

Regulatory Challenges: New Novel and other Critical Materials

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CMC Conference 2018

Phoenix, AZ

**Critical Materials Council of
Semiconductor Fabricators**

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- ❖ Workplace safety and health

- Conflict Minerals Update
- U.S. Chemical and Materials Regulation Update
 - TSCA New Chemicals Changes
 - TSCA Prioritization / Risk evaluation
 - Nanoscale materials
- Int'l Chemical and Materials Regulation Update
 - China
 - Taiwan
 - Korea
 - EU

Conflict Minerals Update

Conflict Minerals Update - US



- **2010 Dodd-Frank Act** – Avoid financing conflict in Congo (DRC) region. SEC’s CM rule:
 - (1) Public companies using tantalum, tin, tungsten, gold (3TG)
 - (2) Conduct ‘country of origin’ inquiry re source of 3TG;
 - (2) Due diligence investigation, auditing and report if uncertain;
 - (3) File form SD
 - (4) Publish statement on websites: Whether “*not DRC-conflict free*”
- **Court:** Ruled it partially unconstitutional (final, April 2017)
- **SEC:** “No enforcement of CM report, audit, disclosure” (Apr 2017)
- **SEC and State Dept:** solicit public comment on CM rule utility/burden
- **House:** Passed two bills: strike language and defund enforcement
- **Treasury Dept:** Report calling for scrapping the CM rule

Conflict Minerals Update – *not dead yet*



- After SEC Guidance - Some U.S. CM rule duties remain:
 - Country of origin inquiry
 - Form SD submittal
 - Due diligence investigation
- No. of 2017 reports suggest no significant drop
- Senate did not pass the CM rule repeal legislation
- Still strong support for CM accountability in many corners
- Voluntary reporting (at very least) likely to continue for many
 - UN supply chain standards; OECD diligence guide
 - Socially responsible investor pressure
 - NGO pressure
 - Corporate social responsibility policies

Conflict Minerals Update – *expanding?*



- 2017: Voluntary investigations re conflict-free **cobalt**
- 2017: EU's enacts its own conflicts mineral rule (May 2017)
 - 3TG *metals importers*: Due diligence – audit – public consult
 - Effective Jan. 1, 2021
 - Not restricted to Congo area - all “*conflict affected and high risk areas*”
 - *EU Importers need to actively map/manage supply chains*
- Continued investment in supply chain awareness necessary

Chemical and Materials Regulation Update

❖ *United States*

- 2016 Toxic Substances Control Act (TSCA) Amendments
- Nanomaterials reporting



- Frank R. Lautenberg Chemical Safety for the 21st Century Act
 - Significantly amended Toxic Substances Control Act (TSCA)
- Takeaways in two areas:
 - Regulation of New Chemicals
 - Prioritization and risk evaluation of existing chemicals

TSCA: Changes to “New Chemicals” Program



■ 2016 Key “New Chemical” Changes:

- Amendments changed the decision-making process in subtle but important ways
- Arguable loss of decision-making flexibility
- Effectively removed 90-day limit for EPA decision-making

■ Current effects:

- Very long decision-making periods
- More compelled testing
- High proportion of new substances are regulated before commercialization
 - Increased cost to introduce and use “new chemicals”
 - Time, transaction, testing
 - Ongoing order/rule compliance and management
 - Stigma of “regulated chemical” may chill customer interest/adoption

■ **What can you do?**

- Consider exemptions (low volume, test market, export only)
- Plan ahead for long lead times
- Be proactive in the PMN process

■ **Prepare PMNs that anticipate & answer the important questions**

- Preview results using EPA’s hazard, exposure and risk estimating tools /models
- Voluntarily develop information to avoid EPA reliance on conservative modeling assumptions (physchem properties, exposure, hazard)
- Consider pre-notice meeting before submitting; engage during review

TSCA: Prioritizing /Risk Evaluation Existing Chems



- **New mandate to review safety of all chemicals in commerce**



- **Key Take Away Points:**

1. **Companies need to be participate substantively in these proceedings by providing data and information**
 2. **Value chains need to prepare well ahead to participate**
- *In the absence of data, EPA uses conservative assumptions*
 - *Once the process starts there is no time to develop data*

TSCA: Prioritizing /Risk Evaluation Existing Chems



- **New mandate to review safety of all chemicals in commerce**



- **Key Take Away Points:**

1. **Companies need to be participate substantively in these proceedings by providing data and information**
 2. **Companies and industries need to prepare well ahead to participate**
- *In the absence of data, EPA uses conservative assumptions*
 - *Once the process starts there is no time to develop data*

2014 TSCA Work Plan Chemicals



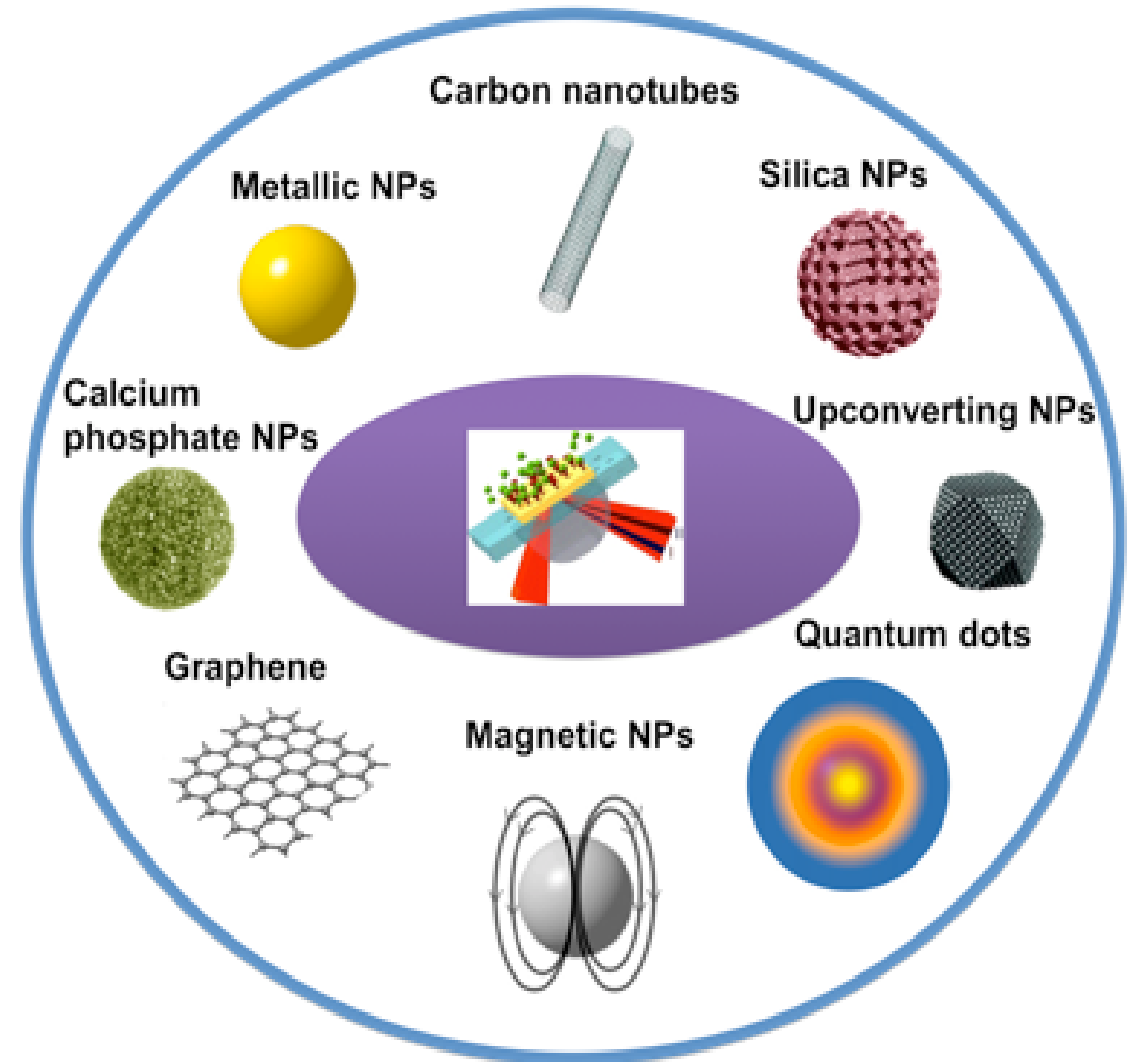
1. Pigment Violet 29
2. Asbestos & Asbestos-like Fibers
3. 1-Bromopropane
4. Carbon tetrachloride
5. Decabromodiphenyl ethers (DecaBDE)
6. 1,4-Dioxane
7. Hexabromocyclododecane (HBCD)
8. Methylene chloride
9. N-Methyl-2-pyrrolidone (NMP)
10. Pentachlorothio-phenol
11. Tetrachloroethylene (PERC)
12. Trichloroethylene (TCE)
13. Tris(2-chloroethyl) phosphate (TCEP)
14. 2,4,6-Tris(-tert-butyl)phenol
15. Acetaldehyde
16. Acrylonitrile
17. tert-Amyl methyl ether
18. Antimony & Antimony Compounds
19. Arsenic & Arsenic Compounds
20. Barium Carbonate
21. Benzenamine
22. Benzene
23. Bisphenol A (BPA)
24. 1,3-Butadiene
25. Pigment Yellow 83
26. Butanamide, 2-[(4-methoxy-2-nitrophenyl) azo]-N-(2-methoxyphenyl)-3-oxo- (Pigment Yellow 65)
27. Butyl benzyl phthalate (BBP) 1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester
28. 4-sec-Butyl-2,6-di-tert-butylphenol
29. Cadmium & Cadmium Compounds
30. Chromium & Chromium Compounds
31. Cobalt & Cobalt Compounds
32. Creosotes
33. Cyanide Compounds (Limited to dissociable compounds)
34. Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester)
35. o-Dichlorobenzene
36. p-Dichlorobenzene
37. 3,3'-Dichlorobenzidine
38. 3,3'-Dichlorobenzidine dihydrochloride
39. 1,1-Dichloroethane
40. 1,2-Dichloroethane
41. trans-1,2-Dichloroethylene
42. 1,2-Dichloropropane
43. Dicyclohexyl phthalate
44. Di-ethylhexyl phthalate (DEHP) (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)
45. Di-isobutyl phthalate (DIBP) (1,2-Benzene-dicarboxylic acid, 1,2-bis(2methylpropyl) ester)
46. Di-isodecyl phthalate (DIDP) (1,2-Benzene-dicarboxylic acid, 1,2-diisodecyl ester)
47. Di-isononyl phthalate (DINP) (1,2-Benzene-dicarboxylic acid, 1,2-diisononyl ester)
48. 1,2-Dimethoxyethane (Monoglyme)
49. 2-Dimethylaminoethanol
50. Di-n-octyl phthalate (DnOP) (1,2-Benzene-dicarboxylic acid, 1,2-dioctyl ester)
51. Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl)-
52. Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)-
53. Ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro- 2,3,8,8-tetramethyl-2-naphthalenyl)-
54. Ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro- 2,3,8,8-tetramethyl-2-naphthalenyl)-
55. Ethylbenzene
56. Ethylene dibromide
57. bis(2-Ethylhexyl) adipate
58. 2-Ethylhexyl 2,3,4,5-tetrabromobenzoate (TBB)
59. bis(2-Ethylhexyl) -3,4,5,6-tetrabromophthalate (TBPH)
60. Formaldehyde
61. 2,5-Furandione
62. Hexachlorobutadiene
63. 1-Hexadecanol
64. 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)
65. 2-Hydroxy-4-(octyloxy) benzophenone
66. Lead & Lead Compounds
67. Long-chain chlorinated paraffins (C18-20)
68. Medium-chain chlorinated paraffins (C14-17)
69. 4,4'-Methylene bis(2-chloroaniline)
70. 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)
71. Molybdenum and Molybdenum Compounds
72. Naphthalene
73. 2-Naphthalenecarboxylic acid, 4-[(4-chloro-5-methyl-2-sulfohenyl) azo]-3-hydroxy-, calcium salt (1:1) (Pigment Red 52)
74. Nickel & Nickel Compounds
75. N-Nitroso- diphenylamine
76. Nonylphenol and Nonylphenol Ethoxylates (NP/NPEs)
77. Octamethylcyclotetra-siloxane (D4)
78. 4-tert-Octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol)
79. p,p'-Oxybis(benzenesulfonyl hydrazide)
80. Phenol, isopropylated, phosphate (3:1) (iPTPP)
81. Phosphoric acid, triphenyl ester (TPP)
82. Phthalic anhydride
83. Styrene
84. Tribromomethane (Bromoform)
85. 1,1,2-Trichloroethane
86. Triglycidyl isocyanurate
87. Vinyl chloride
88. m-Xylene
89. o-Xylen
90. p-Xylene

Example Current or Phased-out Semiconductor Chemicals on EPA Work Plan

1. N-Methyl-2-pyrrolidone (NMP)
 2. Antimony & Antimony Compounds (Antimony Trioxide)
 3. Arsenic & Arsenic Compounds
 4. Chromium & Chromium Compounds
 5. Ethylbenzene
 6. Formaldehyde
 7. Trichloroethylene (TCE)
 8. Carbon tetrachloride
 9. 1,1,2-Trichloroethane
 10. m-Xylene
 11. o-Xylene
 12. p-Xylene
- ... and PFAS**

Nanoscale Materials Reporting Rule

40 CFR 704.20



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Nanoscale Materials Reporting Rule*



- **First EPA regulation of nanoscale materials as a class**
 - First prospective reports (where triggered) starting August 2017
 - First retrospective reports *due August 14, 2018* (3 year look back)

- **Rule Presents Four Macro Challenges:**
 - Long lead times – New NM processors must report 135 days before starting
 - Burden – EPA estimates 170 man hours to complete report
 - Chill innovation? – Lead time and burden may stigmatize products; may hinder markets
 - Compliance – Ongoing diligence

* *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; Final Rule, 82 FR 3641 (Jan. 12, 2017).*

■ Which materials must be reported?

- **Solid** at 25°C /atmospheric pressure (including, e.g., suspensions)
- **Size:** ≤ 100 nm in 1 dimension (excluding aggregates/agglomerates > 100 nm)
- “Discrete forms” separately reportable: Significant and intentional variations/changes to certain properties may trigger additional reporting:
 - **Unique and Novel Properties:** Size-dependent property, different than in larger size forms
 - **Intent:** Made/used in nanoscale form in part *in order to exploit* the special property

■ Key Exemptions:

- R&D materials • Articles • *Formed* in/as thin film on surface • $< 1\%$ NM wt/wt
- BUT reporting **triggered by any amount** (no minimum volume threshold)

■ What is reported?

- Extensive information - chemical identity, use, hazard, environmental release and human exposure information, across life cycle
- To the extent known or reasonably ascertainable

■ Who? Applies to Importers, Manufacturers and Processors (“IM&Ps”)

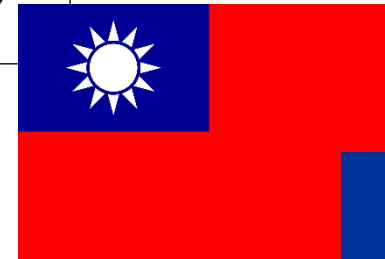
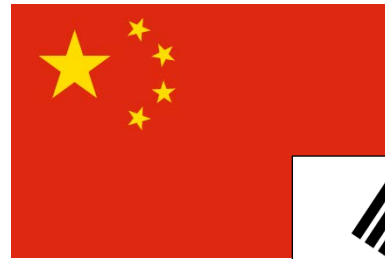
- Separate report for each person/material combination
- Result is many reports for the same material

■ When?

- Current/Past IM&Ps (prior 3 years): Aug 14, 2018
- Future IM&Ps:
 - **135 days before commencing** I, M or P; or
 - **30 days after forming intent** to I, M or P (if can't meet 135-day deadline)

Chemical and Materials Regulation Update

- China
- Korea
- Taiwan
- Europe



New Chemicals

- **2017: MEP updated key new chemicals notification guidelines**
 - Eased human and eco-tox data requirements (testing closer to EU-REACH)
 - Curbed discretion of officials; expanded exemption scope
 - Data quality requirements / responsibilities for labs (transparency); onsite verification program
 - New exposure assessment guidelines (protocol)

- **2018: Update New Chemicals notification regulation (MEP Order #7)**
 - Clarify CBI claim duration
 - Central review of notifications (past nonconsistency at different ports)
 - Enhanced enforcement consequences
 - More enforcement activity at the border

Existing Chemicals

- **2018: Published first list of priority chemicals to be assessed for safety**
 - Previously no significant assessment requirements for existing chemicals
 - 20+ substances from a range of industries (water pollution control);
 - intrinsically hazardous, highly bio-accumulative
 - Facility discharge restrictions and product use restrictions to follow
 - Risk assessment procedural guidelines (guidance) also expected

First Batch of Priority Chemicals for Assessment

1,2,4-trichlorobenzene	1,3-butadiene	xylene musk	n,n'-bis(methylphenyl)-1,4-benzenediamine
cadmium and compounds	mercury and compounds	dichloromethane	nonylphenol and nonylphenol polyoxyethylene ether
naphthalene	lead compounds	PFOS and its salts	short-chain chlorinated paraffins (SCCPs)
hexavalent chromium	arsenic and compounds	DecaBDE	hexabromocyclododecane
formaldehyde	trichlorethylene	perchloroethylene	hexachloro-1,3-cyclopentadiene
trichloromethane			

CHINA RoHS2

- **2018: Final RoHS2 Catalog Issued**
 - Restrictions on six substances in select categories of electronic products
 - Same substances as EU RoHS: Cd, Pb, Hg, Cr6, PBBs and PBDE
 - Most of the same product categories as EU
 - Small household equipment and medical devices excluded by China
 - Numerous application specific use exemptions (39 uses in electronic products)
 - Compliance due in March 2019; yet unnamed conformity assessment system for imports

- **K-REACH: Registration of first 510 Priority Existing Chemicals (PECs) due July 2018**
 - Three year process
 - Many Substance SIEFs still do not have lead registrants
 - 179 of 510 in Apr.
 - Risk that some PECs will not be registered on time
 - Both a compliance and business interruption risk
 - Importers
 - Korean users and export users
 - In supply chain

- **Amended K-REACH Final Approval (Mar. 2018)**
 - Effective January 2019
 - Will require registration of all new/existing substances made or imported > 1 TPY
 - Will require pre-registration of existing substances
 - First registrations: 2021 (based on tonnage band)
 - Aim to register 7,000 substances in next 12 years
 - Information for downstream users strengthened
 - Less data required for GHS “non-hazardous” substances

- **Significant amendments to the Toxic Chemical Substances Control Act (Mar. 2018)**
 - Renamed Toxic Chemical Substances and Chemicals of Concern Act (TCSCCA)
 - Scope expanded to regulate “chemicals of concern” + toxics
 - Strengthen registration procedures
 - Incentives for the public to report violations
 - Stricter than current rules
 - Makes DOL and EPA rules consistent

- **First designated list of substances for standard registration designated (Jan 2018)**
 - 122 chemicals
 - Manufactures/importers must submit information on manufacture, use, exposure, hazard classification, labels, phys-chem properties, human and ecotox information, hazard assessment and exposure assessment
- **Second batch** of designated substances expected later this year
 - Timing of registration period based on tonnage band

■ EU ROHS-2 amendments

- New exemptions for narrow uses of lead in electronic equipment
- Extended 2019 exemption for spare parts / secondary market sales

■ REACH registration:

- End of transition: Registrations for 1 – 10 TPY due May 31
- Practical deadline is sooner – completeness checks
- Miss deadline? Out of the market for several months

■ REACH Evaluation (CORAP)

- 108 Substances being evaluated for potential controls *by Member States*, to be completed by 2020
- Evaluations may lead to new testing obligations; controls
- 17 chemicals newly added

Regulatory Developments – Europe (cont'd)



2018-2020 Additions to CORAP List

2018	Germany	Antimony trichloride
2018	Germany	2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4] tetradecane
2018	Spain	3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane
2019	France	Chromium(III)Oxide
2019	France	Tetraphenyl m-phenylene bis (phosphate
2019	Sweden	N,N-diethylhydroxylamine
2020	France	Triclocarban
2020	Germany	Benzyl salicylate
2020	Germany	2-ethylhexyl salicylate
2020	Germany	4,4'-methylene bis(dibutyldithiocarbamate)
2020	Italy	Trimethyloctadecylammonium chloride
2020	Italy	Butan-2-one O,O',O''-(vinylsilylidyne)trioxime
2020	Italy	Butan-2-one O,O',O''-(methylsilylidyne) trioxime
2020	Sweden	Acetic acid, oxo-, sodium salt, r/products w/ ethylenediamine,phenol, iron sodium salts
2020	Sweden	EDDHMAFEK
2020	Sweden	R/product of phenol, formaldehyde, ethylenediamine diacetic acid, iron chloride & potassium hydroxide

■ BREXIT (and REACH)

- Huge potential problem for companies with material supply chains that run through the UK
- Uncertain if/how UK companies will maintain their registrations
- Concern in EU of loss of UK suppliers in supply chain
- UK OR's moving to EU
- UK government loses its seat at the REACH table
- Associate membership in ECHA? Much uncertainty remains
- *Reached a deal to maintain status quo post BREXIT through the end of 2020*



THANK YOU

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