Clean Law 45: Hana Vizcarra Discusses Changes to TSCA with Kevin McLean, May 28, 2020

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Robin Just: Welcome to CleanLaw from the Environmental & Energy Law Program at Harvard Law School. In this episode, Hana Vizcarra speaks with Kevin McLean, former associate general counsel for EPA's Pesticides and Toxic Substances Law Office about chemical substances' regulation and implementation of the 2016 revisions to TSCA, or the Toxic Substances Control Act. We hope you enjoy this podcast.

Hana Vizcarra: So today we're speaking with Kevin McLean, an over 20-year veteran of EPA's Office of General Counsel. Kevin, welcome.

Kevin McLean: Good afternoon.

Hana: Before we get started, let's give our listeners a little more detail about your background. You've had a long career with EPA and that's included two associate general counsel positions, one in the Air and Radiation Law Office, and probably most pertinent for our discussion today is the Pesticides and Toxic Substances Law Office. Can you tell us a bit more about your path at EPA and what those specific roles entail?

Kevin: I started with EPA back in 1990 after being in private practice here in Washington, and started off in the Air Office dropping in in the midst of work on what turned into the 1990 Clean Air Act Amendments. And then I worked in a variety of positions in the Air Office, moving up to branch chief and deputy associate general counsel for the Air and Radiation Law Office. And then served as the acting associate there for an extended period of time. And then finally in 2013, became the associate general counsel for the Pesticides and Toxic Substances Law Office, which was an opportune time because that was a couple of years before things really kicked into high gear on, again, what turned into the Lautenberg Act, probably the most significant and substantive environmental law revision in many years at that point. And I remained in that position until retiring from EPA at the end of 2017.

Hana: And we here at Harvard Environmental & Energy Law Program have been the beneficiaries of your expert career and this trajectory. In February, we published your white paper titled "Three Years After: Where Does Implementation of the Lautenberg Act Stand?" And that's essentially the topic of our conversation today. I've got to say reading the paper, it delves into the history and purpose of the Toxic Substances Control Act or TSCA and reviews progress in implementing the

revisions that were passed in the Lautenberg Act. And it's really significant in both its breadth and level of analysis. There's a lot in there.

Hana: So I don't know that we'll be able to touch on everything that you've covered in the paper. So I definitely encourage our listeners to download it from our website. Not only for the wonderful analysis of where things stand and how things are developing on the implementation of Lautenberg Act revisions. But also what I found really wonderful was the extensive history that you provide and how that really effects our implementation now. So why don't we start with a bit about the history and purpose of TSCA? It was one of a slew of major environmental laws passed in the 70s. And in your paper, you note it was first proposed by the White House Council on Environmental Quality and went through about five years, I think, of legislative debate before it was passed in '76.

Hana: And you discuss CEQ's original report proposing the changes and that legislative debate that ensued and how it talked about the purpose of TSCA. Could you tell us some of the key points that were made in the CEQ report during this period and the debate in Congress that we really need to understand in order to evaluate these recent evolutions in the law?

Kevin: Sure. And as you mentioned, TSCA or the original TSCA was one of the huge amount of work done in the environmental law area in the 70s when basically all the other key statutes for EPA work were passed, I suppose, other than FIFRA, the pesticide law, which was actually passed back in the 1910s as far as the progressive movement back then and well before EPA was in the eyes of anyone. But TSCA was seen or the need for it was seen by CEQ at the time, not just to deal with chemicals, but to deal with them in a different way than the media-specific acts like the Clean Air Act or Clean Water Act dealt with issues. CEQ saw a need for a law that was one more proactive in terms of dealing with risk before they occurred rather than after emissions were occurring.

Kevin: So saw a need for some sort of pre-market clearance on the part of the agency for new chemicals, but saw also a need for existing chemicals to be dealt with, but be dealt with in a more comprehensive manner that took into account total human exposures, total effects on the environment of chemicals. Not just focusing, for example, on their impact on air pollution and health issues due to air pollution. So that was really very important at the time, was looking at it as a comprehensive approach that allowed an overarching approach to deal with risk posed by chemicals that could affect people and the environment through many different pathways rather than focusing on a single one like air or water.

Hana: So as you described, Kevin, this is really a fundamental change from these earlier specific media focused environmental statutes that many of us environmental lawyers spend our time with and studiously avoiding TSCA. Why did you choose to

spend time delving into this history to set up your article? Can you explain a little bit of that connection with these implementation efforts we're seeing in the Lautenberg Act?

Kevin: The reason I thought it was important was it's a lot of lost history. I think that many aren't aware of. I wasn't aware of all of it until I started really delving into it more than I had in the past. But it's very helpful to see what a comprehensive statute, TSCA, was intended to be, which helps inform how the revised TSCA post 2016 could or should be used in terms of how it's being implemented. I think that in many ways, TSCA, and I'm sure we'll get to this later in the interview, became to some degree a moribund statute. It wasn't perceived as particularly useful because of some of the problems that had occurred years ago in its implementation and had a fairly narrow focus. But that wasn't what Congress thought or what CEQ thought when they started, what Congress thought when it passed it, nor what EPA originally thought back in the 70s when they first started using it and even considered using it for dealing with the stratospheric ozone problem before there were some amendments made to the Clean Air Act to deal with it and looked into using it for major problems like dioxin.

Kevin: So it was a very broad breath statute that early on, I think the thought was it would be used in a very comprehensive way to deal with a variety of possible environmental problems. And then over the years, didn't get used so much, but even now, or after the 2016 amendments, it wasn't necessarily perceived as the sort of very broad authority that it was originally intended to be.

Hana: Let's turn to the passage of the Lautenberg Act and what led to it. You mentioned that TSCA had sort of become, to some extent, a moribund statute or at least had not been utilized to the breadth that it initially was imagined and as effective in that scope. So what were the specific circumstances or cases that drove the need for the revisions that were passed in 2016?

Kevin: I think they really got started right around 1990 at the same time the Clean Air Act was being revised, which was about the time the agency made a huge effort to use TSCA to deal with a major existing chemical problem, asbestos, and lost a major court case, the corrosion proof case. And saw that at least in the world of existing chemicals, those that are already out in the marketplace as requiring a lot of analysis that was very difficult to do and difficult to do in a way that met some of the statutory criteria in the original TSCA to regulate chemicals. And so there was a turning away from that partly because I think it was sort of a paralysis by analysis issue. There was so much work do to deal with existing chemicals and other ways the agency could take on environmental problems that it didn't get a lot of attention.

Kevin: The new chemicals portion of TSCA did continue to get attention, did continue to serve as a review process for new chemicals being introduced into the marketplace. So that continued to function well and more, but the existing chemicals and the actions EPA took to deal with them were few and far between in a sense I think that the major drivers for that were not just, one, the amount of analysis that was needed, but two, there were really no mandates from TSCA on the agency. And so it was authority, but it was no push with deadlines to get things through the system, meaning through the system, through the entire executive branch, including OMB and others. Not the mandatory duties, the deadlines that could help drive work for the executive branch.

Hana: And that no mandates issue is one of the fundamental changes that you point to. I mean, that is a significant difference with the revisions made in the Lautenberg Act. You actually outline, I think I counted five fundamental changes. One was eliminating the role of costs and economic factors and evaluating the chemical substances present and unreasonable risks. Establishing deadlines, so as you just mentioned, and a schedule for EPA to review existing chemicals, really trying to get at that problem of the paralysis by analysis that you mentioned, and a new process for conducting these reviews requiring EPA to affirmatively approve new chemicals before they enter the marketplace. And it modified the provisions of TSCA governing the disclosure of information, as well as the preemptive effects that the law on state laws and regulatory or administrative actions.

Hana: We're going to talk about all of that, but I think let's start with the revisions to unreasonable risk standard. This is a pretty significant change. And certainly one, I think, from a, how does the law work and protect the environment and public health? Definitely one that warrants quite a bit of explanation. So explain how the 2016 Act changed the risk standard to eliminate costs and economic factors from EPA's valuation of the risk chemicals pose.

Kevin: Prior to 2016, TSCA essentially contained a benefit cost for regulation. And not only that, but in terms of regulations that were actually imposed, EPA also had to show that it was adopting the least burdensome requirement, which meant that it would have to evaluate other alternative and possible requirements and prove that the one that was selecting was the least burdensome. This is part of what under corrosion proof case on asbestos, as well as the basic benefit cost approach.

Kevin: What Congress did in 2016 is throughout the act, numerous points, I haven't counted them up, changed the language of the risk standard that applies to EPA's decisions to explicitly exclude the consideration of cost and benefits. It left the basic language, which was an unreasonable risk to human health or the environment, it left that unreasonable risk language there. But in essence, it completely redefined it from the preexisting sort of more general common law

concept of reasonableness or unreasonableness, which includes considerations of costs and economic issues to one that doesn't.

Kevin: And so the fundamental standard for both existing and new chemicals is now a risk standard only that does not include that consideration of costs and setting that basic standard. EPA can still consider costs in how it decides to regulate to eliminate an unreasonable risk. However, under the new act, its regulations with some exceptions like if they would have a catastrophic effect on the economy, it has to eliminate the unreasonable risk with those regulations. So while it would still be sort of driven towards the least costly method of doing that, it has to satisfy a test of eliminating that unreasonable risk, which is identified upfront as a risk without regard to cost. So it's a much stronger environmentally protective standard than pre-2016.

Hana: So essentially becomes sort of a two-part process, right? One, identifying the risk regardless of cost. Then the consideration comes in when going through the process of determining the method of addressing that risk, right?

Kevin: Yes, that's correct.

Hana: You talk about how this change also makes it easier to petition EPA to control a chemical. This changed the unreasonable risk standard. How does it do that?

Kevin: Well, that's through section 21 of TSCA, which was largely untouched in the 2016 amendment, but that doesn't mean it didn't change. That provision allows folks out there, citizens or others, to petition the agency, to control a chemical, undertake other steps. They can petition for other actions by the agency, not just restrictions on its chemicals use or production. And it provides a real driver for the agency to have to act on that because if the agency doesn't act within the prescribed statutory time period, 90 days, it's deemed a rejection of that petition and the petitioners can go straight to US district court. They have 60 days.

Kevin: So unlike other petition provisions and other statutes, it's not just a deadline for the agency to act that if it fails to meet, then the agency can get brought into a deadline suit litigation, which can take quite some time to resolve before it has to act. But what's important as far as standard goes is that because the Lautenberg Act fundamentally changed the unreasonable risk standard, it now means that a petitioner they're showing no longer needs to include the same sort of economic analyses or demonstrations of the costs and benefits of controlling a chemical. Now they're showing is really much more limited to the health or environmental effects part of the analysis. And that is certainly a reduction in the burden on the petitioners and makes it somewhat harder for EPA to deny petitions, which in the past they may have at times denied petitions really because the petitioner has

failed to make an adequate showing on the economic grounds. And that is now dispensed as possible grounds for denial.

Hana: Yeah, that definitely would be quite a shift in the burden. And I think some of this two-part approach of risk versus cost is it's a tug of war we see in other areas of environmental law and something we see this administration grappling with the balance of in different ways. I want to talk about both the existing chemicals sections and new chemicals sections and the changes made. As you mentioned, existing chemicals, the TSCA provisions addressing them, and I think it's section six that primarily addresses that, was one of the toughest areas for the EPA to deal with before the Lautenberg Act. And the changes certainly created some new burdens on the agency as well, but also an effort to shift their focus quite a bit.

Hana: So some of the primary changes involved prioritization, having the EPA establish a risk-based screening process and designate substances as high or low priority for review and issuing a prioritization rule to establish this process. And also having EPA move forward even while they're in the process of prioritization with what are referred to as the first 10 chemicals. Risk evaluations on the first 10 chemical substances, even before promulgating the prioritization rule. And then their process for risk evaluations was also changed, conducting risk evaluations once a chemical is designated at high priority, publishing a scope. They're then required to publish a scope of the risk evaluation describing the hazards, exposures, conditions of use, susceptible populations, etc. And then complete the risk evaluations along the lines that you mentioned with that consideration of what unreasonable risk really means.

Hana: And then it also established requirements for how many risk evaluations EPA has to conduct at any given time. So really making sure they're making progress, I guess, is what that provision would do. So we're gonna talk about all of that in how it's being implemented because one of the kind of critical questions here is the act was passed in 2016. The process for implementation began, but then the agency was thrown into a change of administration. And so any transition from one administration to another requires adjustment, sometimes requires some reassessment of the way forward. And particularly when implementing such an expansive new law or revision to a substantial law as this one. So let's start with the first 10 chemicals. What are the first 10 chemicals, first of all? They had to choose 10 to start before even moving forward with this prioritization process. Where did that come from and why does it exist?

Kevin: Well, Congress wanted to be sure EPA moved on chemicals from the get go under the new law and didn't have to wait for the framework rule-makings required in terms of the risk evaluation process and prioritization process, which would be a key towards moving on existing chemicals. After that, they reached back in a sense to 2014 and EPA at that point had adopted a work plan for, in a sense,

higher priority chemicals not under a formal statutory scheme, but ones that were more concerned from a health and environmental perspective. And they called on EPA to pick 10 off that list. That's where they came from. They included some chemicals like asbestos. They included other ones, a dye that was of high concern called PV29. And I'm not going to bore you with the list of the other eight. And they're chemical names. They're all available and people can find what they are in the agency.

Hana: They're also all listed in your paper.

Kevin: The agency is moving forward on them. The concern is long-term, even with these mandates for action, they are so limited relative to the total volume of existing chemicals. There are tens of thousands of existing chemicals and starting with 10, having 20 ongoing at any given time, obviously, the agency is never going to get through the list of existing chemicals. It will take hundreds of years probably to do that. So this was just really a way of making sure things got started quickly and they did.

Hana: Yeah, I think the EPA announced the 10 chemicals that they were choosing as their first 10 in November, 2016. So quite quickly, they asked for public comment and then they released initial scoping documents for the risk evaluations in June, 2017. And then they also published formulation documents. That was in the new administration, though, in 2018, right?

Kevin: It was.

Hana: What is the difference between those two? So the scoping document that was sort of an initial outline of hazards, exposures, etc., but it was further refined in these formulations.

Kevin: Right. With more detail and more precise identifying further details that were needed to really carry out the risk evaluations, which themselves are presumably going to take a couple of years. A statute provides for something on the order of three to three and a half years for a risk evaluation. Yeah, it's a pretty extensive process, especially for a significant chemical. So that's going to take some time. The work is ongoing on those. The documents that have been published to date by the agency have raised some legal issues, which will be interesting to see how they play out. But to me, chief among these has been how the problem of formulations dealt with the issue of jurisdiction of TSCA compared with other statutes. And this is part of why I delved in the paper into the ancient history of TSCA that these documents indicate that basically, the agency intends to take the position that if a particular pathway or exposure route for a chemical is under the jurisdiction of another statute, that it's not going to look at that in the risk

evaluation. It's going to exclude that upfront on basically the theory that it's under the jurisdiction of another statute.

Kevin: So for example, if air emissions of a chemical from facilities that are producing it are dealt with by the Clean Air Act's Air Toxics Program, they would say, "We don't need to look at that in the risk evaluation under TSCA or impacts of those emissions."

Hana: And you actually argue in the paper that that's contrary to law. That both the legislative history that you discussed early and in how TSCA had been applied since then, that's not the appropriate way to interpret their authority.

Kevin: Yeah, it's correct. I think that both the old legislative history, but the precise language of TSCA as it still stands and was amended in 2016 contains the provisions in section nine that addressed the overlap of TSCA with other statutes and section nine is written in such a way that evaluation of whether or not the risk reductions that you could achieve under another statute, that evaluation of the sufficiency of those reductions is to be undertaken after the unreasonable risk is identified under TSCA. To me, that clearly indicates that that's not supposed to be part of the risk evaluation under TSCA, but that's an independent step taken after you have identified the risk under TSCA, not taking into account cost under the new statute. And then look to see how much reductions in that risk are achieved under other statutes, which may have very different basis for their authority. And that may be enough, it may not be, but it's not a matter of slicing those evaluations out at the beginning of the process.

Kevin: And I think interestingly enough, then Judge Kavanaugh, without addressing this issue explicitly, but there was a DC Circuit decision in the Mexichem Fluor case back in 2017, which ruled against EPA's attempt to regulate HFCs under certain provision of the Clean Air Act. And in doing that, Judge Kavanaugh on the DC Circuit pointed out that not only could EPA regulate the HFCs under a different provision in the Clean Air Act, that they have other statutory authorities to directly regulate non-ozone depleting substances that are causing harm to the environment including TSCA. And so I think implicitly, in the sense explicitly, he recognized at that time that EPA could have dual authority to regulate a substance under both Clean Air Act and TSCA in that instance.

Hana: Current Justice Kavanaugh has in Mexichem sort of validated the long history and sort of original concept for this broad non-media specific idea of TSCA is what it sounds like. I think that'll be quite interesting area to watch because I can't imagine that we won't get through the process of some of these evaluations without litigation to address these issues.

Kevin: That's the safest bet you can make.

Hana: Yeah, pretty much in almost any environmental law area. In fact, there have been some draft risk evaluations released for public comment already, and they've faced some criticism as well. Particularly some of the criticism you mentioned in your papers from the EPA Scientific Advisory Committee on Chemicals. What were some of SACC's primary concerns with the draft evaluations?

Kevin: They raised a number of concerns with several of the evaluations, partly just that they were not sufficiently detailed, but I think more seriously in a sense that they thought the number of cases, EPA's conclusions, that there were not unreasonable risks that were not supported by sufficient evidence. That they were extrapolations on the basis of uncertain data without really flagging the extent of the uncertainty that was there. They also pointed out that they would have liked to see more testing called for by EPA to substantiate, more fully inform the conclusions that were being reached in the risk evaluations. So basically, it was a sense that in a number of these cases, not all of them, but a number of them, that the analyses were simply not robust enough and fully supported enough for the conclusions to withstand scrutiny.

Hana: And again, stay tuned for litigation that I'm sure will come up again later. So we've talked quite a bit about the first 10 chemicals and how the implementation of that process has proceeded. You mentioned as well the framework rules that are now required by statute, and that includes the prioritization rule and risk evaluation rule, which are really sort of process rules about how the agency will handle these evaluations and decision making about what chemicals to start with outside of the first 10. So they were under a deadline, a statutory deadline to get these out. They were proposed to January, 2017 and finalized in June, 2017 on the day of the deadline, which was June 22nd. And you highlight... That's quite a significant achievement for an agency as far as meeting those deadlines. These were pretty major rule-makings and a year turnaround is not a lot of time. And your experience at EPA, I'm sure you appreciate the feat. That is to turn a major rule round in a year.

Kevin: Well, and particularly when it's in the middle or covers a transition from one administration to the other, which obviously involves a lot of turmoil and people out of jobs and jobs not being filled at high levels and new people coming in. And still to make the one year deadline I think was a very significant achievement in terms of getting these rules out on time.

Hana: Having this fall over a transition period presented some other interesting aspects to analyze because there were significant changes between the proposed and final rules. What changes did we see on the prioritization rules from the initial proposal to the finalized rule?

Kevin: Basically, there were three significant revisions, and this really was a process rule about how EPA would conduct the process for determining which chemical substances would become high priority substances, which is a key starting point for the whole process of evaluating existing chemicals. And the three changes, significant changes that occurred were, one, EPA had proposed a sort of pre-prioritization process to kick things off that was dropped entirely. It also eliminated a mechanism whereby under the proposal, any chemical that failed to qualify as a low priority chemical would be automatically designated high priority. That was dropped. And finally, the rule added some explicit references to the best available science standards that were contained in section 26(H) of TSCA, which in a sense wasn't that significant because they would have applied to the EPA actions anyway, but it did reflect them in the regulatory text.

Hana: Does that change the automatic designation of a chemical that failed to qualify as low priority? Dropping that automatic designation of qualifying it as a high priority chemical, does that mean then that the chemical receives no designation? It's as if it wasn't evaluated at all?

Kevin: At that time, and like the thousands of other chemicals would be in a bin where it has been designated either high or low.

Hana: And as you mentioned, this is a process rule, and these are process changes. Are there any particular concerns or comments that you have on what this means for the agency's ability to implement their prioritization process?

Kevin: Not strong concerns. I think that the rule was for less significant in terms of concerns that it raised in the risk evaluation rule, the other major framework rule. And hopefully that things will proceed on the prioritization relatively smoothly as things move on in terms of implementation.

Hana: I think it's important to tease that out with such a technical statute and technical implementation process. Understanding there are so many pieces of this that are just about making the agency's ability to implement the statute better and others that can actually have a pretty significant impact on sort of how that statute is interpreted. And I think the risk evaluation rule, as you alluded to, some of the changes in there may inch a little closer to that side of things. What were some of the changes that we saw between the proposed and final rule of the risk evaluation rule and what are your impressions of those?

Kevin: I think that the two most significant there, concern one, concern so-called conditions of use, which is a term under the statute and it occurs in a variety of contexts. But mostly here, the importance was centered around how the agency was to evaluate in a risk evaluation, the conditions of use of the chemical. Basically meaning how it's used, how it's processed, what industries, how it's

used, whether it's consumer applications or industrial applications. All of those are different conditions of use. And the environmental groups took a position in the litigation that was much more akin to the position that EPA proposed, which was that all conditions of use had to be evaluated under the statutory language.

Kevin: The final rule adopted a different position asserting that the agency had the discretion to exclude conditions of use from its evaluation. So even though a chemical might have say 10 conditions of use, the agency could decide it's only going to evaluate eight of them. The rule itself provided little guidance on how the choice would be made, indicating that it was going to be a case by case determination. Suggesting that de minimis authority or de minimis exposures in some cases could provide a basis for that, but basically left ambiguous as to how that determination or the application of that discretion would apply.

Hana: And the Ninth Circuit heard this case, right? The challenged, and had a pretty interesting, I thought, opinion that one of those opinions were where the environmental orgs sort of lost, but also kind of really won.

Kevin: That's true. They sort of won and lost at the same time. In a sense, a number of their issues related to conditions of use, the Ninth Circuit ruled were not justiciable at the time basically, that the rule wasn't clear enough about how the agency would actually carry out the risk evaluations and so that the challenges would need to await the actual implementation of the provisions and individual risk evaluations. Certainly, that's a loss for the environmental organizations that petitioned. It means a loss of time. The agency could proceed down whichever pathway it wanted to, and that challenges couldn't be brought in court until years down the road after the work had been done. That's a realistic loss in terms of potential loss to the environment certainly from their perspective.

Kevin: On the other hand, the court certainly indicated in parts that it didn't think that the rule was really susceptible of the reading that the agency was giving it. Even though it was ambiguous, they thought that some of what the agency was asserting wouldn't really fly in the end. And so while it denied the environmentalists petition, some of the reasoning it gave was clearly a win on the substance for the environmentalists in terms of how EPA would need to approach conditions of use.

Hana: It almost kind of created bumpers on the agency in a way if you think about this on a bowling lane. They are limited in how they can now interpret the statute because the Ninth Circuit said there are certain ways they can and can't and we don't think that this rule necessarily goes outside of those.

Kevin: Correct. That's right.

Hana: When they go through the specific risk evaluations, these organizations will then be on the lookout for their interpretation and whether it strays too far outside of the limits that they saw in the Ninth Circuit case.

Kevin: Yep. That's true.

Hana: So again, stay tuned for litigation again and probably for a very long time. So the final rule that we've seen in these sort of larger framework rules on existing chemicals was the inventory rule which was also issued on June 22nd, 2017. And required companies to notify EPA of active and inactive chemicals. Explain a little bit about what that rule is and what we've seen from the implementation of it.

Kevin: Sure. That rule relates to the inventory of existing chemicals that EPA keeps, which is, I'm not sure now how many chemicals, 50,000, something like that. It was tens of thousands of chemicals were on it. And this was a statutory requirement the Congress put in basically aimed at helping clean it up a bit by requiring what the core of this was, which was to notify EPA of which chemicals were actually still actively being produced and in commerce so the agency could know that some chemicals hadn't been produced for 15 years and nobody was using them anymore. And so that was basically an updating of information pertinent to the inventory and what was really still active and a concern.

Hana: Does this essentially feed back into the prioritization process then?

Kevin: Providing sort of a basic pool of information about what's active, how much is being done with that chemical. And so it provides information to the agency that is relevant to the prioritization process. And there were other aspects of the rule that were somewhat controversial that did lead to litigation. And those primarily related to CBI questions relating to chemical substances and how much public disclosure there needed to be. Which was one of the issues that was in general an issue during the 2016 amendments with some of the environmental organizations pushing for greater disclosure of what had heretofore been allowed to be confidential information. But they believed was actually resulted in less information being made available to the public than should be for people to be able to determine the risks of chemicals out there or for first responders, how to respond to chemical accidents out there.

Kevin: And so the CBI issue in terms of striking a balance between the public's need or rights or benefits of knowing versus industries' benefits for business reasons, keeping information confidential. And it was a key issue and the balance sort of moved in the 2016 amendments more towards the environmental and the public groups than had been the case before. And in this case, EDF challenged a number of the provisions. They lost most of their challenges. However, they did have a couple key victories. One was on standing where they successfully argued for

informational standing, which could be significant for cases in the future, not just TSCA, but elsewhere where the importance of public disclosure of information itself provides a ground for standing to challenge agency rules. And the other win for EDF concerned the way companies would substantiate their claims for keeping confidential the actual chemical identities, the real identity of the chemical. Not some generic name for it. And the court found that EPA had wrongly eliminated questions that were to be posed to companies about the viability of reverse engineering chemicals. Told the agency they basically had to put those questions back in.

Hana: So these questions were essentially sort of a burden that the companies had to meet in order to show that there was a need for this information to be designated confidential business information?

Kevin: The law had changed so that the company would have to substantiate that a chemical couldn't be taken and reverse engineered by somebody else in order to support the ability of the chemical to remain confidential.

Hana: There have been other actions on existing chemicals as well. We've spent a lot of time on existing chemicals, and I do want to talk about new chemicals. So I don't don't want us to necessarily delve too far into this, but what are some of the other particularly important actions that have been taken so far dealing with existing chemicals beyond these framework rules in the first 10 chemicals?

Kevin: In a sense, most of the work on existing chemicals has really been the continued work on high priority chemicals, the prioritization. EPA has identified 20 high priority chemicals and the first 20 low priority chemicals. EPA is beginning to move forward on the risk evaluation process for the high priority chemicals it's identified. So that's really the major piece of work there. They did move forward, at least partially on a ban on a chemical, methylene chloride.

Hana: Was that a first 10 chemical or one of the 20 high priority?

Kevin: It was really neither. It was one that EPA had proposed a ban prior to the change of administration from both consumer products and commercial products, but EPA in 2019 moved forward only with the ban on consumer products. Did not go forward at that point with any sort of a ban on its use in commercial products. It also sort of stepped back from a couple of other proposals that had been made late in the Obama administration and has deferred action on them in terms of dealing with existing chemicals. But some of those are being treated like TCE is. They are continuing to look at TCE, but they've stepped back from the proposed action that had already occurred. That's primarily the areas of activity, I think, to date on the existing chemical front.

Hana: That is a lot. We have spent quite a bit of time on existing chemicals. Of course, as you mentioned from the beginning, that was an area of substantial change as far as how the agency was approaching them and the burdens on the agency. The sort of requirements that they move forward and have deadlines and affirmative action on these chemicals. And as you mentioned, if their inventory is 50,000 plus, that is quite the feat. So let's turn to new chemicals, which the new chemical process was quite active before the Lautenberg Act. But there have been changes to that process as well with the 2016 revisions. And they've generated some controversy as well, and particularly related to some changing positions that we've seen during the implementation. So what are some of the changes to new chemical review as a result of the act that we should be aware of?

Kevin: Well, I think the two most important or one, the change that was made throughout the act in terms of the standard. Again, the unreasonable risk standard course was carried through in the new chemical provisions. And the other was the addition of a requirement that EPA makes actual affirmative decision on a chemical that it's not likely to present an unreasonable risk for it to be introduced into commerce. Under the previous TSCA, while EPA had a deadline for acting, which was quite short on the order of 90 days. And if EPA didn't act on the notice for a new chemical that it received within 90 days, the manufacturer could just go forward. So it was always possible for EPA just to sit on it and not have to develop a record for its decision.

Kevin: Now, EPA had to make a decision one way or another, and it has to have a record for those decisions because it could be challenged. So that's a new burden on the agency. And that certainly led to some longer time periods than perhaps anticipated in the processing of new chemicals coming into the agency when the Lautenberg Act was passed because it didn't provide really any sort of transition period. EPA also had to apply those new provisions to pre-manufacturer notifications or what are called PMMs for chemicals that were sitting in front of it at the time.

Kevin: So it basically faced a huge backlog right at the beginning, as well as a continuing stream of PMMS coming in for new chemicals or new uses of chemicals under the new law. And that has been quite an implementation burden or an issue. The agency has worked to really reduce that so that it's processing chemical applications much more smoothly than at the beginning, but that was largely due to the existing backlog coupled with, gee, all of a sudden, we've got some new standards, some new provisions of the law. We have to figure out how to apply that.

Hana: And if I understand this correctly, in the prior version of TSCA or the unrevised version of TSCA, by not acting, it wasn't necessarily an approval, but it wasn't a denial and companies could move forward with manufacturing or processing.

Kevin: That's correct.

Hana: That's flipped in the revision. So a lack of determination is actually treated as a denial. So they really do have an affirmative obligation to act.

Kevin: That's correct. And that's really a fundamental change in how that provision works.

Hana: And certainly an incentive to move, both from their perspective, as well as from stakeholders because companies that they wouldn't be able to manufacture, so they are going to be pressing for quicker response, I would imagine.

Kevin: Yes, obviously. It leads to greater interest on the part of stakeholders. They need an affirmative decision to move forward as opposed to the agency feeling perhaps that the chemical is okay, but not having to go to the trouble of developing a record and a decision record to support that decision.

Hana: And you mentioned the unreasonable risk standard and how it weaves through the entire statute with this revision. How does EPA determine a new chemical substance or significant new use is not likely to present an unreasonable risk?

Kevin: Basically, it has to analyze in a short time period the information that comes in about the chemical from a manufacturer or a processor or a new use of the chemical. Look at what it knows about similar chemicals. Even though this one's new, it may have information about the effects of, again, chemicals that are structured molecularly in a very similar fashion and make a judgment, again, within a very short span of time, whether it considers it likely to present a risk or not likely, or is sort of an intermediate category and needs more information. The agency can also extend the time period for acting from 90 to 180 days to give itself some more time, but it hasn't generally been doing that.

Kevin: So basically, it's really a need to do a very quick assessment. It's not the years long process that it is for existing chemicals, but under the circumstances really doing the best that they can to evaluate the potential risks of a chemical.

Hana: And we've seen some assumptions made that have generated a bit of controversy as EPA has done this around how manufacturers and processors protect workers from exposure and how that factors into this risk assessment. I think if I understood it correctly in your paper, EPA is now assuming manufacturers and processors will supply workers with adequate protective equipment, but that's a bit of a change from their prior approach. Is that correct?

Kevin: Yes, it is. That's one thing that did stand out to me for sure. And looking at how the agency has been implementing these provisions now is that in the past, the

agency did not assume that manufacturers or processors of chemicals would supply workers with necessary PPE, personal protective equipment, to protect themselves from chemicals. Whether it's masks or ventilators or gloves or suits of some short. Now, the agency seems to be saying, "Well, we're going to assume that the companies are going to do that for their employees. And so that we're going to assume that whatever risks there may be from occupational exposure, that would be mitigated by that, or we'll assume they will be mitigated by that." As opposed to saying, "There's a risk there, and to mitigate it, we need to require the manufacturer to do that."

Hana: Maybe the approval would have included a requirement that they provide that equipment.

Kevin: Correct. It's true.

Hana: And then of course, the issue of conditions of use that we've talked about already around what's reasonably foreseen, and this risk assessment comes into play again with these new chemicals assessments.

Kevin: Right. I mean, that is an area that involves some ambiguous terms in the statute. It's a difficult area in the sense of what is a reasonably foreseen use of a chemical? Congress apparently thought that this was something beyond what a manufacturer intended the use to be because it's reasonably foreseen, not just intended. But presumably, that can't be or wasn't intended by Congress to include totally speculative uses that somebody might say, "Gee, somebody could just decide to use chemical X for this purpose. So therefore it's reasonably foreseeable even though there was no basis for that guess that it might be used that way." And so somewhere between those two poles of what the manufacturer knows it's going to be used for, and a totally speculative use of the chemical, that's to me sort of a factually difficult issue to deal with where you draw that line and really may depend on the individual chemical facts involved.

Hana: So the Lautenberg Act really has three major takeaways, I think, that we've spent our most time on. Significant, reorganization of how the agency handles the existing chemicals and processes them and sort of new burdens on the agency to do so. Some shifts in how they approach new chemicals. And then this sort of overarching change in the process for risk evaluation that goes across much of their work, both for new and existing chemicals. There was one other provision I wanted to just briefly touch on before we talk a bit about your sort of takeaways from all this work that you've done and analyzing the implementation of the Lautenberg Act and that was on preemption provisions. The act did also change some of the ways TSCA preempt state law and regulation. Could you explain a little bit about what the shifts were here?

Kevin: I will try. The preemption provisions go on for quite a long section of the act. They were quite simple before and basically not very preemptive. The 2016 amendment brought in both many more words and more preemption. Which is not to say complete preemption of the States by any means. There are various exemptions and waivers that are provided, but it's definitely a more preemptive path has been charted for TSCA regulation than previously existed. And basically, it's more aimed at providing a uniform national set of rules at least where the concerns are really the same that EPA may have applied in its risk evaluation of a chemical. The same condition to use, same hazards, the same risk to people and exposures that if EPA decides that there's not a risk or if EPA decides that there is a risk and decides how to handle it, it is much more preemptive on states though, again, there are avenues for action based on other statutes, authority, or long-existing state authority if it exists.

Kevin: Particularly California is one that certainly has some long-standing authority that it can exercise and some other states as well. But there's no question that it moved in a more preemptive direction. And I think that was, in some ways, the primary way that there was an agreement among industry that allowed this to move forward with some significant tightenings on the environmental side in terms of the standard and in terms of mandates for EPA to act and in terms of the need for affirmative determinations on new chemicals. That there was a broadening of preemption on the other hand. So that's where that has gone. There hasn't really, I don't think, been any real court litigation. I'm not aware of any yet on that. Of course, a lot of the decisions haven't really been made yet in terms of existing chemicals. The risk evaluations are just underway and there are no final decisions on those.

Hana: Right. We're still very much in the implementation process. And really, as we've discussed, there's been quite a lot of activity. It's still quite early. We're still quite early in this process. It takes time to go through and do these extensive risk evaluations on individual chemicals. And there are, as you point out, quite a few. So after delving into how EPA has pursued the implementation in the Lautenberg Act, since she left the agency, what are some of your primary takeaways about the process and sort of where we're going with these revisions and what it really means for regulation of chemicals and toxic substances in the US?

Kevin: I think it's still, as you suggested, still early in the process, and it's still fluid. The agency has shifted course on a number of issues. Should the agency try to shift course in a different direction in the future, that will require some effort and time to do that because these decisions are being carried out in the context of risk evaluations and ongoing work as opposed to many of them being carried out in hard and fast rules like the framework rules, which were final actions on the part of the agency and will make regulatory form. There will be room to make some changes, but that would require work and an evaluation on how that could be

done because some of these are cast in terms of documents that have put out by the agency or may soon be put out such as documents concerning the scope of the risk evaluations of the high priority chemicals, which are not out yet in final form, but they may be out in the next few months.

Kevin: It'll be a fluid and I think evolving process to see, but I don't think it's one where much of this has yet been sort of fixed in stone as opposed to directions that are currently being taken.

Hana: Kevin, thank you so much for joining us today on CleanLaw. I can tell you that throughout this process, everyone at EELP, the staff, and students that work with us have just really enjoyed getting the benefit of your expertise and helping teach us something about TSCA and how it actually is implemented in the agency. You also were so generous with your time to work with a number of our students who helped support you in some of the initial research and digging into the background for your paper. And I have heard from them that they really did enjoy doing that. The regulation of toxic substances is quite a technical area and many environmental attorneys don't necessarily have a comfortable understanding of the law if they didn't specialize in it. So I encourage everyone to read your paper and appreciate your time and the effort you put into that and your willingness to speak to us about it. So thank you.

Kevin: Well, thank you. It's been a great opportunity.

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