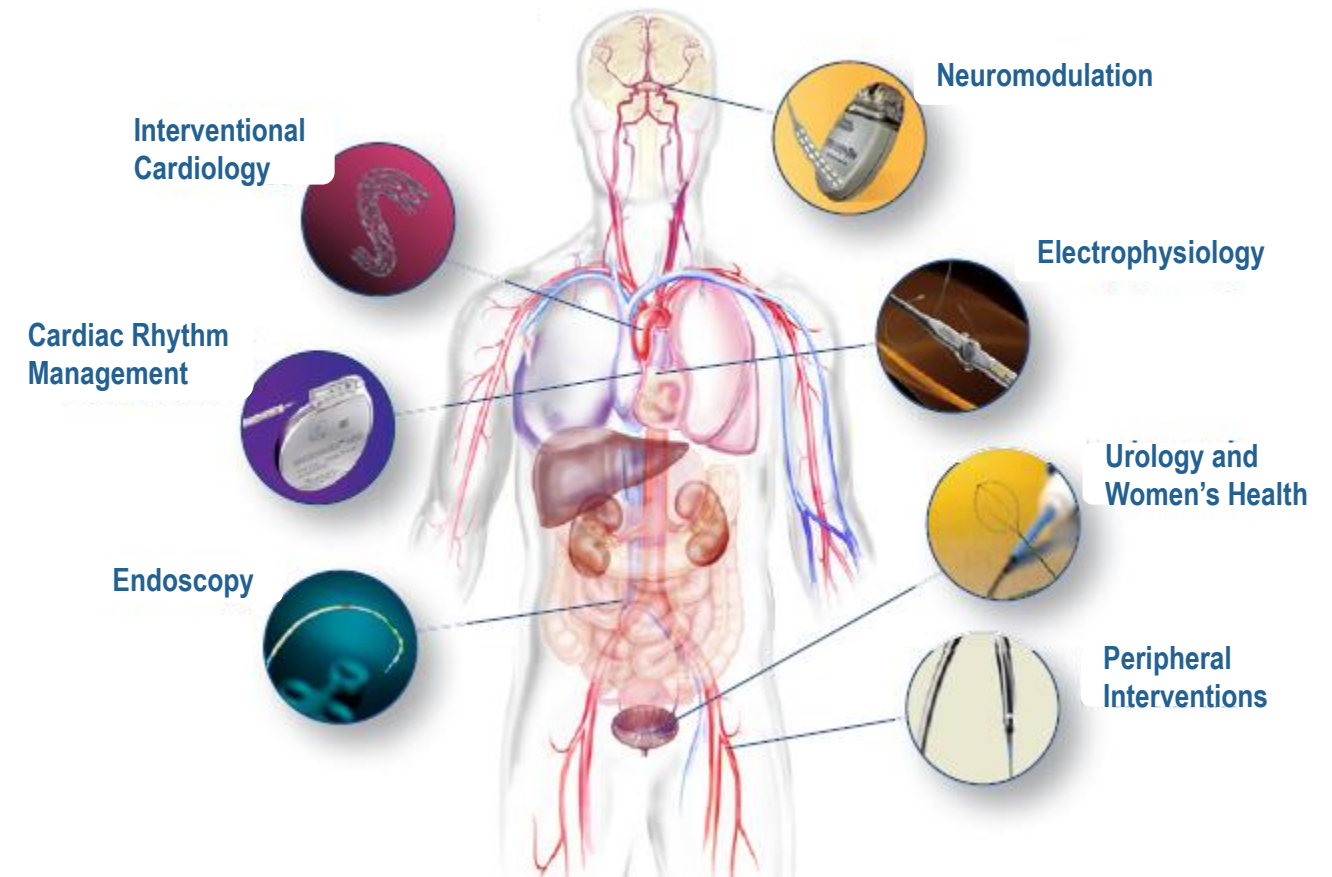


Company: Boston Scientific Corporation (BSC)

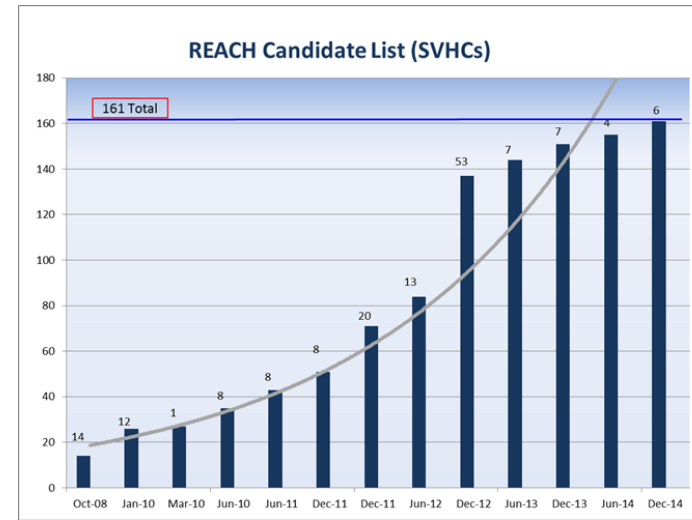
- **Katie Crawford**
 - Regulated Materials Program Manager, Global Supply Chain
- **Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices for over 30 years**
 - 1 of the worlds largest medical device companies
 - Advancing the practice of less-invasive medicine providing patient's alternatives to surgery
 - Global Corporate HQ in Marlborough, Massachusetts (USA)
 - 18 manufacturing facilities worldwide
 - Market presence in approximately 100 countries worldwide
- **Boston Scientific advances science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare.**



**Boston
Scientific**
Advancing science for life™

Learning Objectives

- ❑ Understand the challenging landscape of material regulations
- ❑ Discuss benefits of utilizing an automated data collection system (Product Analytics)
- ❑ Review a unique one-stop form for collecting material content from suppliers
- ❑ Describe best practices for optimized material information data collection



Import Data | Print | Save

Boston Scientific Electronic Component Material Assessment (eCMA)

Request Date: Return by Date:

Supplier Information

Supplier Name: SAP Vendor #:

Part Information

Part Description: Type of Supplied Good:

List the part's mass per each discrete part OR per unit length, area, or volume. Then complete the table for all parts included in this form with the same composition and mass per unit. If "each" is selected for the unit, Units per Part is 1. For raw materials, leave Units per Part blank. Multiple part numbers can only be included on one single form if the mass per unit and composition breakdown are consistent across all included parts.

Mass (g)	per Unit	BSC Part Number	BSC Revision	Supplier Part Number (For reference only)	Units per Part	Add Another Part with Same Composition
X						

Instructions

The term "part" is used throughout this form and refers to the supplied good, whether that is a raw material, manufactured component, sub-assembly, or supplied finished medical device, etc. Please begin with providing the homogeneous materials composition and processing aids per the sections below. Providing full materials disclosure, adding up to 100% material composition will allow Boston Scientific to automatically evaluate the material against new regulations and may, therefore, reduce the need for future regulation declaration requests.

The homogeneous material composition declaration consists of a BOM-structure approach. For parts manufactured from only one homogeneous material, only one part/subpart and one homogeneous material will be reported. Homogeneous material is defined as "one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disintegrated or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes." Each homogeneous material must account for a percentage (wt/wt) of the part/subpart and each substance must account for a percentage (wt/wt) of the homogeneous material in which it is used.

Exemptions claimed relate to EU RoHS, which is described on the following page. For any substance use that meets a defined EU RoHS exemption, select the corresponding exemption from the pull-down menu.

Homogeneous Material Composition Declaration

Only parts with "each" as the selected unit above may have more than one part/subpart below. Complete Subpart Mass field only if more than one subpart is listed.

+P inserts a new part/subpart +M inserts a new homogeneous material +S inserts a new substance - Deletes the line

Part / Subpart Name	Subpart Mass (g) (For "each" parts)	Homogeneous Material Name (Supplier, trade or grade name, number)	% of subpart	Substance Name	CAS #	RoHS Exemption Claimed	% of material
+P -P							

Processing Aids

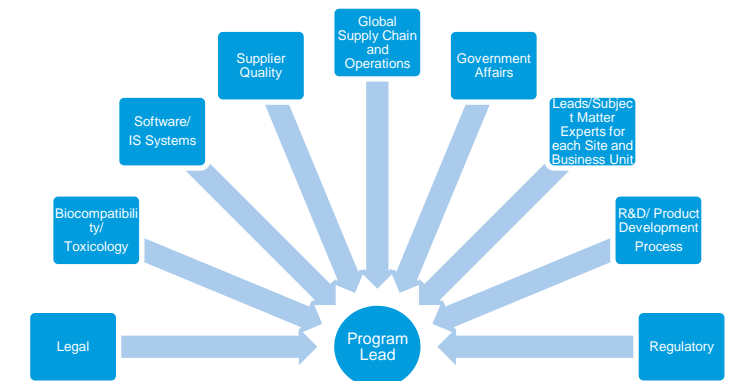
A processing aid is defined as a material or chemical present at a detectable amount on the finished part, existing as a residue or impurity from the manufacturing process, which is not present by design or intent of the manufacturer.

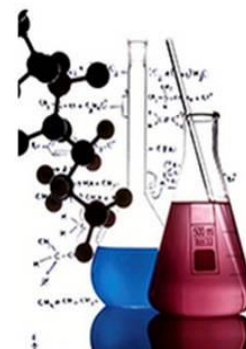
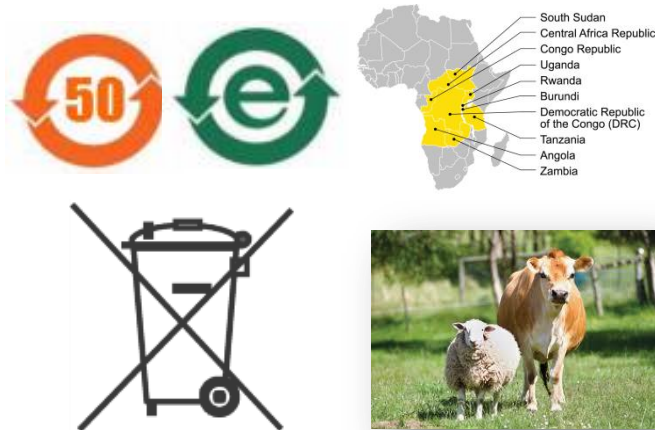
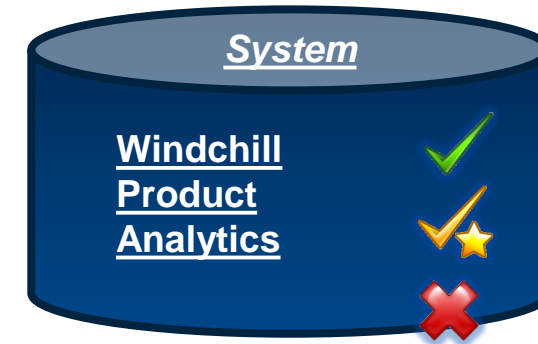
Are any processing aids utilized in the production of the part? Yes No

Does Natural Rubber Latex or Dry Natural Rubber contact the part during manufacturing? Yes No

Please provide a listing of the processing aids utilized. Processing Aid ID refers to the grouping of multiple materials present within one processing aid. For example, a mixture of a cleaning agent and water would be listed below in two rows, one row for each material. Both rows would have the same Processing Aid ID since they are included in the same processing aid.

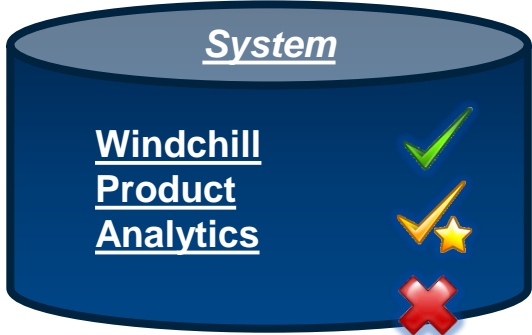
Processing Aid ID	Material Name	CAS #	Obtained from Animal Source?	Add Processing Aid Material
X			<input type="radio"/> Yes <input type="radio"/> No	





eCMA Process (and Form)
electronic Component Material Assessment





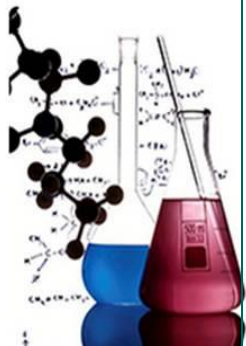
Define Need/ Requirements

Build Team

Develop Process & Tools

Implement System and Data Collection

Sustain



eCMA Process (and Form)

electronic Component Material Assessment

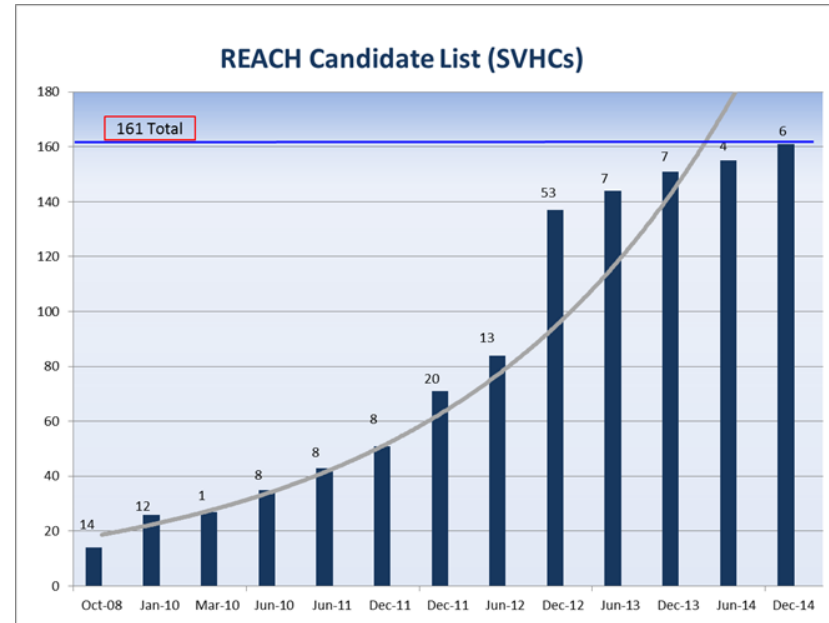
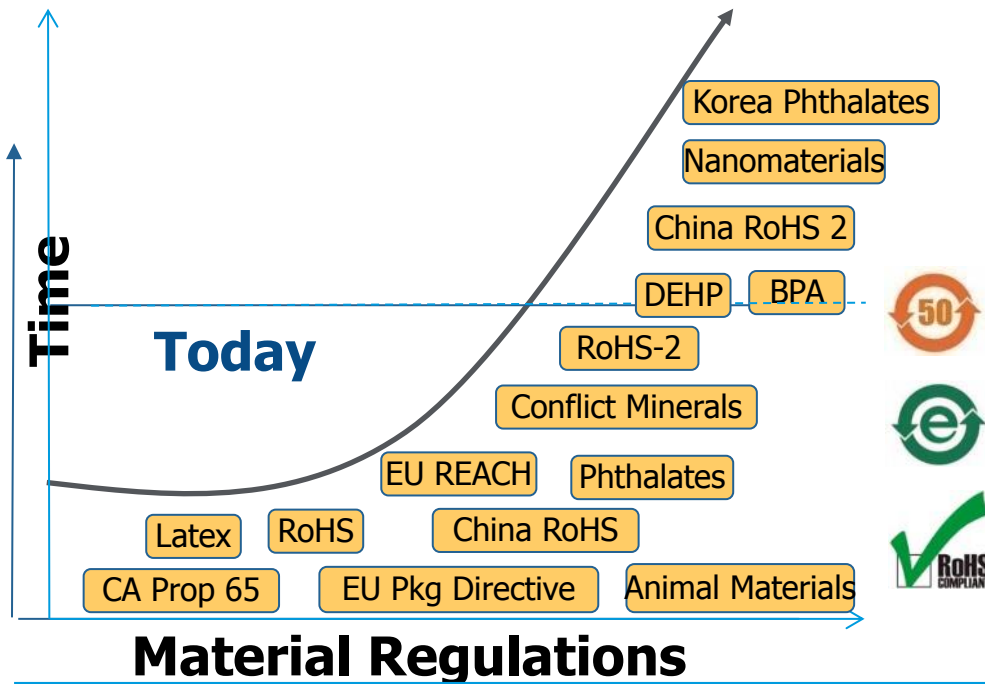


Need: The rough and tumble landscape of material regulations

↑ Number of material regulations

↑ Scope of existing regulations

↑ Complexity of regulations



Conflict Minerals



Photo credit: Darc Red

Requirements: Types of Material Regulations

Environmental Regulations

Restriction of Hazardous Substances



Medical Device Regulations

Animal Materials



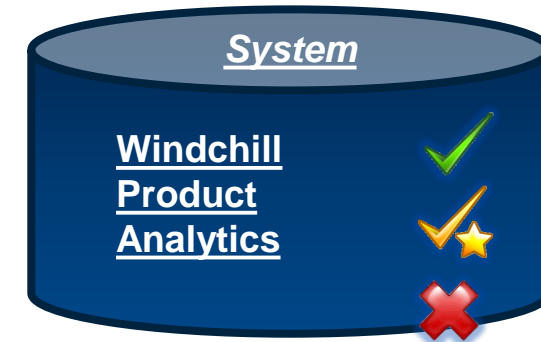
Other Regulations

Conflict Minerals



DRC Adjoining Countries

Angola	Republic of the Congo	Tanzania
Burundi	Rwanda	Uganda
Central African Republic	South Sudan	Zambia

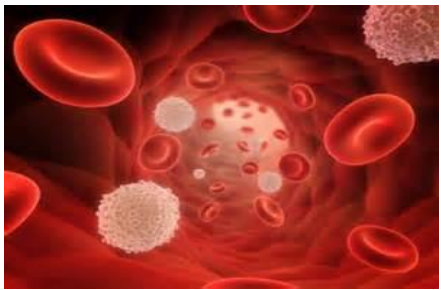
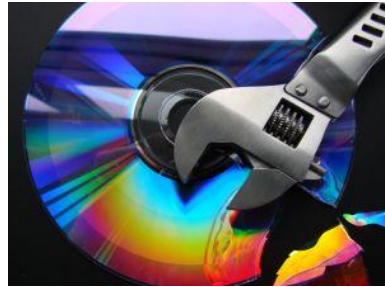


eCMA Process (and Form)
electronic Component Material Assessment

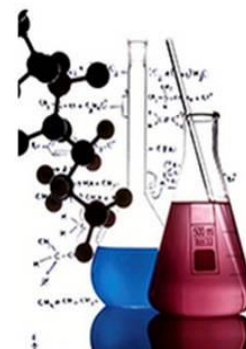
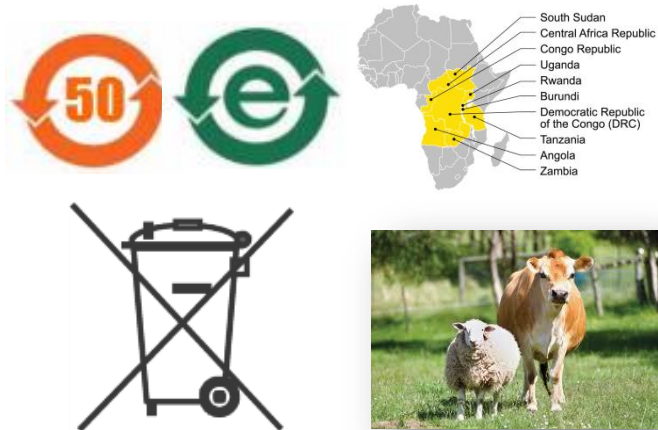
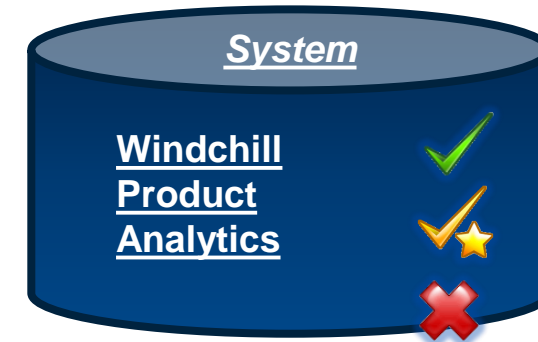


Best Practice: Agile, High-Performance

I improve the Quality of Patient Care and all things Boston Scientific.



Company	Boston Scientific								
Business Sector	Cardiovascular			Rhythm Management			MedSurg		
Division	IC	PI	CRM	EP	Endoscopy	Uro & WH	NM		
	Stents	Vascular Disease	High Voltage	Electrophysiology	Biliary	Urology	Spinal Cord		
Franchises	Core	Interventional Oncology	Low Voltage		Core GI	Gynecology	Deep Brain		
	Imaging	Hypertension	Externals		Luminal Patency				
	Structural Heart		Accessories		Bronchial Thermoplasty				



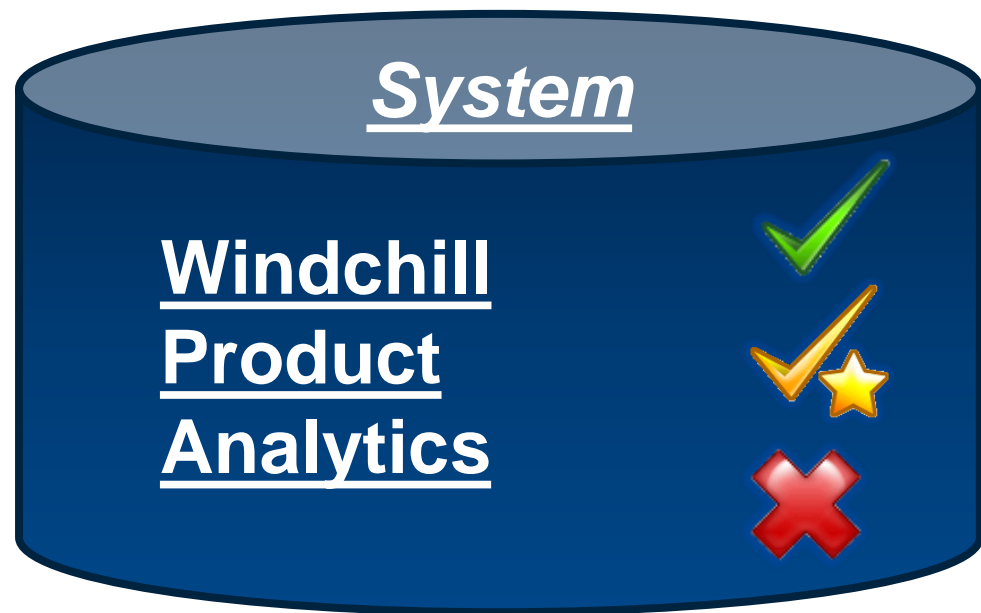
eCMA Process (and Form)
electronic Component Material Assessment



A sustainable solution includes teamwork between IS systems, business procedures and forms

Software System: PTC Windchill Product Analytics (WPA)

One-Stop Form: electronic component material assessment (eCMA)



eCMA Process
(and Form)

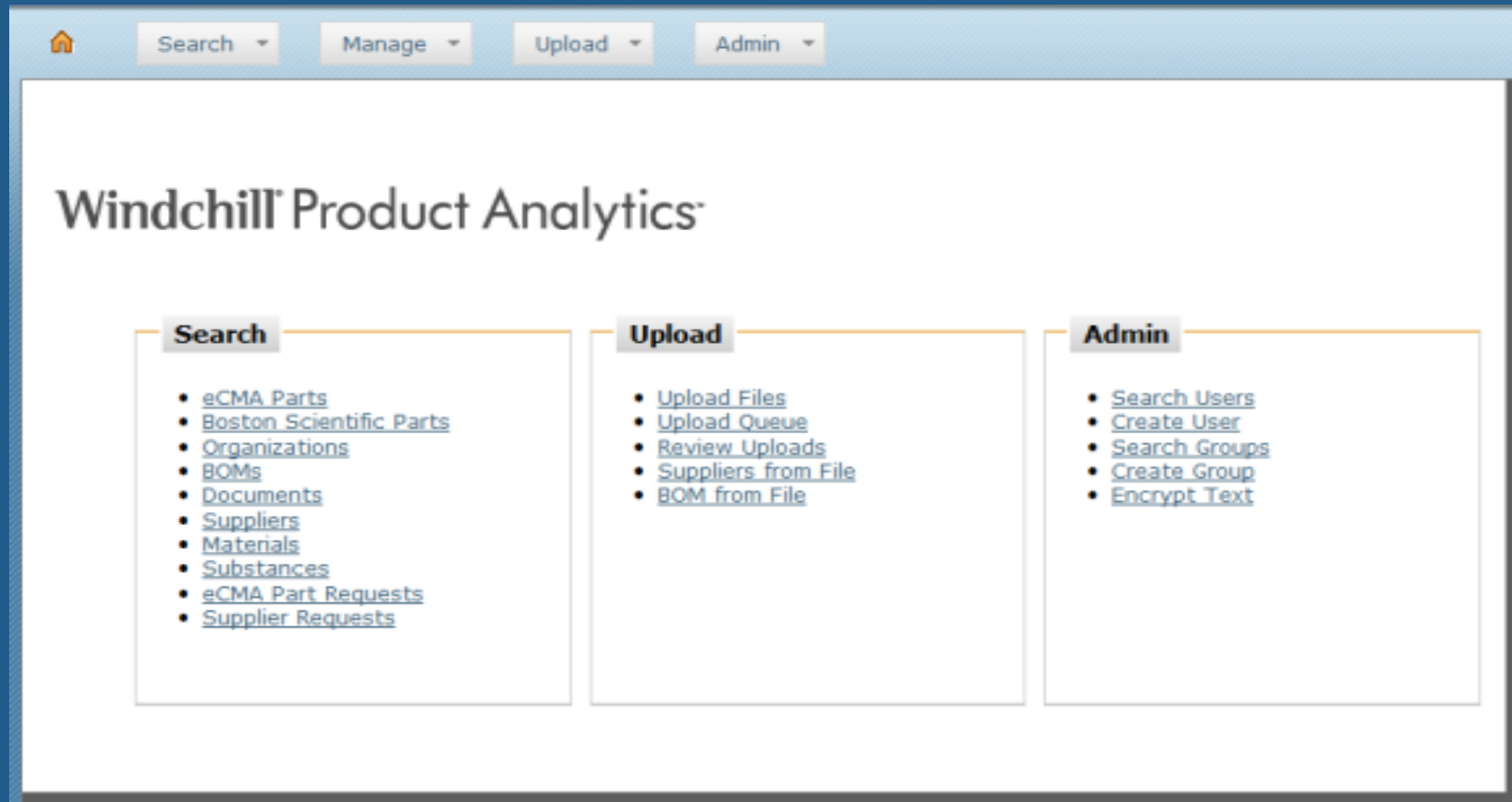
electronic
Component
Material
Assessment



Photo Credit Darc Red

Key Tool: Software System

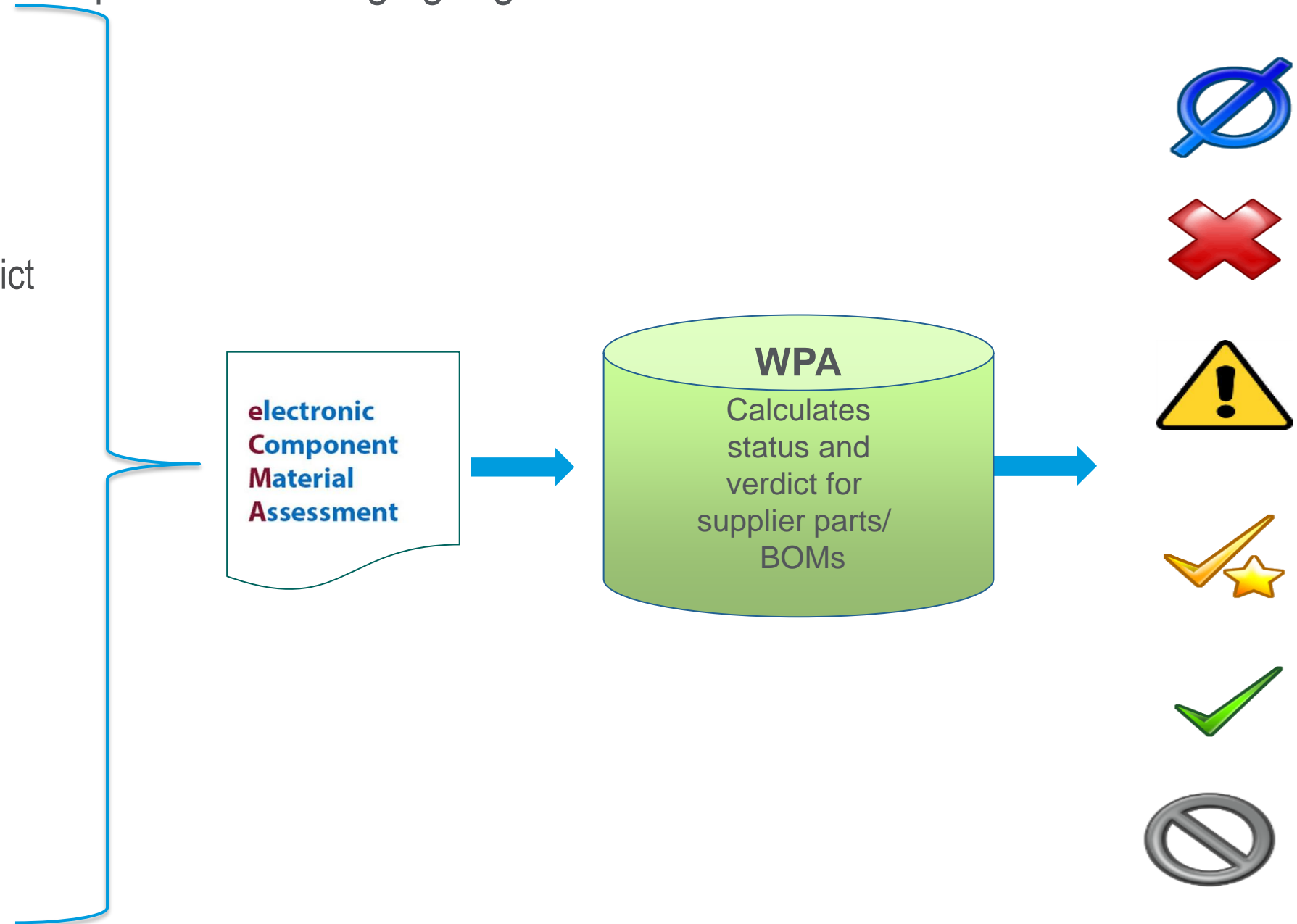
Windchill Product Analytics



- Quality:
 - Comprehensive for material regulations
 - Material information requests/response tracking
 - Version history tracking
- Efficient:
 - Searchable system
 - User-friendly interface
 - Connection with PLM system & purchasing system
 - Connection to supply chain for material
- Adaptable:
 - Compliance specifications can accommodate rapidly changing and new regulations

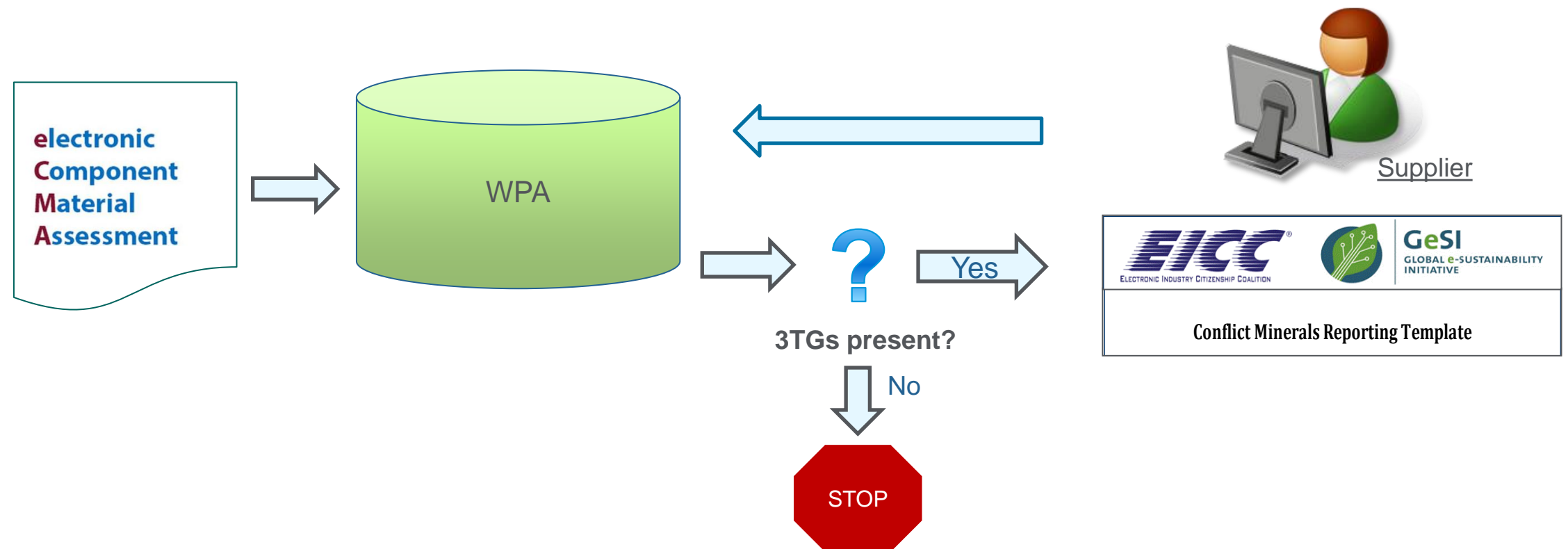
Compliance specifications designed to be adaptable for changing regulations

- **PTC specifications**
 - Managed by PTC
 - Updates available when regulation updates
 - Includes: EU REACH, EU RoHS, Conflict Minerals, etc.
- **Customer defined specifications**
 - Managed by customer (BSC)
 - Medical device regulations ‘
 - Customer business rules



Comprehensive for key material regulations. For example:

- Requests/response tracking
- Storage and revision history
- Validations performed on incoming data



Key Tool: Boston Scientific's custom material declaration form

- Comprehensive:
 - Key regulations & substances
 - Processing Aids
 - Emerging regulations
- User-Friendly:
 - Auto-fill of part/supplier information
 - Validations for correct completion
- Efficient:
 - Multiple components on one form (when applicable)
 - Allows both Y/N declarations and ability to provide full material disclosure

Import Data Print Save

Boston Scientific Electronic Component Material Assessment (eCMA)

Request Date:

Supplier Information

Supplier Name:

Part Information

Part Description:

Mass (g): per Unit:

Supplier and Part Information

Instructions

The term "part" is used throughout this form and refers to the device, etc. Please begin with providing the homogeneous material composition will allow Boston Scientific to automatically declaration requests.

The homogeneous material composition declaration consists of one homogeneous material will be reported. Homogeneous of materials, that cannot be disjoined or separated into different homogeneous material must account for a percentage (wt/wt) which is it used.

Exemptions claimed relate to EU RoHS, which is described on exemption from the pull-down menu.

Homogeneous Material Composition Declaration

Only parts with "each" as the selected unit above may have more than one subpart is listed.

Part / SubPart Name	SubPart Mass (g) (for "each" part)	CAS #	RoHS Exemption Claimed	% of material
+P -P				

Processing Aids

Are any processing aids utilized in the production of the part? Does Natural Rubber Latex or Dry Natural Rubber contain any processing aid.

Please provide a listing of the processing aids utilized. Processing Aid ID since they are included in the same processing aid.

Processing Aid ID	Obtained from Animal Source?	Add Processing Aid Material
X	<input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/>

Instructions

Homogeneous Material Composition Declaration

Processing Aids

Supplier Approval

Medical Device Regulation Related Questions

Please indicate if any of the following chemicals are utilized in the production of the part. If "yes" is marked for any chemical use below, please email the supplier for full materials disclosure, adding up to 100% of the homogeneous material.

Material Name	CAS #	Declaration
bis[2-ethylhexyl] phthalate (DEHP)	117-81-7	<input type="radio"/> Yes <input type="radio"/> No
Dibutyl phthalate (DBP)	84-74-0	<input type="radio"/> Yes <input type="radio"/> No
Benzyl butyl phthalate (BBP)	85-84-9	<input type="radio"/> Yes <input type="radio"/> No
Methoxy ethyl phthalate	117-82-8	<input type="radio"/> Yes <input type="radio"/> No
Diisopentyl phthalate	605-20-5	<input type="radio"/> Yes <input type="radio"/> No
Diisobutyl phthalate	84-69-5	<input type="radio"/> Yes <input type="radio"/> No
Polyvinyl Chloride	9002-86-2	<input type="radio"/> Yes <input type="radio"/> No

Medical Device Regulation Questions

Environmental/Other Regulation Questions

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals. Please indicate if any of the chemicals listed on the following website are used in the production of the part.

CA Proposition 65: Please indicate if any of the chemicals listed on the following website are used in the production of the part.

RoHS, Packaging and Batteries Directives: Please indicate if any of the following chemicals are utilized in the production of the part, alongside the homogeneous material composition declaration on page 1, alongside the homogeneous material composition declaration. Therefore, please complete this section regardless if EU RoHS component exemptions are claimed.

Material Name	Declaration
Mercury & Mercury Compounds	<input type="radio"/> Yes <input type="radio"/> No
Lead & Lead Compounds	<input type="radio"/> Yes <input type="radio"/> No
Cadmium & Cadmium Compounds	<input type="radio"/> Yes <input type="radio"/> No
Hexavalent Chromium & its compounds	<input type="radio"/> Yes <input type="radio"/> No
Polybrominated Biphenyls (PBB)	<input type="radio"/> Yes <input type="radio"/> No
Polybrominated Diphenylethers (PBDE)	<input type="radio"/> Yes <input type="radio"/> No
Hexabromocyclododecane (HBCDD)*	<input type="radio"/> Yes <input type="radio"/> No

Environmental/Other Regulation Questions

Conflict Minerals: Please indicate if any of the following chemicals are utilized in the production of the part.

Material Name	Declaration
Tin	<input type="radio"/> Yes <input type="radio"/> No
Tantalum	<input type="radio"/> Yes <input type="radio"/> No
Tungsten	<input type="radio"/> Yes <input type="radio"/> No
Gold	<input type="radio"/> Yes <input type="radio"/> No

Other Related Information

Does the part contain or is it manufactured with nanomaterials intentionally designed to exhibit physio-chemical effects? Yes No

Resin SPI code, if applicable:

Pre-consumer recycled content in component (%):

Supplier Approval

By submitting this information, I certify that the above information is true and correct to the best of my knowledge.

Approver Title:

Approval Date:

Supplier Approval

Key Concept: material content breakdown & full material disclosure (FMD)

Homogeneous Material Composition Declaration

Only parts with "each" as the selected unit above may have more than one part/subpart below. Complete SubPart Mass field only if more than one subpart is listed.

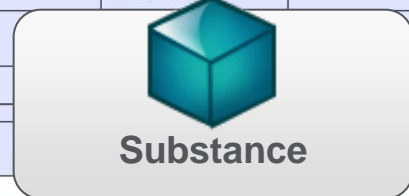
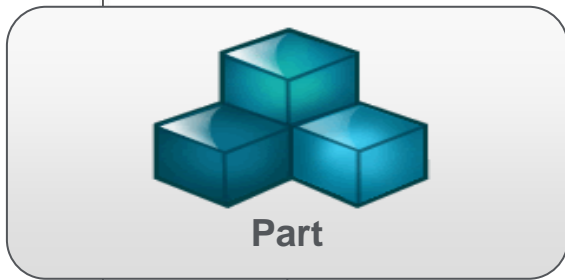
+P Inserts a new part/subpart

+M Inserts a new homogeneous material

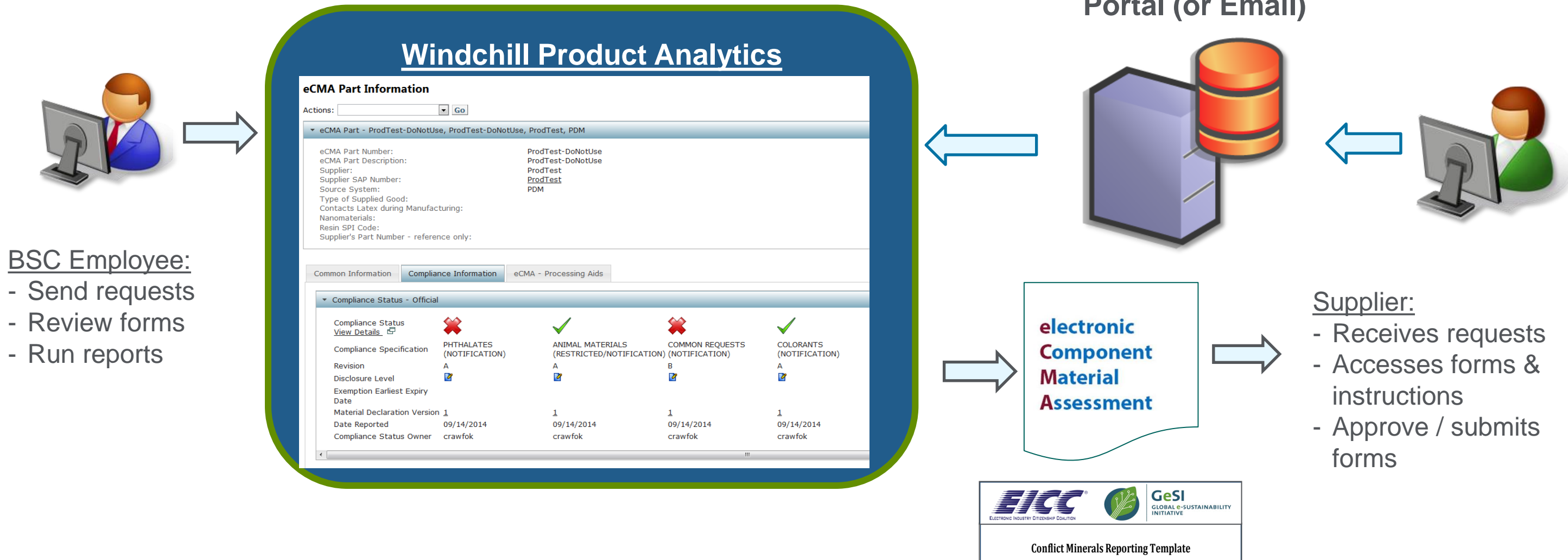
+S Inserts a new substance

- Deletes the line

		Part / SubPart Name	SubPart Mass (g) <small>(for "each" parts)</small>			Homogeneous Material Name <small>(supplier, trade or grade name, number)</small>	% of subpart			Substance Name	CAS #	RoHS Exemption Claimed	% of material
+P	-P	Outer Casing	1.9	+M	-M	Polypropylene Casing	100	+S	-S	Polypropylene	9003-07-0	<input type="checkbox"/>	85
								+S	-S	Calcium Carbonate Filler	471-34-1	<input type="checkbox"/>	15
+P	-P	Ink	0.1	+M	-M	Water-based Ink	100	+S	-S	Ferrous sulfate	7720-78-7	<input type="checkbox"/>	30
								+S	-S	Water	7732-18-5	<input type="checkbox"/>	65
								+S	-S	Gallic Acid	149-91-7	<input type="checkbox"/>	3
								+S	-S	Gum Arabic	9000-01-5	<input type="checkbox"/>	2
+P	-P	Ball Point	0.2	+M	-M	Stainless Steel	100	+S	-S	Iron	7440-89-6	<input type="checkbox"/>	68
								+S	-S	Carbon	7440-44-0	<input type="checkbox"/>	0.08
								+S	-S	Cobalt	7440-48-4	<input type="checkbox"/>	0.1
								+S	-S	Chromium	7440-47-3	<input type="checkbox"/>	19
								+S	-S	Copper	7440-50-8	<input type="checkbox"/>	0.3
								+S	-S	Manganese	7440-96-5	<input type="checkbox"/>	2
								+S	-S	Molybdenum	7439-98-7	<input type="checkbox"/>	0.22
								+S	-S	Nitrogen	7727-37-9	<input type="checkbox"/>	0.1
								+S	-S	Nickel	7440-02-0	<input type="checkbox"/>	9.125
								+S	-S	Phosphorous		<input type="checkbox"/>	0.045
								+S	-S	Silicon		<input type="checkbox"/>	1
								+S	-S	Sulfur		<input type="checkbox"/>	0.03

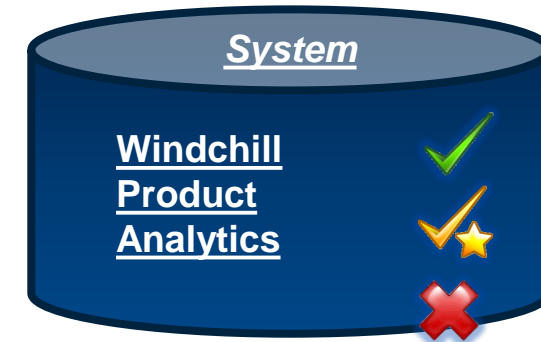


Key Tools Work Together



- BSC Employee:**
- Send requests
 - Review forms
 - Run reports

- Supplier:**
- Receives requests
 - Accesses forms & instructions
 - Approve / submits forms



eCMA Process (and Form)
electronic Component Material Assessment



Communication, communication, communication...

Who is the right contact?

Contacts		Locations	Alternate IDs	Documents
No.	First Name	Last Name		
1	Raul	Otero		
2	John	Wayne		
3	Unknown	Unknown		
4	Bob	Cat		

What is needed?

- Material Declaration via eCMA Form
- Full Material Disclosure
- Conflict Minerals Information

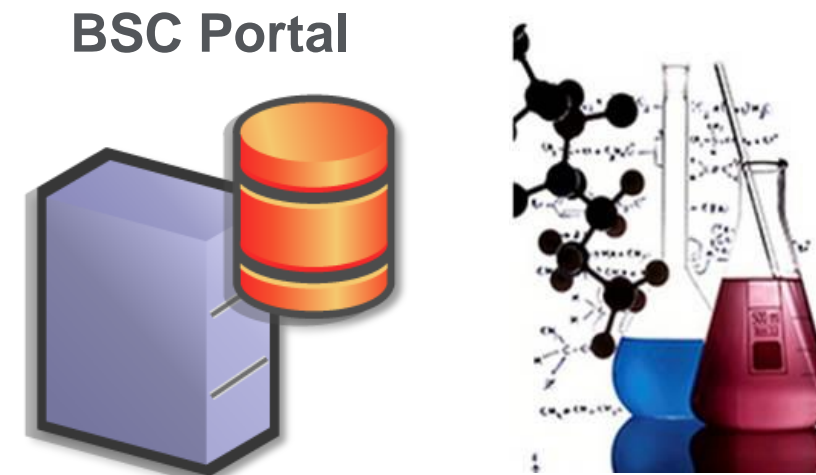
**electronic
Component
Material
Assessment**



When is the deadline?

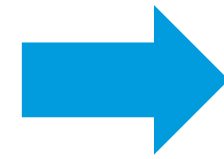
OCTOBER 2014						
SUN	MON	TUE	WED	THU	FRI	SAT
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

Where to go?

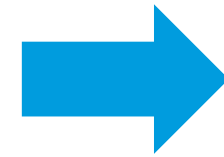


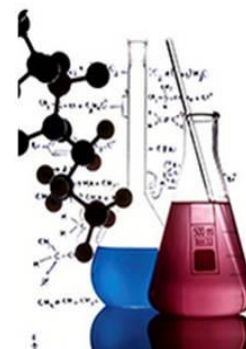
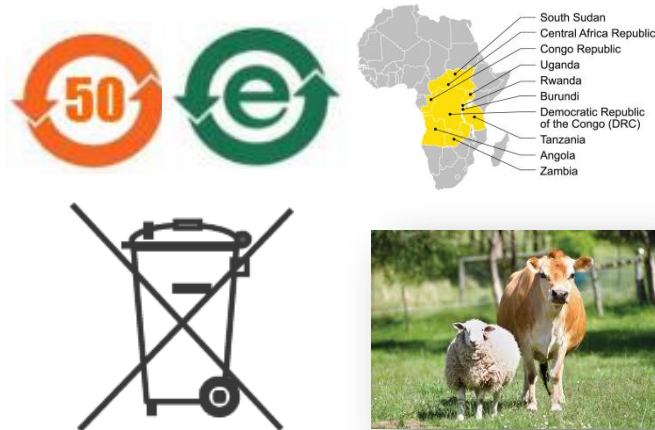
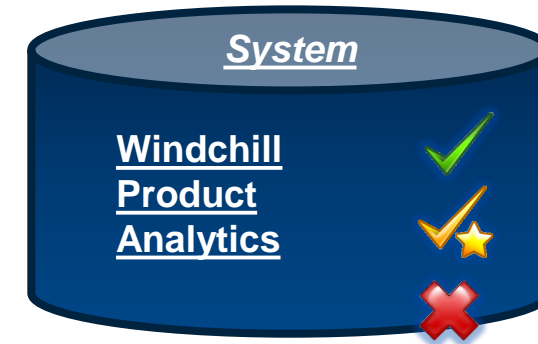
How to handle challenges

- No response from supplier?
- Incorrect contacts?
- Unable to obtain information?



- Escalation (internally, at supplier)
- Go to tier II or tier III suppliers
- Use other methods to obtain data

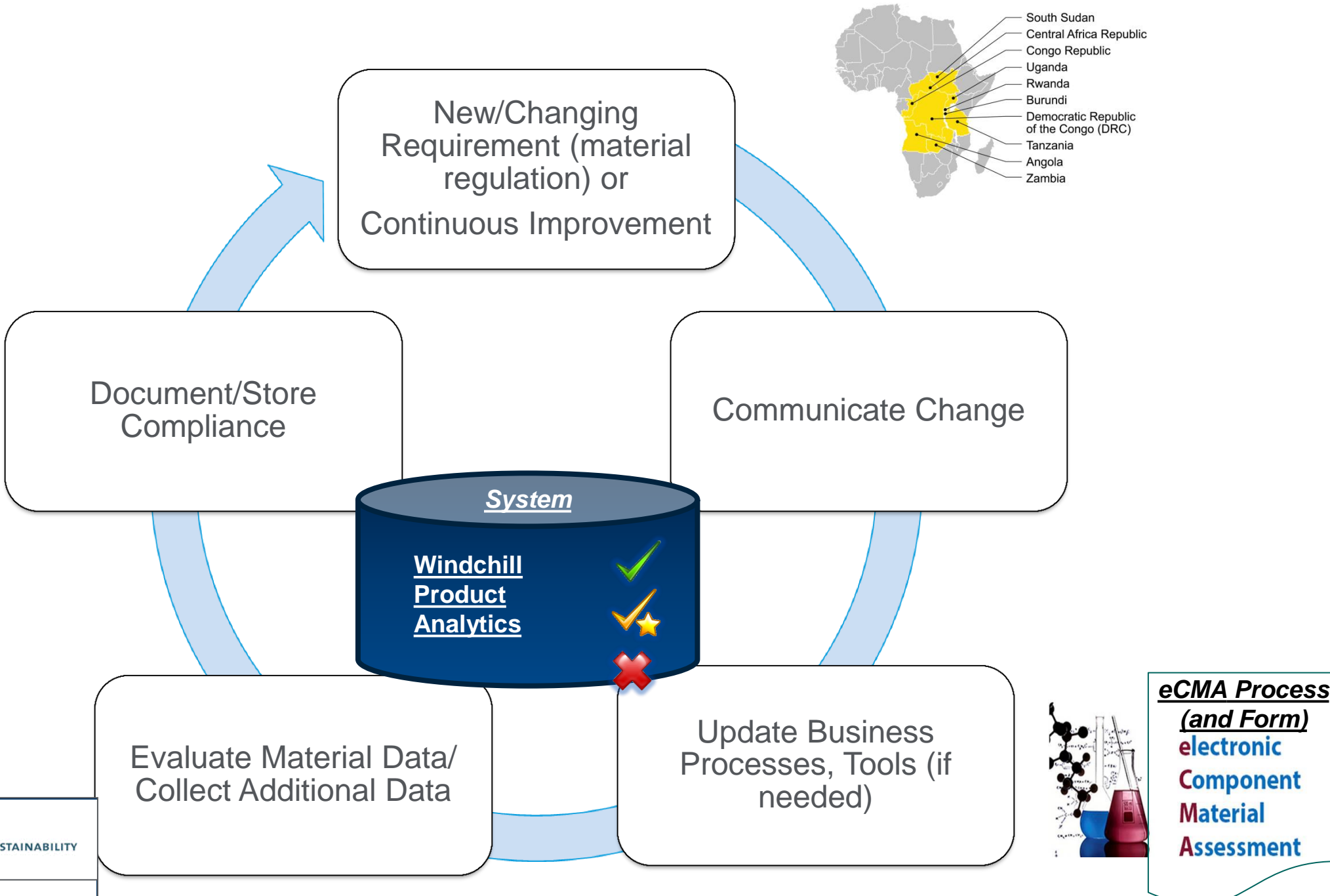




eCMA Process (and Form)
electronic Component Material Assessment



A Sustainable Program






GeSI
GLOBAL e-SUSTAINABILITY INITIATIVE

Conflict Minerals Reporting Template

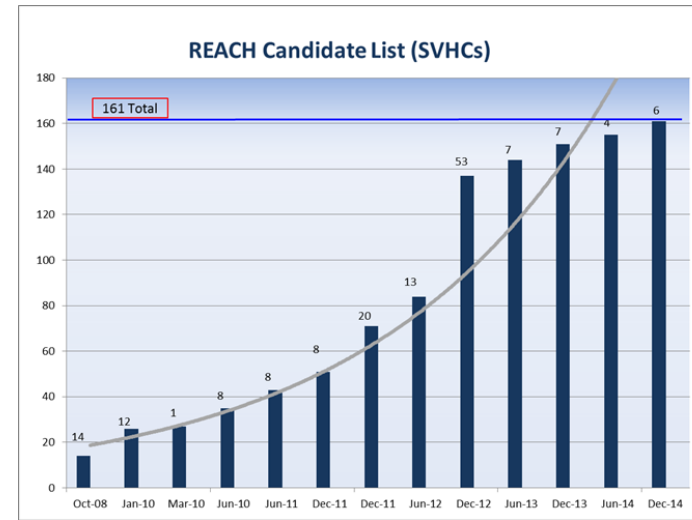


Q&A



Learning Objectives

- ✓ Understand the challenging landscape of material regulations
- ✓ Discuss benefits of utilizing an automated data collection system (Product Analytics)
- ✓ Review a unique one-stop form for collecting material content from suppliers
- ✓ Describe best practices for optimized material information data collection



Boston Scientific Electronic Component Material Assessment (eCMA)

Request Date: [] Return by Date: []

Supplier Information: Supplier Name: [] SAP Vendor #: []

Part Information: Part Description: [] Type of Supplied Good: []

Mass (g)	per Unit	BSC Part Number	BSC Revision	Supplier Part Number	Units per Part	Add Another Part with Same Composition
X						

Homogeneous Material Composition Declaration

Part / Subpart Name	Subpart Mass (g)	Homogeneous Material Name	% of Subpart	Substance Name	CAS #	RoHS Exemption Claimed	% of Material

Processing Aids

Are any processing aids utilized in the production of the part? Yes No

Does Natural Rubber Latex or Dry Natural Rubber contact the part during manufacturing? Yes No

Processing Aid ID	Material Name	CAS #	Obtained from Animal Source?	Add Processing Aid Material
X			<input type="radio"/> Yes <input type="radio"/> No	



- Your feedback is valuable
- Don't miss out on the chance to provide your feedback
- Gain a chance to win an instant prize!
- Complete your session evaluation now

PTC[®] Live Global