

Electrical and Electronic Device-related regulations including TSCA Reform and IPC 1752A Material Declarations

米国改正TSCAを中心とする電気電子機器関連規制および
IPC1752Aマテリアルデクラレーション

Environment Japan K.K.
エンバイロメント・ジャパン株式会社
Kanji Tamamushi, Ph.D.

Contents

- Toxic Substances Control Act (TSCA) Reform
- California State Proposition 65 Exposure Warning
- IPC 1752A Material Declarations BOMcheck.net

U.S. Regulations

■ Federal Laws and Regulations

– EPA

- Clean Air Act (CAA), Clean Water Act (CWA), Resource Conservation and Recovery Act (RCRA), Toxic Substances Control Act (TSCA), Spill Prevention, Control, and Countermeasure (SPCC)...

– OSHA

- Hazard Communication Standard (HCS)/Safety Data Sheet (SDS)/OSHA Label, logout/Tagout (LOTO), Confined Space Entry, Personal Protective Equipment (PPE), Hot Work, Machine Guard, Fall Protection, Medical Record...

■ State Laws and Regulations

– E.g. California State

- Proposition 65
- Electronics Waste Recycling Act
- Safer Consumer Products (SCP) Regulation (Green Chemistry Law)
- Rigid Plastic Package Container (RPPC) Program
- Composite Wood Products Regulations (Formaldehyde released amount)

U.S. Regulations for SEMICON

Chemicals

- **TSCA**
 - New chemicals
 - Existing chemicals
- **California Proposition 65**
 - Exposure Warning
- **OSHA SDS/Label**
- **Import Restriction**
- **Contents Restriction**
- **Notification**
 - Chemical Data Reporting (CDR)

Electronics Devices/ Equipment and Component

- **TSCA**
 - New chemicals
 - Existing chemicals
- **California Proposition 65**
 - Exposure Warning
- **Import Restriction**
- **Waste Product Recycling**

Facility Operation in U.S.A.

(Warehouse, Manufacturing Plant, R&D Lab.)

- **Environment Due Diligence for M&A**
 - CERCLA
 - ASTM E1527
- **EPA**
 - CAA, CWA, RCRA, SPCC, TRI...
- **OSHA**
 - HCS/SDS/Label, LOTO, PPE, Hot Work, Machine Guard, Medical Record...

TSCA

- **TSCA Inventory**

- New Chemicals are not listed on TSCA Inventory
- Existing Chemicals are listed on TSCA Inventory

- **New Chemical Import**

- Notification
 - PMN (Pre-Manufacture Notice)
 - LVE (Low Volume Exemption)
 - Polymer Exemption
 - R&D Exemption
 - etc.

- **Exiting Chemical Import**

- Soon new requirements (by TSCA Reform)

TSCA Reform

- **Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016 (Called TSCA Reform)**
 - TSCA Inventory Active–Inactive Notification Rule for Existing Chemicals
 - Retrospective Reporting “Notice of Activity A” → Completed (Oct. 5, 2018) *10-year look back period*
 - Active <– substances that are reported
 - Inactive <– substance not reported
 - Forward-looking reporting (Notice of Activity B) “inactive” → “active”
 - A notification will be required for inactive substances
 - Who’s covered?
 - Manufacturers, importers and processors
 - Reporting timeline
 - Effective date: 90days after publication of Inventory with final “active” and intended “inactive” designations

TSCA Reform (2)

■ New Chemical Review

Unreasonable risk ... 不当なリスク

- Conditions of Use
 - Unreasonable risk of harm to health and the Environment
 - Manufactured, processed, distributed, use or disposal
 - Potentially exposed or susceptible subpopulations
 - Infants, children, pregnant women, workers and the elderly
- PMN (EPA Risk Evaluation and Conclusion)
 1. Presents unreasonable risk of injury → EPA issues rule restricting substance
 2. May present unreasonable risk of injury → EPA orders substances pending data development → Manufacture may commence → consider whether to promulgate SNUR
 3. Not likely to present unreasonable risk of injury → Manufacture may commence → consider whether to promulgate SNUR

TSCA Reform (3)

- 5(e) Orders
 - Restrictions on use of a new chemical substance
 - Testing requirements
- SNURs
 - Another way EPA can restrict use
 - Requires notification to EPA before anyone can engage in “new use” of a substance

TSCA Reform (4)

■ Existing Chemicals

– Risk Evaluation

■ Active Substances

– Prioritization of Active Substances

□ High Priority goes to risk evaluation

- If substance presents unreasonable risk, then goes to risk management rulemaking

□ Low Priority does not go to risk evaluation

■ First 10 Chemicals

- Asbestos, 1-Bromopropane, Carbon Tetrachloride, 1,4-Dioxane, Cyclic Aliphatic Bromide Cluster (HBCD), Methylene Chloride, N-Methyl Pyrrolidone, Perchloroethylene, Pigment Violet 29 (draft risk assessment available), Trichloroethylene

■ Next 20 High Priority Chemicals

- By December 2019

TSCA Reform (5)

■ TSCA Fees from October 2018

– TSCA Section 5

- Premanufacture Notice (PMN) ... \$16,000
- Significant New Use Notice (SNUN) ... \$16,000
- Low Volume Exemption (LVE) ... \$4,700

– TSCA Section 6

- EPA-initiated risk evaluation ... \$1,350,000
- Manufacturer-requested risk evaluation on a chemical included in the work plan ... 50% of total actual costs; \$1.25M initial payment
- Manufacturer-requested risk evaluation on a chemical not included in the Work Plan ... 100% of total actual costs; \$2.5M initial payment

Other TSCA Issues

- **CBI (Confidential Business Information)**
 - Disclosure to health care professionals, etc.?
- **Nano Materials**
 - Particle size 1–100nm
- **Formaldehyde emission regulation from Composite Wood Products**
 - Voluntary standard
 - Consistent with California Composite Wood Products regulations

California State Proposition 65 Exposure Warning

- **A Clear and Reasonable Warning**
- **Exposure Levels**
 - For Cancer ... No Significant Risk Level (NSRL)
 - Reproductive Toxicity ... Maximum Allowable Dose Level (MADL)
- **About 900 chemicals**
 - <https://oehha.ca.gov/proposition-65/proposition-65-list>
- **Effective August 30, 2018**
 - New Warning Language
 - Tailored Warning for Specific Products/Facilities
 - Consumer Product Exposure Warning, Food Exposure Warnings, Vehicle Exposure Warnings, etc.
 - Responsibilities along the supply chain

Proposition 65 New Warning Label Examples

Article 6, Clear and Reasonable Warning effective in August 30th, 2018

発がん性物質に暴露する場合(例) For carcinogen



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

生殖毒性物質に暴露する場合(例) For reproductive toxins



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

発がん性物質と生殖毒性物質の両方に暴露する場合(例)
For carcinogens and reproductive toxins-contained products



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

発がん性と生殖毒性の両方を示す化学物質に暴露する場合(例) For carcinogens and reproductive toxins



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

IPC 1752A Material Declarations

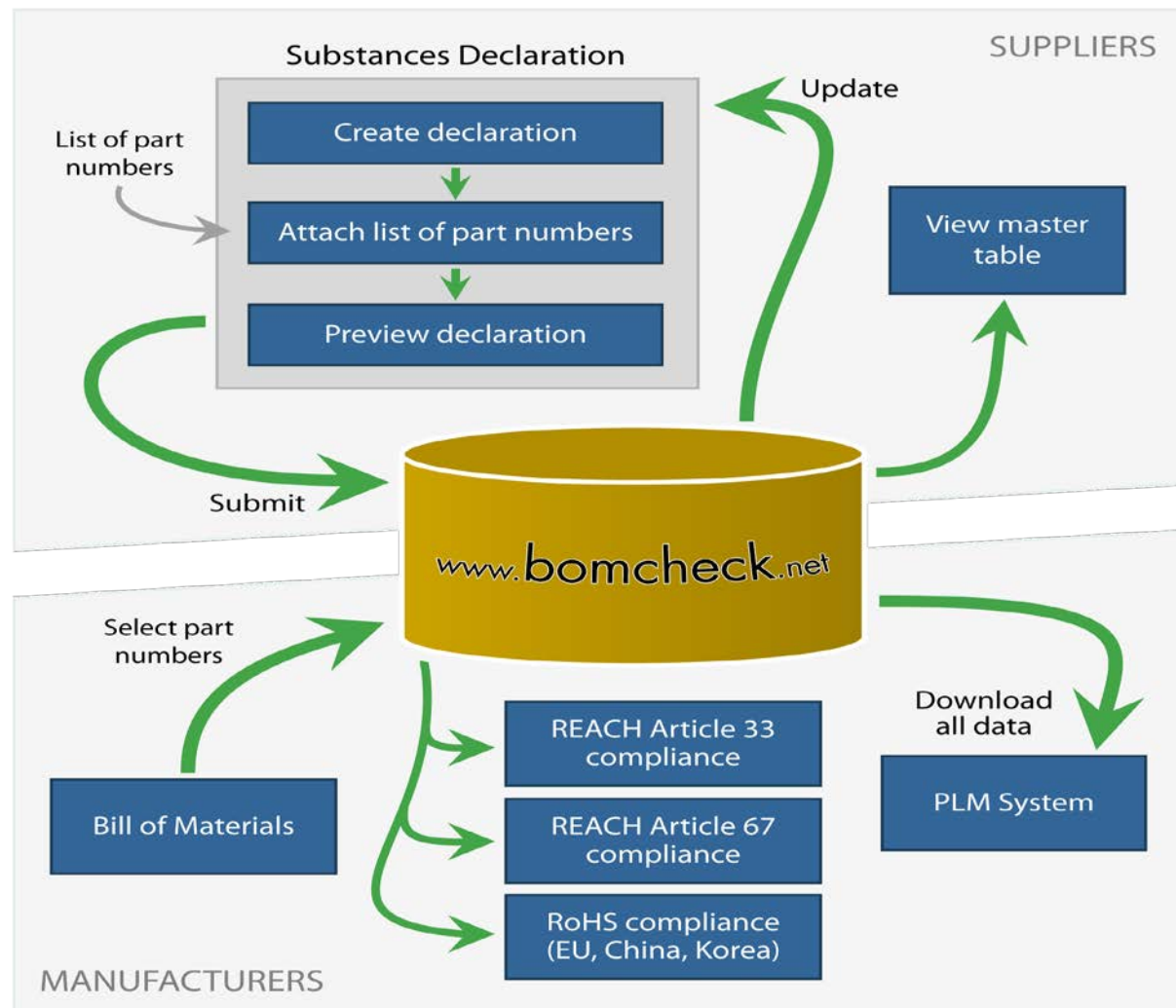
- **IPC–1752A: a standard reporting format for material declaration data exchange between suppliers and manufacturers.**
- **For electronics devices, components, etc.**
- **Data exchange between IPC1752A and IEC 62474? (Compatibility?)**

BOMcheck.net developed by EU and U.S. major manufacturers

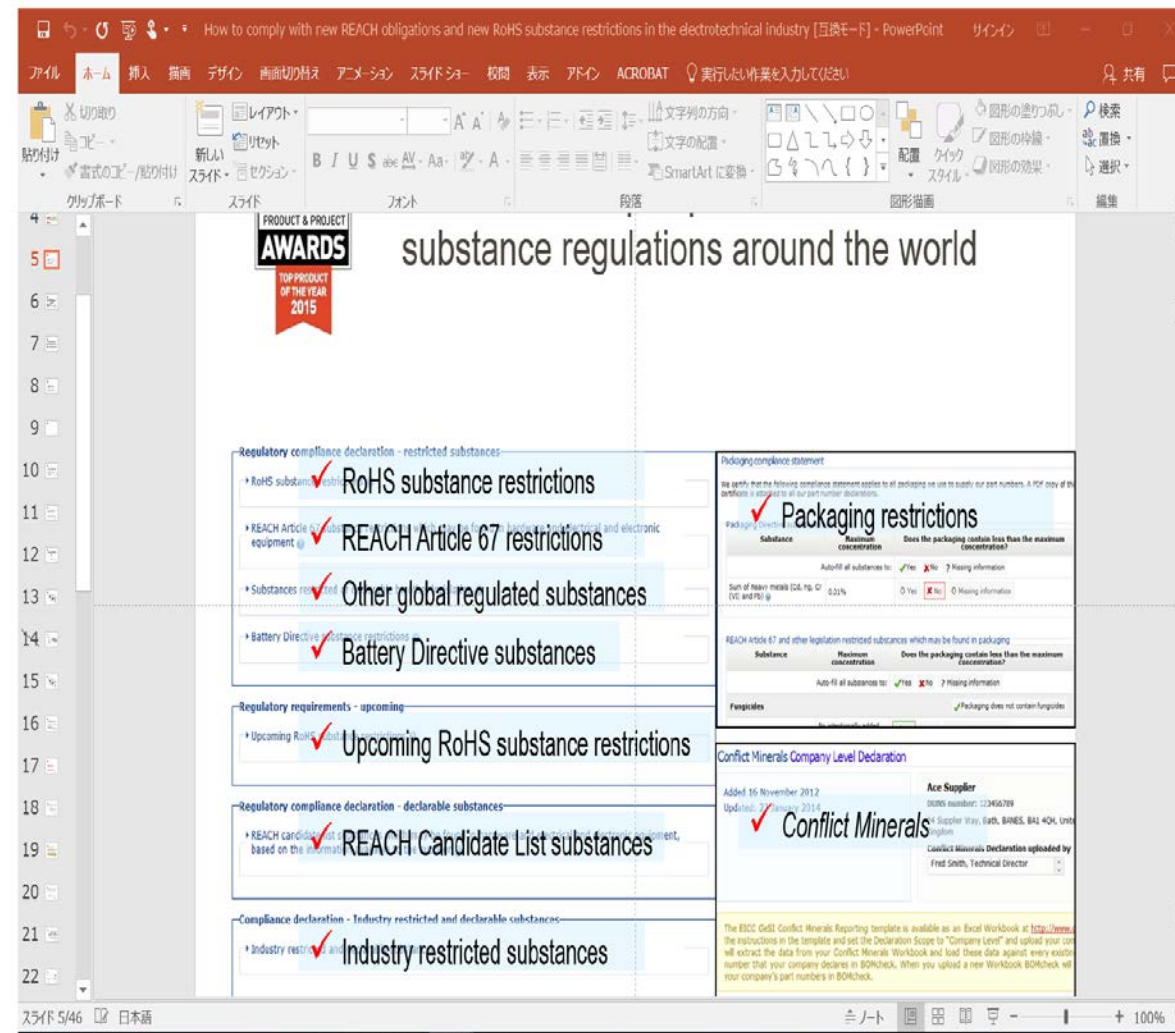
- **Compliance tools for REACH, RoHS, Conflict Minerals, Proposition 65, etc.**
- **Introduced 10 years ago**
- **Now about 1,000 manufacturers and about 8,500 suppliers using BOMcheck worldwide**

BOMcheck

欧米企業が利用するサプライチェーンにおける化学物質情報共有化システム



www.BOMcheck.net



BOMcheck

Substance Declarations and Conflict Minerals Web Database

[HOME](#) [SUPPLIERS](#) [MANUFACTURERS](#) [SUPER USERS](#) [REACH](#) [ROHS2](#) [CONFLICT MINERALS](#) [PROP 65](#) [CONTACT](#)

Suppliers
Have your customers asked you to join? 

Manufacturers
Do you need a system to gather compliance data? 

Super Users
Are you a supplier and a manufacturer? 

Substances Declarations and Conflict Minerals Web Database

Centralised web database saves time and cost for suppliers to keep up-to-date with new substance regulations around the world. Suppliers can manage their data securely in the database and download declarations in industry standard IPC 1752A XML, PDF or Excel Formats.



Login:

Password:

[Forgot password](#)

Need help?
[Ask Assistant](#) 

 [Watch pre-recorded webinars](#)

 [Join live training webinar](#)

 [Information Security](#)

"We receive a lot of individual questionnaires about REACH SVHC, RoHS, etc. BOMcheck provides a user friendly tool to create standardized declarations which our customers are more and more happy to accept."
Product Stewardship Manager
Umicore AG & Co. KG

Conflict Minerals 

RoHS2 

REACH 

Covered Regulations List

BOMcheck.net

[User Guide for Suppliers and Manufacturers](#)
[Watch pre-recorded webinars](#)

Version 5.0
Release Date 14 May 2018

Account overview

▼ Enter data

Add declaration

XML Upload

Map a parts list

Add conflict minerals company level declaration

Packaging compliance statement

Statement on emissions from products and packaging during transport


Statement on substances used in manufacturing processes

► Retrieve data

View manufacturers list

View suppliers list

Resources

 **ACE SUPPLIER**


Logged in as:
Ace Supplier (Fred Smith)

[Edit user account](#)

[Logout](#)


Need help?

[Ask Assistant](#)



Material risk database

[Screen a material](#)



Regulatory compliance declaration

Update ALL RCDs

Full materials declaration

Update ALL FMDs

1 ATTACH PARTS LIST OR TYPE IN A PART NUMBER

2 SET PRODUCT SCOPE AND PROVIDE COMPLIANCE STATUS

3 ATTACH ANY EVIDENCE DOCUMENTS

4 SET CONFIDENTIALITY AND PREVIEW DECLARATION

5 APPROVE DECLARATION TO PUBLISH IN BOMCHECK


Product scope


This regulatory compliance declaration tool provides lists of regulated substance which are applicable to parts used in electrical and mechanical products. If your parts can be used in Medical Devices, you can extend these lists and use the tool to make declarations for additional regulated substances which are applicable to parts used in these types of products. If your parts are not used in Medical Devices then answer 'No' to the question below.

Can the part(s) be used in Medical Devices?


☐ Yes ☐ No

Regulatory compliance declaration - restricted substances


► RoHS substance restrictions (Directive 2011/65/EU) 

► REACH Article 67 substance restrictions which may be found in hardware and electrical and electronic equipment (Regulation 1907/2006) 

► Substances restricted or declarable by other legislation 

► Battery substance restrictions 

Regulatory requirements - upcoming


► Upcoming RoHS substance restrictions (Directive 2011/65/EU, as amended by Directive (EU) 2015/863 of March 2015) 

Regulatory compliance declaration - declarable substances

► REACH candidate list substances (Regulation 1907/2006)

► Proposition 65 substances which may be found in mechanical and electrical products

Compliance declaration - Industry restricted and declarable substances

► Industry restricted and declarable substances 

< Previous

Next >

© 2006 - 2018 BOMcheck

Regulatory Compliance Declaration (example)

Regulatory compliance declaration - restricted substances

▼ RoHS substance restrictions (Directive 2011/65/EU) ⓘ

Substance	Maximum concentration	Do all <u>single homogenous materials</u> in the parts contain less than the maximum concentration?			
Auto-fill all substances to:		<input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Cadmium/Cadmium compounds ⓘ	0.01%	<input type="radio"/> Yes	<input type="radio"/> No, but exempt in the EU	<input type="radio"/> No, but exempt for Medical Devices and Monitoring and Control Instruments in the EU	<input type="radio"/> No
Hexavalent Chromium ⓘ	0.1%	<input type="radio"/> Yes	<input type="radio"/> No, but exempt in the EU	<input type="radio"/> No, but exempt for Medical Devices and Monitoring and Control Instruments in the EU	<input type="radio"/> No
Lead/lead compounds ⓘ	0.1%	<input type="radio"/> Yes	<input type="radio"/> No, but exempt in the EU	<input type="radio"/> No, but exempt for Medical Devices and Monitoring and Control Instruments in the EU	<input type="radio"/> No
Mercury/Mercury compounds ⓘ	0.1%	<input type="radio"/> Yes	<input type="radio"/> No, but exempt in the EU	<input type="radio"/> No, but exempt for Medical Devices and Monitoring and Control Instruments in the EU	<input type="radio"/> No
PBBs ⓘ	0.1%	<input type="radio"/> Yes	<input type="radio"/> No		
PBDEs ⓘ	0.1%	<input type="radio"/> Yes	<input type="radio"/> No		

Results of Regulatory Compliance Declaration

(example)

RoHS ▼

✓ Cadmium/Cadmium compounds

✓ Mercury/Mercury compounds

✓ Hexavalent Chromium

✓ PBBs

✓ Lead/lead compounds

✓ PBDEs

REACH Article 67 ▼

Other legislation ▼

Battery Directive ▼

Upcoming RoHS ▼

REACH candidate list ▼

Proposition 65 ▼

✓ Lead and Lead Compounds

✓ Di-n-hexyl phthalate (DnHP)

✓ Antimony Oxide (Antimony trioxide)

✓ Mirex

✓ 3,3'-Dimethoxybenzidine-based dyes metabolized to 3,3'-dimethoxybenzidine

✓ 1-Amino-2-methylantraquinone

✓ Disperse Blue 1

✓ Asbestos

✓ Tar oils and creosotes

✓ Mercury/Mercury compounds

✓ 4,4'-isopropylidenediphenol [Bisphenol A; BPA]

✓ Disodium 4-amino-3-[[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)

✓ Diisononyl phthalate (DiNP)

✓ Tris(1,3-dichloro-2-propyl) Phosphate (TDCPP)

✓ Tetrabromobisphenol A

✓ Benzophenone

✓ 3,3'-Dimethylbenzidine-based dyes metabolized to 3,3'-dimethylbenzidine

✓ Direct Blue 6 (Technical Grade)

✓ Naphthalene

✓ Azocolourants and azodyes which form certain aromatic amines

✓ Cadmium/Cadmium compounds

✓ PBBs

✓ DEHP (Di(2-ethylhexyl) phthalate)

✓ BBP (Benzylbutyl phthalate)

✓ 4-Aminoazobenzene

✓ Polychlorinated biphenyls (PCBs)

✓ Di-isodecyl phthalate (DIDP)

✓ Tris(2-chloroethyl) Phosphate

✓ Tris(2,3-dibromopropyl)phosphate

✓ 2,2-Bis(bromomethyl)-1,3-propanediol

✓ Benzidine-based Dyes

✓ D&C Orange No. 17

✓ 1-Amino-2,4-dibromoanthraquinone

✓ Direct Brown 95 (Technical Grade)

✓ Any individual PAH compound

✓ Perfluorooctanoic acid and its salts

✓ Nickel and nickel alloys

✓ Hexavalent Chromium

✓ PBDEs

✓ DBP (Dibutyl phthalate)

✓ SCCP (Short-chained chlorinated paraffins)

✓ PFOS (Perfluorooctane Sulfonates)

Industry substance restrictions ▼

Attached parts list

Part number	Part name	Part weight	Material unit
EJKK20180802	EJpractice	100 g	each

Declaration actions

☒ Approve declaration

☐ Cancel declaration

Please confirm your password:

« Previous

Submit declaration

Harmonization between IPC1752A and IEC 62474

IPC 1752A	IEC 62474 FDIS (draft)	BOMcheck IPC1752A対応
Class C	Declaration for compliance	Regulatory Compliance Declaration (RCD)
Class D	Composition declaration	Full Material Declaration (FMD)

Compatibility?

QUESTIONS?

THANK YOU!



Kanji Tamamushi, Ph.D.

www.EJKK.co.jp

k.tamamushi@ejkk.co.jp

ktamamushi@earthlink.net