### Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

**Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals** 

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Work on the Globally Harmonized System of
Classification and Labelling of Chemicals:
Potential hazard issues and their presentation
in the Globally Harmonized System

# Proposal to reconsider the inclusion of endocrine disruptor in the GHS hazard classification

Submitted by the expert from China

#### I. Introduction

1. In April this year, the European Union officially added endocrine disruptor as a hazard class in the CLP Regulation (Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures). And the European Union is now proposing to add endocrine disruptor as a hazard class to the GHS.

## II. Proposal

2. The expert from China suggests the Sub-Committee reconsider the inclusion of endocrine disruptor as a hazard class in the GHS, for the following reasons.

#### III. Justification

- 3. First, endocrine disruption is a mode of action that may lead to an adverse effect rather than an adverse effect itself. The original intent of GHS was to establish a globally harmonized classification and labelling system to classify, categorize and communicate hazards in order to raise awareness and to take appropriate risk management measures to protect stakeholders. The major concerns are the expected hazardous effects after exposure (e.g., corrosive to the eyes or acute toxicity by inhalation route) and the appropriate risk management measures. The GHS focusses on classifying and communicating harmful effects, no matter how they are caused. The mode of action triggering the hazardous effects should not be the focus of attention of GHS and will not be informative for non-experts. Endocrine disruption might result in harm that is already addressed by existing GHS hazard classes (e.g., reproductive toxicity, specific target organ toxicity, etc.). However, whether the reproductive toxicity, for example, is caused by endocrine disruption does not make a difference to the hazard itself. By adding endocrine disruptor as a hazard class, it actually changes the effect-based "principle" of the classification system.
- 4. Second, the inclusion of endocrine disruptor as a hazard class may lead to double classification and thus compromise the clarity of hazard communication. For example, a substance may be reproductive toxic due to endocrine disruption. By

employing both hazard statements for reproductive toxicity and endocrine disruptor, we actually use two phrases to describe the same thing. And, it seems this would not enhance the level of protection provided for stakeholders, but would rather raise confusion in hazard communication.

- 5. Last but not least, our science and technology in evaluating endocrine disruption is still under development, but the potential impact for the inclusion of endocrine disruptor as a hazard class can be significant. Current assessment criteria proposed for endocrine disruption are inadequate, lacking valid and reliable standardized test methods, and the mechanisms of action are presumption and to be understood. Because of the insufficiency of science and lack of rigor in criteria, the implementation of classification criteria tend to be stricter than necessary. For example, the criteria for endocrine disruption assessment used in the European Union CLP regulation deviate from the WHO definition of endocrine disruptors, by allowing chemical substances to be classified as endocrine disruptors, Category 2 in the absence of evidence of significant adverse effects in whole organisms. And, the European Commission assumed in the CLP Impact Assessment that 9% of REACHregistered chemicals would be classified as endocrine disruptors in accordance with the CLP Regulation. Is it really wise using the premature science to classify such a great amount of chemicals as hazardous without additional protection to health and environment? Will disparities in knowledge and information on this subject exacerbate inequality between countries or regions, going against the sustainable development idea behind GHS?
- 6. Thus, the expert from China invites the Sub-Committee to reassess the necessity to include endocrine disruptor as a new hazard class.

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