A Support Programme for Assisting Hong Kong SMEs To Effectively Achieve Hazardous Substances Compliance through Adoption of IECQ QC 080000 Hazardous Substances Process Management System

Funded by

Organized by

Implemented by









IECQ QC 080000, Chemical Risks and Product Recall Workshop (1)

Tim Chan
Hong Kong Productivity Council
22 Jan 2015



IECQ QC 080000 HSPM 有害物質流程管理體系培訓工作坊 2015年1月22日(星期四)

程序

2:15 - 2:30	登記
2:30 - 3:45	講題:國際有害物質管理發展趨勢及IECQ QC 080000 HSPM 標準解讀講者:香港生產力促進局助理顧問陳樹添先生
3:45 - 4:00	小体
4:00 – 4:45	講題:企業案例分享-孩之寶遠東有限公司 講者:孩之寶遠東有限公司經理-化學技術(中國)杜鴻溢博士
4:45 - 5:00	答問時間
5:00	研討會完畢



研討會演講資料及花絮會被放在以下網站供大家參考:

• 香港工業總會網站: www.industryhk.org/cindex.php

• 香港生產力促進局綠色製造網絡網站:www.gmn.hkpc.org

Business Needs in Mitigating Chemical Risk

BACKGROUND

NEWS OF UNSAFE PRODUCTS ARE EVERYWHERE!



The Telegraph









This Sept. 9, 2010 photo shows an Olympus Innov-X Delta Handheld XRF Analyzer testing glassware decorated with a Ronald McDonald character for cadmium, lead and other toxic elements in Los Angeles. The device is used for the analysis of ··· more

(AP) — Drinking glasses depkting comic book and movie characters such as Superman, Wonder Woman and the Tin Man from "The Wizard of Oz" exceed federal limits for lead in children's products by up to 1,000 times, according to laboratory testing commissioned by The Associated Press.

Back-to-school study finds high levels of phthalate chemicals in kids backpacks, supplies

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(CBS News) Children's back-to-school backpacks and other supplies may contain higher levels of potentially toxic chemicals than the government allows in most toxs, a new study shows.



Business Needs in Mitigating Chemical Risk

BACKGROUND

PRODUCT RECALLS -> FINANCIAL LOSS

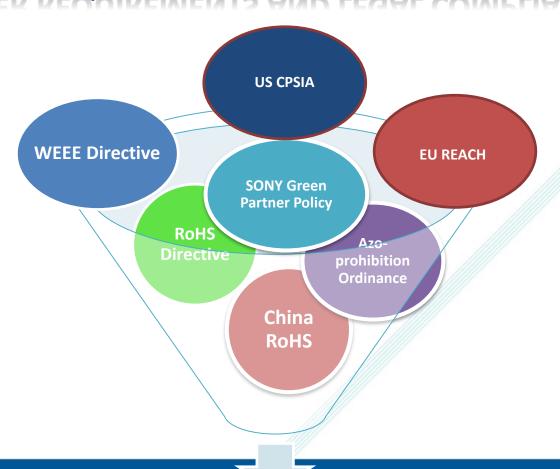
Year	Company Involved	Cause	Financial Loss (USD)
2001	Sony	Excessively high Cadmium (Cd) in PlayStation Consoles during Christmas	\$150 million in lost sales and product reformulation
2006	Mattel	Lead (Pb) in paint in Barbie dolls	\$110 million recall cost including communication campaigns; and stock price down 18%
2007	RC2 Corporation	Lead (Pb) paint discovered on its Thomas % Friends toy trains	\$47.6 million legal fees; and stock price down 50%
2007	Palm	Treo 650 failing to meet RoHS	Stock price down 14%
2010	McDonald's	Cadmium (Cd) in Paint in Shrek-themed Happy Meal glasses (13.4 million)	\$3 refund for each glasses, around 40 million in US and Canada



Business Needs in Mitigating Chemical Risk

BACKGROUND

CUSTOMER REQUIREMENTS AND LEGAL COMPLIANCE

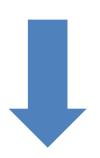




Business Needs in Mitigating Chemical Risk

BACKGROUND

SOLUTIONS – OLD VS NEW



Traditional Solution

- Conduct Separate Tests for Individual Buyers and Compliance
- Extra Compliance Cost due to Extra Testing

Systematic Solution

- Integration with ISO 9001 Standard
- One System to Fulfill Requirements of Multiples Buyers



INTRODUCTION

- Established by IEC
- ~ 2,600 companies certified worldwide
- Intended for uses by manufacturers, suppliers, repairers, and maintainers of products
- A process approach instead of individual product approach



No. of IECQ HSPM Companies in Different **Countries CHINA TAIWAN OTHERS** HONG KONG



INTRODUCTION

KEY CONCEPTS

- HS Hazardous Substances any substances regulated by applicable legal or customer requirements as to prohibit, restrict, reduce its use or notify it existence
- It could be RoHS substances or other chemicals required by customers



INTRODUCTION

CONCEPTS

- Through process management rather than individual testing, a company can achieve HSF (HS Free)
- Based on belief that achievement of HSF cannot be realized without effective process in place



INTRODUCTION

OVERVIEW

- 1. Scope
- 2. Normative Reference
- 3. Terms and Definitions
- 4. Hazardous Substance Process Management System
- 5. Management Responsibility
- 6. Resource Management
- 7. Product Realization
- 8. Measurement, analysis and improvement

Relationship to ISO 9001 and ISO 14001



INTRODUCTION

DEFINITIONS OF STANDARDS

- **Shall** indicates a mandatory requirement
- **Should** among several possibilities, one is recommended as particular suitable/preferred option
- May permissible within the limits



GENERAL REQUIREMENT

THE STANDARDS SAYS:

Section 4.1 General requirements

Each organization shall include in its ISO 9001 mandated quality management system the procedures, documentation, and process management practices necessary to achieve HSF product and production processes.



GENERAL REQUIREMENT

ISO 9001	ISO 14001	QC 080000
Quality Policy	Environmental Policy	HSF Policy
Customers' focus	Environmental Aspects	List of HS
Continual Improvement	Environmental Objectives and Targets	HSF Objectives
N/A	Materials/Equipment Purchasing	Measurement, analysis and improvement



THE STANDARDS SAYS:

Section 4.2 Documentation requirements The quality management system documentation shall include:

- a.) HSF Policy and Objective with inclusion of a timeline for elimination of use of all HS
- b.) HSF process management plan
- c.) Documented procedures and records
- d.) A List of HS



THE STANDARDS SAYS:

Section 5. Management responsibility

Top management **shall** provide evidence of its commitment to the development and implementation of practices consistent with achieving HSF products and production processes and the continuous improvement

- 5.1 Management Commitment
- 5.2 Customer Focus
- 5.3 HSF Policy
- 5.4 Planning
- 5.5 Responsibility, Authority and Communication
- 5.6 Management Review



POINTS TO NOTE

- How HSF Policy is communicated? Through notice, meeting, or training?
- How management determines their HSF requirements? Through questionnaire, survey or legal regulations?
- How HSF related responsibilities and authorities are defined and communicated? Who responsible for what?



EXAMPLES OF MANAGEMENT RESPONSIBILITIES

Department	Function(s)
General Manager	Set up overall HSF plan
HR Department	Identify the needs of HS training
Engineering Department	Identify the opportunity to improve product design
QC Department	Testing HS content of products
Procurement Department	Buying RoHS compliant materials
Production Department	Implement the HSF Plan
Sales Department	Understand clients' HSF needs



VENDORS EVALUATION

Through vendor evaluation, classify suppliers into 3 types:

Type A – incoming materials have **critical** impacts to the HS content of products

Type B – incoming materials have **important** impacts to the HS content of products

Type C – incoming materials have minor impacts to the HS content of products



DOCUMENTS THAT AUDITORS MAY LOOK FOR:

- Contract Review Statistics Relative to HSF Compliance
- Correction Action Report
- Legal Documentations related to HS
- Supply Chain Compliance Report
- HSF Research and Design Activity Report
- Customer HSF Satisfaction Report



INFORMATION OF LEGAL REQUIREMENTS

- European Environmental Bureau Chemicals http://www.eeb.org/index.cfm/activities/industry-health/chemicals/
- 國家環保總局網站 http://www.zhb.gov.cn/
- 國家標委會網站 http://www.sac.gov.cn/



THE STANDARDS SAYS:

Section 6. Resource Management

The organization **shall** determine and provide the resources needed to implement and maintain HSF processes and products, to continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

- 6.1 Provision of resources
- 6.2 Human resources
- 6.3 Infrastructure
- 6.4 Work environment (new in 2012 version)



HUMAN RESOURCES

Similar to ISO 9001 and ISO 14001, companies need to address the following:

- How are employees trained?
- Are there training procedures?
- How will the training be documented?
- How will the effectiveness of training be measured and communicated?



INFRASTRUCTURE AND WORK ENVIRONMENT

6.3 Infrastructure **shall** be maintained to achieve conformity to HSF process

Infrastructure include:

- Buildings, workspace and associated utilities,
- Process equipment and testing equipment
- Supporting services (testing, data computing, etc.)
- 6.4 Work environment shall also be maintained to achieve HSF



THE STANDARDS SAYS:

Section 7 Product Realization
The organization shall plan and develop the processes needed for HSF product realization.

- 7.1 Planning of HSF process and product realization
- 7.2 Customer-related process
- 7.3 Design and development
- 7.4 Purchasing of HSF products
- 7.5 Production and service provision



THE STANDARDS SAYS:

Section 8 Measurement, analysis and improvement The organization **shall** plan and implement the monitoring, measurement, analysis and improvement processes

- 8.1 General
- 8.2 Monitoring and measurement
- 8.3 Control of HSF nonconforming product
- 8.4 Analysis of HSF data
- 8.5 Improvement of hazardous substance process management system



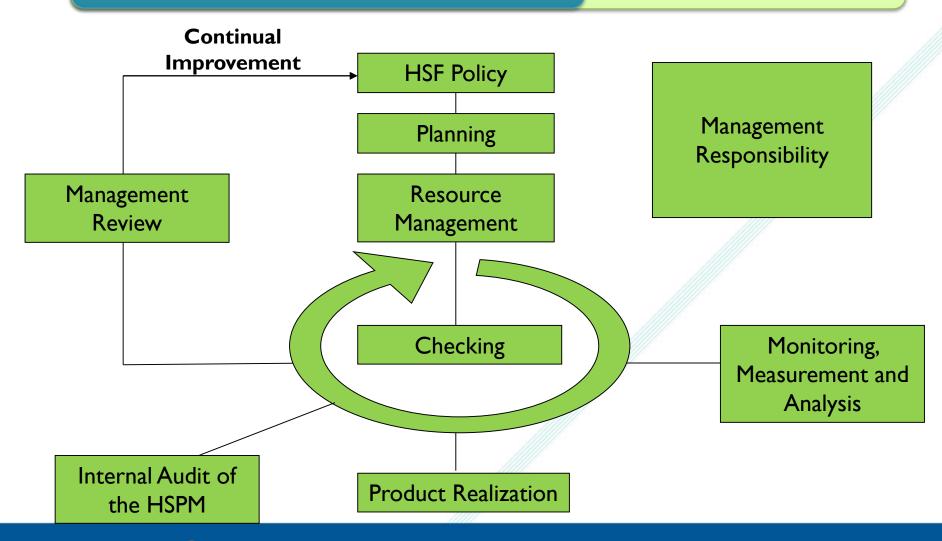
EXAMPLES – INTERNAL AUDITS AND CONTINUOUS IMPROVEMENT

To achieve improvement of HSPM, internal audits must be carried out:

- Internal auditors appointed by the Management Representative
- With qualifications and knowledge, i.e. auditor training
- Avoid conflicts of interests arisen from divisions/department



OVERVIEW





SME Support Programme to Adopt IECQ QC 080000 HSPM



How do We Assist SMEs?

 A 18-month Support Programme, aiming to help SMEs to:

Understand

the importance of a HSPM System

Acquire

the knowledge of IECQ QC 080000 HSPM system

Learn

the principles and essentials of an effective HSPM system

Adopt

the HSPM System to enhance competitiveness



Initiative I – Seminars and Industry Outreaches

Activities:



2 Seminars - October 2014 and February 2015



Visits to 10 industry associations

Beneficiaries:

- Companies seeking effective hazardous substance management management
- **Industry associations** representing SMEs



Initiative 2 – Industry Consultation Visits and e-Fact Sheets

Activities:



On-site visits to 10 pioneer companies



Production of 10 e-Fact sheets

Beneficiaries:

- Pioneer companies of IECQ QC 080000 implementation and hazardous hazardous substance management
- e-Fact sheets will be uploaded to website for widespread sharing



Initiative 3 – Online Practical Guide

Activity:



Production of an online step-by-step guide for effective QC 080000 implementation

Beneficiaries:

- **Key personnel** responsible for hazardous substance management for their management for their companies, **factory managers**, **compliance managers**, etc.



Initiative 4 – Product Recall Workshops

Activity:



Organizing 2 workshops to address legal issues, compliance strategies, emergency plans and action in case of product recall

Beneficiaries:

- **Key personnel** responsible for hazardous substance management for their management for their companies, **factory managers**, **compliance managers**, etc.



Thank you

Tim Chan Hong Kong Productivity Council





Chemical Management System

Speaker:

Dr. Rodney Thu

Chemical Technical Manager, Hasbro Far East Ltd.

Why do we need to know?



Requirements: Lead & 7 other heavy metals, 6 Phthalates, EU RoHS

2007 & 2008

A year of recalls



(It's a different world out there!)

Regulatory actions

US – CPSIA, State Laws

EU – Toy Safety Directive (TSD), REACH

Bans on Phthalates (DEHP, DBP, BBP, DINP, DIDP etc.)

Hasbro

Mandatory testing & certification

Why do we need to know?

<u>June 2007:</u> The *Thomas and Friends Wooden Railway* toys were recalled due to risks of Lead Poisoning from the **Paint**.

<u>November 2007:</u> A popular children's toy, *Bindeez* (also known as Aqua Dots, in the United States), was recalled when it was discovered that 1,4-butanediol had been substituted for 1,5-pentanediol in the bead manufacturing process. The human body metabolises the substance to form the **anesthetic GHB**.

November 2007: About 175,000 *Curious George* 12-inch plush dolls with plastic faces were recalled due to the risk of Lead exposure and poisoning.

<u>June 2010:</u> *McDonalds* recalled the Shrek Forever After cups due to risks of Cadmium poisoning from the cups' paint.

<u>September 2010:</u> Fisher Price recalls 10-million products, including enough toys to merit this as the largest toy recall in history

Many more...



Why So Many Chemical Regulations? Market Drivers

Regulators (Federal, State and Global)

- Evolving chemical requirements with more focus on formulations/substances.
- State Level activity increasing.
- Global requirements increasing

Media/NGO Activity

- Center for Environmental Health Reports/Studies
- Safe Kids Worldwide
- Kids In Danger
- Greenpeace

Retailer Requirements

- Market requirements
- Brand requirements
- Entering new emerging markets (i.e. growth potential)

Consumer Demand

Demanding more "green" products

Hasbra

Environmentally conscientious

Regulatory & Compliance

- Regulatory (Global basis)
 - Compliance (bans/limits on use/registration of usage)
 - Chemical Safety Assessments (CSA)
 - Reporting Obligations ME, WA, VT
 - Publically Accessible Databases
 - Fees (VT)
 - Warning Labels CA Prop 65; IL Lead Labelling
 - Conflict Minerals Reporting (Dodd-Frank Act)
 - Green Chemistry CA (other states considering)
 - Alternative assessment process/substitution



Regulatory & Compliance

- Regulatory (Global basis)
 - EU has toughest chemical restrictions
 - TSD not only heavy metals but
 - Chemical safety assessment
 - Carcinogens, Mutagens, Reproductive Toxins (CMRs): > 1000
 - Appendix C
 - REACH Not only phthalates and total cadmium but
 - Substances of Very High Concern (SVHCs): > 155
 - Annex 17
 - Registration and preregistration
 - Other regulations
 - Biocides regulations
 - Persistent organic pollutants
 - RoHS II (=possible new restricted chemicals)

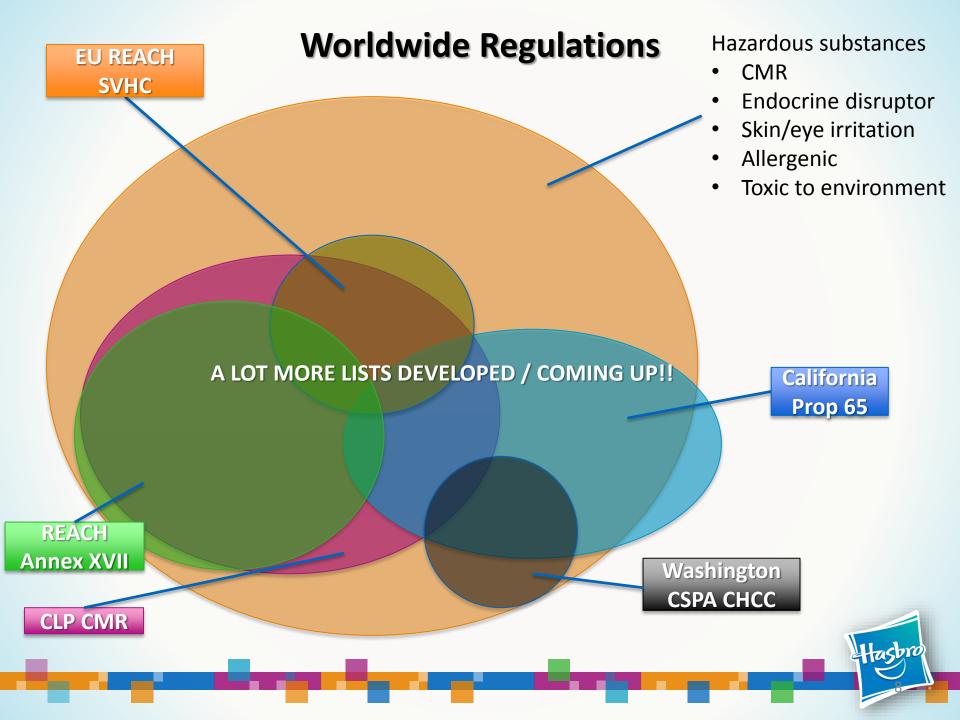


Regulatory & Compliance

- Regulatory (Global basis)
 - Turkey, China, Korea, Japan = REACH
 - Japan Chemicals
 - RoHS being widely deployed
 - Chile Toluene
 - Russia ?????

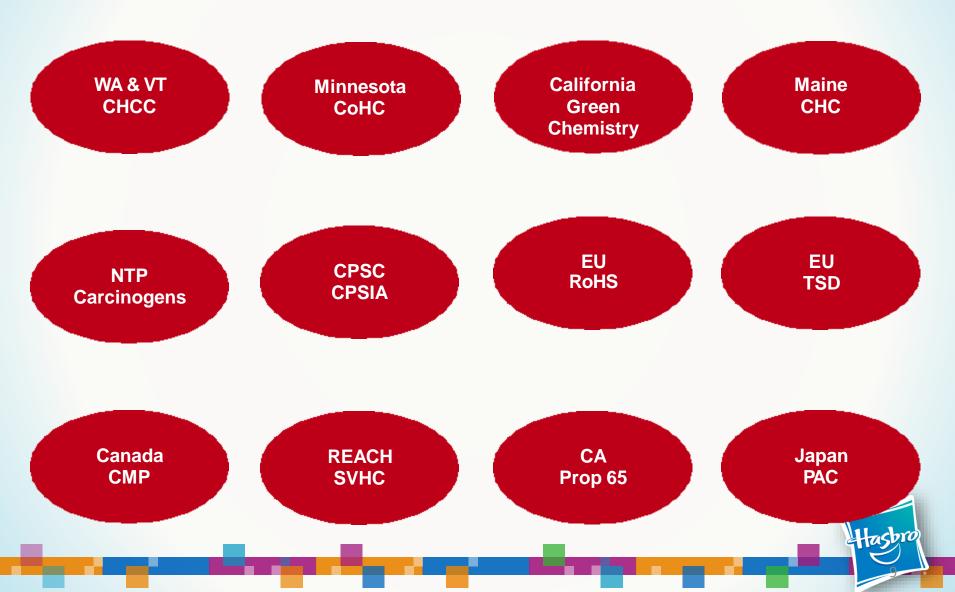
Similar topics <u>but</u> divergent requirements!





Chemical Data Management/Solutions

Lists, Lists and More Lists





How Has Hasbro Reacted?

Hasbro Policy

SRP-017: bans/restrictions on many chemicals

SRP-025: supplier certification in addition to SRP-017

QA049: Hazardous chemicals control system

IT Tools
Implement CMD and SciVera
for chemical management



BOM/BOS Requirement
Require BOM/BOS of products from 2012 (SRP-023)



Conformity assessment procedures

- Module A: Internal production control
 - Factory Audits and Vendor Quality systems
 - Safety assessment (encompassed within extensive Hasbro procedures)
 - Chemical safety assessment
 - QN process
- Voluntary standards
 - Compliance with voluntary standards encompassed within extensive Hasbro procedures

Third party testing to Harmonised standards may be used as a verification method.



Simplified flowchart on QA049 – HCC requirements

Procurement control

Communication on Hasbro spec. Supply chain management

Batch information

Incoming material control

Traceability records
Production summary

Process control

Finished product

SKU / datecode

Bill of Substances (BoS) – CMD
Test reports
Designated storage area
Labeling on each container

Control auxiliary tools
Cleaning records
Designated production line

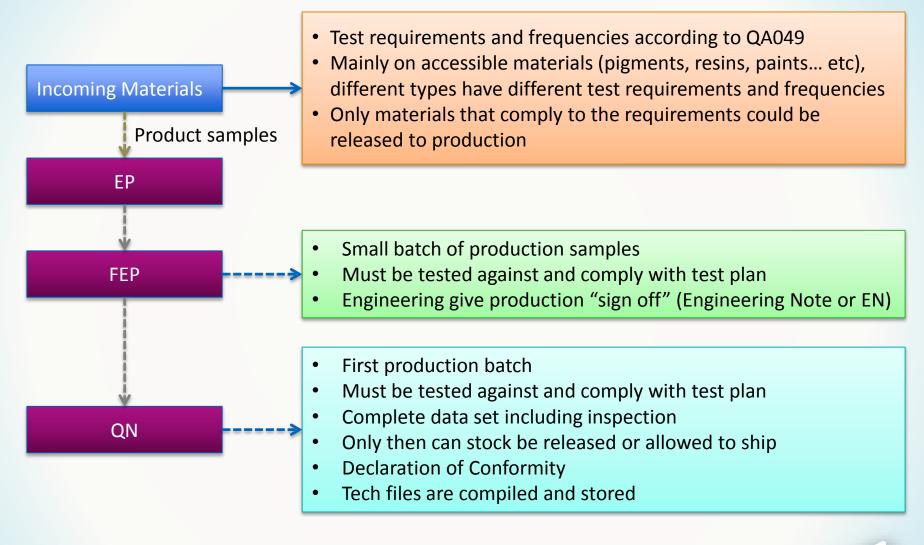
VSP, EP FEP QN, renewal...etc

FIFO

Internal training
Internal audits



Key development stages





Post development controls

- Inspection controls
 - Each batch of production
- Vendors perform testing
 - Qualified vendors perform internal testing in their own facilities
- Supply chain management
 - Audit of suppliers
 - BoM / BoS
 - Vendor substance management (CMD)
 - Random testing
 - Commodity supplier approval
- QN process restarts in case of significant change or period without production (6 months).



Test specifications

- Test plan
 - Based around Hasbro's Safety and Reliability Specifications (SRS)
 - Key document in product approval and safety assessment
 - Includes:
 - Functional performance criteria
 - Life specifications
 - Reliability specifications
 - Torque/Tension specifications
 - Other "specialist requirements" (Electrical, Sound levels)
 - Revised at key stages of product development



Safety and Reliability Specifications (SRS)

- Around 120 individual specifications
 - Covers hazards from small parts, hemispheric shapes, heavy metals, nitrosamines in rubber...
 - Reliability measures include transportation tests and accelerated use tests
 - Combination of ASTM F963, ISO8124 and EN71
 - Includes requirements learned from product experience
 - Most stringent approach including margin of error where appropriate



Other procedures

- Product Development Requirements (PDR)
 - Around 50 individual procedures including Small part prevention, battery qualification, age grading....
- Safety and Reliability Procedures (SRP)
 - Around 20 individual procedures including Recall, consumer complaints, social compliance...
- Factories have QM systems
 - Must pass Hasbro Quality audit (based on ISO9001)



Hasbro Test capability

- Hasbro internal test lab, She Kou
 - 30 staff/785Sq.m
 - Qualified chemists
 - Heavy element testing
 - Phthalate content testing
 - Full physical lab incl. flammability
 - Microwave digestion
 - ICP-OES
 - LC-ICP Mass spectroscopy
 - GC Mass spectroscopy
 - UV-vis
 - XRF scanning
- Operation to ISO17025



Bill of Substance (BoS)

- Obtain complete BoS for accessible materials in toys
- BoS is not required for:
 - Non-retainable packaging materials
 - Inaccessible materials

Incoming Materials

Example of BoS

Trade name	Supplier	CAS no.	Chemical name	% Conc.	Function
Solvent A	AAA	78-93-3	Butan-2-one	40 – 60	Solvent
Super Black	BBB	1333-86-4	Carbon Black	1 – 2	Pigment
PolyX	ссс	25034-86-0	2-Propenoic acid, 2-methyl-, methyl ester, polymer with ethenylbenzene	20 – 30	Resin in paint
ВҮХХ	DDD	64742-48-9	Naphtha (petroleum), hydrotreated heavy	10 – 20	Flowing agent

- Maybe disclosed in the form of SDS, MBOS, declarations... etc.
- All BoS information should be compiled into BoM (Bill of Materials and input into CMD

Two options of CMD:

- Full installation in factory's server (more expensive, suggested for factories with larger no. of SKUs)
- One time BoSConnect input service (much less expensive, web-based, suggested for factories with small no. of SKUs)

Hasbro CMD to SciVera LENS for Chemical Safety Assessment (CSA)



Why The BoS Way?

Testing not viable

Millions of \$\$\$\$.
Test methods not even available/possible.

Questionnaires and declarations

Need verification & frequent updates.

Fast changing regulatory environment

Need to re-assess entire supply chain with upcoming requirements.

Need for data to prepare periodic regulatory reports.



What's a Bill of Substance (BoS)?

Detailed description of a material including:

Chemical Name

Chemical Abstract Number (CAS No.)

Percentage

Example: TK Leoman Printing Ink - BoS

Chemicals	CAS#	%	
C.I. Pigment Yellow 174	78952-72-4	5-10	
C.I. Pigment Yellow 12	6358-85-6	5-10	
Rosin, polymer with p-tert-butylphenol, formaldehyde and pentaerythritol	68213-62-7	20-30	
Distillates (petroleum), hydrotreated heavy paraffinic	64742-54-7	25-35	
Linseed oil	8001-26-1	15-25	
Poly(ethene)	9002-88-4	< 10	
Octanoic acid, cobalt salt	6700-85-2	< 1	
			asbro

BoS v.s. Material Safety Data Sheet/Safety Data Sheet (MSDS/SDS)?

- MSDS/SDS usually only include information on the potential hazards (health, fire, reactivity and environmental) and how to store & work safely with the chemical substance.
- Example TK Leoman Printing Ink MSDS
 Hazardous Ingredients

INGREDIENT	CAS NO.	Weight%	ACGIH	
			(TLV-TWA*2)	
Carbon black*1	1333-86-4	10~20	3.5mg/m ³	
Octanoic acid, cobalt salt	6700-85-2	<1	_	

^{*1 :} Carbon black is contained only in BLACK ink.

Does not usually contain all the information necessary to identify & evaluate chemical composition!

^{*2 :} Threshold Limit Value - Time Weighted over 8 hours

Validating CAS Number

A CAS Registry Number[®] includes up to 10 digits which are separated into 3 groups by hyphens. The first part of the number, starting from the left, has 2 to 7 digits; the second part has 2 digits. The final part consists of a single check digit.

Second part: 2 digits, substance types

First part: 2 to 7 digits



Check digit

http://www.cas.org/content/chemical-substances/checkdig

EXAMPLE

CAS No. 7440-19-3

$$6x_{1}^{2} + 5x_{4}^{2} + 4x_{4}^{2} + 3x_{0}^{2} + 2x_{1}^{2} + 1x_{9}^{2} = 89$$

Check digit: 89 / 10 = 80 + 9 / 10, check digit = **9**

CAS No. 7440-19-3 is invalid as its check-digit "3" is incorrect.

- Organic compounds
- · Inorganic compounds
- Metals
- Alloys
- Minerals
- · Coordination compounds
- Organometallics
- Elements
- Isotopes
- Nuclear particles
- Proteins and nucleic acids
- Polymers
- Nonstructurable materials (UVCBs)



Validating CAS Number

In addition to organic and inorganic substances, REGISTRY has:

65,812,577 sequences

CAS RN 1632279-96-9 is the most recent CAS Registry Number

Specialized Substance Collections Count

CASREACT⁽¹⁾ 75,709,800 Single and multi-step reactions, and synthetic preparations

CHEMLIST 312,229 Inventoried/regulated substances

CHEMCATS 74,326,293 Commercially available chemicals

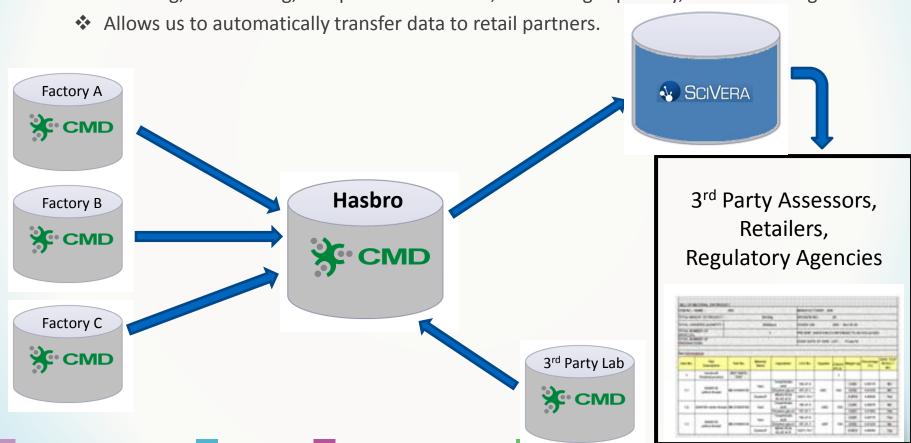
MARPAT 1,057,421 Searchable Markush structures

Hasbro CMD Workflow

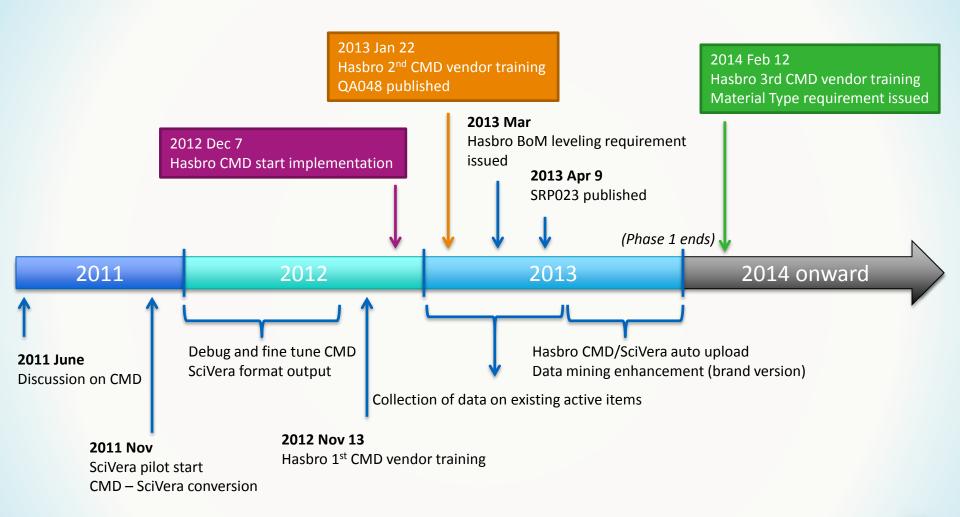
Chemical Information Management

Developed by Hong Kong Toys Council, software company and Toy Brands

Minimizes redundancy of multiple data entry at various location, real time status checking, data mining, compliance validation, auto filing capability, email alert engine



Timeline on Hasbro CMD Implementation





In Summary

- Most stringent approach in the world
- Designed and manufactured to requirements in advance of current safety standards
- Audited, verified and inspected
- Becoming more stringent and transparent



Thank You!

? Questions?



Thank you for your attention! Open Questions?





Rodney Thu Ph.D Chemical Technical Manager

Hasbro Far East Limited

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