary of health, safety and environmental effects.
26. A limited notification package and assessment is required for up to 1000 kg/12-month period. May be extended to 2000 kg/24 months. Can be renewed once only
27. Sufficient justification especially if > 2000. Should only apply for a volume that is needed.
28. No formal assessment - Permit may be granted based on specific use and summary of health, safety and environmental effects.
29. New permit. Maximum volume = 10,000 kg. Notification is required. Test data required only when volume exceeds 10,000 kg
30. Polymers which meet certain criteria, such as low health or environmental hazard.
31. Substance transferred to inventory after 5 years. May be placed on a confidential inventory for another 3 or 6 years.
32. Assessment time may be longer if extra data requested.
33. Risk assessment reports from other schemes may be acceptable as part or all of notification statement.
34. Fees increase on July 1<sup>st</sup> of every year by the CPI
35. Maximum per offense
36. DAO 29 is Department Administrative Order or implementing guidelines
37. PICCS - Philippine Inventory of Chemicals and Chemical Substances
38. Abbreviated notification for substances listed on approved inventories: United States, Japan, European Union, Australia, Canada

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39. Only if exceeding low volume
40. Not consistent
41. Costs given in pesos per chemical
42. Industries found to be avoiding the requirements and regulations of Title II of DAO 29 can be fined or imprisoned or both depending upon the type of violation committed.
43. PEANCS – Provisions on the Environmental Administration of New Chemical Substances
44. IECSC – Inventory of Existing Chemical Substances in China
45. ALL exemptions require an application to SEPA and annual renewal. SEPA review = 30 days.
46. <100 kg/yr for “Scientific Research” and < 1000 kg/yr for “Technical Research and Development”
47. Registration Certificate Holders must notify the County EPA within 5 days after EACH import, manufacture or transfer
48. Only Certificate Holder can import. Substance not added to the IECSC until SEPA decides to (no defined period of time established)
49. No limit stated in the regulations unless the applicant files a waiver on confidentiality
50. Notification requirements include a requirement to conduct acute fish toxicity and degradability testing in China
51. Simplified Notification if listed on 4 or more existing inventories; Application form and report on ecotoxicity conducted in China
52. No testing required for any of the exemption notifications
53. Toxicity and Environmental data is not required for a Polymer of Low Concern (PLC)
54. The regulations indicate there are fees; however, these notification fees have not yet been established. SEPA will reportedly announce fees at some future date and companies will be charged retroactively
55. SEPA can also refuse to process any notifications for the company for a period of 3 years
56. Chemical Substance Control Law (Kashinho in Japanese)
57. Existing and New Chemical Substances list (also known as METI or MITI inventory)
58. Small Quantity New Chemical Substances
59. Low Production Volume Chemicals. Manufacture and import of these chemicals are permitted even if their toxicity is unknown, as long as they are persistent and not-bioaccumulative.
60. If the substance is bioaccumulative toxicity data for humans, plants and animals is required
61. If little or no potential for exposure
62. Low concern criteria include < 1% below 1,000 daltons, polymer is stable, low water solubility; low solubility in certain organic solvents, no heavy metal content, not bioaccumulative
63. Approximate time before inventory listing published in gazette. May be extended up to 5 years for “white” (nonhazardous) substances.
64. HSNO – Hazardous Substances and New Organisms Act. Only substances classified as “hazardous” are regulated under HSNO.
65. NZIoC – New Zealand Inventory of Chemicals. If a substance is not hazardous or if it already has a HSNO approval, it is not required to be listed on the NZIoC.
66. Corporate penalties vary: \$10,000,000NZ or 3 times the value of the corporate gain or 10% of the turnover of the corporate body and all of its interconnected corporate bodies
67. Toxic Chemicals Control Law
68. Korean Existing Chemicals Inventory (combines Korean Existing Chemicals List (KECL) Existing Chemicals List (ECL))
69. Polymers defined as “stable” eligible for reduced testing – nonionic MW > 10,000; MW < 10,000 – testing requirement; MW > 1000 – low water soluble
70. Renewable for successive 3-year periods