

Public Consultation on the Implementation of the UN Globally Harmonised System (GHS) Hazard Classification for Reference Standards

Consultation ends 30 April 2011



The European Directorate for the Quality of Medicines & HealthCare (EDQM) has completed the United Nations Economic Commission for Europe (UNECE) Globally Harmonised System (GHS) hazard classification assessment of substances that the EDQM supplies as reference standards. The proposed classifications are available at the Quality, Safety & Environment webpage of the EDQM Internet [website](#)¹. All stakeholders are invited to review and, if necessary, comment on the proposed classifications of the reference standards. Comments that are justified, supported by raw data and submitted either by e-mail QSEU@edqm.eu or via the EDQM [HelpDesk](#)² will be taken into consideration. This consultation ends on 30 April 2011, after which the EDQM will finalise and publish the classifications. This article also outlines the EDQM's basic principles of hazard management of substances.

1 Regulatory background

The United Nations Economic Commission for Europe (UNECE) Globally Harmonized System (GHS) sub-committee develops recommendations for classification and labelling of chemicals³. The recommendations have been enacted in European Union law⁴ and are in the process of being introduced into national legislature globally, for example in Switzerland, Russia, China and the USA. The GHS addresses hazards to occupational health and the environment based on the intrinsic properties of chemicals, irrespective of quantities. Therefore, the GHS is applicable to Reference Standards. The GHS also underpins the recommendations or laws for substances of very high concern, such as United Nations Environmental Programme agreements⁵ and REACH⁶. Biological preparations are outside the scope of the GHS⁷

¹ <http://www.edqm.eu/en/Quality-Safety-amp-Environment-76.html>

² <http://www.edqm.eu/hd,topic:02-Quality,SafetyandEnvironment/07.HowcanIcommentonyourMSDS?>

³ More information currently at http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

⁴ Regulation (EC) No 1272/2008.

⁵ Rotterdam Convention, Stockholm Convention, Strategic Approach to International Chemicals Management *etc.*

⁶ Regulation (EC) No 1907/2006 corr.

⁷ Directive 2000/54/EC instead applies in the EU.

2 EDQM implementation of hazard management

2.1 Objectives and responsibilities

The EDQM, together with the network of competent authorities of Council of Europe member states, oversees public health through programmes ensuring the quality of medicines and healthcare. Occupational health and environmental risks are managed by avoiding the use of substances of very high concern when alternatives are available. For reasons of quality, the quantities of reference standards in the containers are usually limited to a single use. The total quantity of any EDQM material, including reference standards, is below one tonne per year. The materials dispatched by the EDQM are intended for laboratory use under controlled conditions. These materials are not released to the environment under normally or reasonably foreseeable conditions of use.

This public consultation aims to improve the accuracy and completeness of the hazard classifications of the materials that the EDQM supplies as Reference Standards for the European Pharmacopoeia or, on behalf of the World Health Organization (WHO), for the International Pharmacopoeia. The EDQM proposed classifications are only intended for consultation at this stage and any other use is the sole responsibility of the user. Suppliers and downstream users are responsible for protecting occupational health and the environment at their site in accordance with applicable laws, notably when handling pharmacologically active substances in large quantities. The Organisation for Economic Co-operation and Development (OECD) and the European Chemicals Agency (ECHA) are endeavouring to harmonise hazard classifications.

2.2 Source data

The secretariat of the EDQM classifies reference standards based on the OECD/EU harmonised classifications, supplier Safety Data Sheets (SDS) and literature research. In addition and when applicable, the EDQM assesses the risks with regard to the pharmacological properties, as described in the Summaries of Product Characteristics (SmPC) published by the competent authorities of member states and the Anatomical Therapeutic Chemical (ATC) classification system of the WHO Collaborating Centre for Drug Statistics Methodology. The classifications of the International Agency for Research on Cancer (IARC), also part of the WHO are likewise taken into account. The EDQM does not carry out toxicity or eco-toxicity studies of the OECD Test Guidelines⁸. The information used by the EDQM for classification may be incomplete, especially for synthesis by-products, degradation products and other impurities, as well as substances for well-established use.

2.3 Hazard classification

The EDQM classifies all materials supplied as reference standards according to the GHS or Directive 2000/54/EC.

⁸ Enacted by Regulation (EC) No 440/2008, as amended

2.4 Hazard communication on Safety Data Sheets (SDS)

Once the consultation has been finalised the EDQM will incorporate these classifications into the SDSs of all potentially hazardous Reference Standards for which GHS data is available. Thus, the EDQM will maintain SDSs for:

- all pharmacologically-active substances,
- impurities with EC EINECS/CAS numbers, *e.g.* raw materials for synthesis,
- impurities with known or suspected genotoxicity, and
- biological reference preparations (BRP) classified as infectious in accordance with Directive 2000/54/EC.

Having regard to the article 31 (1) of Regulation (EC) No 1907/2006 as amended, the EDQM will publish a list of reference standards with no identified hazards.

The EDQM considers substances for which no GHS data exists, in particular synthesis by-products and degradation products, as being at least as hazardous and the substance to which they are related. The EDQM will refer to them in the SDS of the Reference Standard to which they are related.