Regulating Nanotechnology in the European Union

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ABSTRACT

Concerning the regulation of nanotechnology, the presumption is that the E.U. will adopt a cautious approach, whether or not based on regulation currently in place. Much like in the U.S. and elsewhere, there is no tailor-made regulatory framework for nanotechnology that currently exists in the E.U. Some in the industry fear that Registration, Evaluation, Authorization, and restriction of Chemicals ("REACH"), the new E.U.'s chemical policy, may be used as a source of inspiration for the regulation of nanotechnology, which might imply a qualified shift of the burden of proof with regard to safety, from the authorities to the manufacturer. Product liability law is less likely to play a preponderant role, at least at the E.U. level (as opposed to within the individual Member States) because the E.U.'s harmonization in this field of practice is limited. In this article, Geert van Calster provides an overview of current and future E.U. regulation of nanotechnology, with some comparisons between the E.U. and U.S. regulatory frameworks.

> The uniform, constant and uninterrupted effort of every man to better his condition, the principle from which public and national, as well as private opulence is originally derived, is frequently powerful enough to maintain the natural progress of things toward improvement, in spite both of the extravagance of government, and of the greatest errors of administration. Like the unknown principle of animal life, it frequently restores health and vigour to the constitution, in spite, not only of the disease, but of the absurd prescriptions of the doctor.
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> *Adam Smith, The Wealth of Nations, Book II Chapter III*

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It is often a quote's fate to be taken completely out of context. And undoubtedly this is also true for the above statement. The above quotation illustrates the exasperation sometimes felt by those at the receiving end of regulation for new technologies. This is in particular the case vis-à-vis the E.U. answer to regulatory, especially Safety, Health and Environmental concerns.

I. THE CURRENT REGULATORY FRAMEWORK

1. There Is No Such Thing as an Unregulated Technology

Regulatory *confusion* (as opposed to solutions) for nanotechnology is well documented, albeit typically in general terms. The danger of such confusion is regularly cited as hampering the development of technology. To date the author has no knowledge of any tailor-made nanotechnology law in any jurisdiction.

Clearly, nanotechnology will never go "unregulated." In other words, it will never be a "lawless" technology. Ordinary principles of law will apply to nanotechnology should one not develop a specific regime for it. These ordinary legal frameworks include, for instance, tort law (including advanced forms of duty of care), as well as the more specific product liability rules. Indeed, the health implications, in hindsight, of both tobacco products and chrysotile asbestos, present a case in point. Neither product was subject to product-specific regimes, but this did not prevent the establishment of liability for harms arising from use and/or manufacture of those products. Both examples of course also underscore the need for proactive regulation of new technology when it poses unknown risks.

Both from an economic policy point of view as well as from the point of view of public health and the environment, an ounce of prevention is better than a pound of cure. Encapsulating established risks most certainly is preferable to having to deal with the unwarranted aftermath. Key in this approach is of course the identification of "established" risks as opposed to those which are merely perceived risks—hence the debate on the application of the precautionary principle, which will be further examined in this article. Absence of a regulatory regime by the time nanotechnology products are deployed on the mass market, is what industry would like to avoid.[1] It is in this context, in particular, that one looks to the biotechnology and genetically modified organism ("GMO") debacle as an example of that which ought *not* to be followed.[2] As a consequence, some in the industry, arguably more than ever before, have made efforts to form a regulatory alliance with environmental, health and safety activists.

This article succinctly reviews the existing regulatory framework which might apply to development and use of nanotechnology in the U.S. and in the E.U. The article focuses, however, on current and future regulation in the E.U. However the brief look into the U.S. regulatory framework may serve as a benchmark for comparison between the two. An overview of both systems is important given that the regulation of nanotechnology is already being viewed as providing fertile ground for increased regulatory co-operation between the U.S. and the E.U.

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[1] *See* JOHN C. MILLER ET AL., THE HANDBOOK OF NANOTECHNOLOGY: BUSINESS, POLICY, AND INTELLECTUAL PROPERTY LAW 63 (2004) (noting that the lack of a formal regulatory review process provides political ammunition for those opposed to the technology, e.g., on precautionary grounds).

[2] *See* R. Sandler & W. D. Kay, *The GMO-Nanotech (Dis)Analogy?*, 26 BULL. OF SCI. TECH. & SOC'Y 57 (2006) (warning against the oversimplification of some of those analogies).

2. The Existing Regulatory Framework in the United States

One often usefully distinguishes between nanotechnology processes and nanotechnology materials.[3] This distinction is potentially useful from a domestic regulatory point of view, but it also potentially serves an important purpose in international trade law (discussed, *infra*, in the product incorporated/non-incorporated issue).

The Toxic Substances Control Act of 1976 ("TSCA"), provides a useful starting point for comparison and possesses an advantage in terms of its breadth. The TSCA covers all environmental agents, air, water, soil, etc.; other forms of environmental regulation, in contrast, typically focus on one agent only.[4] Moreover, the trigger for the application of the TSCA is the qualification as a "chemical substance (or) mixture." The TSCA defines this as "any organic or inorganic substance of a particular molecular identity." In that respect, the TSCA acts as a *lex generalis*, with proviso for the coverage of specific types of products by *lex specialis* such as pesticides, drugs, cosmetics, and medical devices.[5]

It has been noted, however, that, while the TSCA could theoretically apply to nanotechnology, the TSCA, specifically, and chemicals legislation, more generally, does not at first glimpse provide a suitable instrument for regulating nanotechnology.[6] First, most chemical regulation assumes a direct relationship between volume of material and exposure; however, for toxicity of nanotechnology materials is presumed to be related to surface area rather than to weight or volume. Moreover, nanotechnology products typically are incorporated into a larger, non-nanoscale structure. Hence, Dr. Davies notes that it is difficult to predict the behavior of the basic nanotechnology form given that it may be incorporated into a wide array of differing applications and structures.[7] This is also cited as the reason for excluding polymers[8] from both the U.S. TSCA and, in an initial stage at least, from its E.U. counterpart (discussed

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[3] J. CLARENCE DAVIES, MANAGING THE EFFECTS OF NANOTECHNOLOGY (Woodrow Wilson International Center for Scholars, Paper for the Project on Emerging Nanotechnologies, 2006) *available at http://*www.innovationsgesellschaft.ch/images/publikationen/manangingeffects.pdf (last visited July 14, 2006). Over and above the specific references in this section, this section is largely based on Dr. Davies' analysis.

[4] *Id*.

[5] The EPA, in its applying the TSCA, has also exempted chemicals produced in volumes of 10 MT or less per year—an exemption which obviously will need to be amended should one consider applying TSCA to nanotechnology products.

[6] *See* DAVIES, *supra* note 3, at 8; *see also* LINDA K. BREGGIN, SECURING THE PROMISE OF NANOTECHNOLOGY: IS US ENVIRONMENTAL LAW UP TO THE JOB? (2005).

[7] *Id.*

[8] *National Geographic* defines these as "[t]iny molecules strung in long repeating chains." National Geographic Society, *What Are Polymers?* (1997), *at* http://www.nationalgeographic.com/education/plastics/describe.html. The European Commission's proposal on a new European chemicals policy, defines them somewhat more legalistically as follows:

> *Polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
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> (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
>
> (b) less than a simple weight majority of molecules of the same molecular weight.
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> In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer.

Comm'n of the Eur. Communities, *Proposal for a Regulation of the European Parliament and of the Counsel concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation {EC} on Persistent Organic Pollutants, Proposal for a Directive of the European Parliament and of the Council, amending Council Directive 67/548/EEC in Order to Adapt it to Regulation (EC) of the European Parliament and Council concerning the registration, evaluation, authorization, and restriction of*

further, *infra*). However, with respect to the latter, the European Commission has already signaled that it is considering ways of cost-efficiently assessing the most dangerous polymers. Moreover, the building blocks of these polymers, monomers, are of course subject to the regulatory requirements currently in place in the E.U and U.S. The E.U. framework aims precisely at identifying potential risk associated with downstream applications by requiring downstream users to send user data up the supply chain.

A more cumbersome shortcoming of the TSCA concerns the requirements it imposes on the Environmental Protection Agency ("EPA") for it to be able to regulate a given chemical. Under section 5(e) the Act, in the event of absence of information "to permit a reasoned evaluation of the health and environmental effects of a chemical," the EPA can delay or prohibit the manufacture of that chemical only if it can show that the chemical "may present an unreasonable risk." This indeed is a Catch-22 situation,[9] amounting in effect to a presumption of safety in the event of absence of sound data. Because the risks of nanomaterials are largely unknown at this stage, manufacturers have nothing to report in the TSCA set-up.[10]

Moreover, TSCA is of course product-focused, while other pieces of environmental regulation are facility-based. Hence even if TSCA has many qualities which make it a prime candidate for regulating nanotechnology, an integrated regulatory approach, including regulations which address the facility-based element, will be needed.[11]

The Occupational Safety and Health Act of 1970 ("OSHA") aims at improving safety and health in the course of employment and in places of employment. While the broad goals Act would seem to provide active regulation of nanotechnology processes, its practical use is seriously undermined by two limitations. First, the difficulty in detecting nanoparticles and hence securing their safe use undermines OSHA's ability to adequately ensure workplace safety involving nanotechnology. Second, OSHA's effectiveness is further limited by the understaffing suffered by the agencies and officials charged with enforcing it.[12]

The Food, Drug and Cosmetic Act ought to provide some assurance for early applications of nanotechnology in the fields of drugs, medical devices, cosmetics, and food. For drugs and medical devices, manufacturers need approval by the Food and Drug Administration ("FDA") for their products to be marketed within the U.S. This approval process imposes very stringent requirements, especially given that the manufacturers have to prove that their products are safe. Applications involving nanotechnology may, however, lead to a range of practical complications in administering the seemingly complete review process. To begin with, it may become increasingly difficult to classify a nanomedical application under the current *modi operandi* as either mechanical, chemical, or biological;[13] many products that are being developed already combine two or more of these. Moreover, nanotechnology applications may very often be used to develop more advanced versions of existing products.[14] That raises questions of substantial equivalence, and of the sufficiency of data required to give such applications a quick regulatory approval.

While drugs and medical devices, in particular, are currently very well regulated by FDA, the most important issue presented is to what extent nanotechnology presents a new characteristic which possesses the potential to expose a flaw in an otherwise comprehensive regulatory scheme. It has been suggested

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chemicals, {SEC(2003 1171)}, Chap. 2, Art. 3(4), COM (2003) 644, *available at* http://europa.eu.int/eur-lex/en/com/pdf/2003/act0644en03/1.pdf (last visited July 14, 2006).

9 *See* DAVIES, *supra* note 3, at 11-12.

10 MILLER ET AL., *supra* note 1, at 53.

11 *See* BREGGIN, *supra* note 6, at 9.

12 *See* DAVIES, *supra* note 3, at 13. A similar issue may apply to the FDA regulation (see *infra*) in the future. *See* MILLER ET AL., *supra* note 1, at 102.

13 MILLER ET AL., *supra* note 1, at 90.

14 *See id*. at 95.

that cosmetics might go largely unregulated under the Act because they are not subject to prior approval.[15] The Act's approval process may produce unwarranted health risks mainly associated with cosmetics, consequently. This may provide one of the reasons why early applications of nanotechnology concern precisely the field of cosmetics.

In fairness, while the formal regulatory framework for cosmetics may seem somewhat flimsy, in practice, the act's emphasis on cosmetic self-regulation does increase safety. The added safety from these seemingly weak regulations on cosmetic safety results mainly from the Act's requirement, naturally, that cosmetics are safe prior to marketing, combined with the strong incentive of avoiding products liability lawsuits (class action or otherwise). Moreover, some of the more risk-prone ingredients, such as color additives, are subject to approval prior to being marketed.

The FDA has up until now relied on the existing regulations to deal with any nanotechnology products that may be subject to its authority. This approach assumes both that the existing terminology suffices to adequately describe and characterize nanotechnology applications and that existing risk assessments mechanisms likewise suffice to address any safety concerns associated with the technology. As readers are aware, this approach is now being contested by the International Center for Technology Assessment in a petition lodged with the FDA, requesting precisely that the FDA define nanotechnology, conduct an impact review of nanotechnology and state its official opinion on the regulation of the products at issue that contain nanomaterials.[16]

Finally, from the specific environmental, health and safety point of view, environmental laws such as the Clean Air Act ("CAA"), the Clean Water Act ("CWA") and the Resource Conservation and Recovery Act ("RCRA"), suffer a limitation in their operational capacities to effectively address nanotechnology. This operational limitation results from the absence of standardized detection of nanoparticles. The CAA does provide for emission limits for particulate matter, including those at a small scale (2.5 micrometers in diameter, i.e., far larger than the largest nanoparticle usually captured by the definition of nanotechnology). As both the U.S. and E.U. examples show (discussed, *infra*), the enforcement of emission limits for small particulate matter will often fail to address many applications of nanotechnology. The current size limitations, therefore, result in a soft spot for legislation such as CWA and CAA in so far as both require intensive monitoring and extended data mining prior to regulation; even then, the smaller of size of nanoparticulate matter may not be adequately addressed by those pieces of legislation.[17]

In addition to the active regulatory legislation discussed above, an overview of the regulation of nanotechnology in the U.S. without reference to the states' various products liability laws would be woefully incomplete. This is the area in which the nanotechnology/asbestos analogy most aptly applies. Despite the analogies between products containing nanomaterials and asbestos, the poor fate of the asbestos industry has not so far scared those in the nanomaterials industry away from innovation. Product liability implications under U.S. law have recently been reviewed in this journal.[18] While there is as yet no nanotechnology-specific products liability case law, guidance derived from existing case law (e.g., the early cases involving asbestos), shows that manufacturers can limit some of their exposure by following a set of purely procedural guidelines, such as document retention policies.[19]

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[15] DAVIES, *supra* note 3, at 13.

[16] *See* International Ctr. for Tech. Assessment, *Citizen Petition to the United States Food and Drug Administration*, http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf (last visited July 14, 2006).

[17] BREGGIN, *supra* note 6, at 12 *ff*.

[18] *See* John C. Monica, Jr., Patrick T. Lewis & John C. Monica, *Preparing for Future Health Litigation: The Application of Products Liability Law to Nanotechnology*, 3 NANOTECH. L. & BUS. 54 (2006).

[19] *Id*.

3. The Existing Regulatory Framework in the E.U.

Just as in the U.S., there is as yet no complete, all-encompassing review of the applicability of existing laws to nanotechnology.[20] Tellingly, when efforts are made to list E.U. nanotechnology laws, one typically refers to the European Commission's research and development programs as being "the law on nanotechnology." Or, with reference to the mooted laws and regulations, one refers to the European Commission's policy documents on nanotechnology as constituting the law on nanotechnology.[21] The European Commission itself is currently reviewing all existing laws and regulations in-house in order to determine their suitability for nanotechnology-related applications.

Many quote the legislation on GMOs as providing a useful benchmark of what specific nanotechnology regulation should look like. This, in itself, provides some cause for alarm because it is precisely the application of the European regulation of GMOs which caused the biotechnology backlash in Europe and, ultimately, the condemnation of the E.U. regime by a Panel of the World Trade Organization.

However the European GMO Directives in themselves are not likely to apply to a wide range of nanotechnology research or applications because the scope of application of these Directives is confined to "organisms," which are defined as "any biological entity capable of replication or of transferring genetic material."[22] With the possible exception of tissue engineering,[23] this would not seem to apply to most applications using nanotechnology.

Europe's legislation concerning chemicals is notoriously dense and ineffective from an environmental and public health point of view. Coordination and improvement of the public health and environmental aspects of the legislation lie at the heart of the current, long-winded drive to change the regime. The regime change goes under the acronym of "REACH," referring to "Registration, Evaluation, Authorisation and restriction of Chemicals."

A cornerstone of the current regime is Directive 67/548 on the classification, packaging and labeling of dangerous substances,[24] as repeatedly amended. This Directive defines "substances" as "all kinds of chemical elements and their compounds in the natural state or obtained by any production process . . . ." Somewhat surprisingly, the Directives do not define "chemical elements," unlike the U.S. regime, which as explained above, defines "chemical substance [or] mixture" as "any organic or inorganic substance of a particular molecular identity."

Substances are classified as dangerous if they fit within any of fifteen categories, including toxicity, harmfulness, and danger to the environment. While toxicity and harmfulness, amongst others, are defined in terms of either scientific certainty or, at the least, a strong indication of harm or danger of the substance involved, "danger for the environment" is defined under Article 2(2)(o) of the Directive as "substances which, were they to enter the environment, would present or may present an immediate or delayed danger for one or more components of the environment."

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[20] Stefan M. L. Tormans, *Nanotechnology in Europe—Regulating the Infinitely Small*, ENERGY AND ENVIRONMENTAL LAW—2005: RECENT DEVELOPMENTS IN INTERNATIONAL, EUROPEAN, AND COMPARATIVE ENERGY AND ENVIRONMENTAL LAW (Geert van Calster & Kurt Deketelaere eds., 2005), *available at* http://www.law.kuleuven.be/imer/Yearbook%20-%20Energy%20&%20Environmental%20Law_2005.pdf (last visited July 14, 2006) (reviewing the "usual suspects").

[21] Comm'n for Eur. Communities, *Welcome to the Nanotechnology Homepage of the European Commission*, CORDIS.EUROPA.EU, http://cordis.europa.eu/nanotechnology/ (last visited July 14, 2006) (listing various policy documents with regard to nanotechnology regulation in Europe).

[22] Council Directive 2001/18, art. 2(1), 2001 O.J. (L106) 1.

[23] *See* Tormans, *supra* note 201, at 489.

[24] Council Directive 67/548/EEC, of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, 196 O.J. 16.8.1967, at 1.

Especially in combination with the E.U.'s recurrent application of the precautionary principle, this Directive and its satellites are likely to apply to nanoparticles in particular, although it is unclear what type of measures the regulatory regime ought to impose in order to contain the perceived danger to the environment due to the very lack of data on the particles' behavior. Indeed in principle, under the E.U.'s notification scheme, "new" chemicals need to be notified and accompanied by an extensive risk analysis; but to our knowledge, there has not yet been any such notification for nanotechnology applications.

Hence, it is clear that, while the cornerstone of the E.U.'s chemical legislation certainly in theory could be applied to nanotechnology applications, its application in practice is not geared towards nanotechnology. That, in effect, puts the E.U. in very much the same position as the U.S. in terms of the application of its chemicals legislation.

REACH[25] is not likely to change this altogether. REACH is, however, considered generally to be something that has the potential to provide the guiding principles as to how the E.U. may tackle nanotechnology regulation in the future, in particular by its reliance on the precautionary principle. Some examples of how the precautionary principle is implemented, quoted by the European Commission itself, are the following:

> Safety assessment: If there is uncertainty over scientific evidence (e.g. conflicting data exist), the safety assessment should normally be based on the evidence that gives rise to highest concern….
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> Risk management measures: While a company is awaiting further test data on a particular hazard it should make sure that the risk management measures appropriate for the potential risk are in place and describe these measures in the safety assessment; in the case of PBTs and vPvBs, industry is requested to minimise exposure at all times….
>
> Authorisation: Industry is required to seek authorisation for uses of substances of very high concern, regardless of the measures taken to control the risks.
>
> Restrictions: Member States and the Commission can suggest immediate restrictions in case there are indications of severe risks associated with the use of a given chemical. In this way the precautionary principle could be implemented in cases where it would take too long to establish the data necessary for a scientific evaluation or where data does not allow the risk to be determined with sufficient certainty. [26]

However it has also been suggested that the provisions of REACH which would not have been introduced but for the precautionary principle are few and far between.[27]

Cosmetics regulation in the E.U. does not differ all that much from the U.S. regime, at least not with respect to the main characteristics of the regime. Just as in the U.S., pre-approval is not required other than for a specific number of colorants, active ingredients of sunscreens and preservatives. While in the U.S., the systematic compilation of data is mainly restricted to the voluntary registration scheme, manufacturers in the E.U. are obliged to keep a full technical data file available for inspection. The E.U., like the U.S., employs a "negative" list of active ingredients (i.e., ingredients which must not be used following adverse or negative safety assessments, conducted in peer-reviewed fashion). Although one would assume that some of the heralded "nano" sunscreens must have a nanomaterial as the active

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[25] *See* Comm'n of the Eur. Communities, *supra* note 9, and accompanying text.

[26] Comm'n of the Eur. Communities, *Questions and Answers on REACH*, EC.EUROPA.EU (Mar. 23, 2006), http://register.consilium.eu.int/pdf/en/05/st15/st15921.en05.pdf (last visited July 14, 2006).

[27] Veerle Heyvaert, *Guidance without Constraint: Assessing the Impact of the Precautionary Principle on the European Community's Chemicals Policy, in* 6 *Yearbook of European Environmental Law* 27 (Thijs Etty & Han Somsen eds., 2006).

ingredient and, hence, subject to pre-approval process, the author has not found any publicly available decisions to that effect. This may, of course, imply that claims with respect to the "nano" characteristics of these sunscreens are, well, cosmetic only (as is the case with many nanotextiles).

Regulation concerning drugs and medical nanotechnology generally suffers from a lack of standardized safety assessments. However, medical applications of nanotechnology seem to have a fairly comprehensive, even if not tailor-made, regulatory framework, as set out in detail in a previous issue of *Nanotechnology Law & Business*.[28]

Applications of nanotechnology to food products have, of course, attracted some of the wildest nanotechnology dreams and simultaneously some of the gravest concerns. Again, there is no specific regime in E.U. law that could be characterized as an individual regime for nanofoods. Issues with regard to nanofoods mainly concern packaging and processing of the food, with intelligent packaging as a prime example (e.g., forewarning the consumer if a product goes by its sell-by date or has somehow become contaminated). Other applications concern the food directly, such as food ingredients which are only released if and when the body or specific cells were to be in need of them (e.g., vitamins in winter time).[29] To the extent the technology has a bearing on the foods itself, the E.U.'s Novel Food Regulation would apply.[30]

The E.U.'s environmental liability regime imposes, *inter alia*, a strict liability regime for "operators" carrying out "hazardous" activities.[31] They will be held strictly liable (i.e., there will be no need to show fault or negligence) for preventing or restoring any damage caused by those activities to land, water and protected habitats and species. It is noteworthy that the liability Directive does not cover "traditional damage," (i.e., personal injury and damage to personal goods and property); for such damage, the various liability regimes of the Member States apply.

"Hazardous activities" include manufacture, use, storage, processing, filling, release into the environment and onsite transport of those substances which are classified as dangerous substances under the E.U.'s chemical legislation, referred to above. Hence, there is a direct link between the classification under the E.U.'s chemical policy and the ensuing liability.

Again, though, no specific proviso has been made in the liability Directive for nanotechnology *per se*. Interestingly, at the time of negotiation of the Directive, the need was discussed for a specific liability regime for GMOs in order to address the uncertainty associated with the technology. Eventually, a consensus emerged to leave GMOs within the standard remit of the Directive, pending further evaluation of the need to review this by the Commission. Hence, the Directive fully applies to GMO technology, including the Directive's defenses. If the release of the GMO was specifically authorized, or if it was not possible to anticipate the damaging effect on the basis of the state of scientific and technical knowledge at the time, and if the operator was not negligent (all of which the operator has to prove), then the competent authorities can exempt him/her from liability. For example, an operator would be negligent and thus liable if it does not follow the instructions provided by the GMO manufacturer or the competent authority authorizing the release.[32]

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[28] Giorgia Guerra, *A Model for Regulation of Medical Nanobiotechnology: The European Status Quo*, 3 NANOTECH. L. & BUS. 84 (2006).

[29] TIJU JOSEPH & MARK MORRISON, NANOTECHNOLOGY IN AGRICULTURE AND FOOD, NANOFORUM.ORG (Apr. 2006), http://www.nanoinfo.jp/whitepaper/WP81NA.pdf (last visited July 14, 2006).

[30] Regulation 258/97 on novel foods, 1997 O.J. (L43) 1. *See also*, RAYMOND O'ROURKE, EUROPEAN FOOD LAW 300 (3d ed. 2005).

[31] Council Directive 2004/35, 2004 O.J. L(143) 56.

[32] Comm'n of the Eur. Communities, *Questions and Answers Environmental Liability Directive*, Memo 04/78 (Apr. 1, 2004), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/04/78&format=HTML&aged=0&language=EN&guiLanguage=en (last visited July 14, 2006).

Similar considerations obviously apply to nanotechnology. In the current regulatory state, nanotechnological applications are not likely to have been specifically authorized; hence, the defense one would be able to raise relates to its not having been possible to anticipate the damaging effects based on the scientific knowledge available at the time.

Finally, E.U environmental law consists a wide array of legislation of a so-called "procedural" nature, which does not specifically or expressly include nanotechnology. However, these procedural laws may apply to nanotechnology should the standard triggers for application be present by the applications themselves. For instance, the laboratories where nanotechnology research is being carried out may be subject to permits under the Integrated Pollution Prevention and Control ("IPPC") Directive, the Environmental Impact Assessment Directive, and perhaps others.

As for products liability laws, while the European Product Liability Directive[33] has been found to go further than merely minimum harmonization,[34] the regime in practice leaves so much to the Member States that one wonders whether the extent of harmonization truly deserves anything else but the qualification, "minimum." Indeed, a large number of issues that lie at the core of liability considerations, such as causation, remoteness of damage, standard of proof, contributory acts, assessment of damages, and discovery, are all left to the discretion of domestic law makers.[35] Hence, to truly have an insight into how products liability law impacts on the development of new technology, one would have to review all of the case law of the various Member States, or at least the key States. The danger of having twenty-five different liability regimes often provides a strong incentive for the Commission to act on the basis of its powers for the preservation of the Internal Market. This might include requiring manufacturers to produce in accordance with agreed health, safety, and environment standards. In such a manner, the Internal Market may then be safeguarded.

4. Indications of Diverging Directions

There is some speculation that the regulation of nanotechnology will lead to the adoption of conflicting regimes in the E.U. and the U.S. This assumption underscores one of the stronger arguments in favor of developing a comprehensive regulatory scheme prior to any effective disputes arising. The biotechnology sector, in particular, is considered in this respect as the example which ought *not* to be followed. The usual suspect of the regulatory divide in public health and environmental protection in the E.U. and the U.S. is the precautionary principle in this case.

In early 2000, the Commission adopted a Communication on the precautionary principle, which, tellingly, was specifically designed to ease trade tensions with the U.S.[36] The Commission insists in this document that the precautionary principle in its European context is a justified part of risk management. The latter, the Commission insists, is not a purely scientific exercise, but, to a considerable degree, a policy process. The communication states that any measures taken on the basis of the principle have to be proportionate vis-à-vis the level of environmental protection sought; it goes further to state that they must not be discriminatory in their application (in particular, vis-à-vis the trading partners of the E.U.). In addition, it states that they have to be consistent with any measures which have already been taken (i.e., establish consistency). Further, they must be based on technical analysis and, where possible, economic cost and benefit analysis. Finally, they are subject to constant monitoring and evaluation, including potential review (most particularly, with a view toward integrating potential new scientific developments).

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[33] Council Directive 85/374, on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, [1985] O.J. L210.

[34] *See* Gonzalez Sanchez v. Medicina Asturiana S.A., [2002] ECR I-3901, Eur. Ct. of Justice, Case No. C-183/00.

[35] DUNCAN FAIRGRIEVE, PRODUCT LIABILITY IN COMPARATIVE PERSPECTIVE 1 (2005).

[36] COM (2000) 1.

However, while the precautionary principle may usefully be quoted as a focal point for the divide, in reality, the dichotomy between the U.S. and the E.U. in terms of risk analysis goes further than that.

The E.U. and its Member States view risk analysis as a linear process, in which the various steps of a risk analysis process (risk identification, risk assessment, risk management, and risk communication) are neatly divided. Importantly, the E.U. assigns the responsibility and the main lead in each of these steps to different professional groupings. While the steps of risk identification, and, certainly, that of risk assessment, are a responsibility of scientists, the step of risk management is very firmly seen as a *political* step, in which elected politicians on both the national scene and the European scene, take the lead. This preponderant role of politicians in risk management makes the process prone, so its critics say, to being susceptible to scaremongering, and to recourse to the precautionary principle.

Recently, the E.U. has increased the role of so-called regulatory and advisory agencies in assisting with risk analysis (e.g., with respect to food safety). This may eventually lead to more of a U.S.-style approach to the process. However, even more recent signs indicate that the Member States (as opposed to the Commission) are seeking to reverse that emphasis. Indeed, in the recent management of GMO approvals, Member States have criticized the presumption in flavor of the scientific opinion of the E.U.'s advisory panels, and in favor of the Commission, in those cases (which are plentiful) where the Member States cannot agree on giving the green light to a request for GMO marketing.

Particularly in the area of nanotechnology, there are early signs of regulatory cooperation, albeit embryonic. For the moment, cooperation would seem to exist in recognizing the need for avoiding regulatory competition on the issue. However, this does not mean, of course, that, over the course of the coming years, a regulatory divide between the E.U. and the U.S. is excluded, *per se*. There is one area in which cooperation does harbor early promise, namely in the standardization of metrology. The International Standards Organization's ("ISO's") technical committee on nanotechnology has a large portfolio of tasks (e.g., terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; and science-based health, safety, and environmental practices); despite this large portfolio, however, the latter, in particular, are not guaranteed to lead to true harmonization.

5. A Broad Regulatory Agenda

The above, succinct analysis presents a picture of the status quo: there is no *lex specialis* in either the E.U. or the U.S. that specifically or expressly applies to nanotechnology. Current environmental, health, and safety laws do apply to some degree, at least. However, at the time they were enacted, none of these regulations could contemplate the specific type of environmental, health, and safety issues posed by nanotechnology, including the specific detection issue faced by nanoparticles and the more general concern of scientific uncertainty, shared with applications in biotechnology.

Hence, there are two, divergent, but not necessarily conflicting views as to why we need a tailor-made regime for nanotechnology. The first view suspects that the current regulatory regime may not sufficiently address the environmental, health, and safety concerns of the technology and its applications. The second is of a more immediate economic nature and emphasizes that a regulatory framework needs to be in place prior to more or less mass deployment of nanotechnology applications, so as to avoid a regulatory gap which may endanger the very sector, or at the very least seriously slow down its development (rather like what happened with GM technology in the European Union).

Both approaches are now confronted with a larger agenda than perhaps was previously expected. Indeed, rather than "simply" regulating the environmental, safety, and public health implications of nanotechnology, current regulatory drives are responsible for an increased regulatory agenda. In the relevant documents being produced by the European Commission, the U.S. National Science Foundation,

the Royal Society and Royal Academy of Engineers of the U.K., etc., relevant topics are being discussed and incorporated into a regulatory agenda, and are summarized below:

(1) The very application of existing law and regulatory frameworks to nanotechnology (i.e., does international, European, and national regulatory law apply to nanotechnology at all?). As noted, even in the absence of any product-based applications, some general legal principles will apply, such as liability and duty of care;

(2) The requirements imposed by modern environmental and consumer protection law on the regulation of new technologies. This includes the precautionary principle (while contested, this principle at any rate applies generally in European environmental law), liability for environmental damage, etc.;

(3) The public participation principles of international and European environmental law, as exemplified by the *Aarhus* process[37]: access to information, public participation, access to the courts;

(4) Other requirements of international environmental governance, such as the plight of developing countries and the need to avoid what the Commission calls a "knowledge apartheid";[38]

(5) The application of international trade law, in particular the law of the World Trade Organization;

(a) The General Agreement on Tariffs and Trade ("GATT"), which imposes general requirements of non-discrimination, among other things;

(b) The Agreement on Technical Barriers to Trade, which goes beyond the "simple" duty not to discriminate and requires WTO Members to design product regulation, including for nanotechnology, in such a way as to lead to the least restrictive trade regulation;

(c) The Agreement on Sanitary and Phytosanitary Standards ("SPS"), which applies to the food and feed applications of nanotechnology, and requires, among other things, minimum standards of objective and sound research;

(6) Somewhat related to (5), above, is the likelihood of and limits to international coordination in regulating new technologies.[39] Generally, so-called "positive" harmonization of regulatory law is generally perceived as a precondition to a successful counterpart of "negative" harmonization, brought about in particular by the World Trade Organization.[40] Positive harmonization proactively avoids regulatory tension between the constituent parts of a regional (such as the E.U.) or global grouping (such as the WTO), by creating a minimum threshold which Members must not undercut. "Negative harmonization" strikes down regulatory barriers which are seen as obstacles to trade and as infringements of regional or global free trade rules. In the area of nanotechnology, harmonization is not just seen as a driver for free trade, but also as a necessity in the light of the political and military dimensions of the technology;[41]

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[37] The *Aarhus* Convention grants the public rights and imposes on parties and public authorities obligations regarding access to information and public participation and access to justice. *See* http://www.unece.org/env/pp/treatytext.htm (last visited July 14, 2006)

[38] Comm'n for the Eur. Communities, *Towards a European Strategy for Nanotechnology*, at 22, COM(2004) 338 (2004), *available at* http://ec.europa.eu/research/industrial_technologies/pdf/nanotechnology_communication_en.pdf (last visited July 14, 2006).

[39] Mihail C. Roco, *The Emergence and Policy Implications of Converging New Technologies Integrated from the Nanoscale*, 7 J. OF NANOPARTICLE RES. 129, 129-43 (2005); David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law*, 30 YALE J. OF INT'L L. 81, 81-123 (2005).

[40] GEERT VAN CALSTER, INTERNATIONAL AND E.U. TRADE LAW—THE ENVIRONMENTAL DIMENSION (2000).

[41] Graeme Hodge & Diana Bowman, *Governing Nanotechnology: Setting the Regulatory Agenda*, 10 J. OF CONTEMPORARY ISSUES IN BUS. & GOV'T 25 (2004).

(7) The ambitions of regulatory innovation provide grounds for a final theme (i.e., the drive to devise new forms of regulation as an alternative to "command and control").[42] This is particularly poignant in the nanotechnology sector, where the drive to take products and applications to the market is of such urgency as to require a true partnership between industry and the legislator/regulator.

II. CONCLUSIONS: INDICATIONS OF REGULATORY DIRECTION

Regulation of new technologies need not always be driven entirely by the purely environmental/public health impact which one seeks to manage. Other societal interests penetrate the debate, too, and quite justifiably so. In the case of nanotechnology, there would seem to be quite strong externalities other than the purely environmental/public health concerns which emerge as the driver behind regulation. These externalities play somewhat differently in the traditional strongholds of the technology.

Comparing the case of biotechnology presents an interesting context in which to view regulation of nanotechnology. On the one hand, whether rightly or wrongly, Europe's regulators and would-be regulated refer repeatedly to the regulatory failure vis-à-vis biotechnology as a strong incentive for introducing tailor-made regimes for nanotechnology. Hence, the motivation for developing the necessary laws and regulations becomes strongly intertwined with the business sector developing the technology. The very existence of a regulatory framework consequently becomes a value in itself—a precondition for supporting people's belief in the technology, or at the very least an incentive for them not to reject the technology.

Experiences with asbestos liability also provide some interesting lessons for those involved with nanotechnology. A second factor in the development of the regulation is similarly less focused on the very contents of the regime and more focused on the hazards of not having a regime. In this regard, the benchmark is not biotechnology, but rather asbestos. Laws and regulations are then needed to encapsulate product liability so as not to endanger infant products and industries. This is generally perceived to be an issue of particular importance to common law countries. However, in civil law countries, the tendency has been for the legislator to issue acts which limit exposure to liability for specific products, including asbestos fibers.

REGULATORY INNOVATION AND VOLUNTARY INITIATIVES. On both sides of the Atlantic (but also outside the classic U.S.-E.U. debate), much has been made of industry's involvement in the development of the regime.[43] So far, it is unclear whether industry's interest in speedy regulation (for the reasons explained above) will lead to comprehensive, sector-wide, voluntary regulation (as opposed to screening and selective withdrawal for product liability reasons), especially in the long run. Rather, it appears much more likely that one will evolve towards a form of what the E.U. coins "co-regulation." The co-regulation formula would be more akin to a true contract between the regulator and industry. This type of instrument exists already. In the E.U., they are currently called "environmental agreements." Under the

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[42] Gary E. Marchant, Genomics and Environmental Regulation—Scenarios and Implications, Paper Published for the Foresight and Governance Project of the Woodrow Wilson International Center for Scholars, 2002, *available at* http://www.law.asu.edu/files/Programs/Sci-Tech/Commentaries/marchantwhitepaper.pdf (last visited July 14, 2006); Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 HARV. J. OF L. & TECH. 179 (2003); Scott Segal, *Environmental Regulation of Nanotechnology: Avoiding Big Mistakes for Small Machines*, 1 NANOTECH. L. & BUS. 290 (2004); Jason Wejnert, *Regulatory Mechanisms for Molecular Nanotechnology*, 44 JURIMETRICS J. 1 (2004).

[43] More details in the author's forthcoming contribution in Geert van Calster, *Governance Structures for Nanotechnology Regulation in the European Union*, ENVT'L. L. REP. (forthcoming, manuscript on file with author).

new name of "co-regulation," they would be characterized by increased involvement of the European Parliament and of the Council of Ministers, as well as by a stricter monitoring mechanism.[44]

SCOPE FOR HARMONIZATION. While various jurisdictions will consequently come to the regulatory table with different incentives, most of them, perhaps, industry-related rather than health and safety related, they are finding common ground in seeking international harmonization of at the least some of the early stages of risk analysis. Within the ISO, Technical Committee 229 ("TC 229") has been set up with the following mandate:

> Standardization in the field of nanotechnologies, with specific tasks being classification, terminology and nomenclature, basic metrology, characterization, including calibration and certification, risk and environmental issues. The methods of test are to include methods for determining physical, chemical, structural and biological properties of materials or devices for which the performance, in the chosen application, is critically dependent on one or more dimension of <100nm. Test methods for applications, and product standards shall come within the scope of the TC.[45]

TC 229 has three working groups: Terminology and Nomenclature; Measurement and Characterization; and Health, Safety and Environmental Aspects of Nanotechnologies.[46] The establishment of TC 229 within ISO is not groundbreaking in and of itself, but it occurred in surprisingly swift manner. Further, it is a sign of the importance which is being attached to the technology, and to the need for early harmonization of some key concepts.

PRODUCT OR PROCESS-BASED? In the biotechnology/GMO debate, the U.S. and the E.U. were locked into an irreconcilable dispute as to the nature of the distinction between GM and non-GM products. In particular, the E.U.'s view held that the very use of biotechnology renders the final product "unlike" any other. The U.S. put forward that, while the technology used in preparing the product may be different from conventional technology, the end-product was the same as the "conventional" one. In terms of the GATT and the World Trade Organization, like products evidently are to be treated alike, while unlike products can receive different treatment. The GATT and World Trade Organization have never been keen on product distinctions made on the basis of so-called "non-product incorporated" production processes and methods ("PPMs"). Non-product incorporated PPMs do not reflect in the final characteristics of the good at issue. Negative externalities such as environmental pollution during production or the use of child labor are typical examples of non-product incorporated PPMs as is, in the U.S. view at least, the use of biotechnology in the manufacturing of products. Eventually, the similar versus dissimilar product issue was not reviewed by the World Trade Organization Panel ruling on the E.U.'s GMO regime because the Panel found other defaults in the E.U. measures.[47]

Crucially, developments for nanotechnology would seem to go a different way. Both the U.S. and the E.U. would seem to want to tackle technology using a broad, process-based approach, and not a purely product-based approach as could have been the case for the U.S. Part of this shift in focus may be explained by the fact that unlike in the case of biotechnology, there are important health and safety considerations in the manufacturing of nanotechnology products. This distinction may result in the consequential involvement of, among others, U.S. trade unions in the regulatory debate.

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[44] COMM'N OF THE EUR. COMMUNITIES, EUROPEAN GOVERNANCE: A WHITE PAPER, (Apr. 2001), COM (2001) 428, *available at* http://ec.europa.eu/governance/white_paper/en.pdf (last visited July 14, 2006).

[45] ISO, *TC 229: Nanotechnologies*, http://www.iso.org (last visited July 14, 2006).

[46] *Id*.

[47] The interim ruling is available at http://www.foeeurope.org/biteback/WTO_decision.htm (last visited July 14, 2006).

Whether this new fondness for a coordinated approach will lead to harmonization beyond the technical scope of the ISO Committee remains to be seen. However, the prospects for a transatlantic tug of war over the regulation of the technology do seem more remote than with any recent transatlantic regulatory stand-off.