Implications of the REACH Chemicals Regulation on Air Conditioning in Vehicles

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Outline

1. Purpose of REACH Regulation
2. Registration
3. Evaluation
4. Restrictions
5. Some specific issues for vehicle air conditioning
6. Conclusions
1. A New EU Chemicals Policy

Registration, Evaluation & Authorisation of Chemicals

- **Objective: Sustainable Development**
  - Protection of human health and the environment
  - Enhance innovation and competitiveness of EU’s business
  - Maintain Internal Market
  - Increased transparency and consumer awareness
  - Integration with international efforts
  - Promotion of non-animal testing
  - Conformity to WTO obligations

- **Covers about**
  - 27 000 chemical companies
  - 30 000 chemicals
Key elements of REACH

- Introduces a Single Coherent System for new (non phase-in) and existing (phase-in) substances

Key elements:
- Registration by industry of manufactured/imported chemical substances > 1 tonne/year (staggered dead-lines over 11 years)
- Increased information and communication throughout the supply chain
- Evaluation of some registered substances (Agency and Member States)
- Authorisation only for use of substances of very high concern
- Restrictions: “Safety net” (Community wide action)
- Chemicals Agency to efficiently manage the system

Focus on priorities:
- High volumes (chemicals with greatest likely exposure register first)
- Greatest concern (CMR and R50/53 register first)
REACH influences global chemicals market: The EU is world's leading trader in chemicals

### Major regions in world chemicals:

<table>
<thead>
<tr>
<th>Region</th>
<th>Share in world imports</th>
<th>Share in world exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Union</td>
<td>46.0%</td>
<td>55.3%</td>
</tr>
<tr>
<td>Asia</td>
<td>21.1%</td>
<td>24.0%</td>
</tr>
<tr>
<td>NAFTA</td>
<td>14.3%</td>
<td>16.0%</td>
</tr>
<tr>
<td>Rest of Europe</td>
<td>7.0%</td>
<td>6.2%</td>
</tr>
<tr>
<td>Latin America</td>
<td>4.0%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Africa</td>
<td>1.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Oceania</td>
<td>1.0%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

Implications of REACH on vehicle air conditioning
2. Registration: Aim

- Manufacturers and importers obtain information on their substances and
- Use this knowledge to ensure responsible and well-informed management of the risks these substances may present

Registration Dossier = Documentation

- Technical Dossier: starting at 1 tonnes per year
- Chemical Safety Report: starting at 10 tonnes per year

No formal acceptance - industry retains responsibility
Who Has to Register?

• Manufacturers and importers.
  – Downstream Users cannot register!

• Producers of articles (in the conditions of Article 7).

• Manufactures of substances outside the EU may appoint an “only representative” to fulfil their REACH obligations.
  – “Only representative” relieves importers of their duties.
  – Importers are then considered Downstream Users.
What Must Be Registered?

• Registration only concerns substances.....
  – ......on their own, in preparations or in articles
  – Preparations and articles themselves are not registered
  – Only substances manufactured/imported over 1 ton/year

• Exempted from registration
  – Annex IV (well-known substances e.g. water, oils, CO2...).
  – R&D
  – Product and Process Oriented Research and Development (but subject to notification)
  – etc.
Substance to be registered

> 10 tonne/year

Substance dangerous or PBT/vPvB

Technical Dossier
- Identify of the manufacturer/importer
- Identity of substance
- Info- manufacture and use of the substance
- Classification and labelling
- Guidance on safe use of the substance
- Study summaries – substance properties
- Test proposals (if relevant)
- Exposure information

Chemical Safety Report
- Hazard and PBT Assessment

Chemical Safety Report
- Hazard and PBT Assessment
- Exposure Assessment
- Risk Characterisation AND
  *Exposure Scenarios*
Information requirements (inherent properties)

• Physical-chemical properties (e.g. solubility, vapour pressure)
• Toxicity properties (e.g. acute toxicity, irritation, mutagenicity, carcinogenicity)
• Fate properties (e.g. (bio)degradation, partition coefficients)
• Ecotoxicity properties (e.g. toxicity to aquatic or terrestrial organisms)
Use of information in a regulatory context

• Information needs to be adequate for Classification and Labelling and the Chemical Safety Assessment

• Industries’ responsibility to decide and justify which further information they consider necessary (starting from a minimum data set)
Different treatment of “Phase-in” and “non-phase-in” substances

• Phase-in substances:
  – Existing substances – listed on EINECS
  – A few other types: See REACH Article 3(19)

• Non phase-in substances:
  – If not a phase-in substances, i.e. equivalent to ‘new substances’ not yet placed on the market today
Timelines for Registration

- **Entry into force**:
  - 1 June 2007
  - 1 June 2008
  - 1 December 2008
  - 30 November 2010
  - 31 May 2013
  - 31 May 2018

- **Pre-registration**:
  - Non-phase-in substances

- **100 - 1000 t/y**
  - > 1000 t/y CMRs (> 1 t/y)
  - Very aquatic toxic (R50/53) > 100 t/y

- **1 - 100 t/y**

Implications of REACH on vehicle air conditioning
3. Evaluation

Provide confidence that industry is meeting obligations
Prevent unnecessary testing

Dossier evaluation
- Check test proposals
- Compliance

Substance evaluation
- Examine any information on a substance

Output:
- Further information decisions
- Info to other parts of REACH/other legislation
When will the Agency perform a Compliance Check?

• The ECHA may perform a compliance check of any registration dossier.

• Some priority setting is suggested in the legislation:
  – Dossiers where information is submitted separately
  – Dossiers [1, 10t], not full Annex VII (not fulfilling the criteria of Annex III)
  – Substance is on Community Rolling Action Plan (Substance Evaluation)

• Random selection

• **Member States** can communicate with Agency on their needs for compliance check…
Selection of substances for Substance Evaluation

• The ECHA, in co-operation with MS shall select substances for evaluation, using a risk-based approach.

• When?

• As it is the only possibility to formally request further information…
  – Suspicion of risk?
  – Need for harmonised classification?
  – Is it a substance of very high concern?
Summary of Evaluation

- Evaluation is the main tool to request further information.
- Evaluation should ensure the quality of registration dossier.
- Industry responsibility lightens the evaluation process.
- Still a task for the Authorities to figure out whether potential for risk (e.g. due to aggregated tonnage).
4. Restrictions

• May be applied to:
  – manufacture, use and placing on the market
  – a substance on its own, in a preparation or in an article

• When:
  – an unacceptable risk to human health or the environment
  – the risk needs to be addressed on a Community-wide basis

• Restrictions will be included in Annex XVII
  – takes over existing restrictions of Directive 76/769/EC
5. Specific issues for MACs

- R134a and all alternatives need to be registered
  - Exception: R744
- High volumes from at least 2011 onwards (>2000 tonnes)
  - Good to prepare well in advance
- Are alternatives Phase-in (i.e. "existing") or Non-phase-in (i.e. "new") substances?
- Chemical Safety Assessment/Report
  - Information to car manufacturers and system suppliers
- Registration
  - Information to public at large
- Evaluation
  - Dossier evaluation by the ECHA
  - Substance evaluation by Member States
- Restriction, if
  - an unacceptable risk to human health or the environment
6. Conclusions

• REACH is a major overhaul of the EU chemicals legislation
• Shift if burden of proof to industry is key
• Major challenges ahead for all stakeholders
• June 1st is 3½ months from now!!!!!!!
ESIS (European chemical Substances Information System): http://ecb.jrc.it/esis/
Contains
- EINECS (European Inventory of Existing Commercial chemical Substances),
- ELINCS (European List of Notified Chemical Substances)
- NLP (No-Longer Polymers),
- PBT (Persistent, Bioaccumulative, and Toxic) or vPvB (very Persistent and very Bioaccumulative),
- BPD (Biocidal Products Directive) active substances listed on Annex I or IA of Directive 98/8/EC,
- HPVCs (High Production Volume Chemicals) and LPVCs (Low Production Volume Chemicals),
- C&L (Classification and Labelling)
- IUCLID Chemical Data Sheets
- Priority Lists, Risk Assessment process and tracking system in relation to Existing Substances Regulation (ESR).