

Data quality ?

The perspective from workers

Tony MUSU

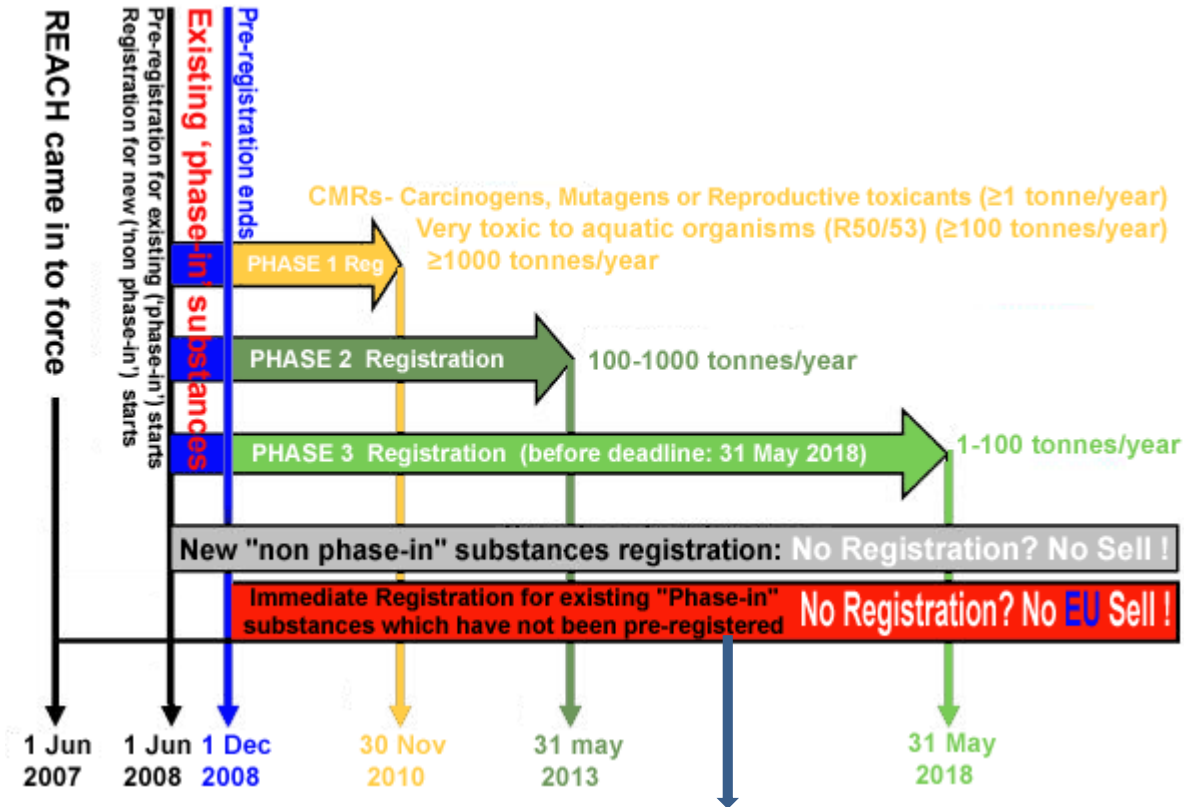
European Trade Union Confederation

Mind the Gap – Data availability in REACH Registrations – Berlin, 2 March 2015

The REACH perspective ?

- ❑ The purpose of REACH is to ensure the safe use of chemicals on the EU market
- ❑ Industry must collect data, assess the risks arising from the use of their chemicals and recommend risk management measures in the supply chain (eSDS)
- ❑ ECHA's role is to guarantee that industry adequately exerts its duties in ensuring safe use (Evaluation in REACH)
- ❑ A pre-requisite is that data collected by industry is of “high quality” so that the overall system works

Registration calendar under REACH



March 2015:
 50 000 dossiers for
13 000 unique substances
 registered

Data quality a clear problem in REACH registration :

helpdesk luxembourg
REACH & CLP
Un service du Centre de Recherche Public Henri Tudor
En partenariat avec le Ministère du Développement durable et des Infrastructures,
et le Ministère de l'Économie et du Commerce extérieur

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The enforcement of REACH registration dossier quality
CW Briefing, / Europe

INTERMEDIATES: ECHA URGES 574 REGISTRANTS TO IMPROVE THE QUALITY OF THEIR DOSSIERS

News Briefing Events Service Providers

NGO says REACH dossiers lack relevant EDC data
ClientEarth wants companies accountable for quality
23 July 2013 / Europe

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ECHA launches tool to improve registration dossier quality

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INSIGHT: Data quality still an issue in Reach registrations
12 April 2013 15:49 [Source: ICIS news]
By **Tom Brown**
LONDON (ICIS)--As winter in Europe starts to grudgingly give way to spring lengthening evenings and the blossom dotting the trees will remind compl

Other RSC s

World > News > 2012 > March

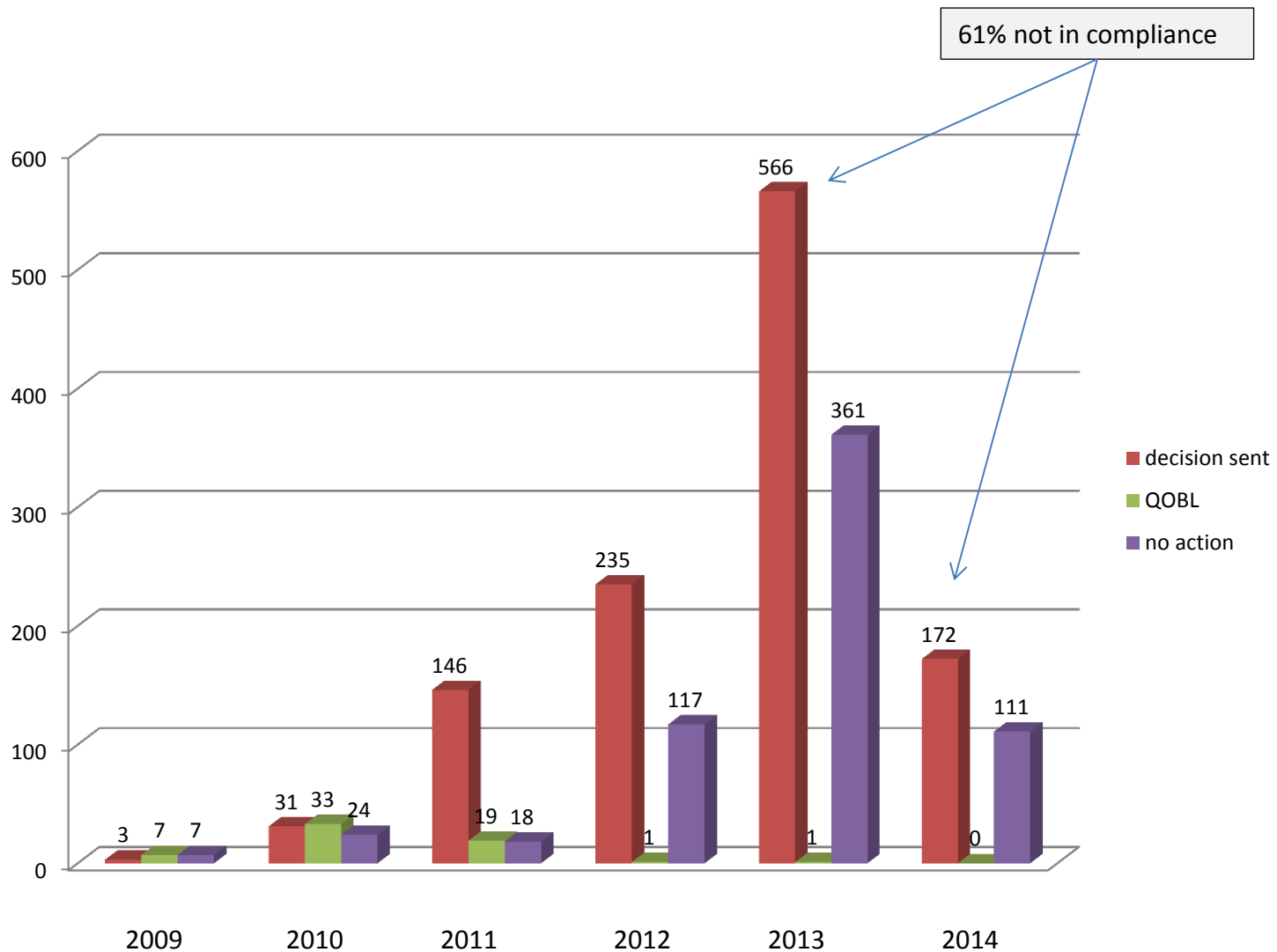
Reach dossiers failing on data
02 March 2012
An evaluation of the first tranche of registration dossiers submitted to REACH (registration, evaluation, authorisation and restriction of chemicals) suggests the vast majority have inadequate data. But



Consequences of bad quality data in registration dossiers:

- not possible to ensure that the risks are properly controlled for workers, consumers & environment
- in particular for workers: Risk Management Measures and conditions of use in extended Safety Data Sheet not reliable
- no confidence amongst citizens in the REACH system
- bad image for the Chemical industry
- questions about ECHA's efficiency

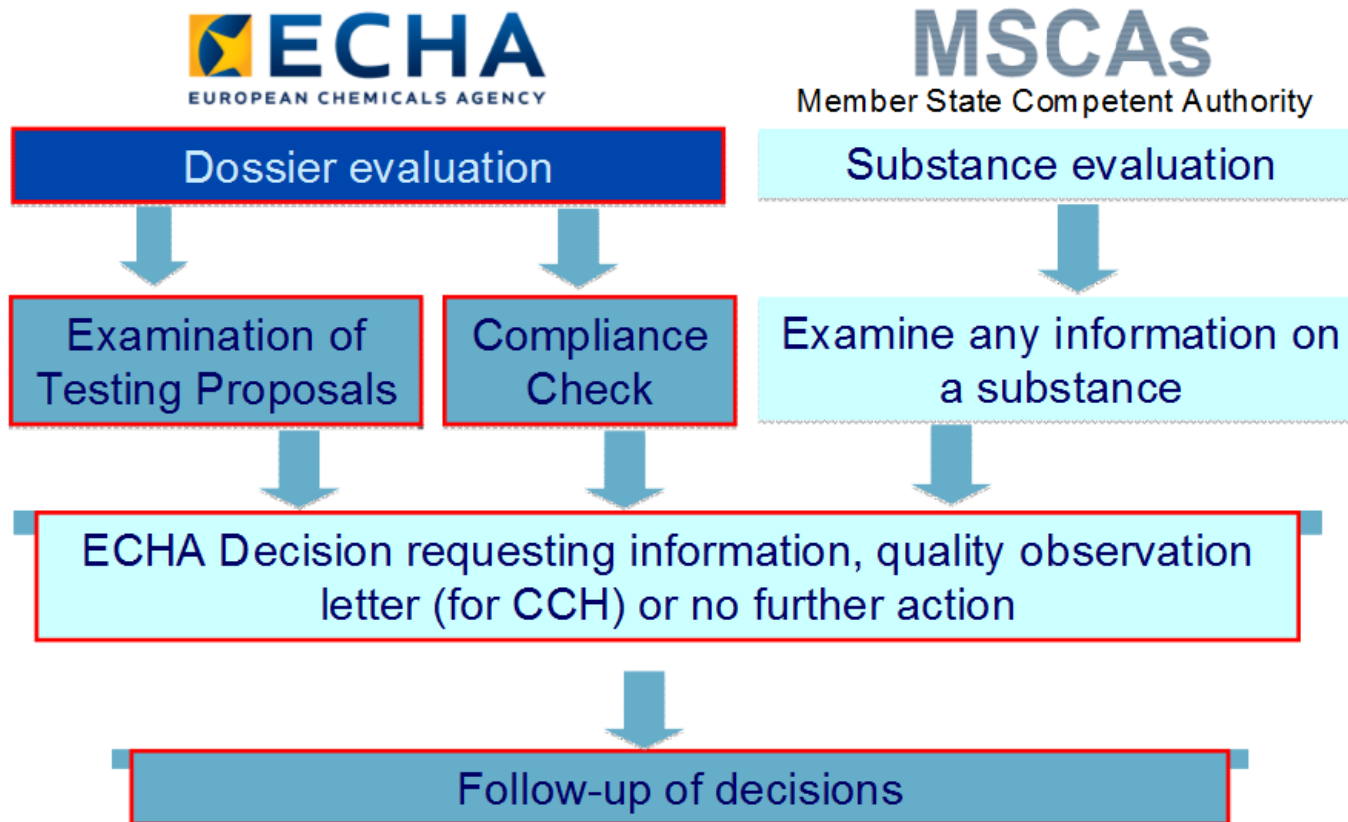
Number of concluded Compliance Checks per year :



Most frequent shortcomings with quality of data:

- substance identity (SID)
- exposure assessment
- risk characterization
- invalid waiver justifications
- prenatal developmental toxicity study
- sub-chronic toxicity study
- physicochemical properties

Evaluation under REACH



New ECHA's compliance check strategy in 2014 to improve data quality

Objectives:

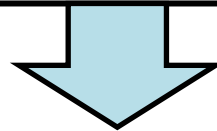
- identify substances that matter the most for the protection of people and the environment
- maximum impact on safe use of chemicals
- more efficient use of limited ECHA evaluation resources
- improve transparency for Member States, stakeholders, registrants
- provide confidence amongst stakeholders that REACH is delivering

Comparison of EU IOELVs with long-term worker DNELs

Table adapted from Tynkkynen et al, Ann. Occup. Hyg., 2015, 1-15

Substances	CAS number	IOELVs (TWA 8h) mg/m ³	DNEL (workers, long-term exposure) mg/m ³
Chloroform	67-66-3	10	2,5
1,2-Dichlorobenzene	95-50-1	122	10
2-Ethoxyethanol	110-80-5	8	0,083
Toluene	108-88-3	192	192
Cyclohexane	110-82-7	700	700
Ethylacrylate	140-88-5	21	21
Chlorobenzene	108-90-7	23	23/42,3*
Heptan-2-one	110-43-0	238	394
Oxalic acid	144-62-7	1	4,03

* Two registrations giving different DNELs



When DNELs > OELs, compliance checks are needed !

Possible solutions to improve data quality :

(1) Increasing the number of compliance check

Article 41(1) of REACH:

ECHA may examine any registration in order to verify any of the following:

- (a) information in technical dossier complies with the requirements;
- (b) adaptations to information requirements comply with the rules;
- (c) CSA/CSR comply with the requirements;
- (d) that any "opt-outs" have an objective basis

Article 41(5) of REACH:

To ensure that registration dossiers comply with REACH, ECHA shall select a percentage of those dossiers, no lower than 5% of the total received for each tonnage band for compliance checking.

Possible solutions to improve data :

(2) Withdrawing registration number

- loophole: registration numbers are attributed after completeness check and payment of the fee
- in case of very poor quality dossiers, severe data gaps or non-compliance, the REACH principle “no data, no market” should be applied strictly
- it is possible from a legal point of view (registration numbers already revoked for unpaid fees)
- More sticks and less carrots (soft measures) are needed to improve general data quality in registration dossiers

Possible solutions to improve data quality:

(3) increase transparency



~~CONFIDENTIAL~~ 1 (9)

Decision number: CCH-D-0000004290-83-02/F Helsinki, 20 December 2013

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For 4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with 2,4'-diisocyanatodiphenylmethane and oxydipropanol, CAS No 88288-99-7 (EC No 500-270-4), registration number [REDACTED]

Addressee: [REDACTED]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for 4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with 2,4'-diisocyanatodiphenylmethane and oxydipropanol, CAS No 88288-99-7 (EC No 500-270-4) submitted by [REDACTED] (Registrant).

The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration dossier as submitted with submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 31 October 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

The compliance check was initiated on 25 April 2012.

On 25 April 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [REDACTED].

By 27 May 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 31 October 2013 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit

Possible solutions to improve data quality:

(3) increase transparency

information already disseminated on ECHA's website:

- final decisions (with some data blanked out)
- substances potentially subject to compliance checks in 2015
- status of appeal cases and Board of Appeal's decisions

additional information that could be disseminated:

- name of compliant & non-compliant companies (Fame & shame concept)
- which substances are under dossier evaluation
- status of dossier evaluation
- date of dossier updates
- which data have been updated
- upstream transparency: **Chemical Safety Reports need to be made public (with details on DNEL/DMEL derivation)**

(4) increase enforcement actions

Thank you, further info on:

<http://www.etuc.org> > Our activities > REACH

<http://www.etui.org/Topics/Health-Safety/Chemicals-and-REACH>