

# GHS AND REACH



# GHS - GLOBALLY HARMONIZED SYSTEM

## of Classification and Labelling of Chemicals

GHS is a system proposed by the United Nations (UN) for the harmonised world-wide classification and labelling of chemical products. The aim of GHS is the international harmonisation of existing classification and labelling systems.

In the European Union, GHS is implemented by Regulation (EC) No. 1272/2008, which is also known in short as the CLP Regulation (CLP = Classification, Labelling, Packaging). It gradually supersedes the previous classification and labelling system (EU system) valid until 2015 which is based on Dangerous Substances Directive 67/548/EEC and Dangerous Preparations Directive 1999/45/EC.

### Timetable for the introduction of GHS labelling:

Substances	EU system or GHS	GHS only	
Compounds	EU system or GHS	GHS only	
	20.01.2009	01.12.2010	01.06.2015

### What is new?

- **Signal word:**
  - DANGER** denoting high hazard level
  - CAUTION** denoting a lower hazard level
- **Hazard and Precautionary Statements:** Hazard Statements (H) and Precautionary Statements (P) supersede the previous Risk Phrases (R) and Safety Phrases (S).  
New coding and in part different wordings.  
Example: R 39 „Danger of very serious irreversible effects.“  
-> H 370 „Causes damage to organs“.
- **Hazard pictograms:**



Exploding bomb



Flame



Flame over circle



Gas cylinder



Corrosion



Skull and crossbones



Health hazard



Exclamation mark



Environment

## What changes do the new pictograms bring?



New hazard class and new pictogram: „gas cylinder“

Denotes gases under pressure.

Pressurised gases were not previously labelled according to the EU system.

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New pictogram: „health hazards“

Denotes substances involving different types of health hazard:

- substances causing allergy on inhalation,
  - substances which can be fatal upon swallowing and entry into the respiratory passage,
  - substances which are carcinogenic, mutagenic and/or toxic to reproduction
  - substances which can cause organ damage.
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New pictogram: „exclamation mark“

This is used for less serious hazards and replaces the symbol „harmful“ (St. Andrew's Cross) in certain cases.

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The definition of the pictogram „corrosion“ has been expanded:

- It still denotes the corrosive effect on the skin and mucus membranes.
- It now also denotes the corrosive effect on metals. According to the EU system, there was previously no identification mark for metal corrosion.

**Please read the hazard warnings on the label precisely.**

Note: substances which can cause serious eye damage and were previously marked „Xi“ now require the pictogram „corrosion“ for classification into category 1.

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The pictogram „skull and crossbones“ denotes only harmful effects which occur within 24 hours after a substance or mixture has been swallowed, exposed to the skin, or inhaled for 4 hours („acute toxic“ effects). Chronic effects on health, e.g. CMR properties, are not labelled with „skull and crossbones“, rather with the new pictogram „health hazards“. A further significant change is the new toxicity limits as of which substances are to be classified as acutely toxic, with the result that some substances previously marked with the St. Andrew's Cross now require the „skull and crossbones“ pictogram.

**This does not alter the effect of substances.**

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The „St. Andrews Cross“ (marking harmful) will no longer be used acc. to GHS.

Depending on hazard class and category, it will be replaced by





# REACH - REGISTRATION, EVALUATION AND AUTHORISATION OF CHEMICALS

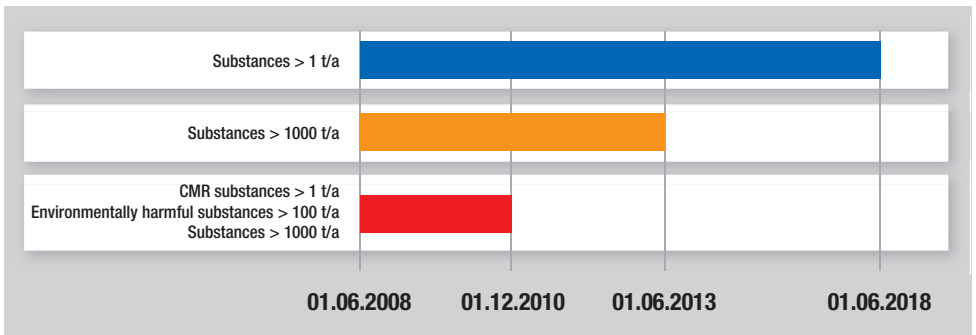
## No data, no market

The European chemicals regulation REACH has been in force since 1 June 2007. Since 1 June 2008, chemicals in quantities of 1 t/a or more may only be manufactured or imported if they have previously been registered and evaluated. This means that all existing substances (i.e. substances which came onto the market before 1981) over 1 t/a must now be checked systematically for their hazardous properties, this previously being requisite for new substances only. Particularly hazardous substances are subject to an approval procedure. Manufacturers and importers must procure the data required for evaluation. The extent of the data to be presented with the application is dependent upon the amount of the substance to be produced. Compliance with REACH is monitored by the European Chemicals Agency (ECHA) in Helsinki and the competent national authorities.

If during the safety assessment conducted as part of the registration process it is found that a substance has hazardous properties, the manufacturer or importer must determine the potential exposure based on known uses; in future, the substance may only be put to these specific uses.

## Registration

For phase-in substances, essentially the above-mentioned existing substances, REACH allows transitional arrangements depending on the amount produced and the hazardousness of a substance. To be able to invoke such transitional arrangements, the substances must have been preregistered by manufacturers and importers during 2008. In January of 2009, the ECHA published on its website a list of all preregistered substances. Preregistered substances may continue to be placed on the market until such time as they are finally registered. Deadlines have been established for final registration, these being dependent upon the amount manufactured (per manufacturer or importer).



*Deadlines for registration under REACH*

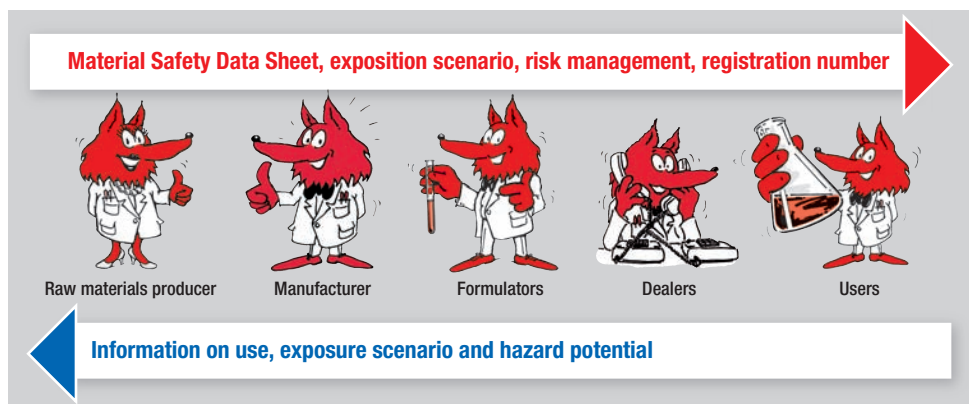
## Information exchange fora

The purpose of preregistration is to group together all manufacturers and importers of an identical substance in a SIEF (Substance Information Exchange Forum) in order to avoid duplication of studies and obtain agreement on the classification and labelling of a substance.

## Information along the supply chain

Under REACH, chemical, physical, toxicological and ecotoxicological data must be acquired in an application and exposure related manner, made available and communicated along the supply chain. Information flows not only from the manufacturer via the dealer to the user; the user is also obliged to give back information. If any user has new information about hazardous properties of a substance, the user must pass this information on to the supplier.

This information must be transmitted by means of extended safety data sheets. The registration number which the ECHA allocates to a substance as soon as the registration dossier is complete must be stated in the Material Safety Data Sheet.



## Chemical Safety Assessment

The registering party must conduct a Chemical Safety Assessment (CSA) for substances manufactured or imported in a quantity of 10 t/a or more. The results of the Chemical Safety Assessment are based on the Chemical Safety Report (CSR) which is submitted to the ECHA along with the registration dossier.

Exposure scenarios together with their respective conditions of use and risk management measures for adequate hazard control can be derived from the Chemical Safety Assessment.

The exposure scenarios are depicted in the Chemical Safety Report and communicated to downstream users as an annex to the Safety Data Sheets.

## **Authorisation, Restrictions**

Certain substances listed in Annex XVII of the REACH Regulation may only be manufactured, placed on the market or used if the conditions specified therein are met. These restrictions must be observed by manufacturers and importers, but also by downstream users. They do not apply if substances have been manufactured, placed on the market or used in conjunction with scientific research and development. CMR substances, PBT and vPvB substances as well as substances with similar serious impacts on human health or the environment are classified as „substances of very high concern“ (SVHC). These are, irrespective of quantity thresholds, subject to an authorisation procedure and included in a directory in Annex XIV of the REACH Regulation.

The first six substances have recently been added to Annex XIV, and the procedure for inclusion into Annex XIV of several other substances is ongoing. After inclusion, each listed substance will have a specified date after which it may no longer be produced or used without authorisation by ECHA.

Moreover there exists a List of Candidates containing 46 substances which have been proposed for inclusion in this directory. These substances are not yet subject to any restrictions, but manufacturers and importers are already obliged to notify users of their presence in products.

## **REACH at ROTH**

ROTH has used the preregistration phase to preregister all relevant substances. Therefore, ROTH can guarantee that its current product portfolio will remain available as it is until the expiration of the registration deadlines. In addition, ROTH will ensure that its proven products remain unrestrictedly available beyond this date. ROTH undertakes to meet all its obligations to inform its customers, and will provide them with all necessary information in good time.

After registration, the registration number will be specified in the Material Safety Data Sheet along with the supported use and exposure categories. Only when you, the downstream user, receive the new Material Safety Data Sheet containing a registration number do any of the obligations in connection with the stated exposure scenarios come into effect. We will update existing Safety Data Sheets as soon as new risk management measures are made known to us.

## **Do you have any queries regarding REACH or need any assistance with REACH?**

Please contact our REACH specialist, Dr. Hagel:

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Alternatively, avail yourself of the information and assistance provided by the Federal Institute for Occupational Safety and Health and the German Industry Association:

<http://www.reach-clp-helpdesk.de>

<http://reach.bdi.info>

## REACH and GHS

Different areas of regulation based on the same data:

### REACH

Registration, evaluation  
and authorisation

All substances

Only above defined  
quantity thresholds



### GHS

Classification, labelling  
and packaging

Only substances and mixtures  
with hazardous properties

Irrespective of quantity

Physicochemical, toxicological and ecotoxicological data



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