GHS and REACH
Differences in the systems and timing of implementation has been required a coordination of efforts within Rhodia.

- share information on the levels of requirements and timing of implementation in the zones;
- facilitate share, acquisition and validation of the data on endpoints to be considered (hazard identification);
- develop enough experience for appropriate and harmonized dissemination of training (use of criteria and methodology for classification) and recommendations for communication (MSDS and labels) to the affected sectors: workers, transport, consumers, …
- develop tools for communication such as an e-room, letters, meetings, …
- evaluate the expected calendar and timing expected on (Material) Safety Data Sheets, Users and Transportation Labelling, and, more generally, IT systems
GHS (Globally Harmonized System) Objectives

19.27. A globally harmonized hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000.
Purpose of the GHS

- To enhance the protection of human health and the environment by providing an internationally comprehensible system for hazard communication;
- To provide a recognized framework for countries without an existing system;
- To reduce the need for testing and evaluation of chemicals; and
- To facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis.

The GHS includes:

- Harmonized criteria for the classification of substances and mixtures according to their physical, health and environmental hazards; and
- Harmonized hazard communication elements (including requirements for labels and safety data sheets).
Purpose of the GHS

Agreed Principles

- **Level of protection offered should not be reduced** as a result of harmonizing classification and labelling systems;
- **Hazard classification done on the basis of intrinsic properties** of chemicals;
- **Harmonization**: common and coherent basis for chemical classification and communication;
- **Scope of harmonization**: hazard classification criteria + hazard communication tools;
- **Transitional measures** for the implementation of the new system should be included;
- **Involvement of international organizations** should be ensured;
- **Comprehension of chemical hazard information** should be ensured;
- **Validated data under existing systems should be accepted** for reclassification of chemicals according to the new system;
- New system may require **adaptation of existing methods for testing** of chemicals;
- **In relation to chemical hazard communication, the safety and health** of workers, consumers and the public in general, **as well as the protection of the environment, should be ensured while protecting confidential business information**, as prescribed by the competent authorities;
Application of the GHS

The **GHS** will allow the **hazard communication elements of the existing systems to converge**.

**Competent authorities** will decide how to apply the various elements of the GHS based on the needs of the competent authority and the target audience.

The **harmonized elements of the GHS** may be seen as a collection of **building blocks** from which to form a regulatory approach.

**Countries are free to determine which of the building blocks will be applied in different parts of their systems.**

**However…**

…where a system covers something that is in the GHS, and implements the GHS, **that coverage should be consistent**. For example, if a system covers the carcinogenicity of a chemical, it should follow the harmonized classification scheme and the harmonized label elements.

**GHS is not intended to harmonize risk assessment procedures or risk management decisions** (such as establishment of a permissible exposure limit for employee exposure), which generally require some risk assessment in addition to hazard classification.

Chemical inventory requirements in various countries are not related to the GHS.
### GHS Labelling

#### Acetone

<table>
<thead>
<tr>
<th>Current Classification European Directive 67/548/EEC</th>
<th>Proposed EU Classification GHS</th>
<th>Japanese Classification in force GHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable liquids: Category 2</td>
<td>Flammable liquids: Category 2</td>
<td>Flammable liquids: Category 2</td>
</tr>
<tr>
<td>Serious eye damage / eye irritation: Category 2</td>
<td>Serious eye damage / eye irritation: Category 2</td>
<td>Serious eye damage / eye irritation: Category 2</td>
</tr>
<tr>
<td>TOST single exposure: Category 3</td>
<td>TOST single exposure: Category 3</td>
<td>TOST repeated exposure: Category 2</td>
</tr>
</tbody>
</table>

**Pictograms**

#### Toluene

<table>
<thead>
<tr>
<th>Current Classification European Directive 67/548/EEC</th>
<th>Proposed EU Classification GHS</th>
<th>Japanese Classification in force GHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable liquids: Category 2 Aspiration Hazard: Category 1</td>
<td>Flammable liquids: Category 2 Aspiration Hazard: Category 1</td>
<td>Flammable liquids: Category 2 Aspiration Hazard: Category 1</td>
</tr>
<tr>
<td>Skin corrosion / irritation: Category 2</td>
<td>Skin corrosion / irritation: Category 2</td>
<td>Skin corrosion / irritation: Category 2</td>
</tr>
<tr>
<td>TOST single exposure: Category 3</td>
<td>TOST single exposure: Category 3</td>
<td>TOST repeated exposure: Category 2</td>
</tr>
<tr>
<td>Toxic to reproduction: Category 2</td>
<td>Toxic to reproduction: Category 2</td>
<td>Toxic to reproduction: Category 1</td>
</tr>
</tbody>
</table>

**Pictograms**
Brazil – Current Status

**Safety Data Sheet**
Draft ABNT NBR 14725 from December 2007.

**Labelling**

**Classification**

**Terminology**

End of August 2008 → expected to be submitted to public consultation. In force 18 months after official publication.
Brazil – Current Status

Too much work still to be done ...

- FISPQs, Labelling, Classification and Terminology standards must be approved and published;
- **Transition rules** and **deadlines** for implementation must be defined;
- Similar classification systems acceptance *(mostly during transition)*;
- Acceptance criteria for internationally recognized data and/or tests performed before GHS in force must be established;
- National laboratories must be prepared to perform GHS tests *(with international recognition)*;
- Brazilian regulations should be reviewed to minimize conflict and/or redundancies with GHS;
- CBI – Confidential Business Information;
- Training and awareness;
- Costs.
The current EU classification and labelling system for chemicals is set out in three key instruments:

- the Dangerous Regulation (EC) 1907/2006; originally the Safety Data Sheet Directive (Substances Directive 67/548/EEC);
- the Dangerous Preparations (i.e. mixtures of chemicals) Directive 1999/45/EC;
- Annex II of the REACH 91/155/EEC.

These Directives and the Regulation are very closely linked.

For international transport purposes, classification and labelling systems mirror the international transport regulations for all modes of transport. For national transport purposes Directives 94/55/EC (road) and 96/49/EC (rail), as amended, apply the provisions of ADR and RID respectively.
GHS in the European Union

EU Context and Implementation Update

The recommendation of the World Summit on Sustainable Development has been taken up by all EU Member States. In several instances Member States called upon the Commission to adopt the GHS. Accordingly, the Commission services have indicated in various fora that the GHS will be incorporated into Community legislation.


Both the European Council and the European Parliament consider the Regulation implementing the GHS as a high priority, and are working with a tight agenda to secure final adoption in the autumn 2008. Formal adoption by the Council and Parliament in the autumn would allow publication and entry into force of the Regulation by end of 2008, allowing the European Union to honour its international commitments to have the system operational by 2008.
Next steps

Safety Data Sheets

One of the next tasks of the Commission services will be to adapt Annex II of the REACH Regulation which includes the provisions on Safety Data Sheets, to align them fully with the UN GHS provisions.

Guidance documents

The preparation of detailed guidance for the application of the GHS criteria is under development in the framework of REACH Implementation Project 3.6 (RIP 3.6 – Classification and Labelling). It is expected that the guidance will be finalised in early 2009.

In parallel to specific guidance, general guidance is also being developed, focusing on basic features and procedures related to classification and labelling in the EU context. The guidance is addressed to those who want to have a quick overview of the new legal requirements for classification and labelling in the EU, i.e. suppliers of chemicals and non-EU target groups. This guidance document will be made available by the time the EU legislation enters into force.
### GHS in the European Union

#### 1. Acute Toxicity – Oral

<table>
<thead>
<tr>
<th>EU</th>
<th>T R28</th>
<th>T R25</th>
<th>Xn R22</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD₅₀(*)</td>
<td>≤ 5</td>
<td>5-25</td>
<td>25-50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GHS</th>
<th>Cat. 1</th>
<th>Category 2</th>
<th>Category 3</th>
<th>Category 4</th>
<th>Category 5</th>
</tr>
</thead>
</table>

**Remarks:**

(*) Alternative EU criteria when using the “Fixed Dose” procedure:

- T R28: oral, rat ≤ 5 mg/kg: < 100 % survival
- T R25: oral, rat 5 mg/kg: 100 % survival but evident toxicity
- Xn R22: oral, rat 50 mg/kg: 100 % survival but evident toxicity
- 500 mg/kg: < 100 % survival

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**Responsible Care Latin America**

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GHS in the European Union

11. Carcinogenic Substances

<table>
<thead>
<tr>
<th>EU</th>
<th>Category 1</th>
<th>Category 2</th>
<th>Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T R45 &amp; T R49</td>
<td>T R45 &amp; T R49</td>
<td>Xn R40</td>
</tr>
</tbody>
</table>

**Criteria**

- **Category 1**
  - Substances known to be carcinogenic to man.
  - There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

- **Category 2**
  - Substances which should be regarded as if they are carcinogenic to man.
  - There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:
    - appropriate long-term animal studies,
    - other relevant information.

- **Category 3**
  - Substances which cause concern for man owing to possible carcinogenic effects.
  - Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in Category 2.

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**GHS**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Category 1A</th>
<th>Category 1B</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemicals known to have</td>
<td>Chemicals presumed to have carcinogenic potential</td>
<td>Suspected human carcinogens</td>
<td></td>
</tr>
<tr>
<td>carcinogenic potential</td>
<td>for humans; the placing of a chemical is largely</td>
<td></td>
<td></td>
</tr>
<tr>
<td>for humans; the placing</td>
<td>based on human evidence</td>
<td></td>
<td></td>
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<tr>
<td>of a chemical is largely</td>
<td>Based on strength of evidence together with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>based on animal evidence</td>
<td>additional considerations, such evidence may be</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>derived from human studies that establish a</td>
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</tr>
<tr>
<td></td>
<td>causal relationship between human exposure to</td>
<td></td>
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<tr>
<td></td>
<td>a chemical and the development of cancer (known</td>
<td></td>
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<tr>
<td></td>
<td>human carcinogen). Alternatively, evidence may</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>be derived from animal experiments for which</td>
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<tr>
<td></td>
<td>there is sufficient evidence to demonstrate</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>animal carcinogenicity (presumed human carcinogen)</td>
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<td></td>
<td>In addition, on a case by case basis, scientific</td>
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<td></td>
<td>judgement may warrant a decision of presumed</td>
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<tr>
<td></td>
<td>human carcinogenicity derived from studies</td>
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<tr>
<td></td>
<td>showing limited evidence of carcinogenicity in</td>
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<tr>
<td></td>
<td>humans together with limited evidence of</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>carcinogenicity in experimental animals</td>
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<td></td>
</tr>
</tbody>
</table>

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R45 = may cause cancer
R40 = Limited evidence of a carcinogenic effect