

**REACH – Notifizierung gemäß Art. 7
Übersicht, Prozess, Inhalt,
Zusammenfassung der Arbeitsannahmen
-1. revidierte Fassung-**



10. BDI-REACH-Workshop
February 23, 2011

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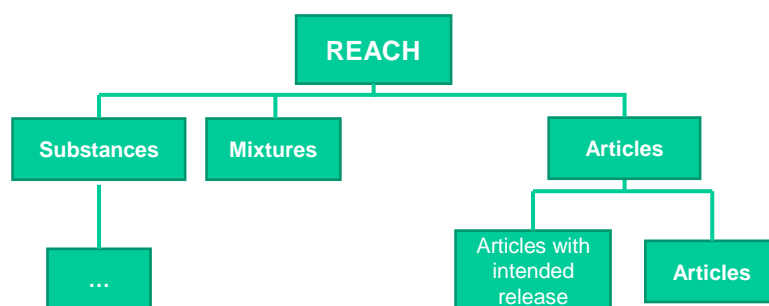
- 1 Overview REACH SVHC obligations**
- 2 Which business processes are affected by REACH?**
- 3 How does the overall process look like?**
- 4 How to perform a notification – status?**
- 5 Where is the journey taking us?**

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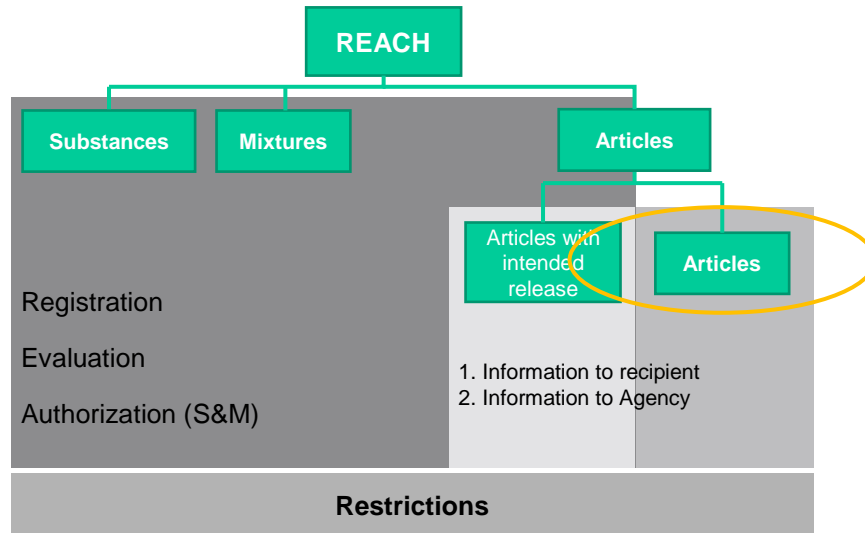
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Question 1 in REACH: What do I deal with?



Question 1 in REACH: What do I deal with?

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Overview on article obligations

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No.	For what	What	When	Who	Volume	Reference	Where
1	articles	Inform the recipient on candidate list substances present > 0,1% B2B: push B2C: pull	Since Oct 28 2008, then with every new CS immediately	Suppliers	No volume	Product	Art 33
2	articles	Submit notification to ECHA	By June 1 2011, then ongoing	Importers & Producers	<ul style="list-style-type: none"> Conc.> 0,1% + 1t/year 	SVHC substance and legal entity	Art 7

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Which business processes are affected by REACH?

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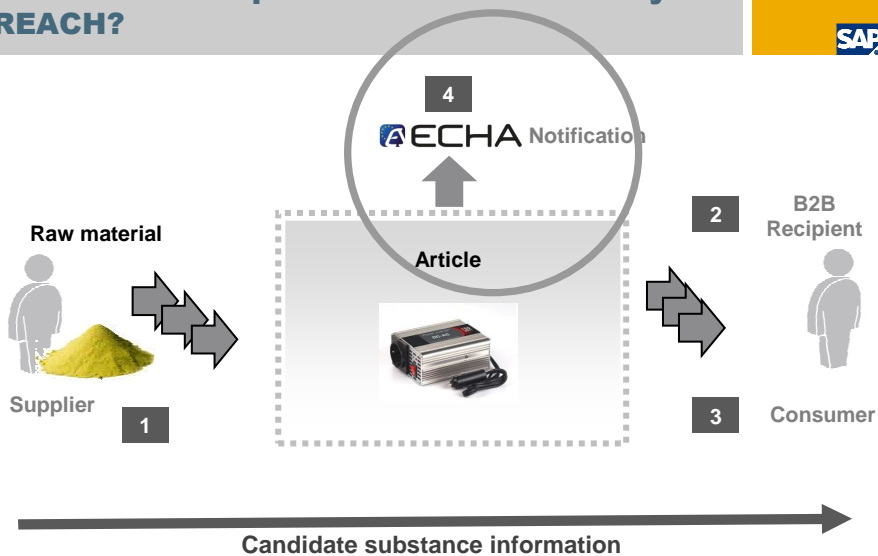


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Status notice



Differ „REACH Art. 7 Notification“ from „CLP Notification“

REACH Art. 7 Notification incompletely described in REACH

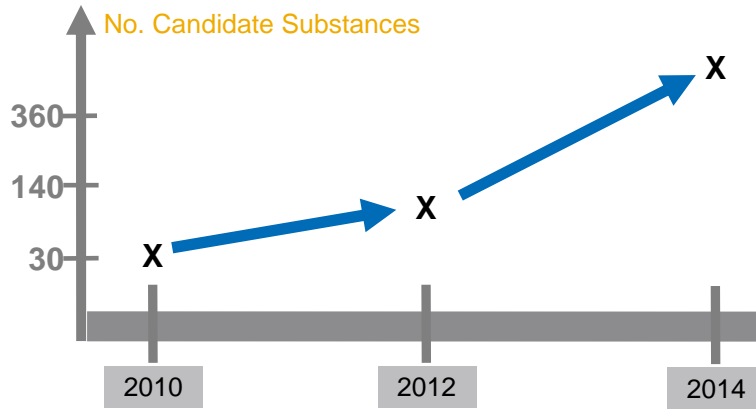
Next ECHA Guidance on Articles will NOT clarify all notification process gaps

Obligation starts June 1, 2011

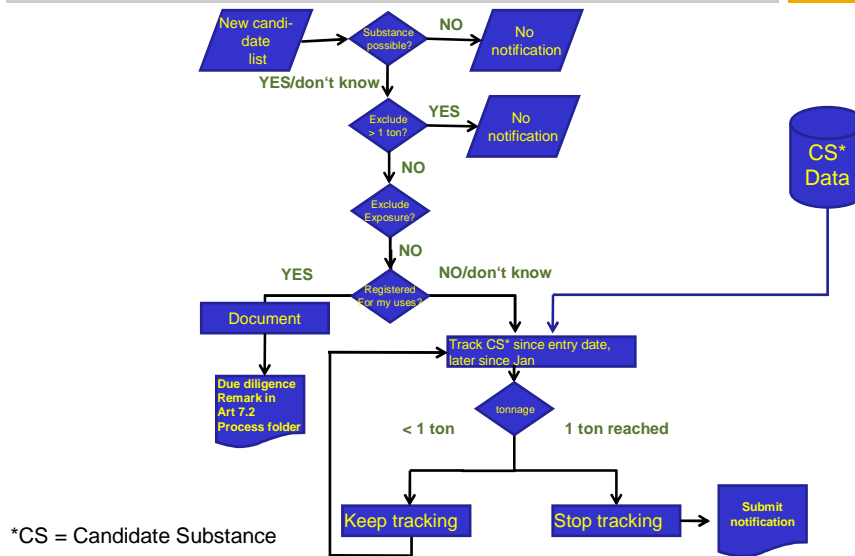
Notification process can only be designed on basis of working assumptions

This presentation gives the current SAP status of knowledge based on SAP working assumptions

Candidate List: 6 month cycle expected



Flow Notification Process



Working Assumptions Notification Art 7 -proposal-



1. Art 7 notification for 1 SVHC needs only to be done once, not every year the CS is imported or contained in produced articles > 1 ton
2. Therefore a notification for a CS does not need to be updated if the tonnage range changes in a later year
3. The definition of „per year“ is Jan to Dec per Art. 3(30)
4. In the year when a new CS enters the CL the CS quantities are determined from that moment on and not from Jan (reason: this would be a retrospective notification).
5. The deadline for notification is the moment when 1 ton is reached. The tonnage range then eventually needs to be estimated for the rest of the year. 1 exception:
6. Per Art 7(7) the notifier has a 6 months deadline to notify after the date a new CS has entered the CL IF the tonnage comes > 1 ton in that period (reason: the tonnage is per definition 0 at the moment when the new CL comes onto the list/ in line with point 4.)
7. The 1st notification for June 1 2011 is made on the basis of the CL version of Dec 1 2010 and the tonnage is consequently to 3. measured from Jan 1 2011 on. The deadline for this quantity is June 1 2011.
8. The quantities of the same CS both imported in articles and contained in produced articles are summed up per legal entity
9. If only a part of the uses of a CS can be found registered then the quantities of non-registered uses must be notified/ calculated for notification

How do I find if a CS* was registered for my use?



1. [Describe your uses with Use Descriptor System](#)
2. [Compare to uses describes in registration dossiers:](#)
 - <http://apps.echa.europa.eu/registered/registered-sub.aspx>
 - Request to ECHA (helpdesk, specific process?)
 - Request to the Supplier
 - Request to the SIEF
 - Research eSDSes



*CS = Candidate Substance

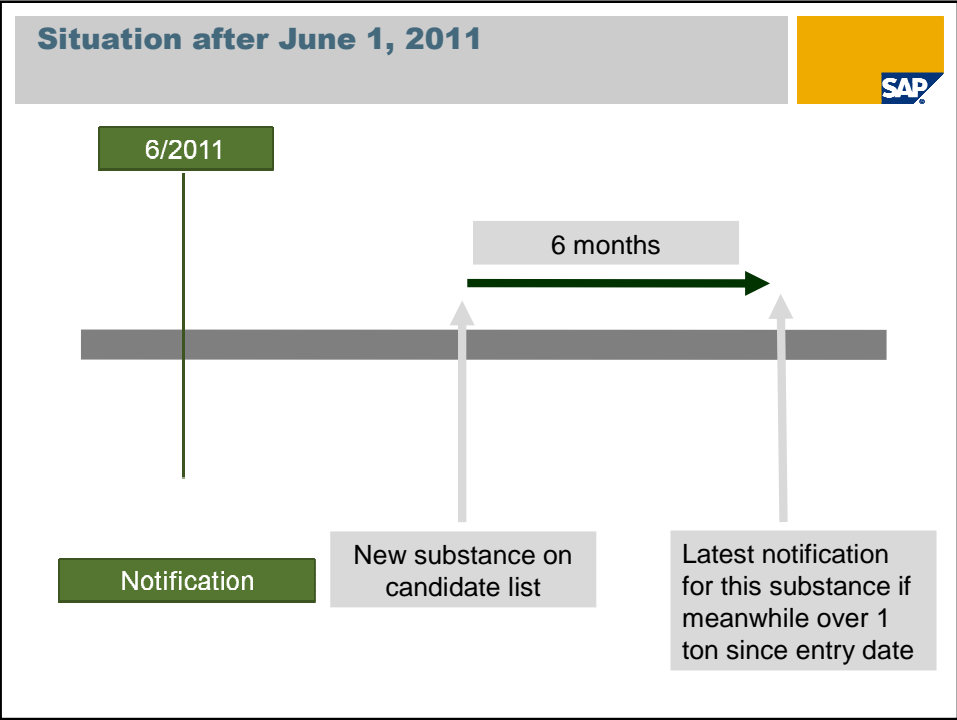
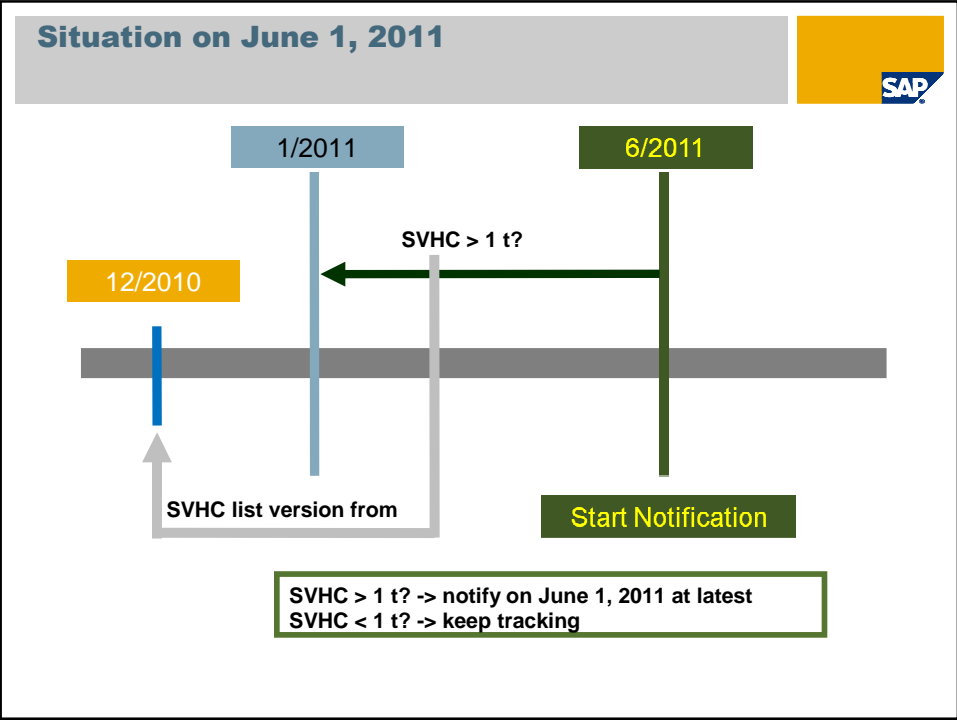


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How to perform a notification: REACH Art 7.4



The information to be notified shall include the following:

- a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites
- b) the registration number(s) referred to in Article 20(1), if available
- c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI
- d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI
- e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s)
- f) the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on

Notification



- a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
Name, address, telephone number, fax number and e-mail address, Contact person
- b) the registration number(s) referred to in Article 20(1), if available;
- c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
 - 2.1. Name or other identifier of each substance
 - 2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)
 - 2.1.2. Other names (usual name, trade name, abbreviation)
 - 2.1.3. EINECS or ELINCS number (if available and appropriate)
 - 2.1.4. CAS name and CAS number (if available)
 - 2.1.5. Other identity code (if available)
 - 2.2. Information related to molecular and structural formula of each substance
 - 2.2.1. Molecular and structural formula (including SMILES notation, if available)
 - 2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
 - 2.2.3. Molecular weight or molecular weight range

Notification



- 2.3. Composition of each substance
 - 2.3.1. Degree of purity (%)
 - 2.3.2. Nature of impurities, including isomers and by-products
 - 2.3.3. Percentage of (significant) main impurities
 - 2.3.4. Nature and order of magnitude
- d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI
 - 4.1. The hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC.

In addition, for each entry, the reasons why no classification is given for an endpoint should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification).
 - 4.2. The resulting hazard label for the substance(s), resulting from the application of Articles 23, 24 and 25 of Directive 67/548/EEC.

Notification

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AND

CLP Art 4,2.(b):

Without prejudice to the requirements of paragraph 1, manufacturers, producers of articles and importers shall classify those substances not placed on the market in accordance with Title II where:

(a) ...

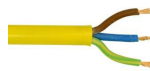
(b) Articles 7(2) or 9 of Regulation (EC) No 1907/2006 provide for notification.

Notification d): CLP Annex VI, an example

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Example:

Candidate substance DEHP used as plasticiser in PVC electric cable isolation



STROBE

1. DEHP \geq 0,1% in the cable AND
2. DEHP \geq 1 ton imported or included in cable per legal entity

Notification d): CLP Annex VI, an example



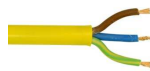
Index No	Intentional Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
607-313-00-7	neodecanoyl chloride	254-875-0	40292-82-8	Acute Tox. 2 ** Acute Tox. 4 ** Skin Corr. 1B	H330 H302 H314	GHS06 GHS06 Dgr	H330 H302 H314		STOT SE 3; H335; C ₂ 5%	
607-314-00-2	ethiofamate (ISO); [S]-2-ethoxy-2,3-dihydro-2,3-dimethylbenzofuran-5-yl methanesulfonate	247-525-0	36225-79-6	Aquatic Chronic 2	H411	GHS09	H411			
607-315-00-8	glyphosate (ISO); N-(phosphonomethyl)glycine	213-997-4	1071-83-6	Eye Dam. 1 Aquatic Chronic 2	H318 H411	GHS05 GHS09 Dgr	H318 H411			
607-316-00-3	glyphosate-trimesium; glyphosate-trimethylammonium	—	81591-81-3	Acute Tox. 4 ** Aquatic Chronic 2	H302 H411	GHS07 GHS09 Wag	H302 H411			
607-317-00-9	bis(2-ethylhexyl) phthalate; di-(2-ethylhexyl) phthalate; DEHP	204-211-0	117-81-7	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
607-318-00-4	diethyl phthalate; DBP	201-557-4	84-74-2	Repr. 1B Aquatic Acute 1	H360FD H400	GHS08 GHS09 Dgr	H360FD H400			
607-319-00-X	dehtamethrin (ISO); (S)-cyano-5-phenoxybenzyl (1R,3R)-2,2-dimethylcyclopropanecarboxylate	258-256-6	52918-65-5	Acute Tox. 3 ** Acute Tox. 3 ** Aquatic Acute 1	H331 H301 H400	GHS06 GHS09 Dgr	H331 H301 H410			
607-320-00-5	bis[4-(phenylacetyl)oxy] 1,3-benzenedicarboxylate	413-930-0	100066-57-8	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wag	H317 H410			
607-321-00-0	(S)-methyl-2-chloropropionate	412-470-8	73246-45-4	Flam. Liq. 3 STOT RE 2 ** Eye Irrit. 2	H226 H373 ** H319	GHS02 GHS08 Wag	H226 H373 ** H319			

Notification d): CLP Annex VI, an example



Example:

Candidate substance DEHP used as plasticizer in PVC electric cable isolation



STOBLSTATION

DEHP:

The hazard classification of the substance: Repr. 1B

The resulting hazard label for the substance: GHS08

Notification d)

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d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI

1. Legal classification in CLP Annex VI

2. If no legal classification

Then CLP Title II applies:

Literature research for classification and labeling

- Request to the Supplier
- Request to the SIEF
- Research SDSes
- CLP classification inventory



Open question:
What if you find several classifications?

Notification

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e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s)

R.12: Use Descriptor System

1. process by which the substance has been included in the article: PROC

2. into which type of article the substance has been incorporated: AC

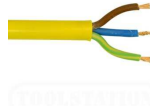
Notification

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e) brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s)

Example:

Candidate substance DEHP used as plasticiser in PVC electric cable isolation



process by which the substance has been included in the article:

“PROC 14: Production of preparations* or articles by tableting, compression, extrusion, pelletisation”

into which type of article the substance has been incorporated:

“AC2: Machinery, mechanical appliances, electrical/electronic articles”

Additional remarks

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Ad: content of a notification

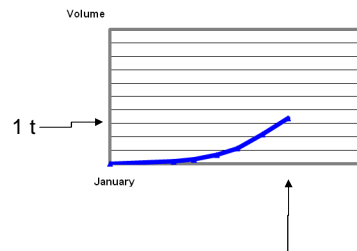
- Worst case: long and/or worldwide supply chain
- Example: retailer importing very divers articles, electronics, electrical white goods, toys
- No chance to get notification data/SDS on raw material CS in the products (impurities, optical activity, CLP classification)
- CLP art 4: the retailer must classify the CS per Title II: this may lead to a variety of classifications in a literature research. How to choose now? The retailer does not have the substance and has in most cases no contact to the chemical manufacturer
- Description of use: it is unlikely that the retailer has enough product manufacturing knowledge so that he can describe the use of the CS in the different products. Not with the use descriptor let alone beyond. There is the danger of invention.

Notification



- f) the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on

“Per year” as Year-to-date: time of notification is when 1 ton is reached:



Open questions



Open issue	Suggestion
Deadline	1 ton reached
How to find registered uses	See Options
Substance identity description	Probably not needed
Tonnage band update needed	No as not in Art 7, in line with helpdesk answers
CLP classification likelihood/procedure	?

Evaluation of the notification process



- Process is needed in cases > 1 ton
- Notification PROCESS runs with very new relevant SVHC substance!
- Notification not worth avoiding
- But no simple automated process
- Requires expertise
- Plan dedicated resource for this process

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Where is the journey taking us?

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138 candidate substances by 2012 (goal)

Approximately 470 candidate substances in focus

Political force to refer to “sub-components”

REACH-EN-FORCE 2 controlling Art. 33 from 2011 on

REACH notification expected to have enforcement attention

Substances in articles will require a somewhat higher background level of resource demand in companies



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Questions



Thank you!

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