

**Ninth Antimicrobial Workshop  
Remarks by  
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**Introduction**

Good afternoon.

I want to thank the American Chemistry Council, the Consumer Specialty Products Association and ISSA for inviting me to be here today.

I am extremely honored to have been chosen by President Obama to be the Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances at EPA under Administrator Lisa Jackson.

It has been almost four months since I began at EPA. Over that time, I have been learning plenty about a wide range of issues, including antimicrobial products.

These products have a unique and important role to control viruses, bacteria and other bad things people don't want to think about.

I look forward to working with you during my tenure at EPA and learning more about the issues and challenges facing your industry.

## **Administrator Jackson's Priorities**

Let me start by talking about the priorities of our new EPA Administrator, Lisa Jackson and some of the announcements I have made over the last four months.

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 has made scientific integrity a cornerstone of her Administration.

She 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 basis for our decisions.

So let me talk for a moment about some of the things we've been doing lately at OPPTS, including steps we have taken already to expand transparency. Then, if we have time, I will spend a bit of time talking about the effort to reform the Toxic Substances Control Act (TSCA).

While I understand TSCA is not the primary statute for your industry, it does affect inert ingredients such as adjuvants, as well as chemical intermediates used in the manufacturing of pesticide active ingredients.

Also, your letter of invitation mentioned this issue, and we have been working closely with the ACC and the CSPA on TSCA reform.

### **New Transparency in Registration Decisions**

Recently we announced new public participation opportunities for registration actions.

For all new active ingredients, a first food use, first outdoor use, or first residential use, EPA will post the risk assessment and proposed decision in the public docket.

So far we have two new active ingredients posted.

The documents can easily be accessed at [www.regulations.gov](http://www.regulations.gov)

The risk assessment and proposed decision will be available for a 30-day public comment period.

After the comment period closes, EPA will prepare and make public a response-to-comment document.

We think there will be broad benefits to the public, the user community, and others to be informed about the risk assessment and risk management processes associated with registration activities.

## **Design for the Environment**

Another priority is to improve how consumers and other pesticide users easily recognize safer products.

So over the next several months EPA is launching a new pilot to evaluate several pesticide products for inclusion in the Design for the Environment Program.

And these products that will be evaluated happen to be antimicrobial products.

But before a DfE logo is allowed on a label, EPA undertakes a robust scientific evaluation to ensure that the product is formulated from the safest possible ingredients.

A DfE logo means that the DfE scientific review team has screened each ingredient for potential human health and environment effects and that—based on the best currently available information and on EPA predictive models and expert judgment—the product contains only those ingredients that are among the safest chemicals in their class.

So today, I am announcing a new pilot where EPA will evaluate antimicrobial products to determine if they qualify for the DfE logo.

So if this pilot goes smoothly, we could expand this program in the future.

## **H1N1 Guidance**

Last week we issued Guidance for Testing and Labeling Claims against the 2009 H1N1 Virus and posted the guidance on our website.

The guidance sets forth our position that data previously submitted to support influenza A virus label claim is sufficient to support label claims against the 2009 H1N1 influenza A virus. Virus-specific data against the 2009 H1N1 influenza A virus does not need to be generated or submitted for registration.

The guidance is applicable for antimicrobial pesticides sold as dilutable liquids and powders, ready-to-use or spray formulations, and towelettes that are used to treat hard non-porous surfaces in healthcare facilities, commercial, industrial, institutional and residential settings against the 2009 H1N1 influenza A virus.

We received some inquiries from the CSPA about the need to get this guidance posted ASAP, and we definitely wanted to get this done.

### **Endocrine Disruptor Screening Program**

As part of Administrator Jackson's charge to improve the way we assess and manage chemicals, tomorrow EPA will start issuing test orders to move forward to screen 67 pesticide chemicals for hormone effects.

It has taken EPA far too long to get this program moving, but we are now taking an important step forward with the test orders.

The data generated from the screens will provide robust and systematic scientific information that will help EPA identify and regulate as appropriate potential endocrine disrupting chemicals.

## **Nanotechnology**

Let me turn now to a quick discussion about our work on nanotechnology. We are addressing nanomaterials under both FIFRA and TSCA.

### **Nanotechnology under FIFRA**

We all recognize that nanotechnology has enormous possibilities, including various antimicrobial applications, but there are significant questions about its potential health and environmental risks.

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 two currently registered pesticides.

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 next week under the auspices of the FIFRA Scientific Advisory Panel.

We will ask these experts for advice about 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.

### **Nanotechnology under TSCA**

In addition to our work on nanopesticides under FIFRA, we are looking at how nanomaterials should be treated 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.

So we are taking a look at this policy decision.

I cannot say what the outcome of that review will be, but I can tell you that we are taking a fresh look at this issue and at the basis and reasoning for the decision made by EPA last year.

### **Toxic Substances Control Act (TSCA) Reform**

Finally, let me give you a quick update on TSCA reform.

One of Administrator’s Jackson’s top priorities for EPA 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, including pesticides.

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 for new chemicals to EPA except under limited circumstances.

TSCA also creates some challenges 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 shortcomings of TSCA and the increasing concern among the public about the safety of chemicals and the products they are made from, there is a growing consensus among industry, the environmental community, states and the Administration that TSCA needs to be reformed.

TSCA is the only major environmental law that has not been updated since its passage more than 30 years ago. It's time to bring TSCA into the 21<sup>st</sup> Century.

### **Principles for Chemical Reform**

On September 29<sup>th</sup>, the Obama Administration announced its principles to guide the reform of TSCA.

It is important to understand that these are the Administration's principles for TSCA reform, not just principles articulated by EPA alone.

First, we need to review all chemicals against safety standards that are based solely on considerations of risk:

- We must set these standards at levels that are protective of human health and the environment.

Second, safety standards cannot be applied without adequate information, and responsibility for providing that information should rest on industry.

- Manufacturers must develop and submit the hazard, use, and exposure data demonstrating that new and existing chemicals are safe.
- If industry doesn't provide the information, EPA should have the tools to quickly and efficiently require testing, without the delays and procedural obstacles currently in place.

Third, both EPA and industry must include special consideration for exposures and effects on groups with higher vulnerabilities – particularly children.

- Children ingest chemicals at a higher ratio to their body weight than adults, and are more susceptible to long-term damage and developmental problems. Our new principles offer them much stronger protections.

Fourth, when chemicals fall short of the safety standard, EPA must have clear authority to take action.

- We need flexibility to consider a range of factors – but must also have the ability to move quickly.
- In all cases, EPA and chemical producers must act on priority chemicals in a timely manner, with firm deadlines to maintain accountability.

- This will not only assure prompt protection of health and the environment, but provide business with the certainty that it needs for planning and investment.

Fifth, we must encourage innovation in green chemistry, and support research, education, recognition, and other strategies that will lead us down the road to safer and more sustainable chemicals and processes.

- All of this must happen with the utmost transparency and concern for the public's right to know.

Finally, we need to make sure that EPA's safety assessments are properly resourced.

- Clearly we've had a successful track record with PRIA and so we think under the TSCA programs industry should contribute its fair share of the costs of implementing new requirements.

## **Conclusion**

Thank you for the opportunity to be here today.

I hope that you continue to have a successful conference.