

# SDS - what is to be improved: observations from an enforcement perspective

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1

## Observations from an enforcement perspective

- Formal enforcement perspective: recap of the duties
- Enforcement perspective on information in SDS
- Enforcement perspective on extended SDS

2

## Formal enforcement perspective

### Formal REACH duties related to safe use information:

- Assessment of safe use needs (manufacturer, importer)
- Communication of safe use information (supplier)
- Implementation/application of safe use information (end user)

## Formal enforcement perspective

### REACH duties regarding the assessment of safe use needs:

#### Article 14 para 1

- *"... a chemical safety assessment (CSA) shall be performed and a chemical safety report (CSR) shall be completed for all substances ... in quantities of 10 tonnes or more per year per registrant ..."*

#### Article 14 para 6

- *"Any registrant shall identify ... the appropriate measures to adequately control the risks identified in the chemical safety assessment ..."*

## Formal enforcement perspective

REACH duties regarding the assessment of safe use needs:

Article 14 para 7

- "... shall keep his chemical safety report available and up to date"

Article 22 para 1

- "... updating his registration without undue delay with relevant new information ...  
... new identified uses and new uses advised against,  
... new knowledge of the risks (change in SDS or CSR)  
... any update or amendment of the chemical safety report ..."

## Formal enforcement perspective

REACH duties regarding communication of safe use information:

Article 14 para 6

- "Any registrant shall identify the appropriate measures to adequately control the risks and ... recommend them in the safety data sheets which he supplies in accordance with Article 31"

Article 31 para 1 and para 2

- The supplier ... shall provide ... a safety data sheet (SDS)
- "... ensure that the information in the SDS is consistent with the information in the chemical safety assessment ..."

## Formal enforcement perspective

REACH duties regarding communication of safe use information:

Article 31 para 7

- "Any actor ... who prepares a CSR ... shall place the relevant exposure scenarios ... in an annex to the safety data sheet covering identified uses ..."
- Also downstream users/distributors to include/pass on the exposure scenarios in their SDS

Article 31 para 9

- "... update the SDS ... as soon as new information which may affect the risk management measures ...becomes available"

## Formal enforcement perspective

REACH duties regarding communication of safe use information:

Article 34

- "communicate ... up the supply chain ... information that might call into question the appropriateness of the risk management measures identified ..."

Article 37 para 5

- ... downstream user shall ... recommend appropriate measures to adequately control risks identified in ... the SDS(s) supplied to him ..."

## Formal enforcement perspective

REACH duties regarding implementation/application  
of safe use information:

Article 14 para 6

- *"Any registrant shall identify and apply the appropriate measures to adequately control the risks ..."*

Article 37 para 5

- *"... downstream user shall identify and apply ... appropriate measures to adequately control risks identified in ... the SDS(s) supplied to him ..."*

## Observations from an enforcement perspective

- Formal enforcement perspective: recap of the duties
- **Enforcement perspective on information in SDS**
- Enforcement perspective on extended SDS

## ECHA Enforcement Forum & Stakeholders: joint action: quality of SDS

- Identify common deficiencies in SDS and propose solutions for improvement of SDS
- Initiate pro-active measures targeting SDS improvements
- Joint action of ECHA Forum and stakeholder organisations
- Project finished 2019, public report available

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11

11

## Joint action on quality of SDS: results

- Missing uses advised against, unclear identified uses in Section 1
- inadequacy of information provided on occupational control measures (engineering control, details on personal protective equipment, ...) in Section 8
- Information not specific enough, or too generic to be useful, *inter alia* in Sections 7, 8
- Consistency in SDS, e.g. between Section 8.1.1 (OEL) and 8.1.3 (monitoring)
- SDS in-line / up to date with current (chemical) legislation

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12

12

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## ECHA Forum control action "REF-5"

- Consistency of extended Safety Data Sheets (ext SDS) with the chemical safety report
- Communication in the supply chain (SDS and Exposure Scenarios (ES))
- Use of risk management measures (RMM) and operational conditions (OC) recommended in ext SDS by end user
- Inspections in 2017, public report available

## Duty holders targeted in REF-5

First level suppliers	Suppliers	Users
<ul style="list-style-type: none"> <li>○ Importers</li> <li>○ Manufacturers</li> <li>○ Re-importers</li> <li>○ Only Representatives</li> </ul>	<ul style="list-style-type: none"> <li>○ Formulators</li> <li>○ Refillers</li> <li>○ Distributors</li> </ul>	<ul style="list-style-type: none"> <li>○ Professional users</li> <li>○ Industrial users</li> </ul>

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15

15

## REF-5 main results

- 29 participating EEA/EU Member States
- 898 companies inspected
- 1435 substances/SDS checked
  - 375 different substances
- Non-compliance:
  - 18% companies (of which 42% are first level suppliers !)
  - 17% ext SDS (includes also very common substances like ethanol !)

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16

16



## REF-5 main results

- **First level suppliers**  
 General low (3-10%) non-compliance in relation to obligations to include information on workers / environmental protection in the ext SDS
- **Suppliers**  
 General low (1-9%) non-compliance in relation to the communication duties up/downstream
- **Users**  
 General low (2 and 10%) non-compliance in relation to the use of safe use information

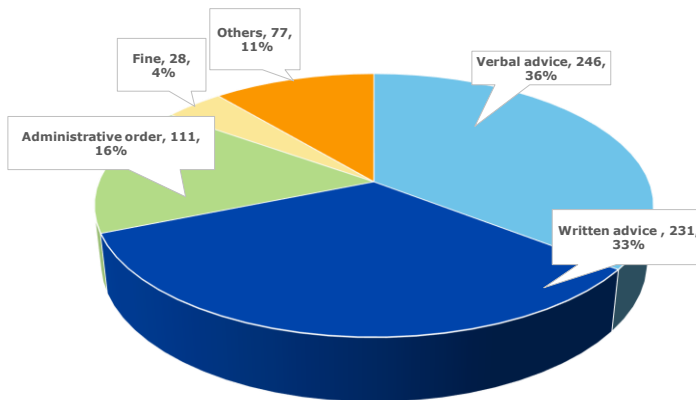
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17

17

## REF-5 main results

### Distribution of enforcement measures



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18

18

## REF-5 conclusions

- Systems are in place for transfer and communication of safe use information within the supply chain
  - Consistency between CSR / ext SDS
  - Low quality information in the CSR and in ES / ext SDS
- Intention of CSA/CSR concept not attained (yet)

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19

19

## REF-5 recommendations

### To Industry

- **Registrants:** Propose more functional risk management measures as part of the CSR and the corresponding ES in the SDS
- Ensure that registration dossiers and associated CSR and the ext SDS are kept up to date
- **Downstream users:** continue working in the communication up the supply chain, by providing feedback to the suppliers on incorrect/inappropriate RMM/OC information in the ext SDS received
- **All:** Use the available tools (e.g. the ones generated by ENES) to help improving the quality of the ES / ext SDS

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20

20

To European Commission:

- Prioritise and follow-up on the REACH review 2018 actions 1 and 3(2)

To ECHA Enforcement Forum:

- Repeat the project in a few years, focusing more on the quality of the information in the ext SDS

To Member States / enforcement authorities:

- Campaigns/workshops/training aiming to improve safe use information in the supply chain

To ECHA:

- Information campaigns/guidance/standards on how to improve the use of ES

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21

21

## Conclusion

Findings from recent enforcement actions on SDS support:

- the European Commission assessment on supply chain communication found in the REACH Review 2018
- the need for standard tools for supply chain communication which are in the focus of ENES
- the need for harmonised technical rules

... in order to **improve efficiency and effectivity** of communication of safe use information

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22

22

## Thank you for your attention

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