IGS INSTITUTE FOR INNOVATION AND GOVERNANCE STUDIES

IGS Conference 9 and 10 September 2010 (in collaboration with MESA+)

Organizers: Dr. Bärbel Dorbeck-Jung & Nupur Chowdhury

Conference venue: University of Twente, Drienerburght Conference Center

Governing responsible nanomedical innovation – regulatory responses to emerging applications, health and environment concerns

Introduction

Since the European Commission is committed to responsible nanotechnological development governance questions have been discussed intensively. At the heart of this discussion lies the problem of how to support beneficial nanotechnological development without neglecting health and environment risk concerns. To get grips with this dilemma we can build on successes and failures of regulatory governance that have been experienced in similar policy fields. This Conference explores appropriate governance responses to the challenges of nanomedicine. Nanomedicine is a field where the University of Twente is developing high level expertise in science, product development and governance. Worldwide, nanomedicine is regarded as one of the most advanced sectors where high expectations on beneficial applications have been raised. The Conference starts with an overview of nanomedical applications and their potential benefits (mainly in the field of therapeutics). It then deals with health and environment concerns and their policy implications. Lessons from European medical technology regulation will be explored and concrete regulatory problems in the field of nanomedicine will be discussed with main stakeholders. The lessons are embedded in a debate on soft regulation and other governance methods that are at the forefront of nanotechnological regulation. Comments based on the experience with innovative regulatory governance clarify the appropriateness of current nano(medical) governance.

Key Objectives

- Explore different public administration policies and regulatory practices for enhancing innovation in regulatory governance in the context of technology innovation
- Establish and support multidisciplinary partnerships on the issue of regulatory governance of nanomedical innovation
- Provide for a platform for the establishment of a multi-stakeholder dialogue process through the establishment of a network on regulatory governance for nanomedical innovation

Participation only on invitation

MESA+ INSTITUTE FOR NANOTECHNOLOGY

Programme

Day 1

10.45 – 11.10	Opening Speeches by - Ed Brinksma (Rector Magnificus UT) - Kees Aarts (Chair IGS) - Bärbel Dorbeck-Jung (on behalf of Organizers)
11.10 – 12.40	**Session I – Setting the Scene** (*Chair: Dave Blank UT*) - Introduction to UT Nanomedical Applications (Vinod Subramanian/Séverine Le Gac, UT) - Health and Environmental Safety of nanoparticles (Wim de Jong, RIVM and SCENIHIR) - Workers Safety (Pieter van Broekhuizen, IVAM, UvA) - General discussion
12.40 – 14.00	**LUNCH**
14.00 – 15.30	**Session II – Medical products in Europe: Regulatory Experience and Lessons** *(Chair: Maarten IJzerman UT)* - Lessons from medical devices to nano devices (Christa Altenstetter, City University of New York) - Medical Products regulation and nanomedicines (Nupur Chowdhury, UT) - EU governance of human material (Anne-Maree Farrell, University of Manchester) - General discussion
15.30 – 16.00	**COFFEE/TEA BREAK**
16.00 – 17.30	**Session III – Governance of Innovation: Multistakeholder Panel Discussion on Regulatory Issues of Nanomedicine** *(Chair: Bärbel Dorbeck-Jung UT)* - Representative EMA/CAT Committee (Hans Ovelgönne) - Representative German Institute for Drugs and Medical Devices (Birka Lehmann) - Legal Advisor Drug and Medical Devices Development FDA & EMA Washington (Richard Canady) - EU WG on New and Emerging Technologies in Medical Devices (Robert Geertsma) - Philips (Rob Slobbe) - European Technology Platform Nanomedicine (Joan-Albert Vericat) - Patient Organization (Alastair Kent) - General Discussion
18. 00 onwards	**DRINKS and DINNER**

Day 2

09.00 – 10.30	**Session IV – Innovative regulatory governance of nanotechnologies** *(Chair: Tsjalling Swierstra, UT)* - Nanotechnology governance – overview and evaluation (Diana Bowman, Melbourne University) - Strengths and weaknesses of voluntary regulation (René van Schomburg DG Research) - Issues of Standardization of nanoparticles (Peter Hatto, Chair ISO TC-229) - General discussion
10.30 – 11.00	**COFFEE/TEA BREAK**
11.00 – 12.30	**Session V – Regulatory governance of nanotechnologies in the context of risk regulation and governance of innovation** *(Chair: Ramses Wessel, UT)* - Uncertain risks regulated (Ellen Vos, University of Maastricht) - From risk regulation to the governance of innovation (Arie Rip, UT) - General Discussion
12.30 – 13.30	**LUNCH**
13.30 – 15.00	**Visit to MESA+ (including discussion with Scientists, Technology Transfer Point and Spin-offs)**
15.00 – 16.00	**Discussion on Regulatory Governance Network on Nanomedical Innovation (special registration)** (Led by Bärbel Dorbeck Jung, UT)