Recognition to the OSOR and 'no data-no market' principles

> ECHA Forum meeting 6 November 2014 by Karine Van de Velde and Hugo Waeterschoot (Eurometaux)



What's the issue?

Multiple registration dossiers (individual or joint submissions) outside the existing joint submission **for the same substance**, that:

- do not respect OSOR principle
- do not respect 'no data no market' principle incomplete dossiers pass the TCC
- make incorrect use of opt out (of entire dossier instead of for certain endpoints- art 11(3) and 19(2))



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Scope?

• Is this a metals issue only? => NO it is clearly a GENERIC ISSUE

BUT: "metals" and/or "data-rich substances" may be vulnerable:

- Large numbers of potential registrants
- Many importers
- High investment in quality registration files
- Significant amounts of propriatory information (Consortia level)
- Data rich, so financial benefits of an opt out may be higher

What about enforcement/compliance check experience?

Enforcement/compliance check, so far...

- Multiple registrations seem not inspected nor stopped by ECHA when receiving the registrations
- Lack of an **enforcement strategy** by Member states on the OSOR principle
- No structural follow-up strategy by ECHA on multiple registrations
 - E.g. prioritisation for compliance check on use of opt out





Actions taken by industry, so far...

Identification and raising the issue:

• Discussed issue with DG ENT, DG ENV, ECHA

Broadening the support base

- Press release Chemical Watch (May 2014) and Trends (Sept 2014)
- On agenda of REACH FORUM of 26 June 2014

Individual cases :

- Letter from Belgian State Secretary for the Environment to ECHA's Exe.
 Dir. urging to take action against these free-riders (Sept 2014)
- Charcoal board of Appeal case ongoing

Reasons for bringing this up

- Undermines the objective to promote REACH as an efficient tool to improve chemicals management status
- Number of cases may grow significantly
 - Creating an increasing number of precedents
 - Some consultants actively offer 'cheap opt out dossiers'
- Undermines work of industry consortia
 - How to persuade registrants to continue investing in regulatory compliance and updates?
- Impossible to convince a free-rider to share cost once a registration number is granted
- Distorts competition



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NEED for **collaborative attention** and **action** to maintain a balance between "motivation" and "compliance"

Objectives

Short term Medium term Long term

• Short term:

- A clear message from ECHA/Member States to free-riders that incorrect opt-out dossiers are NOT accepted
- Medium term:
 - Adapt the REACH-IT system such that the ground for multiple registrations are checked and validated before accepting them
 - Promote compliant companies to continue investing in updating their REACH dossiers rather than needing to challenge "free riders"

• Long term:

- Ensure fair, balanced, transparent and non-discriminatory enforcement (including data sharing) for future & current registrants
- Garantee a proper implementation of the Regulation.



Anticipated actions from the FORUM

The highground:

A clear "moral signal" from the Forum

Prevention and identification:

- REACH IT not automatically accepting individual dossiers outside an existing joint submission
 - unless a plausible justification is provided
- Multiple joint submissions triggering a procedure
 - eventually up to a targeted CC in absence of proper response

Apply enforcement when needed

- An enforcement strategy to discourage free-riders.
 - Check on legitimate access of used data.

But also work on existing cases

Whistle blowing on real mal practices

