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אילטם - איגוד משתמשים לפיתוח מתקדם
של מערכות מורכבות ומערכים (ע"ר)

ILTAM USER'S ASSOCIATION

Sustainability and news in green directives

Best Practices for REACH Compliance

July 19, 2017
Herzlia, Israel

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Agenda

- Review of REACH Compliance concerns facing Article Producers
- FMD – Benefits and Limitations of Full Material Declarations
- Best Practices for SVHC Compliance Validation
- Best Practices for REACH Annex XIV and XVII Compliance Validation
- Changes to the definition of an “Article”
- Open Forum Q&A Session – Any/All Topics

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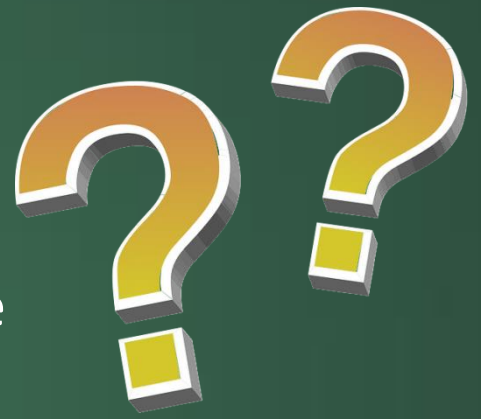
REACH

A Review of Compliance Concerns facing Article Producers

REACH – Areas of concern for article producers

- Important things to consider when applying REACH requirements to articles such as EEE:
  - Does the article expel any mixtures or substances?
  - Is the article manufactured in the EU or imported into the EU?
  - A clear understanding of the definition of an article is required
  - Which Annex XVII restriction entries apply to your type of product?
  - Regular data updates – every 6 months
- Customer requirements
  - The type of data required by your customers will define what type of data is required from your suppliers



Producer Responsibilities

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Condition	Communication Requirements Professional Users	Communication Requirements Consumers (Upon Request)	Notificaiton Requirements	Authorization Requirements	Registration Requirements	Restrictions on use
SVHC not present in Article or sub-article over 1000ppm	None	None	None	None	None	None
SVHC Present in Article or sub-article over 1000ppm	**<Article 33(1)>** The name of the substance must be provided as well as any information available to ensure safe use of the article.	**<Article 33(2)>** Must provide the name of the substance and if available, safety information about the SVHC and the article.	None	None	None	None
SVHC Present in Article or Sub-article over 1000ppm and as a result over 1 tonne annually of the substance is imported or produced for sale in the EU.			**<Article 7(2)>** Must notify ECHA of the SVHCs present in the article	None	None	None
SVHC Present in Article or Sub-article over 1000ppm and as a result over 1 tonne per of the substance is imported or produced for sale in the EU, and the SVHC is intended to be released during normal article use.				None	**<Article 7(1)>** SVHC must me registered with ECHA for use in the article, if not prev registered.	None
Article contains **Annex XIV** substance which has not been authorized for the specific use. (Articles manufactured in the EU only)	None	None	None	**<Article 56>** Substance must be authorized for use before incorporating into an article in the EU.	None	**<Article 56>** Manufacturers should ensure the substance is authorized for the specific use in the manufacturing process.
Product contains **Annex XVII** substance which is used in a manner restricted under one or more Annex XVII Entry.	None	None	None	None	None	**<Article 67(1)>** Substance cannot be used. The Article cannot be imported or produced for sale in the EU.

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FMD – Benefits and Limitations of Full Material Declarations

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Full Material Declarations (FMD):

❖What is a Full Material Declaration?

- ❖A full material declaration is a breakdown of **all** the substances present in a product.
  - ❖Should list all homogeneous materials present in the product, as well as all substances present in each material.
  - ❖Substance mass or concentration must be provided.
  - ❖Mass of the product must also be provided
  - ❖Can optionally include compliance statements and exemption info, but not all do.

- ❖ IPC 1752A (Class D) and IEC 62474 (Composition declaration) are considered full material declarations.

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Full Material Declarations (FMD):

❖What is a Full Material Declaration?

Orderable Part			Total weight (mg)	101.45
Homogenous Material	Weight (mg)	Substance in Mat.	CAS #	% Avg. Weight
Mold Compound	48.07	Ortho Cresol Novolac Resin	29690-82-2	10
		Phenolic Resin	9003-35-4	10
		Fused silica	60676-86-0	65
		AlHydroxide	21645-51-2	14.5
		Carbon black	1333-86-4	0.5
Leadframe	46.99	Cu	7440-50-8	97.5
		Fe	7439-89-6	2.4
		Zn	7440-66-6	0.1
Die Attach	3.45	Pb	7439-92-1	92.5
		Ag	7440-22-4	2.5
		Sn	7440-31-5	5
Plating	1.82	Sn	7440-31-5	100
Die	1.12	Si	7440-21-3	100

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Full Material Declarations (FMD):

❖Benefits of a Full Material Declaration

- ❖ If all substances in a product are known, the product can be evaluated against any current or future substance restriction without the need to recollect data.
- ❖ Homogenous material disclosures can assist in determining the status of sub articles within the product.
- ❖ Full Material Declarations can be used as supporting documentation for certificates of compliance.

Full Material Declarations (FMD):

❖Limitations of a Full Material Declaration

- ❖ Not all Full Material Declarations are created equal!
- ❖ Some suppliers may not be able to disclose every substance due to proprietary information or trade secret mixtures.
- ❖ An FMD with proprietary substances, may not be able to used for SVHC validation, depending on the concentration of the substance.
- ❖ For the purpose of REACH SVHC validation, FMDs should be viewed as one of three types:
  1. FMD with no proprietary substances listed
  2. FMD with proprietary substances < 1000ppm at the sub-article level
  3. FMD with proprietary substances > 1000ppm at the sub-article level

Full Material Declarations (FMD):

Orderable Part			Total weight (mg)	101.45
Homogenous Material	Weight (mg)	Substance in Mat.	CAS #	% Avg. Weight
Mold Compound	48.07	Ortho Cresol Novolac Resin	29690-82-2	10
		Phenolic Resin	9003-35-4	10
		Fused silica	60676-86-0	65
		AlHydroxide	21645-51-2	14.5
		Carbon black	1333-86-4	0.5
Leadframe	46.99	Cu	7440-50-8	97.5
		Fe	7439-89-6	2.4
		Zn	7440-66-6	0.1
Die Attach	3.45	Pb	7439-92-1	92.5
		Ag	7440-22-4	2.5
		Sn	7440-31-5	5
Plating	1.82	Sn	7440-31-5	100
Die	1.12	Si	7440-21-3	100

No Proprietary Substances Listed. No Certificate of Compliance is needed for SVHC Validation.

Proprietary Substance over 1000ppm Listed. Certificate of Compliance is needed for SVHC Validation.

Orderable Part			Total weight (mg)	71.99
Homogenous Material	Weight (mg)	Substance in Mat.	CAS #	% Avg. Weight
Mold Compound	28.58	Ortho Cresol Novolac Resin	29690-82-2	2
		Phenolic Resin	9003-35-4	5
		Epoxy + Phenol Resin	n/a	5
Leadframe	37.61	Cu	7440-50-8	96.9
		Fe	7439-89-6	2.35
		Ag	7440-22-4	0.6
		Zn	7440-66-6	0.12
		P	7723-14-0	0.03
Die Attach	2.4	Ag	7440-22-4	75
		Epoxy	129915-35-1	25
Plating	1.89	Sn	7440-31-5	100
Die	1.33	Si	7440-21-3	100
Wire Bond	0.18	Cu	7440-50-8	100

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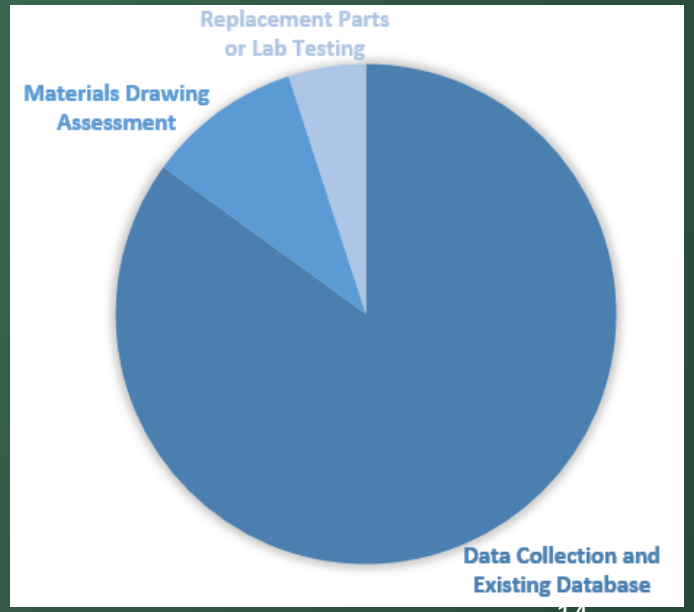
Best Practices for SVHC Compliance Validation

Best Practices for SVHC Compliance Validation:

- What we should be doing:
  - Collect **Full Material Declaration (FMD)** data when possible. Pay close attention to the use of proprietary substances.
  - Be persistent and be patient with suppliers, and have a process-oriented collection process to ensure the quality of collection (comprehensiveness).
  - On average, from GreenSoft's experience in dealing with collection of REACH data from suppliers – it takes an average of **four iterations** of communications in emails or phone calls to obtain valid data and documentation. **Be prepared for the amount of resources needed to perform collection.**

Best Practices for SVHC Compliance Validation:

- A process that covers all parts and materials:
  - Have a data validation process on the required data and documents per your compliance requirements. (Garbage in / Garbage out)
  - Built-to-spec items typically do not have supplier data available, and other processes and strategies need to be defined and deployed in these cases.
  - On average, from GreenSoft's experience in dealing with the data collection for EEMs, data collection and the existing database (over 64M parts) will generate around 80-85% of the parts.
    - Assessment based on materials or drawing files would generate another 7-10% of parts.
    - The remaining would either go through replacements or lab testing.



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Best Practices for REACH Annex XIV and XVII Compliance Validation

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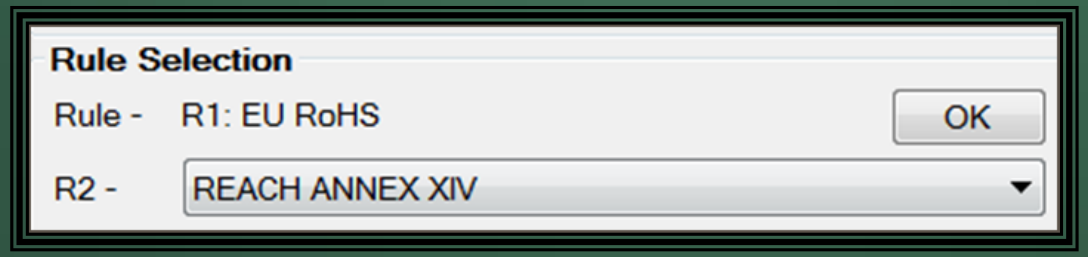
REACH – Annex XIV

GreenData Manager

- Best Practices for REACH Annex XIV (Authorization List) Compliance validation:
  - Collect a combination of FMD and **Certificates of Compliance (CoCs)** - due to proprietary substances.
  - There is no minimum threshold for use of these substances – SVHC declaration CoC is not valid for Annex XIV.
  - Software tool capable of rolling up all component data to the product level. All versions of GreenSoft's **GreenData Manager** software have complete Annex XIV compliance validation capabilities.



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REACH – Annex XVII

- Best Practices for Validating product compliance to Annex XVII:
  - Collect a combination of FMD and CoCs - due to proprietary substances.
  - Tool capabilities – A software tool is essential. The tool should provide the ability to apply the substance restrictions based on category applicable to the specific product.
  - Due to the number of applicable substances, and varied application scopes, pre-filtering based on entry applicability is important.

REACH – Annex XVII

- Best Practices for Validating product compliance to Annex XVII:
  - All versions of GreenSoft's GreenData Manager software have this capability built in.
    - Our team has scrubbed all Annex XVII restricted substances, including substances in (EC) 1272/2008 conforming to stated classifications.
    - The software has detailed rules divided up into 20 use-categories. Simply select the categories applicable to your product/BOM, and instantly view the compliance status of your product.
    - Components and parts can be classified by commodity code, so only the Annex XVII restrictions that apply to the component are applied.

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REACH – Annex XVII

Rule Name	Category	Description
REACH Annex-17 #11 Measuring Devices	Measuring Devices	Examine compliance of Mercury on measuring devices. Mea...
REACH Annex-17 #11 Measuring Devices ...		Scan Mercury on all parts
REACH Annex-17 #12 With Skin Contact	With Skin Contact	Examine compliance of substances including the ones per E...
REACH Annex-17 #12 With Skin Contact Sc...		Scan substances that are not intended for skin contract incl...
REACH Annex-17 #13 Placed in Mouth by ...	Placed in Mouth b...	Examine compliance of substances per Entry 63 on not placi...
REACH Annex-17 #13 Placed in Mouth by ...		Scan substances that should not be placed in the mouth of ...
REACH Annex-17 #14 Extender Oils	Extender Oils	Examine compliance of substances including the ones per E...
REACH Annex-17 #14 Extender Oils Scan		Scan substances of extender oils including the ones per Ent...
REACH Annex-17 #15 Air Freshener	Air Freshener	Examine compliance of substances including the ones per E...
REACH Annex-17 #15 Air Freshener Scan		Scan substances of air freshener including the ones per Ent...
REACH Annex-17 #16 Jewellery	Jewellery	Examine compliance of substance
REACH Annex-17 #16 Jewellery Scan		Scan substances of jewellery per
REACH Annex-17 #17 Toys or Ornamental ...	Toys or Ornament...	Examine compliance of substance
REACH Annex-17 #17 Toys or Ornamental ...		Scan substances of toys or ornam
REACH Annex-17 #18 Mixtures	Mixtures	Examine compliance of substance
REACH Annex-17 #18 Mixtures Scan		Scan substances of mixtures inclu
REACH Annex-17 #19 Substances	Substances	Examine compliance of substance
REACH Annex-17 #19 Substances Scan		Scan substances of chemicals or
REACH Annex-17 #20 Other Annex-17 Arti...	Other Annex-17 A...	Examine compliance of substance
REACH Annex-17 #20 Other Annex-17 Arti...		Scan substances of other Annex-

Rule Name	Category	Description
REACH Annex-17 #01 All Applications		Examine compliance for all applications with substances incl...
REACH Annex-17 #02 Metals	Metals	Examine compliace of substances per Entry 23 and 46 on m...
REACH Annex-17 #02 Metals Scan		Scan substances of metals per Entry 23 and 46
REACH Annex-17 #03 Metal Plating	Metal Plating	Examine compliance of substances per Entry 23 on metal pl...
REACH Annex-17 #03 Metal Plating Scan		Scan substances of metal plating per Entry 23
REACH Annex-17 #04 Plastics	Plastics	Examine compliance of substances per Entry 23 on plastics....
REACH Annex-17 #04 Plastics Scan		Scan substances of plastics per Entry 23
REACH Annex-17 #05 Paints	Paints	Examine compliance of substances including the ones per E...
REACH Annex-17 #05 Paints Scan		Scan substances of paints including the ones per Entry 16, ...
REACH Annex-17 #06 Leather or Textiles	Leather or Textiles	Examine compliance of substances including the ones per E...
REACH Annex-17 #06 Leather or Textiles S...		Scan substances of leather and textiles including the ones p...
REACH Annex-17 #07 Wood	Wood	Examine compliance of substances per Entry 18, 19, 23 and...
REACH Annex-17 #07 Wood Scan		Scan substances of wood per Entry 18, 19, 23 and 31
REACH Annex-17 #08 Adhesives	Adhesives	Examine compliance of substances including the ones from ...
REACH Annex-17 #08 Adhesives Scan		Scan substances of adhesives including the ones per Entry ...
REACH Annex-17 #09 Aerosols	Aerosols	Examine compliance of substances including the ones per E...
REACH Annex-17 #09 Aerosols Scan		Scan substances of aerosols including the ones per Entry 40
REACH Annex-17 #10 Paper	Paper	Examine compliance of substances per Bisphenol A on ther...
REACH Annex-17 #10 Paper Scan		Scan substances of thermal paper per Bisphenol A after 2 J...

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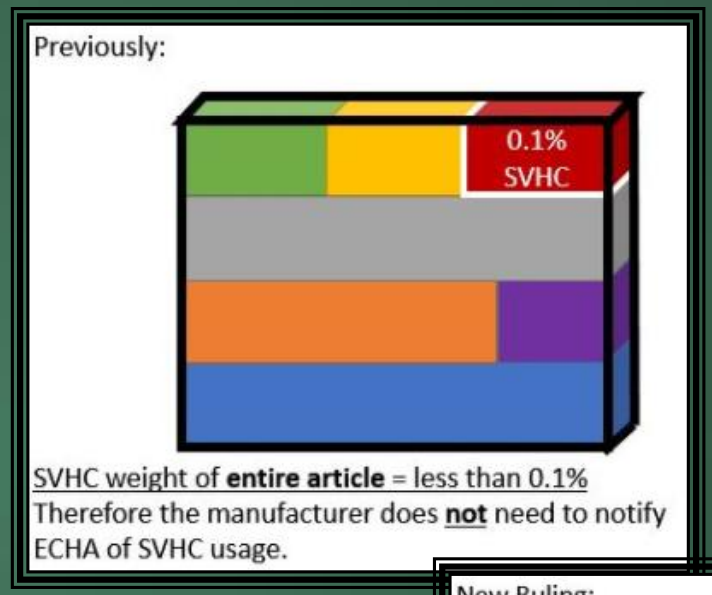
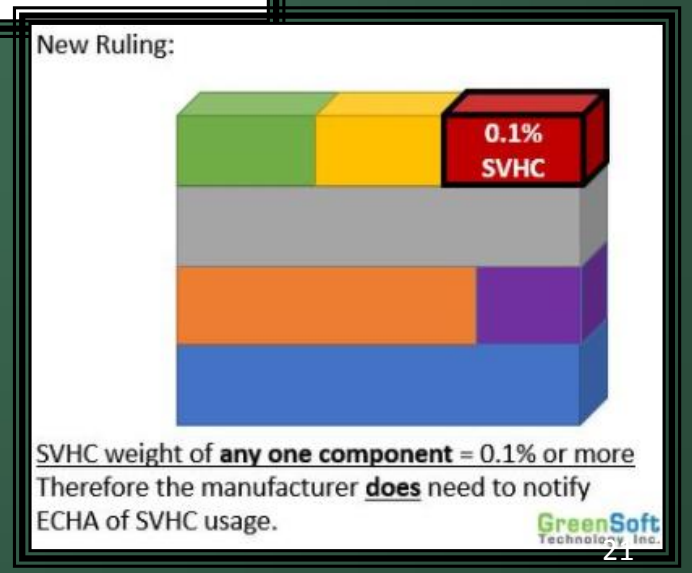
Changes to the Definition of an "Article"

A review of the impact to manufacturers of EEE

Changes to Article Definition under REACH

- Background
  - Original Definition – Final Article
    - Substance Aggregation at final article (final product)
  - EU Court of Justice decision – 10 Sept. 2015 in case C-106/14
    - Once an Article, Always an Article
  - Guidance document Version 4.0 has been officially released – JUNE 28, 2017
    - Examples of how to calculate the SVHC in an article are provided
    - Subparts of components confirmed to be potential articles





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How to deal with the new Article Definition

- Example 1: Integrated Circuit
  - Step 1: Identify homogeneous materials using existing FMD data:

A	ON Semi		
	TL431AIDG		
	IC, ADJUSTABLE PRECISION SHUNT REGULATOR, 2.5 to 36 V, SO-8 Package, 30ppm; RoHs Compliant		
	A1	Mold Compound	
	A2	Leadframe	
	A3	Die Attach	
	A4	Plating	
	A5	Die	
	A6	Wire Bond	

How to deal with the new Article Definition

- Example 1: Integrated Circuit
  - Step 2: Determine which materials meet the definition of an Article. For materials that do not, determine which article element base they below to:

A	ON Semi				
	TL431AIDG				
	IC, ADJUSTABLE PRECISION SHUNT REGULATOR, 2.5 to 36 V, SO-8 Package, 30ppm; RoHs Compliant				
				Article Flag	Article Status
	A1	Mold Compound		A	No
	A2	Leadframe		A2+A4	Yes
	A3	Die Attach		A	No
	A4	Plating		A2+A4	No
	A5	Die		A5	Yes
	A6	Wire Bond		A6	Yes
	A				Yes

How to deal with the new Article Definition

- Example 1: Integrated Circuit
  - Step 3:
    - Calculate the SHVC compliance status for each “article”
    - The final SVHC status for Article “A” (the entire IC) can be aggregated as shown:

A	ON Semi				
	TL431AIDG				
	SHUNT REGULATOR, 2.5 to 36 V, SO-8 Package, 30ppm; RoHs Compliant				SVHC(X): SVHC compliance status (Yes/No) in X X(SVHC): SVHC amount in X
			Article Flag	Article Status	SVHC Status (Yes/No)
	A1	Mold Compound	A	No	
	A2	Leadframe	A2+A4	Yes	SVHC(A2) = (A2(SVHC)+ A4(SVHC))/(A2+A4) <=1000ppm
	A3	Die Attach	A	No	
	A4	Plating	A2+A4	No	
	A5	Die	A5	Yes	SVHC(A5) = A5(SVHC)/A5 <=1000ppm
	A6	Wire Bond	A6	Yes	SVHC(A6) = A6(SVHC)/A6 <=1000ppm
	A			Yes	SVHC(A) = SVHC(A2)+SVHC(A5)+SVHC(A6)+ ((A1(SVHC)+ A3(SVHC))/A <=1000ppm)

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How to deal with the new Article Definition

- Example 2: Capacitor
  - Step 3:
    - Calculate the SHVC compliance status for each “article”
    - The final SVHC status for Article “B” (the entire cap) can be aggregated as shown:

B	VENKEL					
	C0603C0G500-220JNP					
	CAPACITOR, CERAMIC, 50V, C0G, 5%, 0603, 22 PF, ROHS COMPLIANT					SVHC(X): SVHC compliance status (Yes/No) in X X(SVHC): SVHC amount in X
				Article Flag	Article Status	SVHC Status (Yes/No)
	B1	Ceramic Body(dielectric)		B1	Yes	SVHC(B1) = B1(SVHC)/B1 <=1000ppm
	B2	Inner electrode		B2	Yes	SVHC(B2) = B2(SVHC)/B2 <=1000ppm
	B3	Inner Termination		B3+B4+B5	Yes	SVHC(B3) = (B3(SVHC)+B4(SVHC)+B5(SVHC))/(B3+B4+B5) <=1000ppm
	B4	Plating Ni		B3+B4+B5	No	
	B5	Plating Sn		B3+B4+B5	No	
	B				Yes	SVHC(B) = SVHC(B1)+SVHC(B2)+SVHC(B3)

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Best Practices on complying with the new Article Definition

- Have a process in place to ensure suppliers have evaluated their components for SVHC compliance at the sub-article level.
  - This may require additional information on component construction.
  - Consider communication methodologies for your customers to provide this level of information as well.
  - Evaluation of construction can be complex. For example, how a wire was made determines if the insulation is an article or not.
  - GreenSoft can do this evaluation for you and ensure supplier data is validated to be in accordance with the new article definition.
- Software Tool:
  - Any software tool used to validate product compliance for REACH SHVC should have the ability to dynamically apply article aggregation bases for each material present in a part. (Article Flags)
  - Note that software cannot determine the article status of materials. This requires human intervention for construction analysis. Our EXPERTS can do this for you!

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The GreenSoft Advantage

Why Partner with GreenSoft?

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The GreenSoft Advantage

- Why partner with GreenSoft?
  - Existing part database of 64M parts decreases data collection time – improving time to market. Leverage the work we have already done!
  - Collection of FMD data allows leveraging across current and future regulations and customer requirements. Only collect CoCs where needed. Avoid future data collection.
  - Data Validation – ISO 9001 certified Quality Assurance process ensures 99.9% data quality/accuracy.

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The GreenSoft Advantage

- Why partner with GreenSoft?
  - Data Maintenance – GreenSoft will maintain your compliance data at a 6 months freshness level – always be confident your data is up-to-date!
  - Software – With Hosted, Browser, Workgroup, and Desktop editions available, GreenData Manager software is available for every size company and every budget. GreenData Manager offers complete integration with ERP/PLM systems. Software is automatically updated for regulation changes.

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The GreenSoft Advantage

- Why partner with GreenSoft?
  - Cost
    - GreenSoft estimates the average cost of doing data collection internally is around $46 per part on average of 10K parts ($460,000 total). Outsourcing to GreenSoft costs a fraction of that.
    - GreenSoft's GreenData Manager software offers the best value in the industry, with complete compliance product tracking, analysis, and reporting capabilities starting at a low entry cost.

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Summary

- Some best practices for REACH compliance we have covered…..
  - Your customer requirements and your position in the supply chain will define your compliance processes to a large extent
  - Collect FMD whenever possible, but has a process in place to deal with proprietary or undisclosed substances.
  - Include Annexes XIV and XVII in your REACH validation plan.
  - Have a documented collection process, but be patient during the data collection process – it will take resources to collect and validate the data you need.
  - Have a process in place to ensure suppliers are providing SVHC calculations and validations in accordance with the new article definition.

Summary

- Some more best practices for REACH compliance we have covered…..
  - Utilize a tool which can pre-filter Annex XVII categories to provide meaningful compliance validations.
  - Consider partnering with an established leader such as GreenSoft, to improve data collection times, data quality, and product compliance reporting capabilities.

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OPEN FORUM

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THANK YOU!

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