

# Options for State Chemicals Policy Reform

A RESOURCE GUIDE



Lowell Center for  
Sustainable Production

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## The Lowell Center for Sustainable Production

The Lowell Center for Sustainable Production (LCSP) uses rigorous science, collaborative research, and innovative strategies to promote communities, workplaces, and products that are healthy, humane, and respectful of natural systems. The Center is composed of faculty, staff, and graduate students at the University of Massachusetts Lowell who work collaboratively with citizen groups, workers, businesses, institutions, and government agencies to build healthy work environments, thriving communities, and viable businesses that support a more sustainable world.

This report was produced by LCSP's Chemicals Policy Initiative, whose objectives are to significantly advance policy dialogue on reforming chemicals policy in the United States; assist in the development of sustainable chemicals management outside the US; encourage the development and use of safer alternatives by creating and promoting a comprehensive framework for alternatives assessment; and identify tools and appropriate ways of assisting green chemistry innovation and safer supply chain management of chemicals.

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## MODULE 7

# Applying the Chemical Policy Options to Emerging Technologies and Materials: Adaptations and Challenges

■ STEFFEN FOSS  
HANSEN &  
DAVID REJESKI

**Can the template developed in this report for chemicals policy reform be applied in assessing the hazards of emerging technologies and what considerations are involved for state governments?**

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As new discoveries are made, new truths discovered, and manners and opinions change with the change of circumstances, institutions must advance also to keep pace with the times.

— Thomas Jefferson

In the past, it has often taken a long time to identify and establish the direct and indirect short- and long-term risk and benefits of past “emerging technologies,” such as chemicals, nuclear power, and genetically modified organisms. The reasons are many. Some of them are specific to the nature of the emerging technologies in question; others, it seems, are constant from one technology to another. Society periodically faces the same kinds of situations with great proclaimed potential benefits for an emerging technology, but uncertainty or ignorance about its potential short- and long-term adverse effects on human health and the environment. Recurring problems include how to validate proclaimed benefits; how to establish hazards; problems estimating exposure; controversy about whether there is a safe dose of exposure and what it might be; whether the pros outweigh the cons; when we will know enough to implement regulatory measures; and whether lack of information justifies action in and by itself.

Although many of the questions are not new and have been discussed and written about extensively<sup>1-3</sup>, they have yet to be resolved to the extent that they have been implemented proactively. Furthermore, they are not outdated since they keep coming up in the discussion of the “emerging technologies” of our decade, such as nanotechnology, stem cell research, biotechnology, and information and communications technologies. Explanation for why they recur could be that they are always relevant in an ever-changing society with changing priorities and values, and that the specific circumstances of the technology change markedly with every new technology so that it does not make sense to duplicate past practices employed on past emerging technologies.

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However, under the assumption that it is not necessarily always the case and under the assumption that there is a lot we can learn from the past, the purpose of this module is to go through the previous modules and identify adaptations (if any) that would have to be made in order for the individual policy options to be applicable to today's emerging technologies, as well as to the chemicals for which they were originally intended. This approach will use different past and present emerging technologies and materials as examples of how the policy options identified in the modules can be implemented.

First, we provide a definition of emerging technologies and some examples of emerging technologies that are projected to have profound impact on our future. Then we discuss how to proactively identify emerging technologies. Drawing on Denison's work (see Module 1, Denison), we follow by analyzing how one can generate information to manage the technologies given their variety and the diversity of their future applications. Once they have been identified and initial information on them has been generated, Tickner's module (see Module 3, Tickner) is used as inspiration for what to do with this information and how to evaluate and prioritize various emerging technologies. A key element in the evaluation process of chemicals is the availability of safer alternatives, which — based on Rossi's module (see Module 4, Rossi) — will be discussed in the context of emerging technologies. Looking beyond the evaluation process, the timely flow of accurate information to the actors who make decisions is equally important, and a number of recommendations will be made drawing on Massey's work (see Module 2, Massey). This process leads to a discussion about which kinds of capabilities would have to be in place, based on the contribution by Kyle (see Module 6, Kyle), to oversee such multifaceted processes as the ones outlined by Denison, Rossi, Tickner, and Massey.

It is important to ensure that one is on the forefront of the development, information generation, and management of emerging technologies. Also important is establishing short- and long-term incentives to guide research institutions, industry, and others onto a specific innovative path towards sustainability by pre-defining a set of rules that any technology should fulfill. Drawing on Geiser and McPherson's module (see Module 5, Geiser and McPherson) on green chemistry, we discuss how such principles can be broadened beyond well-established technologies and become part of a proactive strategy for the safe management of emerging technologies. A comparison will be made between the policy options described in the modules applied to emerging technologies with a view to these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency. Finally, some reflections on what local and state governments can do will be provided.

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## DEFINING AND IDENTIFYING EMERGING TECHNOLOGIES

The term "emerging technologies" can be broadly defined as "science-based innovations that have the potential to create a new industry or transform an existing one."<sup>4</sup> According to a recent NIOSH publication on emerging technologies and the safety and health of working people,

“Emerging technologies exist where the knowledge base is expanding, the application to existing markets is undergoing innovation, or new markets are being tapped or created.”<sup>5</sup> The term “emerging technology” is broad and a number of technologies have earned the label: from communications technology to biotechnology and nanotechnology (and various others in transportation, energy, and food handling). Here, **the term emerging technologies and materials is limited to those that affect manufacturing processes**, for instance, new materials, and it does not include emerging technologies that affect social interactions, such as the internet, cognitive radio, second life, and so on.

A vital first element of a proactive strategy on emerging technologies is to have a system in place that generates information that allows one to identify emerging technologies and materials. It could take the form of an agency, an office under an agency, or an intra-agency working group (see Module 6, Kyle) that have time and resources to look consistently for emerging technologies and materials. Given their nature, such an agency would have to be interdisciplinary and *not* media-specific. In some countries, such agencies exist already or are being set up. For instance, in the United Kingdom (UK), the Department for Environment, Food and Rural Affairs launched a Horizon Scanning and Futures Programme in 2002 and the government has committed itself to the establishment of a Centre of Excellence in Horizon Scanning, which aims in part to spot the implications of emerging science and technologies.<sup>6,7</sup> In the U.S., the situation is rather strange since such an agency actually existed from 1974 until 1995 in the form of the U.S. Congress’ Office of Technology Assessment (OTA). When Congress voted to withdraw funding in what some have called “Death by Congressional Ignorance,”<sup>8</sup> the OTA had more than 140 full-time employees who provided nonpartisan highly qualified and widely respected analytical assistance to Congress on complex highly technical issues.<sup>9,10</sup> The reasons for setting up the OTA were much like the challenges today with emerging technologies. In the establishing OTA Act, Congress argued that:

1. As technology continues to change and expand rapidly, its applications are:
  - a. Large and growing in scale; and
  - b. Increasingly extensive, pervasive, and critical in their impact, beneficial and adverse, on the natural and social environment.
2. Therefore, it is essential that, to the fullest extent possible, the consequences of technological applications be anticipated, understood, and considered in determination of public policy on existing and emerging national problems.<sup>11</sup>

Emerging technologies are fairly easy to identify since they signal their arrival long before they bloom into full-fledged commercial successes and their emergence is routinely covered by major scientific and engineering societies and journals.<sup>5,12</sup> Further, several websites are dedicated to emerging technologies and studying the future (see NIOSH<sup>5</sup> for a full list of web sites and other sources of information on emerging technologies). *Technology Review* from Massachusetts Institute of Technology has an annual issue identifying ten technologies the editors call the most “exciting and most likely to alter industries, fields of research, and even the way we live.”<sup>13</sup> For the most recent technologies listed by *Technology Review*, see Box on page 208.



## Most Recent Emerging Technologies

1. **Neuron control** which controls neural cells with flashes of light turning selected parts of the brain on and off providing precisely targeted treatments for psychiatric and neurological disorders with greater effectiveness and fewer side effects;<sup>14</sup>
2. **Augmented reality** which adds a GPS sensor, a compass, and accelerometers to smart phones making it possible for users to calculate distance, retrieves the names and geographical coordinates of nearby landmarks and restaurants from an external database;<sup>15</sup>
3. **Peer-to-peer (P2P) file distribution technology** which puts less of a burden on internet networks, saving bandwidth. In P2P networks, there are no central servers in contrast to current networks and each user's PC exchanges data with many others in an ever-shifting mesh;<sup>16</sup>
4. **Digital imaging and compressive sensing** which uses a single image sensor to collect just enough information to let a novel algorithm reconstruct a high-resolution image, saving energy since it does not need to compress images like today's digital cameras;<sup>17</sup>
5. **Light-focusing optical antennas** which increase the capacity of DVDs and the power of computer chips and higher-resolution optical microscopes by adding nanoscale "optical antennas" to a commercially available laser;<sup>18</sup>
6. **Quantum-dot solar power** which uses tiny crystals of semiconductors just a few nanometers wide to convert light energy into electrical current potentially making solar cells much cheaper and making solar power cost-competitive compared with electricity from fossil fuels;<sup>19</sup>
7. **Nano-healing** which uses the ability of nanoscale protein fragments, or peptides, to accelerate healing of damaged brain and spinal tissue potentially saving lives by stopping bleeding and aiding recovery from brain injury;<sup>20</sup>
8. **Artificially structured metamaterials** made up of precisely arranged patterns of two or more distinct materials that can manipulate electromagnetic radiation, including light, in ways not readily observed in nature and which could transform telecommunications, data storage, and even solar energy;<sup>21</sup>
9. **Personal medical monitoring** which uses computer networks to help physicians interpret large amounts of physiological information, such as temperature and blood pressure readings, MRI scans, electrocardiogram (EKG) readouts, x-rays, and so on, making diagnostics more personal;<sup>22</sup> and
10. **Single-cell analysis** which uses ultra-sensitive techniques to isolate cells and reveal molecules inside them that no one even knew were there and detecting minute differences between individual cells that could improve medical tests and let doctors quickly decide on proper treatment.<sup>23</sup>

Not all emerging technologies, of course, will alter industries or the way we live or have potential impact on health and the environment. Being proactive in identifying emerging technologies and generating the initial information for management decisions might turn out to be premature, since the technology might never realize its potential. However, if this happens, the initial time

and resources wasted would tend to be small. They also would be outweighed by the occasions when the technology “makes it,” since the earlier agencies engage in the develop a new technology, the easier it is for them to secure an overview, follow its development, and determine whether it will indeed take off.

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## GENERATING INFORMATION FOR CHARACTERIZATION AND MANAGEMENT OF POTENTIAL RISKS

Once the technologies have been identified, four parts of Denison’s module (Module 1) on generating information become especially relevant: the types of decisions for which information is needed; types of information; testing and alternative methods to generate information; and government’s options for generating information.

### ***Types of Decisions for Which Information Is Needed***

The types of decisions for which information is needed have been controversial in relation to emerging technologies. The types of decisions seem to range from a ban of the technology to a laissez-faire attitude.

Multiple policy options are available for decision-makers engaged in managing emerging technologies, including:

1. Implementing a ban or a time-limited moratorium on research and development (R&D) and commercialization of the technology and products based on it, such as happened in the case of supersonic transport in the 1970s in the U.S.;<sup>1</sup>
2. Implementing a ban or a time-limited moratorium on commercialization of the emerging technology only and products based on it, but maintaining R&D, such as happened in the case of research in recombinant DNA in Cambridge, Massachusetts in the 1970s and the commercialization of genetically modified organisms in the European Union (EU) in the 1990s;
3. Launching a comprehensive, in-depth regulatory process specific to the emerging technology in question with the purpose of forming and implementing a new regulatory framework that takes potentially widely different applications into consideration;
4. Adapting existing regulation so that it covers the emerging technology and ensures the generation of environmental, health, and safety (EHS) information and the protection of human health and/or the environment;
5. Initiating and funding EHS studies at government and non-governmental research facilities and collecting data about, for instance, production, use patterns, and best practices in relation to EHS;
6. Relying on voluntary environmental programs to ensure that human health and the environment are protected and EHS information is generated, such as the U.S. EPA has recently chosen to do in regard to nanomaterials;
7. Relying on current regulatory frameworks to cover the emerging technology and assuming that it is adequate to protect human health and the environment and generation of EHS information; and

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8. Relying on market forces to ensure that human health and the environment are adequately protected, such as in the case of many information and communications technologies.

Which one (or which combinations) of these policy options is eventually adopted by decision-makers will vary depending on the nature and the circumstances of the emerging technology as the modules in this volume illustrate in the case of chemicals.

Given the increasing pace of technological development and the increasingly complex and pervasive uncertainty about their potential beneficial and adverse impacts on the natural and social environments, identifying the right options or the right combination of options must be an iterative process between decision-makers, stakeholders, and the public.

Having the federal government develop an oversight system by itself is not an option in the case of emerging technologies simply because of the pace of technological development. The development of nanotechnology is a good example. The period before 2005 has been labeled the first generation of nanotechnology; it involved the exploration of passive nanostructures and materials, such as zinc oxide in sunscreen. Since 2005, the second generation has moved more toward the development of bio- and physico-chemical active nanostructures. By 2010–2015, it has been projected, scientists will employ guided assembly of nanosystems, and by 2015–2020, the field is expected to expand to molecular nanosystems or atomic design.<sup>24</sup>

Given the high pace of development in fields such as nanotechnology, “it is both unnecessary and impractical to leave the oversight role entirely to a limited set of already overburdened federal agencies,”<sup>25</sup> Greenwood has stated. Developing adequate oversight requires federal outreach to stakeholders — such as industry, academia, non-governmental organizations (NGOs), and others — since these actors are the ones who know the technology “inside out” and they are involved in developing consensus standards, codes, and understandings.<sup>25,26</sup> In the analysis of possible alternative developmental paths, clarification of all stakeholder interests is essential.<sup>26,27</sup> One benefit of such outreach is that it limits the time of uncertainty about future government policies, uncertainties that can be problematic and anxiety-producing for innovators, potential investors, stakeholders, and the public.<sup>28,29</sup>

Any discussions about what policy option(s) are preferable for emerging technologies has to include the public. It is important that discussions not aim to convince and educate the public about emerging technologies to have them accept the technology. That approach has failed stunningly in the past, for instance, on issues of food irradiation and genetically modified crops, for several reasons. First, it assumes that the experts know the true risk and, as Shrader-Frechette<sup>30</sup> has argued, often they do not. Second, it assumes that the perception of risk by laymen is wrong. Although they may lack certain basic information, their conceptualization of risk is richer than that of the expert, including factors such as considerations about uncertainty, controllability, the benefits of taking a specific risk, and threats to future generations.<sup>30–33</sup> Third, when proponents of emerging technologies call for “public education,” they often mean public persuasion. It is



problematic because it not only assumes that the communicator knows what is true, but also that he or she knows what is good and right.<sup>34</sup>

Although one should take care in drawing parallels through history, the cases of food irradiation and genetically modified crops underline that the public should be viewed as a legitimate partner and be involved in both the risk assessment and the risk management process of emerging technologies.<sup>25–28,35</sup> Past experiences have shown that the public may contribute substantially to a scientific decision-making process.<sup>36</sup>

The public may be involved in several ways: for instance, consensus or “layperson” conferences, scenario workshops, and science shops,<sup>37–39</sup> but in many cases (for example, food irradiation), a “due consideration” model has been chosen in the U.S. Normally, it involves the agency (for instance, the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA)) taking a position in advance of public hearings and inviting public comments on its position. Afterward, the agency is obliged to give due consideration to all relevant facts and arguments and explain why it chose the option that it finally adopted.<sup>39</sup> These methods have a number of limitations. For instance, the regulatory decisions already may have been made, so that it cannot be said that the public was involved, but rather that it was allowed only to comment on the issue. Such a scenario would not really reflect the call for a more transparent and democratic decision-making process.<sup>26,27,37,38,40</sup>

Under the right circumstances, public perceptions and reactions can override the customary workings of the regulatory process.<sup>41</sup> Lessons learned from the debate about genetically modified crops (or genetically modified organisms (GMOs)) in the UK stress the importance of considering the concerns of the wider public early during research and development when there is still time for the public’s views to inform the development of new technologies. Early public research on nanotechnology in the UK indicates that the public does not oppose it but has concerns about the path of innovation and the lack of regulatory oversight, offering an opportunity for governments to involve the public and address the issues.<sup>26,28</sup>

### ***Types of Information***

A key question about generating information on emerging technologies is what types of information is needed to inform sound management. Due to the fact that emerging technologies and materials in industrial settings almost by definition would involve application and exploitation of properties not realized before, the new properties are where the focus should be placed in generating health and safety information. Information is needed about the new properties and characteristics: how to determine them; how they affect current methods used to establish hazards, exposure and risks; and — probably most importantly — whether current health and safety protection measures are adequate in the new context and circumstances. Ideally, the information would be available—and applicable — at all stages of the technology’s development, from basic R&D to full-scale commercial launch.<sup>42</sup> For instance, in the case of nanomaterials, the exploitation of additional properties — size, surface chemistry, surface charge, and so on — is what makes

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these materials so different from bulk chemicals. The hazards of nanomaterials would be related to their chemical composition, but also to the effect of these additional properties on biological activity and behavior that scientists do not fully understand now. So in choosing types of information to inform sound decisions about safe management, decision-makers need to include many (if not all) of the elements listed by Denison in addition to extra information that might tell where, for instance, the nanostructure is located in the system (that is, in the bulk, as surfaces, or as particles); the size distribution; surface charge; surface area; solubility; and others.

The amount of information needed to understand the properties, risks, and exposure routes of emerging technologies is likely to be more extensive, and expensive, than for conventional chemicals and product developers, without doubt, will face higher prices on toxicity and other tests until testing becomes routine.

Although one could argue that the tests and their costs are just another hurdle among many barriers<sup>4</sup> to innovation, they will almost inevitably contribute to slowing down commercialization. Costs might be disproportionately high for small- and medium-sized enterprises and might force them to sell their license rather than try to commercialize it themselves. Since much innovation in emerging technologies (nanotechnology and biotechnology, for instance) comes from small companies around the world, attention must be given to providing incentives for companies to do proactive testing of their products.<sup>4,25</sup> A number of ways exist to do this. One could include extra funds to do Environmental Health and Safety (EHS)-related research in grants given through the Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program. The SBIR and STTR programs were set in place to ensure that small, high-tech, innovative businesses became a significant part of the federal government's R&D efforts and the programs are sponsored by eleven and five governmental agencies respectively. Until now they have awarded \$2 billion to small high-tech businesses.<sup>43</sup>

Another possibility is to provide research, education, and technical guidance and support to small- and medium-sized companies, for instance, through establishment of a facility such as the Massachusetts Toxics Use Reduction Institute (TURI), which is mentioned and discussed by Rossi (Module 4) and Tickner (Module 3).

### ***Testing and Alternative Methods to Generate Information***

In the case of chemicals, using methods such as *in vivo* testing and QSARs to generate information are options. But for many emerging technologies, it is not the case. Often, we must apply current ways of testing for hazards and exposure in the workplace and/or in the environment. But the methods often were developed with other technologies in mind; their limitations become more apparent when applied to emerging technologies. It is sometimes unclear whether they are applicable or even directly misleading, and thus new methods must be developed.

Many current test procedures are based on the assumption that mass is a good metric for establishing a dose-response relationship, but it seems not to be the case with nanomaterials.<sup>44,45</sup> Further, a number of the current methods fall short when it comes to materials that are less soluble in water than the substances on which the test protocols were originally designed.<sup>45</sup> Other issues are how to measure not only concentration by mass, but also other characteristics such as size, surface chemistry, surface area, and surface charge, in the air of a workplace setting, in wastewater, and in the environment. In many cases, science does not know whether current methods work or are even applicable to emerging technologies such as nanomaterials.

















The same is true of “alternative methods” like QSARs and exposure models. For many methods, one needs basic background data on the nature and properties of emerging technologies in order to develop and validate alternative methods.

Another pathway is to use genomics and proteomics to identify and assess adverse effects and exposure to nanomaterials through changes in the expression of specific genes and proteins in cells, if patterns between key genes and exposure to nanomaterials can be identified.

### ***Government’s Options for Generating Information***

All four options listed by Denison are available for governments in the case of emerging technologies, and many of the pros and cons of each of the individual options as well. With that said, the nature of the pros and cons differ substantially from option to option and is something that decision-makers will have to consider when they decide how to generate information about a given technology. For instance, the level of demand on government and the level of transparency differ substantially between the government collecting and generating information itself (Denison’s option 1) or requesting that information be provided voluntarily by companies (Denison’s option 3). If the government decides that it needs to collect and generate information itself, resources and expertise need to be allocated to the job, however, the information generated in most cases will be publicly available, thus ensuring a high level of transparency. On the other hand, if the government asks companies to voluntarily provide information about EHS issues, fewer resources will have to be allocated to oversee the submissions; however, in many cases, the information generated will have to be classified as CBI (Confidential Business Information) in order to get companies to participate in the voluntary program. See Table 1 for a comparison of the various policy options described in the module by Denison applied to emerging technologies with various criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution) and transparency.

TABLE 1 A Comparison of the Various Policy Options Described in the Module by Denison Applied to Emerging Technologies

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Generating Information	Gov. collect generates info				
	Gov. requires producers and users to report				
	Gov. request voluntary reporting and provides incentives to do so				
	Gov. helps develop market incentives				

Note: The higher the column the better the option fulfills the criteria.

EVALUATION AND PRIORITIZATION OF EMERGING TECHNOLOGIES–POLICY OPTIONS FOR STATES AND THE FEDERAL GOVERNMENT

In the case of emerging technologies as well as that of many chemicals, large gaps exist in knowledge about the risks for humans and the environment and that situation probably will continue for some time. Past questions about the risks of emerging technology, we also note, often have been raised initially only after the technologies have been commercialized and after workers, consumers, and the environment have been exposed to dangers and, sometimes, been harmed substantially.

As Denison (Module 1) points out, data derived from existing and alternative methods can be used to screen or prioritize chemicals for further scrutiny or management. The same is true in the case of emerging technologies. The hazard information available on the chemical composition of the nanomaterial in question is a logical starting point for screening and prioritizing, although it is important to remember that there is more to nanomaterials than their chemical composition, and hence nanomaterials should not be considered safe based on safety information related only to the bulk material.<sup>25</sup>

In regard to screening options mentioned by Tickner (Module 3), the optimal solution seems to be some combination of the three options. Screening on the basis of existing data and known properties (Tickner’s option 3) has limitations in emerging technologies due to their unique new properties, as already mentioned. For agencies to provide tools to undertake regulatory or voluntary screening (Tickner’s option 1) on emerging technologies and/or materials seems not to be a realistic option in many cases since no one knows whether existing tools actually work.<sup>45</sup> It is especially true in the early stages of the development of a technology. This is not to say that the validation and development of such screening tools should not be pursued, but that it cannot be done by local, state, and federal agencies alone. It must be done in collaboration with industry, academia, and other stakeholders and requests or requirements that industry submit information or undertake screening (Tickner’s option 2) seems to be a key to obtain relevant up-to-date infor-

mation. Collaborating with industry and academia is key since they study, characterize, and have access to basic information to do environmental, health, and safety screening and testing.

Ideally, evaluation and prioritization should be done at various development stages, starting when the technology is still in basic R&D. As proposed by Environmental Defense and DuPont in the case of nanomaterials, periodic re-evaluation and re-prioritization should be done when the technologies move into the next development stage and as new information emerges. At a minimum, it should happen when it reaches: 1) prototyping; 2) pilot testing; 3) test marketing; and finally 4) full-scale commercial launch.<sup>42</sup> Especially during the early stages, any evaluation and prioritization should be based on both preliminary hazard characteristics and a preliminary assessment of where the highest level of exposure of current and potential uses is going to occur across the lifecycle. The evaluation and prioritization will help realize gaps of knowledge and research needs and, optimally, produce more information as the technology matures. Thus, any emerging technology that reaches the marketplace would have been evaluated and prioritized six times for new evidence about inherent hazards and potential current and future uses and exposures.<sup>42</sup>

The model for evaluation and prioritization that is most relevant for any given emerging technology depends on its nature. In the case of nanomaterials, the generic scheme outlined by Muir and cited by Tickner seems helpful. One major challenge with nanomaterials is that their risk depends on the chemical and physical characteristics of the nanomaterial (chemical composition, size, shape, surface characteristics, and so on); the location of the nanostructure in the system (in the bulk, surface bound, free particles, particles suspended in a liquid, and so forth); the route of exposure (inhalation, ingestion, dermal, or injection), and its fate and behavior in the environment and biological systems.

In the case of nanomaterials, the highest level of potential hazard exposure currently seems to be when the material takes the form of free particles for workers and particles suspended in liquids or creams for consumers.<sup>46</sup> Some consumer products, sunscreens for one, directly expose consumers to the nanomaterials in the products. In Muir's scheme, these products fall into the category of controlled use and direct exposure. Other nanoproducts use nanoparticles suspended in a solid, for instance, various golf balls, baseball bats, badminton bats, and other sorts of sports gear. In Muir's scheme, these products fall into the category of product ingredient, a closed system, and outdoor consumer use. By using the scheme, it seems obvious that products with dispersive and indoor use and direct exposure should get a higher priority than products that are controlled and used outdoors in a closed system. Filling out Muir's scheme as a part of the evaluation process at each stage of the developmental advancement of the product, from basic R&D to final commercial launch and eventual disposal, could help agencies prioritize. However, in doing so, it is important to focus on every stage of the lifecycle and not only on exposure during use of the product.









































Evaluation and prioritization based on the inherent hazard characteristics, such as persistency, bioaccumulation, and toxicity, probably would have to be based on chemical composition in the case of nanomaterials, although other characteristics are important as well. They include, for instance,

surface chemistry. But science currently does not know enough yet to evaluate and prioritize these additional characteristics. If the chemical composition is known to be hazardous and there is a high level of potential exposure, then those factors might lead to a higher prioritization, whereas if the chemical composition is known to be harmless and there is a low level of potential exposure, they might lead to a low prioritization. Ultrafine particles become more hazardous the smaller their size so another possibility is to use size rather than chemical composition as a way to prioritize. One also could use analogies between crystalline silica, talc, titanium dioxide, or carbon black for which more is known, such as suggested by Greenwood.<sup>25</sup>

However, as Tickner stated, it is important to remember that although initial screening processes can be used to prioritize, initial screening processes should not lead to determinations of safety, given the lack of knowledge about key hazard properties of nanomaterials.

See Table 2 for a comparison of the various policy options described in the module by Tickner applied on emerging technologies considering these criteria: cost effectiveness, demands on

**TABLE 2 A Comparison of the Various Policy Options Described in the Module by Tickner Applied to Emerging Technologies**

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Evaluation and Prioritization	Provide industry the tools to do screening				
	Require industry to submit info or undertake screening				
	Gov. screening based on existing data				
	Gov. doing rapid/detailed substance assessment				
	Gov. agency doing rapid classification/prioritization				
	Provide tools to industry to do substance assessment				
	Gov. initiates authorization requirements				
	Gov. develops regulatory risk management programs based on the results of the screening and prioritization				
	Gov. issues list of high and lower concern and develops voluntary substitution programs				
	Gov. initiates voluntary industry self-classification challenge to self/classify and reduce use				

Note: The higher the column the better the option fulfills the criteria.



government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

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## SUBSTITUTION, ALTERNATIVES ASSESSMENT, AND EMERGING TECHNOLOGIES

A key element in the evaluation and prioritization process of chemicals is the question of substitution and the results of alternatives assessment. The definition of substitution of chemicals cited by Rossi\* also would be applicable to many emerging technologies, including nanomaterials and biotechnologies. Although it might not make sense to discuss substitution in nanotechnology, biotechnology, and stem cell research, it does make sense to talk about substitution for individual materials and applications of, for instance, nanomaterials. A good example is the use of nano-sized diamond powders as alternatives for silica-coated Cadmium Selenide quantum dots for which toxic ions might be released during diagnosis and treatment.<sup>47</sup> However, a key issue is how to determine whether one material and its application is indeed safer for workers and the environment along the lifecycle of the material compared with another material. It is especially problematic in cases where not much is known about the two materials, applications, and/or processes being compared (see Rossi, Module 4).

There is no reason why the process of substitution listed by Rossi should not apply to emerging technologies like nanomaterials. With that said, many reasons to do substitution probably would be based on what is currently known about the bulk materials, even though other aspects such as surface chemistry, are known to be additional determinants of risks of the individual nanomaterials. Another reason might be the wish to eliminate toxic substances in the process of manufacturing nanoscale materials.<sup>48</sup>

Obtaining information about the incorporation of emerging technologies in specific products has repeatedly been a controversial issue in manufacturers' efforts to bring such products to market. One reason has been manufacturers' efforts to keep their business information confidential. It is important to note the distinction between the public authorities obtaining information versus the public and other stakeholders getting access to information. The public authorities often have access to more information than the public does and past controversies have mainly focused on the public and other stakeholders not having access to important risk-related information.

Obtaining information is of key importance for emerging technologies as well as for chemicals for a number of reasons.

First, if it turns out that there are adverse environmental and health effects related to use of the product, it is vital that governmental and federal agencies know what was in the product so that

\* "The replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organizational measures."

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the culprit can be identified immediately and exposure can be limited (for this and other uses as well). This stance should be the case whether it is based on emerging technology or not. Second, it is important to know the composition of the products to ensure that using emerging technologies indeed adds benefits to society; why would anyone want to take even the slightest risk if there are no benefits associated with it? In the past, even well-meaning and clearly necessary “technological fixes” have led to unforeseen and unintended adverse effects on human health and the environment. CFCs and ozone depletion is a good example. CFCs originally were developed to be a safe substitute for fluids such as ammonia, methyl chloride, and sulphur dioxide in refrigerators. These substances are toxic, flammable, or corrosive. CFCs seemed like a useful substitute since they have great chemical stability. Further, they are almost entirely non-toxic and non-flammable. It later turned out, however, that they were so stable that eventually they ended up in the stratosphere and depleted the ozone layer.<sup>49</sup>

Stories like this warn us about easy “technological fixes” and, although unforeseen risks of implementing emerging technologies cannot be avoided entirely, an impact analysis and stakeholder analysis and consultation can help identify potential adverse outcomes of implementing new technologies. Such openness brings different perspectives and opinions into and thereby reduces the dangers of unintended consequences.<sup>50</sup> In addition, different methodologies exist to identify potential unintended consequences. They include trade-off analysis<sup>51</sup> and work-environment impact assessment.<sup>52</sup> Some risks from emerging technologies also are bound to come as surprises resulting from sheer ignorance, such as in the case of CFCs. Although they seem almost impossible to avoid, adverse impacts of risks can be minimized by looking for “red flags” and “early warnings” and reacting proactively to them.<sup>53</sup> By exploring and implementing a range of preventive options, including multiple perspectives in decision-making processes; using a multi-disciplinary scientific lens and systems perspective to examine the risks of emerging technologies; and developing methods to monitor for “red flags” and “early warnings,” adverse effects can be minimized or avoided.<sup>54</sup>

A third reason why information is important is to ensure that emerging technologies are not misused to make unreasonable claims and that they are not used in false marketing schemes. As Rossi mentioned in the case of chemicals, the purpose of adding emerging technologies to, for instance, consumer products is unclear, as is the amounts in which they are employed. The consumer nano-inventory established by the Project on Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars now shows more than 500 products claiming to entail nanomaterials or based on nanotechnology. The manufacturers promise benefits from using these products and at times refer specifically to “nano” as the provider of the benefits. But it is unclear whether the products actually are based on nanotechnology or whether adding the term “nano” is just used as a marketing scheme. Further, the proclaimed benefits are unclear and it is questionable whether it is necessary to add nanomaterials to or use nanotechnology at all in many consumer products. A consumer group in Korea found little to no improvement in effectiveness after producing a washing machine claiming to use nano-silver as an anti-bacterial agent.<sup>55</sup> In the U.S., *Consumer Reports* made a similar finding when testing stain-resistant Nano-Tex slacks and nano-waxes.<sup>56</sup>

Given the fact that the benefits of adding nano-silver are uncertain and that it is toxic to the environment, it seems that the costs outweigh the benefits, as may be true in other cases as well.

Such violations risk giving the emerging technology a bad name without justification. Recently, a protective glass and bathroom sealant known as “Nano Magic” was recalled in Germany after approximately one hundred consumers experienced severe breathing problems using it. The incident has been seen as an early warning, a “wake-up” call, for nanotechnology and has temporarily led to a greater focus on the potential health and environmental threats of this new technology. It later turned out that the product did not entail any nanoparticles,<sup>57</sup> however, one major issue was that neither the German government nor the manufacturer knew what was in the product. Cases like this one could potentially shape people’s perception of emerging technologies and undermine public trust in the government’s ability to protect them.

See Table 3 for a comparison of the various policy options described in the module by Rossi applied on emerging technologies for these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

**TABLE 3 A Comparison of the Various Policy Options Described in the Module by Rossi Applied to Emerging Technologies**

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Alternatives Assessment	Chemical use information				
	Chemical hazard data and classification				
	Supply-side options				
	Selections policy				
	Multi-attribute options				

Note: The higher the column the better the option fulfills the criteria.

## FACILITATING AND ENSURING THE AVAILABILITY OF INFORMATION ON EMERGING TECHNOLOGIES UP-AND-DOWN THE SUPPLY CHAIN AND OTHER INTERESTED PARTIES

Massey (Module 2) argues that “sustainable chemicals policy requires the timely flow of accurate information to the actors who make decisions about chemicals.” Actors include chemical manufacturers or suppliers, downstream users of chemicals, policy-makers, workers, and members of the public. In the case of emerging technologies, flow of accurate information is of key importance as well for a number of reasons. The public and other stakeholders need access to accurate information in the process of deliberation over the acceptability of a given emerging technology, its risks, and how to respond to the risks.

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Massey mentions a number of disincentives for the free flow of information among manufacturers, downstream users, and the third-party stakeholders in the case of chemicals. They include competition among manufacturers; confidential business information; liability; and supply chain dynamics. These disincentives are applicable to emerging technologies as well. Companies manufacturing nanomaterials compete in exploring and exploiting the various unique properties that materials have at the nanoscale and in many cases the service they are commercializing is a unique combination of these properties. So there is definitely a disincentive for companies to reveal this information to other manufacturers. It is unfortunate that it is access to information about the same unique properties that one needs to do risk assessment. Although it is important to protect confidential business information, it should not be done at the expense of protection of health and the environment.

In some cases, business is required to submit basic information to public regulatory agencies before commercialization. But it is one thing for agencies to obtain information about the content of products and another thing entirely if they provide the information to consumers or other interested parties.

In many cases, such information will almost automatically be classified as confidential business information (see Denison, Module 1) and hence it is impossible for downstream users and any third party to obtain information about the nature of the emerging technologies they may use. In the limited number of cases in which the U.S. EPA has received premanufacture notice on nanomaterials, almost all of the information is classified as confidential. It ranges from the person and company submitting the information, impurity and CAS registry number, synonyms and trade names, to byproduct, first 12-month production volume, use information, site of operation, number of workers exposed and duration of activity, environmental release and disposal. In some cases, even the Material Safety Data Sheets may be classified as confidential.<sup>58-64</sup>

Some claims of CBI seem unreasonable and providing wider access to at least some information seems to be an important step in facilitating the availability of information up-and-down the supply chain and to other interested parties. At a minimum, information made publicly available for chemicals under REACH — name; classification and labeling; physicochemical data, including information on pathways and environmental fate; results of each toxicological and ecotoxicological study; any derived no-effect level or predicted no-effect concentration; guidance on safe use; and, for some chemicals, analytical methods for detecting direct human exposures or discharge of the chemical to the environment—should be made available in the case of emerging technologies, including nanomaterials.

Disincentives such as liability and supply chain dynamics are very relevant in regard to emerging materials and the question becomes what can be done to eliminate these disincentives? Recently, Davies<sup>65</sup> suggested that the two be combined in the case of nanomaterials so that the insurance industry would refuse to insure any nanomanufacturer who did not adopt some oversight framework such as the one recently proposed by Environmental Defense and DuPont (see Appendix A for a summary), which urges companies to share not only information, but also insight into

the basis of risk assessment and management decisions with “[o]ther companies within the supply chain, including those involved in managing waste from the manufacture, use, or disposal of the material or product.”<sup>42</sup>

Just as International Flavors and Flavorings Inc. had guidelines to protect its workers in the case of diacetyl, mentioned by Massey, many companies working with nanomaterials do so as well. Some companies treat all nanomaterials below a 100 nm as hazardous materials as a precautionary measure, but as with International Flavors and Flavorings Inc., the guidelines are not always passed on to downstream users. One way to communicate health and safety throughout the supply chain is MSDSs; however, as in the case of chemicals, companies are not required to do separate MSDSs for nanomaterials and those that report on nanomaterials have serious limitations — they may treat nanomaterials the same way as they treat their bulk chemicals, although properties may differ substantially.<sup>66</sup>

Providing consumer and other downstream users with information in the form of labels has been controversial in the past and is likely to be contentious for emerging technologies as well.<sup>25</sup> Some of these technologies are seen as good marketing schemes, as mentioned earlier. It seems to have been the case in the early development of both nuclear power and nanotechnology that everything seems to be better when it says “atomic” or “nano;” the opposite seems to have been the case with food irradiation and genetically modified crops. The issue of whether to label products containing or processed by emerging technologies keeps coming up. For food irradiation and genetically modified crops labeling requirements eventually were implemented (at least in parts of the world) with the intention to provide consumers a choice, although opposition was fierce.





















As Massey (Module 2) and Rossi (Module 4) mention, governments can facilitate the availability of information on the chemical constituents in products by requiring warning labels on products that contain chemicals of high concern. It is not possible to classify many emerging technologies as safe or as “high concern” in the absence of data so requiring a warning label seems out of the question. However, that does not eliminate all labels.

When governments decide to let manufacturers market products using emerging technologies with or without pre-market EHS testing, government could facilitate information by having a label that states that: 1) the product contains or is based on an emerging technology; 2) that there is limited or no environmental, health, and safety information available at the time; and 3) a telephone number where to call should adverse effects be observed.<sup>65</sup>

There has been an increasing call for labeling of consumer products containing nanomaterials from various stakeholders. *Consumer Reports* has called for labeling, asking consumers to investigate the products they buy; asking them to learn more about nanotechnology; and to contact the FDA and researchers.<sup>56</sup> Further, the ETC Group had an on-line competition on who could come up with the perfect “Beware of Nanotechnology” warning label and received 400 proposals.<sup>67</sup> Given the calls for labeling, one could imagine that some companies might voluntarily start labeling their products or one would advertise that they do not use nanomaterials in their products.

See Table 4 for a comparison of the various policy options described in the module by Massey applied to emerging technologies with these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

**TABLE 4 A Comparison of the Various Policy Options Described in the Module by Massey Applied to Emerging Technologies**

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Ensuring Information flow through the supply chain	Require chemical suppliers to provide information on chemical properties				
	Require toxics use reporting				
	Require public disclosure of product ingredients and health effects				
	Sponsor supply chain collaborations				
	Create databases of information voluntarily submitted				

Note: The higher the column the better the option fulfills the criteria.

## CAPABILITIES NEEDED, IMPORTANT DYNAMICS, AND POSSIBLE MODELS

Kyle (Module 6) outlines the capabilities needed, important dynamics, and possible models for implementation of chemicals policy that would have to be put in place for emerging technologies as well as for chemicals. She lists: 1) keeping track of information; 2) developing procedures and methods; 3) conducting assessments that end with judgments; 4) disseminating and translating information and judgments for relevant audiences; and 5) enforcing required elements. Due to the nature of emerging technologies, new kinds of expertise might be needed within regulatory agencies and, in some cases, they would have to be built from the ground up. Sometimes it will be necessary to find the right combination of regulatory expertise in well-established fields, such as physics, chemistry, technology, and (eco-)toxicology. The challenge will be to establish truly interdisciplinary research units and agencies. This seems to be the case with nanomaterials; however, the current lack of staff with in-depth understanding and training in nanotechnologies in agencies is a potential problem.<sup>65</sup> With other technologies, no established field of research is available that ensures that broader health and safety considerations are included in their development and, hence, regulatory bodies may have to fund and train in new disciplines by establishing undergraduate and graduate courses.

Tracking information may be even more complicated in the case of emerging technologies than in the case of chemicals. It may not be at all clear from the outset what kinds of information should be gathered. This circumstance means that many emerging technologies require identification of key hazard properties to build a database. Information is likely to be required beyond what is



accessible from traditional sources for more well-known technologies. In addition, the fast pace at which emerging technologies develop in their infancy puts extra difficulties on the job of gathering and tracking key information. Information gathering must be broad in scope until key properties — inherent hazard, exposure pathways, protection methods, and others — have been established. For many technologies, the information will not be available in the early stages of development. These circumstances increase the costs and burden on government. But the effort can reward since playing catch-up is costly and burdensome as well.

According to Kyle, a system for chemicals must track the status as follows: a) data and testing requirements; b) screening requirements; c) evaluation; d) any use restrictions or limitations on use; e) pending requirements for additional data, assessment, or action; f) uses reported up and down the product chain. For emerging technologies, a number of basic information requirements also would be of great value should it turn out that risks exist that are associated with the technology. Information that could be gathered without knowing the risk includes number and location of research units looking into the emerging technologies; raw materials used for the research; how emerging technologies are used; number of people potentially exposed; production units; commercially available products; and so forth. Production units or volumes per producer and overall would be of great interest, for instance, in regard to nanomaterials since that information could suggest the number of people potentially exposed. Information about production settings and methods, nanomaterials properties and how they are determined, and risk management practices in place also would be relevant since these factors have been found to influence the overall hazard, exposure patterns, and risk of some nanomaterials.<sup>42</sup>

Whether testing for hazards is a feasible option will depend on the nature of the emerging technology. There is a big difference in testing for the hazards of nuclear power at individual plant sites compared to having to test for the hazards of the great variety of nanomaterials and biotechnologies in a laboratory setting or having to test nano- and biomedicine in humans and genetically modified crops in field trials. Nanotechnology and biotechnology involve a great range of technologies, methods, materials, material properties, and applications and the decision to test for hazard will have to consider such issues. One way is to focus primarily on testing for the hazards of technology to which most people are exposed or the ones for which environmental exposure is the most likely now and in future. Besides the fact that existing methods of testing hazards need to consider the sheer number of possible combinations of, for instance, nanomaterials and related properties, it also would mitigate against a single-nanomaterials or genetically modified organisms (GMOs) testing strategy. Uncertainties in predicting exposure and the variable nature of exposure patterns over time and space mean that solely relying on exposure to determine whether to develop any hazard data seems risky. A new generation of hazard and exposure information is needed to decide whether exposure is significant.

See Table 5 for an evaluation of the various policy options described in the module by Kyle applied to emerging technologies for these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

**TABLE 5 A Comparison of the Various Policy Options Described in the Module by Kyle Applied to Emerging Technologies**

Policy Option			Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Ensuring capabilities	Assessing data quality	Laboratory accreditation program	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
		Verification by a different laboratory	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
	Assessing data	Better standardize testing requirements + comparable protocols	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
		Vest the responsibility in an independent agency	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
		Create a health protective default in place until assessments are completed	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
	Disseminating and translating data + judg. for all audiences	Design a largely self-executing system that translated submitted data in understandable entries	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
		Have separate labeling requirements for consumer products	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
	Ensuring capabilities	Enforcement	Administrative penalties	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
Civil penalties			<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
Criminal penalties			<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
Institutional forms		Create a single purpose chemicals agency	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
		Developing a program within an existing public agency	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
		Creating a hybrid organization combining public agencies and research entities	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
		Networking different entities together	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
		Creating a multi state entity or consortium	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>

Note: The higher the column the better the option fulfills the criteria.

















## ENSURING THAT EMERGING TECHNOLOGIES ARE GREEN AND SUSTAINABLE

Although much of what Geiser and McPherson (Module 5) write on options for innovation and green chemistry is directed toward chemicals, there is no reason why many of the points they make should not be equally applicable to many emerging technologies. Besides green chemistry, a number of other more or less well-established technologies have gone “green” — for instance, green engineering, good electronics, and green nanotechnology. Although, the individual principles of green chemistry, engineering, and electronics, vary in wording, they basically boil down to the same vision, which is to promote sustainable development by identifying clean technologies and minimizing human health and environmental impacts at the early stages of development.<sup>48</sup> This issue is not only relevant for more well-established technologies, but also applies to emerging technologies. When compared to well-established technologies such as chemicals, the emphasis on basic principles for sustainable development, green chemistry, and green engineering, should be stressed even more when the benefits and risks are unclear (as they are with most emerging technologies) since the principles potentially could safeguard us from unpleasant surprises. One emerging technology where basic principles are being adopted more often is in the field of green nanotechnologies.<sup>68</sup> Recently, the Project of Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars published a report on green nanotechnology by Schmidt<sup>48</sup> urging the U.S. government to develop a strategy for stimulating green nanotechnology. The report is full of good examples of green nanotechnology. For one, it includes James E. Hutchison’s development of a way to synthesize nano-gold in a cheaper and faster way without the use of flammable and explosive solvents.<sup>48</sup>

By adopting the basic principles of these “green fields,” in the development of emerging technologies at the earliest possible stage (that is, the design phase), one could help ensure that all emerging technologies are “green” from the outset so that ideally the distinction between “green” and conventional technologies eventually will disappear. The question is, what regulatory or other measures would have to be in place in order to encourage the “green” alternative to a given technology at an early stage? Although some of the challenges are of a scientific and technical nature,<sup>68</sup> it is well-recognized that governments play a considerable role in every stage of development from research to building its early infrastructure to sorting out its social repercussions.<sup>69</sup> Governments do so through a number of mechanisms, such as providing legal and public institutions that discourage and encourage certain paths of innovation; funding basic research and infrastructures with no short-commercial value; and by providing subsidies. Most of the funding currently used in nanotechnology R&D stems from public sources. Governments should help to guide and shape the future path of innovation in the direction of sustainable development to secure greater overall individual and societal benefits.

See Table 6 for a comparison of the various policy options described in the module by Geiser and McPherson applied to emerging technologies for these criteria: cost effectiveness, demands on government, performance for achieving safety goals (information, evaluation, substitution), and transparency.

TABLE 6 **A Comparison of the Various Policy Options Described in the Module by Geiser and McPherson Applied to Emerging Technologies**

Policy Option		Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Green Innovation	Research and development support				
	Technical assistance				
	Targeted procurement				
	Economic policies				
	Regulations promoting green chemistry				

Note: The higher the column the better the option fulfills the criteria.





































CONCLUSION

In Tables 1–6 we used four criteria of cost effectiveness (including speed of implementation and putting burden on industry), demand on government, performance, and transparency to evaluate the various policy options in the light of the policy options listed by the authors in their respective modules on chemicals. In Table 7 (page 227), we have tried to evaluate the various policy options available in regard to emerging technologies (listed in section 3.1) in the light of the same four criteria.

When looking at Table 7, options such as banning, banning some applications, a moratorium on R&D and/or commercialization, in general, rank high in regard to cost effectiveness. Various reasons account for it, including that some options are assumed to be faster to implement compared with, say, an incremental approach or developing a new regulatory framework. In addition, imposing a ban or a moratorium on both/either/or R&D and commercialization puts a burden on industry due to lost investments (in the case of a ban); lost income while EHS data is generated, and a potential mandatory obligation to generate EHS information (in the case of a moratorium).

Options such as bans do not normally put much burden on government besides the question of how to enforce such a measure except in cases of enabling technologies that are applied in a large number of products, methods, and settings. Implementing a moratorium either on R&D and/or commercialization puts more demand on government since it will have responsibility for generating EHS information while the moratorium is in place or must provide incentives for companies to do so.

**TABLE 7 Policy Options for Emerging Technologies Evaluated in the Light of the Four Criteria: Cost Effectiveness, Demands on Government, Performance for Achieving Safety Goals (Information, Evaluation, Substitution), and Transparency**

Policy Option	Cost Effectiveness	Demand on Government	Performance for Achieving Safety Goals	Transparency
Ban on R&D and commercialization				
Ban on commercialization				
Moratorium on R&D and commercialization				
Moratorium on commercialization				
Initiating and funding EHS studies and collecting data				
Voluntary programs				
Incremental approach				
New regulatory framework				
No additional regulation				

Note: The higher the column the better the option fulfills the criteria.

Which options are the best choices in a particular situation will depend on the potential adverse health and environmental impact of the emerging technology in question. For instance, the ban on supersonic transport in the U.S. was able to prevent adverse impact on the environment. It is important to remember though that reaping the benefits of the technology is not included in the criteria used to evaluate the various policy options in this analysis. This ignores the possibility of missed opportunities that might have led to environmental and health benefits while a ban or a moratorium is in force. In bio- and nanotechnology in the field of medicine, benefits are expected to be substantial and should not be ignored when considering bans or placing a moratorium on commercialization.

The European Parliament's Scientific Technology Option Assessment (STOA) committee has published a study on the role of nanotechnology in chemical substitution of hazardous substances. STOA concluded that although nanotechnology cannot presently contribute in an exceptional manner to a large increase in the substitution of hazardous chemicals, its long-term contribution to substitution is manifold and incremental.<sup>70</sup> An example of an "incremental substitution" of hazardous chemicals is the work by Zhou and his group at Headwater, Inc. Zhou recently won the Green Chemistry award for his discovery of a way of manufacturing hydrogen peroxide using

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a palladium-platinum catalyst based on nanotechnology that requires no hazardous materials and produces no byproduct except water. Further, hydrogen peroxide is a safer alternative to chemicals such as chlorine and chlorine-containing bleaches and oxidants.<sup>71</sup> The substitution of hazardous chemicals by the use of emerging technologies, such as nanotechnology, is a potential opportunity lost by implementing options such as bans or moratoriums by default.

In regard to performance in achieving the overall goal (the third criteria), the policy options that score the highest are the incremental approach (that is, adapting existing legislation, technical guidelines, codes of conducts, and so on) and developing a new regulatory framework. They generally score high because decision-makers can potentially design them to meet the needs identified for, say, generation of information, promoting alternatives assessment, green technologies, and others. The down side with these options is that they put great demand on government. In the case of adapting existing legislation, it is no small task to apply it to, for instance, nanomaterials, due to the sheer number of amendments needed.<sup>65,66,72</sup> Designing a new regulatory framework that is effective and that works in practice requires much effort from already under-funded government agencies that also must take into account the political and/or interagency bureaucracy; stakeholder concerns and interests; public participation; and development of technical support and guidance.<sup>65,73</sup>

Although many of the issues addressed in this module and the policy options outlined above seem most appropriate to implement on a federal level or even a global level, there is a lot that local and state government can do. The recent development in the recognition of the problems associated with climate change in the U.S. stands as a good example of how much impact local communities, individual states, and collaboration between states can have on shaping the debate on a truly global issue.

Having local and statewide bans and moratoriums can send strong signals. Such was the case with the moratorium implemented in the late 1970s on recombinant DNA research in Cambridge, Massachusetts. The most proactive research facilities and companies might see local regulatory oversight as a reflection of a mature understanding of a technology and a reason to establish themselves in a particular area. As has been reported in the case of recombinant DNA though, the risk is real that they might move their research facilities, investments, and workplaces.<sup>74</sup>

Another option is to ask companies to submit EHS information. The city council of Berkeley has pursued this approach on nanomaterials, issuing an ordinance requiring manufacturers to disclose various information about the properties of their materials, production facilities, state of EHS research, and their EHS control measures in force. Although it has been criticized, the approach has led to a much needed debate about whether and how nanomaterials should be regulated and the case provides a good example of one approach that local governments can take when they face emerging technologies.



A third approach is for local governments and/or states to have an active expert and stakeholder deliberation over a longer period of time. This approach is currently being pursued in Cambridge, Massachusetts, in decisions about nanomaterials.

Whereas the action of local governments can have some national impact on the debate about how to approach and regulate emerging technologies, states can have a huge impact on policy development, the path of innovation, and the success or failure of a technology. The promotion of biofuel and stem cell research in California provides a huge push for research and development of these emerging technologies which affect more than just the citizens and industry of California. Another example of the huge impact states can have on emerging problems is the interstate collaboration termed the New England Climate Coalition, which was formed in 2003 by the governors of all six New England States in addition to New York, New Jersey, and Delaware to create a regional program to reduce greenhouse gas emissions.

Some of the larger states and potential coalitions of states have nearly all of the same options available as the federal government because of their access to resources. While local governments hardly have the option or the expertise to generate EHS data themselves, it is certainly an option that state governments potentially could pursue either alone or in collaboration with other states. The state of California initiated EHS-related research in the case of MTBE that finally led to its ban first in California, then in other states, and finally on a federal level.<sup>75,76</sup>

One significant way that states could influence the development and emergence of green technology is by requiring that EHS issues are considered and research is stipulated when they provide funding to develop emerging technologies in their states. Officials in Massachusetts, Pennsylvania, and California have provided between \$60 million and \$95 million each for research on and development of nanotechnology and other emerging technologies.<sup>77-79</sup>

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## APPENDIX A

# Summary of the Nano Risk Framework Proposed by Environmental Defense and DuPont Corporation

In early 2007, the environmental group Environmental Defense (ED) and DuPont Corporation released for public comment a draft Nano Risk Framework, describing a process for ensuring the responsible development of nanoscale materials.<sup>42</sup> The framework was expected to be finalized in summer 2007, after which it could be freely used by companies and other organizations. The intent of the framework is to define a systematic process for identifying, managing, and reducing potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product's lifecycle. It is meant to offer a voluntary approach to facilitating the responsible development of nanomaterials by companies, private and public research institutions.

The framework is designed to be used iteratively at different stages of development advancement (that is, basic R&D, prototyping, pilot testing, test marketing, and finally to full-scale commercial launch) and as new information becomes available. Explaining all elements of the framework is beyond the scope of this module but, in short, the framework consists of six distinct steps:

1. Develop a general description of the nanomaterial and its intended uses, based on information already available and identify analogous materials and applications that may help fill data gaps in this and other steps;
2. Develop profiles of the nanomaterial's properties, inherent hazards, and associated exposures considering all the elements of the nanomaterial's full lifecycle and considering that a material's properties, hazards, and exposures may change during the lifecycle;
3. Evaluate all of the information generated in the profiles and identify and characterize the nature, magnitude, and probability of risks of the nanomaterial and its application. Gaps in the lifecycle profiles should be prioritized and a decision should be made on how to address them;
4. Evaluate the available risk management options and recommend a course of action, including engineering controls, protective equipment, risk communication, and product or process modifications;
5. Decide alongside key stakeholders, experts, and decision-makers whether or in what capacity to continue development and production and document these decisions and their rationale and share appropriate information with the relevant stakeholders; and
6. Update and re-execute the risk evaluation regularly or as necessary to ensure that risk management systems are working as expected and adapt in the face of new information or conditions; document and share appropriate information with relevant stakeholders.<sup>42</sup>

ED and DuPont have developed a system to help guide information generation and update assumptions, decisions, and practices as new information becomes available. At various stages in the product-development process, the draft document provides a worksheet to help participants: 1) organize, document, and communicate the information they have about their material; 2) to acknowledge that information is incomplete; 3) to explain how information gaps were addressed; and 4) to explain the rationale behind the user's risk management decisions and actions. However, the amount of information required in the framework is directly related to potential extent and degree of exposure of the specified application. ED and DuPont recommend that a broad range of stakeholders have access to the worksheet or summaries of it as products move into commercialization in order to facilitate ease of understanding.<sup>42</sup>

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