# REACH and the Plastics Industry: New Developments
## Classification, Labelling & Packaging

**Tuesday 19th October 2010**

*British Plastics Federation, London*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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</thead>
<tbody>
<tr>
<td>10.20</td>
<td><strong>Chairman’s Welcome and Introduction:</strong> Peter Davis, Director General, British Plastics Federation</td>
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<tr>
<td>10.30</td>
<td><strong>REACH: Where are we Now?</strong> Walter Claes, EuPC</td>
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<tr>
<td>11.00</td>
<td><strong>Managing Substances of Very High Concern (SVHC’s)</strong>, Walter Claes, EuPC</td>
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<tr>
<td></td>
<td>• The Candidate List</td>
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<td></td>
<td>• Substances in Articles</td>
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<tr>
<td>11.30</td>
<td><strong>REACH and Recycled Materials and Products</strong>, Mark Burstall, Chairman BPF Recycling Council</td>
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<td></td>
<td>• The Regulatory Situation</td>
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<td>• Obtaining Information</td>
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<td></td>
<td>• Safety Data Sheets</td>
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<tr>
<td>12.00</td>
<td><strong>Managing CLP Compliance</strong>, Walter Claes, EuPC</td>
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<td></td>
<td>• CLP Basics</td>
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<td></td>
<td>• Notification Deadlines</td>
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<td></td>
<td>• CLP and the Recycler</td>
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<tr>
<td>12.30</td>
<td><strong>Networking Lunch</strong></td>
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<tr>
<td>13.30</td>
<td><strong>ECHA Guidance and IT</strong>, Walter Claes, EuPC</td>
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<td></td>
<td>• EuPC REACH Club</td>
<td></td>
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<tr>
<td>14.00</td>
<td><strong>Plastics Exposure Scenario Team (PEST) Project</strong>, Walter Claes, EuPC</td>
<td></td>
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<tr>
<td>14.30</td>
<td><strong>Tea and Coffee</strong></td>
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<tr>
<td>15.00</td>
<td><strong>REACH for Polymers: Industry Steering Workshop</strong>, Richard Walton, Rapra Ltd</td>
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<tr>
<td></td>
<td>• Creating a practical toolkit to help businesses manage their way through REACH</td>
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<tr>
<td>16.00</td>
<td><strong>Round Up and Close of Seminar</strong></td>
<td></td>
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</tbody>
</table>
### Delegate List

**REACH and the Plastics Industry: New Developments Classification, Labelling & Packaging**

**Tuesday 19th October 2010**

**British Plastics Federation, London**

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Marie-Pierre Beatrix</td>
<td>PEP</td>
</tr>
<tr>
<td>Mr Jonathan Bloom</td>
<td>British Plastics Federation</td>
</tr>
<tr>
<td>Mrs Caroline Brown</td>
<td>Renolit Cramlington Ltd</td>
</tr>
<tr>
<td>Mr Mark Burstall</td>
<td>BPF Recycling Council</td>
</tr>
<tr>
<td>Mr Walter Claes</td>
<td>EuPC</td>
</tr>
<tr>
<td>Dr Sean Cockett</td>
<td>Latiumn Building Products</td>
</tr>
<tr>
<td>Mr Peter Davis</td>
<td>British Plastics Federation</td>
</tr>
<tr>
<td>Mr Keith Eynon</td>
<td>Sterilin Ltd</td>
</tr>
<tr>
<td>Ms Anne Fernando</td>
<td>Renolit Cramlington Ltd</td>
</tr>
<tr>
<td>Ms Fran Gardiner</td>
<td>iSmithers</td>
</tr>
<tr>
<td>Mr Steven George</td>
<td>Numatic International Ltd</td>
</tr>
<tr>
<td>Miss Sarah Griffiths</td>
<td>Luxus Ltd</td>
</tr>
<tr>
<td>Mr Greg Hammond</td>
<td>Gabriel Chemie UK Ltd</td>
</tr>
<tr>
<td>Mr Perry Higgs</td>
<td>Symphony Environmental Ltd</td>
</tr>
<tr>
<td>Dr Richard Hooper</td>
<td>Sims Group UK Ltd</td>
</tr>
<tr>
<td>Mr Ray Kerley</td>
<td>Warden Plastics Ltd</td>
</tr>
<tr>
<td>Mr Ashutosh Kumar</td>
<td>2K Manufacturing Ltd</td>
</tr>
<tr>
<td>Mr Ross Law</td>
<td>Ineos Compounds</td>
</tr>
<tr>
<td>Mr Nigel Lawrence</td>
<td>Cope Allman Jaycare</td>
</tr>
<tr>
<td>Ms Sarah Mann</td>
<td>Valpak Ltd</td>
</tr>
<tr>
<td>Mrs Nichola Morden-Tew</td>
<td>Sterilin Ltd</td>
</tr>
<tr>
<td>Mr Paul Nelms</td>
<td>Epwin Group</td>
</tr>
<tr>
<td>Mrs Karen O'Dwyer</td>
<td>Gabriel Chemie UK Ltd</td>
</tr>
<tr>
<td>Miss Rita Ogole</td>
<td>British Plastics Federation</td>
</tr>
<tr>
<td>Mr Chris Palmer</td>
<td>Luxus Ltd</td>
</tr>
<tr>
<td>Miss Sarah Plant</td>
<td>British Plastics Federation</td>
</tr>
<tr>
<td>Mr Noel Plummer</td>
<td>Ashland Distribution</td>
</tr>
<tr>
<td>Mr Keith Price</td>
<td>Distrupol Ltd</td>
</tr>
<tr>
<td>Mr Noel Taylor</td>
<td>GPS</td>
</tr>
<tr>
<td>Mr Mike Walshe</td>
<td>Zotefoams Plc</td>
</tr>
</tbody>
</table>
Mr Richard Walton  
Mr Andrew Waterfield  
Mr Andrew White  

Mr John White  
Mr Gerry Wilson  
Mrs Leena-Marie Wilson  
Mr Peter Winnicki  
Mr Greg Wood  

Rapra Ltd  
Plastrribution Ltd  
Wells Plastics Ltd  
Sumika Polymer Compounds (UK) Ltd  
Performance Masterbatches Ltd  
Zotefoams Plc  
Zotefoams Plc  
Contico Europe Ltd

Delegate List as at 18th October 2010
REACH & CLP
Consequences for Plastics Converters, Compounders & Masterbatchers and Recyclers

Reach & CLP UPDATE

BPF Reach Meeting
London, 19 October 2010

Presentation W. Claes

The Menu of today’s Update:

1. Reach Basics Reminder
2. Reach Registration update: Deadline 30.11.2010 coming up
3. Substances in Articles: Candidate List - Annex XIV Authorisation
4. PEST: Plastics Exposure Scenario Team
5. Recycling and Reach / SDS-R: Safety Data Sheet Recycling
6. ECHA Website: Guidance Updates
7. IT Issues: Reach IT, IUCLID5, TCC, Chesar, ...
8. Dissemination: Application of Art. 119
10. The REACH Review: Application of Art. 138 (6)
11. CLP Basics and Recycling: Online Notification, Groups of M / I
12. The EuPC Reach Club

of 18 December 2006

REACH and CLP …
… in ONE word

Consequences of REACH for Plastics Processing

The basic legislative processes (2001-2007) are over:

* Commission, Parliament and Council of Ministers

1 June 2007 Entry into Force

… and the implementation phase has started on:

1 June 2008 Entry into Operations

* European Chemical Agency
Consequences of REACH for Plastics Processing

The Pre-registration phase 1.6 - 30.11.08 has come to an end
The first Registration phase 1.6.08 - 30.11.10 has started

The main challenge 2010 is the First Registration deadline on 30.11.10 (24h)

Functioning of SIEFs and Consortia
Chemical Safety Report
*Exposure Scenarios*
*Safety Data Sheets*

The REACH system

- The REACH system is a single system for existing and new, manufactured and imported substances:

  - Registration > 1 t/y
  - Evaluation > 100 t/y
  - Authorisation substances of “very high concern” Chemicals

- Making industry responsible for safe use of chemicals
- Extend responsibility along the manufacturing chain
Definitions (+/− Art. 3)
Downstream User, Article, Substance, Mixture (Preparation)

Downstream Users:
formulators and industrial users of chemicals

Article means an object which during production is
given a special shape, surface or design which
determines its function to a greater degree than
does its chemical composition

Substance means a chemical element
and its compounds

Mixture (Preparation) means a mixture or solution
composed of two or more substances

The REACH system
Registration

Registration: out of a total of 100,000 substances:

> 1 t/year: 30,000 main substances
within 11 years following the Entry into Force of the Regulation

> 100 t/year: 6,000 substances
within 6 years following the Entry into Force of the Regulation

> 1000 t/year: 2,400 High Production Volume + CMR 1/2, R50-53
within 3.5 years following the Entry into Force of the Regulation

By 2010 By 2013 By 2018

2007: REACH Entry into Force ‘No Data, No Market’
The REACH system
Evaluation

<table>
<thead>
<tr>
<th>Quantity (t/y)</th>
<th>REACH Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 100,000</td>
<td>Exempted</td>
</tr>
<tr>
<td>30,000 - 1 T/y</td>
<td>REACH: Registration (in vitro)</td>
</tr>
<tr>
<td>10,000 - 10 T/y</td>
<td>REACH: Registration (base-set)</td>
</tr>
<tr>
<td>6,000 - 100 T/y</td>
<td>REACH: Evaluation (level 1)</td>
</tr>
<tr>
<td>2,400 - 1,000 T/y</td>
<td>REACH: Evaluation (level 2)</td>
</tr>
<tr>
<td>&gt; 1,000 T/y</td>
<td>REACH: Authorisation</td>
</tr>
</tbody>
</table>

Consequences of REACH for Plastics Processing

The Pre-registration phase 1.6 - 30.11.08 has come to an end.
The first Registration phase 1.6.08 - 30.11.10 has started.
The main challenge 2010 is the First Registration deadline on 30.11.10 (24h).

Functioning of SIEFs and Consortia
Chemical Safety Report
Exposure Scenarios
Safety Data Sheets
Registration

News Alert:
ECHAM/13/18
Helsinki, 16 April 2010

Downstream Users can check list of intended 2010 registrations

Downstream users of chemicals now have the chance to check whether the critical chemical substances that they need are going to be registered in time. ECHA has today published a list of all the chemical substances that companies have told us they plan to register for the 2010 REACH deadline. If a substance should be registered in 2010 and it is not, it will be illegal to manufacture or sell it within the EU after 30 November 2010.

It is therefore important that downstream users consult the list to make sure that their high volume and hazardous substances are included (lower volume and less hazardous substances don’t have to be registered this year).

Manufacturers and importers should also consult the list and actively help to make it complete by adding their own planned registrations.

The ECHA website provides information on what to do next if a substance that should be registered in 2010 is not on the list. ECHA will update the list periodically to allow companies to check again.
Registrations expected

(on 4th Stakeholder Day of 19.5.2010 in Helsinki)

Registration expected of approximately 5,000 substances

(4,415 identified to be registered as of 16 April 2010)

which will account for

a total number of 38,000 registration dossiers
**Submission pipeline**

- **Up-loading**: Uploading
- **Pre-processing**: Pre-processing
- **Processing**: Processing
- **FCC**: FCC
- **TCC**: TCC
- **OCC**: OCC

This step must be successfully completed before the deadline. These steps can take place after the deadline, reasonable deadline set in case of TCC failure.

Earlier submission recommended!

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**SIEFs – Current State of Play**

(ECHA 27.9.10)

- The expected number of 30.11 2010 Registrations remains ~4,500
- The number of SIEFs in progress is 2,701 (i.e. Lead Registrant known to ECHA)
- Of which 2,210 for the 2010 deadline
- Deadline for 3 week’s dossier treatment expires 1.10.10
REGISTRATIONS – Current State of Play  
(ECHA 4.10.10)

- On 30 September 2010:
  - 6,700 Registration Dossiers received
  - 4,185 Registration Dossiers approved
  - 2,265 Substances covered

Registrations – Deadline Leniency!
(DU Meeting – ECHA Press Release 27.9.10)

- Companies will be given more time to register their substances under the REACH chemicals regulation in exceptional cases.
- ECHA said it will show leniency in five exceptional circumstances.
- Registrants must show they cannot meet the deadline because of circumstances beyond their control.
Registration Leniency Cases

ECHA Press Release 27.9.2010

- Difficulties to provide data required in Annex VII and Annex VIII in due time or difficulties for importers of mixtures to obtain compositional and analytical data of the substances in the mixture from their suppliers (Issue No. 10).

- Impossibility of transferring pre-registrations or submitting a late pre-registration due to legal entity changes (Issue No. 15).

- Failure by the lead registrant to submit a fully REACH compliant dossier (Issue No. 20).

- Downstream users are obliged to become importers, as a substance is not registered by any EU based supplier (Issue No. 21).

- Registrants need to accommodate new/updated guidance and hence have difficulties to provide data in Annex VII and Annex VIII in due time (Issue No. 10).
Issue No. 21

SIEF without an EU manufacturer

If a substance is manufactured only outside EU, it is often difficult for an Only Representative or importer to take up the Lead Registrant role.

Downstream users should take proactive measures to ensure that there is a continuation of supply for them. In case their supplier fails to register, a downstream user may consider taking up the role of an importer and submitting a registration. If the dossier cannot be totally compliant with the REACH requirements due to unexpected circumstances, companies should contact ECHA via the ECHA Helpdesk as soon as they become aware of the situation.
Substances in Articles

Our obligations - Summary

- Art 7 § 1: Registration: ---> always (pre-) Register
  > 1 t if Intended Release

- Art 7 § 2: Notification ---> Agency: if SVHC present,
  > 1 t > 0,1 % but >1.6.11 and if not registered

- Art 33 § 1: Information ---> Recipient: always if SVHC
  > 0,1 % from date of Candidate List
Guidance on requirements for substances in articles

May 2008

Guidance for the implementation of REACH

Guidance for Downstream Users

The European Chemicals Agency (ECHA) has issued a series of fact sheets, with languages in national and other languages. The guidance is available on the ECHA website.

The Guidance Fact Sheet provides a user-friendly overview of the Guidance Document. It includes key information and other references.

If you have questions or comments in relation to the Guidance Fact Sheet, please send your comments to the following address: ECHA at guidance@echa.europa.eu.
Two key Downstream User issues relating to the Registration deadline of 30 November 2010:

- Substances not registered.  
  [the object of the ECHA Press Release 27.9.10]

- DU uses not covered by Registration (SDS / ES).  
  [the object of a DCG paper 23.9.10 – Issue 22]
Issue No. 22
Uses not covered by registration

If the use of a downstream user is not covered by the registration of his supplier or another supplier, he cannot use the substance anymore. Alternatively, he needs to do a CSA for his use, which may be difficult for especially SMEs.

A downstream user may only realise upon receiving the SDS from his supplier that his use is not covered by the registration of that supplier. In that case the downstream user has in principle four different options: 1) he can communicate the missing conditions of his use to the supplier upstream and request him to provide an exposure scenario that covers his use; 2) change his use or his conditions of use of the substance to one that is covered by the SDS provided by his supplier, 3) change supplier to one whose SDS covers his use or 4) report his condition of use to ECHA and prepare a chemical safety report himself.

Substances of Very High Concern
The Candidate List
The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

Authorisation
A Four Step Process

1. Identification of Substances of Very High Concern (by Authorities)
   ---> “Candidate List”

2. Prioritisation Process (by Authorities)
   ---> “Annex XIV List” with “Sunset Date”

3. Application for Authorisation (by Industry)
   ---> 18 months before “Sunset Date”

4. Granting of Authorisation (by the Commission)
Candidate List of Substances of Very High Concern for Authorisation

Several substances are included in the Candidate List that have been identified as Substances of Very High Concern (SVHC). These substances may have very serious and often irreversible effects on human health and the environment. Substances on the Candidate List may subsequently become subject to authorisation by decision of the European Commission.

Further information:
Documents and web pages below help you to understand the topics covered and provide access to relevant tools. The icon indicates that the linked material is available only in English.

- A general description of the authorisation process can be found on REACH process pages of the About REACH section on the ECHA website.
HERENY RECOMMENDS that on the basis of the reasons set out in the Annex to this recommendation the following entries are included in Annex XIII of the REACH Regulation (list of substances subject to authorisation):

<table>
<thead>
<tr>
<th>Entry</th>
<th>Chemical name</th>
<th>EC number</th>
<th>CAS number</th>
<th>Total applications</th>
<th>Toxicological properties</th>
<th>Review period</th>
<th>Exempted (categories of uses)</th>
<th>Exemptions for (IPCPR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4-Chloroaniline (4-CA)</td>
<td>310-02-2</td>
<td>80-17-9</td>
<td>90 (exclude 2187)</td>
<td>Toxicity &gt; Annex XIV</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<td>2</td>
<td>4-Chloroaniline (4-CA)</td>
<td>310-02-2</td>
<td>80-17-9</td>
<td>90 (exclude 2187)</td>
<td>Toxicity &gt; Annex XIV</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<td>3</td>
<td>Aniline, C7-9, n-alkyl (m-cresylphenol, phenolphthalein, etc.)</td>
<td>621-78-4</td>
<td>85526-64-8</td>
<td>87</td>
<td>Toxicity &gt; Annex XIV</td>
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<td>None</td>
<td>None</td>
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<td>4</td>
<td>Hexachlorophene (HCP)</td>
<td>1394-88-6</td>
<td>25987-66-6</td>
<td>117.5</td>
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<td>5</td>
<td>4-Chloroaniline (4-CA)</td>
<td>310-02-2</td>
<td>80-17-9</td>
<td>90 (exclude 2187)</td>
<td>Toxicity &gt; Annex XIV</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<td>6</td>
<td>Benzyl alcohol (BZA)</td>
<td>100-51-6</td>
<td>85-68-7</td>
<td>87</td>
<td>Toxicity &gt; Annex XIV</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<td>7</td>
<td>Benzyl alcohol (BZA)</td>
<td>100-51-6</td>
<td>85-68-7</td>
<td>87</td>
<td>Toxicity &gt; Annex XIV</td>
<td>None</td>
<td>None</td>
<td>None</td>
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</tbody>
</table>

Date of adoption: 30 June 2005

For the European Chemicals Agency.

[Signature]

Guenther JACON, Executive Director
Update Candidate / Authorisation Lists
September 2010

- 21 September 2010: Member States Committee approves 6 substances on Annex XIV
  (Commission recommendation of 1.6.09 minus chlorinated paraffins)

- European Parliament scrutiny 3 months

- Publication first Annex XIV in Official Journal expected by mid-February 2011

- Publication “Guidance on the preparation of an application for authorisation” in the OJ expected “Autumn 2010” in 22 languages
Summary SVHC/Annex XIV Lists (Past)

Candidate List:
- 28.10.08: First Candidate List: 15 substances
- 13.01.10: Second Candidate List: 14 substances
- 30.03.10: “Second ½” Candidate List: 1 substance
- 18.06.10: Third Candidate List: 8 substances
- 30.08.10: Consultation launched on 11 new substances

ANNEX XIV List:
- 01.06.09: Prioritisation of 7 substances
- 28 September 2010: 7 substances not yet on Annex XIV
- 21.9.09: MS Committee votes 6 substances on Annex XIV
- 01.07.10: Second Draft Recommendation: 8 Substances

Summary SVHC/Annex XIV Lists (Future)

Candidate List:
- 25.03.10: Commission objective: 106 additional substances on the Candidate List by 2012 (to the 29)
- 25.03.10: Commissioner objective: + 400 by 2020
- New Candidate List expected December 2010

- 24.1 and 1.8.11: Submission Annex XV dossiers by MS
- 21.2 and 29.8.11: On ECHA website
- June and December 2011: Publication.

ANNEX XIV List:
- Publication OJ 6 substances mid-February 2011?
### Candidate List of Substances of Very High Concern for authorisation

The identification of a substance as a "Candidate List" (or "Candidate List substance") is the first step in the authorisation procedure. Companies may have to comply with legal obligations following such inclusion. This list includes substances that are linked to the list of substances on its own, in preparations and articles. Further documentation or more detailed information on the identification process of substances of very high concern can be found on the [web pages of ECHA's Member State Committee.](#)

You can sort the Candidate List by clicking on the relevant heading:

<table>
<thead>
<tr>
<th>Substance Name</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>Substance characterisation</th>
<th>Date of inclusion</th>
<th>Reason for inclusion</th>
<th>Supporting documents</th>
<th>Decision number</th>
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</thead>
<tbody>
<tr>
<td>2,4-Dinitrotoluene</td>
<td>204-494-0</td>
<td>121-14-2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>(Support doc.)</td>
<td>ED/10/2009</td>
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<tr>
<td>4,4'-Diaminodiphenylmethane (MDA)</td>
<td>102-79-4</td>
<td>10-77-0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>(Support doc.)</td>
<td>ED/12/2008</td>
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<td>Acrylonitrile</td>
<td>105-03-0</td>
<td>70-06-1</td>
<td>-</td>
<td>28.11.2008</td>
<td>PDH (D, E, I, J, K)</td>
<td>(Support doc.)</td>
<td>ED/12/2008</td>
</tr>
<tr>
<td>Allylamine, C3H5N, Chloro (chloroform, chloroform methylene)</td>
<td>108-08-6</td>
<td>8535-90-6</td>
<td>-</td>
<td>28.11.2008</td>
<td>PDH (D, E, I, J, K)</td>
<td>(Support doc.)</td>
<td>ED/12/2008</td>
</tr>
</tbody>
</table>

### Annex XIV Recommendations

The REACH Regulation requires that ECHA identifies the "Candidate List" priority substances to be included in Annex IV of REACH (the "Authorisation List") and recommends Annex XIV entries (i.e. transitional arrangements and, where relevant, exemptions and review periods) for those substances to the European Commission, taking into account the opinions of the Member State Committee. The European Commission finally decides, by "candidate" procedure (with scrutiny), which substances will be included in Annex XIV and with which entries.

The first recommendation of substances to be included in Annex XIV was submitted by ECHA to the Commission on 1 June 2009. Further recommendations will be made at least every second year.

ECHA's first Annex XIV Recommendation: 1 June 2009

**Background documents:**

- General approach for Prioritisation of Substances of Very High Concern (VHCs) for Inclusion in the List of Substances Subject to Authorisation: this document describes the general approach taken by ECHA for prioritising the substances that are cited in this proposal to be candidate substances for inclusion in Annex IV.
- **Substance-specific documents:**

  - Table of substance-specific documents

**Further information:**

- A general description of the authorisation process
- Authorisation-related public consultations
- Prioritisation-related consultations
- Recommendation-related consultations
Use Mapping

Operational Conditions and Risk Management Measures

PEST

= Downstream User Contribution

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Article 37 (1)
Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures


2. Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a preparation with the aim of making this an identified use.

In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment. /.../
Identification of Uses

For substances > 10 t/y the identified uses include:

- the registrant’s own uses as well as

- downstream uses that have been assessed and included in the registration by the registrant.
PEST
Plastics Exposure Scenario Team
Plastics Supply Chain

- Monomer Producers
- Additive Producers
- Polymer Producers
- Masterbatches/Compounders
- Converters
- Users
- Manufacturers
- Formulators
- Downstream Users

PEST - Who we are

- ELISANA
  European Light Stabilisers and Antioxidants Association (LiSAO)
- EXIBA
- German Masterbatch Association

High level of voluntary support
PEST - Working Groups (Summary 1)

◆ Steering Committee (Dave Horst)

◆ WG 1: Uses and Mapping (Joachim Eckstein):
  - Define uses and
  - Map practical uses to identified uses

◆ WG 2: Process Modules (Claire Dury)
  - Define emission possibilities.
  - Define operational conditions and
  - Practiced RMM’s

PEST - Working Teams (Summary 2)

◆ WG 3: Exposure Scenario Development (Jürgen Kashig)
  - Develop exposure scenarios from substance data, operational conditions and RMMs.
  - Elaborate concept for matrix inclusion

◆ WG 4: IT and Communication (Walter Claes)
  - Develop a website for making the ES available.
  - Connection to outside related IT systems.
  - Project communication.
PEST Progress Report (July 2010)

◆ Step 1: Use Mapping Tool completed by 30.11.09.
   ● Launch on 11.11.09 at 11 am
   ● 600 users have submitted a registration.
   ● 60% of use communications in PEST format

◆ Step 2 completed by end 2009:
   ● Data gathering on Operational Conditions and Risk Management Measures for all major Converting Processes.
   ● Translation into Standard Modules of Emissions and Releases

◆ Step 3: GES for classified additives used in Plastics:
   ● 1st example for a group of additives posted on 27.1.2010
   ● GES for typical cases (tier 1 evaluation) in progress
   ● In the meantime: interaction with an Expert Network [next slides].

The PEST Project Implementation
PEST Project - State of play (1)
New progress since Communication Letter 2 of 3.9.2010
Update 1 October 2010 - GTx

◆ PESTool v1.0 was released on 27.9.10 and enables registered users to download generic ECETOC TRAM main sheets created by a regional database covering 5000 generic substances used in the field of thermoplastics and the exposure information gathered by PEST

◆ These sheets can then be used as input for ECETOC TRA calculations. This software is used by substance M/I to make their CSA and develop ESs.
PEST Project - State of play (2)
New progress since Communication Letter 2 of 3.9.2010
Update 1 October 2010 - GTx

◆ PESTool v1.0 enables M/I to speed up their Registrations with Exposure Data closer to the reality of our Industry.

- There is no doubt that the work of PEST and the development of exposure data avoided gross overestimates leading to unnecessary Risk Management Measures.

◆ PESTool v2.0 is a further development to facilitate the generation of Exposure Scenarios for Mixtures. Kick-off was on 1.10.10 with ETHIC taking the lead.

PEST Project - State of play (3)
New progress since Communication Letter 2 of 3.9.2010
Update 1 October 2010 - GTx

◆ More and more information will become available as we approach the Registration deadline of 1 December, but then the game won’t be over since there will be at least one year period following registration for Downstream Users to adapt their process to the new recommended risk management measures contained in the new REACH format Safety Data Sheets.

This period could also be used to refine risk management measures to the individual customer. PESTool v2.0 in development will be aimed at facilitating the implementation of this transition period.
3 Recyclers’ Obligations in 2010

◆ 1. Substance Registration
   ... and Exemption

◆ 2. Safety Data Sheet

◆ 3. Classification and Labelling Notification
2 Recyclers’ Guidance Documents

- Guidance on Waste and Recovered Substances
  (12 May 2010)

- Guidance on the Compilation of Safety Data Sheets
  (April 2011?)

"Recovery" in the final Reach Text


Article 2
Application

7. The following shall be exempted from Titles II, V and VI:

(d) substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and

(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.

N.B. Title II = Registration, V = Downstream Users, VI = Evaluation
Availability SDS (Art. 2.7.d): “Legitimate Access”

ECHA legal services insist on difference between “Confidential Information” and “Intellectual Property Rights” and refers to industry chains and national copyright laws.
Guidance on waste and recovered substances

The European Chemicals Agency (ECHA) is issuing a series of Fact Sheets, each of which provides a simplified overview of a specific topic relevant to REACH. These documents are available in the following 21 languages: Danish, Dutch, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Lithuanian, Latvian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Swedish, Turkish. They are also available in English.

A Guidance Fact Sheet provides a short summary of the key aspects of the corresponding REACH Guidance Document, including bibliographic information and links for further reading.

If you have questions or comments in relation to the Fact Sheets, please send them by email to guidance@echa.europa.eu using the Fact Sheet number, reference number and language version, above.

W. Claes - 09/10/2010 - 72

Guidance on the compilation of safety data sheets

W. Claes - 09/10/2010 - 73
Guidance on the Compilation of SDS
ECHA State of Play 27.9.2010

- PEG discussions still ongoing (1.034 comments!)
- Forum December 2010
- CARACAL January/February 2011
- Publication April 2011?
The SDS-R Project for Plastics Recycling
Update on Guidance Documents
Transfer of Information: a challenge

- 2 Regulations: Reach and CLP – entangled
- 24 Guidance documents on ECHA web site
  - 1 (CSR) has +/- 2.000 pages
  - 2 not available yet (Authorisation, Socio-Economic Analysis)
- 4 new Guidance documents finalised in 2010
- 12 Guidance Documents in “Permanent Revision”
- 8 FAQs in different places
- CARACAL documents, Reach Committee, ...

- Knowledge about other legislations
  - Substances not or partially covered by Reach
    - (cosmetics, food contact, biocides, pesticides, ...)

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**News Alert:**

ECHANA/1031

Helsinki, 2 June 2010

**Moratorium on the publication of ten guidance updates**

ECHHA has placed a six-month moratorium on the publication of ten guidance documents until 30 November 2010 which is the first REACH registration deadline. This should allow industry to concentrate over the next months on preparing dossiers for this as well as the CLP notification deadline which follows soon thereafter. Although finalising these guidance updates during the moratorium period, ECHA already now provides a number of clarifications on some guidance documents based on the legal text and on existing guidance.

Industry associations have indicated that work on guidance updates and new guidance in 2010 is binding a lot of their effort into the consultation processes at a time when the preparation of their members for registering in due time is demanding more of their attention. Taking this into consideration and on the basis of a detailed analysis of the impact of the ongoing updates, ECHA has taken the decision to postpone the issuance of the following ten guidance documents until after the first REACH registration deadline of 30 November 2010:
REACH IT
and
IUCLID5
The new Chemical Safety Assessment and Reporting tool, Chesar, is now available.

Chesar™ is a tool to help companies to prepare their Chemical Safety Assessments (CSA) and Chemical Safety Reports (CSR) which are required by the REACH regulation for substances manufactured or imported at a volume above 10 tonnes per year.

Until now companies have been able to submit registrations with a CSR generated manually, partly supported by the CSR plugin for ECHA made available in February 2009. Chesar now provides industry with an IT tool to produce the full CSA more efficiently and effectively. It will in particular help to structure the information for the exposure scenarios.

For that purpose the principles for carrying out a chemical safety assessment described in the updated REACH Guidance on Information Requirements and Chemical Safety Assessment have been converted into an IT application.

Chesar is also built to facilitate the re-use of all or part of assessments already carried out by the regulator or prepared by industry associations, thanks to data exchange functionalities. This will support cross-industry standardisation of the description of uses and the safe conditions of use.

Chesar 1.0 works as a plug-in of stand-alone version of IUCLID 5.2.

At Chesar 1.0 has only been tested within ECHA, we encourage the registrants to test the tool. All feedback will contribute to the next upgrade of Chesar. Chesar 1.0 does not generate full CSR or the Exposure Scenarios for the enhanced Safety Data Sheets. The first upgrade enabling the full CSR generation is planned to be available in July 2010.
New REACH-IT version released

The new version of REACH-IT is now available. It includes new features such as the 'parallel joint submission' that allows members of a joint submission to submit their dossiers as soon as the lead dossier has been accepted for processing. Additionally, this release introduces a new online functionality to allow companies to prepare their Classification and Labelling notifications directly in REACH-IT. After this update there will be no more new functionalities introduced before November and January deadlines.
**Article 119**

**Electronic public access**


1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e): ...

2. The following information on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned: ...

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**Information disseminated**

<table>
<thead>
<tr>
<th>Article 119(1)</th>
<th>Article 119(2)</th>
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</thead>
<tbody>
<tr>
<td>(a) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC, without prejudice to paragraph 2(f) and (g).</td>
<td>(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;</td>
</tr>
<tr>
<td>(b) if applicable, the name of the substance as given in EINECS;</td>
<td>(b) the total tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;</td>
</tr>
<tr>
<td>(c) the classification and labelling of the substance;</td>
<td>(c) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);</td>
</tr>
<tr>
<td>(d) physicochemical data concerning the substance and on pathways and environmental fate;</td>
<td>(d) information, other than that listed in paragraph 1, contained in the safety data sheet;</td>
</tr>
<tr>
<td>(e) the result of each toxicological and ecotoxicological study;</td>
<td>(e) the trade name(s) of the substance;</td>
</tr>
<tr>
<td>(f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;</td>
<td>(f) the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of six years;</td>
</tr>
<tr>
<td>(g) the guidance on safe use provided in accordance with sections 4 and 5 of Annex VI;</td>
<td>(g) the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:</td>
</tr>
<tr>
<td>(h) analytical methods requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.</td>
<td>(i) as an intermediate;</td>
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<td></td>
<td>(ii) in scientific research and development;</td>
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<td></td>
<td>(iii) in product and process orientated research and development.</td>
</tr>
</tbody>
</table>
Information disseminated

category 2 [Article 119(2)]:
information publicly available, except if the registrant submits
a justification, accepted as valid by ECHA,
as to why publication is potentially harmful
for the commercial interests of the registrant or others
concerned. A fee is charged per each item according to
Annex IV of the Fee Regulation

The dissemination process

1 registration is complete
2 registration dossier is scheduled for dissemination
3 registration dossier is filtered
   = only information listed in article 119 is left in the dossier
for joint submissions: filtered dossiers are aggregated
   = the information on the substance from all dossiers in the
joint submission are merged into one dossier
4 dossier is disseminated on ECHA website
Dissemination & confidentiality claims

Initial Dissemination

Submitted by Registrant

Disseminated by ECHA

REACH Registration Dossier

ALL information claimed confidential according to Art. 119(2) is removed during filtering

Filtered Dossier (Publicly Available)

http://echa.europa.eu
### Search for information on registered substances

Here you can search in the ECHA databases for information on registered substances. The information in the database is provided by companies in their registration dossiers. You can find a variety of information on the substances which companies manufacture or import, their hazardous properties, their classification and labeling and how to use the substances safely, for example.

The amount of information provided can be different for different substances — for example, the higher the production volume of a substance, the more information the companies need to provide. Please be aware that ECHA does not have the information online at all times.

The number of substances for which information is available in the database will increase over time as companies submit more registrations. For further information about the content of the database, please visit the [Guidelines and Norms](#) page.

**How to search**

Enter the name of a substance, or part of it, or its EU or C&I number in the search box. If you do not enter any search criteria, a list of all the substances in the database will be given.

**Feedback**

Please give us your [Feedback](#) about ECHA’s public database with information on registered substances.

### Search results

#### Ser...
Enforcement and Penalisation

REACH Implementation
Sanctions for non-compliance


TITLE XIV
ENFORCEMENT

Article 125
Tasks of the Member States

Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.

Article 126
Penalties for non-compliance

Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 December 2008 and shall notify it without delay of any subsequent amendment affecting them.
The FORUM

✦ “Forum for Exchange of Information on Enforcement“

✦ Launched in April 2009 by ECHA
✦ Enforcement Workshop with Stakeholder Organisations feedback on 18 May 2010

✦ “REACH-EN-FORCE-1”
  • May 2009 – January 2010
  • Focussed on pre-registration and provisions of SDS
  • Inspections in 1600 companies in 25 countries
    - (878 M, 666 I, 83 OR, 858 DU)
  • Covered 105,000 pre-registered substances
  • 24% of companies were not 100% compliant
  • SDS: 11% of companies and 28% of products not compliant
The FORUM (2) Meeting 18.5.10

- Next project REACH-EN-FORCE-2 (April-October 2011): Downstream Users – Formulators of Mixtures

- Stakeholder position:
  - Problem of SDS essentially for mixtures:
    - Registration Numbers will not be available for all substances
    - Some uses may not be covered (yet)
  - 2011 may be a better year to inform and 2012 to enforce

The FORUM Update 27.9.10


- The Forum decided to go ahead and the “Inspections Manual” is in preparation.

- Following the Stakeholders meeting of 18.5.2010 the start of inspections has been delayed to May 2011

- A new meeting with Stakeholders will be held in March 2011.
The 2012 REACH Review

Reach - Council of the EU
The REACH Review


TITLE XV
TRANSITIONAL AND FINAL PROVISIONS

Article 138
Review

6. By 1 June 2012 the Commission shall carry out a review to assess whether or not to amend the scope of this Regulation to avoid overlaps with other relevant Community provisions. On the basis of that review, the Commission may, if appropriate, present a legislative proposal.
The REACH Review in 2012

- **Key elements of the Scope Review** – Tasks by the Contractor:
  - Perform an analysis of all the relevant sectoral Community legislation
  - Compare the elements analysed with those of REACH
  - Assess mechanisms to avoid double regulation
  - Identify gaps and give recommendations.

- **Timing of the scope review**:
  - Contract for 20 months: until end August 2011
  - Commission to finalise review by 1 June 2012
  - Review can conclude to amend or not REACH: after June 2012.

The CLP Regulation
Classification, Labelling and Packaging

of 16 December 2008


The CLP Regulation

Legal aspects


◆ CLP is based on GHS, the Globally Harmonized System developed by the United Nations.

◆ The GHS originated at the Rio de Janeiro (1992) and Johannesburg (2002) UN World Summits on Sustainable Development. Its formal document is the “Purple Book” (2003), with a biennial work programme.
GHS - A short history

• 1992 – Rio Earth Summit (UNCED)
  - International Mandate ‘Agenda 21’
    “a globally harmonised hazard classification and labelling system, including safety data sheets and easily understandable symbols”

• 2002 – Johannesburg – UN World Summit on sustainable development
  - 2008 deadline for implementation

UNSCEGHS

• ‘Purple book’
• First published 2003
• 1st revised edition 2005
• 2nd revised edition 2007
• 3rd revised edition 2009
• UNSCEGHS has a 2 year work-programme to update and amend the GHS text
The CLP Regulation

Legal aspects

- The CLP Regulation:


  - replaces (on 20.1.09): Title XI (C&L Inventory) of the Reach Regulation by Title V of CLP (Harmonisation of Classification and Labelling and C&L Inventory)
The CLP Regulation
Scope (1)

- So the Scope of the CLP Classification is different from the Reach Registration:

  CLP Classification and Notification applies to all Substances “to be placed on the market” and there is no volume threshold

  Reach Registration applies to Substances manufactured and imported above 1 tonne/year

The CLP Regulation
Scope (2)

But based on the Reach Regulation, Classification also applies to substances which are not placed on the market if they are subject to Registration or Notification in line with:

- Art. 6: Monomers
- Art. 9: PPORD (Product and Process oriented Research and Development)
- Art. 17: On-site isolated Intermediates
- Art. 19: Transported isolated Intermediates
The CLP Regulation
Transition Periods

- Transition periods:

  * 1.12.2010 for substances =
    3.5 years after Entry into Force of Reach (1.6.2007)
  * 4.5 years for Mixtures = 1.6.2015

  plus 2 years in case of re-labeling and re-packaging Substances or Mixtures that are re-classified.
The CLP Regulation
The Classification System - Substances

- New features in CLP as compared to DSD / DPD:
  - Physical Hazards: more hazard classes (16 i.i.o 5)
  - Human Health Hazards: GHS Building Blocks used + EU “leftovers” not covered by GHS
  - Environmental Hazards: largely based on current EU system

- In summary:
  - Substances are more severely classified
  - There are more classified Mixtures

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Health effects
Classification criteria

Acute oral toxicity

<table>
<thead>
<tr>
<th>EU</th>
<th>GHS</th>
</tr>
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<tbody>
<tr>
<td>Very toxic</td>
<td>Category 1</td>
</tr>
<tr>
<td>Toxic</td>
<td>Category 2</td>
</tr>
<tr>
<td>Harmful</td>
<td>Category 3</td>
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<td></td>
<td>Category 4</td>
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<td></td>
<td>Category 5</td>
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</tbody>
</table>

http://echa.europa.eu
The CLP Regulation
The consequences for Article manufacturers

- Articles are normally not to be classified. Producers of Articles are only affected by CLP if:

  - they manufacture or import an explosive article
    Annex I § 2.1 of the CLP Regulation

  - Reach requires registration or notification of a substance contained in an article (and such Substances have not already been registered for that use)

    Reach Art. 7.1 and 7.2 on Substances in Articles Registration (Intended Release) or Notification (SVHC) and Reach Art. 9 on PPORD Notification

http://echa.europa.eu
The CLP Regulation – the C&L Inventory

- **Art. 40 § 1**: Any manufacturer or importer, or group of manufacturers or importers (hereinafter referred to as ‘the notifier(s)’), who places on the market a substance referred to in Article 39, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 42:
  - **Art. 40 § 1 (c)** the classification of the substance or substances in accordance with Article 13;
  - **...**
  - **Art. 40 § 3**: Substances placed on the market on or after 1 December 2010 shall be notified in accordance with paragraph 1 within one month after their placing on the market. However, substances placed on the market before 1 December 2010 may be notified in accordance with paragraph 1 before that date.
The CLP Regulation

The consequences for Recyclers

- Exemption from Registration does not mean exemption from Classification and Labeling nor of Notification !!!

- Recyclers as manufacturers of must notify the hazardous Substances that make their Mixture hazardous and that are placed on the market “before and still, or again” on 1.12.2010 (cf. Art. 39 (b) Scope) within one month.

  Current interpretation is: before 3.1.2011 (inclusive).

- And of course they must classify their Mixtures before 1.6.2015.
2.4. Is an establishment which is recovering a substance obliged to classify and notify it to the Classification and Labelling Inventory? (New in CLP FAQ March 2010)

- Under CLP, recovered substances and mixtures will normally have to be treated in the same way as other substances and mixtures under CLP. This means that they have to be classified according to Title II of CLP and the substances have to be notified to the C&L Inventory, unless the establishment undertaking the recovery (manufacturer of the recovered substance) has already submitted a registration under REACH and included the information necessary for a notification.

- In case the establishment undertaking the recovery can rely on the exemption from the REACH registration provisions for recovered substances pursuant to REACH Article 2(7)(d), it would still have to notify the recovered substances to the C&L Inventory, in accordance with CLP Article 39(b) and 40.

When classifying under the CLP Regulation, the establishment undertaking the recovery may take over the classification derived in accordance with Title II of CLP already by the registrant of the same substance, if this is appropriate.

When notifying in such cases to ECHA, it is recommended to retrieve the classification and labelling information provided earlier by the registrant of the original substance from ECHA's Classification & Labelling Inventory and agree to it.
C&L Notification
Outline of IT Tools

- Large companies: creation of 200 data fields in IUCLID 5 (version 2.5 released spring 2010)

- SME’s: simplified online submission direct in Reach-IT with use of default values of C&L Inventory and “I agree” principle (Annex VI for harmonised substances)

- Bulk submission of XML files under certain conditions (CAS/EINECS number, not hazardous, single composition, ...)

A tool for each need...

Compatibility between each submission tool!
Group Submission of Notification

- **Art. 40:** Any manufacturer or importer, or group of manufacturers or importers (...), who places on the market a substance referred to in Article 39, shall notify to the Agency ...

- Corporations with different legal entities, SIEFs, Reach Consortia, Companies that have no specific links with each other ...

- The role of the “Group Notifier” in CLP is not comparable to the “Lead Registrant” in Reach so “trust” will play an important role. He will distribute the “Submission Report”, the proof of fulfilment of CLP obligations.

The CLP Regulation
Mixtures, Hazardous and other terminology

- **Art 57 § 11:** The word ‘preparation’ or ‘preparations’ within the meaning of Article 3 (2) of Regulation (EC) 1907/2006 shall be replaced by ‘mixture’ or ‘mixtures’ respectively throughout the text.

- Dangerous ---> “Hazardous” and includes a.o. “gases under pressure”, “corrosive to metals”, ...

- Category of Danger ---> Hazard Class
  Risk Phrase ---> Hazard Statement
  Safety Phrase ---> Precautionary Statement
The CLP Regulation
Downstream Users, Re-importers and OR’s

- Downstream Users are more affected by CLP than by Reach. They can be subject to Labeling but are exempted from Notification.
  - This includes Formulators of Mixtures, Distributors, and producers and importers of Articles.

- Re-importers are not in the same case as Recyclers: exempted from Registration (Reach Art. 2.7.c) and also from Notification to the C&L Inventory as they are considered as Downstream Users.

- The Only Representative is mentioned nowhere in CLP, so all importers have to Notify themselves (subject to confirmation).

The CLP Regulation
Safety Data Sheets

- Safety Data Sheets: the existing Classification System according to the Dangerous Substances and Dangerous Preparations Directives must remain on the SDS until the end of the transition periods (2010 for Substances, 2015 for preparations)

- “Impurities” influence Classification

- “Nano” is no hazard as such!

- How many Notifications? Between 2 and 20 Millions!
State of Play Notification Submission
28.9.10

◆ 6.762 Notification Files received
◆ 5.640 Files accepted after BRC (Business Rules Check)
◆ 27.979 Substances (Bulk uploads = more than 1 substance)
◆ 308.804 Notifications (Group Notifications !)

Practical Guides and User Manuals
CLP Notification Tools and Manuals

CLP Notification on the ECHA Web Site:

4 IT Tools for Notification Preparation

3 IT Manuals and 1 Practical Guide in 22 languages

4 Notification Manuals

- Practical Guide 7: How to Notify Substances to the Classification & Labelling Inventory. [Link](http://echa.europa.eu/doc/publications/practical_guides/pg_7_clp_notif_en.pdf)


REACH-IT Industry User Manual
Part 15 - Manage your Group of Manufacturers or Importers

REACH-IT Industry User Manual
Part 16 - How to create and submit a C&L notification using the REACH-IT online tool
The CLP Regulation
For more information:

- **Legal text of the CLP Regulation:**

- **The ECHA Guidance and Introductory Guidance have been published on 28.8.09:**

- **ECHA Questions and Answers:**

- **ECHA Frequently Asked Questions:**
  - [http://echa.europa.eu/doc/clp/clp_faq_1_1_1_20100913.pdf](http://echa.europa.eu/doc/clp/clp_faq_1_1_1_20100913.pdf)
The EuPC REACH Club

Build, grow and share
your plastic REACH experience

www.reachclub.eu

Forum | Webinars | News | Network
What is REACH Club?

- A community of plastics experts
- Privileged access to The Forum
- Free access to The Webinars
- Latest News
- Members
  - Responsible for implementation
  - Company member of the EuPC Network

Annual membership fee

- Per individual per year when registering*,**:
  - 1 expert: €1,000 (+21% VAT: € 1,210)
  - 2 experts: € 750 (+21% VAT: € 907.50)
  - 3 experts: € 700 (+21% VAT: €847)

  - Please note that 21% VAT is applicable as indicated except upon proof of VAT exemption.
  - **Please register online under www.reachclub.eu/signup
<table>
<thead>
<tr>
<th>Topic Category</th>
<th>Moderator(s)</th>
</tr>
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<tbody>
<tr>
<td>Plastics Recycling</td>
<td>M. Burstall, A. Furfari</td>
</tr>
<tr>
<td>Compounds &amp; Masterbatches</td>
<td>M. Cornu, G. Cabella, C. Dury, L. Katzmayer, J. Vuylsteke</td>
</tr>
<tr>
<td>Communications - PEST</td>
<td>G. Tillieux</td>
</tr>
<tr>
<td>Legal Issues</td>
<td>P. Bochicchio, S. Dröge</td>
</tr>
</tbody>
</table>
The Webinars

past Webinars 2010

- 15 April : REACH - Behördliche Überwachung und Sanktionen in Deutschland und Österreich
  - Speakers: Sabine Dröge and Leopold Katzmayer

- 4 May : Plastics Building and Construction
  - Speakers: Geoffroy Tillieux and Walter Claes

- 31 May : REACH and Plastics Recycling
  - Speakers: Mark Burstall and Walter Claes

- 28 June : Food contact
  - Speaker: Geoffroy Tillieux

- 27 July : Plastics Exposure Scenario Team project (PEST)
  - Speakers: Walter Claes and Geoffroy Tillieux
Upcoming Webinars 2010

- 20 October: update on PEST project
  - Speakers: Walter Claes and Geoffroy Tillieux

- 26 October, 8, 16 and 26 November:
  Recycling - the SDS-R project, C&L Notification
  - Speakers: Mark Burstall, Geoffroy Tillieux, Antonino Furfari, Walter Claes

- 7 December: REACH Authorization & Restrictions
  - Speakers: Walter Claes and Geoffroy Tillieux

The News
Information & Contact

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Interested in **Webinars**
(all topics)
hold in **French, German** or **Dutch** language?

Please contact me!

Thank you for your attention
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EuPC is the leading EU-level Trade Association, based in Brussels, representing European Plastics Converters. Its powerful European Plastics Network exists to support the beneficial use of plastics worldwide, especially providing plastics converting companies with a voice in European legislation. EuPC now totals about 51 European Plastics Converting national and European industry associations, it represents close to 50,000 companies, producing over 45 millions tonnes of plastic products every year.

The European plastics industry makes a significant contribution to the welfare in Europe by enabling innovation, creating quality of life to citizens and facilitating resource efficiency and climate protection. More than 1.6 million people are working in about 50,000 companies (mainly small and medium sized companies in the converting sector) to create a turnover in excess of 300 billion € per year. The plastics industry includes polymer producers - represented by PlasticsEurope, converters - represented by EuPC and machine manufacturers - represented by EUROMAP.

For further info see the web links below: www.plasticsconverters.eu www.plasticseurope.org www.euromap.org

Open End ...
REACH & Plastics Recycling

- The Regulatory Situation
- Safety Data Sheets
- Obtaining Information
- Next Steps

The Regulatory Situation

- Plastics are not exempt from Reach
- Recyclers are not exempt from Reach
- Waste is outside the scope of Reach
  - End of waste criteria is a matter for waste legislation
- Recovery and Recycling are considered as manufacturing processes
  - Recycled materials fall within Reach when they cease to be waste
"Recovery" in the final Reach Text


Article 2

Application

7. The following shall be exempted from Titles II, V and VI:

(d) substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and

(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.

N.B. Title II = Registration, V = Downstream Users, VI = Evaluation

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REACH and Waste

- Substances
- Mixtures
- Articles

- Waste
  - Disposal (Incineration & landfill)
  - Energy Recovery
  - Recycling

Article 2.7.(d)

- Recyclers are exempt from Registration by virtue of Article 2.7.(d) but to benefit from this
  - Recyclers were required to pre-register
    - (before 30.11.2008)
  - They should be able to show they have “access” to the registration data of their pre-registered substances
    - and that these substances are the same
  - For the purposes of registration they could ignore Impurities below 20%
Recyclers who did not pre-register

- In theory, any recycler who was processing before 1st December 2008 and did not pre-register is now trading illegally
- To rectify that they should register immediately
- However, once someone else has registered the substances that they are recycling they will again be able to rely on the exemption provided by Article 2.7(d)

Waste Recycling Industry Chain (WRIC)

- In early 2009 EuPR was instrumental in forming WRIC which comprises representatives from all the major material recycling streams
- On 26th March 2009, at the invitation of DG Enterprise, a joint workshop was held at the EU offices at which DGs Enterprise and Environment were present together with representatives from ECHA
- We presented a draft guidance document for the preparation of SDS using generic information, which was endorsed by all sectors
- This draft guidance document was welcomed by the Commission and ECHA and was intended to be developed by ECHA to form the basis of official guidance

Update on ECHA Guidance

- On 12th May ECHA published a final version of its guidance on Waste and Recovered Substances
- This can be downloaded from the ECHA website at http://guidance.echa.europa.eu/guidance_en.htm and follow the link "Guidance mainly for industrial users"
- Several important concessions for recyclers were introduced
  - No Exposure Scenarios
  - No Registration Numbers except if Art. 32 applies (Authorisation or Restriction)
  - No "Use Notification" when different from the registered substance - covered by Art. 2.7(d)
Consolidated Draft Guidance

- The documents recovery operators use to provide evidence for the "sameness" and for the safety information can be provided in the form of standardised information prepared by their associations. Such standard documents should cover all relevant aspects for those materials which comply with end-of-waste criteria.

ECHA Guidance and Safety Data Sheets

- The ECHA guidance on Waste and Recovered Substances does not cover Safety Data Sheets as originally expected.
- The SDS-R guidance developed by WRIC has now been included as Appendix 4 in the new general guidance on safety data sheets which has been developed by CEFIC with our active input. This was finalised and submitted to ECHA on 1st March 2010.
- More than 1000 comments have been received on this document and the SDS guidance is now being reviewed
  - None of these comments is on Annex IV
- Final publication is not now expected before Spring 2011
APPENDIX 4: Guidance for the provision of Information in the Supply Chain and Safety Data Sheets for Recovered Substances and Mixtures in accordance with Articles 27.6, 31 and 32 of REACH

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Safety Data Sheets

- Recyclers must provide Safety Data Sheets with their recycled material
  - Deadline to comply is 30th November 2010
- Safety Data Sheets must take account of the presence of any restricted substances or Substances of very High Concern (SvHC)
- Material containing SvHC above the relevant concentration limit triggers information obligations for substances in articles
- SvHC present in small amounts may be relevant for the hazard profile of the substance, its classification and labelling and SDS requirements.
  - They may also be subject to restrictions
What does the SDS-R need to address?

- Basic polymer
- Original additives
- Recycling additives
- Legacy hazards
  - Cadmium
  - Lead
  - Brominated flame retardants
- Contamination from use phase or collection

Sort and separate
- Removal processes
- Know supply chain
- Know process
- Traceability

EuPR Database

- Records of registration data
- All known additives – past & present
  – cross referenced to polymer type, application & historic dosing rates
- SDS information for existing additives
- Hazard profile for all additives without SDS
  – including legacy substances
- Documented data on migration from plastics
- Risk profiles and exposure scenarios for all additives
  – verified by toxicologist

SDS for Plastics recyclers – risk assessment

- Hazard profiles are being constructed for all the additives, some based on data from registration and some compiled on published information for legacy substances
- Where recycled plastics contain SvHC or restricted substances that are above the threshold level an assessment has to be made of the risk to human health and the environment posed by these substances; the risk being proportional to the amount of the hazardous substance
- This risk assessment is required to enable detailed risk management measures to be defined
- The SDS-R project is assessing these risks based on the known information and has employed a toxicologist to verify the methods used for the calculations
The IT Tool

Input = basic data from recycler
(polymer type/application/tonnage/test results)

Access EuPR database

Assess “worst case” and calculate exposure scenario

Output = SDS with risk management measures & CLP information

EuPR Guidance Document

• How to register, pay for and use the IT Tool
• What you need to know before you start
• How to create a Safety Data Sheet
• Extracts from ECHA Guidance
• Frequently Asked Questions

SDS-R Project – State of Play (1)

• Background information and functionalities have been gathered in a database matrix
  – This could lead to some 100 different SDS
  – Toxicologist is writing background report
• The Guidance Document is being developed
• The Web Site is being developed
  – β version 15.10.10?
• A series of workshops will train recyclers during Oct/Nov 2010
  – Free webinar for recyclers on 26.10.2010
SDS-R Project – State of Play (2)

- Recyclers can still input formulations that were not taken into account up to 15.11.2010
- On 15.11.2010 the set of SDS should be complete with available data and Reach compliant
- SDS-R updates will be necessary on the basis of new information from the Registration dossiers
- New information will be inserted after 1.12.2010 and in the 1st quarter 2011 and ongoing

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Activities by National Enforcement agencies

- Members in several countries have reported that their National Enforcement Agencies have started to check on recyclers who pre-registered
- Several have asked to see Safety Data Sheets in particular covering SVHC or restricted substances
  - So far it appears they are satisfied with the response that any SDS will be fully compliant by 30th November 2010
- Big retailers slammed over SVHC disclosure
  - Only 22% of large retailers in Europe met new legal requirements to inform consumers about substances of very high concern (SVHC) in their products, according to compliance checks carried out by green group EEB earlier this year

Thank you!

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REACH FOR POLYMERS

EXPERT WORKSHOP

BPF “REACH & CLP SEMINAR”

TUESDAY, OCTOBER 19th

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REACH FOR POLYMERS - THE PROJECT

Funded by the EU LIFE + Environmental Programme

Project Duration will be from January 2010 to June 2012

A collaborative project involving 8 European partners

- RAPRA Limited (UK - Lead partner)
- iSmithers (UK)
- Proplast (Italy)
- PEP (France)
- ASCAMM (Spain)
- SIRRIS (Belgium)
- PiEP (Portugal)
- CASO (Portugal)

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REACH FOR POLYMERS

PRIMARY Objective

To Create A REACH Toolkit for the European Polymer Industry

CONTRIBUTORY Objectives

- To Assess The Suitability Of Testing Techniques and Methods
- To Produce a REACH Best Practice Manual
- Monitoring and Evaluation of REACH
- Provision of Dissemination Materials and Training Activities
- To Benchmark Current Awareness and Readiness for REACH
The aim was:

- To develop a survey to evaluate the level of awareness, attitudes & practices and understanding of the European polymer industries towards the REACH legislation
- To evaluate industry’s view of the likely future impact of the REACH legislation

Benchmarking Study To Determine Current Awareness & Readiness For REACH

Method Employed

- Agreed an English language questionnaire
- Set up of an electronic version in 5 partner languages (SP – P – IT – EN – FR)
- All partners involved in electronic distribution of the survey
- All partners also conducted at least 20 face-to-face interviews
- Study completed by June 2010
- Repeat study to take place towards end of project

Scope of Benchmarking Study

Overview of Company Profiles in the Survey

- 432 companies completed the questionnaire (on line & via face-to-face)
- 72% of companies surveyed had fewer than 250 employees (many with fewer than 50)
- Main end-use markets: Automotive & Other Transport
- Main Polymer-related sector: Processors and Product Manufacturers (75%)
### Some Headline Results

**Awareness:**
- 92% had at least heard of REACH - but 8% had no idea about REACH !!!

**Level of knowledge:**
- 70% considered themselves as having an average or higher than average level of knowledge about REACH (beware – their own assessment of themselves!)

**Level of preparation:**
- 28% considered their preparation level between 0 and 4 on a scale of 1 to 10 – i.e. Poorly prepared!

**Use of a REACH consultant:**
- 17% had used an external REACH consultant at some point in recent months

### Some Further Headlines

- 20% of those surveyed did not agree with the REACH legislation (Italy: 6% disagreed : Spain 29% disagreed) – still some hearts and minds to win over!
- 62% of companies believe that REACH will have only a moderate impact and 26% said it would have no impact on their businesses
- 54% think that REACH will bring no benefits to their businesses - only 3% expected REACH to bring significant benefits

### Other Unsolicited Comments

- More than 50% expressed concern about the administrative burden (implementation – documentation) in terms of time expended and also developing their own competences – in other words EXTRA WORKLOAD!
- Many were concerned about the lack of clear concise information available about the REACH Legislation
- Many respondents did however concede that the REACH legislation would be of benefit to the environment
Report Availability

The final benchmarking report detailing the results:
• Will be available in the major project languages and disseminated widely
• Will be published on the web site
• Has been (or will be) distributed electronically to all participants at this meeting

The survey will be repeated and completed by early-2012 to evaluate any changes in perception from the market
• It should provide an excellent indicator as to demonstrating the success of the “REACH For Polymers” project overall

Expert Workshop

General Discussion Points

• How best to assist/support SMEs with the WORKLOAD issue
• How best to distil REACH information to just those areas that SMEs respectively need to understand
• How best to emphasise and communicate the positive aspects of REACH to SMEs

Expert Workshop

Detailed Discussion Points

• Administrative Burden – where does it come from – how are companies dealing with this – internal or external resources?
• Expertise – Do SMEs have the core competencies – if not where can they best acquire them?
• Information – Best sources for getting quickly and concisely to what companies REALLY need to know
• Competition – Are there examples of any market advantages by being REACH compliant?
• Compliance – What are the major compliance issues for SMEs?