



Episode Title: Occupational Exposure Limits for Nanomaterials — A Conversation with Carla Hutton

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Lynn L. Bergeson (LLB): Hello and welcome to All Things Chemical, a podcast produced by Bergeson & Campbell (B&C®), a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I am Lynn Bergeson. This week, I sat down with Carla N. Hutton, a regulatory analyst here at B&C. Carla is also coeditor of the Nano blog that B&C has prepared for many years. Carla is uniquely well suited to discuss the report the National Institute for Occupational Safety and Health, called NIOSH, recently issued on developing occupational exposure limits or bans for engineered nanomaterials. There are thousands of chemicals in use in the workplace, but few government-issued, authoritative, peer-reviewed occupational exposure limits for workplace chemicals are in place. The recent NIOSH report discusses an approach to evaluate scientific information to derive occupational exposure limits or bans for engineered nanomaterials.

Now here's my conversation with Carla Hutton.

Carla, thank you so much for being here today. I'm very excited about chatting with you.

Carla N. Hutton (CNH): I'm happy to be here.

LLB: We're here today to talk about this very interesting draft NIOSH report on an approach to developing occupational exposure limits or bans for our favorite chemicals, engineered nanomaterials. And as I noted in the preview, Carla, there is no better person to have in the studio today to talk about this than you. Let's talk a little bit about the background here. Those of us in the legal field know that the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health, otherwise known as [NIOSH](#), are two very different federal agencies. Maybe you can help our listeners understand the difference between these two agencies. Help us understand why they are sometimes confused by even those in the regulated community.

CNH: I think the issue is obviously from the names. They're both concerned with occupational safety and health, and unless you have a need to know, it's easy to assume that NIOSH is perhaps within OSHA. Both agencies were created by the same statute, the Occupational Safety and Health Act of 1970, but while OSHA sets and enforces regulatory standards, including permissible exposure limits (or PELs) and is under the Department of Labor,

NIOSH is a research agency focused on the study of workers' safety and health. NIOSH is actually housed within the Centers for Disease Control and Prevention (CDC), so it's within the U.S. Department of Health and Human Services. OSHA has enforcement authority, while NIOSH's work includes developing *recommended* exposure limits, or RELs. And as that name suggests, since they're NIOSH values, they're only recommendations, unlike OSHA PELs.

LLB: I know sometimes in my dealings with clients, you're correct that NIOSH is assumed to be part of OSHA and in fact, that is not true. And it is strictly research and to a large extent industry support, right?

CNH: It is. And actually, NIOSH, perhaps because they're only offering recommendations versus legally enforceable standards, can move more quickly and has responded to emerging technologies like nanomaterials in a better way than OSHA has. OSHA has perhaps a page on nanomaterials, but the information on it, I think, is a couple of years out of date, while NIOSH has put out some recent reports.

LLB: Exactly, one of which we're going to talk about today. Chemical exposures in the workplace have always been of significant concern, certainly to the government, but also to labor unions, conscientious employers, and certainly workers. OSHA and NIOSH both publish occupational exposure limits. And remember, we just noted that OSHA has enforceable limits. NIOSH has *not* enforceable limits, but nonetheless, very important ones. Are these exposure limits for specific chemicals, classes of chemicals, or both?

CNH: For the most part, they are chemical-specific values, whether from OSHA or NIOSH. For metals, as you might expect, though, the values tend to be for both the metal and its compounds, but it's not as though there is one standard for nanomaterials that would apply to everything.

LLB: Are exposure limits that we're talking about today, we're focusing our discussion on engineered nanomaterials, not all nanomaterials, correct?

CNH: Correct. Engineered or manufactured nanomaterials, something that's intentionally produced at the nanoscale.

LLB: OSHA and NIOSH have -- this is a question; I'm not assuming -- both issued exposure limits specific to nanomaterials?

CNH: Actually, no. OSHA has not issued any nano-specific PELs, or permissible exposure limits. NIOSH has issued three RELs concerning chronic inhalation exposure to certain nanomaterials. The first of these, for titanium dioxide, came out in 2011. In 2013, NIOSH published one for carbon nanotubes and carbon nanofibers, and the PEL is for carbon. And then most recently in May 2021, NIOSH published a REL for silver nanoparticles. All of these have been published as Current Intelligence Bulletins (CIB), which NIOSH intends to disseminate new scientific information about occupational hazards. So the process for each of these included publishing draft reports for public review and comment.

LLB: Let me get this right. Over the past ten years, NIOSH has issued three specific RELs for nanomaterials. My sense is that that's not a lot. It's certainly more than OSHA, and we're not competing here. It's just a question of bandwidth and need, right? There are many different engineered nanomaterials in the work environment, so is it reasonable, Carla, to expect more nano-specific RELs from either agency any time soon?

CNH: I wouldn't hold my breath.

LLB: All right. That's not great news.

CNH: Well, I imagine whether three is a lot depends on your perspective. NIOSH has been working on more issues and chemicals than just those three nanomaterial RELs that came out in the ten years. Based on publicly available information, NIOSH doesn't appear to be preparing any more. For the most recent one, on silver nanomaterials, the public process from the time the first draft CIB came out until the final one, that was five years, from 2016 to 2021. And there were two draft reports. I think there were at least two public stakeholder meetings. And then we got the final report. To address each nanomaterial on a specific chemical basis is very labor intensive.

LLB: Indeed, it is very labor intensive, as your summary just reveals. But there are lots of both standard, or conventional, chemicals used in the workplace. We just recently went through the exercise with revised TSCA to discern that there are some 42,000 chemicals that are considered active, meaning they are in commerce, and presumably many of those are found in the workplace. There are many nanomaterials, engineered nanomaterials, and we have a very limited number of RELs, so far, none from OSHA. Given the amount of time and resources in need for developing a single REL, I'm guessing you're about to tell us that there is a need for an alternative approach, that companies that care about their employees that wish to follow the law -- OSHA requires that all employers provide a safe and healthful work environment -- that in the absence of a REL, there's probably another way to go, correct?

CNH: Correct. NIOSH is certainly aware of the disparity between the number of chemicals that are in use and the ones that have occupational exposure limits, be they from OSHA, or from NIOSH, or peer-reviewed, or even an international standard. So in 2019, NIOSH came out with a report about an occupational exposure [banding process](#). At that time, they estimated that only about 1,000 chemicals have an assigned authoritative limit. As you noted, the TSCA Inventory is currently almost 42,000 chemicals. That means over 40,000 without an authoritative limit. But using NIOSH's report and the occupational exposure banding process detailed, chemicals are assigned to specific categories or bands, based on their potency and the negative health outcomes associated with exposure to those chemicals. An occupational exposure band corresponds to a range of exposure concentrations and is expected to be protective of worker health. Through occupational exposure banding, NIOSH seeks to create a consistent and documented process that companies can use to characterize chemical hazards so they can make timely and well-informed risk management decisions for chemicals that do lack authoritative values, which is almost all of them.

LLB: Right, exactly. Can you provide a brief overview of what that banding process is, so our listeners can understand more precisely what resources are available to them through this draft document, and perhaps maybe they wish to comment on it?

CNH: Sure. The 2019 report applies to conventionally sized chemicals. NIOSH at that time noted that nanomaterials warranted special consideration. The 2019 report is a final report that describes a three-tiered approach with increasing data requirements. Tier 1 is the screening-level process, based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Tier 2 requires additional toxicological data using publicly available sources. Tier 3 is a critical assessment of all available experimental data, and this tier may require more effort and expertise to develop than Tiers 1 and 2.

The NIOSH process then considers the available information across nine toxicological endpoints to determine the potential health impacts to workers. Chemicals are assigned to five exposure bands, ranging from A, the highest recommended exposure concentration, through E, the lowest. NIOSH actually has an e-Tool that it released in conjunction with this report that companies can use to do the Tier 1 and Tier 2 evaluation process.

LLB: That seems relatively straightforward, although as we know well, given all the work we do at Bergeson & Campbell and The Acta Group (Acta[®]), assessing data and calculating occupational exposure limit bands would require some very specialized knowledge and qualified expertise. Now, can the occupational exposure banding process, as you have described, Carla, be applied to engineered nanomaterials, or are there variations on a theme that were required to accommodate these unique novel nanomaterials?

CNH: When NIOSH issued its final report in 2019, it noted that nanomaterials warranted special consideration, that the process it was describing for conventionally sized chemicals didn't quite fit perhaps nanomaterials in all circumstances. But NIOSH has been working on this, so in July 2021, they released a draft technical report on approaches to developing occupational exposure limits, or bands, for engineered nanomaterials. This draft technical report, there's both a report, and then I think a couple hundred pages that's a user guide is available for a public comment period that will close September 13, 2021.

LLB: Can you help our listeners understand what the first step is in the occupational exposure handling process for engineered nanomaterials? These are the intentionally produced materials at the nanoscale that are not found in nature, right, Carla?

CNH: Correct. Engineered nanomaterials, or ENMs, or manufactured nanomaterials, or MNMs. With the draft report, the first step would be to ask whether an occupational exposure limit is available. In the United States, this would include an OSHA PEL or a NIOSH REL, and if an occupational exposure limit is available, then you use that limit and you don't have to proceed to Steps 2 and 3. As we've discussed, though, OSHA has not issued any PELs specifically for nanomaterials, and NIOSH has developed only a few RELs for nanomaterials.

LLB: That would suggest quite a need for this banding process for people that are in this space, employers and others who want to go forward with ensuring that their workplace is safe. This conceptual approach laid out in the July draft report seems to hold considerable promise.

Let's say that I've gone through some of that decision logic, and I don't have a PEL that OSHA issued or one of the three RELs for any of my engineered nanomaterials. What's the next step? What can you tell listeners to do as Step 2 here?

CNH: The second step is to ask if there are enough data available to compute an occupational exposure band. An occupational exposure band defines a range of concentrations that are intended to protect worker health. The draft technical report refers users to NIOSH's 2000 occupational exposure banding guidance to see if there are specific data available for the nanomaterial of concern. Users can also follow the guidance if data are available for a microscale form of a similar substance, and the occupational exposure band is adjusted. The draft technical report, as a side note, is actually a great current source of limits that have been developed for nanomaterials. It just sort of rounds up everything that's out there within the United States and internationally.

LLB: That seems straightforward enough. So Step 1 is see if something is on the books that you can rely upon. Step 2 is if no authoritative limit is established, look to see if you have available data to compute an occupational exposure, a band. What if there are no data available on my unique engineered nanomaterial, or even a comparable macroscale form of a similar substance? Am I just out of luck?

CNH: I've got great news! With the draft report, even if data are lacking for an occupational exposure limit or band, Step 3 of the process proposes several alternative methods. Options include a categorical occupational exposure limit, which is a group-based limit, read-across to similar materials, or defaulting to the most stringent occupational exposure band until more information is available.

LLB: That *is* good news. There's kind of a belt and suspenders approach here, with three different bites at the apple, as it were. Just to contextualize this, I am an employer, I have some very promising engineered nanomaterials that are novel by definition. I want to ensure that my workplace is safe. There are no authoritative OSHA PELs or NIOSH RELs. I have a limited amount of information, but none sufficient to compute an actual occupational exposure limit, given what I have on hand now.

There are several different alternative methods. Even beyond that is a tertiary bite at the apple. That *is* very good news. I hope our listeners are aware of this opportunity both to look at the draft report, which, as you noted, Carla, is available for comment, and maybe even consider submitting comments on it by mid-September is the comment deadline?

CNH: Correct. I believe September 13.

LLB: I would imagine, given all of the entities with whom we work on nanomaterials, both on the innovation side under TSCA, but also on the how do we ensure that everything we are doing in the workplace is safe, effective, and aligned with the current science? I know you and I, Carla, have been doing nano for a long time, and we have long been NIOSH aficionados because the quality of the work that NIOSH has undertaken with respect to engineered nanomaterials is just top-notch. You and I have often commented and urged our clients to review all of the personal protective equipment (PPE) requirements and guidance documents on how to ensure you have an appropriate workplace for your employees. You've looked at the report more than I have, but I'm sure this report is similarly well written, easy to read, and very helpful, correct?

CNH: I focused on the report as opposed to the user guide, which is much more technical for those with the specific tox background and expertise. But like all NIOSH materials, the technical report tries to make things simple, clear, and concise. As you dig deeper, it provides more information, details. The draft report for nanomaterials, I believe, has several different case scenarios to walk you through the process. NIOSH is great in that this isn't the first nano report. We've got a couple nano-specific Current Intelligence Bulletins, but NIOSH has been working on other things: 3D printing and exposures through that, a nano research plan. They're aware that these materials are being used and want to help companies be able to use them safely, and that's what we all want.

LLB: With regard to the *Federal Register* notice that NIOSH issued seeking comment on the draft report, did NIOSH identify any particular areas on which comment would be appreciated, or is it just whatever is in the report, submit comments on and let us know how we're doing?

CNH: Of course, there's that, general, "We welcome comments on anything," but NIOSH did flag several specific issues for emphasis, and we've described this in more detail in our July 13 blog item.

One issue that NIOSH highlighted is whether revision to its 2019 guidance -- which, as we've noted, is applicable to chemicals generally -- is whether the guidance for nanomaterials needs to incorporate a more stringent Band F. According to NIOSH, a critical question regarding a possible band lower than E is, "What additional exposure control options are available to reduce exposures further?" Since the exposure bans are based on eight-hour, time-weighted average concentrations, the options include reducing exposure times or using closed systems in robotics. There are very specific technical issues that companies that are developing and using nanomaterials -- I think NIOSH is welcoming comments from anybody, be it industry or labor, academia. How does the guidance work? Where are the flaws, and what can be strengthened?

LLB: I'm glad you mentioned the July 13 blog item. I had noted previously, Carla, that you're coeditor of the Nano blog. We've been doing that for many years. It's an award-winning blog on our website. The July 13 memo sets out in more detail some of the issues we've been talking about here. Again, to contextualize, NIOSH is an exceedingly receptive federal agency to comment. They rely upon stakeholders that are actually in the business of manufacturing, and using, and processing engineered nanomaterials. If in reviewing the draft report, there are additional issues that NIOSH would benefit in knowing, you too can be instrumental in developing a document that will provide safe and healthful work environments for entities relying upon engineered nanomaterials and just help NIOSH do its job even better than it already is doing.

Are there other materials, Carla, that you can point to on the NIOSH website, in addition to the draft report, that our listeners may be interested in reviewing, or maybe just give the NIOSH Web address if you have it handy there?

CNH: I briefly mentioned that as part of the 2019 guidance on occupational exposure banding, NIOSH also has an e-Tool that allows users to apply toxicology and potency information to generate quantitative exposure guidance for their chemicals. NIOSH intends this tool to assist with Tier 1 and Tier 2 banding. I don't have the URL for NIOSH offhand, but I can certainly -- do we ever link materials with our podcast page?

LLB: We can, and we certainly want everyone to look at the draft report and our summary of it on our [Nano blog](#), where we have information on NIOSH, on OSHA, you name it. Carla, you've been writing for years on European nano initiatives. Anything you might want to know about engineered nanomaterials is in there, and their regulation and different policy approaches, both in the United States and elsewhere, is found in the Nano blog. I would direct people there. And our website is www.lawbc.com, and it's right there on the home page, right?

CNH: Yes.

LLB: All right. Well, Carla, I've really enjoyed our conversation today. I hope our listeners look at the draft report, particularly those listeners that have a stake in the engineered nano community, as I know many of them do, because to my eye, it was a really good draft report and could be made all the better by comments from our listeners. Thank you, Carla.

CNH: Thank you, Lynn.

LLB: My thanks again to Carla for speaking with me today about NIOSH's new approach to derive occupational exposure limits, or bands, for engineered nanomaterials, and the promise this approach offers employers and others wishing to ensure a safe and healthful workplace.

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