

**Remarks by  
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**International Conference on  
Transatlantic Regulatory Co-operation:  
Securing the Promise of Nanotechnology**

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**INTRODUCTION**

Good morning.

I am delighted to be here today to share with you EPA's work on nanotechnology and the new direction the Obama Administration is charting on public health and environmental protection.

I want to thank the sponsors, including the Chatham House, the London School of Economics, the Woodrow Wilson International Center for Scholars, and the Environmental Law Institute, for organizing this conference.

I hope that the dialogue that we have over the next two days will be in keeping with the tradition of Chatham House. The past generations of leaders who made history here clearly were looking out for future generations like ours.

I also hope is that future generations will look back on the work we have done and conclude that we too made the right decisions.

One of the biggest challenges we face as environmental regulators and policymakers is to take a far-sighted look at the issues presented by new substances like nanomaterials. And in

doing so, we need to make sure that we don't regulate too much or too little, but that we instead "get it right."

The consequences of not getting it right can be significant. For example, in the Office of Prevention, Pesticides & Toxic Substances at EPA, we routinely deal with the multitude of problems created by legacy chemicals, such as asbestos, PCBs, mercury and lead, all of which at one point provided benefits to our society but were inadequately controlled in the past.

The potential benefits of nanotechnology are enormous. And in our consideration of nanotechnology, we need to make sure that we do not stifle innovation or place unwise restrictions on nanomaterials or their uses.

But we also must ensure that our policies do not create a whole new generation of legacy chemicals with a whole new set of problems. Our task is find the right balance – to "get it right" – and allow the promise of nanotechnology to be realized, while protecting against unwanted implications for future generations.

So how do we do that? How do we get it right?

## **ADMINISTRATOR JACKSON'S PRIORITIES**

Let me start to address that question by talking about the priorities of our new EPA Administrator, Lisa Jackson.

Administrator Jackson has made scientific integrity a cornerstone of her Administration. She believes very strongly that our environmental protection decisions must be governed by three fundamental principles: science, transparency and the rule of law.

Having worked at EPA previously in her career, Administrator Jackson knows how important it is to rely on the expert judgment of EPA's career scientists and independent advisors. She also recognizes that the public trust in EPA demands that we follow the rule of law. We must reach out to all stakeholders fairly and impartially, consider the views and data presented carefully and objectively, and fully disclose the information and rationale that form the bases for our decisions.

Administrator Jackson has outlined five key programmatic priorities for EPA. One of these is managing chemical risks.

Indeed, on her first day on the job, Administrator Jackson announced that we need to revise and strengthen the way EPA assesses and manages the potential risks that may be posed by chemicals. This includes nanomaterials.

## **NANOTECHNOLOGY**

While nanotechnology has enormous possibilities, there are significant questions about its potential health and environmental risks.

As part of our effort to address these questions, EPA has been collaborating with other federal agencies, U.S. stakeholders, and our international partners on a range of activities, including research, regulations, and voluntary initiatives.

Through these collaborations, we have enhanced our understanding of the benefits and risks of nanotechnology.

But as a regulatory agency, it is EPA's responsibility to have the appropriate oversight mechanisms in place to ensure that the public is protected from any unreasonable risks that may be posed by nanoscale materials.

The Office of Prevention, Pesticides and Toxic Substances is reviewing -- and regulating – nanomaterials under both the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Manufactured nanomaterials used in industrial chemical applications fall under TSCA, while nano-pesticides are governed by FIFRA.

These two programs address nanomaterials differently due to the different legal authorities and requirements in each statute.

## **TSCA**

Let's talk about TSCA for a moment.

As many of you know, there are limits to EPA's ability to regulate chemicals under TSCA.

TSCA does not require EPA to determine the safety of *existing* chemicals, and it does not require manufacturers of existing chemicals to submit health and safety data to EPA except under limited circumstances.

TSCA also places some obstacles that must be overcome before EPA can obtain data from industry on the health and environmental effects of existing chemicals.

And TSCA makes it difficult for EPA to take action to limit or ban chemicals even when they are found to cause unreasonable risks to human health or the environment.

Because of the problems with TSCA, there is growing consensus in the United States, including among industry, that TSCA must be reformed. TSCA is the only major US environmental statute that has not been updated by Congress since it was initially

enacted more than 30 years ago. We need to bring TSCA into the 21<sup>st</sup> Century.

We are hopeful that TSCA will be updated by Congress. But while we are working for legislative reform, we at EPA also intend to use our current authority to the fullest extent under the law to address chemical risks and protect public health, including potential risks presented by nanotechnology.

Many nanoscale materials, such as carbon nanotubes, are clearly “chemical substances” under TSCA subject to EPA oversight. Where nanoscale materials are considered “new chemicals” under TSCA, we require pre-manufacture notices (PMNs) to be submitted for them. To date, EPA has received over 70 PMNs for nanoscale materials.

We are proposing Significant New Use Rules (SNURs) for carbon nanotubes that will prevent environmental releases and protect against exposures to these substances.

Last year, under the previous Administration, EPA launched a Nanoscale Materials Stewardship Program to encourage the voluntary submission of data and information from manufacturers and processors of nanomaterials. While some helpful data was gathered, that program was less than a resounding success.

For example, two-thirds of the chemical substances from which commercially available nanoscale materials are based were not reported.

Moreover, approximately 90% of the different nanoscale materials that are likely to be commercially available also were not reported.

In this new Administration, EPA now is taking a more proactive approach toward oversight of nanomaterials to the extent possible

under TSCA to fill the data gaps and develop an appropriate regulatory approach.

For example, we are developing a reporting rule under TSCA section 8(a), which we expect to propose in 2010, to require companies to report a range of information on nanoscale materials, including:

- data on existing uses,
- production volumes,
- specific physical properties,
- chemical and structural characteristics,
- methods of manufacture and processing,
- exposure and release information, and
- available health and safety data.

We also are developing a test rule under TSCA section 4 to require companies to test several manufactured nanomaterials for health and environmental effects.

The information submitted under these regulations will further our understanding of the uses and potential risks of manufactured nanomaterials, and strengthen the scientific basis for taking appropriate risk management actions.

Let me also raise one more important point about EPA's approach under TSCA.

As you know, in January 2008 during the previous Administration, EPA announced that it would determine whether a nanoscale substance is a new or existing chemical for purposes of TSCA based on the "molecular identity" of the nanomaterial rather than its physical attributes such as particle size and/or any physical or chemical properties that result from the difference in particle size.

Under this policy approach, a nanoscale substance that EPA determines to have the same molecular identity as a substance listed on EPA's TSCA Inventory is considered to be an existing chemical under TSCA and consequently is subject to much less scrutiny from EPA because of that designation, due to the different ways TSCA treats existing and new chemicals.

In the new EPA under Administrator Jackson's leadership, however, we are reviewing a number of the policy choices made by the previous Administration. This includes the policy on how nanomaterials should be treated under TSCA. I cannot say what the outcome of that review will be, but I can tell you that we will be taking a fresh look at this issue and at the basis and reasoning for the decision made by EPA last year.

## **FIFRA**

Let me now talk about FIFRA for a moment.

EPA regulates the distribution and use of pesticide products under FIFRA. Under FIFRA, before a company may sell any new pesticide product, it must apply for and receive EPA's approval in the form of a "registration." Before a registration can be granted, EPA must determine that the pesticide product meets the safety standards of FIFRA.

Applicants for registration must generate or supply the data needed to demonstrate that their products meet these standards.

As with commercial chemicals, nanotechnology is beginning to be used in the manufacture of pesticides. In fact, we recently discovered the presence of nanosilver in at least one currently registered pesticide. This discovery has led us to begin checking

other registered pesticides to determine whether they may contain nanosilver.

There are likely other pesticides in the marketplace that intentionally or inadvertently contain nano-scale constituents. We will be looking at these products closely.

We also are becoming aware of a number of unregistered products that claim both to contain nanoscale materials and provide pesticidal control. We don't yet know whether these products really contain nanoscale ingredients, but we are actively investigating them.

And we have heard from more than half a dozen companies that want to make and market new pesticides containing nanoscale ingredients. These too will get a close look before we approve any new registration.

Most of the products we are seeing involve the addition of nanosilver to material substrates such as plastic, textiles, and coatings, to impart an antimicrobial property to the treated material.

These products raise a number of challenging questions such as what data are needed to evaluate the safety of these pesticides, how should studies on them be performed, and how should EPA assess any potential risks.

To help address these questions, we are convening a meeting of experts on nanotechnology and risk assessment in November of this year under the auspices of the FIFRA Scientific Advisory Panel.

We will ask these experts for advice of what types of data should be required to assess the risks of nanoscale pesticide ingredients

and what our research priorities should be. And we will use this advice to inform our decisions on how to evaluate pesticide products that contain nanoscale ingredients.

## **RESEARCH**

There is a great deal to learn about the environmental and health applications - and implications - of nanotechnology. Research is critical in addressing many of the data gaps and in informing the decisions we must make in our regulatory programs.

In June of this year, EPA's Office of Research and Development issued its Nanomaterial Research Strategy to guide its research program. The Strategy focuses on four key areas:

- Identifying sources, fate, transport, and exposure
- Understanding human health and ecological effects
- Developing risk assessment approaches, and
- Preventing and mitigating risks

At present, the research program focuses on five types of nanomaterials: carbon tubes, and fullerenes; cerium oxide; iron; silver; and titanium dioxide.

EPA's research strategy is designed to address questions that decision makers need answered, such as:

- What nanomaterials, in what forms, are most likely to result in environmental exposure?
- What particular nanomaterial properties may raise toxicity concerns?
- Are nanomaterials with these properties likely to be present in environmental media or biological systems at

concentrations of concern, and what does that mean for risk?

- If nanomaterials are present at levels of concern, can we change their properties or mitigate exposure?

Answering these questions will enhance the scientific basis for regulations and policies under both TSCA and FIFRA that minimize potential adverse impacts and maximize the benefits of nanomaterials.

## **INTERNATIONAL COLLABORATION**

Finally, let me spend a few minutes on the importance of the cooperative work being done on nanotechnology in the international arena.

US collaboration with our international partners has been instrumental in enhancing our understanding of both the benefits and risks of nanomaterials.

The OECD Working Party on Manufactured Nanomaterials – the WPMN -- is the United States' most active forum for international burden-sharing and harmonization on nanomaterial environmental, health and safety matters.

As many of you know, EPA, on behalf of the United States government, had the honor of chairing the WPMN for several years. We greatly appreciate the support and assistance we received from the European Commission and EU member countries in that effort. We remain strongly committed to all WPMN projects.

Through our ongoing dialogue with our European partners, a common understanding has emerged:

Strong partnerships are essential to develop the data and tools to assess and manage nanomaterials;

The United States, the EC and EU member countries can continue to learn from the experiences of each other; and

We can and should share the burden – and results - of testing and research across jurisdictions.

In addition to the WPMN forum, EPA has regularly held bilateral discussions with the EC, Canada, Japan, and Australia on nanomaterials.

We also have been collaborating in other OECD groups and international organizations.

For example, the US government participates in the Working Party on Nanotechnology, which was established by OECD's Committee on Science and Technology Policy (CSTP) in March 2007. This group is focused on promoting the development of nanotechnology and its benefits and coordinates its work with the WPMN and other intergovernmental organizations.

EPA also actively participates in the International Organization for Standardization's (ISO) technical committee ISO/TC229, which is developing international standards for terminology and nomenclature, metrology and instrumentation.

We are particularly pleased that, at its last meeting, the International Conference on Chemicals Management, part of the Strategic Approach to International Chemicals Management, or SAICM, passed a resolution on manufactured nanomaterials that proposed holding regional workshops in developing countries and countries with economies in transition. We understand that

UNITAR, working together with the SAICM secretariat and the OECD will be organizing them.

## **Conclusion**

In conclusion, let me re-emphasize that the goal of many of EPA's current efforts toward nanotechnology is to obtain the best scientific data possible to inform our evaluation of the safety of new products and materials that contain nanoscale ingredients.

We will continue to support efforts to strengthen international cooperation to develop this much-needed data, and we pledge to continue our active participation in international oversight approaches wherever appropriate.

The opportunity for real progress is at hand, and I look forward to working with all of you to strengthen our cooperation on approaches to nanotechnology.

Thank you again for including EPA as part of your meeting and for inviting me to speak to you today. I am very much looking forward to the discussion over the next two days.