

# Preparation of a joint/ separate CSR

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- Technical aspects
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# Introduction <sup>(1)</sup>

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- What is a CSR?

A **Report** documenting the **Chemical Safety Assessment** which determines:

- If a substance is dangerous (and needs exposure scenarios)
- Which Risk Management Measures and Operational Conditions are relevant for protecting HH and Environment



The report include two parts:

- Part A: Summary of RMM, declaration that RMM are implemented, declaration that RMM are communicated
- Part B: the CSA on its own



# Introduction (1)

- REACH Regulation: joint submission is optional



guidance:

- Recommendation to cooperate in the industry to draft the CSR and the ES for sake of coherence and consistency
- A separate submission of CSR in case of Confidential Business Information (CBI) issues

## DEFINITION: Confidential Business Information

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, which are lawfully in control of the information, to keep it secret.



**N.B.: exposure data are not confidential except data on HH related to workers**

REACH ER WS, 5 February 2012

### First thoughts...

– Joint Submission of CSR - Potential advantages:

- One assessment carried out for all registrants
- Update facilitated by the LR
- Evaluation of only one assessment



### HOWEVER

– Issues to be taken into consideration:

- Share responsibilities between the LR and the registrants related to part A
- CBI questions related to sharing of information on uses and tonnages

# CSR submission: 4 main options



1. No joint submission of CSR: CSR developed and submitted individually

2. No joint submission of CSR: CSR developed jointly but submitted individually

3. Joint submission of CSR part B and individual submission of CSR part A

4. Joint submission of CSR

## Option 1: No joint submission of CSR: CSR developed and submitted individually



| Pros   | Cons   |
|--|--|
| Maximum protection of information on uses, tonnages, processes...    | High workload for each registrant to develop individual CSR  |
| Update and improvement of CSR without involvement of other companies | Negative impact on DUs due to potential discrepancies in recommendations (e.g.: non-harmonized use conditions) |
| Decrease workload and responsibility of the LR                       | In case of Evaluation, each registrant will be contacted for CSR related questions.                            |
| No need to involve a Trustee   |  |

## Option 2: No joint submission of CSR: CSR developed jointly but submitted individually



| Pros   | Cons   |
|--|--|
| Reduce workload for the registrants                                  | Higher workload at LR or consortia level to draft CSR  |
| Positive impact on DUs: consistency in recommendations               | Require the involvement of a Trustee   |
| Update and improvement of CSR without involvement of other companies | In case of Evaluation, each registrant will be contacted for CSR related questions.  |
| Decrease workload and responsibility of the LR                       | In case of update of the « common » CSR: risk to have discrepancies in what is submitted to ECHA due to the individual need to submit the updated CSR. |
|  | In case of individual update of the « common » CSR: could lead to discrepancies impacting the DUs  |



## Option 3: Joint submission of CSR part B and individual submission of CSR part A (and partially part B)



| Pros   | Cons  |
|--|---|
| Reduce workload for the registrants  | Higher workload at LR or consortia level to draft CSR   |
| Positive impact on DUs: consistency in recommendations                         | CSR update and improvement only possible with the involvement of other companies  |
| In case of Evaluation, only the LR will be contacted for CSR related questions | Require the involvement of a Trustee  |
| Avoid LR –registrants co-liability on part A                                   | Only the LR know exactly what has been submitted to ECHA – the registrants have no direct access to the information on REACH-IT |
|  | Splitting the CSR document in up to 3 parts requiring discipline in documentation and compiling information for SDS             |

## Option 4: Joint submission of CSR



| Pros  | Cons   |
|---|--|
| Reduce workload for the registrants   | Higher workload at LR or consortia level to draft CSR  |
| Positive impact on DUs: consistency in recommendations  | CSR update and improvement only possible with the involvement of other companies   |
| In case of Evaluation, only the LR will be contacted for CSr related questions                | Require the involvement of a Trustee   |
| For the registrants: LR will assume the responsibilities in relation to jointly submitted CSR | Only the LR knows exactly what has been submitted to ECHA – the registrants have no direct access to the information on REACH-IT |
|   | LR – registrants co-liability on part A  |

# Other considerations...



## Nature of the substance:

- Common well-known uses: no CBI
- Very specific uses: CBI



## Number of members of the Joint submission:

- Large number of co-registrants, the advantage can be considered larger



## Level of knowledge in the SIEF

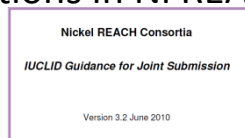


## Existing available data – e.g.: existing EU-RA



- Option 4: **Joint Submission of the full CSR**: work done by the Secretariat of the Ni REACH Consortia (8 FTE + external consultants) and the input of the Ni REACH Consortia Working Groups
- Support to the LR:
  - In-house training on IUCLID and REACH-IT
  - Specific recommendations in Ni REACH Consortia Registration guidance documents:

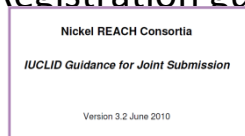
- IUCLID guidance
- REACH-IT guidance on joint submission for LR



Nickel REACH Consortia  
*Draft guidance for Lead Registrant to create Joint submission<sup>1</sup>*  
Vs 1.0. February 2010

- Support to co-registrants (including SIEF members not members of the Consortia):
  - Helpdesk (by phone and e-mail) after the LR submission until the Registration deadline (1st December 2010)
  - Ni REACH Consortia Registration guidance documents:

- IUCLID guidance
- REACH-IT guidance on joint submission for co-registrants



Nickel REACH Consortia  
*Draft guidance for Co-Registrants to join the Joint submission<sup>1</sup>*  
Vs 1.0. February 2010

# CSR Joint submission in practice

Template to be used for part A in case of joint submission of the full CSR

|  |
|--|
| <b>A1. Summary of Risk Management Measures</b>   |
| <i>The risk management measures are described for all Exposure Scenarios in Section 9 of part B of this document.</i>  |
| <b>A2. Declaration that risk management measures are implemented</b>   |
| <i>Each registrant, having decided to mandate the lead registrant to submit this CSR on his behalf, endorses the declaration that he implements those risk management measures described in section 9 of part B of this document, that are relevant to his manufacture and own uses.</i>   |
| <b>A3. Declaration that risk management measures are communicated</b>  |
| <i>Each registrant, having decided to mandate the lead registrant to submit this CSR on his behalf, endorses the declaration that he communicates those risk management measures described in section 9 of part B of this document to his customers, that are relevant for their uses.</i> |
| <b>N.B. Please note:</b> The distribution of liability between the lead registrant and the member registrants covered by the joint CSR would need to be settled through contractual arrangements   |

# CSR Joint submission in practice



| Registrant                            | Coverage of CSR submitted   | Part A (preferred option 1 from ECHA) | Part A (alternative option 2) | Part B              | Tick box in IUCLID dossier header | Doc attached in IUCLID section 13        |
|---------------------------------------|-----------------------------|---------------------------------------|-------------------------------|---------------------|-----------------------------------|--|
| Lead Registrant                       | Joint CSR                   | Not included                          | Included as Joint Declaration | Partial or complete | Ticked                            | Joint CSR part B or Joint CSR (option 2) |
| Member registrant and Lead Registrant | Fully covered by joint CSR  | Submit on its own                     | Not submitting on its own     | Not included        | Ticked                            | Own CSR part A or nothing (option 2)     |
|                                       | Partly covered by joint CSR | Submit on its own                     |                               | Partial or complete | Ticked                            | Own partial CSR part AB                  |
|                                       | Submit on his own           | Submit on its own                     |                               | Complete part B     | Not ticked                        | Own CSR                                  |

After Joint submission of CSR, if you change your mind...

The REACH-IT system does not allow withdrawal from joint submission, to avoid that JS-members would become non-compliant if LR unilaterally decides to change the approach.



Recommendation is:

- All members of the joint submission must upload a full individual CSR
- LR must prepare a letter to ECHA co-signed by all members of the joint submission that they want to change their CSR strategy
- LR must contact ECHA via the helpdesk with their request to change the status of the joint CSR object in REACH-IT and for a discussion on the way forward.

In summary, please think twice about your CSR strategy to avoid heavy administrative procedure !



# Conclusions

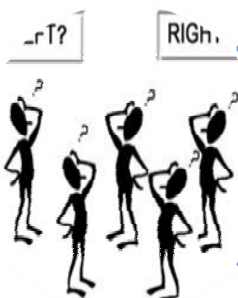
ACT NOW!  
REACH  
2013



All the options are relevant and valid depending on the SIEF members and substances in question



Whatever option chosen, benefits and drawbacks must be carefully assessed



The first decision to be taken: common or individual CSR development . Critical to take it early in the process!





The second decision to be taken: Joint or individual submission



A clear communication on this issue is required



Clock is ticking! Don't lose a minute and work on your registration dossier!

## References

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- Data Submission Manual 19: How to submit a CSR as part of a joint submission?:  
[http://echa.europa.eu/documents/10162/17248/dsm\\_19\\_how\\_joint\\_csr\\_en.pdf](http://echa.europa.eu/documents/10162/17248/dsm_19_how_joint_csr_en.pdf)
- Joint Submission of the Chemical Safety Report (CSR), Cefic:  
[http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/JS-of-CSR\\_Analysis-of-options\\_%20final%20\(2\).pdf](http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/JS-of-CSR_Analysis-of-options_%20final%20(2).pdf)



**Thank you for your attention!**