Speaker 1:

Welcome to Legal Environmental Insights, a Greenberg Traurig podcast.

Bernadette Rappold:

Well hello, this is Bernadette Rappold and welcome to Getting Through, the Greenberg Traurig podcast on environmental issues during the pandemic. I'm so happy today to be joined by my dear friend and colleague Travis Klein. He is the senior principal toxicologist at Geosyntec, a consulting firm that does environmental work, etc. We've worked together on a lot of different projects, but today we're talking about a statute and an issue that doesn't necessarily leap to the front of people's minds, but it has become of more acute interest since the pandemic began, and that is the topic of FIFRA, which is the Federal Insecticide, Fungicide and Rodenticide Act.

Bernadette Rappold:

We'll explain why we are talking about that today. So, Travis, what is FIFRA? What does it do?

Travis Klein:

Right. Well, first thanks very much for having me on, Bernadette. It's a real pleasure. So FIFRA is the Federal Insecticide, Fungicide and Rodenticide Act. It's administered by USEPA. It governs registration of products and devices that make antimicrobial or other pesticidal claims. There are conventional chemical pesticides for insects and weeds, etc., bio pesticides and antimicrobial pesticides. It's interesting that it's not initially the chemicals, though, involved in your product that subject you to FIFRA, although that's the focus of required testing.

Travis Klein:

It's the claims you make on your product label, your website, your external facing materials, which first wrote the compliance requirement. And I should mention that there are registrations for active ingredients, TAGIs, manufacturing use products and end use products. End use products are like the bottle of spray disinfectant you see on the shelf at the grocery. And those really are the focus of our talk today. I think that's where everyone's interest lies.

Bernadette Rappold:

Right. Obviously the interest in disinfectants has risen tremendously since the beginning of the pandemic. I think we all remember right after the shutdown first began last March, it was really difficult to get any of these products in the store. They were just wiped out. So to your point though, Travis, what you're basically saying, it's the claims that matter. Right?

Travis Klein:

Right. So let's say you have an alcohol-based saturated wipe. That can be sold as a disinfectant wipe implying it kills germs or as a finish clean wipe because alcohol leave no residuals. In that latter case, you're not making any pesticidal claims. The former's a pesticide. The latter's not under FIFRA definitions. So for products with a widely recognized anti-microbial capacity like ethanol, you don't have to make those specific claims on the label and that can allow a company to get a product to market early while they pursue FIFRA registration in the background, which can take quite a while.

Travis Klein:

I think we'll talk about that. As an aside, since I mentioned wipes, EPA requires testing of the expressed or squeezed out liquid for these wipes, but there is some talk of including the weight of the wipe in future testing.

Bernadette Rappold:

That's good to know. Just to start with, and we'll turn back to this later, but this is an issue, FIFRA registration is an issue, not just for the entities that manufacture these products and want to bring them to market in the first place, but also for retailers who might be selling products on their shelves. So it's obviously going to be important for retailers to make sure that they don't have products that are making pesticidal claims without being registered. But, here's a more fundamental question. When I think about pests, I don't necessarily think about COVID.

Bernadette Rappold:

And what do pesticides really have to do with COVID? It's a little bit of a confusion for folks.

Travis Klein:

Right. So under FIFRA, microbes, like the novel coronavirus, the SARS-CoV-2, they're considered pests. So before you sell or distribute a pesticide, it has to be registered with the EPA. The EPA has prioritized their review of products that are designed to help us respond to the current pandemic. So normally their registration process for a pesticide can include EPA's review time of your submission of maybe six to 12 months. And that's been shortened to a goal of four months for qualifying product. And when I speak of qualifying products, EPA maintains a list of products shown to be effective in controlling the SARS-CoV-2 viral strain, and that's called list N.

Travis Klein:

The admission to list N is predicated on efficacy testing on a related coronavirus or a harder to kill viral strain. EPA also allows for what's called an emerging pathogen statement or claim for qualifying product labels that isn't specific to SARS-CoV-2 and presumes efficacy against whatever the next iteration is, as well as SARS-CoV-2. So right now we have these coronavirus strains and alternates just cycling through the Southern hemisphere. And to qualify for this claim, you must prove efficacy against two small non enveloped viral strains, typically a norovirus and a rhinovirus.

Bernadette Rappold:

Got it. That sounds pretty detailed. Maybe you could explain a little bit more about what registration of a product really entails.

Travis Klein:

Right. This is a fairly complicated process, I think, out of necessity. So both the plant where the pesticide is made, which is termed the establishment, and the pesticide itself, the product, they have to be registered with the EPA.

Bernadette Rappold:

Wow. So that sounds right there pretty involved. Can you tell us a little bit about what that process looks like?

Travis Klein:

Sure. So people often think of EPA permits as license to pollute, different registrations are in essence licenses to kill like a Double O designation. Mr. Bond. The data requirements are prescriptively strict, even for disinfectants that use common active ingredients or have already been registered by others. But the alternative for unregulated use of these products obviously is not so appealing.

Bernadette Rappold:

Right. I know from working on these matters with other clients that under FIFRA, you can be assessed a penalty for each sale and distribution of the product, the unregistered or improperly registered product or improperly labeled. And that can add up really, really quickly. So I know that FIFRA has been around for a long time, but can you explain, and I think most people can understand that it makes sense for pesticides to be so vigorously tested and so forth. But why is there such a detailed testing, reporting and review process for chemicals that are already approved for use and on the market?

Travis Klein:

It's a good question. Right. So alcohol is a good example. We have ready availability and access to alcohols. But when they're used in a product designed to kill pests, there are particular regulations that's related to its use. So first of all, because company A can safely make a chemical A at the right strength when the right delivery package, doesn't necessarily mean that company B can. Plus, companies often add other ingredients to their products like fragrances or emulsifiers that can have additive or inhibitive or other unintended effects or otherwise potentially cause a problem.

Travis Klein:

At the end of the day, EPA wants to make sure that the product is safe and effective when used in accordance with its label.

Bernadette Rappold:

Right. And I think anyone who's ever looked at a can of pesticide at home will have remembered seeing the line, it is a federal violation to use this product in a manner not consistent with its label or words to that effect. And that's part of why we practitioners say the label is the law. Right?

Travis Klein:

That's exactly correct. EPA loves that slogan. Yeah. This is not, I mean, we do have to on some level plan for misuse of these products. So the registration process considers the implications for improper use, not grossly improper use like someone mixing up a cocktail with a disinfectant, but unintended use. So this definitely is a case where if the doctor says, go home and take two aspirin, you don't go home and take the whole bottle.

Bernadette Rappold:

Imagine I wanted to bring a new disinfectant to market now, what are my first steps?

Travis Klein:

Okay. I think it's a good idea at the outset to engage a consultant with the right background and experience and the law firm to help guide you through this process because there are a lot of places to get tripped up. And with the right planning, there's real opportunity here to truncate the overall

process, saving you time and money. Also, there may be other requirements such as FDA reporting, certain active ingredients and have the vast majority of the data requirements waived by EPA, such as for sodium hypochlorite.

Travis Klein:

While other products may have a smaller subset of available or pertinent waivers, we don't have to test for exclusivity for silver ions, for instance. The primary options include purchasing a currently registered product and repackaging it with your brand name, supplemental registration, purchasing a registered active ingredient from a supplier, that would be called a non-integrated registration, selecting an active ingredient with widely accepted anti-microbial efficacy, that would be an integrated registration, which is frequently selected over the non-integrated option based on costs for high volume producers or developing a novel formulation to discriminate your product from marketplace competitors.

Travis Klein:

In a 100% repack, their registered wholesaler must manufacture package and apply your label for you with only distribution and volume reporting left on your plate. And you can tell if you look on the back of any of these products' labels, which products are supplemental registrations, meaning they're purchasing this product from another manufacturer, as these have three letter groupings as their USEPA registration number. The first number tells you what company the primary registrant is. The second will identify the product and the third identifies the supplemental registered product.

Bernadette Rappold:

Gotcha. So pretend I come to you, Travis, and I say, okay, here's my product. What do you do? What are the steps that you take when someone comes along and says, help me, how do I bring this to market?

Travis Klein:

Right. These days are more challenging than ever. But, okay, so taking a deep breath. We typically start with a review of the active ingredients and the inerts list along with a critical review of any in-house or ancillary data lines the client has collected, usually in consultation with its active ingredient manufacturer where they're purchasing a TAGI. Next, we can check to see whether there is an existing registered product on EPA's rolls that is virtually identical to our product. And if so, we can take advantage of EPA's site all or selective site all registration options.

Travis Klein:

These options allow some streamlining in developing your lines of evidence to support registration. This process allows you to take advantage of prior studies that have already been approved by EPA, so they don't have to spend a lot of time reviewing data. This is achieved either through research to identify master record identifiers provided the data are less than 15-years-old or through a compensatory offer to the original registering, to ask for access to their data.

Bernadette Rappold:

Just to tee this up for our listeners, essentially what we're saying there is under FIFRA, there sometimes as this opportunity to rely on data that have already been reviewed and accepted by EPA, but generally you, as the new potential registrant, are going to have to pay to use that data.

Travis Klein:

Right. There are subscription services with access to databases that will allow you to, again, identify master record identifiers so that you can tell EPA, even though you don't have access to those studies, you can tell EPA in your registration package exactly where to go to their files through review data that is directly applicable to your submission. But it's either that or a compensatory offer to a currently registered product and registrant. And that compensatory offer actually doesn't need to be accepted. You can't blame someone for not wanting to help a competitor product enter the market.

Travis Klein:

But if EPA agrees that their rejected compensatory offer was reasonable, you can tell them what it was, they can make a decision to allow you to attach the registered product data outcomes to your product. You won't see the actual confidential business info report or data, but it's essentially upended to your registration application by EPA for requirement fulfillment, simply by identifying the "financially similar product." And this serves two purposes, as you were saying, for that it streamlines EPA's efforts and gets more products designed to help respond to the pandemic to the shelves.

Travis Klein:

And it minimizes needless and expensive animal testing such as the acute toxicity six pack, which no one really wants to do anymore. And this reduction in animal testing is consistent across many of US EPA's programs and goals under other related programs like the Toxic Substances Control Act or TSCA. And there are other options for residual claims for things that for like long-lasting films or coatings that are effective over a period of weeks to years. For disinfectants that have a residual component, they can be demonstrated to be effective once sprayed on a surface or wiped on for up to 24 hours.

Travis Klein:

Or coatings and films like something that would be stretched across a food preparation table, that's typically limited to several weeks. Usually we say 27 days, so it's just less than four weeks. And then there are fixed products like solids or paints, which can show efficacy over a period of years. These residual claims follow draft guidance promulgated by the agency just in October of 2020. So it's still a pretty new process for everyone. But we are seeing more and more interest in films, again for covering things like food prep tables, or hospital exam tables or elevator buttons for that matter, and then paints, which incorporate anti-microbial capacity.

Bernadette Rappold:

Whoa, is what I want to say there. There's a lot of science packed into that. And one of the things I tell clients when they're bringing a product to market, especially if it's using a chemical that is fairly common, is that again, and you mentioned this earlier, Travis, that FIFRA registration recognizes that just because company A can do something correctly doesn't necessarily mean that company B can. And so FIFRA has some very, very detailed and rigorous testing requirements. And sometimes it makes folks sort of shake their heads.

Bernadette Rappold:

But there are opportunities to truncate some of these requirements by using some of the methods that you've cited to begin with. And one of the things that we found is that it's really helpful and almost it's not exactly mandatory, but really helpful to have a pre-application meeting with EPA. that's something that you might do for clients of yours.

Travis Klein:

Yeah. Once we have all our sort of lines of evidence gathered, then the pre-application meeting with EPA is absolutely a must. The anti-microbials group at EPA is super helpful, especially if you're looking to get agreement from the agency on data interpretation so you don't get a surprise four months down the road. It also gives you the option to get approval for waivers from testing requirements you don't feel are pertinent based on your product and its anticipated use like dielectric breakdown voltage for your mask, saving you time and money.

Travis Klein:

Under the current program, EPA, I know it seems onerous, but they have a vested interest in making your life easier because it makes their life easier, less time spent reviewing essentially the same study.

Bernadette Rappold:

Right. I mean, as a former EPA person, I can say that generally speaking EPA people have no desire to sort of reinvent the wheel because they're human beings just like us, but yet they want to make sure that the requirements of the law are satisfied. Can you say a little bit more about some of the data requirements? There are these sort of general data requirements and specific data requirements. What are those kind of in concept and how does that work?

Travis Klein:

Right. So I'll try to stay out of the weeds here and gloss this over, but this dragged into the technical end of things here for a sec. So there are on the most basic level, several chief components, including product characterization, basic things like pH, efficacy, toxicological testing. Testing includes an assessment of product batching consistency, and the development of what's called the lower compliance limit or LCL. All of the efficacy testing on microbes occurs at the LCL, which can represent a very narrow allowable window.

Travis Klein:

And it can be a challenge for some formulators to consistently hit this mark. If you're slightly below, this is what we recommend. If you're slightly below the lower threshold for the LCL, but your product is effective in testing, EPA will accept the results. If you're even slightly elevated, the test is going to have to be repeated. There are some options to try and speed this process forward if this happens, maybe diluting the sample and retest in some cases, but often this requires new batching, which can be disheartening late in the process.

Travis Klein:

And we really work pretty hard to keep from having to deal with this. As I mentioned before, there different efficacy testing requirements, depending on the type of product. Just to give you an example, let's focus on disinfectants. They're garnering the most attention these days as the market strains to meet everyone's demand. And there are limited spectrum, broad spectrum and hospital grade products. And as we mentioned earlier, we recommend pursuing the emerging pathogens claim, which sets your company up to respond to future challenges rather than limit testing now and claims to a narrow set of organisms and current conditions.

Travis Klein:

So to achieve the emerging pathogens claim, we recommend testing on three bacterial strains, including staphylococcus, salmonella, and pseudomonas. And again, two small non envelope viruses, usually a norovirus with feline calicivirus and a rhinovirus. The rotaviruses are actually the hardest to kill, but not as commonly employed. The standard efficacy testing exposure time when you spray a disinfectant on organisms is 10 minutes, but many products you're going to see on the shelves target much shorter times in an effort to demonstrate efficacy and track consumer attention.

Travis Klein:

And these can be as short as 10 seconds. That's the ethicacy exposure time, not the average American consumer's attention span. To prove efficacy for residual products like coatings, films or paint, there's a three log reduction requirement. That's equivalent to a 99.9% kill rate. And it has to be proven in two hours or less.

Bernadette Rappold:

Wow. That's a lot to unpack there, Travis, because there's a lot of detailed efficacy testing and demonstrations that you've got to meet. And this is why I think most people who work in this space say it's really good to work with both a technical consultant and a lawyer because there's just a lot of stuff to wade through. Let's suppose we've gotten all of the data in. We feel pretty happy about what that data shows we've talked. We've had a pre-application meeting with EPA. We put our application together. So what do you do next? Ho do you actually submit your application?

Travis Klein:

But the application itself is not the challenge here. So once we have all our data lines and ducks in a row, but we can produce the application that gets sent into EPA, there is a pesticide application improvement act or extension act or PREA based fee schedule, depending on your product category and the claims you make, like how many species of microbes you say your product is effective against. And there's a presumptive timeframe by regulation by which EPA has to act and respond. I should also mention while we're on the subject of fees, that once you're registered with the EPA, your product then has to be registered in every state and territory where you plan to sell.

Travis Klein:

And this is a simpler disclosure process, nothing like EPA submission with an attended annual fee, although some of the states are multi-year, but it's one that needs to be advanced after EPA registration. Well actually you can do California concurrently, but we generally don't recommend it until we've resolved all the issues with USEPA.

Bernadette Rappold:

Got it. And circling back to something we talked about earlier, when we both mentioned the old FIFRA adage, the label is the law. When you submit your draft or you submit your application, you also have to submit your draft labeling, right?

Travis Klein:

That's right. The final label is a required component of your FIFRA application. So once approved by EPA, it really can't be changed except by resubmission to EPA. Unless EPA comes out with an update, which they do periodically to allow based on a preponderance of the evidence and additional testing to allow

additional claims to be made for particular products, the only change you can you make to your label after EPA approves it though typically is the addition of your EPA registration number.

Bernadette Rappold:

Right. And when you submit your application to EPA, it doesn't just sort of fall into a black hole necessarily. Well, it doesn't fall into a black hole, I can say for sure. But there sometimes are you sometimes have interactions with the people at EPA. It's not that they just kind of go and toil and silence and you don't hear from them all along. Right?

Travis Klein:

Right. Yeah. There'll be questions. It'll be an iterative process. And at the end, there'll be a period where EPA may sort of gather any additional questions they may have, and there'll be a grace period, which will allow you to respond. But yeah, there'll be questions along the way for sure once the application is submitted.

Bernadette Rappold:

Right. That's something we've definitely seen in our practice as well. Well, I suspect, in fact, I know that the EPA team's pretty busy right now, given the plethora of disinfectants that are coming to market in light of COVID. So how's that been factoring into timing and other processing of applications?

Travis Klein:

Yeah. EPA is busy, obviously trying to help everyone, society here in the US respond to the COVID pandemic and the forthcoming iterations. So it's super important to anticipate questions and make sure there are no holes in your application. It's just going to make everything that much smoother. The EPA backlog is certainly significant now in response to the COVID-19 pandemic, and partner lab backlogs are also stretching out. So for certain products, it could be two months to get in line and two and a half months to get the testing results. Testing takes a while.

Travis Klein:

Not the efficacy testing, that can be run very quickly. But for ancillary testing, such as storage, stability and packaging, which normally progresses over six months to a year, but can be accelerated through application of heat and shortened to a period, I think, less than two months at this point. I should probably mention devices here. For devices that are employed to reduce contact with microbes, like UB lighter filters, you don't need to apply for FIFRA registration, but sort of what we were speaking about just a minute ago, EPA can request your supporting data in a critical review of any claims you make on your label.

Travis Klein:

So it's best to have all your paperwork and your ducks in a row when you're ready to get to market. Because if EPA doesn't agree that your data lines are substantiated, you're off the market. So for devices that claim of percent kill rate or other pesticidal claim, maybe a mask impregnated with an anti-microbial agent, for instance, those are subject to FIFRA.

Bernadette Rappold:

Right. And that again is I hate to be a broken record, but some of these devices that also incorporate registered pesticides in them or on them are pesticides in their own right. And so it's really important to understand if you're making a claim or undertaking an activity that takes something that might not otherwise be a pesticide and basically renders it a pesticide within the meaning of the law. So it's not always the easiest thing to tell at first blush. I guess what I'd like folks to listening to this podcast to think about, or to take away from this is that pesticide registration is really complicated and very data driven.

Bernadette Rappold:

And it's really important to get the process right the first time.

Travis Klein:

Yeah, absolutely. There's so much variability in terms of the products that are subject to FIFRA and the nature of products that have to be reviewed by USEPA. And it's super important to have all your ducks in a row for testing because we can see some vastly shortened development times, and I suppose, EPA review times, or at least not see that four month target be expanded. They're not precisely loopholes, but there's tremendous opportunity for truncating the required testing, not only through taking advantage of things like a site all application where you're leaning on someone else's work, but also to go through the guidance in terms of required testing and identify those tests, which aren't pertinent to your product.

Travis Klein:

So that we're not just automatically defaulting to the guidance based full monty suite of tasks. And like we said earlier, it's important to get agreement from EPA from the anti-microbials group before you submit your applications so that you don't get a surprise. We don't want to go through this process and have to start over six or eight months later. Acceptance by EPA isn't guaranteed.

Bernadette Rappold:

Yeah, that's right. That really is the big takeaway. If you do this right with planning, using the available testing waivers and other opportunities to focus in on the real data needs for your product, you can shorten the times necessary for doing that testing and hopefully shorten the review period at EPA. Well, Travis Klein, I would like to thank you very much for being here today. Thanks so much for your time.

Travis Klein:

It's my pleasure, Bernadette. I had fun.

Bernadette Rappold:

Good. And to our listeners, thank you for joining us today. In the meantime, please stay safe, take care and thanks.