Current Status of Enforcement of ECHA Report on Quality of SDS

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How REACH is enforced

- Enforcement is through national authorities
  - National legislation in each MS specifying powers and penalties
    - List of National Inspectorates https://echa.europa.eu/regulations/enforcement/national-inspectorates
    - Report on penalties in each MS https://ec.europa.eu/environment/chemicals/reach/pdf/report_reach_penalties.pdf (2010)
  - Approach differs in each MS!

How REACH is enforced

- ECHA have no enforcement responsibilities
  - But undertake a variety of activities in support of COM and MS
- Loose strategic coordination of MSCAs via ECHA "Forum"
  - Share good practice, identify enforcement strategies, develop working methods for inspectors, advise on enforceability of proposed restrictions
  - Coordinate harmonised enforcement projects
- Agreed Q&As published on ECHA website

How REACH is enforced

- Pressure from customers, consumers, NGOs ….

A third of chemicals break EU safety laws

12 October 2018

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In breach of REACH: Europe's chemical dieselgate

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By Bart Staes and Sven Giegold

Oct 24, 2018

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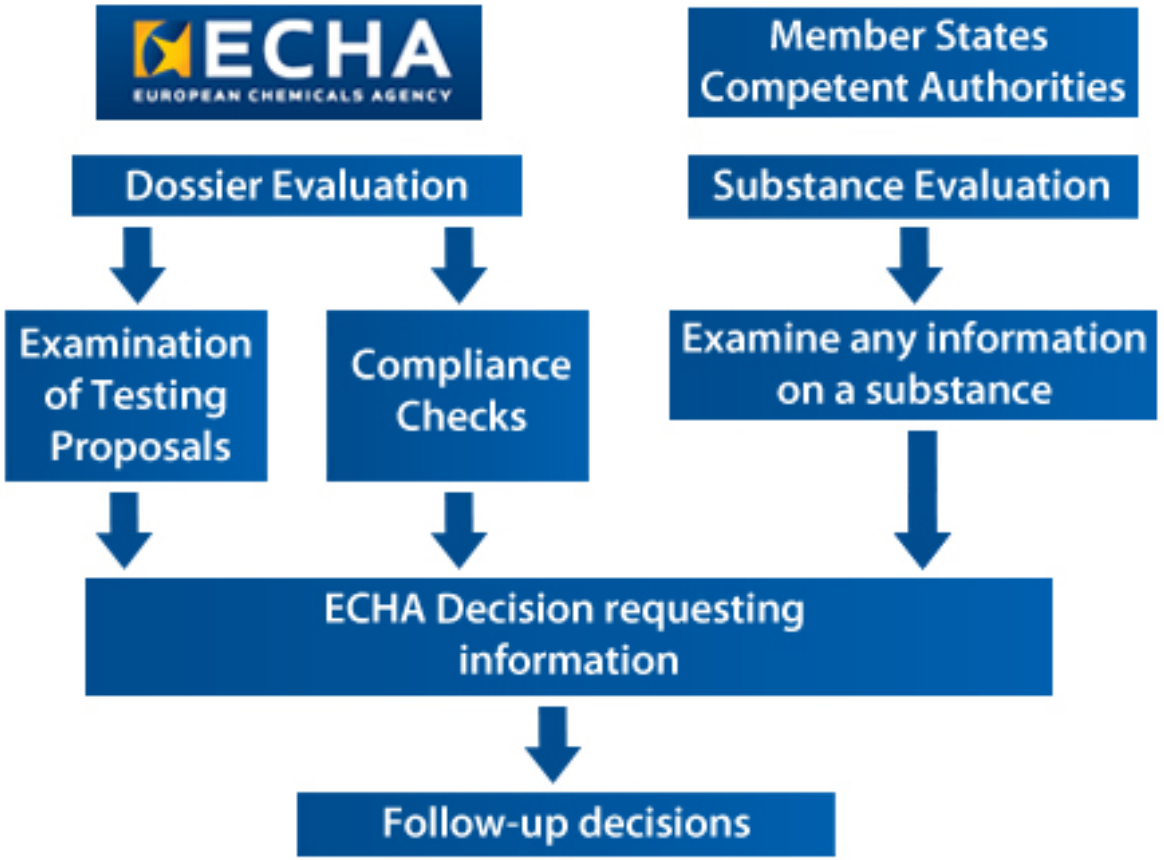
Key topics in enforcement

- Greater scrutiny of registration dossiers
- Improvements in SDS
- CLP - classification of mixtures, internet sales …

Evaluation process



Evaluation of registration dossiers

- Drivers for improving evaluation
  - REACH Review – working but inefficient
  - Study by German Federal Institute for Risk Assessment – high levels of non-compliance
- Evaluation target being raised from 5% of dossiers to 20% in each tonnage band (approx. 30% overall)
  - Commission regulation needed to change the target
  - Screen all dossiers submitted by 2018 deadline - targets 2023 for dossiers 100 t +, 2027 for 1-100 t
  - Changes to processes for dossier evaluation to improve efficiency

Common compliance issues

- Waiving of data requirements not correctly justified
- Adaptations (read-across, QSAR, WoE) failing due to incorrect justification or lack of documentation – leading to data gaps for higher tier information requirements
- Documentation insufficient - e.g. insufficient level of detail in robust study summaries to allow for an independent assessment

Selecting dossiers for compliance checks

- No longer publishing early warning lists for compliance checks
- According to ECHA, selection criteria likely to include
  - Presence on CoRAP, PACT etc
  - Screening scenarios – high tonnage, widespread dispersive uses, adaptations for higher tier endpoints
- I would add:
  - Dossiers that have never been updated, dossiers with lots of adaptations, read across not based on 2017 RAAF, significant opt-outs by JS members, issues with substance identity …

Recommendations to registrants

- Be proactive, keep dossier up to date
- Ensure there is a mechanism (and funds!) within SIEF for periodic review
- Join JS if opted out
- Check substance identity
- Review and update read across, waivers etc if not to latest guidance
- https://echa.europa.eu/recommendations-to-registrants

Other REACH issues

- Certificates of compliance
  - No official certificates under the legislation
  - General declarations of compliance been provided for some time
- Declarations that imported substances (alone or in mixtures) are covered by Importer registrations or OR agreements
  - Might be demanded by customer, increasingly also by carriers
  - REACH-EN-FORCE-7: Enforcement of Registration obligations in cooperation with ***customs authorities*** including verification of SCC for intermediates
- Declarations that articles don't contain SVHCs (above 0.1%)
  - Suppliers often not co-operative – education often needed

Improvements in SDS

- REACH-EN-FORCE projects 2 & 5 identified that many SDS were not compliant
  - No details, however, on key issues
- Joint action between enforcement forum members and accredited stakeholder organisations
  - FORUM Report on Improvement of Quality of SDS
  - https://echa.europa.eu/documents/10162/22749747/echa_sds_report_en.pdf
  - Focussed on sections 1, 2, 3, 7, 8, 9, 10, 11, 12 and 15

Section 1

- 1.1 A few cases where product names on SDS don't match labels; registration numbers not yet updated on substance SDS
- 1.2 Information on uses absent or inadequate, no information on uses advised against
  - More guidance needed to clarify requirements
- 1.4 Emergency telephone numbers (numbers for poison centres) missing
  - Requirements not well understood, expected to improve as a result of new CLP Annex VIII

Section 2.1

- Incorrect classifications due to harmonised classifications not being followed,
- Too wide concentration ranges in section 3 resulting in classification inconsistent with ingredients
- Missing hazard statements
- Inconsistency with labelling
- Inconsistency with sections 9, 11, 12

Section 2.2

- Not following harmonised classifications for substances
- Incorrect or missing pictograms, signal words, hazard statements and precautionary statements
- Missing or incomplete supplemental information, e.g. EUH208

Section 2.3 and general comments

- Not indicating additional hazards, e.g freezing
- Not indicating whether PBT/vPvB criteria are met

- Some SDS still had sections 2 & 3 the wrong (old) way round, some still only classified to the now revoked DPD
- EU importers should request non-EU suppliers either provide EU format SDS or sufficient info for importer to check hazards correctly identified and compile their own SDS if necessary

Section 3

- Substances – substance identity not correct

- Mixtures
  - Concentration ranges too wide – top of range needs to be consistent with product classifications
  - Incorrect or missing classifications for components
  - Missing registration numbers for components
  - Check fully details for ingredients on supplier's SDS (and on CLI), don't just rely on software

Section 7

- 7.1 and 7.2 Generic or missing information on handling and storage
  - Use sufficient/good ventilation….
  - Improvements to software – can SDS authors tailor statements to cover specific uses?
- 7.3 – not well completed
  - Legal text and guidance are too vague, better guidance needed on transferring information from exposure scenarios for mixtures

Section 8.1

- 8.1.1 Control values – national exposure limits not included
  - Software translation problem? Lack of knowledge?
  - https://www.dguv.de/ifa/gestis/gestis-internationale-grenzwerte-fuer-chemische-substanzen-limit-values-for-chemical-agents
- 8.1.2 (monitoring), 8.1.3 (contaminants), 8.15 (control banding) – expect this to be included, indicate if not relevant
- 8.1.4 DNELs and PNECs not always included for mixture components

Section 8.2

- 8.2.1 (Engineering controls) Inadequate or missing information
  - Use sufficient/good ventilation….
- 8.2.2 Inadequate specification of PPE
  - Particularly RPE and gloves (glove material, thickness, breakthrough times …)
- 8.2.3 (Environment) Remarks provide no useful information …

Section 9

- Physical properties missing
  - Software issue – some omit if not completed?
  - "Not applicable" and "not available" - no reason given why
  - Extreme pH not reflected in classification
  - For mixtures, clarification over which properties apply to the mixture as a whole and which to component substances
- Forthcoming amendments to section 9 to implement GHS 6th/7th Rev Ed expected to help

Section 10

- Issues mainly related to missing information, particularly section 10.1 (reactivity) and section 10.5 (incompatible materials)
  - Check consistency with other sections, especially section 7
- Do people really understand what to put in these sections????

Section 11

- Main problems
  - Incorrect or missing available toxicology data.
  - Contradiction between the toxicology data and classification.
  - No further indication which data have been used for classification.
  - Relevant hazard classes not covered.
  - Relevant effects not covered.
  - The standard phrase ‘based on available data, the classification criteria are not met’ for non-classification is not used.
  - Wrong toxicity data of single ingredients led to mistakes in mixture classification.

Section 11

- Be clear whether tox data refers to mixture or components and how it is relevant to the classification
- Software tools to check plausibility between sections 11 and sections 2/3?
- More software tools to check against data in ECHA databases (registration dossiers, CLI)?
- And to check calculations?

Section 12

- Much of the feedback from the assessments was not actually useful …
  - Too much use of "no data" or brief, generic statements such as "biodegradable"
  - Give reasoning for statements or justify why not relevant
  - Be clear if data applies to mixtures or component substances
  - Consistency with other sections

Section 15

- Missing/inadequate information
  - Missing information on EU legislation, e.g. detergents, OSH, Seveso, BPR
  - Missing information on national regulations
  - Missing information on relevant REACH provision, e.g. Annex XIV (Authorisation), Annex XVII (Restrictions)
  - Software solutions – databases of regulations
- 15.2 - State whether a Chemical Safety Assessment has been carried out for substance or mixture components

Key messages

- All required sections to be completed with sufficiently specific information.
  - When the information is not relevant or available, the reason for this should be indicated as required by the legal text.
- SDS should be up-to-date with current chemical legislation i.e. harmonised classifications
- Consistency between the different sections of the safety data sheet

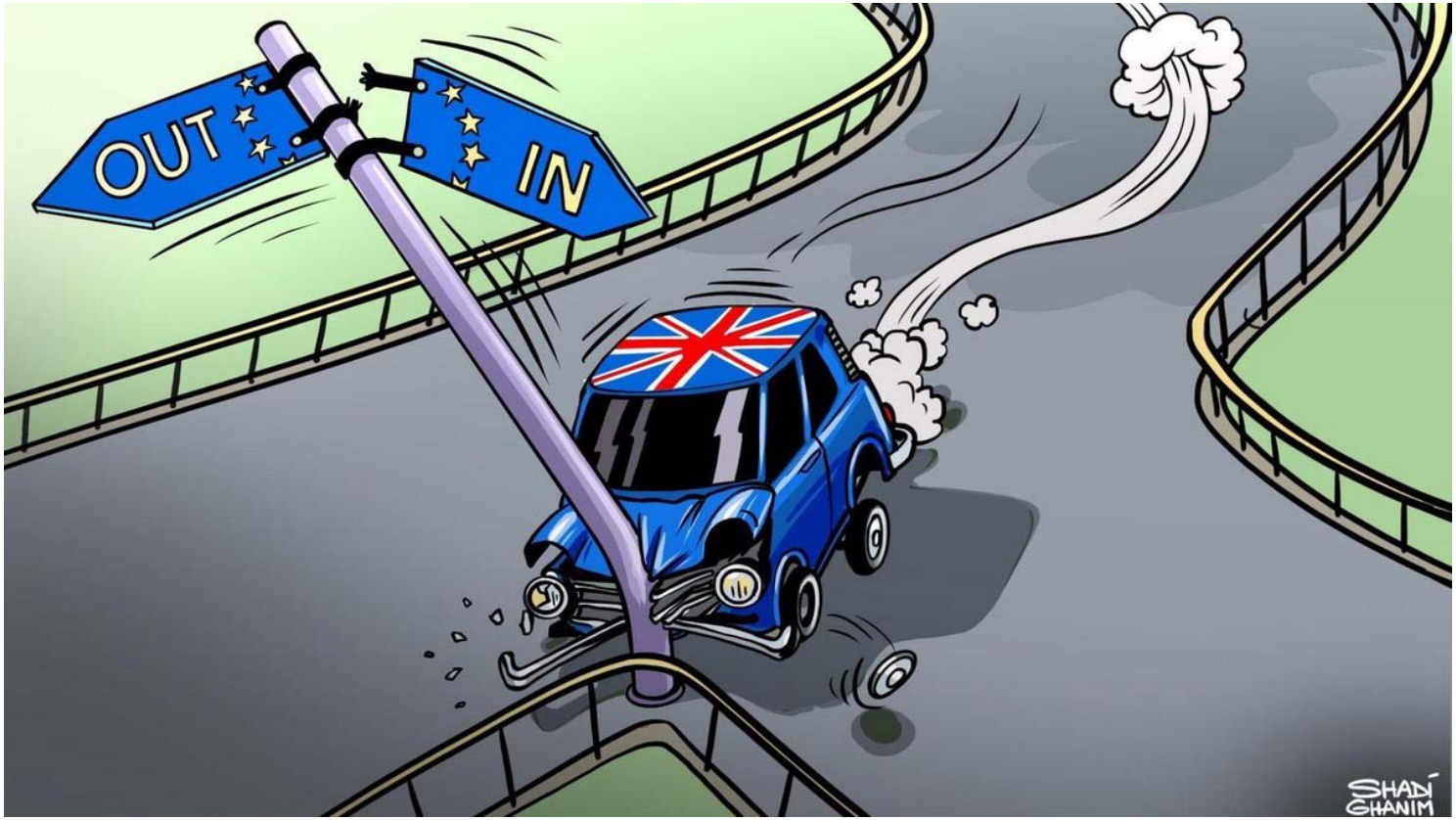
Do you do a human sanity check of your SDS, or do you let the software do it all for you?

CLP

- Two REACH-EN-FORCE projects of interest:
  - REF-6 Classification and Labelling of Mixtures
    - Due to report Q4 2019
    - Pilot project focussing on classification of mixtures and of detergents and cleaning products in particular announced in July
  - REF-8 Enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold on-line
    - Follows earlier pilot project
    - Operational phase in 2020

CHCS
CHEMICAL HAZARDS COMMUNICATION SOCIETY

BREXIT



Brexit options for chemicals regulation

Possible scenarios:

Option 1: UK leaves with "no deal" and is completely out of the EU system on 31st October 2019

- Or maybe later ….

Option 2: UK negotiates an acceptable withdrawal agreement by mid October

- Expected to include a transition period before it takes effect …. Until when????
- Future trade agreement to be negotiated during transition period may include some sort of "associate membership" of ECHA and other relevant bodies (EFSA) …. or not ….

Option 3: UK revokes Article 50 and remains in the EU

- Everything carries on as normal
- Maybe … if there's another referendum …

Brexit – No deal Option

- ECHA webpages provide a good analysis of the "no deal" situation for EU based companies
  - https://echa.europa.eu/uk-withdrawal-from-the-eu
- UK preparations for "no deal" (or a deal that doesn't include chemicals legislation)
  - https://www.hse.gov.uk/brexit/index.htm
  - Systems are in place, might be a bit rough and ready to begin with, but will be functional

Any questions?