

# Importance of Policy and International Activities to NbA Companies

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## My impression is....



You are very busy

Your day is full running your business

You need to find ways to keep revenues up and costs down

You recognize the need to include compliance requirements in your company's activities

It may not be apparent how getting involved in regulatory policy development and international activities is going to help you deal with the things above.

But you **NEED** to be involved!

Why....?

# Why...



You want to get to market faster – Make \$\$ faster!

You will have more time to plan for new requirements – Keep costs down.

Regulatory changes are coming – e.g. TSCA

# Regulatory Policy Development



## Issues:

Companies may believe that their materials are defined by single set of measured properties

Each regulatory body may look on the properties in ways that help them achieve their mission

For example – Particle Size

Is a primary particle with size between 1-100 nm a nanomaterial?

What about 110 nm?

Are fused aggregates of 1-100 nm primary particles NM?

How important is surface area?

Is a treated particle (e.g. for improved matrix compatibility) still the same NM or is it a new NM?

# Regulatory Policy Development



## **Ways to be involved:**

As important stakeholders it may be possible for NbA members to encourage regulatory agencies to increase their coordination when possible.

NbA members could consider increased engagement with regulatory bodies to help improve the chances of achieving a more common understanding

## International Activities - OECD



There is already international communication between regulatory agencies through the OECD Working Party on Manufactured Nanomaterials. EPA & FDA are active

There is also international communication with between other government agencies through the OECD Working Party on Nanotechnology. FDA and NNI are active.

Industry does have a voice in each one of the Working Parties through the Business and Industry Advisory Committee (BIAC) to the OECD and the US organization that feeds into BIAC is the US Council of Industry & Business (USCIB). NbA companies could consider getting their voices heard by the OECD WP's through USCIB/BIAC and its Nanotechnology Committee.

## International Activities - ISO



There is active international coordination in establishing standards that will affect nanotechnology through the ISO Technical Committee 229.

Much of the work is aimed at establishing standards (e.g. how to measure things) but there is also a lot of effort being put in to create Technical Reports that will help establish more common thinking in how to approach problems.

Two Technical Reports close to completion pertain to Product Stewardship and Minimum Datasets for Characterization needed for Toxicology.

## International Activities - Labelling



A specific example of where industry (and other stakeholders) should be involved is a British Standards Institute proposed standard for labelling of nanomaterial containing products. (BSI PAS 130)

If implemented and followed it would lead to an expectation that all products - consumer and industrial - would have to have information provided on product labels that there are nanomaterials inside.

In the initial form "nanomaterials" are not well defined. There is also a concern that the conclusion of those who read the labels could be that nanomaterials are hazardous. Why else would this information be provided?

This proposed standard is now being considered by the EU standards body - CEN - to be used across the EU. Implementation at this level could have significant trade implications. To its credit, ISO has asked to be included in the discussions to help inform all involved about the international impacts.

## International Activities - NbA?



NbA members could consider engaging in the standards setting process either individually and/or...

or collectively through the NanoBusiness Alliance and/or...

with other groups that are already involved. These include sister organizations such as the ACC Nanotechnology Panel that has members who are active in both OECD and ISO committees.

## Benefits to getting more engaged



Best case – Regulatory Agencies take NbA perspectives into account when developing regulatory programs resulting in more sound and robust actions. Great for business!

Worst case – Becoming aware of impending programs allows extra time to respond to them. Good for business!

## Questions? Comments?



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