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## EPA Issues First-Time TSCA Regulatory Order For Controversial Nanomaterial

EPA has taken an important step in its effort to regulate nanomaterials, issuing a first-time regulatory notice under the Toxic Substances Control Act (TSCA) that imposes some limits on the production of a multi-walled carbon nanotubes (MWCNT) -- a product activists say exhibit similar characteristics as asbestos -- until the company conducts additional study of the material, according to a copy of the order obtained by *Inside EPA*.

But the move is drawing criticism from a key environmentalist, who charges the notice raises more questions than it answers about EPA's approach to regulating nanomaterials. Richard Dennison, a nanomaterial expert at the Environmental Defense Fund (EDF), says the move is a "step in the right direction," but cautioned that numerous clauses in the order gave undue leeway to the company at the expense of human health and environmental safety.

Sources say that EPA is poised to unveil the TSCA premanufacture notice (PMN), a document that EPA normally grants to "new" products that it plans to regulate under the toxics law. While the document does not name the company, Thomas Swan & Co. Ltd., a UK-based chemical company, said in a statement last month that EPA had completed review of a PMN the company submitted for its MWCNT.

Under the terms of the order, the company will perform a 90-day inhalation toxicity study of the nanomaterial in rats, as well as providing additional risk characterization information to EPA. The company will also be required to provide a 1-gram sample of the substance to the agency along with its Material Safety Data Sheet, as well as ensure the use of protective measures in the workplace, including special respirators, clothing and gloves.

The additional data could help the agency determine whether additional regulatory steps are needed for the nanomaterial, which has been shown to have asbestos-like effects in a high-profile study released earlier this year.

EPA approval of the PMN is significant because it marks what may be the first step to regulate a nanomaterial under TSCA. The PMN process has been called into question amid disagreements over whether it can adequately be applied to nanomaterials.

Industry officials, for example, argue that some nanomaterials may not qualify as "new" materials requiring a PMN because they are reconfigured "existing" materials and exempt from requirements. However, environmentalists and others argue that all nanomaterials should be considered "new" and subject to PMN requirements. (*see related story*)

So far, EPA has sidestepped making a policy commitment to regulate all nanomaterials using

PMNs and is instead proceeding on a case-by-case basis. (*see related story*)

In this case, Swan officials say they expect the order to set a standard for the rest of the industry. “The work with EPA has validated the responsible approach that key players need to adopt in this industry to ensure that it develops in a controlled managed environment,” Chuck van Fleet, president of New Jersey-based subsidiary Swan Chemical, says in the statement. “This is an important step in our strategy to ensure our nanomaterials customers can work with identical materials from early stage-research through product development to the full commercialization of their projects,” he said.

Carbon nanotubes have been of great concern as the nanomaterial was shown to act similar to asbestos in a study released last May, with many advocacy groups calling for additional federal research in the environmental, health and safety risks of the substance. The study, published in the scientific journal *Nature*, found that certain carbon nanotubes -- believed to be one of the most promising nanomaterials due to their tensile strength -- behave similarly to asbestos fibers when injected into the body cavity of mice.

“This is of considerable importance, because research and business communities continue to invest heavily in carbon nanotubes for a wide range of products under the assumption that they are no more hazardous than graphite,” the study said. “Our results suggest the need to further research and great caution before introducing such products into the market if long-term harm is to be avoided.”

While the order could lead to additional risk assessment information of the substance, EDF's Dennison says the document illustrates the shortcomings of EPA's current chemicals management law. “Only if EPA already has evidence of a potential effect can it conclude that it is unable to determine whether there is an effect and call for testing,” he writes on the blog. “If EPA doesn't have evidence of a potential effect -- even if it has no data at all -- it's ready to conclude that no significant effects are expected.”

Dennison also points out that EPA “may waive the Order's requirement to conduct an inhalation toxicity test” in rats if the company signs up for the in-depth phase of the agency's Nano Materials Stewardship Program, a voluntary program designed to collect information from industry on nanomaterials. According to the program's Web site, Swan is one of three companies currently signed up for this phase of the program.

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