

# ANSI Chemical Network 21 January 2016

## REACH Enforcement

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# REACH Enforcement

- Enforcement - the actors and the activities
- ECHA Forum's role and initiatives
- Enforcement targeted to importers
- Enforcement of SVHC in articles

**"enforcement"** = compliance checks, formal enforcement, sanctioning (fines, criminal procedures)

## Compliance, official controls, inspections, enforcement, ... - the actors in the EU

### REACH provisions:

- REACH evaluation competence of **ECHA** and **Member State Competent Authorities** (Title VI of REACH)
- General competence for formal enforcement by **National Enforcement Authorities** (NEAs) in the Member States (Title XIV REACH)
- **ECHA Forum** is competent for “coordination” of national enforcement (Title X of REACH)
- ECHA and NEAs have certain “**borderline competences**” related to control (e.g. another coordination role of Forum along the line ECHA <—> NEAs)

## The REACH enforcement in Member States

Various options for organisational structures:

- One **central** enforcement authority (e.g. Slovenia)
- **Regional** enforcement authorities (e.g. Poland)
  
- **One** enforcement authority competent for REACH  
- central or regional structures (Austria)
- Split (or parallel) competences among **several** NEAs (UK)
  
- One **uniform** competence scheme within a Member State (France)
- **Variations** in the competence scheme between the regions in a Member State (Germany)

→ Any REACH enforcement is linked to ECHA Forum

see: [www.echa.europa.eu/web/guest/regulations/enforcement/national-inspectorates](http://www.echa.europa.eu/web/guest/regulations/enforcement/national-inspectorates)

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## Efforts in place towards harmonisation of enforcement

### Joint efforts of ECHA and Forum with NEAs:

- Enforcement strategies, minimum criteria for enforcement, interlinking actors, methodology for coordinated enforcement projects, IT tools (“RIPE”)
- Training, guidance and manuals for inspectors
- Coordinated inspection projects with NEAs (annual broad REF projects and several parallel pilot-sized projects)
- Enforceability advices to the regulators (restriction proposals, ECHA guidance, ...)

## Forum REACH-EN-FORCE projects

- REF-1: pre-registration and registration duties (SDS duties, 2009)
- REF-1, prolongation: same focus as REF-1 (2010/2011)
- REF-2: duties of formulators (supply chain communication, SDS, registration, CLP notification, 2011/2012)
- REF-3: registration duty (mainly importers and Only Representatives, 2013/2014)
  - cooperation with customs (!)

## Ongoing / upcoming areas for harmonisation of enforcement

Joint efforts of COM, ECHA and Forum with NEAs:

- Enforcement of **ECHA decisions** covering multiple registrants while evaluating substances
- Enhanced practical documentation covering a **summary of safe use information** for substance/uses being **authorised** \* \*
- Targeted inspector **training for “exposure scenario”** in 2016

\* \* [echa.europa.eu/view-article/-/journal\\_content/title/new-summary-table-available-for-applications-for-authorisation](http://echa.europa.eu/view-article/-/journal_content/title/new-summary-table-available-for-applications-for-authorisation)



# Ongoing / upcoming areas for harmonisation of enforcement

Joint efforts of COM, ECHA and Forum with NEAs:

- **Inspection project** and methodology for **14 restrictions** from Annex XVII/REACH with involvement of customs (REF-4 in 2016) \*
- **Inspection project** and methodology addressing **substances subject to authorisation** (2 projects in 2015 and in 2016)

\* [echa.europa.eu/view-article/-/journal\\_content/title/forum-starts-a-project-on-extended-safety-data-sheets-exposure-scenarios-risk-management-measures-and-operational-conditions](http://echa.europa.eu/view-article/-/journal_content/title/forum-starts-a-project-on-extended-safety-data-sheets-exposure-scenarios-risk-management-measures-and-operational-conditions)

# Ongoing / upcoming areas for harmonisation of enforcement

Joint efforts of COM, ECHA and Forum with NEAs:

- Planning for the **inspection project** 2017 (REF-5) on **extended Safety Data Sheets, Exposure Scenario** and safe use information in the supply chain
- Compilation of a pool of analytical methods relevant for substance restrictions in Annex XVII of REACH (a first, broader testing in course of REF-4, public in Q2/2016)
- COMs piloting study on enforcement indicators linking to Member State's 5 year reporting under REACH and CLP \*

\* [ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\\_id=8280&lang=en](http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8280&lang=en)

## Harmonisation “in a world of changes”

Conceptual changes / amendments in the *aquis communautaire* (regulations, court decisions) and guidance:

- **New CLP/GHS criteria** replacing old criteria in the REACH Regulation (based on dangerous substance/preparation directives)
- **Frequent changes** in Annex II of REACH for SDS (last amendment in Regulation (EU) No 830/2015)
- New instrument of **Community wide authorisation decisions** for SVHCs issued by the Commission

## Harmonisation “in a world of changes”

Conceptual changes / amendments in the *aquis communautaire* (regulations, court decisions) and guidance:

- Court of Justice **ruling on 0.1% concentration** for SVHC in articles and Art 7 / Art 33 of REACH \*
- Board of appeal ruling on the specific **status of ECHA’s Statements of Non-compliance** (SONC) issued in context of the REACH evaluation instrument \*\*
- General Court **ruling on intermediate status** \*\*\*

.....

\* [echa.europa.eu/view-article/-/journal\\_content/title/echa-will-update-the-guidance-on-substances-in-articles](http://echa.europa.eu/view-article/-/journal_content/title/echa-will-update-the-guidance-on-substances-in-articles)

\*\* <http://echa.europa.eu/documents/10162/801b5b63-4aee-4cee-9861-46c29c0ba566>

\*\*\* <http://curia.europa.eu/juris/document/document.jsf?text=&docid=168621&pageIndex=0&oclang=EN&mode=lst&dir=&occ=first&part=1&cid=772913>

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## Enforcement targeted to importers

- Cooperation with **customs** authorities
- In some Member States customs inspectors have a REACH enforcement competence
- Use of **customs data** (data from import declarations) specifying the imported goods:
  - customs code (CN number) of the goods
  - name of the goods
  - weight of the goods
  - identity of the importer (consignee, declarant)

# Use of customs declaration (import)

ZIP	City	Name	Address	CN	Description	Origin	Date	Net mass kg
1111	MyCity	Company A GmbH	A Street	3206110090	PIGMENTE AUF D. GRUNDLAGE V. TITANDIOXID	UA	26.03.2012	4.000,00
							26.03.2012	16.000,00
					Titandioxidpigmente 93%	UA	27.01.2012	20.000,00
							22.02.2012	20.000,00
							08.03.2012	20.000,00
							03.04.2012	20.000,00
					B Street	3206110090	PIGMENTE AUF D. GRUNDLAGE V. TITANDIOXID	UA
			29.05.2012	3.000,00				
		Titandioxidpigmente 93%	UA	24.04.2012			20.000,00	
				08.05.2012			20.000,00	
				06.06.2012			20.000,00	
				15.06.2012			20.000,00	
				19.06.2012			20.000,00	
			17.07.2012	20.000,00				
	18.07.2012	20.000,00						
	13.08.2012	20.000,00						
	14.08.2012	20.000,00						
		Titandioxidpigmente 93% (TiOx-280)	UA	04.09.2012	20.000,00			
		TITANIUM DIOXIDE	UA	06.08.2012	2.000,00			
				06.08.2012	18.000,00			
		TITANIUM DIOXIDE PIGMENTAL GRADE CRIMEA TiOx-280	UA	30.05.2012	20.000,00			

## Enforcement targeted to importers

REACH duties relevant for importers:

- Registration (Art 5, etc.)
- Notification (Art 7)
- Authorisation (Art 62, Annex XIV)
- Restriction (Art 67, Annex XVII)
- Information in the supply chain (e.g. Art 31, 33)



## Enforcement targeted to importers

### Enforcement activities:

- **Registration:** REACH-EN-FORCE 3 (also focus on Only Representatives and “their” importers)
- **Authorisation:** Pilot projects on Authorisation 1 + 2
- **Restriction:** REACH-EN-FORCE 4 project in 2016
- **Information in the supply chain:**
  - Safety Data Sheets (REF-1 and REF-2)
  - SVHC in articles (Pilot Project in 2017)

## Enforcement targeted to importers

Importer's registration compliance in REF-3 (2013/2014):

Role	Proportion of non-compliant companies within each role	
Manufacturer only	7%	
Manufacturer inter alia	6%	
Importer only	19%	
Importer inter alia	15%	!!
OR only	34%	!!

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## Enforcement of SVHC in articles

### Definition of “article”:

- Since REACH is in force **differing views** in the EU
- **Court of Justice ruling** (10.09.2015) on 0.1% concentration for SVHC in articles and Art 7 / Art 33 of REACH \*
- Duty holder’s **obligations** are always relevant for the **article supplied** by them:
  - Notification under Art 7 REACH:
    - **EU producer** of an article always refers to “his” article (i.e. a car producer refers to the car produced)
    - An **importer** always refers to the articles imported (also to the articles which are parts of the imported product)

\* [echa.europa.eu/view-article/-/journal\\_content/title/echa-will-update-the-guidance-on-substances-in-articles](http://echa.europa.eu/view-article/-/journal_content/title/echa-will-update-the-guidance-on-substances-in-articles)

## Enforcement of SVHC in articles

### Definition of “article”:

- Duty holder’s **obligations** are always relevant for the **article supplied** by them:
  - Information under Art 33 REACH:  
**Always to refer to the article** (also to the articles which are parts of product supplied)
- **ECHA guidance** “substances in articles” version 12/2015 will need a full update (available in end of 2016)
- Clarification **European Commission/Member States:**  
“The substance concentration threshold of 0.1% (w/w) applies to every article supplied. This threshold applies to each article of an object made up of more than one article, which were joined or assembled together.”  
(draft CARACAL paper 11/2015)

## Enforcement of SVHC in articles

### Enforcement activities:

- ECHA Forum **Pilot Project for enforcement of SVHC in articles** is prepared for 2017
- Individual **Member State control activities** related to Art 33 have been conducted in several Member States in the past and will continue
- Clarity in the definition of “article” important in order to **enhance the enforcement activities**

## Enforcement of SVHC in articles

Typical enforcement approach in Member States:

- **Sample taking** in retail (wholesale) and **laboratory analysis** of selected SVHCs
- **Request for Article 33 information** from the duty holder (e.g. retail) on SVHC > 0,1%
- Also non-formal enforcement in form of **system checks** at the duty holders (e.g. questionnaire): how is necessary information in the supply chain handled / available ?
- German **inspection result** for information on SVHC being consistent with authorities laboratory results:
  - **34% mismatching** information on SVHC
  - **55% consistent** information on SVHC

**Thank you for your attention**

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