



REACH & GHS UPDATE

April, 2008

UPDATE ON GHS [EU regulation to implement the UN Globally Harmonised System for classification and labelling of substances and mixtures and amend parts of REACH (EC/1907/2006)]

Summary

This proposal is now going through the European Institutions. The Council Working party (Member States forum) is examining the detail and the European Parliament is yet to consider it. They are both aware of the need for adoption in 2008 to align with the REACH timetable.

Background

In order to honour international obligations, the European Commission submitted its proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures on 27 June 2007. The GHS proposal is taking some priority in negotiations in the EU institutions.

There are 2 elements to the negotiations on the GHS proposal:

1. Relates to REACH. The ongoing implementation of REACH requires early adoption of the GHS regulation so that it can be implemented in parallel with the various steps of REACH. The only means to achieve this is to reach a first reading agreement between the EU Institutions – the Commission, Council and Parliament (historically this has been difficult to achieve).
2. Relates to the effect GHS will have on other downstream legislation on chemicals which covers environmental, health and safety aspects of the use and disposal of substances.

Implications for REACH

The Council Working Party on Technical Harmonisation (Dangerous Substances) has started a detailed examination of the proposal. A first reading of all the articles in the text has been achieved and an informal network of experts has been established

to examine the contents of the Annexes to check their conformity with the UN GHS and with existing Community legislation.

At this stage, all EU Member States (MS) have welcomed the proposal and confirmed that they are prepared to contribute to a swift adoption of it but many have, as usual, in such negotiations “reserved their positions”. Several member states have specific reservations on certain articles and almost all have linguistic reservations.

The main concerns are:

a) Although most delegations agree that the proposed regulation shall, in principle, only apply to substances and mixtures already within the scope of the EU legislation on classification and labelling, many requests for clarification of the scope have been made.

b) The exact obligations for the different actors in the supply chain (manufacturers, importers, distributors and downstream users) have been discussed against the background that they do not have the same access to information relevant for classification and labelling.

c) The confidentiality provisions of the proposal have been questioned by delegations as they believe that they could lead to a decreased level of protection of consumers and other users of chemicals, in particular as concerns occupational health.

d) The proposal contains special rules for labelling of, and information concerning, chemicals distributed in small or otherwise awkward packages. Here, it has been questioned whether the information provided to users will be as complete as under the current EU system.

e) A distinction is made in the proposal between the concepts "hazardous" and "dangerous". This distinction is important for downstream legislation. In most Community languages however one single word is used for both concepts. Various attempts to resolve this problem have been suggested, but none of them has so far been sufficiently developed.

f) Many delegations stress the need for adequate information to be available in the language of the end users and therefore see a need to further scrutinize the provisions on language-use on labels.

g) Many members have also expressed concern that changes to the regulation can be made by internal Commission provisions (Comitology) and have insisted that in accordance with the new Comitology Decision, the regulatory procedure with scrutiny must be applied when measures of general scope designed to amend non-essential elements of the Regulation are adopted through Comitology.

Implications for other legislation

Classification of substances and preparations under the currently applicable Directives on substances and preparations triggers obligations in other pieces of EU legislation, referred to as downstream legislation. Since the Regulation on classification, labelling and packaging of substances and mixtures is intended to replace these Directives, amendments to the downstream legislation must also be introduced.

The Commission has so far presented two Proposals covering a number of downstream acts (to bring them in line with classification under GHS) in the areas of cosmetics, toys, volatile organic compounds (VOCs), end of life vehicles, waste from electronic and electrical equipment, VOCs in paints, varnishes and vehicle refinishing products and detergents. These proposals will be examined by the Working Party with the aim of reaching an agreement between the Institutions on these at the same time as an agreement is reached on the GHS Proposal.

There are other downstream requirements, including the Seveso II Directive on control of major hazards, where the implementation of GHS is expected to have a substantial impact, and where the necessary measures will have to be introduced in further separate amendments.

The progress was formally noted at the Competitiveness Council session of 22 and 23 November.

The Parliament is examining the proposal in the Environment Committee and hopes to give its first-reading opinion in May or June 2008.

UPDATE ON REACH FEES

In the latest informal draft currently being considered within the Commission there has been a change to the fees proposed for 'only representatives'. Only representatives will be entitled to claim a reduction in fees payable by SMEs only after an assessment of the total size of the non-EU manufacturer that they represent. The change from the Commission's earlier draft appears to have come in response to the lobbying of EU industry groups.

UPDATE ON GUIDANCE DOCUMENTS

The list below contains the current state of play on the Guidance Documents which are available, or will be available, on the website http://reach.jrc.it/guidance_en.htm . They will help businesses and enforcers implement REACH by describing good practice on how to fulfil the obligations; N.B. they will be guidance only and not legally binding although a court would no doubt take them into consideration. Some parts of these documents have been or will be translated into all the European Community languages. These documents have been developed with the participation of many stakeholders (Industry, Member States and NGOs) within projects managed by the Commission. They are categorised under:

Guidance on the different processes under REACH

- a. Guidance mainly for Industry use
- b. Guidance mainly for Authorities use
- c. Guidance on the different methods under REACH

Information on the guidance on the different processes under REACH mainly for Industry Use is identified below:

Guidance on registration

Can be found at http://reach.jrc.it/docs/guidance_document/registration_en.pdf

This document describes when and how to register a substance under REACH. It consists of two parts: one on Registration tasks and obligations and the other on the preparation of the Registration Dossier.

Guidance on pre-registration

This document is not yet available. Nevertheless, the Guidance on data sharing is available now and it contains a chapter on pre- registration. The document will describe how to identify the substances that can be pre-registered as well as when and how to pre-register them.

Guidance on data sharing

Can be found at http://reach.jrc.it/docs/guidance_document/data_sharing_en.pdf

This document describes data sharing mechanisms for phase-in and non phase-in substances under REACH. It includes the communication within the SIEF and the cost sharing guidance. The document also describes the Confidential Business Information and Competition Law issues in the context of data sharing.

Guidance for intermediates

Can be found at http://reach.jrc.it/docs/guidance_document/intermediates_en.pdf

This document describes when and how the specific provisions for the registration of intermediates under REACH can be used.

Guidance for monomers and polymers

A revised version, made available in March 2008, can be found at

http://reach.jrc.it/docs/guidance_document/polymers_en.pdf

This document describes the specific provisions for polymers and monomers under REACH.

Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)

Can be found at http://reach.jrc.it/docs/guidance_document/ppord_en.pdf

This document describes specific provisions under REACH for substances manufactured, imported or used in scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD).

Guidance on Classification and Labelling notification

This document is not yet available but will describe when and how to notify a classification and labelling for a substance under REACH.

Guidance on requirements for substances in articles

The final version of this document is not yet available. It is being developed within RIP 3.8 (see <http://ecb.jrc.it/reach/rip/> for more information). It is expected that a final version will not be available until late 2008.

The document will assist producers and importers of articles in identifying whether they have obligations under REACH; in particular in relation to registration and notification according to Article 7, and in relation to article supply chain communication according to Article 33.

Guidance for Downstream Users

The final version of this document is not yet available. It is being developed within RIP 3.5 (see <http://ecb.jrc.it/reach/rip/> for more information). In order to cover the most urgent guidance needs two key sections have been finalised. These documents can be found on the ECB website (<http://ecb.jrc.it/reach/>) in the DOCUMENT section. Select PUBLIC ACCESS and then RIP FINAL REPORTS

RIP 3.5 DOWNSTREAM USERS REQUIREMENTS

RIP 3.5-2 DOWNSTREAM USERS REQUIREMENTS

The documents will describe the roles and obligations of downstream users, and will advise them on how to prepare for the implementation for REACH.

Guidance on the preparation of an application for authorisation

The final version of this document is not yet available. It is being developed within RIP 3.7 (see <http://ecb.jrc.it/reach/rip/> for more information)

The document will describe how to prepare an application for authorisation and will provide guidance on analysis of the alternatives and substitution plan. It also will describe how third parties may prepare and submit information on alternatives.

Information on the guidance on the different methods under REACH of relevance to industry is:

Guidance for identification and naming of substances in REACH

Can be found at http://reach.jrc.it/docs/guidance_document/substance_id_en.pdf

This document describes how to name and identify a substance under REACH.

Guidance on how to comply with the provisions of the new Regulation on Classification, Packaging and Labelling of substances and mixtures (under GHS)

The final version of this document is not yet available. It is being developed within RIP 3.6 (see <http://ecb.jrc.it/reach/rip/> for more information). It is expected that a final version will be available in 2008. This document aims to assist industry and authorities to implement the new GHS criteria within the EU which are based on the UN Globally Harmonised System for the Classification and Labelling of chemicals (GHS) and to fulfil the relevant procedures.

Guidance for the preparation of the Chemical Safety Report

The final version of this document is not yet available. It is being developed within RIP 3.2 (see <http://ecb.jrc.it/reach/rip/> for more information). It is expected that a final version will be available in 2008. This document aims at assisting industry in conducting Chemical Safety Assessments and preparing Chemical Safety Reports, when required, as part of a registration dossier (for a substance on its own or as part of a preparation or as released from an article), as part of an authorisation application or as part of downstream user obligations. It also sets out the basic principles for authorities preparing a risk assessment in support of a restriction proposal, and when required as part of a Substance Evaluation.

Guidance on information requirements under REACH

The final version of this document is not yet available. It is being developed within RIP 3.3 (see <http://ecb.jrc.it/reach/rip/> for more information). This document will provide guidance on the collection and assessment of the available information on the intrinsic properties of the substances to be registered, on the requirements specified by REACH, on the identification of data gaps and on the generation of the additional information required to comply with the Regulation.

Guidance on Socio Economic Analysis

The final version of this document is not yet available. It is being developed within RIP 3.9 (see <http://ecb.jrc.it/reach/rip/> for more information). It is expected that a final version will be available in 2008. This document will assist the different actors in

preparing a socio-economic analysis or input for one as part of the Authorisation and Restriction procedures.

Guidance on priority setting for evaluation

The final version of this document is not yet available. It is being developed within RIP 4.5 (see <http://ecb.jrc.it/reach/rip/> for more information). The document will describe the different priority setting methods developed to prioritise dossiers, testing proposals or substances for evaluation and will give guidance for the Agency and the Member States Competent Authorities on the application of these methods.

Guidance on IUCLID

http://reach.jrc.it/docs/guidance_document/iuclid_en.pdf

This document (running to more than 2000 pages) describes how to use IUCLID 5 and how to prepare the dossiers for different REACH requirements.