This chapter was originally published in the book *Nanoengineering*. The copy attached is provided by Elsevier for the author's benefit and for the benefit of the author's institution, for non-commercial research, and educational use. This includes without limitation use in instruction at your institution, distribution to specific colleagues, and providing a copy to your institution's administrator.

All other uses, reproduction and distribution, including without limitation commercial reprints, selling or licensing copies or access, or posting on open internet sites, your personal or institution’s website or repository, are prohibited. For exceptions, permission may be sought for such use through Elsevier’s permissions site at:

http://www.elsevier.com/locate/permissionusematerial


ISBN: 9780444627476

Copyright © 2015 Elsevier B.V. All rights reserved.

Elsevier
CHAPTER 2.7

The EU Regulation of Nanomaterials: Smoother or Harder? The Precautionary Tool Chest as the Basis for Better Regulating Nanomaterials

Raphaël Gellert, Eugenio Mantovani, Paul De Hert
Law, Science, Technology & Society Studies (LSTS) Vrije Universiteit Brussel, Brussels, Belgium

1. THE EU POLICY FRAMEWORK FOR NANOMATERIALS

1.1 General

The European Union (EU) is an economic and political union of 28 member states that operates through a system of supranational independent institutions and intergovernmental decisions by its member states.

The EU regulatory framework on nanomaterials falls mainly within the shared competence of the EU and of its member states. This means that the sources of the regulation of nanomaterials are found primarily in the law promulgated in Brussels, if Brussels thinks fit to draft laws in these areas, which is the case. The EU regulatory toolbox includes directives and regulations which are binding on member states, as well as the so-called “soft law” instruments (not binding instruments) such as recommendations and communications. The European Commission (EC) and its agencies and research centers play a central, propulsive role in the regulatory process. The Commission has authored two essential documents, “communications,” regarding nanomaterials.

1.2 The 2008 Communication on Regulatory Aspects of Nanomaterials

In 2008 the EC issued a communication on Regulatory Aspects of Nanomaterials (NM) [1]. The Communication is very legalistic of tone and consists of two parts.

First, the communication assesses whether the scope ratione materiae of nanomaterials is covered by existing legislation and reviews four fields of legislation: chemicals, health and safety at work, product legislation, and environmental legislation. It concludes that nanomaterials were adequately addressed by existing legislations (since there is a relevant legislation at each stage of the “nano-process”). Hence, no nano-specific instrument is required.

1 Cf. infra Section 2 describing the several legislations applicable to nanomaterials.