

Invitation to the seminar organized by the Contact Group Health and Chemistry (CGC) and the The Netherlands Society of Occupational Medicine (NVAB) with the title:

## **To a harmonized system for classification of chemical substances. How to weigh the evidence for reproductive toxicity?**

**On Thursday June 10 2010 starting 13:00 h at the Golden Tulip Hotel Central,**  
Burgemeester Loeffplein 98, 5211 RX 's-Hertogenbosch, tel. +31 73 6926926  
Hotel Central is situated at the market on walking distance from the railway station,  
see [www.goldentuliphotelcentral.nl](http://www.goldentuliphotelcentral.nl) for directions

### **Background**

During your work as a health professional, you have probably discovered how practical it is to be able to consult a list with all the substances that have been known for their reproductive hazard. Today, we will look behind the scenes and find out how difficult it is to decide whether substances should be on this list or not. How to weigh the evidence from animal experiments when no human data are available? Is a reduction in growth rate of a pup an adverse effect? What is the critical effect of a substance and when do we consider an effect adverse? In this meeting, we want to compare the methods of classification of chemicals for reproductive toxicity used in the USA and The Netherlands.

In the USA, the state of California publishes a list of chemicals known to cause developmental toxicity as part of Proposition 65 ([http://www.oehha.org/prop65/prop65\\_list/Newlist.html](http://www.oehha.org/prop65/prop65_list/Newlist.html) is the website; it includes a link to the complete current list). Chemicals can be proposed for listing on Proposition 65 by a variety of ways, including those based on an evaluation conducted by an authoritative body. One authoritative body is the Center for the Evaluation of Risks to Human Reproduction (CERHR), as part of the National Toxicology Program (more information at <http://cerhr.niehs.nih.gov/>). For this meeting, we invited the acting director of this program, Dr. Kristina Thayer, to explain their selection mechanism and the procedure followed for the classifications, and to highlight some of the dilemmas encountered in the process of classification.

The classification in the Netherlands is carried out by the Subcommittee on Classification of Reproduction toxic substances of the Dutch Expert Committee on Occupational Safety (DECOS) of the Health Council (more information at <http://www.gezondheidsraad.nl/en>). This committee currently uses the Directive 93/21/EEC of the European Union to classify chemicals at the request of the Minister of Social Affairs and Employment. Two members of this subcommittee will participate in the meeting. Dr. Nel Roeleveld will present the methodology used for classification and explain the difficulties regarding classification based on human studies and hazard information, while trying to perform an assessment in terms of risk. Dr. Aldert Piersma will focus on classification based on animal studies. He will also discuss agreement on a unified methodology for classification of chemicals for reproductive hazards in a globally harmonized system (GHS) on both sides of the Atlantic.

### **Program**

- 13.00 - 13.30 Welcome reception with coffee and tea
- 13.30 - 13.35 Announcements from the board of the NVAB by Kees van Vliet and from the CGC  
Introduction to the subject of the seminar by Paul Scheepers (CGC)
- 13.35 - 14.10 Introduction to the method of classification by the Health Council of the Netherlands,  
evidence from human data - Nel Roeleveld
- 14.10 - 15.00 "Level of Concern" evaluations conducted by the NTP Center for the Evaluation of Risks to  
Human Reproduction - Kristina Thayer
- 15.00 - 15.30 Break

- 15:30 - 16:00 Classification & Labeling in Europe under the GHS system, evidence from animal studies - Aldert Piersma
- 16.00 - 16.30 Panel discussion
- 16:30 Closure

### **Information on the background of the speakers**

Dr. Nel Roeleveld, Associate professor of Reproductive Epidemiology at the department of Epidemiology, Biostatistics and HTA, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands studied Environmental Sciences at Wageningen University in the Netherlands, where she graduated in 1984. She majored in Occupational Health/Hygiene and Epidemiology and took a job as Occupational Epidemiologist (teaching and research combined) at the Institute of Social Medicine of the Radboud University in Nijmegen. In 1992, she obtained her PhD degree in Biomedical Sciences on a study on mental retardation and parental occupation, which was the starting point of a research program on Reproductive Epidemiology. After a two year period as Visiting Scientist at the National Institute for Occupational Safety and Health (NIOSH) in Cincinnati, OH, USA, she became the leader of this research program in 1995 and was appointed Associate professor of Reproductive Epidemiology in 2004. Over the years, the research focus has been expanded and now includes a large range of exogenous factors (occupational, environmental, lifestyle, nutrition) as well as genetic factors and gene-environment interactions.

Dr. Kristina Thayer, Acting Director of the National Toxicology Program - Center for the Evaluation of Risks to Human Reproduction (CERHR), <http://cerhr.niehs.nih.gov/index.html>. CERHR was established in 1998 to serve as an environmental health resource to the public and regulatory and health agencies. CERHR publishes monographs that assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as “substances”) cause adverse effects on reproduction and development and provide opinion on whether these substances are hazardous. CERHR monographs are recognized as authoritative evaluations by regulatory agencies such as the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), the US Environmental Protection Agency (EPA) and the California Environmental Protection Agency under Proposition 65. For example, CERHR evaluations were cited as the basis for listing of 5 different phthalates, 1-bromopropane, 2-bromopropane, and methanol as reproductive or developmental toxicants under California’s Proposition 65. In November 2008, the Center published a monograph on bisphenol A.

Dr. Aldert Piersma of the National Institute of Public Health and the Environment in Bilthoven, The Netherlands studied Biology at the University of Utrecht in the Netherlands where he graduated in 1981. Specific expertise was gained in Developmental Biology, Tumor Immunology and Pharmacology. In 1985, he obtained his Ph.D. degree in Medicine at the Erasmus University Rotterdam, as the result of an investigation on the role of fibroblastic reticular cells in the hemopoietic stroma in the regulation of proliferation and differentiation of hemopoietic stem cells in mice. He spent two years as a postdoc at the National Institute for Developmental Biology on the development of a battery of in vitro methods for the identification of teratogenic agents and their mechanisms of action. In 1988 he was appointed as reproductive toxicologist at the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands, where he has lead the Reproductive Toxicology group since. In 2007 he was appointed part-time Professor of Reproductive and Developmental Toxicology at the Institute for Risk Assessment Sciences, University of Utrecht.

### **Contact Group Health and Chemistry (CGC)**

The CGC is an independent Dutch/Flemish foundation that was established 30 years ago and provides a platform for exchange of information and discussion for professionals from different disciplines involved in the field of chemistry and health. This goal is achieved by organizing five seminars for occupational physicians, safety engineers, occupational hygienists, toxicologists, and environmental physicians each year. These seminars are organized in collaboration with each of the five professional associations in the above-mentioned fields. Reports of these seminars are published in the Dutch peer-reviewed journal “Tijdschrift voor toegepaste Arbo-wetenschap” (Journal of Applied Occupational Sciences).

You can become a member of the CGC by sending an e-mail to [info@epsnet.nl](mailto:info@epsnet.nl)

The upcoming CGC seminars will be on:

September 16<sup>th</sup>, 2010 in collaboration with the environmental physicians (NVMM)

November 11<sup>th</sup> 2010 in collaboration with the occupational hygienists (NVvA)

January 20<sup>th</sup> 2011 in collaboration with the safety engineers (NVVK)