

Intermediates

REACH Implementation Workshop IX

21 – 22 June 2011

Brussels



L. Heezen
1



-
- **Legal text and guidance sequence**
 - **Consequences**
 - **Examples of Business impact**
 - **Survey on macro effects**
 - **Conclusions**
 - **What do we propose**

REACH and intermediates



- **Art 17: Registration of on-site isolated intermediates under SCC**
 - If SCC is fulfilled, only submission of available information is necessary
- **Art 18: Registration of transported isolated intermediates under SCC**
 - If SCC is fulfilled, only submission of available information is necessary, but > 1000 t/a Annex VII information is obligatory
- **If intermediate is not handled under SCC, Art 10 registration is obligatory**
- **Monomers, are considered as intermediates, but can not profit from reduced registration**
- **On-site isolated intermediates are not subject to evaluation**
- **Intermediates are not subject to authorisation but restrictions could apply**
- **Reduced registration fee applies for intermediates under SCC**

December 2010 ECHA Guidance On Intermediates



Two Main Issues

1. Definition of an Intermediate
2. Interpretation of Strictly Controlled Conditions (SCC)

Issue1: Definition of an Intermediate



- **The REACH legal text clearly defined an Intermediate.**
- **In June 2010 a “clarification” guidance re-defined Intermediates.**
 - **Excluding classes of chemicals clearly within the REACH definition.**
 - **Requiring full Registration for these chemicals.**
- **Cefic has two Independent Legal Opinions supporting the non-compliance of this guidance with the REACH Legal Text.**
- **Companies are responsible for their own actions in this area.**

Issue 2: Interpretation of SCC



- Previous ECHA Guidance documents were developed jointly with industry.
- In December 2010 a new Guidance document was issued ignoring previous industry input on SCC. It:-
 - Restricts the flexibility of using strictly controlled conditions
 - Banned the use of HH and ENV data as part of an SCC strategy.
 - Defined mechanical SCC control strategies in Bands 1 to 5 and decreed that Bands 1 and 2 could not meet SCC.
 - Banned Personal Protective Equipment (PPE) from any SCC Strategy.
- Possible consequences
 - Either Technically Modify existing plant to meet Bands 3 – 5 Theory. Mostly very cost intensive and often not feasible
 - Update dossier and submit each intermediate to a full Art. 10 Registration
- In either case there are massive socio – economic implications

SCC Strategy: Tech. Modification Implications



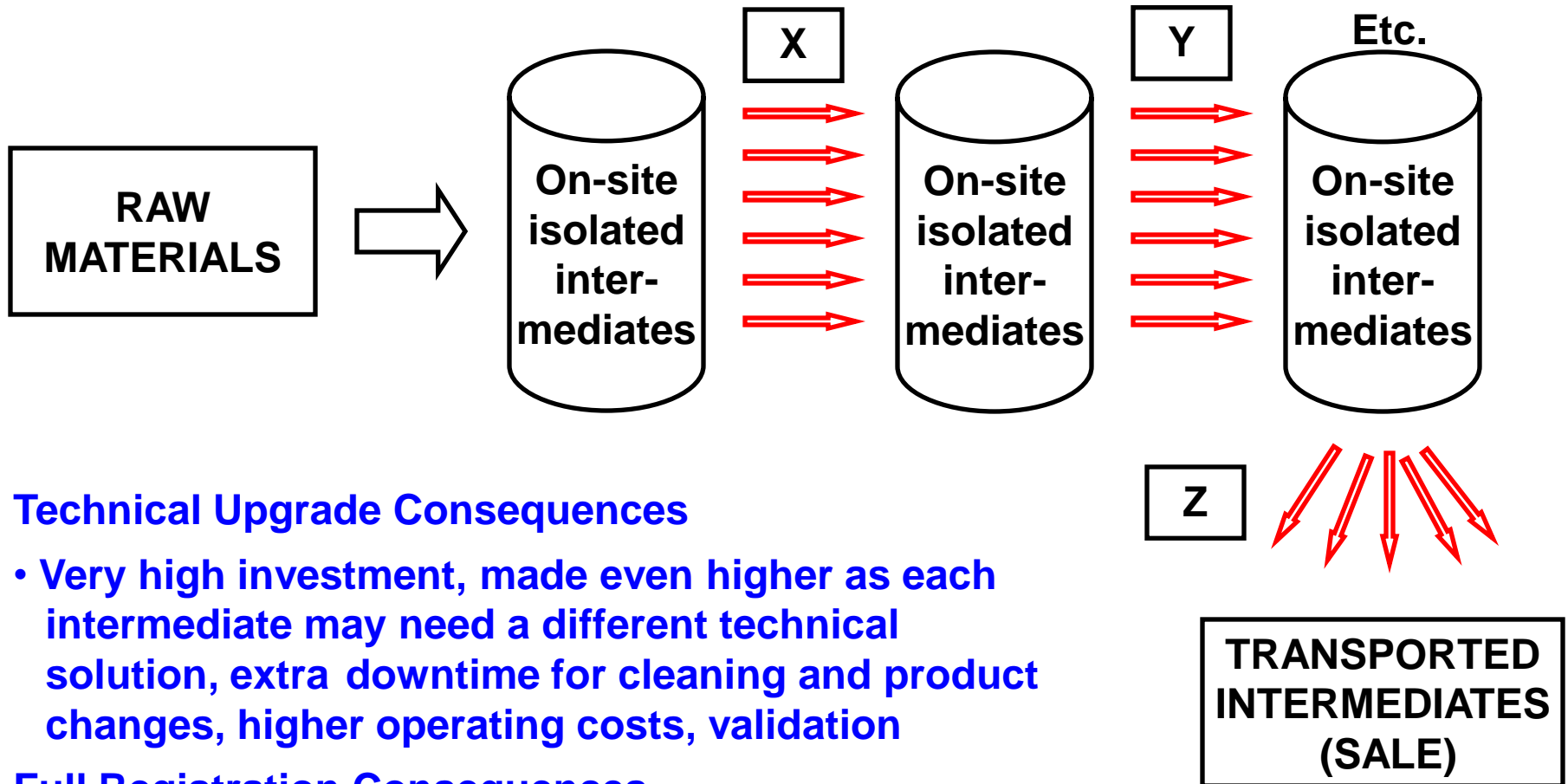
- **Band 2, not seen as part of SCC, involves Local Exhaust Ventilation (LEV) which is currently an EU wide, regulator approved industry norm shown by extensive monitoring to protect HH and ENV, dependent on hazard potential and physical properties of the compound.**
- **Upgrading multi purpose batch processing plants to Bands 3-5 is extremely expensive and will raise operating costs and downtime (e.g. for cleaning)**
- **It's required throughout supply chains, raising the risk of non-EU sourcing**
- **It is highly unlikely that an intermediates' profitability could support either the investment or the added operating cost, let alone the down time involved in plant modification.**
- **The high investment in technical upgrade would not contribute to a significant improvement of HH or Env.**
- **PPE would still be required by regulated industrial hygiene and company procedures. The mechanical and air dynamic barriers offered by the control banding approach finally could not eliminate PPE measures**

Intermediates: Strictly Controlled Conditions



- The new ECHA guidance narrows the definition of SCC but remains, concerning SCC, just as the October draft version within the scope of REACH
- With severe (socio)-economic consequences
 - Intermediate manufacturers and importers
 - Multistep intermediate processes
 - Multipurpose plants
 - Batch processing
 - Toll manufacturers
 - Threat to strategic intermediate product supply – move of intermediate and final product out of EU
- Cefic published together with FECC position paper on SCC
- Cefic published Q+A on updated guidance
- This guidance is not legally binding and companies have to decide case by case what to do here.

Impact on Multipurpose/Multistage Batch Plant



Technical Upgrade Consequences

- Very high investment, made even higher as each intermediate may need a different technical solution, extra downtime for cleaning and product changes, higher operating costs, validation

Full Registration Consequences

- Full Dossier costs for X+Y+Z intermediates, depending on number of production steps. Cost can only be recovered on final intermediate.

Examples on business impact



- **Cefic and EFCG have asked for examples showing the impact of the updated ECHA Guidance**
- **In total 13 examples were received.**
- **Examples will serve to explain different cases**
- **Will serve as input to determine Socio – Economic macro effects**
- **Two examples to show consequences:**

Case Study 2



Location	France
SME?	No
Volume band (tpa)	100 - 1000
Number Inters	6
Number Stages	?
Technical Upgrade Cost (k euros)	-
Full Registration Cost (k euros)	1200 10% of turnover
SIEF Members? (Sharing cost?)	Yes, varies with Inter
Jobs at Risk	40
Remarks	Mother Co has 200 Inters impacted

Case Study 3



Location	UK
SME?	Yes
Volume band (tpa)	> 1000
Number Inters	1
Number Stages	3
Technical Upgrade Cost (k euros)	2,250
Full Registration Cost (k euros)	600 - 820
SIEF Members? (Sharing cost?)	0
Jobs at Risk	40
Remarks	Company suspects supply chains will quit EU •Losing 29% annual sales, 40 jobs Company makes 60+ Inters



Animal testing

- Upgrade to art 10 dossier for > 100 t/a intermediates will require additional tests with animals
- Number of animals sacrificed per substance dossier: > 1000

Cefic survey on macro effects



	Small	Medium	Number of intermediates	Number of production steps (average)	Total Cost (euro millions)
1	0	1	25	4	7.7
2	1	0	100	1	30.2
3	0	1	3	3	0.9
4	0	1	1	1	0.3
5	0	1	2	2	0.6
6	0	1	6	6	1.8
7	0	1	5	5	1.5
8	0	1	14	3	4.3
9	0	1	20	3	6.1
10	1	0	5	2	1.5
11	0	1	6	2	1.8
12	0	1	4	4	1.2
Total	2	10	191	3.0	58.1

**Total Cost (direct)* for 12 chemicals
SME valued at
euro 58 Millions (22% of Turnover)**

Cefic survey on macro effects



	Number of companies	Number of intermediates	Total Cost (euro million)	Average Cost by company (euro million)	Increased costs (% turnover)
SMEs	12	191	58.1	4.8	22%
Large	31	1257	392	12.7	5.7%
Total	43	1448	450		

Total Cost (direct)* for 31 chemicals Large Enterprises valued at euro 392 Millions (5.7% of Turnover)



Conclusions

- Dec. 2010 revised ECHA Guidance does major damage to the intermediate using industry (manufactures and users of chemicals)
- It affects commodity business but the biggest impact is on fine chemicals (FC) industry and smaller companies.
- EU FC business is \$30B, leading the Global market with a 30% share.
- Cefic survey shows that for surveyed companies, the cost of revised dossiers to meet the new ECHA guidance averages 22% of annual turn over for SMEs, 5.7% for large firms.
- This cost, or the investment to technically upgrade existing plants, will dramatically reduce EU competitiveness forcing closures and the transfer of business and supply chains off-shore.
- The high costs for a full registration will not necessarily enhance the level of protection of workers and the environment.
- Full dossiers for intermediates will increase the number of animals sacrificed for test significantly
- Old Guidance met the SCC requirements of REACH and gave a good balance between information requirements and risk based strategy for SCC

Outlook



- **More flexibility in, strictly controlled conditions is necessary with**
 - **Acceptance of present good industry practices of SCC**
 - **Use of hazard data, including those on effects on human health and the environment as part of SCC strategy**
 - **Use of LEV as part of SCC strategy**
- **Revision of the new guidance is important and necessary**
- **Companies should check case by case and decide where action is necessary**
- **Cefic's Q & A can be used as a current support**

What do we propose



- Dec 2010 guidance under moratorium
- Clearer understanding of SE impact of new guidance
- Leading to a decision to go back to earlier version of the draft guidance, including a discussion on minimum data requirements, where:
 - Acceptance of present good industry practices of SCC
 - Use of hazard data, including those on effects on human health and the environment as part of SCC strategy
 - Use of LEV as part of SCC strategy