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SYMPOSIUM TRANSCRIPT

DECIDING WHAT'S ON THE DINNER DOCKET

NOVEMBER 15, 2024

VICE DEAN ALLISON MARTIN, OPENING COMMENTS

Vice Dean Allison Martin: Good morning. I want to say thank you for being here. I'm Allison Martin, Vice Dean, and a professor here at IU Robert H. Mckinney school of law, and it is my pleasure to welcome you to the law school's Indiana International and Comparative Law Review Symposium.

I'm going to begin by reading Indiana University's Land Acknowledgement and Institutional Neutrality policy. IU Indianapolis acknowledges our location on the traditional and ancestral territory of the Miami, Potawatomi and Shawnee people. We honor the heritage of Native peoples, what they teach us about the stewardship of the earth, and their continuing efforts today to protect the planet. Founded in 1969, IU Indianapolis stands on the historic homelands of Native peoples and, more recently, that of a vibrant Black community, also displaced. As the present stewards of the land, we honor them all as we live, work and study at IU Indianapolis. Consistent with the Indiana University Statement of Policy on Institutional Neutrality. The comments contained in this symposium are solely the views of the speakers. Such comments and content are not intended to be construed and shall not be construed as the views of Indiana University or comments made on behalf or by Indiana University.

Today's event, titled, "Deciding What's on the Dinner Docket" comes at a pivotal time, as the demand for healthier lifestyles continues to rise, the role of food regulation has become increasingly significant. People are more conscientious than ever about what they consume, looking to food standards, safety practices, and ethical sourcing as guides for their choices. Today's symposium will delve into this critical field with expert speakers who will discuss the complex legal frameworks shaping the food we eat and the challenges they address to ensure public health, transparency, and sustainability.

Over the next three hours we'll hear from four distinguished speakers who will address a range of pressing topics within food regulation. The first presentation by Professor Amy Berg is an international comparison of food, safety, and synthetic chemicals. Following her, we'll hear from Zachary Maciejewski, an

associate at Faegre Drinker Biddle & Reith, who will discuss supply chain implications of new USDA Organic Regulations. Then, after a short break, Todd Janzen, founding partner of Janzen Schroeder Ag Law, will explore how climate change drives changes on the farm. Lastly, Brianna Schroeder, named partner at Janzen Schroeder Ag Law, will present on "Consumers as the New Food Regulators." Each presentation will end with a Q&A session moderated by Farrah Goodall, a current member of the Indiana International Indiana Comparative Law Review Executive Board. Please feel free to enjoy complimentary food and coffee available just outside the courtroom throughout the morning.

And now, I am honored to introduce our keynote speaker for today's event, Amy Berg. She is a partner at Ice Miller and an adjunct professor right here at IU Mckinney. Amy's practice focuses on assisting clients with complex environmental food and agriculture, regulatory and compliance issues. She counsels clients in the permitting operations and reporting processes of Federal and State regulatory programs, and contributes her experience to litigation at administrative proceedings, including matters related to emerging contaminants such as PFAS. Amy also assists companies of all sizes on compliance with the U.S. Food and Drug Administration and the U.S. Department of Agriculture regulations, guidance, policies, procedures regarding food and agricultural products. She helps her clients with environmental issues involved in property, redevelopment and real estate transactions. She also has created and teaches a course titled Agricultural Law and the Environment at McKinney. Amy has her Master of Science in Agronomy and Environmental Soil Chemistry from Purdue University, and her Juris Doctor from St. Louis University, where she graduated Magna Cum Laude. Please join me in welcoming Amy, who will kick it off with her presentation: "An International Comparison of Food, Safety, and Synthetic Chemicals."

PROFESSOR AMY BERG, AN INTERNATIONAL COMPARISON OF FOOD SAFETY AND SYNTHETIC CHEMICALS

Thank you for that introduction, and to Alex and Julia for all their assistance, and for the Law Review for their invitation to speak today. Okay, let's get right into this. I probably have too many slides that for me to get through today. And I tend to go on with this topic because I find it really interesting. So, I'm going to do my best to get through it and leave some time for questions.

First, what are we going to talk about today? Chemicals we consume, and we're just going to talk briefly about what that means. I'll give some examples and talk about regulation and approval – whether that's in the United States or the EU. I can't talk about every country's system, but we'll touch on some highlights and some differences. We'll also touch on prevention and monitoring a little bit. And if we have time, I'll mention some emerging issues (but I

probably won't).

Global Food Crisis

I just want to level and set the stage a bit with the global food crisis before we get started. We're going to go into some really specific detailed chemical usage today, approval and etc. This statistic from the FAO, the United Nation's ("UN") Food and Agriculture Organization, just highlights, that there are many people that face acute hunger every day, and there are things that we can do with trade to help alleviate that. We have acute hunger issues in the United States, and I want to keep this thought in mind, as we're going through some of these chemicals that we use in food, in trade, and some of the different issues that we run into with regulatory approval, and what we can do to help some of these more global issues. Agriculture, and food is a global economy, and we'll mention that briefly as well.

You'll hear people say, "food security is national security," and food security means a lot of things. We'll talk about food safety today and how food safety is a component of food security. When you talk about food security, you're talking about economic and physical access to food, nutritious food, available food, safe food. There's a lot of things that go into that. It's really important, not only United States, but also from a global perspective.

Food Quality, Identity, and Safety

For food safety, we're going to talk today about certain chemicals, what process is involved to get approval, whether it's from the FDA under the Food Drug & Cosmetic Act, or if it's in the EU. But there are a lot of measures that have been put in place under U.S. law to protect the consumer and to facilitate food safety. The system in the United States was developed over many years, and it's a fairly robust law. It has some overlapping provisions, some of that is intentional. Some of that overlap is intentional because we don't want a loophole where someone can introduce something that would maybe fall out of regulation. But there are certain systems, labeling standards of identity, that I'm not going to talk about today, but those are vital for food safety, and we don't think about them necessarily, as in the food safety aspect, but they really do facilitate food safety.

Labeling and Misbranding

The labeling. When you think about labeling, there are really detailed specifications from the FDA, and the EU as well, on what needs to be on your food product. How the nutritional label needs to be presented, and that's really important because if you have, for example, a food allergy you need to know that there's soy in that product. If you are concerned about what chemicals are in your food, you need to have something tells you what's in your food.

However, some of us don't care, we like our Doritos, and we're going to buy them. We're going to eat them. We don't really care what's in them, but some of us want to know, and it's important that those of us who want to know can have that information available.

Additionally, we're not going to talk about pathogens today, we're focusing on chemicals, but in reality, the majority of recalls in the United States are related to pathogen exposure or allergens when they've either been inadvertently introduced into the food, or there was some sort of labeling issue that the allergen wasn't properly disclosed. That's a huge safety risk if the consumer consumes something that has an allergen in it.

Standards of Identity and Adulteration

Standards of identity were developed over many years here in the United States, and that's really the intention of that is so that when you go buy peanut butter you know that that's going to be a consistent product. Peanut butter has a standard of identity – there's certain things that can be in it, and so every time you go by peanut butter, you're going to get what you think is peanut butter. If you don't follow those rules as a food company, you could be considered misbranding, and it could be considered adulterated food. There are certain penalties associated with that, and all of that comes together to protect us as consumers. It's not fail-safe, and keep in mind many of the products that we buy at the grocery store or from your local farmers market, they don't have an FDA inspector reviewing those and testing those before they hit the shelves. If you are in a meat processing facility, there is an FDA inspector on the line grading the meat, reviewing the meat and evaluating that situation. But most of the food that we consume is really it is on the honor policy, and it's the onus is on the company that is producing that food, to produce it in a manner that is safe in accordance with all of the laws, and to label that appropriately. So there needs to be measures in place to make sure that companies are doing that. Thus, there's laws, penalties for violation, and, more than anything, the penalty for a company that doesn't disclose or has a pathogen is consumer confidence in their product. It really hurts the pocketbook in the end, if you're not consistently maintaining your product.

Food Supply Chain

The food supply chain. This is a very simplistic diagram of the food supply chain, but I just want to mention it here. I didn't put arrows, because really it doesn't flow like this for everything. If you have produce that you grow and you harvest, you may transport that produce directly to the consumer. Or you may transport it to a grocery store; they may process it or may cut it up. Then you can go to the grocery store, buy pre-cut watermelon which is fantastic - it's ready to eat. There are several touch points along that path, and my point in showing

this slide is not that we sort of memorize this path specifically, but to understand how many different touch points there are, how many potential points for exposure to packaging and some sort of contaminant and packaging exposure to environmental contaminants, human exposure and equipment exposure. So that's really when you think about our food system in the United States, and in many countries it's really quite safe. It's no longer what you read about in some of the historical books. And if you've read "The Poison Squad" and some of the things that they used to be able to put in food and get away with it. But yet, it's a very complex system, and there are many points along the way where something can potentially go wrong.

U.S. Agricultural Trade

So, as I mentioned, the agricultural economy is a global economy, and this is just one figure that I chose to display how much trade has increased over the last several years. This graph shows from 1990 to 2020; over the last thirty years in the United States agricultural trade has significantly increased. We're talking five to eight times, depending on if we're talking about exports or imports. This is in dollars on the Y-axis, but really any access could be used here to depict that trend. The United States is really good at producing certain food. We export a lot of food from the United States and a lot of grain, and we have certain surpluses that we try to get rid of the best we can, but there are certain things that we can't grow in the United States because we don't have the climate for it, or whatever it may be. Coffee is an example, we import a lot of coffee, and we have very specific food tastes in this country, and we want a variety of foods, and so we need to have the means to get that, and a lot of that comes from imports. And so, keep that in mind too as we're talking about trade and chemical review and approval and movement of foods from one country to the next.

Chemicals Present in Foods

Okay, so let's get into chemicals and food. I think "chemical" has a bad connotation. As a former chemist myself, I think chemistry is really interesting, and so I don't necessarily think just because it has a complex chemical structure, that it's a bad thing. But not all of us are familiar with the food products and the food chemicals that we see on our food packaging. So, let's talk about some of those.

Food contact substances. As I mentioned before, you can have exposure to packaging, and some substances from that packaging can actually end up on your food. It's important to know what those substances are, and if that is happening.

Intentionally added. We intentionally add chemicals to some of our foods, right? And we'll talk about that and what those chemicals do and why we add them.

Contaminants. We have a variety of different contaminants.

Environmental. You can have exposure to soil.

Process. Processing, or the process of heating can actually introduce certain contaminants to your food.

Toxins. Toxins that can be produced from different sources. For example, we finished harvest, and we have a lot of corn in the grain bin, and if those conditions get moist that can produce and facilitate the growth of various fungi that can produce aflatoxin, and there are limits associated with aflatoxin, so we don't want that happening. We want to control for that.

Pesticides. We'll talk about pesticides in a little bit.

Risk Analysis

But before we get started on the legal aspects I do want to mention risk analysis. Okay, "the dose makes the poison" is a phrase that's credited to Paracelsus, a 16th century (sort of) the father of toxicology. He worked in the medical area and with drugs and sort of changed our thinking about drugs. To a large extent, that same sort of philosophy applies to chemicals and food, and to the environmental context as well.

Risk analysis involves looking at the particular substance. (1) Hazard. What is the hazard associated with that substance? (2) Exposure. Do you actually get exposed to it? What are the exposure routes? Are there multiple exposure routes? If it's a pesticide that's used on many food products, we need to consider how many food products you could be exposed to, and how many sources of this chemical you could be exposed to. (3) Vulnerable groups. (4) Fate in the environment.

This is a very technical analysis, risk analysis. With multiple data sets and modeling and people with very technical training doing this analysis and deciding sort of the risk and the potential harm for certain chemicals. That's not what we're going to talk about today, but it underlies everything that we're going to talk about today. Because when you talk about asking whether there a reasonable certainty of harm, you decide that by using this risk analysis. So it kind of underlies everything that we're going to talk about.

Food Additives

Okay, finally, let's get into some specifics. Food additives. Here's the definition for food additives, (at least the partial definition for food additives). You can see it's very broad: "any substance that may be a component of food." There are

specific exclusions from that definition that I haven't included on this slide, but regardless, the definition is very broad. For the most part, food additives are direct additives, something we're intentionally adding to the food, but you also have these indirect additives like I talked about before from packaging, storage handling, and etc.

Why do we have food additives? To a large extent, they perform a really important function. Here's a summary of some key uses for food additives, there are obviously many, and those have to be disclosed when you seek approval for your food additive. One is: maintain consistency. So let's say, for example, you have an emulsifier, and you put in your product because you want that product to have a uniform consistency. And let's say, yogurt, for example, when I open my yogurt I want it to look the same, and I want it to have the same mouth feel every time I consume it. If you have ingredients that are separating out as it sits in the refrigerator, and you go to then consume that product the next time, and those products have separated, the product itself may still be fine, may still be healthy still within its shelf life, but to you it may look like it's gone bad. Thus, maintaining consistency facilitates maintenance of that product and reducing food waste. Consumers are very picky. When they go to buy a product, they want it to be the same every time, and when they go to get their yogurt and they go back in a week, they want it to look the same right?

Improve and maintain nutritional value. When in the processing of food, you may lose nutrients, so you may choose to add some nutrient value back. You may add vitamins, and that vitamin will be considered a food additive. You have breads that are fortified with vitamins, or milk that is fortified with vitamin D. Those are all considered food additives.

Maintain palatability and wholesomeness, (sort of already mentioned), not only consistency, but maintaining the shelf life, especially as we talk about trade and getting food to areas with acute hunger. We need to make sure that food is good, and quality for as long as possible.

Provide leavening agents or control acidity/alkalinity. When you bake your bread, you need your bread to rise. That's a chemical reaction right? And so, we need to add those products that we see in our bakery or in our pantry all the time, to make sure those leavening agents are added so that our bread can rise. When you think about it, food additives means a lot of things, some of which we really want in our food.

Enhance flavor or impart desired color. (We'll talk about in a little bit).

You can't just add anything you want to the food and put it on the shelf and sell it. There is an approval process. Pre-market approval is required. You need to prove that your food additive is safe. There's a presumption that new food additives are not safe. The onus is on the company who wants to use the food additive in their product to prove to the FDA that their product is safe, and to submit that petition with all the data to support that their product, their food additive, is safe for that particular use. Keep in mind. I'll talk a little bit later about soy leghemoglobin, and when you get an approval for that soy leghemoglobin, it's not a blanket approval. Rather, it is an approval for a specific use at a specific quantity. If you have a use in one of your yogurt products, and you want to use that same chemical in your beverage product, then that's another separate analysis that has to be done and separate approval.

GRAS

There are certain exemptions under food additive approval requirements, and one of those is: generally recognized as safe ("GRAS"). If you can show that your food additive is generally recognized as safe, which sounds a little bit like a get out of jail free card, but it's not. It is self-determinative, so you can decide as the company you do your review of your food additive, and you decide that it's generally recognized as safe, based on experts in the field and publish scientific evidence, then there's no issue with using your food additive in the product that you want to put it in. But you have to have the supporting data to show that, and you can submit that to FDA as a notification and see if FDA agrees with you. But it is self-determinative, and so, you can make that determination and run with it. And of course it's to your detriment if you're wrong. The fact that it's self-determinative means also that if you get new data that shows the food additive is somehow more harmful or the data has changed, then your data was incomplete and you'll have to make that change. Maybe you'll have to change the level. Maybe you can't use it anymore. You know, that's all part of that risk analysis that has to be done.

Under the Delaney clause, that clause prohibits any food, additive or color additive, that has been shown to cause cancer in man or laboratory animals. And that's an explicit prohibition.

Color Additives

Color additives. The U.S. is unique in the fact that color additives are excluded from the definition of food additives. The approval process is very similar for color and food additives, but they're actually considered separately under U.S. law. The European Union considers color additives as food additives, so it's all sort of one regulation and is set up very similar. Similarly, as in the United States, it's sort of that risk analysis, reasonable certainty of new harm or of no harm. But let's talk about color additives. Obviously, color additives are added

for color purposes. There's presumption that they're unsafe, just like food additives. And so if you want to use a color in your product, you have to prove to the FDA that it's safe for that particular use at that particular level of use, and there is no exemption for generally recognized as safe.

If you are, for example, adding beet juice to your product (we're all familiar hopefully with beets – they have a very distinct color and a very distinct flavor). If you're adding beet juice to your product because you like the flavor, and it's there as a flavor component that will be analyzed under the food additive requirements. And you could say, if you've done the analysis and proven it, that it's generally recognized as safe and move on. However, if your beet juice is added for a color purpose, that is a color additive, and has to be analyzed under those specific laws and regulations, and there is no generally recognized as safe exemption. You would not be able to use that you would have to do pre-market approval through FDA and get approval for that food added, or that color additive.

If you're adding a substance to animal feed, and the intent is for your meat product, your egg product, your milk product to have a color on the back end, and that's why you added that substance, then that's a color additive and requires pre-market approval as well.

So the like, I said, the U.S. is unique in that aspect of having color additives separate from food additives. Those entities that are global entities that are wanting to import food products into United States have to keep that in mind that there's no generally recognized as safe exemption under the EU, so they wouldn't be utilizing that anyways if they were in the EU.

The unique nature of color additives is, there are a certified color additives, additives are color additives that are synthetic man-made chemicals. You may remember seeing blue number one or green number whatever on your food packages. This is blue number one (Blue No. 1), the picture of blue number one, and you can see it's a very nice color, very vibrant. The unique thing about synthetic color additives is they require batch certification by FDA. Every batch of synthetic color additive has to be sampled, submitted to FDA, analyzed and certified to verify that it meets the specifications of that synthetic color additive. It doesn't matter if you're located in the United States and you're producing colors, or if you're located in Italy, or any other country – you have to submit samples to FDA and get certified if you have a synthetic color additive. Then, once you actually pass the certification process, that's when you can use the label "Blue No. 1," or whatever specific color additive you have.

If you use a pigment from natural sources, so a vegetable, etc. Those don't require certification, rather those require pre-market approval. They would in the United States, and they do in the EU, but they don't require that batch

certification process through the FDA, which is a complication for food companies that want to import into United States.

This is an example of just screenshot right from the FDA website showing certain color additives. This one specifically shows the certified synthetic color additives that are approved and on the color additive list. You can see the color name and the status. "Permanently listed" means it's approved and permanently listed and certification required – that's what I was talking about that certification for synthetic color additives through FDA. And then the uses – you can see here "Blue No. 1," which was the example I used, can be used in foods. You do have to have pre-market approval for that. This is just a general summary, but it can be used in drugs and in cosmetics as well. FDA is the authority that regulates food drugs, cosmetics. So those same synthetic chemicals may be used in other purposes. All this information is online. If you're interested, you can go check it out.

Impossible Burger

Let's talk about an example. I find this example fascinating, hopefully, you do, too. The Impossible Burger. You can see here, if you went to the to the market and wanted to buy your impossible plant-based meat substitute then this is what the ingredients a label would say. Its little bit different than a hamburger which would just say "beef," (I've never had an impossible burger, so no judgment on the quality or the taste of the Impossible Burger).

We're going to talk about soy leghemoglobin. What is soy leghemoglobin? Leghemoglobin is a combination of two words: (1) legume, and (2) hemoglobin. We have hemoglobin in our bodies as animals. It has an oxygen binding function in red blood cells, and, interestingly enough, in some legumes they will produce a hemoglobin, and that's referred to as leghemoglobin. You may already know this as a farmer and an agronomist – I like to talk a lot about crops and soils, so some of you may know that legumes are said to "fix nitrogen" (which isn't technically true). The legumes form a symbiotic relationship with a bacteria called rhizobium, and forms nodules on the roots of legumes like soybeans, and in those nodules, the soybean will produce this leghemoglobin. It's produced for a very similar purpose, as in animals, it binds oxygen and facilitates that nitrogen fixation process, which is removing nitrogen from the atmosphere, converting it to a form of nitrogen that can be used in the plant. It's a great sort of relationship, and you want it to happen if you're growing soybeans.

It's very clever that Impossible Foods realized that this leghemoglobin has a very similar flavor, and acts very similarly to the hemoglobin in animals, and it has that heme group that acts very similarly and has similar chemical reaction. Impossible Foods decided to add this to their plant-based meat product, and it's a food additive. It has a similar flavor structure, and so it was added to impart

that similar flavor. If you are used to consuming meat and you want to go, buy your Impossible Burger, then it would taste similar. That's a food additive and thus requires food additive approval.

They [Impossible Foods] did their GRAS analysis. Sometimes you'll hear people refer *to GRAS substances*, but it's actually *GRAS use of substances* – because based on particular use at particular levels. Impossible Foods decided that because leghemoglobin is very similar to hemoglobin, and decided leghemoglobin was safe and they moved on and added it to their products.

But they [Impossible Foods] also want to use soy leghemoglobin to impart a particular color. That that color that we're used to, that reddish color for beef products. As a color additive, that requires a different approval process. GRAS is not allowed for a color additive, so they had to do pre-market approval, submit their petition to FDA and get approval to use soy leghemoglobin in their product as a color additive. It was approved, despite being challenged, it ultimately prevailed. You will see your products that are out there in the marketplace that have soy leghemoglobin in them.

Now the rub for some people and for some countries is: how do we produce soy leghemoglobin? As you can imagine, it would not be particularly easy to go out and harvest the nodules of legumes and of soybeans, and to get all of this soy leghemoglobin that we want. So we've modified. What's happened is they've genetically modified a yeast to produce this hemoglobin, and then they will lyse, or, rupture the yeast cells, collect the hemoglobin, the soy leghemoglobin. And by the way, this is a structural diagram of leghemoglobin and soybeans. [Referring to slides] that's what's used in the impossible meat.

In the United States, we generally take the approach that what you get out on the end, if it's pretty much identical to what you would have gotten under the natural sort of process then we're not too concerned about the means to get there. There's no yeast in the soy leghemoglobin that's collected in the end; none of the GMO product is in there, we're not too concerned about that in the U.S., but in the EU it's a different story.

EU

This is some general information about the EU and the General Food Law Regulation. Soy leghemoglobin has been. They've sought approval from the European Food Safety Authority ("EFSA"), that's the authority that was established under the EU regulations to sort of review these applications as the FDA does in the United States. EFSA approved that product.

They have their own expert panel that reviews GMO products in the EU, and GMOs are treated differently. I would say legally, they're much more sensitive

to anything that we would consider genetically engineered, and the consumers can treat it very differently as well. So that product is currently under review with the GMO panel, we'll see what happens in the end. The interesting thing is, the source is a genetically modified yeast, but you're not consuming the yeast, rather you're consuming this sort of product that's generated in the end. So it'll be interesting to see how they conclude on that issue. Soy leghemoglobin, I think, at least in Canada, New Zealand, Australia (and other countries) have already approved it, and it can be used in those food products.

I want to mention the Codex Alimentarius, and if you're like me and you know nothing about Latin, you have to Google it to figure out what it means – it means "the food code." The Codex Alimentarius Commission was established by the UN Food and Agriculture Organization ("FAO") and the World Health Organization ("WHO") to put in place kind of an international food standard. The Codex Commission now has 187 member countries, the U.S. is one and so is the EU. These countries come together and establish food standards sort of under an international consensus of how food additives should be analyzed, what maximum residue levels should be present for pesticides on food.

It's actually a very robust system and there's been very active engagement, it's a very helpful program. As you can imagine, in developing countries putting together a food law and a food system, to address raw agricultural products wouldn't be as difficult, but given all the products that we have today, all the technologies would be very difficult to put something in place just from the ground up. You know we've established ours for over a hundred years, and so these standards that have been put in place can be utilized by other countries.

The Codex was referenced when the U.S. and EU were engaged in discussions for a treaty that involved food and ag products. The Codex is referenced in other treaties as a standard, or as if nothing else, as a dispute resolution tool. But the idea is to facilitate trade, to harmonize standards, language, and terminology. The United States will refer to the Codex at times, and especially when it comes to pesticide tolerances and to verify what's being established by Codex. The EU will actually, specifically reference international standards and their regulations to harmonize what they're doing within the country, within the member countries of the EU, with the international standards. And this is really like I said before - food is a global economy - we rely on trade, especially here in the United States, so the more we can facilitate that, and make sure that the food is safe, and that it's clearly communicated from country to country what standards are being used, the more we can have safe and helpful trade.

Here's a few expert groups that exist under Codexis, and there's a number of them. This is just an example of how the Codex approaches food additives, which is very similar to how the U.S. does it. How it's done in the EU, looking at reasonable certainty of safety, what are the cumulative risks? What are the

sensitive populations? Sort of that risk analysis?

Pesticides

Now let's talk about pesticides. Pesticides is a hot-button topic. If you're a farmer, and you rely on them, you can have one view, and if you're a consumer you may have another view. Pesticides are interesting because so many different agencies have a role to play with pesticides.

The EPA has the authority to register pesticides, and under that, under the FIFRA, the Federal Insecticide, Fungicide, and Rodenticide Act. EPA *shall* register pesticides if they determine that they meet certain requirements, and there's no unreasonable adverse effects on the environment which includes risk to humans and the environment.

Then EPA, under the Food Federal Food Drug and Cosmetics Act, has authority to set tolerances. If you're using a pesticide on food, or if you have some exposure to pesticides that are utilized in a facility close to food, you may have some residue. Whether it's a contaminant or whether it's a pesticide residue, there's no replacement for good manufacturing practices. There's an assumption that GMPs are going to be utilized by companies, and you can't just say, well, it's within the tolerance so I'm not going to put in protections and controls to not control for this contaminant. It's expected that you're going to follow those GMPs and reduce contaminant exposure as much as possible. Nevertheless, there's that chance that there will be residues present on food. Thus, it's EPA's job to set those tolerances, and if it is safe to do so. If you cannot set a tolerance that's safe, then that product can't be used on food.

FDA has the responsibility for enforcing those tolerances, and that's mainly done through a monitoring program where they're periodically monitoring and sampling products in the food chain and also import-products as well.

The USDA has a role as well, because the USDA has authority over certain food products like meat and poultry, therefore the USDA will monitor those products and the residues associated with those products under the National Residue Program, the FSIS specifically does that. Then they also have their Pesticide Data Program, which is a pretty robust sampling and analysis program where they'll sample a grain and different products in the food system and test for pesticide residue. I don't have the numbers in this presentation, but for the most part, I think 99% of samples are below all tolerance levels when they're tested. So that's good to know.

Tolerances are the maximum allowable levels for pesticide residues on food – referred to that term a few times – that's unique to the U.S. The U.S. uses that tolerances term where most countries, the EU and the Codex will refer to

maximum residue levels.

The EPA will set tolerances if there's reasonable certainty that no harm will result by looking at aggregate exposure and potential other exposure. Maybe there's exposure from water sources, whatever is a potential exposure they have to consider that. The Food Quality Protection Act in 1996, that amended the law, also requires the EPA to consider sensitive populations: infants, pregnant mothers, and the fetus (we'll talk about that here in a minute).

Example – DCPA suspension

DCPA or dactyl. This is a chemical depiction of dactyl or dimethyl tetrachloryl terephthalate (you can understand why they abbreviate that). EPA issued an emergency suspension of this herbicide. That's the first time EPA has done something like that in maybe over 40 years. It just happened in August of this year, and this product is used to control weeds in specialty crops like broccoli and kale in the United States. Interestingly, EPA noted that in some situations, in its order to suspend, that there really is no replacement product. That's a hardship for the grower, if you don't have another product what are you going to do to control weeds? And you may have yield reduction as a result of that. The EPA also noted that these crops are heavily traded internationally. It's unlikely to affect the consumer in the end, because we can get those crops, we can get broccoli from other sources or many sources available in international trade. Therefore, the price is unlikely to increase for the consumer. So how does the producer deal with that? They now have a weed they can't control, they don't have a replacement product, and they may have reduced yield as a result of that. Of course, this suspension was not favored by the producers.

Let's talk about how we got there. As early as 1999, EPA started to consider that there were maybe health effects for a fetus at much lower levels than what they had set for the tolerances previously. They didn't have a lot of data, and EPA under FIFRA has to do a registration review every 15 years. They were doing that in 2013 when they requested that the registrant do some studies. (One reason I put this up here is to show how long it actually took to get to where we are today. This process can be a very long process.)

There was a lot of back and forth along this timeline with EPA going to the registrant and saying what protocols and they wanted to use, and EPA saying, "no, that's not sufficient." Eventually, EPA threatened suspension, suspended the product, got the data, lifted the suspension, reviewed all the data, and said, "oh no, we've got an issue, we're going to issue an emergency suspension" in August of 2024, and then ultimately the product was canceled in October.

Finally, EPA concluded that there was this significant risk of exposure, whether it's to a bystander or someone who enters a field after this product was used,

after DCPA was applied – especially if that under situations where that individual was pregnant and the fetus would be potentially exposed. The limits were so low that EPA found that there was this imminent hazard that could not wait. As you saw the timeline before the process of notice and comment, you know objections to this notice of suspension, and a hearing could take a long time, and EPA concluded, we can't wait. We can't wait for a suspension hearing. We can't wait for a cancellation hearing. We're going to issue this emergency cancellation right now.

With that in mind, do we think that the dactyl tolerances are still in effect? The answer is, yes, the exposure that EPA was considering was this exposure to the product applied in the field, maybe to a bystander nearby, but it wasn't food exposure. They've set those tolerances, and they still believe those tolerances are safe. You may still have some residues on food in the United States, and so those tolerances need to remain in place. You may have foods that are imported that have residues, and so, it's important to have those tolerances in place for that reason.

That brings up another point. Is it possible to have tolerances set for products that aren't registered in the United States? And the answer is, yes, you cannot use or sell a pesticide in the United States unless you've gone through registration under FIFRA and gotten approval. However, we have products that we import into United States that we don't grow in the United States, and there may be chemicals used on those products that we don't use in the U.S., for whatever reason, maybe the climate, maybe the particular crop, the particular weed, the particular insect. EPA will set tolerances for those products, tolerances have to be set. If you import a product, and there is a tolerance or not a tolerance established for that particular residue, then it is adulterated, and it cannot be imported into United States.

Interesting note – DCPA is prohibited in the EU as of 2019. The EU was a little bit, in fact, very much ahead of the United States, in reviewing that product.

Example – Chlorpyrifos

Chlorpyrifos is an insecticide that is widely used in the United States. It's been registered since 1965. In 2007 there was a petition filed by several NGOs to revoke the Chlorpyrifos tolerances. EPA, from my read of things, got an *analysis paralysis.* EPA has to go through these registration reviews, it reviews these human health risk assessments that it updates every time that gets new information. The NGOs kept going to the court and saying, "EPA is dragging its feet." Then the Ninth Circuit would issue an order, say, "make a decision," and then the EPA would blow its deadline again. Then the EPA said "we're going to revoke," and then it said, "no, I take that back, we're not going to revoke. we're going to deny your petition." So, it was kind of all over the place.

The issue was, the EPA felt like it had insufficient data to show that the tolerances were safe and felt like it needed more data. When it got to the Ninth Circuit, of course, the denial of the petition to revoke the tolerances was challenged, got to the Ninth Circuit and the Ninth Circuit, said, "EPA, you didn't do your job, this is arbitrary and capricious." The Ninth Circuit gave the EPA 60 days to go back and either revoke or modify the tolerances which, if you've worked with administrative agencies, you know, 60 days is not very long. But basically, the Ninth Circuit said, "you have two statutory programs you're working under: you have FIFRA, and you have the FFDCA, you have authority to set these tolerances. You [EPA] have to have reasonable certainty of safety to set those tolerances, and if you have insufficient data, if you can't show that they're safe, then you're not meeting your obligation under the FFDCA.

The EPA wanted to wait another 15 years for another registration review and the Ninth Circuit, said, "nope, that's another statutory scheme, and you need to fulfill your obligations under the FFDCA." So, the EPA went back, and I think sort of said, "well, we don't have enough time, we're just going to revoke everything," and of course, that made other organizations and producers unhappy. So, that was challenged. That got to the Eighth Circuit and the Eighth Circuit said, "you try again, you're acting arbitrarily and capriciously because you had data for 11 different uses that you could have reduced those tolerances, you could have modified them under the law, it says, *modify or revoke*, you could have done that EPA, and you didn't, so now you need to go back and do that." The Eighth Circuit vacated the EPA's prior order that revoked all the tolerances. Now we're kind of back to where we were, and the EPA is in the process of evaluating, reestablishing, and modifying those tolerances.

In the EU, Chlorpyrifos is no longer used, and they've set the maximum residue level at the lowest limit of detection for analytical purposes.

PFAS

Let's talk about PFAS. We could talk about PFAS for an hour by itself, but we'll try to get through some of the key points quickly. If you're not familiar with PFAS, you may have heard of "forever chemicals." These are per and polyfluoroalkyl substances that are used, and have been historically used, to a large degree, in many applications. They are great for their intended uses such as stain resistance, heat resistance, etc. They've been used in food packaging, coating of cooking surfaces, in upholstery, in firefighting foam. There are ongoing class actions related to particular PFAS.

This is an example of one on the screen. This is *PFOS* that you hear about sometimes, If you've watched the movie "Dark Waters," or you've watched "The Devil You Know," is the documentary version – that's what they're talking about, they're talking about a particular PFAS chemical in that situation.

PFAS is a very broad term and includes thousands of different chemicals. The problem with that definition is, it includes chemicals that range from sort of this long chain for fully fluorinated carbon that you see on the screen to shorter chain, to polymers, and they all act very differently, they behave differently in the environment, and their toxicity is different. A lot of laws are being established based on this very broad definition, and it's getting to be challenging. Certain States like Maine have a law where they're banning all intentionally added PFAS, by (I forget) 2032 or something. That's a lot of uses when you have a broad definition like what's being used.

PFAS are persistent, bio accumulative, and mobile in the environment and potentially harmful at very, very low levels. These are some potential issues that have been established as a result of PFAS exposure. Primarily certain PFAS exposure – the PFOS and PFOA that you hear about primarily and the ones that were used early on. Obviously, like, I said, depending on the PFAS, you may have different risks associated with those different compounds.

Highest PFAS levels on average in packaging, is in paper bags, historically bowls. Think about paper plates that you get, if there's a coating on it, and it's a paper-based product - so there's something on it that's keeping the water, the grease, whatever from getting onto your hands onto your clothes that you have them resting on – to a large extent that has been a PFAS related product. That is changing and has changed over time.

This is a figure from Shipman and Goodwin. They do a really good job of keeping this up to date. This is state prohibitions on food packaging with intentionally added PFAS. There's a lot going on with EPA, with respect to PFAS regulations, they recently released maximum contaminant levels for certain PFAS compounds and drinking water down to the four part per trillion level. One of the issues with PFAS is that we can only test for about 30 to 50 different PFAS compounds. If you have thousands of different compounds which you can only test for about 50 of them, then it's pretty obvious you don't know a lot about several of them. But anyways, this is [referring to slide] the state prohibitions that are going into place.

The FDA has done kind of an analysis and monitoring mode. Their opinion is a lot of the PFAS that has limited uses of certain compounds on packaging, and those compounds don't really move to the food product from that package. And, for the few issues that they identified those chemicals were removed from being used as food coating, and coating for food packaging. Then, as of February, substances containing PFAS as grief-proofing agents for paper and paper board are no longer used according to FDA, and this voluntary switch that has been done by the companies that manufacture those products.

There have been two recalls for PFOA, and those were in canned clams imported from China. So like I said, there's a lot going on with PFAS in the environmental space and regulatory issues that new things that the EPA is coming out with all the time, but as far as food, your primary exposure is through what's considered through food packaging.

Now let's remember, that food supply chain diagram that I showed earlier. If you have a situation where you have elevated levels in the soil, you have an animal that's getting exposed to water that's highly contaminated. You may have a very different scenario, right? But for the most part the exposure has been through food packaging for food.

The EU is definitely taking a different tact with respect to PFAS, it already has regulations and limits set up. This is an example of *some* of those limits here [referring to slide]. They have limits for PFOS, PFOA, and a couple other PFAS compounds, and then the sum of those compounds. Obviously they're considering that there's an accumulative effect from multiple exposure to those PFAS compounds. Thus, there may actually be a limit for the sum, that's less than what the individual limits are. And they have a number of levels established under the EU regulations for acceptable level of those compounds in food.

I know I'm getting close to my time limit here. Here's some food trends and some issues that are going to be coming up:

Lab grown meat. We're not really at the point where we can grow meat economically in a lab, but they can grow sort of the aroma and flavor of cells, and then add those to products.

Sugars and sweetener. There's different products coming out. There's proteins that are designed to be sweet and give you that sensation of sweetness because we love our sugar in the United States right? Then there's sugars that are being modified so that they have an even sweeter flavor, so that you can use less of the sugar, but still maintain that same level of sweetness. I think you could just reduce sugars in the products, but, like I said, we like our sugars and our flavors.

Then different coatings for different paper containers that are coming out with different sort of natural-based products that can be used in those situations.

I'm a little bit over, but thank you, and I'll take any questions.

Farrah Goodall ("FG"): We can take questions for about 5 min if anybody has anything burning.

PROFESSOR AMY BERG ("AB"), QUESTIONS & ANSWERS

Regarding the potential overturning of *Chevron* and effects on food law. That's an interesting question, a question that we're all sort of grappling with and different things, but the food law is very robust, and it has a lot of provisions in it that explicitly say, who has discretion to do what. So I don't know that *Chevron* or the doing away with *Chevron* is going to have a huge impact in this space. Judges are not in a position to do a risk analysis, so those things are going to be in the purview of the of the experts. But there's always going to be those situations of ambiguity in the law, and someone thinks that they challenge that they will.

FG: Thank you for that.

AB: Yeah, and that that is explicitly in the statute, but that's been decided that being safe before that time, period is not enough. You have to have more than that. That's helpful in showing that wide usage over a period of time that didn't result in any health effects, but you also have to have the experts and the published scientific evidence to support that determination. Yeah, it's good point. Thank you for that question.

FG: Any others back there?

AB: Yeah, and that's a real concern. We were actually talking about last night. Companies want to push the limit on what they put on their products. But consumers are rigorous right, and they're evaluating your statements. And there's this misinformation out there. Usually, if you have the evidence to support whatever's on your product, and what's in your product, for us those challenges as they come up. For marketing purposes, your position in a grocery store can be so important. So we're always counseling our clients to make sure what you're saying is actually true, and that you can back up what you're saying. If it's a statement about if it's just boasting, or if it's trying to make some comment about levels in your food, you need to have it. Yeah, it's definitely an interesting challenge, say, with all the information that's out there. Thank you.

FG: Way in the back.

AB: Yeah, and it's not necessarily catfish that's the issue. Catfish are under the authority of the USDA. (And it gets really interesting, what's with USDA? What's with FDA?). There are certain issues that arise in fishing, because sometimes our waters are used as our dispensary, right? Dilution is the solution, and they may have certain issues in the water and come into contact with certain levels of chemicals that other products don't. More often than not, the issues that you run into – you'll see tuna issues with mercury – they're not synthetic, they're contaminants like lead, mercury and stuff like that. But those are more

the issues that come up sort of in the aquatic aspect.

FG: I think we have time for one more.

AB: Yeah, and sometimes what is good and what is bad is personal preference right? Sometimes that's hard to answer. The thing that I suggest is really review your product. There's a lot of new labeling that's coming out such as the bioengineered disclosure requirements. If you don't want a product that's genetically modified in any way that's your right, and that information is disclosed. Definitely look at the label. Sometimes you have to look something up, to be sure what it what it is, and what it means. All of those sort of USDA or FDA labels on the food products are there to inform you of something. And yeah, we don't want to go to the grocery store and have to spend a minute reviewing everything, but it is important to look at what's on those food labels.

FG: Well, thank you so much Professor Berg, join me in giving her a warm round of applause.

5 MINUTE BREAK

FG: Take about 5 minutes just to transition speakers. If you need a quick coffee, break or something, go ahead and feel free to do that, and around 10:10AM I'll introduce the next speaker.

ZACHARY MACIEJEWSKI, THE STRENGTHENING ORGANIC ENFORCEMENT RULE: SUPPLY-CHAIN IMPLICATIONS OF NEW USDA ORGANIC REGULATIONS

FG: Hello, everyone! I'm going to introduce our next speaker, Zachary Maciejewski. He is an associate here in Indianapolis, at Faegre Drinker Biddle and Wreath. He helps clients navigate the complexities of FDA regulatory concerns as they look to market new food, beverage, dietary supplement and cosmetic products. He helps clients draft Food Safety Modernization Act (FSMA) compliance programs for animal feed and human food manufacturing facilities. He addresses complex licensing, permitting and regulatory needs and helps navigate the intricacies of state and federal licensing entities. Zac also works with companies looking to import and export food and beverage products internationally, helping them understand compliance requirements and interface within the U.S. and foreign export authorities. Zac focuses on issues related to food safety, marketing, regulatory compliance, intellectual property, indemnification, import/export, inspections and recalls.
Please welcome Zac Maciejewski.

Zac Maciejewski ("ZM"): Thanks everybody for being here this morning. I want to before we get going, thank Alex and Julia for all of their hard work

putting this together. It's no easy task putting together any sort of symposium or event, so they've done a great job.

I'm going to be talking about the New USDA Strengthening Organic Enforcement Regulations. These regulations could probably fill an entire day of conversation. So, what I'll be doing in 25 min is a significant overview of these regulations, and their impact now on the on the food supply chain in the United States.

A little bit of a roadmap for my presentation. We're going to talk about the rationale for why USDA implemented these updates to the organic regulations. Who they apply to. Why they matter, and then we'll talk about some of the changes, noncompliance, repercussions and supply chain disruptions, and how to mitigate those disruptions.

The first slide here is, "who do they apply to?" But I think it's more important to first talk about why these regulations are put in place, and I'm going to read off USDA's five bullet points for why they implemented these new regulations: (1) to protect organic integrity, (2) to strengthen farmer and consumer confidence in the USDA organic seal, (3) to improve market traceability, (4) to increase import oversight, and (5) to enhance enforcement ability.

The key driver behind the new SOE regulations is organic fraud. Since the implementation of the organic program, it's been rife with fraud because it's been very hard to enforce compliance. Particularly with products that are imported foreign countries. Obtaining the organic seal in the United States, for the longest time, there wasn't really a nexus between foreign supplier and domestic seller. Which led to significant fraud.

There are a few cases that USDA cited in its rules leading up to the promulgation of the new regulations. One was *United States v. Hakan Adro DMCC, et al.*: the DOJ indicted and convicted multiple individuals and entities from Turkey for committing organic fraud. They charged as much as a 50% premium on organic grain that they deemed organic, but which was not organic. Another one here in the United States is *U.S. v. Wolf*. The defendant there pled guilty to a 46-million-dollar conspiracy to sell non-GMO corn and soybeans. These were just a couple of the cases there. There are many more out there, and they kind of underpin the rationale of why USDA implemented these new rules.

Who do they apply to?

Prior to the implementation of the new SOE rules, the regs were very vague as to who was considered a handler. It was traditionally understood to be just entities that physically handle organic products. So, think your farmer, your picker, your distributor whose warehouse, or who's handling bulk products.

These entities are still regulated, but the new rules now go into entities that do not physically handle organic ag agricultural products. So, the definition of "handle" is: an entity that sells processes or packages organic agricultural products. Within this definition now includes entities that sell trade, facilitate the sale or trade or import or export products. Regulations are capturing entities that were on the fringes of the organic regulations before that were not necessarily directly regulated, and pulls them in. Sales brokers are a big entity that's now regulated. Brokers are very prominent in the produce industry, oftentimes they never actually physically touch the product. They're arranging sales between a farmer and a buyer, and they're now required to be certified by a USDA certifying agent as organic if they want to facilitate those sales. The same applies to importers and exporters of organic products.

These entities used to not be regulated and part of the broad sweep of these new regulations, trying to capture these entities who have a significant role in sale of organic products in the United States. Pulling in as many entities in the supply chain as possible. It's been interesting watching U.S. entities work with their foreign suppliers to become compliant with the regulations because it's essentially forcing a foreign arm, in some instances, to comply with U.S. regulations. There's, as you can imagine, a host of issues with convincing foreign entities to comply with U.S. regulations – but seems to be moving relatively smoothly from what I've heard. Still, in the U.S., legally, you have to do it, and so it's been working okay, from what we've heard.

Then there are certain entities that are not within the rule, mainly retail establishments. Like grocery stores that don't process organic products or process them at the point of final sale; customs brokers; logistics brokers; transportation companies that that only handle transportation of the product; warehouses that only handle tamper-evident packaged products are exempt, but warehouses that handle bulk product are not exempt. So, if they're handling bushels of apples, they're not exempt. If they're handling packaged cans of apples they are except.

Why do the regulations matter?

They matter for food companies for a variety of reasons, one of them being noncompliance. Well, one not compliance can lead to a company's inability to market product as organic. Marketing organic products is a significant selling factor for a lot of a lot of companies, especially produce companies. Failing to confirm that your entire supply chain is compliant with the organic regulations can lead to your inability to market organically.

There's also consumer fraud class action risk for marketing products that are not organic as organic, this is false and misleading to consumers and can a company susceptible to consumer fraud litigation which is rampant in the United States

right now. A lot of it for good reason, being honest and truthful to consumer is important, especially with respect to organic products that carry a premium among consumers.

There's also significant business-to-business litigation risk. If company A Sells Company B product, then Company A says, is organic, but it's not. This leads to breach of contract issues and to business litigation issues.

Then there's also the risk of regulatory enforcement. Of course, there's the risk of losing your organic certification, but there's also criminal liability. Any entity that knowingly sells or labels a product as organic when the product has not been produced or handled, pursuant to the regulations they're subject to civil penalties of up to $21,689 per violation. That number is actually specified in the regulations. And any person who makes a false statement to a certifying agent or state organic program governing official is subject to imprisonment of not more than 5 years and additional fines. So, there are hefty, regulatory enforcement measures in place with the new regulations, and there's significantly increased litigation risk associated with noncompliance.

As I kind of already talked about, the regulations from a 30,000-foot view. There's a broadened definition of handle capturing. Importantly, entities that don't physically handle or don't physically touch organic products, particularly importers and exporters.

The regulations now also require entities to develop a fraud prevention plan, essentially outlining the measures that they're taking to ensure that organic products aren't susceptible to fraud throughout the supply chain. Then, as I also mentioned, increased enforcement.

Given that a big focus of the today's presentations, or some of the focus, was trying to bring in as much international influence as possible. I wanted to focus just a little bit more about the impact on importers and import suppliers. One of the key requirements now is that entities must have their certification prior to shipping products to the United States. It's not a ship and get it later type of scenario. It's you have to become certified, and then you can ship. Given that the implementation date for the regulations went into effect back in March, I think, we're probably beyond some of those initial headaches. But there certainly were issues where entities were shipping product on the water and then finding out that they needed to become certified with USDA important denials and a lot of supply chain bottlenecks. Then entities are also now required to obtain a NOP import certificate prior to importing product in the United States – their document essentially confirming that all of the products in the shipment are certified, organic, be submitted to U.S. Customs and Border Protection Agency part of the lot.

There are also additional labeling requirements for organic products. I'm not going necessarily bore you all with what those are, but they are significantly enhanced, and it's essentially marking everything as organic and describing where you received it from and where it's going.

The broader picture here is USDA is trying to envision any possible scenario where there could be fraud in enforcing people to say, "this is organic, it's not fraudulent" as many times as possible.

Import certificate process. Needless to say, it's just initial, and it's another hurdle for warrant suppliers to obtain documentation from them from their certifying agents prior to shipping it to the United States. Interestingly, they can import certificate to comply to multiple shipments. It can be valid for up to a year, I believe at times. Which has caused a lot of industry to say, "how is this actually producing organic fraud, if the first shipment is compliant, but the rest of the shipments throughout the year are not?" And there's no oversight from a certifying agent, verifying that those subsequent shipments are compliant – are we really achieving the end purpose? The flip side of that is, certifying agents, there's not enough of them in the world to verify each shipment of products. Don't let the good be the enemy, don't let great be the enemy of good end of scenario.

Some of the potential supply chain disruptions, that we're seeing, that are kind of important (just for placing these regulations in context), is that a lot of foreign suppliers and certifiers simply don't have the capacity to manage these requirements. U.S. regulators are putting a lot of strain on entities that were no longer that used to not be regulated at all, and subjecting them to U.S. Government regulation now, and it's definitely resulted in some supply chain bottlenecks. They're certainly becoming more ironed out as time goes on.

Another is a lot of the way that these products are declared organic when they're imported in the United States is through customs and border protection. Harmonized tariff schedules. Some products don't have an organic code. So, if you import soybeans (is a bad example, because there's definitely an organic code and non-organic code, but let's just say there's no organic code) and you import soybeans. CBP has no way of knowing – "are these organic soybeans or are these non-organic?" The shipment still requires the import certificate, the shipping documentation must still say that the product's organic, but at the end of the day that product gets into the United States after CBP approves it, and the CBP is not having to approve organic or not organic. Thus, certain products are susceptible to misclassification and fraud, and I think that there is some sort of effort to try to rewrite some of those tariff schedules, but that requires cross agency work, and that takes a long time.

Then, as I mentioned, the broad applicability of the NOP import certificate to multiple shipments of products can complete the product. One shipment, on January first, is subject to the same certificate as the shipment on December 31st. A lot can happen in that year, and throughout that time period.

Some of the key takeaways, you know, throughout all this, in in my view, is revisiting your supply chain verification. We're going back and working with your suppliers to verify that they're compliant at the end of the day. It's the U.S. entity that's responsible for making sure that their foreign suppliers are compliant. It's the U.S. entity that's going to be subject to fraud, litigation, or the U.S. breach of contract action. It's on them to confirm that their suppliers, and everybody throughout their supply chain, is certified and is maintaining transactional records. It's incredibly important, and something I didn't talk about a ton, but which is important, is reviewing, or looking at your product labels – making sure that you actually have certification for each individual product that you are selling as organic. The organic process supplies on a per product basis, so each new product is now required to go through the certification process again with and making sure that those labels are accurate.

With that I'll answer any questions.

FG: Let's see from the crowd?

ZAC MACIEJEWSKI, QUESTIONS & ANSWERS

ZM: The seal, well, carrots aren't adulterated right? They're still safe. Non-organic carrots are still safe and safe to eat. They're not going to cause (assuming that they're not contaminated with the pathogen or chemical), they're not going to cause any harm, so they're not adulterated. Organic products are subject to different growing requirements and different handling requirements than non-organic products, and there's a premium price that consumers place with those products. Arguably, those products are healthier because they're not subject to certain growing processes that not organic products are re subject to. But they're not adulterated. It's a good question, because as a consumer, you see an organic product, and you think this is healthier, this is better than the other one. . . And cost! [laughter] Chain constraints, growing constraints.

FG: Go ahead.

ZM: Yeah, between non-GMO and organic. An interesting question (honestly, I don't know with certainty). Foods that are genetically modified cannot (99% sure) be considered organic. That definitely factors into the analysis of organic and non-GMO, but whether that modification occurs over time, or whether that was human induced I'd have to look at it and get back to you. I admittedly am not an expert in that. It's a good question.

FG: Thank you for that. Next question, go ahead.

ZM: Ingredients versus finished products, absolutely. I mean finished product theoretically is, you know, think of a tortilla chip. The issue comes down to the ingredients. That's where a lot of the fraud comes from, and intermixing. If you're shipping in containerfuls of corn or soybeans, it'd be incredibly easy to pick that half of it's going to be organic and half of it's not. We're going to mix it together and hope they don't test it right? That was a case in California a few years ago, where a farmer had five fields; one of them was organic and four of them were conventional, non-organic. The court said that the claim wasn't preempted because his organic claim was fraudulent. USDA preempts a lot of consumer claims. If a product is certified organic by a certifying agent (unless there was some sort of knowing fraud committed against that agent) the claim is going to be preempted under USDA. But fraudulent advertising is not, according to this California court that . . . long roundabout rant.

FG: Go ahead.

ZM: Sorry, just to make sure I'm understanding it correctly. The process to become certified. Yeah, so, you have to develop an organic system plan, and it has to be verified by a USDA certifying agent. There are entities that USDA certifies as kind of carrying forth their regulations and making sure that entities are individually certified. USDA doesn't actually individually certify anybody. Rather, it hires third parties to go out and inspect farms and look at organic system plans and then make a determination that entity is satisfy the requirements. It's per entity, but also per product. For example, if an entity sells five products, the entity is going to be certified organic to sell orange soybeans and a grain product, but maybe they also sell tomatoes, then that product would not be covered. And, if you go on the USDA database (the organic integrity database), kind of search around for individual companies and see what their products are, and the product itself is not listed. [Re-asks question] Oh, it would be that entity. Yeah, the USDA is pretty serious about this, too, because they connect the penalty supply also to people that are call it responsibly connected. On an individual basis held liable for committing fraud, because that's where a lot of this is coming from.

FG: And I have a question – Compared to the EU, for example, are our regulations stricter, or do we see any difference between other countries?

ZM: Great question that I don't know the answer off the top of my head. I know that a big push behind a lot of these regulations. Generally speaking, the EU is much stricter. My hunch is comparable countries are much stricter. It would be incredibly hard, for the for USDA to make this law more robust than it individually inspecting everything, and marketed as a well.

FG: Thank you. Next Question.

ZM: I probably think it was difficult at the beginning, I mean, industry had so much time with this, that doesn't mean that's asking a small farm the middle of Europe comply with USDA organic. Some farmers might find it incredibly difficult, because they haven't had to do it before, but a lot of them are probably growing organic product, and in their country and selling it throughout. You know the EU or Asia, or wherever: and it's really growing practices. But, it was more so just the documentation requirements. I think that we've got more hard work involved now than there used to be. And nobody likes more paperwork.

FG: Okay, well, if there are no further questions, please give a warm round of applause to Zac.

Thank you for your attention. So far, we're at the halfway point of the morning, so we're going to take a little bit longer of a break. The next speaker will start promptly at 10:55. If you could be back here with a few minutes to spare so I can introduce them.

If you haven't found them already. The restrooms are out this door to the left, and if you need to leave early this morning, please sign out on those iPads that you signed in on so that way you can get your CLE credit. If there's any questions, Alex and Julia are around, and we'll see you all in a few minutes. Thank you.

½ WAY BREAK

FG: Hi, everyone. If you wouldn't mind finding your seats. Our next speaker is Todd Janzen, founder and partner at Janzen Schroeder Ag. Law here in Indianapolis. Todd is a frequent author and speaker on legal issues affecting agriculture. His reach includes testifying before the U.S. Senate and House subcommittees on issues concerning ag, data collection, privacy, and technology. He writes a regular blog column on law and technology issues, the Janzen Ag. Tech Blog, which has been republished on Farm Journal's AgWeb, Successful Farming Precision Ag., Hoosier Ag. Today, and Precision Farming Dealer. Todd has been interviewed by various publications on agricultural topics including the Wall Street Journal, Farm Journal, and the Progressive Dairyman. Todd is a regular commenter for Market Day Report and Ag. Day on RFD TV. In addition to his thriving practice, Todd also serves as the administrator for the Ag Data Transparent Project, a national effort to bring transparency to contracts between farmers and technology providers.

Please welcome Todd Janzen.

TODD JANZEN, CLIMATE CHANGE DRIVES CHANGES ON THE FARM

Todd Janzen ("TJ"): Well, thank you very much, and especially thank you, Alexandra and Julia, for setting this all up and hosting dinner last night. Let me slide over here in front of the microphone.

So just to get a feel for who is here today, raise your hand if you're a current law student. So I have an idea. All right, that's most of you. What about, raise your hand if you're a currently practicing lawyer. All right, so some people getting CLE credit, too. What about professors? I guess, you are also currently practicing lawyers. Okay great.

All right. Well, hey! I am a 2002 graduate of IU Law School of Indianapolis. It actually wasn't called McKinney back when I graduated, but I can say a few great things about going to law school here. I was one of the classes that started in the old building, which is over there, and ended up finishing up in the new building. So, this was really state of the art when we started here. I'm also the very first class, first day of law school was with Professor Roisman. And it was her first day here as well, I think, teaching. So, she really kicked us off with a bang, because if you've had her, she's tough, expects a lot. And I will say I probably learned more about property law in law school than any other subject, thanks to her. So, she's hard and tough on you, but I feel like you get what you pay for.

I'm happy to be here today. Obviously, our practice involves agriculture. And so I'm going to talk about, not necessarily on the food side of it, like the other speakers you've heard today, but more on the production side of it. And talk about how climate change and the various initiatives that are out there have really trickled down to impacting the farmers that we work with on a day-to-day basis. And so, thinking back to when I first got involved with agricultural law, I did it because I was a farm kid. And also, because I noticed there wasn't a ton of interest in lawyers coming out of law school to go, you know, spend a day getting their boots dirty on a farm. But it really appealed to me, and I thought there was a real need for lawyers who also wanted to work in agriculture. And I'm happy today that, I'd say, an agricultural lawyer is not a rare thing. There's actually quite a few people in that space.

Climate Change Drives Changes on the Farm

So today I want to talk about three different types of contracts that we see farmers signing that didn't exist ten years ago, for sure didn't exist back in the days when I was in law school. And how these are really being driven by climate change initiatives on a national and even global scale. And how that trickles down to farmers that we work with here in Indiana. The first one is Soil Carbon Contracts, then we'll talk about Pore Space Carbon Sequestration Contracts, and

finally end with Anaerobic Digester Contracts.

Our Story Begins . . .

Because this is a thirty-minute presentation, these will be pretty high-level points and so we won't get too much into the weeds of specific provisions and contracts. But I'll tell you, I say the story begins with a Big Mac, because I think that the reason all this is happening is because corporate America, for the most part, has decided that it wants to reduce its emissions. And there are various reasons for doing that. But if you look at really any statement from a large corporation, a food corporation in the United States, they will all say we have pledged to reduce our emissions by a certain amount. McDonald's, for example, wants to reduce its greenhouse gas emissions by fifty percent by the year 2030. So that's not that far away. And what that means is that they have to achieve certain metrics by certain dates to get to that place. And the reason it impacts farmers is, you know, one thing they can do, they can change light bulbs from the old incandescence to the more energy efficient light bulbs that are LEDs. You can do all those little things, but at the end of the day that only moves the needle so far. Ultimately, what you have to do is really change what's happening throughout your supply chain. And if you can't meet these goals by doing that, what you have to do is purchase carbon credits from some other industry.

Carbon Farming Basics

So, the carbon farming contracts I'm going to talk about this is – I'm not a scientist, I'm happy to admit that – but the general gist of how this works is: when a plant grows, like a corn plant, it pulls CO_2 out of the atmosphere through photosynthesis. When that plant dies, then that CO_2 is ultimately returned into the soil in the form of carbon. But then, as decomposition takes place, that CO_2 goes, or that carbon, goes back into the atmosphere.

So, the idea with a soil carbon contract is that, if we can disrupt this cycle a little bit and we can get more carbon to stay in that soil for the long term, we can pull CO_2 out of the atmosphere. And there are companies that are willing to pay farmers to undertake these things.

Creating a Carbon Credit Takes Multiple Parties

A soil carbon contract, I think of, has four typical parties. So where we might get involved would really be in the first part of this, which would be the contract between the farmer and what we call a broker or ecosystem service broker. And they enter a contract, which I'll go through in a little more detail in a second. But this broker what they do then they also have a contract with companies like McDonald's that say we will sequester carbon for you for a certain price, and the unit of measurement is a carbon credit, which represents one metric ton of

carbon dioxide. So McDonald's pays a company like Indigo to remove carbon from the atmosphere. In return, Indigo would provide a carbon credit to McDonald's that it can then use to show that it reduced its emissions. The fourth party here is the Verifier. So there are a number of companies out there, these are private companies that will verify that what apparently is supposed to happen is really taking place. And so that the carbon credit is really being generated, the farmer really is sequestering carbon, and this is all happening as it's supposed to. You can tell there's a lot of legal issues with this sort of arrangement, and it's still in its infancy, I would say, as far as a trading platform goes.

But the contracts themselves – so, we want to talk about that first contract between the farmer and the broker who is selling the carbon credits. What does that look like? So, since carbon is the sixth element. I will give you six elements of a soil carbon contract. Although obviously there are many more, but these are the big six.

1. Enrollment of Land

So, one is the enrollment of land. All these contracts require that farmers enroll certain land into these programs. What is interesting here, I would say, is that essentially what we have is the creation of a deed restriction. So, when you enroll land, you're saying you're going to do XYZ on that land for this company. But we're not using the contract forms that we used to use for deed restrictions. And so that brings some complications I'll talk about in a little bit. But think about that as we go through this.

These are usually, I'd say, contracts for anywhere from one to ten years. And they're not recorded so it's more or less a farmer saying, I'm going to enroll this eighty-acre field in your carbon program.

2. Mandated Farming Practices

The company then would say, okay, if you're enrolling that land, here are the things you have to do, and there's a list of different practices that a company would, or I'm sorry, farm would be required to do in order to hopefully sequester more carbon on that land. Some examples would be cover cropping during times when a normal crop isn't planted; no tilling, so instead of tilling, which releases a lot of carbon into the atmosphere, you would pledge to no-till; and then other things as well. It's sort of an evolving science right now, I would say.

One thing to note is the additionality requirement. These companies only want to pay for somebody to do things for the most part that they weren't doing previously, or that they will continue to do. So, the best candidates for these programs are probably the farms that are generate the most CO_2.

3. Data Collection

So, okay, how do you take care of making sure that it's actually happening? Usually, the farmer is required to upload certain data about how they are practicing what they're doing on the farm. And so eventually, I think we'll get to a place where this can be done in an automated fashion, just using satellite imagery and algorithms and analysis by the images. But we're not there yet. And so, what we have to have is ground truthing and determination that this is really happening.

4. Third Party Verification

The fourth element would be third party verification. So these companies, that collect this data are trying to generate the carbon credit, will use a verification standard from another company, and there are a number of companies out there that do this like Gold Standard or Vera. And so, they'd be subject to spot check through these third-party verification platforms.

5. Prohibitions on Stacking

The fifth element would be what we call prohibitions on stacking. And the interesting thing about this – since there's not a recorded deed, restriction, or anything like that – is that in theory a farmer could take one field and sign up with five different brokers and get paid for generating the same carbon credit five different times. To prevent that, the farmers are required to say that they won't do that. They won't stack different programs on top of each other.

But of course this raises interesting questions because there is no way for Company A to verify that a farmer hasn't signed up with Company B unless they're exchanging information, and that would raise all sorts of antitrust collusion concerns.

6. Sale of Carbon Credits

So anyways, assuming there's no stacking and everyone's doing what they say they are going to do, then what you get to is the sale of a carbon credit. So a company like indigo would say, we actually have been able to determine this farmer generated this many carbon credits. We sell that to MacDonald's farmer gets paid, the broker gets paid, MacDonald's reduces its emissions. Everything works. I call it a system of environmental cryptocurrency because it is, these carbon credits are not a real thing, like a dollar bill. They're more like a cryptocurrency that they're built on the system of trust. And as long as everyone believes in the system, it can work.

Legal Issues with Soil Carbon Contracts

Just a few wrap-ups on this first topic. Big legal issues I see here are that these carbon credits, or these carbon contracts, are supposed to run with the land and stay on a certain field that's enrolled for ten years or so. But there's nothing that prevents a farmer from selling that land, and since it's not recorded in the chain of title, the next farmer doesn't have to follow those practices. They're supposed to, but there's no legal requirement that they do.

There's also no way to verify, no stacking is occurring.

And you know the other issue, this is not necessarily a legal one, but there's not really good rewards under this sort of program for those farms that have been doing these practices for many years because they've already achieved a lot of the soil carbon sequestration that these others are trying to reach.

Pore Space Carbon Sequestration

So, let's move on now to talk about pore space carbon sequestration contracts. And I think I put this down as a deep well carbon sequestration contract in the materials. So, what is this? Pretty interesting I would say. The idea here is that you can take carbon dioxide, compress it, inject it deep underground, and it will stay there forever. And so, it's a way to reduce CO_2 in the atmosphere. And when I say deep, I'm talking about injecting it, you know, a half mile or a mile underground. So if you think about, usually groundwater you'd hit at ten to thirty feet or so in Indiana. You're injecting this, you know, orders of magnitude deeper. So, there should be no impact on groundwater.

An interesting thing to note for you law students is that Indiana is a state that has a lot of good underground formations that are good for this. And so, Indiana is one of the States in the Midwest that we're seeing a lot of activity on these sorts of contracts.

But as you recall from first year, property law in order to put something underground, whoever owns that property owns everything from, you know the property line borders all the way down to the center of the earth, and likewise up in the sky as well.

Why Use Pore Space CO_2 Sequestration?

So, to get to that place, you have to enter into a contract with the surface owner of the land. A couple of points here. What's driving this? Why are companies going to this trouble to try and inject CO_2 underground? It's really being driven, I would say, by states like California, that have developed low carbon fuel standards. And also, by industries like the fossil fuel industry, like coal burning

power plants, or refineries that want to reduce their CO_2 emissions. Ethanol plants are a great example here in Indiana, because, although ethanol is a green fuel – it's made from growing plants like corn, same with biodiesel – the actual refining and making of that product generates quite a bit of CO_2. And so, if they can capture that CO_2 in the refinery process and inject it deep underground, then it suddenly makes ethanol a very renewable green fuel, sustainable fuel.

Pore Space Contracts

So, here's what the actual contracts look like. There's a few different elements to them. I'll talk about each element just in general and not necessarily get into the weeds. So, you have usually, let's say, a source of the CO_2, maybe it's an ethanol plant or a refinery, and it needs to get the CO_2 that it captures into an underground pore space. And once in a while, they're lucky and there's actually a pore space formation right under the facility. So that's pretty easy. They could drill straight down and pump their CO_2 in there. But more often than not they have to transport it to the location where it be injected. And I think it's economically it doesn't seem feasible to truck it to these locations. And so instead, what they want to do is build transmission pipelines to get the CO_2 to the locations where it can be injected. This will require an easement across land just like any other construction of any other pipeline.

And if you want to be a lawyer that works in the space where this is happening, I mean the Midwest is the place to be because building these pipelines across midwestern farmland is quite controversial in some areas and so, we're seeing like, just a ton of local use issues in States where they're trying to move the CO_2 long distances. South Dakota is one, for example, where they have to get, there's different permission levels in every county, and so to move a pipeline of CO_2 across the State is just an enormous burden for these companies. Indiana doesn't seem to be as difficult and so we haven't seen that sort of level of sort of local hostility to these sort of projects.

But anyways, the way it works, an easement is created, and would be ultimately granted by the landowner, who would be paid an annual fee. And I would say, for the most part, like any pipeline, once it's installed and the owner gets a royalty check every or an easement payment every year, there's not a whole lot else to the easement itself.

A little more complicated, I'd say, would be the actual contracts for the injection wells and the lease of the pore space. So, as I mentioned, the surface owner owns that land or owns the land, and they own the land underneath, including the pore space. And if you're a farmer, and you happen to get one of these contracts, if you don't have an injection well on your property, you may never even know that this is occurring right? Because the sequestration is happening a mile underground in a formation. And so, there's really no impact, I would say, on

surface use. But nevertheless, these companies will still pay you to use that pore space, because you, as the landowner, own that pore space. And if you have an injection well on your property, they'll pay you additionally, because there actually is something on the surface that you can see, and that might impact your use of the property.

Another thing about these leases of poor space – they are very long term, because the idea is that this will stay in the pore space forever.

Unique Aspects

Some unique aspects of these contracts, I would say. One is that we have seen some legislation in Indiana where we've tried to establish or get ahead of some legal issues like who owns that poor space. So, Indiana actually says that title does vest with the surface owner. Unless there's some carve out for a mineral estate, and somebody has sold that off. And there's a question, of course, about who owns that space underground. If you think about it, it's kind of like a reverse mineral estate, because, instead of the right to extract minerals out of the land, it's the right to inject minerals into the land.

The other unique thing about this or interesting aspect is that under Indiana law you don't have to get a hundred percent of pore space owners to agree to these sort of arrangements. If a company can get, let's say, 70% of the owners of the poor space in a given area, that's enough and they can drag along the 30% who are reluctant to sign up to do this, or even hostile to sign up to do this. But they do have to still compensate these owners, just like they do the 70%. And so I think that that raises some very interesting questions that we will probably see some litigation about. Can you force this 30% to go along with this? Statute says you can. But of course, rights are not always governed by statute. So, this will be fun to see how this plays itself out.

Anaerobic Digesters

All right in the last few minutes. Let me talk about anaerobic digester contracts. This is the third of our carbon trifecta here. So anaerobic digesters, I think most people have a general idea of what they are. They are a way that you take a waste stream, and as you heat it, it generates gas, biogas that can then be collected and used for other purposes.

Why Now?

And you may think, well, okay, why would generating more gas be good for the environment instead of be bad for the environment? Because if we're trying to reduce emissions, why are we generating more gas? Well, the idea is that the gas would be generated one way or another, from manure is what it is. And

whether it's put on a field or collect it in a lagoon or put in a digester, it's going to generate this gas. So, if we can capture that gas and use it, and let's say, power the same truck that would have been powered by diesel fuel with a renewable gas that comes from cow manure, then we've essentially taken a bunch of fossil fuels out of the supply chain, and we've reduced the emissions.

And so, the way this is working for our clients is, as I mentioned, California and other states have these clean fuel standards. And that means they'll pay a premium for renewable natural gas. Gas that is generated by these sort of anaerobic digesters. And for years we saw just a few digesters in the state of Indiana, because the economics were just not there. Once a state like California enacted its renewable natural gas standards or low carbon fuel standards, we suddenly saw a lot of interest in Indiana and building digesters here. And it's probably not known to most people, but what actually happens is, a dairy farm in, let's say, northeast Indiana that sells its milk to the Walmart plant in Fort Wayne, it is close enough to a pipeline that it can build a digester. They clean that gas, they inject it directly into a natural gas pipeline, and it comes out of the pipeline somewhere in California, where it is used to fuel, a vehicle. And so, it's pretty wild to think about the milk that you drink here came from a farm that's also generating a biogas that's powering vehicles in the State of California. And so, you know, even though every state tends to do its own thing, it seems like we're all in this together when you look at a scheme like this.

Dairy Farm → Manure Transfer → Digester → Biogas Production → Biogas Upgrader → Pipeline → Use

The actual digester itself – don't need to spend too much time on this, because I think I already explained it. But you know the dairy farm makes the manure. You can also use other waste streams that generate a lot of methane. Or, landfill waste, food waste, things like that goes into these giant digesters where it's heated. Gas is collected, and then it's upgraded. So it's made into a good enough quality that you can use it directly in a vehicle and it won't hurt the engine. And it's ultimately used in trucks. So, you see this last picture here, for example, this Coca-Cola truck might be using renewable natural gas and Coca-Cola is able to say that they've reduced their carbon footprint by doing this.

Legal Issues for the Farmer

So legally, the way that this works on the dairy farm, or any farm dairies just tend to be the ones that are doing it right now because the economics work for them, but I think eventually we'll see it in other sorts of farming operations. The unique thing is that the often case it's a third-party that comes onto the farm to build the digester. They're the ones that have the contracts with Coca-Cola, or Shell, or whoever it may be in California. And so it's a third party that constructs and builds these digesters on a dairy farm. The way it's done usually there's a

lease of land to this third party, and then there's also a manure supply agreement.

And I always joke, it's fun when the Westlaw salesman calls me and says, "you know, we want you to use our products. You know we want you to sign up for all these different services we can offer." And I always tell them, you don't have what we need. "Yes, we've got every form." You don't have the type of work we do. And then he'll say, "okay, give us an example." And I'll say I need a form of a manure supply contract. "Yep, you're right, we don't have that." So it's its own world.

Takeaways

Okay, a few more things. And then I think we have a little bit of time for questions. I would say, for me as a lawyer and a farm kid, it's neat to see that there are new revenue sources for farmers that allow them to diversify their income streams. And you know, even when we see, let's say, in Washington, whether or not we want to tackle climate change or not seems to be a lot of political debate always about that. But things are actually happening on the ground whether Washington figures out what it wants to do, whether it wants to tackle climate change issues or not. Things happen on the ground, and things are happening on the farm.

These contracts, I think they all touch real property law, but I also think they are often very unique in how they address certain issues. And then, finally, for people like myself and Brianna Schroeder, who you'll hear next, it's neat, and it's fun to work in an area of law where you sort of you really are on the cutting edge. And you're doing things that lawyers didn't do twenty-five years ago when I was in law school. And so that's where we are today.

So, I'm going to stop there. Here is my contact info. If you want to reach out to me, and I also have to say that we have a newsletter you can sign up for at our law firm website. So, if you're interested in these sort of topics, sign up; we, we don't use it to spam you or bombard you. We just send out a newsletter once or twice a month.

TODD JANZEN, QUESTIONS & ANSWERS

FG: Thank you. We have a few minutes for questions. Go ahead.

TJ: That's a good question. I don't know the answer to the second one. I don't know that there's any limit on how much or how many carbon credits they could acquire. I think you probably could, if you had the money, the resources, you could buy enough to offset all of your emissions. That's right. Yeah, if they're buying those offsets. I think that's possible.

FG: Thank you. Yes, go ahead.

TJ: Yes, I actually think there will be a USDA, some involvement in this at some point. When we had, the Inflation Reduction Act had the partnership for Climate Smart Commodities Grant Program at USDA. So, USDA released three billion dollars in grant money. And there were all these projects out there to really look at the science behind these sort of projects, and to figure out like, is this really working, because I think there, that's still somewhat unknown. Can we really make a meaningful difference by having farmers do these sort of activities and sequester more carbon in their soil? And it's so fractured right now. There are all these private industry initiatives out there that I think in the long run there does have to be some role for USDA to standardize and say, like, this is the verification standard that we're going to use to say things like, we will be like the last place where all these credits are retired, and so they can't be used again. So if you, McDonald's buys carbon credits from a company like Indigo, you know maybe they show them on their balance sheet that their emissions calculations. But maybe they decide, hey, the value of these has gone up, so let's resell them and we'll deal with the consequences later. But I think you have, USDA could be a clearing house for, or retirement home for these carbon credits. So, you would know once they're there they can't be resold.

FG: We'll take one more. Go ahead, Lauren.

TJ: I'd say. Not under the way property law is governed now. Because maybe they pay farmers five or ten dollars an acre to do these practices a year, and that isn't really enough to go to the trouble of creating deed restrictions and just jumping through all the hoops that is necessary to require, or to record, documents in the local chain of title. Now, we could fix all that with some work at the State level, right? If we simplified how things are recorded and you didn't require somebody actually going down to the county recorder's office and filing a piece of paper. And it's not that backwards today. But I use that as an example.

FG: Thank you. Let's give a round of applause to Todd. Thank you.

We're just going to take about two to three minutes and then we'll get started with the next speaker.

BRIANNA SCHROEDER, CONSUMERS AS THE NEW REGULATORS: HOW CONSUMER DEMAND IS CHANGING FOOD PRODUCTION

FG: Hello, everyone. Our last speaker of the day is Brianna Schroeder. She is a named partner at Janzen Schroeder Aglaw, which you just heard from Todd, the founding partner. Brianna works with the agriculture industry as she provides expertise such as litigating complicated environmental matters, drafting contracts for agribusinesses, and helping livestock farms navigate regulatory

compliance. She has a diverse group of clients, including farmers, rural landowners, agriculture companies, and industry groups. Brianna's perspective includes experience in complex litigation, civil defense, property liability, environmental law, and insurance coverage. Along with her thriving law practice, Brianna is committed to sharing insight with the industry as a sought-after speaker and author. She has authored numerous articles and given presentations on a variety of agricultural, environmental, and legal topics—including the Right to Farm Act, zoning, renewable energy, sustainability, the Clean Water Act, employment law, agritourism, farm security, and insurance coverage.

Please welcome Brianna Schroeder.

Brianna Schroeder ("BS"): Hello! I get to be your last speaker standing between you and the start of the weekend. So, I'm going to try to follow up on all the other lovely speakers you've had today. My name's Brianna. Like Todd, I grew up a farm kid; and eventually, in my practice, found a way to practice law, where some days I can be walking around a dairy farm in jeans and boots and some days I can be arguing summary judgment in a trial court. So, it's the best of both worlds, and very lucky to have this practice. We didn't plan it, but it ends up being that Todd's presentation blends nicely into mine, because I'm going to be focusing on how consumers are acting essentially as regulators of our food chain. And like Todd, I'm going to focus on the production side of things. We can talk about food, but we all know that food, generally speaking, starts on the farm. And my presentation is going to dive into the way that farms on the ground are changing the way they produce milk and meat and eggs and grains – not because they're legally required to, not because Indiana law or Federal law has said you must do this, or you cannot do that—but because that behavior has been incentivized by consumer demands. And how sometimes we see that can be more powerful than a new rule or a new regulation that comes out.

Consumers Want . . .

Transparency, Traceability, Information

So, first of all, I think, where this all kind of stems from is the idea that we've got more of a disconnect today between our ultimate food consumers and those people producing food. Right? It's like something less than 1% of the population is involved in farming. But we all eat, right? And so, I think, in part because of this disconnect—and the distance really between the consumers and the farmers, the producers – we've seen this kind of increased drive for kind of a demand for transparency, for information about the whole supply chain. People want to know where their food comes from. We see that in a lot of ways, right? I like restaurants. I'm a bit of a foodie, or I pretend I am. And so, we've all been to

the restaurants where it says this isn't just chicken, right? "This is Fischer Farms chicken," or "these are Indiana eggs," "this is cheese produced just north of Indianapolis." And as consumers, we like that, right? We feel a little closer to the farmers and the producers when we know where it came from. And so, what are consumers asking for? It's things like transparency, just the knowledge, traceability. You've probably seen some egg cartons; now, you know, you can scan it and find out where did these eggs come from?

Organic, Non-GMO

We've had organic around for a long time. I'm not going to dive too deep into that. You could have a whole day's worth of organic presentations. Non-GMO, same thing.

Animal Welfare

Now we have consumers asking questions about animal welfare. "How was this animal raised?" "How much space did they have?" "Did they have access to the outdoors?" "Was there a climate-controlled area for them to be in?"

Employee Welfare

People are also asking questions now about the employees who work on those farms. "How are they treated?" "How are we handling immigration concerns at these farms?"

Climate

Todd talked about three different ways we see farms changing because of climate concerns and a lot of times that comes through the consumers. There's no law saying you've got to do some kind of carbon storage, or you've got to adopt various climate smart technologies, but farms are doing it. Sure, part of it is farmers live here, too, and they want to make sure our planet's around and safe to our kids and grandkids to live in. But also, because it sells right? We like to know that we're buying a product that was produced responsibly.

And so, we see consumers demanding all of these things in different ways, right? And we're going to talk about that. Consumers vote with their wallets. Consumers also vote in some states through direct initiatives. And we're going to talk about that a bit. So let's dive into some examples

<u>Examples</u>

Like Janzen, we've got to kind of stay at a high level based on our time constraints. But I'll give you my contact information, too, and if anybody wants

to chat further about any of this, I'd love to. So, some examples of how consumers are changing the way we do things on the farm dairies are a great example.

Daries → Climate Smart Tech

Dairies now are entering into some direct supply agreements. Some are still selling onto the market, and you don't necessarily know where the milk is going to end up. Some are signing agreements – either it's with Walmart, it's with a yogurt company, it's with a restaurant chain. And that restaurant chain, or that retailer, or that yogurt company is going to say we are going to make representations to our consumers about this product and we need you to get on board. So, you're going to sign a contract that specifies how these cows are going to be treated, raised, how the farm is going to work so that we can accurately make these representations downstream to our consumers.

Now this could be everything from: How are you powering the farm? What kind of technologies are you adopting? Dairies now use a whole lot less water than they used to use. So, it's items like that that can be very costly for a dairy farm to put into place. But in order to get this contract – where maybe they're getting a premium right – they've got to agree to make these changes, raise these cows in this way, treat cows in a certain way, treat employees a certain way, provide specific benefits to employees. All of this. This whole package can be required through some of these direct marketing contracts.

Grains → Carbon Index Score

Grains. I won't dig into that too much, because Todd talked about that. But again, you're not legally required to plant a cover crop. However, you might get a premium, some kind of a bonus, if you can establish a low carbon index score. So that's another way. Again, you want to buy cereal, you want to buy products that are being grown in a way that's responsible, that's climate forward – companies are willing to pay farmers extra to adopt those practices, to allow them to ultimately make that claim.

Hog Farms → Animal Welfare

Pork is a big one, and I'm going to talk a little bit about Prop 12 here in a minute. But a lot of times when we think about pork, we think about animal welfare is one of the big things. And the way that programs are put into place, whether it's from a state law, or whether it is from a contract with a retailer. How are you going to check up on these things? If you've got a farm that says, "yes, we agree to do X, Y, and Z." That's great, but there's got to be some teeth in it, right? So what we're seeing, of course at Prop. 12 California law, there are going to be auditors. There's going to be certifications required. Even aside from what the

California voters did, a contract may require to say you can represent that you are this type of farm, certified, We Care program. But that means you're going to have folks come out to the farm to ensure that the way you're raising those animals complies with the representations that consumers are looking for.

Egg/Poultry → Cage Free

Eggs and poultry, this is one of the big ones. And I think, from my perspective, this is one of the earliest ones that we saw. And I've got another slide about that. That again, it's not by law that we have to have cage-free eggs, at least not here in Indiana. Not yet. But there's a ton of farms that have shifted over from a conventional egg production system to, you know, the sky's the limit. Right? Cage-free, pasture, free range. You know, you could make up a new one. Right? How do you want your eggs to be? They all have names, they, you know, they're all swaddled at birth. Come up with it and market it because consumers are going to buy it, right? But it costs more money to run those farms: it costs money for those capital investments, it costs money for the land – if you think about the amount of land required to produce the same number of eggs, if each chicken has, you know, a whole football field to itself, as opposed to being indoors, that takes money right? So, we see how that these consumer requests are turning into capital investments for farmers outside of any change in law.

On Farm Changes → Contracts, Investments, Audits, Reporting

Some of the ways we see that, as I mentioned, those direct contracts, supply contracts that say: if you are going to be a farmer and you are going to raise eggs that have our name on them, you have to agree to do it in a certain way, because that's what our consumers require. You're going to sell your eggs to McDonald's, you are going to have to raise those chickens and treat them in a certain way so that McDonald's can turn around and tell consumers: "we only use cage-free eggs." That can be done through contracts, legally binding contracts that the farmer is entering into with these downstream retailers, restaurants.

It requires a lot of investment, and that's sometimes the piece, I mean to get on my soapbox for a second here, that's sometimes the piece that I think politicians maybe don't understand. Because we can have these great ideas, right? In a perfect world, here's how we do things. That's great, and I'm on board with that. But when the consumers make these demands or voters enact a direct initiative that requires something to meet those standards, sure, maybe McDonald's pays a couple more cents a dozen for their eggs, right? Ten cents a dozen more. But you follow those eggs back through the supply chain, where are the biggest changes being made? It's not by McDonald's. It's by that farmer in Southern Indiana raising chickens who lay eggs. She is the one who has to make actual physical changes to her barns, to the farm, in order to satisfy these contracts and

these consumer demands. And if any of you are involved at all in agriculture, you know that's not a number one way to get super rich, to be a farmer, so margins are thin. And so, when you say now we're going to ask you to put in all of these new measures and it's going to cost you X number of dollars, that's got to come from somewhere. Some companies are willing to help offset some of those costs in the beginning. Otherwise, you're talking about hopefully you're, maybe you're independently wealthy, or you're going back for more loans. So again, the most concrete changes that we see are being made by the farmers. The demand or the request for these different levels of products comes from, you know, outside forces. But it does trickle back to the farmer, and that's where the real changes get made.

Audit and Reporting

And as I mentioned, we can make all these changes, we can do all these things, but it's really no good unless you can prove it. So, we have third party certification programs where they will come onto the farm, inspect the animals, the structures, the buildings, and provide that sort of independent certification back so that you can get your stamp and show we qualify for whether it's a United Egg Producers certain level or a We Care Pork Producer level; you can show that you meet that.

Cage Free Trends

Consumers → Restaurants and Retailers → Processors → Farmers

I always think cage free eggs are kind of the easiest way to think about this, and partly because that's been around for the longest. So, consumers cry out either by complaining or by writing letters, by activists, by advocates and they say "we want cage-free eggs." I taste the difference in my McMuffin or whatever, and I've got to have those cage-free eggs or I can't sleep at night. So they start making those requests, then the restaurant says, "oh, it looks like we need these cage-free eggs, where are we going to find them?" They go to the retailers, to the processors, and say, "I know we've been buying ten million conventional eggs per year, but now we need five million of those to be cage free." So then, that processor goes to the farmers and says, "we've been buying your eggs for year, but would you like to make a little bit more money? Because if you could get us some cage-free eggs we're going to pay you a little bit more." And so, you could trace it back through that supply chain.

These are all restaurants that even several years ago had pledges that they were only going to use cage-free eggs. And that's one of the most physical and very real ways to think about what those changes look like.

What does this mean?

1. Vertical Integration

So, what does that mean? We see a lot of vertical integration which is where you've got, there's a lot of different ways to think about integrators in agriculture. You see them a lot in in poultry, in eggs, in pork. Where you've got a company, let's talk about pork, you've got a company who's going to own the pigs. They're going to send you their pigs. You're going to raise them, but you don't own those pigs. That company is going to tell you how you raise those pigs: Here are the different things you've got to agree to do. We're going to be checking up on you to make sure you do that. And then in a set amount of time, we'll come back and get those pigs, or you'll deliver them to us. You'll clean your barns out, and we'll bring you another batch of pigs. And again, you've got to raise pigs in the way we tell you to raise pigs because they're our pigs.

2. Shift in control of means of production

So we see more and more of that in the Ag space. What goes along with that is kind of this shift in who controls how we produce our food. It's less and less where the farmer wakes up one day and says, "I'm going to have a farm that is going to focus on pigs that have X amount of space to turn around and jump around." And more and more becoming, "who's going to pay me? How can I get paid to do this?" And that means of control comes from further down the supply chain.

3. Decrease in volatility; potential increate in profitability

It's not all bad because these farmers can make more money. You can have a guarantee. You don't have to be quite so reliant on what the market is doing today. You can get a contract to pay a specific amount with a premium if you can meet these standards.

4. Increase in consumer influence on the farm

And at the end of the day, it comes down to, we see consumers directly impacting what you do on the farm.

California Proposition 12

So, I want to talk a little bit about what I think is kind of the ultimate expression of a consumer saying, "here's what I want to see on the farms." And, as oftentimes happens, these changes come from California and they trickle out to the rest of the country. So, Prop 12, you could talk about Prop 12 for hours. I've been to presentations where they talk about Prop 12 for hours. I promise not to

do that.

In shorthand, Prop 12 was a California direct initiative, which we don't have here in Indiana. But in California the voters turned out and enacted this into law. It sets out space requirements for how pigs, chickens, veal, things like that are raised. The key difference between Prop 12 and lots of other State laws like this, is Prop 12 doesn't say, if you raise these animals here in California, here's how you have to do it. It says, if you are going to sell pork into the California market, that pork has to come from a farm that raised their pigs in a certain way. So, we see California reaching out into every other State that raises pigs to say, if your pigs are going to end up on our market, here's how you've got to do it. And this is again, the voters in California making this call.

Prop 12 Legal Challenge

Of course, this is good job security for lawyers. Lots of lawsuits filed right away. Ultimately, they went all the way up to the Supreme Court and in 2023 the justices considered this case. Lots of dormant commerce clause challenges, which is something I hadn't thought about since law school. So, it was a good kind of refresher. You guys probably know more about it than I did.

January 1, 2024: Prop 12 went into full effect

But at the end of the day the court upheld it. And what's really crazy to me is this law –again, you think about that certification, or that reporting part – how is the California Government going to know how you are raising pigs here in Indiana? They're gonna send somebody to your farm. And so that sort of complicates even further this idea of the commerce clause, dormant commerce clause because you're going to have California not just theoretically reaching out, but literally hiring, or sending, or requiring someone to physically enter your Indiana farm to make sure you comply with California law.

NPPC v. Ross

So, there's lots of challenges to this, and I think the Supreme Court Justice Gorsuch decision was really interesting because he sort of starts out and comes at it from the consumer perspective. "What kind of goods should be in our stores?" What should we be selling in our shelves at our grocery stores? And the idea is, the California voters expressed their kind of interest in morality, they phrased it as a morality type issue, and said that the challengers, which included National Pork Producers and various farm groups said, this is California again exerting its will on other States in violation of the commerce clause, the dormant commerce clause. And Justice Gorsuch says, "[w]hile the Constitution addresses many weighty issues, the type of pork chops California merchants may sell is not on that list." And said, look, this law doesn't obviously

discriminate –California hog farmers are held to the same standards. It doesn't have a discriminatory intent. It's not setting out to really get Ohio. Of course, California eats a lot of pork doesn't produce a lot of pork. So, the vast majority of the impacts of this law are felt in other States.

Toward the end of the decision, Gorsuch says something that I think again comes back to this idea of consumers are driving the bus. Because they say, how do we settle this dispute between the interest a farmer has in making decisions about their own pork and how they raise pigs versus consumers interest in controlling what's on their shelves and having a say based on the morals and values of your average Californian. And the court says, man that's anybody's guess. Actually wait. it's your guess. "Your guess is better than ours." "Policy choices like these usually belong to the people," and that's what we're seeing here. And Prop 12 is just a real clear distillation of that idea.

Massachusetts Question 3

Massachusetts was kind of like a tag along; they had Question 3 – kind of the same thing that California did. So, I like to blame California, but they're not the only offender here. We've got other states that are saying, not just if you produce food in this state, but if you want to sell that food in this state you need to meet our requirements.

Responses to Prop 12

So, we've seen a lot of responses to this or proposed responses. Some State governments are kind of clapping back and saying, "well, okay, California, if you're going to sell almonds in our state, then you have to meet our standards and here's what our standards are." You can imagine that's kind of a race to the bottom.

We've seen some proposed Federal responses. Justice Gorsuch said, "these kinds of decisions belong to the people and their elected representatives." What are the odds that our elected representatives in Washington can get something done like this? Feels unlikely to me. But we've had proposals in the Eats Act, maybe to put it in the Farm Bill, to say something about States cannot control pre-harvest methods of production just because it's ultimately sold into that State. And so far, not a lot of traction on any of those. But the point is, our markets are so interconnected that a consumer in California can impact the way eggs are produced in Indiana. Because our commerce is fluid and we don't draw a line outside California and say, well this this pork will never make it into that state. So ultimately, almost everybody has to comply with this law because it is so interconnected.

Takeaways

So some of the takeaways. Again, we could talk about this for a lot longer. But we are seeing the way consumers impact on farm production. Some of that is through activists, you know, through board meetings, through advocacy. We also see it through, as I mentioned, with Prop 12 things like those direct voter initiatives.

Another way, I've seen it more recently, on the ground is kind of a hyper local issue, which is zoning. So, a lot of these farms – in particular livestock, eggs, poultry – before a new farm can be built, or perhaps expanded or changed, they need not just state permits to do that, they need local zoning permits. And so that's going to your local Board of Zoning Appeals (your BZA) and presenting to them. That's a body of five people from the county and saying, "here's what we'd like to do, we need your permission to do it, we need a special exception, or we need a variance, or we need some kind of permit from the county." There's a public hearing period where members of the public, consumers, can just come up to the microphone and say, "here's what I think about your proposal." And sometimes it's very specific based on maybe their proximity to that farm or the amount of times per week they drive by that farm; and so what they want to see on that farm. I've also heard people get up to the microphone and say, "you know well, this is a dairy going in, and I eat yogurt fifteen times a day every day and so here's how I think it ought to be done." And now some of that is crazy, and it gets ignored, and we all move on. But some of it finds its way into the permits for these farms through special conditions that are attached to that local zoning permit. Now, it might be something just like the number of trees planted around the property. It might have to do with the amount of water used in the feeders. It might have to do with the direction that the barns are oriented. But all of these changes come from the consumer speaking out at a public hearing, making written comments as part of this permitting process, and saying, "here's what I'd like to see on that farm, either as a neighbor or a consumer I want to sort of impose on this farm my idea of how these animals should be raised." So again, we're seeing that consumer impact on farm level.

From a legislative perspective, in states like Indiana we don't have those direct initiatives. But a lot of States do and it almost doesn't matter now that we don't have it, because we're seeing now, and the Prop 12 case has given us kind of a blueprint for how to do it. For how local consumers, local voters can make decisions that ultimately require on farm changes, not just in that State, but around the country. So, I don't think we've seen the end of those direct voter initiatives addressing food products, agricultural products, and how they are raised. I think there will be more of them. You can use that *NPPC v. Ross*, the Prop 12 decision as a blueprint to draw up exactly how a law in Indiana could impact California or in Ohio could impact Wyoming. And until the Federal Government steps in, I think we're going to continue to see that. And the

chances of the Federal Government stepping in feel low.

So, the takeaways, and we have these conversations with our farmer clients all the time, are usually we're talking about incentivizing. Usually, it's not something like Prop 12. It's just what kind of investment, how would you change the way you farm if you were willing, if you could get paid a couple cents extra per dozen eggs, or a little bit extra for each piece of pork that you produce. And then it's that on-farm changes that that farmer has to decide, is that worth it? Can I handle the upfront cost to down the road have these bigger contracts? And these are the kind of very sophisticated decisions I think, that farmers are making on the ground to comply with all the things that consumers are asking for.

So I think we have 5 min for questions. I'm gonna put up my contact info, you can send me an email, go to our website if you guys have questions. We're local, we're up by Keystone Crossing if anybody is in the area. Stop by or drop us an email.

BRIANNA SCHROEDER, QUESTIONS & ANSWERS

FG: Yes, so are there any questions? Oh, go ahead.

BS: Great question. I think you've got a crystal ball there. I think that is where we're headed. And historically, I think you would say, well, the commerce clause, right commerce clause, and the flip side of it, the dormant commerce clause, those are the laws that are going to apply. And what the Prop 12 decision said, if it applies equally to in-state producers as well as out-of-state producers, if it's not based on a clear, discriminatory intent. The law doesn't say if you're an Indiana farmer, you have to do XYZ. Those laws are going to be allowed to stand. So to your point, what happens when Texas says, "well, if you're going to sell pork into Texas, you have to use gestation crates for pigs. You cannot have pigs that are just roaming around with all of this space." You set up a clear conflict. My concern is that who gets caught in that pinch is going to be the farmers. Are we going to end up with two separate supply chains? Because right now, and they talk about this at length in the Prop 12 case, the supply chain is mingled. Not to be gruesome, but pigs get cut up, turned into meat, and they go all different which ways. So part of a pig can go here, part of it can go here, which is why we can't really separate out California into its own economy. So, what happens when you've got the Texas California divide? Farmers get caught in the pinch. We end up, maybe with two different supply chain systems. Unless we can get a Federal law on the books. Or it ends up back at the Supreme Court again to say, "okay, Supreme Court, you come up with this neat little rule. Now apply it here." I mean, probably ask your professors, they're much smarter than I am. I would say. Great question, though.

FG: After Prop 12, did you know if there was a decrease in farmers willing to comply with California regulations? Or were they like, we need to make money, we're going to comply with it?

BS: That's a great question. They talk about that in the decision. Because what's interesting is Prop 12, we all talk about the pork side of things – it also applied to eggs, it applied to veal. But you saw some farms kind of proactively make those changes. They, whether it was just based on the extra dollars they could make, but you saw farms making those changes before Prop 12 actually went into effect. It went into effect just this, January 2024. So, as part of the lawsuit, there were a lot of suggestions by different parties that nobody's going to be able to comply with this. And what we're seeing is, farmers are resilient, and they are making these changes. And so, I think it's happening. We're still waiting to see kind of that wave of inspectors and third party certification happening here on the ground, because the law is just going into effect. So, again I don't think we've seen the end of this. I don't think we've seen the end of litigation over Prop 12, either.

FG: Shibani

BS: I mean, ever is a long time. Right? So who knows? I think in the short term, probably not. Those things have been proposed. I think Senator Booker maybe proposed something a couple years ago. But there is this real push for local control. Usually, when we talk about regulating farms, we regulate them on the environmental side, and that's at the state level. And then on the Federal side, there is meat packing, there are other laws federally that do apply. But not in terms of how much space an animal needs or do all eggs have to be cage-free chickens, so I don't think we're there yet. It could happen, I mean who knows? Right? But right now, we're not seeing anything like that.

FG: I think that's all the time that we have. So please give a warm round of applause to Brianna. And then one of our executive editors for the Symposium has some concluding remarks.

JULIA BARLEY, CONCLUDING COMMENTS

Julia Barley ("JB"): Hi, everyone! My name is Julia, and I am the Executive Symposium Live Editor. I just want to say, thank you everyone for joining us today. We're so happy you're here. And a special thank you to our four speakers, who just did a wonderful job. These topics are so interesting, and I think ending with Brianna's topic just really shows how important it is to us right now as consumers.

Before we conclude, I just wanted to share with you all that a full transcript of today's event, we're going to post it with our publication. And we're going to

have three papers that are going to be published. The first is by Professor George Wright, from McKinney, who provides a comprehensive analysis of *The* Loper Bright *Regulatory Landscape*. I know we had one question about *Chevron* deference and how that's kind of changed. Professor Wright is an expert, in my opinion, and he kind of delves into this and discusses *Chevron*, and how *Loper Bright* changed that. And then Professor Amy Berg. She expanded on her presentation in a paper, and has written on *An International Comparison of Food Safety and Synthetic Chemicals*. And then the third paper is by Professor Jordan Paradise from Loyola University School of Law. Her piece is very interesting, titled *Cheech and Chong go to Court: Legal Challenges to California's Prohibition of Hemp and Food Products*. We're looking forward to reading that paper as well.

We encourage you all to stay and continue conversation. Grab some food, coffee on your way out, we have plenty. And thank you once again for coming and supporting our Symposium, and we hope that you enjoyed your time.

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SYMPOSIUM

THE *LOPER BRIGHT* REGULATORY LANDSCAPE

R. GEORGE WRIGHT*

I. THE LAW PRE-*LOPER BRIGHT*

The aim of this contribution is to provide a very brief introduction to the administrative regulatory state of play in light of the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*.[1] This introduction will necessarily be selective, speculative, and contestable in some respects. Still, there is value in a general mapping of the territory, even if some of the landmarks are at some future time shifted or removed.

Unsurprisingly, a necessary but hardly sufficient condition for understanding *Loper Bright* is a sense of the most relevant prior case law. Immediately below is a sampling of some of the most doctrinally significant pre-*Loper Bright* judicial landmarks.

As it happens, two of the cases of the greatest continuing interest were decided just before the adoption of the crucially relevant Administrative Procedure Act of 1946.[2] These two cases were *National Labor Relations Board v. Hearst Publications* and *Skidmore v. Swift & Co*.[3] *Hearst* involved a determination by the NLRB that so-called "newsboys" generally fell within the category of employees for collective bargaining purposes.[4] The Court initially declared that the relevant statute must be interpreted by looking to the legislative "history, terms and purposes" of the statute, along with "the statute's background," and the statutory context, given "the mischief to be corrected and the end to be attained."[5]

The *Hearst* Court thus initially assigned the bulk of the statutory

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1. Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244 (2024).

2. *See* 5 U.S.C. § 706 (1946) (on the available levels of judicial review of federal administrative actions in the forms of rulemaking and adjudication). *See also* Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410-20 (1971), *abrogated by* California v. Sanders, 430 U.S. 99 (1977).

3. NLRB v. Hearst Publications, 322 U.S. 111 (1944), *overruled by* Nationwide Mut. Ins. Co. v. Darden, 503 U.S. 318 (1992); Skidmore v. Swift & Co., 323 U.S. 134 (1944).

4. *See Hearst*, 322 U.S. at 130-32.

5. *Id.* at 123-24.

interpretation authority, power, and responsibility to the courts rather than to the administrative agency, given the courts' overall greater competence at this level of generality.[6] In this respect, *Hearst* may be seen as loosely anticipating *Loper Bright's* general empowerment of the federal courts.[7]

The *Hearst* Court, however, then distinguished what we might think of as more granular, case-specific, application-focused interpretations of statutory terms. In *Hearst*, the crucial role in interpreting the key statutory term "employee" was said to have been "assigned primarily to the agency created by Congress to administer the Act."[8] As a matter of common sense, experience and expertise in administering the relevant statute ordinarily lies mainly with the congressionally empowered agency, rather than with non-specialized general jurisdiction courts.[9]

In seeking to limit the tensions between these two lines of argument, *Hearst* sought to distinguish among levels of generality and specificity.[10] Thus the Court ultimately declared that "[u]ndoubtedly questions of statutory interpretation, especially when arising in the first instance in judicial proceedings, are for the courts to resolve, giving appropriate weight to the judgment of those whose special duty is to administer the questioned statute."[11] Thus, in such cases, the primary interpretive responsibility typically lies with courts, to whatever degree, but as limited by some unspecified level of judicial deference to the relevant agency.[12]

If the interpretive question is more contextualized, however, the balance of authority shifts toward the agency. *Hearst* thus declares that "where the question is one of specific application of a broad statutory term in a proceeding in which the agency administering the statute must determine it initially, the reviewing court's function is limited."[13] More concretely, but with fascinating implications that were eventually challenged in *Loper Bright*,[14] the court in *Hearst* concluded that "the Board's determination that specified persons are 'employees' under the Act is to be accepted if it has 'warrant in the record' and a reasonable basis in law."[15]

The *Skidmore* case, as well, displays similar duality, if not an ambivalence, toward the question of judicial authority in interpreting statutory terms. On the one hand, the *Skidmore* Court declared that administrative judgments need not

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6. *See* Marbury v. Madison, 5 U.S. 137, 177 (1803) (Chief Justice Marshall's famous observation that it is "emphatically the province and duty of the judicial department to say what the law is.").

7. *See infra* Part II.

8. *See Hearst*, 322 U.S. at 130.

9. *Id.*

10. *Id.* at 130-31.

11. *Id.*

12. *Id.*

13. *Id.* at 131.

14. *See infra* notes 75-77 and accompanying text.

15. *See Hearst*, 322 U.S. at 131-32 ("[t]he record sustains the Board's findings and there is ample basis in the law for its conclusion.").

have been more or less formally arrived at in order to deserve some degree of judicial deference. Thus:

> [t]he fact that the Administrator's policies and standards are not reached by trial in adversary form does not mean that they are not entitled to respect. This Court has long given considerable and in some cases decisive weight to . . . interpretive regulations . . . that were not of adversary origin.[16]

In that respect, *Skidmore* stands for relatively high deference to agency statutory interpretations. Thus, an agency's "rulings, interpretations and opinions . . . while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts . . . may properly resort for guidance."[17]

Importantly, though, *Skidmore* endorses an apparently less deferential judicial approach to agency interpretations of statutes as well. On this relatively less deferential approach, *Skidmore* declares that in a given case, the weight of the agency determination "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."[18]

In that respect *Skidmore* affords only minimal judicial deference. Assessing apparently *de novo* the validity of an agency's reasoning is hardly deferential at all. A teacher who independently assesses the validity of a student's math reasoning does not even rebuttably presume the likely correctness of the student's work.

As well, an agency may change its interpretation of a statute, thereby creating an inconsistency over time, for a range of more or less legitimate reasons. Agency inconsistency may reflect not mere arbitrary partisanship, but a thoughtful and responsible reassessment. The accumulating evidence may, for example, clearly suggest that the agency's initial assumptions and predictions were mistaken.[19] Not all cases of an agency's inconsistency over time in interpreting its statute should be equally suspect or detract equally from judicial deference.

The Supreme Court's crucial case of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.* was then decided four decades after both *Hearst* and *Skidmore*.[20] *Chevron* adopted broadly applicable rules with respect to the division of authority among Congress, the agencies, and the courts in interpreting statutory language. However interpreted, *Chevron* also held sway

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16. *Skidmore*, 323 U.S. at 140.

17. *Id.*

18. *Id.*

19. For a classic such case, see *Syracuse Peace Council v. F.C.C.*, 867 F.2d 654 (D.C. Cir. 1989).

20. Chevron, U.S.A. v. NRDC, Inc., 467 U.S. 837 (1984).

for four decades.[21]

Chevron uncontroversially declared that "[t]he judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent."[22] More specifically, though, *Chevron* also held more narrowly that "[i]f a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect."[23]

Frequently, though, and for various reasons, no relevant specific congressional intent will be discernible. In such cases, "the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation."[24] Instead, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute."[25]

Chevron then seeks to distinguish between instances in which Congress has left agencies with either an explicit, or else an implicit, delegation of authority to address statutory gaps and ambiguities, assuming any delegation of any kind has been intended by Congress.[26] Where Congress "has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation."[27] Agency regulations adopted under and pursuant to such express delegations "are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute."[28] Where the congressional delegation of authority is thought to instead be merely implicit, "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency."[29]

Over the past forty years, this multi-part *Chevron* test been subjected to a

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21. *See Loper Bright*, 144 S. Ct. at 2271.

22. *Chevron*, 467 U.S. at 843 n.9.

23. *Id.*

24. *Id.* at 843.

25. *Id.*

26. *Id*. at 837 (quoting Morton v. Ruiz, 415 U.S. 199, 231 (1974)).

27. *Id.* at 843-44.

28. *Id.* at 844. One problem is that tests such as for "arbitrariness" can be applied in more and less vigorous versions. *See, e.g.*, *Overton Park*, 401 U.S. at 410-20. More broadly, see R. George Wright, *Arbitrariness: Why the Most Important Idea in Administrative Law Can't Be Defined and What This Means for the Law in General*, 44 U. RICH. L. REV. 839 (2010).

29. *Chevron*, 467 U.S. at 844. Setting aside the complications of how to determine when there has or has not been a merely implicit delegation, one might wonder whether there is any realistically enforceable difference between "arbitrariness" and "unreasonableness," or why the latter would be imagined, presumably, to be the less deferential standard for courts to apply to agency interpretations of statutory terms.

number of interpretations, reinterpretations, and significant exceptions.[30] At one point, the Court confined *Chevron* deference only to agency interpretations adopted in ways that would normally carry the force and effect of law, as through, for example, informal notice-and-comment rulemaking, as opposed to procedural mechanisms such as mere agency opinion letters, interpretive bulletins, agency manuals, mere interpretive rules, or enforcement guidelines.[31] Agency interpretations of statutes adopted through the latter, relatively casual procedural mechanisms, would then receive only what we have referred to as the less deferential version of judicial review under *Skidmore*.[32]

This at least relatively simple approach was, however, then quickly "murkified" in *United States v. Mead Corporation*.[33] The Court in *Mead* required *Chevron* deference when Congress somehow delegated lawmaking authority to an agency, and the agency somehow promulgated its rule pursuant to and in the exercise of that authority.[34] Crucially, according to *Mead*, such congressional delegation of binding law-making authority, assuming that it was granted at all, "may be shown in a variety of ways."[35] Certainly, notice-and-comment rulemaking power would normally indicate such a congressional intent.[36] But *Mead* also referred to the possibility of "some other indication of a comparable congressional intent"[37] to delegate law-making authority to the agency that could be exercised by less formal means.[38] And *Mead* emphasized the possible vitality of meaningful *Skidmore* deference to agency interpretations undeserving of *Chevron* deference.[39]

Following up on *Mead*, the case of *Barnhart v. Walton* reiterated that agency interpretations arrived at thorough procedures less elaborate than notice-and-comment rulemaking could still, in some instances, deserve relatively high *Chevron* deference.[40] Justice Breyer in *Barnhart* declared that "the fact that the Agency previously reached its interpretation through means less formal than 'notice and comment' rulemaking . . . does not automatically deprive that

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30. *See infra* notes 92-94 and accompanying text. For a brief reference to the "clear statement" and "major questions" limitations on *Chevron* deference, see *Gonzales v. Oregon*, 546 U.S. 243, 274-75 (2006). *See also infra* note 94.

31. *See* Christensen v. Harris Cnty., 529 U.S. 576, 587 (2000).

32. *See* Syracuse Peace Council v. F.C.C., 867 F.2d 654 (D.C. Cir. 1989). That is, agency interpretations adopted through entirely in-house or relatively casual mechanisms would be "entitled to respect" by courts "only to the extent that those interpretations have the 'power to persuade.'" *See Christensen*, 529 U.S. at 587 (internal citation omitted).

33. United States v. Mead Corp., 533 U.S. 218 (2001).

34. *Id.* at 218-19.

35. *Id.* at 227, 229-31.

36. *Id.* at 227.

37. *Id.* at 218-19 (referring implicitly to at least some of the procedural mechanisms listed in text).

38. *Id.*

39. *Id.* at 234-35 (citing, *e.g.*, the value of nation-wide uniformity in the interpretation of a statutory term or phrase).

40. Barnhart v. Walton, 535 U.S. 212, 221-22 (2002).

interpretation of the judicial deference otherwise its due."[41] In the *Barnhart* case itself, this amounted to *Chevron* deference.[42]

Characteristically, Justice Breyer sought to distinguish between the applicability of *Chevron* deference and *Skidmore* deference through an unweighted multi-factor balancing test.[43] In the *Barnhart* case itself,

> [t]he interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that Chevron provides the appropriate legal lens through which to view the legality of the Agency interpretation here at issue.[44]

Roughly, then, this was the state of play under *Chevron* and *Skidmore* deference prior to *Loper Bright*.

II. THE *LOPER BRIGHT* CASE ITSELF

The *Loper Bright* case overruled, at least in some difficult-to-specify sense, the *Chevron* relatively high level deference case law. [45] *Loper Bright* first presented its own exegesis of *Hearst* and of *Skidmore*. [46] Under the subsequently adopted Administrative Procedure Act ("APA"),[47] though, the "courts decide legal questions by applying their own judgment."[48] Emphatically, "courts, not agencies, will decide 'all relevant questions of law' arising on review of agency action."[49] And specifically, *Loper Bright* observed that the APA "prescribes no deferential standard for courts to employ in answering those legal questions."[50]

In this regard, *Loper Bright* sought to somehow draw a viable line between judicial review of agency determinations of law and judicial review of agency policy making.[51] The Court observed that the APA does, explicitly, mandate deferential review of the latter, but not the former.[52] In contrast, the Court concluded, "questions of law are for courts rather than agencies to decide in the

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41. *Id.* at 221.
42. *Id.* at 221-22.
43. *Id.* at 222.
44. *Barnhart*, 535 U.S. at 222 (as distinct from a relatively broad or fundamental legal question). Note the important difference between an agency's careful or thoughtful consideration over time, and an agency's consistency over time in interpreting the term, as under *Skidmore*, 323 U.S. at 140.
45. *Loper Bright*, 144 S. Ct. at 2273.
46. *Id.* at 2259-60.
47. *See* 5 U.S.C. § 706 (1946).
48. *Loper Bright*, 144 S. Ct. at 2261.
49. *Id.* (quoting 5 U.S.C. § 706).
50. *Id.*
51. *Id.*
52. *Id.*

last analysis."[53] And the "courts must exercise independent judgment in determining the meaning of statutory provisions."[54]

The crucial problem, though, is that having the final or ultimate say on questions of law, and indeed, exercising completely independent judgment in doing so tells us precisely nothing about whether that final and independent, autonomous judicial judgment should attach any measure of credence or weight to the judgment of the agency. One can exercise one's own final, independent, autonomous, unconstrained judgment as to, say, the completeness of quantum theory. But that exercise may attach no weight, or, usually more sensibly, quite substantial weight, to the judgments of the physicists.[55]

The *Loper Bright* Court recognized that the upshot of a court's own independent assessment of a statute may be that whatever the substantive content of that statute, the statute also somehow indicates a congressional intent that the administrative agency largely control the substantive legal meaning of that statute.[56] And even in the absence of any such congressional intent, there is inevitably what we might call the rationality of autonomous deference to epistemic superiority.[57] People often make the ultimate autonomous decision to acknowledge the plainly greater expertise of others.

Thus, the Court continues to validate both the higher and lower levels of *Skidmore* deference. In particular, courts may still continue to "seek aid from the interpretations of those responsible for implementing particular statutes."[58] Common-sensically, agency interpretations may "constitute a body of experience and informed judgment to which courts . . . may properly resort for guidance consistent with the APA."[59] Contemporaneously issued, and consistently adhered to, such agency interpretations "may be especially useful in determining the statute's meaning."[60] *Loper Bright* here criticizes what it takes to be the *Chevron* requirement that "courts mechanically afford binding deference to agency interpretations, including those that have been inconsistent over time."[61]

Loper Bright crucially emphasizes that not every statutory gap or ambiguity, in and of itself, intends, or amounts to, a delegation of interpretive authority to

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53. *Id.* at 2262 (citation omitted).

54. *Id.*

55. For broad background, see LINDA TRINKAUS ZAGZEBSKI, EPISTEMIC AUTHORITY: A THEORY OF TRUST, AUTHORITY, AND AUTONOMY IN BELIEF (2012); Lara Buchak, *Faith and Rational Deference to Authority*, 108 PHIL. & PHENOMENOLOGICAL RES. 637 (2024); R. George Wright, *Epistemic Peerhood in the Law*, 91 ST. JOHN'S L. REV. 663 (2017).

56. *See Loper Bright*, 144 S. Ct. at 2263.

57. *See infra* note 65.

58. *Loper Bright*, 144 S. Ct. at 2262.

59. *Id.* (quoting *Skidmore*, 323 U.S. at 140). *See also* Union Pacific Railroad v. Surface Transportation Bd., 113 F.4th 823, 833 (8th Cir. 2024).

60. *Loper Bright*, 144 S. Ct. at 2262. *See also* Gonzales & Gonzales Bonds & Ins. Agency, Inc. v. U.S. Dep't of Homeland Security, 107 F.4th 1064, 1085-86 (9th Cir. 2024) (Johnstone, J., concurring).

61. Again, the possibility of both well-justified and entirely unjustified changes in an agency's interpretation over time is often ignored. *See Loper Bright*, 144 S. Ct. at 2262.

an agency, on the theory that some such gaps and ambiguities are merely unrecognized by Congress at the time of enactment.[62] In a phrase, ambiguity does not imply delegation of rulemaking authority, even implicitly, to any agency. This is so even though Congress is aware of its own fallibility and limited insight. Curiously, though, *Loper Bright* insists at the same time that no matter the statutory gaps, ambiguities, silences, and apparent contradictions, essentially every legal question has some single, unique, unequivocally best or right answer.[63] That is, "such statutes, no matter how impenetrable, do – in fact, must – have a single, best meaning . . . 'fixed at the time of enactment.'"[64]

The claim that statutes, and their constitutive terms, usually have some single, unique best interpretation is intensely contested.[65] Professor Ronald Dworkin's "right answers" thesis is the best known defense of such a view.[66] Such views run up against the sense of frequent, and often important, legal indeterminacy.[67] *Hearst*, after all, had distinguished between uniquely correct and a range of reasonable or permissible agency interpretations of a statute.[68] And the APA seems to presume elsewhere that a statute may, at least rarely, be formulated "in such broad terms that . . . there is no law to apply."[69] Such a case would amount to an extreme, rather than a moderate or substantial, statutory indeterminacy.

Loper Bright thus holds that in the vast majority, if not all cases, there actually is no range of reasonable or permissible legal interpretations of statutory language.[70] If an interpretation "is not the best, it is not permissible."[71] Even if the statute is ambiguous, "there is a best reading all the same – 'the

62. *Id.*

63. *Id.* at 2266.

64. *Id.* (quoting Wisconsin Central Ltd. v. United States, 585 U.S. U.S. 274, 284 (2018)). *See also* Restaurant Law Center v. U.S. Dep't of Labor, 115 F.4th 396, 400 (5th Cir. 2024) ("[i]nstead of declaring a particular party's reading 'permissible' in such a case, courts use every tool at their disposal to determine the best reading of the statute and resolve the ambiguity." (quoting Loper Bright, 144 S. Ct. at 2266)).

65. Ronald Dworkin, *No Right Answer?,* 53 N.Y.U. L. REV. 1 (1978), *reprinted in* RONALD DWORKIN, A MATTER OF PRINCIPLE 119 (1985). *See also* RONALD DWORKIN, LAW'S EMPIRE 266-71 (1986) ("[t]he sheer existence of a single right answer, however, tells us nothing about the ascertainability in practice of that sole best answer."). *See* Dworkin, *No Right Answer?*, at 30. For discussion, see, for example, Charles F. Capps, *Does Law Ever Run Out?*, 100 NOTRE DAME L. REV. (forthcoming 2025); Richard H. Fallon, Jr., *Selective Originalism and Judicial Role Morality*, 102 TEX. L. REV. 221, 291-92 (2023). Justice Scalia took the "one correct interpretation" view to have been overruled by *Chevron*. *See* Barnhart v. Sigmon Coal Co., 535 U.S. 226, 226 (2002) (Scalia, J., concurring in part and concurring in judgment).

66. *Id.*

67. *See, e.g.,* Kenneth J. Kress, *Legal Indeterminacy*, 77 CAL. L. REV. 283 (1989); Mark Tushnet, *Defending the Indeterminacy Thesis*, 16 QLR 339 (1997).

68. *See Hearst*, 322 U.S. 111 (1944).

69. See 5 U.S.C. § 701 (a)(2) on reviewability, as discussed in *Overton Park*, 401 U.S. at 410.

70. *See Loper Bright*, 144 S. Ct. at 2266.

71. *Id.*

reading the court would have reached' if no agency were involved."[72]

In this respect, *Loper Bright* seems to imply an odd sort of judicial relativism. Imagine a case in which the Ninth Circuit independently interprets a statutory term to mean one thing, and the Fifth Circuit interprets the same term to mean the opposite. What can we, as observers, then say that the term "really" means? The term, evidently, means one thing in one circuit, and its opposite in another.

Meaning of statutory terms is thus crucially relative to, and dependent upon, circuit. This sort of relativism, if not subjectivism, would certainly be controversial in the ethical or scientific domain.[73] Of course, the Supreme Court might, at some later point, resolve this apparent or actual conflict. But what is the law, "really," in the meantime? Does the "real" law then exist only in a deeply mysterious, perhaps indeterminate state of superposition, akin to a Schrodinger-type cat that has not yet been observed by the Supreme Court?[74]

Less mysteriously, *Loper Bright* then flatly and broadly declares that "agencies have no special competence in resolving statutory ambiguities. Courts do."[75] Here, though, the course of future litigation post-*Loper Bright* may turn out to be more nuanced than the Court seems to imagine. We may, for example, perhaps suppose that a court may have a better sense of what constitutes a "gift" than does the relevant tax agency. And some statutory terms, such as a "crime of violence," may just be inherently difficult, whichever branch of government is making the determination.[76]

But the case for an absolute advantage of a court over the relevant agency is clearly questionable in cases of at least partly scientific, technological, technical, or field-specific statutory terms. Imagine a case in which Congress allocates funding to the National Science Foundation to support the advancement of "string theory." In such cases, courts may claim to have an advantage over expert agencies in interpreting the term. But inevitably, courts will realistically tend to pay greater deference to the agency here than in other more familiar sorts of cases.

Thus, in all likelihood, and whether doctrinally acknowledged by courts,

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72. *Id.* (quoting *Chevron*, 467 U.S. at 843 n.11).

73. *See, e.g.*, Chris Gowans, *Moral Relativism*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY (rev. ed. Mar. 10, 2021), https://plato.stanford.edu/entries/moral-relativism [https://perma.cc/H9VS-N74Y].

74. For an accessible treatment, see, for example, JOHN GRIBBIN, IN SEARCH OF SCHRODINGER'S CAT: QUANTUM PHYSICS AND REALITY (1984). *See also* Philip Ball, *Real Life Schrodinger's Cats Probe the Boundary of the Quantum World*, QUANTAMAGAZINE (Jun. 25, 2018), https://www.quantamagazine.org/real-life-schrodingers-cats-probe-the-boundary-of-the-quantum-world-20180625/ [https://perma.cc/U37K-H56R].

75. *Loper Bright*, 144 S. Ct. at 2266.

76. *See* Willem de Haan, *Violence as an Essentially Contested Concep*t, *in THEORIZING VIOLENCE* (2009) (applying W.B. Gallie, *Essentially Contested Concepts*, 56 PROCEEDINGS OF THE ARISTOTELIAN SOC'Y 167 (1956)). Justice Sotomayor usefully points out that "domestic" violence is not merely a subset of some broader, generic concept of "violence." *See* United States v. Castleman, 572 U.S. 157, 164-65 (2014) (noting the divisions as well among judicial opinions addressing "violence" as a statutory term).

over the long term, the courts will tend to give greater weight to agency interpretations of statutory terms where professional experience and accumulated subject-matter expertise evidently matter. Consider more generally the observation of the celebrated Professor Louis Jaffe:

> [T]he administrative and the judiciary share the role of law pronouncing and law making. They are in partnership. The court may supersede the administrative and itself determine the question of law; it is the senior partner. According to one view it must decide every question of law. With this view I do not agree.[77]

Ultimately, any pretense to universal judicial superiority over agencies in matters of legal interpretation may be practically trivial, and largely formalistic. No doubt Congress would prefer a "correct" over a "wrong" but nationally uniform interpretation of a statutory term. But any such claim is too question-begging to provide much guidance.[78] And no one disputes, post-*Marbury*, that courts, rather than agencies, bear the "ultimate interpretive authority."[79]

Loper Bright itself thus recognizes that Congress often, though not always, endows administrative agencies with discretionary law and policy-making authority, subject to judicially enforceable statutory and constitutional limits.[80] And as a general matter, an agency's formally non-binding interpretation "may be especially informative to the extent it rests on factual premises within [the agency's] expertise."[81] There are, *Loper Bright* recognizes, many considerations that continue to counsel some form of *Skidmore*-type deference in appropriate cases.[82]

Finally, *Loper Bright* notes that any simple application of *Chevron* deference across the board has been precluded by the gradual accretion of judicially adopted limits and exceptions, including, for example, cases of agency procedural errors and so-called major questions. [83] *Loper Bright* understandably

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77. LOUIS L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 546 (1965) (citing Hearst, 322 U.S. at 135-36 (Roberts, J., dissenting)).

78. *Loper Bright*, 144 S. Ct. at 2267.

79. It would mischaracterize Chevron itself to say that it denies "ultimate" authority to the courts. "Ultimacy" of judgment is compatible with giving substantial weight to the opinions of others in the course of making that ultimate judgment.

80. *See Loper Bright*, 144 S. Ct. at 2267 (quotation omitted).

81. *Id.*

82. *Id.* at 2268-69.

83. *Id.* at 2268 (quoting Encino Motor Cars, LLC v. Navarro, 579 U.S. 211, 220 (2016) (in turn quoting Mead, 533 U.S. at 227)); *id.* at 2269 (quoting King v. Burwell, 576 U.S. 473, 486 (2015)); West Virginia v. EPA, 597 U.S. 697, 723 (2022)). Perhaps the major questions doctrine will often now operate merely to help find the supposed one best legal answer. *See also* Jonathan H. Adler, West Virginia v. EPA*: Some Answers About Major Questions*, 2021 CATO SUP. CT. REV. 37 (2022); Thomas B. Griffith & Haley N. Proctor, *Deference, Delegation, and Divination: Justice Breyer and the Future of the Major Questions Doctrine*, 132 YALE L.J. 693 (2022); Cass R. Sunstein, *Two Justifications for the Major Questions Doctrine*, 76 FLA. L. REV. 251 (2024).

takes the various accruing exceptions to amount to daunting judicial complications.[84] But this approach raises its own complications. One might take each of the exceptions to the basic *Chevron* deference test as justified improvements over any oversimplified deference test. As judicial experience with *Chevron* deference has accumulated, we might thus say that a more complex but better justified *Chevron* deference test gradually emerged.

Overall, the scope and depth of *Loper Bright's* overruling of *Chevron* deference will, of course, be clarified only over the course of time. But one justifiable reaction is to anticipate something less than a revolution in practice. Doubtless agencies and courts will, with *Loper Bright*, change their approaches in some respects. Undeniably, *Loper Bright* expresses a change in judicial mood.[85]

But no change of judicial mood can abolish the undeniable fact that regardless of congressional intent or the absence thereof, some cases are best suited, in a realistic, practical sense, though not in a formal, ultimate sense, for resolution by expert agencies rather than by general jurisdiction courts. Where the courts choose to draw any relevant dividing line in this regard is likely to follow a pendulum-like swing, to and from, over a substantial period of time, as the costs of an excessive swing in either direction accrue or are thought to become disproportionate.[86]

III. LIGHT AND DARKNESS POST-*LOPER BRIGHT*

As we have seen, the application of *Chevron* deference resulted in a number of gradually accruing complications and uncertainties.[87] The jurisprudence of *Loper Bright* must, as we now see as through a glass darkly, eventually involve complications of its own.

Some such complications already seem apparent. For one, the current remarkably complex and exception-bound jurisprudence of strong judicial deference to an agency's informal interpretations of its own vague legislative rules would, after *Loper Bright* seem to be in jeopardy.

As thus briefly stated in *Auer v. Robbins*, currently, an agency interpretation of its own regulation is "controlling unless 'plainly erroneous or inconsistent

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Perhaps the major questions doctrine will often now operate merely to help find the supposed one best legal answer.

84. *Loper Bright*, 144 S. Ct. at 2273. *Loper Bright* understandably invokes the doctrine of stare decisis to presumptively sustain prior judicial decisions invoking Chevron deference. We omit herein the Court's stare decisis analysis in rejecting the Chevron deference test itself.

85. Consider, by analogy, a pendulum-like swing in the area of criminal sentencing between a concern for uniformity in sentencing of similar crimes and a concern for the distinctive individual circumstances in any given case. As the costs of emphasizing either approach continue to accrue, the judicial "mood" changes, and the pendulum tends to swing in the other direction. Individual due process hearing rights, and the costs of such hearings, may follow a similar pattern of oscillation over time.

86. *See infra* notes 92-94 and accompanying text.

87. Auer v. Robbins, 519 U.S. 452 (1997).

with the regulation.'" [88] A number of exceptions have accreted to this notably deferential *Auer* standard.[89] But despite, if not partly because of, the sundry exceptions to strong judicial deference to agency interpretations of their own rules, *Auer* deference may well not withstand the logic and "mood" of *Loper Bright*, despite the Court's recent reaffirmation of the *Auer* doctrine.[90]More broadly, *Loper Bright* may start the Court down a path of increasing complexity with a resemblance to the history of both *Auer* and *Chevron* deference. More fundamentally, though, courts and litigants must somehow come to terms with *Loper Bright's* stronger emphasis on the idea that ambiguity, silence, and limited imagination at the congressional level do not, in themselves, amount to express or implied delegation of law-making authority to an agency. How much this increased emphasis, or this "mood," will really affect judicial outcomes is debatable. Prudence suggests, however, that agencies should devote greater attention than formerly to elaborately establishing their delegated authority to make binding rules, whether that authority is said to be expressly or implicitly granted.[91] Parties contesting a regulation will then have stronger incentives to contest that asserted pedigree.[92]

In particular, critics of a new agency rule will presumably be especially alert to broad, extreme, or adventurous agency rulemaking, and certainly to any arguable inconsistency or change of agency position, whatever the merits of any such change, on the part of the agency.[93] Lack of any agency position adopted at or near the time of enactment may also receive more emphasis than formerly.[94] Critics of a rule will also continue to emphasize any crucial respects

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88. *Id*. at 461 (quoting Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 359 (1989), in turn quoting Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945)). *See also* Kisor v. Wilkie, 588 U.S. 558, 563-64 (2018) (Auer deference as "potent in its place, but cabined in its scope.").

89. *Kisor*, 588 U.S. at 563-64. For a recent application of *Kisor* itself, see *United States v. Johnson*, 104 F.4th 662, 665-66 (7th Cir. 2024). It is unclear why the doctrine of stare decisis does not suffice to uphold Chevron deference, but would suffice to uphold Auer deference, with its many exceptions and complications. *Auer* may confer substantial law and policy making authority, in practice, on even relatively casual agency determinations.

90. *See* Kristen E. Hickman, *Anticipating a New Modern Skidmore Standard*, 15 (Minnesota Legal Stud. Rsch. Paper No. 24-37, 2024), https://dx.doi.org/10.2139/ssrn.4941144 [https://perma.cc/MXZ5-U4SA]; Christopher Walker, *What Loper Bright Enterprises v. Raimondo Means for the Future of Chevron Deference,* YALE J. ON REG. (Jun. 28, 2024), https://www.yalejreg.com/nc/what-loper-bright-enterprises-v-raimondo-means-for-the-future-of-chevron-deference/ [https://perma.cc/LT7Z-JY2P] (arguing that *Loper Bright*'s delegation-but-independent-judgment standard will be no more practically manageable than the Chevron deference standard).

91. *See* Cass R. Sunstein, *The Consequences of Loper Bright*, 1 (Harvard Pub. Law Working Paper, Paper No. 24-29, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4881501? [https://perma.cc/2THH-HFDV] (last visited September 9, 2024).

92. *See id*.

93. *See id*.; *see also* Hickman *supra* note 90, at 9-10 (citing *Loper Bright*, 144 S. Ct. at 2265, 2272 on the distinction between justified and unjustified agency inconsistency).

94. *See* Jonathan H. Adler, *from "Deference" to "Respect"—The Real Import of Loper Bright*, REASON (Jul. 3, 2024), https://reason.com/volokh/2024/07/03/from-deference-to-respect-the-real-import-of-loper-bright/ [https://perma.cc/D49G-2SD3].

in which the agency rule does not require or has not received any technical or scientific expertise peculiar to the relevant agency.

In contrast, though, litigants defending an agency interpretation will, whatever the rubric, presumably emphasize the sheer pragmatic necessity of broad and frequent delegation, at least implicitly, of binding rulemaking authority to administrative agencies. As one commentator has observed, "litigants defending agency action should position *Loper Bright* to demonstrate that Congress 'often' provides agencies with broad discretion to effectuate the purpose of a given statute in rapidly changing complex areas of regulation."[95]

Finally, a less agency-deferential *Loper Bright* regime will likely tend to raise the stakes in determining whether any given issue, in rulemaking or in adjudication, is really a question of law, and thus subject to *Loper Bright*, or else instead a question of policy, or even of complex fact, and thus perhaps outside the purview of the *Loper Bright* rule.[96] Advocates on both sides of the case will thus have an increased stake in delving more aggressively into these often disputable law, policy, and fact distinctions.

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95. Patrick Jacobi, *Administrative Law After* Loper Bright Enterprises v. Raimondo, YALE J. ON REGUL. (Aug. 28, 2024), www.yalejreg.com/nc/administrative-law-after-loper-bright [https://perma.cc/YU49-KUBF]. For a thoughtful analysis of some uncertainties arising from post-Loper Bright appellate court opinions, see Haley Proctor, Loper Bright *in Action*, YALE J. ON REGUL. (Aug. 26, 2024), www.yalejreg.com/nc/loper-bright-in-action [https://perma.cc/CM83-GYQF].

96. For some complications in these sorts of classifications, see, for example, *United States v. Mateo-Mendez*, 215 F.3d 1039, 1042 (9th Cir. 2000); *Holly D. v. California Institute of Technology*, 339 F.3d 1158, 1180 n.27 (9th Cir. 2003). *See also* Pullman Standard v. Swint, 456 U.S. 273, 287-88 (1982) (citing Baumgartner v. United States, 322 U.S. 665, 671 (1944)). For an especially provocative discussion, see the conflicting opinions in Allentown Mack Sales and Service v. NLRB, 522 U.S. 359 (1998). For further development of the occasional malleability, if not elusiveness, of this distinction, see Ronald J. Allen & Michael S. Pardo, *The Myth of the Law-Fact Distinction*, 97 NW. U.L. REV. 1769 (2003). We set aside herein questions of congressional responses to Loper Bright, including the value of more explicit but broad delegations of authority to agencies, as well as the possibility of a statutory codification of the Chevron doctrine, or something akin thereto. *But see Warren Leads Senate Response to End of Chevron Doctrine,* U.S. SENATE (Jul. 23, 2024), https://www.warren.senate.gov/newsroom/press-releases/warren-leads-senate-response-to-end-of-chevron-doctrine [https://perma.cc/8KHG-DTLM].

FOOD SAFETY AND SYNTHETIC CHEMICALS – AN INTERNATIONAL COMPARISON

AMY S. BERG*

I. INTRODUCTION

Global food trade is integral to the food supply system and necessarily impacts food safety and food security. Over the past thirty years, global food trade expanded and increased in complexity, but the primary exporting countries, including the United States ("U.S."), have remained relatively stable.[1] About one-quarter of all food produced in the world is traded on international markets, with ten nations supplying the bulk of this food.[2] Global food trade facilitates the distribution of essential nutrients and provides nourishment to those most in need.[3] With a growing global population, geopolitical issues, environmental challenges, and changing weather patterns, the global food system will grow in size and complexity, but also become more vulnerable.[4]

Food safety laws and regulations also impact global trade partners. A study of the global trade of maize (a.k.a. corn) and aflatoxin regulations showed that international trade partners had similar food safety regulations.[5] Key trading partners have a large amount of power in determining regulations elsewhere worldwide, and similar food safety regulations can facilitate and influence trade patterns. While protecting human health is the primary consideration, the U.S. and other nations should consider the potential implications and impacts of food safety standards on global trade and their trade partners.

The food system in the U.S. consists of a complex system of production, transport, and processing, imports, and exports that provides consumers with a variety of food and beverage products. The food supply chain includes various points which risk exposure to pathogens, contaminants, and other potential hazards. The Food Safety Modernization Act ("FSMA") and the U.S. Food and Drug Administration's ("FDA") implementing regulations were established to

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1. Jieyong Wang & Chun Dai, *Evolution of Global Food Trade Patterns and Its Implications for Food Security Based on Complex Network Analysis*, 10 FOODS 1, 13 (Nov. 2, 2021), https://www.mdpi.com/2304-8158/10/11/2657 [https://perma.cc/2DN3-3H8G].

2. Joel K. Bourne, Jr., *Eating the Earth: The burgeoning global food trade is a lifeline for billions, but it is fragile and hard on the planet*, 386 SCIENCE 956, 958 (Nov. 29, 2024), https://www.science.org/doi/epdf/10.1126/science.adu8006 [https://perma.cc/W6CA-AGFH].

3. Stephen A. Wood et al., *Trade and the Equitability of Global Food Nutrient Distribution*, 1 NATURE SUSTAINABILITY 34 (2018), https://www.nature.com/articles/s41893-017-0008-6 [https://perma.cc/VGG8-E2SH].

4. Bourne, *supra* note 2.

5. Aflatoxins are mycotoxins, which are secondary metabolites produced by different fungal species. Mycotoxins produced by *Aspergillus* spp. are known as aflatoxins. Aflatoxins are commonly produced by *Aspergillus flavus* and *A. parasiticus*. Saba Shabeer, et al., *Aflatoxin Contamination, Its Impact and Management Strategies: An Updated Review*, 14 TOXINS 307 (Apr. 21, 2022), https://pubmed.ncbi.nlm.nih.gov/35622554/ [https://perma.cc/6UH3-P5FW]; Felicia Wu & Hasan Guclu, *Aflatoxin Regulations in a Network of Global Maize Trade*, 7 PLOS ONE 8 (Sept. 25, 2012), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0045151 [https://perma.cc/VJ96-ZTQ6].

shift focus from responding to hazards and foodborne illnesses to preventing them.[6] International trade links the diverse global food systems of countries and plays a role in economic development, moving food from surplus to deficit areas or providing a wider variety of food options.[7] While trade may enable global food security, it presents challenges concerning food safety and food standards.[8]

Foods may contain a variety of chemicals, some of which are intentionally added or naturally occurring, and others which are contaminants.[9] The FDA ensures exposure to chemicals in food is safe. This includes chemicals authorized for use in and with foods during production and harvest, food packaging, processing, or other handling, or contaminants that enter the food supply through the growing or processing environment. Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"),[10] a food is deemed adulterated if, among other things, it contains any poisonous or deleterious substance rendering the food injurious to health, an unsafe pesticide residue, or any food additive or new animal drug that is unsafe; its preparation, packaging, or storage under unsanitary conditions rendered the food injurious to health; or its container is composed of any poisonous or deleterious substance rendering the contents injurious to health.[11]

The FDA helps to safeguard the food supply through pre-market and post-market safety evaluations of chemicals as food ingredients and substances that come into contact with food, such as through food packaging, storage or other handling to ensure these uses are safe. The FDA also ensures that industry is

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6. Food Safety Modernization Act, 21 U.S.C. §§ 2201–2252 (2021).

7. ANDREA ZIMMERMANN & GEORGE RAPSOMANIKIS, SCIENCE AND INNOVATIONS FOR FOOD SYSTEMS TRANSFORMATION 40 (Joachim von Braun, Kaosar Afsana, Louise O. Fresco, Mohamed Hag Ali Hassan eds., 2023).

8. The Food and Agriculture Organization of the United Nations ("FAO") defines food security as a situation that exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life. Based on this definition, four food security dimensions can be identified: food availability, economic and physical access to food, food utilization, and stability over time. The concept of food security is evolving to also recognize the centrality of agency and sustainability. FAO, IFAD, UNICEF, WFP & WHO, THE STATE OF FOOD SECURITY AND NUTRITION IN THE WORLD 2024 – FINANCING TO END HUNGER, FOOD INSECURITY AND MALNUTRITION IN ALL ITS FORMS 222 (FAO et al. eds., 2024), https://openknowledge.fao.org/handle/20.500.14283/cd1254en [https://perma.cc/PR5P-7WTX].

9. The term "food" means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f); "A naturally occurring poisonous or deleterious substance is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination." 21 C.F.R. § 109.3(c); "An added poisonous or deleterious substance is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase." 21 C.F.R. § 109.3(d).

10. 21 U.S.C. § 321.

11. *Id.* § 342; *see also* 21 U.S.C. § 331 (prohibiting the adulteration of food, including the introduction, delivery for introduction, and receipt in interstate commerce of any food that is adulterated).

preventing when possible, and mitigating when prevention is not possible, unsafe exposure from chemical contaminants that can enter the food supply through the growing and processing environment. The agency monitors the food supply for chemical contaminants and takes action, including through enforcement mechanisms, when the level of a contaminant causes a food to be unsafe. Food manufacturers also have a major role in food chemical safety. The food industry has a responsibility to minimize or prevent hazards from contaminants and ensure the safety of chemicals they use.[12]

To highlight the complexity of the global food system and its myriad food safety laws and regulations, this article describes and compares the evaluation and approval of certain intentionally and unintentionally added synthetic chemicals, specifically food additives, color additives, pesticides, and per- and polyfluoroalkyl substances ("PFAS"), in food or food contact substances under laws established by the U.S. and European Union ("EU"), and under applicable standards established by the Codex Alimentarius Commission.

II. CHEMICALS IN FOOD

The FFDCA defines adulterated as a food that contains any added poisonous or deleterious substance.[13] As such, the FFDCA permits certain intentionally and unintentionally added chemicals in the food supply through the pre-market approval process, with limited exemptions. The word "chemical" can have a negative connotation, especially when associated with food. The Merriam Webster Dictionary website defines a chemical as "a substance obtained by a chemical process or producing a chemical effect."[14] Chemical is a very broad term that includes within the scope of the definition many substances in food that are nutritious, healthy, or otherwise desirable. Consumers tend to be more concerned about a sub-set of chemicals that are synthetic or "man-made."

Generally, synthetic chemicals added to food, whether intentionally or unintentionally, are evaluated using risk analysis. The Renaissance physician Paracelsus (1493-1541) stated "What is there that is not poison? All things are poison, and nothing is without poison. Solely the dose determines that a thing is

12. Food labeling laws and regulations play an important role in food safety but are not discussed in this article.

13. "A food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health." 21 U.S.C. § 342(a)(1); "A food shall be deemed to be adulterated if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title." 21 U.S.C. § 342(a)(2)(A).

14. *Chemical*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/chemical [https://perma.cc/GV9P-5REU] (last visited Nov. 24, 2024).

not a poison."[15] This statement is often referred to as "the dose makes the poison." Others have also stated that "the timing makes the poison."[16]

A thorough discussion of risk analysis is beyond the scope of this article, but it is nevertheless an important component of the evaluation and establishment of acceptable levels of chemicals in food, and ultimate approval under the FFDCA or other laws. The discussion below highlights certain key provisions in the U.S., EU, and the Codex Alimentarius for approval of use or establishment of maximum limits for synthetic chemicals in food.

A. Additives

Additives are generally defined as substances added to another in relatively small amounts to affect a desired change in properties.[17] In general, food additives are substances not normally consumed as food but are added to food for technical purposes, e.g., to improve safety, storage time, and sensory properties. Food additives may be naturally occurring or man-made. As described in more detail below, food additives, including color additives in the U.S., must be evaluated for their safety before use.

1. Food Additives in the U.S.

The FFDCA broadly defines the term food additive, but explicitly excludes, among other things, pesticide chemicals, color additives, and new animal drugs.[18] Food additives are presumed unsafe, unless an exemption applies.[19] To

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15. HARTMANN, FRANZ, THE LIFE OF PHILIPPUS THEOPHRASTUS BOMBAST OF HOHENHEIM, KNOWN BY THE NAME OF PARACELSUS: AND THE SUBSTANCE OF HIS TEACHINGS 2 (1887), https://archive.org/details/lifeofphilippust00hartuoft [https://perma.cc/92XF-9JJF].

16. Philippe Grandjean, et al., *The Faroes statement: human health effects of developmental exposure to chemicals in our environment*, 102 BASIC CLINICAL PHARMACOLOGY & TOXICOLOGY 73, 75 (2007), https://onlinelibrary.wiley.com/doi/10.1111/j.1742-7843.2007.00114.x [https://perma.cc/UX4Z-CB95].

17. *Additive*, MERIAM-WEBSTER, https://www.merriam-webster.com/dictionary/additive [https://perma.cc/LD97-UL4T] (last visited Mar. 7, 2025).

18. 21 U.S.C. § 321(s). The breadth of the definition "food additive" is demonstrated here: "The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), . . . ; except that such term does not include—

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
(2) a pesticide chemical; or
(3) a color additive; or
(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];
(5) a new animal drug; or
(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement."

19. 21 U.S.C. § 348(a).

seek approval for use of a food additive, a person may file a petition with FDA proposing the issuance of a regulation establishing conditions for safe usage of the food additive.[20] The petition must be specific to the intended use of the food additive and supporting data, including the physical or technical effect the food additive is intended to produce and the quantity required to produce such effect.[21] Notice of the filing of a petition will be published in the Federal Register.[22]

FDA regulations provide that safe or safety means "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use," and the agency must consider the probable consumption of the additive, the cumulative effect of the additive in the diet, and appropriate safety factors.[23] Therefore, the FDA must determine – based on the best science available – if there is a reasonable certainty of no harm to consumers when a color additive is used as proposed. Following review of a petition and supporting data, the FDA will issue an order prescribing the conditions under which the food additive may be safely used, for each specific use, or deny the petition.[24] Under the Delaney Clause, a food additive cannot be deemed safe if it is shown to induce cancer in humans or animals.[25] Information regarding food additive petitions under review or held in abeyance by FDA's Office of Food Additive Safety ("OFAS") is available on the FDA website.[26]

Under the FFDCA, use of a substance may be characterized as generally recognized as safe or "GRAS."[27] This exemption allows for the use of safe substances in food without review by the FDA. GRAS use of a food additive "may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food."[28] The expert views may be based on scientific procedures, if equivalent to the quantity and quality of scientific evidence required for a food additive petition.[29] If the food additive was in use prior to January 1, 1958, the expert

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20. *Id*. at § 348(b).

21. *Id*.

22. 21 C.F.R. § 171.

23. 21 C.F.R. § 170.3(i) (noting "[i]t is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance.").

24. 21 U.S.C. § 348(c).

25. *Id.* § 348(c)(3)(A) ("no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal . . .").

26. *Food Additives and Color Additive Petitions Under Review or Held in Abeyance*, U.S. FOOD & DRUG ADMIN. (Dec. 27, 2024), https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FAP-CAP [https://perma.cc/S8BY-7T42].

27. The GRAS exemption is included in the definition of food additive at 21 U.S.C. § 321(s) ("[I]f such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.").

28. 21 C.F.R. § 170.30(a).

29. *Id.* § 170.30(a)(1), (b).

views may be based on common use in food, if there is reasonable certainty that the substance is not harmful under the conditions of the intended use.[30] GRAS status may be self-determined, and a person may notify FDA of its determination.[31] However, new information may at any time require reconsideration of the GRAS status of a food ingredient.[32]

2. Color Additives in the U.S.

The FFDCA defines color additives as dyes, pigments, or other substances that impart a color to food, unless the substance is used for purposes other than coloring.[33] Color additives include substances extracted from natural sources as well as synthetic chemicals.[34] Similar to food additives, color additives are presumed unsafe, and a petition must be filed with supporting data showing the color additive is safe for the intended use.[35] There is no GRAS exemption for color additives, so all color additives require premarket approval from FDA. Notice of filing of a petition and a regulation listing the color additive are published in the Federal Register.[36] The FDA will evaluate the safety of the color additive and may list the color additive for use generally with food or for only specific uses.[37] Safe means there is "convincing evidence that establishes

30. *Id.* § 170.30(a)(2).

31. Substances Generally Recognized as Safe, 62 Fed. Reg. 18938 (proposed Apr. 17, 1997) (to be codified at 21 C.F.R. Parts 170, 184, 186, and 570), https://www.govinfo.gov/content/pkg/FR-1997-04-17/pdf/97-9706.pdf [https://perma.cc/H9H4-VVE6].

32. *Id.* § 170.30(l). The FDA published recognized GRAS uses in food in 21 C.F.R. parts 182, 184, and 186.

33. 21 U.S.C. § 321(t). "The term 'color additive' means a material which—
(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and
(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;
except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.
(2) The term "color" includes black, white, and intermediate grays.
(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

34. *Id.* § 321(t).

35. 21 C.F.R. § 71.1.

36. *Id.* § 71.2, 71.20.

37. *Id.* § 70.42. In deciding whether a petition is complete and suitable for filing and in reaching a decision on any petition filed, the Commissioner will apply the "safe-for-use" principle. This will require the presentation of all needed scientific data in support of a proposed listing to assure that each listed color additive will be safe for its intended use or uses in or on food, drugs, or cosmetics. The Commissioner may list a color additive for use generally in or on food, in or on drugs, or in or on cosmetics when he finds from the data presented that such additive is suitable and may safely be employed for such general use; he may list an additive only for more limited use or uses for which it is proven suitable and may safely be employed; and he is

with reasonable certainty that no harm will result from the intended use of the color additive."[38] Similar to food additives, if the FDA concludes, based on scientific literature, results from biological testing, or the judgment of qualified scientists, that cancer has been induced by a color additive, including its components or impurities, no regulation may issue which permits its use.[39]

Color additives must comply with individual listing regulations issued by the FDA.[40] The use of an unlisted color additive, the improper use of a listed color additive, or the use of a color additive that does not conform to the purity and identity specifications of the listing regulation may cause a product to be considered adulterated under the FFDCA. The FDA may take enforcement action against such adulterated products.

Certified color additives are synthetically produced and require certification with the FDA.[41] The FDA regulations set forth the process for requesting certification of a batch of color additive.[42] There are currently seven certified color additives approved for use in foods called "FD&C" color additives because they also may be used in drugs and cosmetics.[43] A summary of food additives and the associated regulatory status is available on the FDA website.[44]

3. Food Additives in the European Union

The EU reviews and approves foods additives using a system that is fundamentally similar to the U.S., although the legal frameworks are quite different. The European Food Safety Authority ("EFSA") was established to provide scientific advice and scientific and technical support for legislation and policies impacting food and feed safety.[45] The EU regulates food additives under various regulations governing the conditions of use of food additives, risk analysis, and authorization.[46] Similar to U.S. food statutes and regulations, EU

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authorized to prescribe broadly the conditions under which the additive may be safely employed for such use or uses. This may allow the use of a particular dye, pigment, or other substance with certain diluents, but not with others, or at a higher concentration with some than with others.

38. *Id.* § 70.3(i).

39. *Id.* § 70.50(a).

40. *See id.* §§ 73, 74, 82 (providing chemical specifications for the color additives, identifying uses and restrictions, labeling requirements for the marketed color additive, and any certification requirements).

41. *Id.* § 80.35.

42. *See id.* § 80.

43. *Id.* § 74, Subpart A (color additives used in food that are subject to certification include FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, Orange B, Citrus Red No. 2, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6).

44. *Regulatory Status of Color Additives*, U.S. FOOD & DRUG ADMIN. (Oct. 30, 2024), https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=ColorAdditives [https://perma.cc/TD5V-SDUC].

45. Council Regulation 178/2002, 2002 O.J. (L 31) (EC), https://eur-lex.europa.eu/eli/reg/2002/178/oj/eng [https://perma.cc/CV35-UT9F] (last visited Feb. 16, 2025).

46. Council Regulation 1331/2008, 2008 O.J. (L 354) (EC), https://eur-lex.europa.eu/eli/reg/2008/1331/oj/eng [https://perma.cc/M65M-V48A] (last visited Feb. 16, 2025); Council

food law is designed to protect the interests of consumers and allow for informed decisions by preventing fraudulent or deceptive practices, adulteration of food, and practices that otherwise mislead consumers.[47] Food shall not be placed on the market if it is unsafe.[48] Food is deemed unsafe if it is injurious to health or unfit for human consumption taking into consideration the normal conditions of the food, information provided to the consumer, short-term and long-term effects and effects on subsequent generations, cumulative toxic effects, and particular health sensitivities.[49] The EU broadly defines the term food, but certain items like animal feed, live animals, and plants prior to harvesting are excluded.[50] The General Food Law Regulation requires the consideration of existing international standards that are relevant and applicable in the development or adoption of food law.[51] Furthermore, the EU and member states are required to contribute and promote international food and feed standards.[52]

Under EU food law, a food additive must be approved before use.[53] As under U.S. law, food additive is broadly defined under European Commission regulations, but, unlike the U.S., the definition includes color additives and does

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Regulation 1129/2011, 2011 O.J. (L 295) (EC)., https://eur-lex.europa.eu/eli/reg/2011/1129/oj/eng [https://perma.cc/TN67-RH7F] (last visited Feb. 16, 2025).

47. Council Regulation 178/2002, art. 8, 2002 O.J. (L 31) (EC), https://eur-lex.europa.eu/eli/reg/2002/178/oj/eng [https://perma.cc/9GHZ-LF79] (last visited Feb. 16, 2025).

48. *Id.* at art. 14, ¶ 1, 2002 O.J. (L 31) (EC).

49. *Id.* at art. 14, ¶¶ 2–5, 2002 O.J. (L 31) (EC).

50. *See id.* at art. 2, 2002 O.J. (L 31) (EC), which states "For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

(a) feed;

(b) live animals unless they are prepared for placing on the market for human consumption;

(c) plants prior to harvesting;

(d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;

(e) cosmetics within the meaning of Council Directive 76/768/EEC;

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;

(h) residues and contaminants;

(i) medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council."

51. *Id.* at art. 13, 2002 O.J. (L 31) (EC).

52. *Id.*

53. *See* Council Regulation 1331/2008, 2008 O.J. (L 354) 1 (EC), https://eur-lex.europa.eu/eli/reg/2008/1331/oj/eng [https://perma.cc/M65M-V48A] (last visited Feb. 16, 2025); *see also* Council Regulation 1333/2008, art. 5, 2008 O.J. (L 354) (EC), https://eur-lex.europa.eu/eli/reg/2008/1333/oj/eng [https://perma.cc/FCP2-HA5Y] ("No person shall place on the market a food additive or any food in which such a food additive is present if the use of the food additive does not comply with this Regulation.").

not provide a GRAS exemption.[54] An application for a new food additive is sent to the European Commission, which asks the ESFA to carry out a risk assessment and may include an evaluation by other relevant expert panels under the EFSA.[55] Approved food additives and associated specifications are included on the Union lists under Annexes II and III along with a unique identifier, the food additive name, the foods which the additive may be added, conditions of use, and any other restrictions.[56]

4. Codex Alimentarius

The Codex Alimentarius, or "Food Code" ("Codex") is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission ("Commission" or "CAC").[57] The Commission is the central part of the Joint Food and Agriculture Organization of the United Nations ("FAO") and the World Health Organization ("WHO") Food Standards Programme and was established by FAO and WHO to protect consumer health and promote fair practices in food trade.[58] In addition, the Commission is responsible for promoting coordination of food standards work undertaken by international governmental and non-governmental organizations; determining priorities and initiating and guiding the preparation of draft standards; finalizing standards and publishing them in the Codex Alimentarius either as regional or worldwide standards; and amending published standards, as appropriate, in light of developments.[59] Codex can be used to harmonize global food safety standards, guide countries establishing food safety standards, as a standard under international treaties, or as a tool for resolving trade disputes.

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54. Council Regulation 1333/2008, art. 3, ¶ 2(a), 2008 O.J. (L 354) (EC) ("'[F]ood' additive shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods." (exclusions removed)).

55. *Id.* at art. 3, 2008 O.J. (L 354) (EC).

56. *See* Council Regulation 1129/2011, 2011 O.J. (L 295) (EC), https://eur-lex.europa.eu/eli/reg/2011/1129/oj/eng [https://perma.cc/LG2G-CLBL]; Council Regulation 231/2012, 2012 O.J. (L 83) (EC), https://eur-lex.europa.eu/eli/reg/2012/231/oj/ [https://perma.cc/YK37-UZ4X].

57. FAO & WHO, CODEX ALIMENTARIUS COMMISSION PROCEDURAL MANUAL 7 (28th ed. 2023), https://openknowledge.fao.org/items/dfc93e42-67f3-4de9-9dad-b33fb1600b32 [https://perma.cc/2JV6-SZV8] ("Membership of the Commission is open to all Members and Associate Members of FAO and WHO interested in international food standards. Membership shall comprise such of these nations as have notified the Director-General of FAO or of WHO of their desire to be considered as Members . . . Any Member Nation or Associate Member of FAO or WHO which is not a Member of the Commission but has a special interest in the work of the Commission, may, upon request communicated to the Director-General of FAO or WHO, as appropriate, attend sessions of the Commission and of its subsidiary bodies and ad hoc meetings as Observers.").

58. *Id.*

59. *Id.*

The *General Standard for Food Additives* ("GSFA") was developed to include food additive provisions for standardized and non-standardized foods in the Codex.[60] The GSFA was used as a starting point for the EU regulations, but additional specificity was required.[61] Food additives are only listed in the GSFA if an acceptable daily intake (ADI) is established or if determined, on the basis of other criteria,[62] to be safe by the Joint FAO/WHO Expert Committee on Food Additives ("JECFA").[63] The use of additives in foods standardized by Codex is subject to the conditions of use established by the Codex commodity standards and the GSFA.[64]

5. Soy Leghemoglobin Review and Approval in the U.S. and EU

Soy leghemoglobin is an example of a substance that has undergone multiple food additive or color additive reviews, including under U.S. and EU laws. Impossible Foods, Inc. submitted on October 3, 2017, a notice to FDA that a specific use of soy leghemoglobin preparation is GRAS through scientific procedures.[65] Soy leghemoglobin is an oxygen-binding heme protein produced in nodules that performs a similar function to hemoglobin in animals.[66] The notice related to soy leghemoglobin from a strain of *Komagataella phaffi* (yeast), formerly *Pichia pastoris*, for use at a level up to 0.8% soybean leghemoglobin protein to optimize flavor in ground beef analogue products intended to be cooked. Soy leghemoglobin preparation is a mixture containing soy leghemoglobin protein, *K. phaffi* proteins, sodium chloride, and sodium ascorbate, which is red/brown in color. The FDA issued a letter on July 23, 2018, regarding the GRAS Notice and confirmed it had no questions regarding the

60. *Id.* at 31.

61. Commission Regulation 1129/2011, art. 4, 2011 O.J. (L 295) 1129 (EU).

62. FAO & WHO, PROCEDURAL MANUAL, *supra* note 57, at 2 ("Acceptable Daily Intake (ADI) is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk . . . For the purposes of this Standard, the phrase 'without appreciable health risk' means that there is a reasonable certainty of no harm to consumers if an additive is used at levels that do not exceed those in this Standard. The provisions of this Standard do not sanction the use of an additive in a manner that would adversely affect consumer health."); *see also* Shabeer, et al., *supra* note 5.

63. FAO & WHO, CODEX ALIMENTARIUS; INTERNATIONAL FOOD STANDARDS 2 (2023) ("'determined, on the basis of other criteria, to be safe" means that the use of a food additive does not pose a safety concern under conditions of use described by JECFA as being of no toxicological concern (e.g. use levels defined circumstances)). *See also* Joel K. Bourne, Jr., *Eating the Earth: The burgeoning global food trade is a lifeline for billions, but it is fragile and hard on the planet*, 386 SCIENCE 956, 958 (Nov. 29, 2024), https://www.science.org/doi/epdf/10.1126/science.adu8006 [https://perma.cc/W6CA-AGFH] (Bourne Jr., *supra* note 2).

64. FAO & WHO, PROCEDURAL MANUAL, *supra* note 57, at 2.

65. U.S. FOOD & DRUG ADMIN., Re: GRAS Notice No. GRN 000737, https://www.centerforfoodsafety.org/files/gras-notice-grn-737-agency-response-letter_31101.pdf [https://perma.cc/RL9E-KMGT] (last visited Feb. 18, 2025).

66. LINCOLN TAIZ & EDUARDO ZEIGER, PLANT PHYSIOLOGY 330-33 (5th ed. 2010) (soil bacteria called rhizobia form a symbiotic relationship with soybeans wherein the bacteria provide fixed nitrogen to the plant in exchange for other nutrients and carbohydrates).

Notice.[67] Impossible Foods was able to use the GRAS exemption because the soy leghemoglobin preparation was used for the purpose of flavor.

Soy leghemoglobin is also useful as a colorant. Therefore, Impossible Foods sought premarket approval and an amendment to the color additive regulations to provide for the safe use of soy leghemoglobin as a color additive. As noted above, the FFDCA does not include a GRAS exemption for color additives. A notice was published in the Federal Register of December 13, 2018, announcing the filing of Impossible Foods' color additive petition, CAP 9C0314.[68] FDA's final rule listing soy leghemoglobin as a color additive exempt from certification was published in the Federal Register of August 1, 2019.[69] FDA's final rule, response to objections, denial of public hearing requests, and removal of administrative stay regarding soy leghemoglobin as a color additive was published in the Federal Register of December 19, 2019.[70]

Impossible Foods also sought approval from the European Commission for the use of soy leghemoglobin as a food additive, and specifically as a color in meat analogue products.[71] Consistent with its regulations, the European Commission requested the EFSA provide a scientific opinion on the safety of the soy leghemoglobin.[72] The EFSA Food Additive and Flavourings ("FAF") Panel concluded that the use of soy leghemoglobin from genetically modified *K. phaffi* as a food additive does not raise a safety concerned at the proposed use and use level.[73] In addition to the FAF Panel, a food additive that is within the scope of the regulation on genetically modified food and feed must be analyzed by the EFSA Panel on Genetically Modified Organisms ("GMO Panel").[74] The GMO Panel concluded that the leghemoglobin from genetically modified *K.*

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67. *GRAS Notices*, U.S. FOOD & DRUG ADMIN., www.fda.gov/grasnoticeinventory [https://perma.cc/H22H-RFDN] (last updated Feb. 13, 2025).

68. Impossible Foods, Inc.; Filing of Color Additive Petition, 83 Fed. Reg. 64045 (proposed Dec. 13, 2018).

69. Listing of Color Additives Exempt From Certification; Soy Leghemoglobin, 84 Fed. Reg. 37573 (Aug. 1, 2019) (to be codified at 21 C.F.R. Part 73).

70. Listing of Color Additives Exempt From Certification; Soy Leghemoglobin, 84 Fed. Reg. 69620 (Dec. 19, 2019) (to be codified at 21 C.F.R. Part 73).

71. Josep Casacuberta et al., *Assessment of soy leghemoglobin produced from genetically modified Komagataella phaffii, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-162)*, 22 EFSA J. e9060 (2024), https://doi.org/10.2903/j.efsa.2024.9060 [https://perma.cc/M2P8-45L6].

72. *See* Regulation 1331/2008, 2008 O.J. (L 354) (EC), https://eur-lex.europa.eu/eli/reg/2008/1331/oj/eng [https://perma.cc/M65M-V48A] (last visited Feb. 16, 2025); Regulation 1333/2008, 2008 O.J. (L 354) (EC), https://eur-lex.europa.eu/eli/reg/2008/1333/oj/eng [https://perma.cc/FV86-PDMY].

73. Maged Younes, et al., *Safety of soy leghemoglobin from genetically modified Komagataella phaffii as a food additive*, 22 EFSA J. e8822 (2024), https://doi.org/10.2903/j.efsa.2024.8822 [https://perma.cc/WD25-2RPM].

74. Regulation, 1333/2008, art. 13 ¶ 1, 2008 O.J. (L 354) (EC) (stating that "[a] food additive falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community lists in Annexes II and III in accordance with this Regulation only when it is covered by an authorization in accordance with Regulation (EC) No 1829/2003"); Regulation 1829/2003, 2003 O.J. (L 268) (EC), https://eur-lex.europa.eu/eli/reg/2003/1829/oj/eng [https://perma.cc/6RMT-4SWY].

phaffii is safe with respect to potential effects on human health and the environment at the proposed use and use level, as far as the scope of its review was concerned as to the impact of the genetic modification.[75]

Soy leghemoglobin is now approved as a food additive and color additive in the U.S. and as a food additive in the EU, and undoubtedly certain scientific data and risk analyses were useful under both legal schemes, but navigating both systems can be nuanced, time consuming, and potentially delay global trade and access to certain foods.

B. Pesticides

Pesticides are used widely in agriculture for pre-harvest and post-harvest operations, which may result in pesticide residues on food. By their nature, pesticides are controversial, and the approval and use of pesticides are highly controlled in the U.S. and EU.

1. U.S. Regulation of Pesticide Residues

Pesticides are defined under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") as any substance or mixture of substances intended for preventing, destroying, or mitigating any pest, including plant regulators, defoliants, or desiccants.[76] A pesticide must be registered before the pesticide may be distributed or sold.[77] The U.S. Environmental Protection Agency ("EPA") evaluates data submitted by an applicant as part of the registration process.[78] The data includes chemical identity and composition of the pesticide, environmental fate, and residue chemistry, among other things.[79] EPA has authority under the FFDCA to establish, modify, or revoke a tolerance for a pesticide chemical residue in or on food.[80]

EPA evaluates pesticides to ensure that they are safe for human health and the environment when used according to label directions and establishes tolerances,[81] which are the maximum residue level of a specific pesticide

75. Casacuberta et al., *supra* note 71.

76. 7 U.S.C. § 136(u).

77. *Id.* § 136a(a).

78. *Id.* § 136a.

79. 40 C.F.R. § 158.130.

80. 21 U.S.C. § 346a ("The term 'pesticide chemical residue' means a residue in or on raw agricultural commodity or processed food of (A) a pesticide chemical; or (B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical."); 21 U.S.C. 321(q)(2).

81. The EPA Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed, the pesticide will not cause "unreasonable adverse effects on the environment." 7 USC 136a(c)(5)(C). "The term 'unreasonable adverse effects on the environment' means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent

chemical that is permitted in or on a specific human or animal food.[82] Tolerances must be established, and a food with detectable pesticide residues must be below established tolerances for the food to be considered safe for consumption. Specifically, a pesticide is considered unsafe in or on food until a tolerance is established,[83] and a food with an unapproved pesticide residue is automatically deemed adulterated.[84] A raw agricultural commodity is deemed unsafe and adulterated if it contains a level exceeding an established tolerance.[85]

The FFDCA defines "safe" with respect to pesticide chemical residue tolerances to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[86] This includes exposure through drinking water and in residential settings but does not include occupational exposure.[87] FFDCA also requires EPA to give special consideration to the exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue[s.]"[88] EPA must consider several factors when making determinations about establishing, modifying, or revoking tolerances, including the validity, completeness, and reliability of available data; the nature of any toxic effect; available information concerning the relationship of the studies to human risk, dietary consumption patterns of consumers, cumulative effects of residues and other substances that have a common mechanism of toxicity, aggregate exposure levels of consumers, and variability of the sensitivities of major identifiable subgroups of consumers; whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and safety factors.[89] Consequently, for a food-use pesticide (*i.e.,* a pesticide use that is likely to result in residues in or on food) to be sold and distributed, the pesticide must not only have appropriate tolerances or exemptions under the FFDCA, but also must be registered under FIFRA.[90] Food-use pesticides not registered in the U.S. must have tolerances or exemptions in order for

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with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide." 7 U.S.C. 136(bb).

82. 21 U.S.C. § 346(a)(2)(A).

83. *Id.* § 346a(a)(1).

84. *Id.* § 342(a)(2)(B).

85. *Id.* § 321(r) ("The term 'raw agricultural commodity' means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.").

86. *Id.* § 346a(b)(2)(A)(ii), (c)(2)(A)(ii).

87. *Id.* § 346a(b)(2)(D).

88. *Id.* § 346a(b)(2)(C).

89. *Id.* § 346a(b)(2)(D).

90. 7 U.S.C. § 136.

commodities treated with those pesticides to be imported into the U.S..[91]

When establishing a tolerance for residues of a pesticide, EPA must determine whether the Codex has established a Maximum Residue Limit ("MRL") for that pesticide.[92] As part of registration review, EPA determines whether international tolerances or MRLs exist for commodities and chemicals for which U.S. tolerances have been established.[93] Where appropriate, EPA's intention is to harmonize U.S. tolerances with those international MRLs to facilitate trade.[94] EPA must explain its reasons for deviating from any Codex MRL.[95] EPA's effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of the individual human health risk assessments that support each pesticide registration review.[96]

The FDA is responsible for enforcing the EPA tolerances for domestic foods shipped in interstate commerce and foods offered for import into the U.S., except for meat, poultry, catfish (Siluriformes) and certain egg products that are regulated by the U.S. Department of Agriculture's ("USDA") Food Safety and Inspection Service ("FSIS").[97] FDA employs a three-fold strategy to enforce the tolerances for pesticide chemical residues in human and animal foods.[98] FDA selectively tests a broad range of imported and domestic commodities for pesticide residues and may also carry out focused sampling surveys for specific commodities or selected pesticide chemical residues of special interest.[99] In addition, FDA monitors the levels of pesticide chemical residues in foods prepared for consumption in its Total Diet Study ("TDS"), an ongoing program that monitors contaminants and nutrients in the average U.S. diet.[100]

2. EU Regulation of Pesticide Residues

The EU notes that the use of active substances in plant protection products is one of the most common methods of protecting plants and plant products from the effects of harmful organisms,[101] but a possible consequence is the presence

91. 21 U.S.C. § 346a(a)(1).

92. *See id.* § 346a(b)(4).

93. Guidance on Pesticide Import Tolerances and Residue Data for Imported Food, 65 Fed. Reg. 35069 (June 1, 2000).

94. *Id.*

95. 21 U.S.C. § 346a(b)(4).

96. *Id.* § 346a(b)(4).

97. *Id.* § 1401.

98. U.S. FOOD & DRUG ADMIN., PESTICIDE RESIDUE MONITORING PROGRAM FISCAL YEAR 2022 PESTICIDE REPORT 5 (2024), https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-report-and-data-fy-2022 [https://perma.cc/RVJ7-NF6B].

99. *Id.*

100. *Id.*

101. "'[P]esticide residues' means residues, including active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in plant protection products . . . which are present in or on the products covered by Annex I to this Regulation, including in particular those which may arise as a result of use in plant protection, in veterinary medicine and as a biocide." Regulation 396/2005, art. 3 ¶ 2(c), 2005 O.J. (L 70) (EC); Active

of residues in the treated products or in animals feeding on those products.[102] Public health should be given priority over the interests of crop protection, and a primary focus is to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment.[103] Pesticides are evaluated and approved for use in the EU utilizing a distinctly different legal framework than in the U.S., but the foundational principle of each system is the characterization of risk to protect human health and the environment. Plant protection products must meet certain requirements for approval, including effectiveness, immediate and delayed harmful effects (considering vulnerable groups, other sources, and cumulative or synergistic effects), unacceptable effects on plants or plant products, unnecessary suffering and pain to vertebrates to be controlled, and unacceptable effects on the environment.[104] For active substances used on feed or food crops or that indirectly results in residues in food or feed, the dossier submitted for approval of the substance must permit any residue to be defined, predict the residues on food and feed and the effects of processing or mixing, permit a maximum residue level to be defined and methods for detection, permit concentration and dilution factors due to processing or mixing to be defined, and permit, where relevant, a determination of fate and distribution in the environment and non-target species.[105]

Conditions for approval of active substances requires that residues of plant protection products shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects. . ., or on groundwater, and no unacceptable effect on the environment.[106] MRLs are set after consultation of the EFSA and consideration of the established general principles and requirements of food

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substances means "substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products." Commission Regulation 1107/2009, 2009 O.J. (L 309) (EC).; "'[S]ubstances' means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process." Regulation 396/2005, art. 3, ¶ 2, 2005 O.J. (L 70) (EC); Plant protection products means "products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses: (a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products; (b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient; (c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives; (d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants; (e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants." Commission Regulation 1107/2009, art. 2 ¶ 1, 2009 O.J. (L 309) (EC).

102. Regulation 396/2005, 2005 O.J. (L 70) (EC).

103. Commission Regulation 1107/2009, art. 1 ¶ 3-4, 2009 O.J. (L 309) (EC).

104. *Id.* at art. 4 ¶ 3(a)-(e).

105. *Id.* at annex II ¶ 3.1.

106. *Id.* at art. 4 ¶ 2.

law.[107] Considering the EU directive concerning approval of plant protection products, MRLs are to be set at the lowest achievable level consistent with good agricultural practice for each pesticide with a view to protecting vulnerable groups.[108] Additionally, EU trading partners should be consulted about proposed MRLs before adoption, and Codex MRLs should be considered when EU MRLs are set, taking into account the corresponding good agricultural practices. [109]

EU Member States are required to implement a system of controls on pesticide residues to ensure and enforce compliance with regulations.[110] Such controls must include sampling sufficiently to represent the market and appropriate analysis of pesticide residues.[111] Community control programs, National control programs, and annual reporting is also required to assess and report on the risk of exposure to consumers.[112]

3. The Role of Codex in Pesticide Residues

Trade difficulties can arise when maximum legal limits for pesticide residues in foods differ between countries. Codex MRLs can be a useful tool for harmonizing residue limits and facilitating trade. The Codex Committee on Pesticide Residues ("CCPR") is responsible for establishing Codex MRLs for pesticide residues in specific food items or in groups of food or feed that move in international trade.[113]

The process for setting a Codex MRL begins when a Member or Observer nominates a pesticide for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues ("JMPR").[114] Before a Codex MRL can be established, human health risk assessments must be conducted to ensure the food supply is safe. The JMPR is responsible for reviewing the appropriate toxicology and data that reflect approved pesticide use in accordance with good agricultural practice.[115] JMPR's risk assessment includes, among other things, an evaluation

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107. Regulation 396/2005, recital 6, 2005 O.J. (L 70) (EC); *see* Regulation 178/2002, 2002 O.J. (L 31) (EC).

108. *Id.* at art. 3 ¶ 2(d) ("'[M]aximum residue level' (MRL) means the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers."); *see also* Regulation 396/2005, recital 5, 2005 O.J. (L 70) (EC).

109. *Id.* at recital 25.

110. *Id.* at art. 26 ¶ 1.

111. *Id.* at art. 27 ¶ 1-2.

112. *See id.* art. 29-33.

113. FAO & WHO, PROCEDURAL MANUAL, *supra* note 57, at 127 ¶ 166.

114. *Id.* at 131 ¶ 195, 127 ¶ 167 ("The JMPR consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors-General of FAO and WHO according to the rules of both organizations, charged with the task of providing scientific advice on pesticide residues.").

115. *Id.* at 128 ¶ 170 ("Good agricultural practice (GAP) in the use of pesticides includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest

of short-term and long-term dietary exposures.[116] The science-based risk assessments are based on "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius,"[117] and include hazard identification,[118] hazard characterization,[119] exposure assessment,[120] and risk characterization.[121] JMPR recommends specific MRLs to the CCPR, which recommendations, if accepted, are submitted to the Commission for adoption as Codex MRLs ("CXLs").[122] As previously mentioned, Codes MRLs or CXLs are considered by the U.S. and EU is establishing appropriate residue levels for food.

4. Chlorpyrifos – A Complicated Analysis

Chlorpyrifos is an organophosphate insecticide that was registered for use in the U.S. in 1965, and the registration was modified several times since the initial registration. In 2017, chlorpyrifos was the most widely used insecticide in the U.S.[123] Recent developments concerning the registrations and established tolerances (or MRLs) in the U.S. and EU show how differences in the interpretation of the risk analysis and the legal system applied can affect the registration, use, and tolerances (MRLs) of a pesticide.[124]

On September 12, 2007, pursuant to 21 U.S.C. § 346a(d), the Natural Resources Defense Council ("NRDC") and Pesticide Action Network North America ("PANNA") filed a petition with EPA seeking to revoke all tolerances and cancel all registrations for chlorpyrifos.[125] After delays by EPA, plaintiffs sought relief from the court to compel agency action.[126] In 2015, EPA stated it

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authorized use, applied in a manner which leaves a residue which is the smallest amount practicable. Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations. Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed.").

116. *Id*.

117. *See id*. at 99-103.

118. *Id.* at 104 ("The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.").

119. *Id.* ("The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical, and physical agents which may be present in food.").

120. *Id.* ("The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.").

121. *Id.* at 151 ("The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.").

122. *Id.* at 128 ¶ 171.

123. *See* Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances, 82 Fed. Reg. 16581, 16584 (Apr. 5, 2017).

124. Codex MRLs have not been established for chlorpyrifos or chlorpyrifos-methyl.

125. *See* Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35555 (Jul. 24, 2019); *see also* 21 U.S.C. § 346a(d)(1)(A) (allowing "[a]ny person" to file a petition that proposes "revoking a tolerance").

126. Pesticide Action Network North America v. EPA, 798 F.3d 809 (9th Cir. 2015).

was unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of the FFDCA.[127] Therefore, EPA proposed to revoke all tolerances for chlorpyrifos and sought comments on retaining any individual tolerances, or group of tolerances, and whether information exists to demonstrate that such tolerance satisfies the FFDCA safety standard.[128] EPA then sought additional comments on its revised human health risk assessment and drinking water exposure assessment.[129] Then in 2017, EPA denied PANNA's petition and concluded that the data provided with the 2007 petition were not sufficiently valid, complete, and reliable to support the request for revocation ("2017 Order").[130] In 2019, EPA also denied all objections to its March 29, 2017, order ("2019 Order").[131]

Several organizations and states filed petitions for review in the Ninth Circuit challenging EPA's orders.[132] The Court granted the petitions for review, vacated EPA's 2017 Order and 2019 Order, and remanded with instructions to EPA to (1) grant the 2007 Petition, (2) issue a final regulation within 60 days of issuance of the mandate either revoking or modifying the chlorpyrifos tolerances, and (3) modify or cancel related FIFRA registrations for food use.[133] The Ninth Circuit determined that's EPA's denial of the 2007 Petition was arbitrary and capricious, and that EPA can only leave tolerances in place if it finds the tolerance to be safe for the general population and for infants and children.[134]

On October 29, 2021, EPA revoked all tolerances for chlorpyrifos.[135] Several organizations challenged the EPA's final rules, and the Eighth Circuit concluded that the EPA's decision to ignore modification as a possibility was "arbitrary [and] capricious."[136] The Court remanded the matter to EPA and emphasized that EPA remains free to exercise its discretion as long as it considers all "important aspect[s] of the problem" and gives a reasoned explanation for whichever option it chooses.[137] Consistent with the Eighth Circuit's opinion, EPA revised the tolerance regulations to reflect the

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127. *See* Chlorpyrifos; Tolerance Revocations, 80 Fed. Reg. 69080 (proposed Nov. 6, 2015) (to be codified at 40 C.F.R. Part 180).

128. *See id.*

129. *See id.*

130. *See* Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances, 82 Fed. Reg. 16581 (April 5, 2017).

131. Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35555 (July 24, 2019).

132. *See* League of United Latin Am. Citizens v. Regan, 996 F.3d 673 (9th Cir. 2021).

133. *Id*.

134. *Id*.

135. *See* Chlorpyrifos; Tolerance Revocations, 86 Fed. Reg. 48315 (Aug. 30, 2021) (to be codified at 40 C.F.R. Part 180). Effective February 28, 2022, EPA denied all objections to its August 30, 2021, final rule, requests for hearing on those objections, as well as requests for stay of the final rule. *See also* Chlorpyrifos; Final Rule, 87 Fed. Reg. 11222 (Feb. 28, 2022) (to be codified at 40 C.F.R. Part 180).

136. Red River Valley Sugarbeet Growers Ass'n v. Regan, 85 F.4th 881, 14 (8th Cir. 2023).

137. *See generally Chemical, supra* note 14.

reinstatement of tolerances for chlorpyrifos.[138] Certain registrations have been voluntarily cancelled or amended, and EPA is evaluating modification of certain tolerances.

In contrast, on December 6, 2019, at the meeting of the Standing Committee on Plants, Animals, Food and Feed ("PAFF Committee"), the EU Member States voted to not renew the approvals of chlorpyrifos and chlorpyrifos-methyl.[139] The European Commission formally adopted the regulations on January 10, 2020.[140] In April 2019, as part of the standard regulatory renewal of approval processes for these substances, experts from EFSA and Member States including relevant experts from the EFSA Panel on Plant Protection Products and their Residues ("PPR Panel") convened to discuss the human health assessment of chlorpyrifos and chlorpyrifos-methyl.[141] Experts concluded that concerns related to human health exist in relation to possible genotoxicity and developmental neurotoxicity.[142] The European Commission mandated EFSA to provide statements on the main findings on human health for chlorpyrifos and chlorpyrifos-methyl.[143]

On August 2, 2019, EFSA published statements for both substances, confirming that concerns for human health have been identified and that safe levels of exposure cannot be determined based on the available data.[144] EFSA concluded that the approval criteria for human health laid down in the EU legislation are not met.[145] A second expert discussion on chlorpyrifos-methyl took place in early September 2019, and on November 26, 2019, EFSA published its updated statement on chlorpyrifos-methyl, confirming its prior findings.[146] The Member States endorsed a proposal by the European Commission to lower the Maximum Residue Levels (MRLs) of chlorpyrifos and chlorpyrifos-methyl in food and feed to the lowest level that can be measured by analytical laboratories.[147] The new lowered MRLs apply both to food produced in the EU and also to imports.

C. PFAS – "Forever Chemicals"

PFAS – per-and polyfluoroalkyl substances – include thousands of human-

138. *See* 40 C.F.R. § 180.342; Chlorpyrifos; Reinstatement of Tolerances, 88 Fed. Reg. 7625 (Feb. 5, 2024) (to be codified at 40 C.F.R. Part 180).

139. EUR. COMM'N, *Chlorpyrifos & Chlorpyrifos-methyl*, https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists/renewal-approval/chlorpyrifos-chlorpyrifos-methyl_en [https://perma.cc/R4SK-9UKS] (last visited Feb. 21, 2025).

140. *Id.*

141. EUR. FOOD SAFETY AUTH. (EFSA), *Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos*, 17 EFSA J. 1, 5 (2019), https://doi.org/10.2903/j.efsa.2019.5809 [https://perma.cc/K988-SDXS].

142. FAO, IFAD, UNICEF, WFP & WHO, *supra* note 8.

143. Shabeer et al., *supra* note 5.

144. FAO, IFAD, UNICEF, WFP & WHO, *supra* note 8, at 23.

145. *See* Regulation 1107/2009, art. 4, 2009 O.J. (L 309) (EC).

146. EFSA, *supra* note 141, at 11, 21.

147. *See* Regulation 396/2005, rec. 22, 2005 O.J. (L 70) (EC).

made chemicals that have been used since the 1940s for their beneficial properties including oil repellence, stain resistance, and waterproofing.[148] The definition of PFAS varies among industries, state and federal regulatory schemes, and academia.[149] PFAS may be intentionally added to products or result from unintentional inclusion as a byproduct, contaminant, or impurity during the manufacturing process.[150] There are multiple potential exposure routes including through the use of PFAS-containing products and environmental exposure via soil, biosolids, groundwater, or surface water.[151] Many PFAS are persistent and bioaccumulative, which is the basis for the moniker "forever chemicals."[152] Ingestion of contaminated drinking water and food are the primary exposure pathways.[153] With respect to food and beverages, certain consumer products that contain PFAS include nonstick cookware, disposable food packaging and food service ware.[154]

PFAS exposure has been associated with adverse health effects in the liver, immune system, early-life development, and cardiometabolic system, as well as endocrine disruption and reproductive effects.[155] However, the diversity of PFAS chemicals makes characterization of the health effects difficult.[156] Many different regulatory strategies are being deployed to address PFAS exposure. For example, the EPA developed a Strategic Roadmap concerning PFAS regulations and reporting.[157] EPA has implemented many components of its strategy including the PFAS National Primary Drinking Water Rule.[158]

The Codex Committee on Contaminants in Foods recommended addition of PFAS to the priority list for full evaluation, including toxicological assessment and exposure assessment.[159]

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148. RTI INT'L & CONSUMER PRODUCT SAFETY COMM'N, CHARACTERIZING PFAS CHEMISTRIES, SOURCES, USES, AND REGULATORY TRENDS IN U.S. AND INTERNATIONAL MARKETS, ES-2 (2023), https://www.cpsc.gov/s3fs-public/CPSC-PFAS-WhitePaper.pdf [https://perma.cc/6WDQ-4QBW].

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.* at ES-3.

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

157. U.S. ENV'T PROTECTION AGENCY, *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024*, Docket No. EPA-100-K-21-002, (Oct. 18, 2021), https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024[https://perma.cc/A5HR-3PK5].

158. *See* PFAS National Primary Drinking Water Regulation, 89 Fed. Reg. 32532 (Apr. 26, 2004) (codified at 40 C.F.R. Parts 141 and 142) (establishing maximum contaminant levels (MCLs) in drinking water for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA, commonly known as GenX Chemicals), and perfluorobutane sulfonic acid (PFBS)).

159. CODEX ALIMENTARIUS COMM'N, *Priority List of Contaminants and Naturally Occurring Toxicants Proposed for Evaluation by JECFA*, *in* REPORT OF THE 13RD SESSION OF THE CODE

1. FDA Regulation of PFAS in Foods

PFAS were often used in food contact substances to impart grease and water resistance to the substances.[160] Under the FFDCA, a manufacturer or supplier of a food contact substance may, at least 120 days prior to use in interstate commerce, notify the FDA of the identity, intended use, and safety of such food contact substance.[161] The notification becomes effective 120 days after receipt by FDA of the notification, unless FDA makes a determination that the food contact substance has not been shown to be safe.[162] Food contact substances are deemed unsafe unless the food additive petition and approval process has been followed and a regulation issued, or an effective notification has been submitted.[163]

FDA worked with manufacturers and suppliers regarding the voluntary phase out of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) as food contact substances around 2012.[164] On March 16, 2015, FDA announced that it filed a food additive petition submitted by several organization seeking to amend food additive regulations to no longer permit the use of three long-chain PFAS (8 or more carbon atoms in length) as oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods.[165] FDA agreed with the petition concluding that there was no longer a reasonable certainty of no harm from the food-contact use of the substances.[166] FDA also amended the food additive regulation to no longer provide for the use of two additional PFAS as food contact substances because the uses were abandoned.[167] According to FDA, long-chain PFAS were no longer used as food contact substances in the U.S. as of November 2016, and FDA secured a voluntary phase out of food contact applications in the U.S. of certain short-chain PFAS (7 or fewer carbon atoms in length) that contain 6:2 fluorotelomer

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COMMITTEE ON CONTAMINANTS IN FOODS 65, 65-66 (2019), https://www.fao.org/fao-who-codexalimentarius/sh-proxy/jp/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-13%252FREPORT%252FFinal%252520Report%252FREP19_CFe.pdf [https://perma.cc/PBF3-TJD6].

160. 21 U.S.C. § 348(h)(6) ("[T]he term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food."); *see also* RTI INT'L AND CONSUMER PRODUCT SAFETY COMM'N, *supra* note 148, at 4-14.

161. 21 U.S.C. § 348(h)(1).

162. *Id.* § 348(h)(2)(A).

163. *Id.* § 348(a)(3).

164. *See Market Phase-Out of Grease-Proofing Substance Containing PFAS*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/process-contaminants-food/market-phase-out-grease-proofing-substances-containing-pfas [https://perma.cc/MR85-AHYL] (last visited Dec. 17, 2024).

165. *See* Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West, 80 Fed. Reg. 13508 (proposed Mar. 16, 2015) (to be codified at 7 C.F.R. Part 985).

166. *See* Indirect Food additives: Paper and Paperboard Components, 81 Fed. Reg. 5 (Jan. 4, 2016) (to be codified at 21 C.F.R. Part 176).

167. *See id.*

alcohol beginning in January 2021.[168] The FDA announced in February 2024 that grease-proofing substances containing PFAS are no longer sold for use as food contact substances in the U.S.[169]

Since 2019, the FDA has also been analyzing foods collected as part of its TDS as sources for PFAS.[170] Additionally, the FDA targeted sampling of seafood, which had a greater percentage of samples with detectable PFAS, and food grown in certain geographical areas contaminated with PFAS. Two voluntary recalls were issued due to health concerns associated with exposure to PFOA in canned clams.[171] The FDA has not established tolerances for PFAS in foods.

2. EU Regulation of PFAS in Foods

The EFSA requested that the Scientific Panel on Contaminants in the Food Chain ("CONTAM") prepare an opinion "on the importance of food and the relative contribution of the different foodstuffs and food contact materials to human exposure to PFOS and its salts" and advise on further steps.[172] CONTAM also considered PFOA, and derived Tolerable Daily Intake ("TDI") levels for PFOS and PFOA.[173] Following the 2008 CONTAM opinion, the European Commission recommended EU-wide monitoring of PFAS in food.[174]

After a request from the European Commission, the EFSA published a scientific evaluation of the risks to human health related to the presence of perfluoroalkyl substances in food, focusing on the sum of perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), perfluorononanoic acid (PFNA),

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168. *See Market Phase-Out of PFAS, supra* note 164.

169. *See FDA Announces PFAS Used in Grease-Proofing Agents for Food Packaging No Longer Being Sold in the U.S.*, U.S. FOOD & DRUG ADMIN. (Feb. 28, 2024), https://www.fda.gov/food/hfp-constituent-updates/fda-announces-pfas-used-grease-proofing-agents-food-packaging-no-longer-being-sold-us [https://perma.cc/J9NT-7269].

170. *See* U.S. FOOD & DRUG ADMIN., TOTAL DIET STUDY REPORT FISCAL YEARS 2018-2020 ELEMENTS DATA 1 (2022), https://www.fda.gov/food/fda-total-diet-study-tds/fda-total-diet-study-tds-results [https://perma.cc/BB27-X3JS]. Note that results are limited by the approved analytical methods available to detect various PFAS.

171. *See Company Announcement: Bumble Bee Foods, LLC Issues Voluntary Recall on 3.75 Oz Smoked Clams Due to the Presence of Detectable Levels of PFAS Chemicals*, U.S. FOOD & DRUG ADMIN. (Jul. 6, 2022), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bumble-bee-foods-llc-issues-voluntary-recall-375-oz-smoked-clams-due-presence-detectable-levels-pfas [https://perma.cc/49MG-D8F4]; *see also Company Announcement: Crown Prince, Inc. Issues Voluntary Recall of Smoked Baby Clams in Olive Oil Due to the Presence of Detectable Levels of PFAS Chemicals*, U.S. FOOD & DRUG ADMIN. (Jul. 15, 2022), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/crown-prince-inc-issues-voluntary-recall-smoked-baby-clams-olive-oil-due-presence-detectable-levels [https://perma.cc/NPA6-7MZ8].

172. Diane Benford et al., *Opinion of the Scientific Panel on Contaminants in the Food chain on perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts*, 653 EFSA J. 10 (2008), https://pmc.ncbi.nlm.nih.gov/articles/PMC10193653/ [https://perma.cc/4DK9-GZBX].

173. Wood et al., *supra* note 3.

174. *See* Recommendation 2010/161, 2010 O.J. (L 68) (EU).

and perfluorohexane sulfonic acid (PFHxS), and establishing a group tolerable weekly intake ("TWI") of 4.4 ng/kg bodyweight per week.[175] The EFSA experts also concluded that the main contributors to human dietary exposure include fish meat, fruit, fruit products, eggs and egg products.[176] The EFSA noted that two main processes are thought to lead to contamination of food with PFAS – bioaccumulation in aquatic and terrestrial food chains, and transfer from contact materials used in food processing and packaging.[177] Based on the assessment by EFSA, the EU implemented a regulation setting maximum levels for PFOS, PFOA, PFNA, PFHxS, and their sum in specific food products.[178]

Similar to the requirements under the FFDCA for food contact substances, the EU issued a regulation stating that materials and articles in contact with food[179] must be "manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health, bring about an unacceptable change in the composition of the food, or bring about a deterioration in the organoleptic characteristics thereof."[180] An application for a new substance for use with a material or article must be submitted and evaluated by the EFSA and approved by the European Commission.[181] There is no process for notification and automatic approval, unless objected to by FDA, as under the FFDCA.

III. CONCLUSION

Substances that are intentionally and unintentionally added to foods are highly regulated in the U.S. and EU. While personal preferences vary regarding the use of synthetic chemicals in or on food, these man-made or synthetic substances undergo rigorous evaluation before approval. The food regulatory systems in the U.S. and EU are also designed to prevent or control, if prevention is not possible, contaminants and other unintentionally added substances. The U.S. food laws were developed over many years, are complex, and can be cumbersome to navigate. The U.S. and EU food laws were developed using similar foundational principles but with different general approaches. As a

175. EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Dieter Schrenk et al., *Risk to human health related to the presence of perfluoroalkyl substances in food*, 18 EFSA J.157 (2020), https://doi.org/10.2903/j.efsa.2020.6223 [https://perma.cc/C5SC-QNQU].

176. *Id.* at 153.

177. *Id.* at 21.

178. Commission Regulation 2023/915, 2023 O.J. (L 119) (EU).

179. Regulation1935/2004, 2004 O.J. (L 338) (EC) (The regulation applies to "materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state: (a) are intended to be brought into contact with food; or (b) are already in contact with food and were intended for that purpose; or (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.").

180. *See* Organoleptic characteristics refer to any sensory properties of food, including taste, color, smell, and touch; *see also* Regulation 1935/2004, art. 3 ¶ 1, 2004 O.J. (L 338) (EC).

181. Regulation 1935/2004, art. 9-13.

result, these systems can have different end results, which can complicate the global food supply system and global trade. The U.S. and EU are two important systems, but there are also many other countries and laws that are implicated in global trade. While Codex can facilitate trade and harmonizing different systems, trade will continue to be influenced by the key trade partners and the associated food safety requirements, including the use and evaluation of synthetic chemicals, and will likely become even more complicated with new technological advancements, geopolitical issues, and changing environmental conditions.

CHEECH AND CHONG GO TO COURT: LEGAL CHALLENGES TO CALIFORNIA'S PROHIBITION OF HEMP IN FOOD PRODUCTS

JORDAN PARADISE, J.D.*

The status of federal law on marijuana has remained stagnant for decades despite frequent calls to decriminalize it, reschedule it, and release those individuals that have been imprisoned for use and sale of it. In the persistent absence of federal action to change the status quo, states have begun to move into the regulatory space. Several states have provided legal mechanisms to sell and distribute marijuana, establish dispensary businesses, and tax it as a mainstream product. Cannabis and marijuana are both terms that refer to the Cannabis sativa plant.[1] Cannabis, as a scientific term, refers to a broad family of plants; only some of that plant family produce tetrahydrocannabinol, or THC, a chemical with well-documented psychoactive effects. The term marijuana typically refers to the substances and products that contain THC. Products containing cannabis span a vast array of applications, from medicinal to recreational, including the increasing use of THC-containing ingredients in food, beverages, and dietary supplements.

This article explores the realm of hemp regulation as it relates to the broader landscape of marijuana and cannabis law and policy, looking to the state of California as a model for increased oversight of hemp-containing products that pose a danger to public health. Section I describes the three key federal agencies involved in cannabis law and the recent actions to reschedule and to develop a feasible path to regulation. Section II defines the scope of industrial hemp under federal legislation and presents several loopholes created by that legislation. Section III explores California's recent emergency action involving intoxicating hemp and related litigation challenging the state's authority. Section IV addresses general trends in state and global regulation of intoxicating hemp products.

I. FEDERAL SCRUTINY OF CANNABIS AND CANNABIS-DERIVED PRODUCTS: THE DOJ, THE DEA, AND THE FDA

Recently, in May 2024, the Department of Justice (DOJ) through the Drug Enforcement Administration (DEA) put forth proposed regulations to reschedule marijuana from Schedule I to Schedule III under the authority in the Controlled Substances Act (CSA).[2] Schedule I under the CSA means that the

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1. This article will use both the terms marijuana and cannabis.

2. DRUG ENFORCEMENT ADMINISTRATION, Rule, Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597 (proposed May 21, 2024), *available at* https://www.regulations.gov/document/DEA-2024-0059-0001 [https://perma.cc/DGX6-PF74]; Office of Public Affairs, *Justice Department Submits Proposed Regulation to Reschedule Marijuana*, DEPARTMENT OF JUSTICE (May 16, 2024), https://www.justice.gov/archives/opa/pr/justice-department-submits-proposed-regulation-reschedule-marijuana [https://perma.cc/7PRR-H9LE].

use, sale, or distribution of marijuana is illegal under federal law as it has a high potential for abuse, no currently accepted medical use in treatment in the U.S., and there is no accepted safety for use under medical supervision.[3] Schedule III substances are those with a potential for abuse that is less than for those in Schedules I and II, has a currently accepted medical use in the U.S., and abuse may lead to moderate or low physical dependence or high psychological dependence.[4] The DEA, an agency within the DOJ, is responsible for enforcement of the CSA.

The notice of proposed rulemaking follows a directive from President Biden in October 2022, asking the Attorney General and Secretary of Health and Human Services (HHS) to review the scientific evidence underpinning the scheduling of marijuana under federal law.[5] Coupled with this directive, President Biden also issued a pardon of prior federal offenses of the simple possession of marijuana and instructed the Attorney General to implement a process for issuance of certificates of pardon.[6] Biden urged governors to follow his lead in their states.[7] After receiving feedback from HHS and consultation with the Office of Legal Counsel, the Department of Justice initiated its rulemaking authority to notify the public of the intent to reschedule marijuana.[8] The process requires the DOJ to proceed utilizing formal rulemaking proceedings, which are to be on the record after the opportunity for a hearing and adhere to the requirements of the Administrative Procedure Act §§ 556 and 557.[9] Formal rulemaking is more time-consuming than notice and comment rulemaking, resembling adjudicatory proceedings, making the task an onerous one that may take years to complete. The Justice Department has received about 43,000 public comments on the docket,[10] and the preliminary hearing was held on December 2, 2024.[11] The subsequent hearings scheduled for late January,[12] however, have been postponed until further notice.[13]

Recently, the rulemaking process has been challenged in Washington

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3. 21 U.S.C. § 812(b)(1)(A)-(C).

4. 21 U.S.C. § 812(b)(3)(A)-(C).

5. THE WHITE HOUSE, *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022) https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/ [https://perma.cc/FT6M-8DJN].

6. *Id.*

7. *Id.*

8. DRUG ENFORCEMENT ADMINISTRATION, 89 Fed. Reg. 44597 (proposed May 21, 2024).

9. *Id.*

10. *Id.*

11. DRUG ENFORCEMENT ADMINISTRATION, *Notice of Hearing on Proposed Rulemaking*, 89 Fed. Reg. 70148 (proposed Aug. 29, 2024) *available* at https://www.regulations.gov/document/DEA-2024-0059-42928 [https://perma.cc/K6ZP-4JC4].

12. Sam Reisman, *DEA Judge Sets Pot Rescheduling Hearings*, LAW360 (Dec. 4, 2024), https://www.law360.com/articles/2269288/dea-judge-sets-pot-rescheduling-hearings [https://perma.cc/2727-TLQF].

13. Joseph Choi, *Marijuana Rescheduling Runs Into Roadblock*, THE HILL (Jan. 18, 2025), https://thehill.com/policy/healthcare/5092684-dea-hearing-appeal-marijuana-rescheduling/ [https://perma.cc/U8UJ-ZE3E].

federal court under the Administrative Procedure Act by a psychedelic researcher.[14] The researcher, who is also the CEO of Panacea Plant Sciences, argues that the DEA unlawfully excluded some stakeholders from the public hearing process required in the formal rulemaking provisions, particularly representatives of tribal governments and small businesses.[15] Regulations promulgated by the DEA require that interested parties participating in rescheduling hearings must be "adversely affected or aggrieved" by the proposed rule.[16] The DEA had provided a list of twenty-five individuals to the chief administrative law judge overseeing the proceedings.[17] In an October 2024 preliminary order, the judge directed the DEA's designated participants to explain how they met the regulatory criteria to qualify them to take part in the hearing, whether they were in support of the rescheduling or in opposition, and whether they had any conflicts of interest relating to leadership or personnel of the DOJ or DEA.[18]

The DEA administrative law judge also subsequently denied the petition of a group of veterans represented by the Veterans Action Council (VAC) to participate in the hearings.[19] The VAC argued that the DEA should instead reschedule cannabis to Schedule 5, which "will allow the VA doctor to prescribe the medication and for the Veteran Affairs Administration to pay for the product that the Veteran would then go purchase themselves."[20] Schedule 5 is the least restrictive scheduling for drugs with the lowest potential for abuse and a currently accepted medical treatment consisting of preparations that contain limited quantities of particular narcotics.[21] The DEA considers Schedule 5 drugs to be those used generally for, among other things, analgesic purposes.[22]

Historically, the Food and Drug Administration (FDA) has not regulated products containing cannabis, tetrahydrocannabinol (THC), cannabidiols, or cannabinoids under existing statutory authority. The FDA's relevant legal authority encompasses food, including food additives and dietary supplements. The Food, Drug, and Cosmetic Act (FDCA) defines food simply as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3)

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14. Sam Reisman, *Researcher Sues DEA Over Pot Rescheduling Process*, LAW360 (Nov. 7, 2024), https://www.law360.com/articles/2258255/researcher-sues-dea-over-pot-rescheduling-process [https://perma.cc/KG6F-4PLC]; *David Heldreth v. Merrick Garland et al.*, case no. 2:24-cv-01817, U.S. District Court, Western District of Washington.

15. Reisman, *Researcher Sues DEA, supra* note 14.

16. *Id.*

17. *Id.*

18. *Id.*

19. U.S. DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT AGENCY, *Order Regarding Request from a Non-Participant (Veterans Action Counsil) in the Matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana*, DEA Docket No. 1362, Hearing Docket No. 24-44 (Nov. 15, 2024).

20. VETERANS ACTION COUNCIL (VAC), Notice of Request to Present at Hearing, at 1 (Sept. 25, 2024).

21. 21 U.S.C. § 812(b)(5)(A)-(C).

22. DRUG ENFORCEMENT ADMINISTRATION, *Drug Scheduling,* (July 10, 2018), https://www.dea.gov/drug-information/drug-scheduling [https://perma.cc/9383-45DE].

articles used for components of any such article."[23] Food products are generally not subject to premarket approval unless they contain a food additive or color additive that is not listed as safe for use in food. The two basic provisions that apply to food products once they enter the market are adulteration and misbranding, addressing manufacturing and quality, and labeling and product claims, respectively. Food additives are defined as:

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use[.][24]

The definition excludes pesticide chemical residues, pesticides, color additives, substances with prior sanction, a new animal drugs, and ingredients used in dietary supplements.[25] The FDA has developed Generally Recognized as Safe (GRAS) listings that identify those food additives that have been deemed to be generally recognized as safe.[26] Products conforming to these GRAS listings, which may include constraints on type of food products, chemical structures, other allowable ingredients, and threshold levels within the food, may enter the market without premarket approval. Food additives can be either direct additives, or indirect (such as food contact substances like food packaging). The FDA has not considered hemp containing THC as a food additive under its GRAS regime.

Dietary supplements are another subset of food, though legislation carves out specific provisions for supplement labeling, product disclaimers, and use of health and disease-related claims. The definition provides that dietary supplements are:

> intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of

23. 21 U.S.C. § 321(f); Food, Drug and Cosmetic Act (FDCA) § 201(f).
24. 21 U.S.C. § 321(s); FDCA §201(s).
25. 21 U.S.C. § 321(s)(1)-(6); FDCA §201(s)(1)-(6).
26. 21 C.F.R. § §170-189.

> any ingredient described in clause (A), (B), (C), (D), or (E); (2) means a product that— (A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or (ii) complies with section 350(c)(1)(B)(ii) of this title; (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labeled as a dietary supplement.[27]

The FDA maintains that aside from hemp seed ingredients not containing THC (though derived from THC), no other cannabis-derived ingredients have been the focus of a petition for GRAS listing or otherwise approved for use in food.[28]

The FDA does, however, contemplate the regulation of medicinal products containing THC as drugs. These medicinal products are subject to stringent premarket approval requirements to establish safety and efficacy and are limited to a specific intended use.[29] The legislation defines a drug as:

> [A]rticles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article[.][30]

The FDA has not approved any drug containing cannabis, though has approved one cannabis-derived prescription drug and three "cannabis-related" prescription drug products.[31] Epidiolex is approved for the treatment of Lennox-Gastaut syndrome and Dravet syndrome seizures in patients one year and older and treatment of tuberous sclerosis complex symptoms in patients one year and older.[32] The active ingredient in Epidiolex is a purified form of CBD.[33] Both Marinol and Syndros have been approved for the treatment of anorexia associated with AIDS-related weight loss.[34] The two drugs contain dronabinol, a synthetic delta-9-tetrahydrocannabinol (THC).[35] A fourth FDA-approved drug, Cesamet, contains synthetically derived nabilone, which has a similar chemical structure to THC.[36] Cesamet is approved for the treatment of nausea

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27. 21 U.S.C. § 321(ff); FDCA §201(ff).

28. U.S. FOOD & DRUG ADMIN., *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD),* https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#farmbill [https://perma.cc/3Z8F-CKXZ] (last updated July 16, 2024).

29. 21 U.S.C. § 355(b)(1); FDCA §505(b)(1).

30. 21 U.S.C. § 321(g)(1)(B)-(D); FDCA §201(g)(1)(B)-(D). The definition also includes products listed in the U.S. Pharmacopeia/National Formulary (USP/NF). 21 U.S.C. §321(g)(1)(A); FDCA §201(g)(1)(A)).

31. U.S. FOOD & DRUG ADMIN., *FDA Regulation of Cannabis, supra* note 28.

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

and vomiting in patients undergoing cancer chemotherapy who have not responded to conventional antiemetic treatments.[37]

In January 2023, the FDA responded to citizen petitions requesting that the agency issue regulations to allow the marketing of dietary supplements containing CBD.[38] The response indicates that given available scientific evidence, the FDA does not intend to issue such a rulemaking.[39] The reasoning focuses on the fact that such products would not meet the applicable safety standards dictated by the statute and regulations. The agency issued a further statement setting forth its conclusion that the current regulatory frameworks are not appropriate for food and dietary supplements containing CBD.[40] The agency noted the need to partner with Congress to address these types of products, urging the need for a new pathway that utilizes a harm reduction approach.[41] In the enforcement context, the FDA has issued a number of Warning Letters to industry, targeted to products making medicinal claims, human and animal foods containing added CBD, products with routes of administration of concern (*e.g.*, nasal, ophthalmic, and inhalation), and delta-8 THC products specifically. The FDA has also published public announcements warning of the dangers of accidental ingestion of food products that contain THC by children.[42] Peer-reviewed studies conducting assessments of children's exposure indicate a consistent rise in exposure of pediatric populations under six years of age, including exposure involving significant toxicity from edible ingestion.[43]

II. SO, WHAT IS "HEMP"?

Congress passed the Agriculture Improvement Act (also known as the Farm Bill) in 2018, defining industrial hemp as "Cannabis sativa L. . . . with a delta-9 tetrahydrocannabinol concentration not more than 0.3 percent on a dry weight

37. Cesamet (nabilone) New Drug Approval, NDA 18-677/S-011, at 3 (2006), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/018677s011lbl.pdf [https://perma.cc/RX7H-52X6].

38. U.S. FOOD & DRUG ADMIN., *Constituent Update*, *FDA Issues Response to Three Citizen Petitions Related to CBD and Dietary Supplements,* (Jan. 26, 2023), https://www.fda.gov/food/hfp-constituent-updates/fda-issues-response-three-citizen-petitions-related-cbd-and-dietary-supplements [https://perma.cc/A8K3-52L4].

39. *Id.*

40. U.S. FOOD & DRUG ADMIN., *FDA Concludes that Existing Regulatory Frameworks for Food and Supplements are Not Appropriate for Cannabadiol, Will Work with Congress on a New Way Forward,* (Jan. 26, 2024), https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol [https://perma.cc/DVK9-GC7B].

41. *Id.*

42. U.S. FOOD & DRUG ADMIN., *FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC,* (June 22, 2022), https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc [https://perma.cc/CY59-NEAC].

43. *See, e.g.*, Marit S. Tweet, Antonia Nemanich, & Michael Wahl, *Pediatric Edible Cannabis Exposures and Acute Toxicity: 2017-2021*, 151 PEDIATRICS e2022057761 (2023).

basis," including hemp derivatives (*e.g.,* cannabidiol, CBD).[44] The Farm Bill was enacted as part of the 2018 omnibus appropriations bill dealing with food and agriculture and was recently extended for an additional year through September 30, 2025.[45] The legislation removed hemp from regulation by the DEA under Schedule I of the CSA.[46] However, hemp is still subject to regulation by the FDA under the Food, Drug, and Cosmetic Act.[47] The National Academies of Sciences, Engineering and Medicine released an extensive report in September 2024 with recommendations for federal policymakers on ways to uniformly address and implement health standards for federal marijuana regulation.[48] The study scrutinized existing law and policy and specifically assessed the variations in state laws that have legalized cannabis, as well as policy surrounding intoxicating hemp products.[49] The study identified a problematic loophole in the Farm Bill of 2018 that effectively legalized industrial hemp yet allowed synthetic versions of synthetic cannabinoids derived from hemp that had psychoactive effects.[50] Additionally, while there is a 0.3 percent concentration limit in the Farm Bill for industrial hemp,[51] there is no weight limit (*i.e.,* milligram limit) for agricultural hemp products.

As discussed above, food products, including beverages and dietary supplements, containing hemp are currently present in the market in a variety of forms and are subject to oversight by the FDA under exiting authority over food and food additives. Given the language of the Farm Bill, which gives a concentration limit but no weight limit and does not apply to synthetic products, companies are shifting focus to using hemp derivatives like cannabidiol as food ingredients and additives. They are also engaging in targeted marketing campaigns directed to youth and CBD users and often developing packaging that appears like typical grocery products. The FDA makes warning letters to allegedly violative products containing CBD and other cannabis-derived products publicly available on its website.[52] Most of the letters address drug or biologic products rather than hemp, though several address adulteration issues within facilities manufacturing hemp food products or problems with inaccurate

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44. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 stat. 4908 (2018) (also known as the Farm Bill), codified at 7 U.S.C. §1621 et seq.

45. American Relief Act of 2024, Pub. L. No. 118-158, 138 stat. 1723 (2024).

46. Pub. L. No. 115-334, 132 stat. 4908, at §12619(b).

47. 21 U.S.C. §201; FDCA §101.

48. NAT'L ACAD. OF SCI., ENG'G & MED., *To Protect Public Health, Federal Government Should Provide Guidance to States that Have Legalized Marijuana, Close Hemp Regulatory Loopholes, Create Public Health Campaign,* (Sept. 26, 2024), https://www.nationalacademies.org/news/2024/09/to-protect-public-health-federal-government-should-provide-guidance-to-states-that-have-legalized-marijuana-close-hemp-regulatory-loopholes-create-public-health-campaign [https://perma.cc/Y2R3-DEBU]; NAT'L ACAD. OF SCI., ENG'G & MED., CANNABIS POLICY IMPACTS PUBLIC HEALTH AND HEALTH EQUITY (Nat'l Acads. Press, 2024).

49. *Id.*

50. NAT'L ACAD. OF SCI., ENG'G & MED., *To Protect Public Health, supra* note 48.

51. *Id*.

52. U.S. FOOD & DRUG ADMIN., *Warning Letters for Cannabis-Derived Products,* https://www.fda.gov/news-events/public-health-focus/warning-letters-cannabis-derived-products [https://perma.cc/NH4R-HWZD] (last updated Nov. 20, 2024).

labeling of ingredients.[53]

Language in the most recently proposed Farm Bill would address the increasing marketing of synthetic products by excluding from the definition of hemp any "hemp-derived products containing cannabinoids not naturally produced in the cannabis plant or that are naturally produced but were synthesized or manufactured outside of the plant" or "quantifiable amounts of any THC or any cannabinoids that have or are marketed to have similar effects as THC."[54] This language would effectively remove delta-8 products and other intoxicating synthetic cannabinoids that are becoming commonplace in smoke shops and other outlets. However, as of the end of last session, Congress has passed another one-year extension of the existing provisions in the 2018 Farm Bill.

III. CALIFORNIA'S REGULATORY ACTION AND RESULTING LITIGATION

California's action to regulate hemp in food products comes in the wake of the years of inaction by the FDA to clarify regulation of hemp and CBD in foods. While the FDA has pledged to partner with Congress to explore the need for development of statutory and regulatory regimes specific to CBD and hemp, there remains no consistent or predictable oversight. On September 13, 2024, Governor Newsom announced that California's Department of Public Health introduced a *Notice of Proposed Emergency Regulatory Action Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp*.[55] The notice was issued under the authority of the California Health and Safety Code. Section 11065 of the Code provides that the "department may adopt any regulations that it determines are necessary"[56] and "may adopt emergency regulations to implement" those regulations.[57] The Code continues by providing that "[i]nitial regulations regarding industrial hemp shall be exempt from the Administrative Procedure Act"[58] except that "the department shall post the proposed regulations on its internet website for public comment for 30 days."[59]

The *Notice of Emergency Regulatory Action* contains three core features. The first is prohibitory language indicating "[a] person shall not manufacture, warehouse, distribute, offer, advertise, market, or sell industrial hemp final food products intended for human consumption including food, food additives,

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53. *Id.*

54. *Farm, Food and National Security Act of 2024,* H.R. 8567, 118th Cong. (2024); McGlinchey Stafford, *Major Changes Could be in Store for Hemp in 2025*, JD SUPRA (Nov. 6, 2024), https://www.jdsupra.com/legalnews/major-changes-could-be-in-store-for-4508582/ [https://perma.cc/J6GX-6ET6].

55. CAL. DEP'T OF PUB. HEALTH, Finding of Emergency, Regulations for Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp, DPH-24-005E (Sept. 13. 2024), https://www.cdph.ca.gov/Programs/OLS/CDPH%20Document%20Library/DPH-24-005E-FindingsText.pdf [https://perma.cc/Q4J3-2UF6].

56. CAL. HEALTH & SAFETY CODE § 110065(a).

57. CAL. HEALTH & SAFETY CODE § 110065(a) & (b)(1).

58. CAL. HEALTH & SAFETY CODE § 110065(c).

59. *Id.*

beverages, and dietary supplements that are above the limit of detection for total THC per serving."[60] As the Department of Public Health explains, this bans any detectable THC or intoxicating cannabinoids per serving from final food products derived from hemp.[61] The second feature is an age restriction of 21 years old for the offer or sale of such products. The third is a provision limiting serving and package sizes.[62] The effective date for the emergency regulatory action was September 23, 2024.[63] The notice included reference to the intoxicating effects of hemp cannabinoids, the negative impact on cognitive functioning, and "significant reports of hospitalizations among teenagers and young adults."[64] The notice also stated that current California state law is stricter than the Farm Bill because it limits delta-8 THC, delta-9 THC, and "any intoxicating cannabinoid as defined by the department to 0.3% or less."[65] The law also states that industrial hemp "cannot be synthetically derived or contain any THC isolates."[66] The Department's Office of Communication notes that the regulations do not ban hemp-derived CBD products that do not contain detectable levels of THC or intoxicating cannabinoids, nor does it ban cannabis products.[67]

Shortly after Governor Newsom's announcement of the notice of emergency regulatory action, representatives for industry sued, challenging the action under both federal and state law, and alleging violations of procedural due process.[68] The primary trade organizations for the hemp industry, U.S. Hemp Roundtable, Inc., along with Cheech and Chong Global Holdings, Inc., alleged that the action violated California's administrative procedures and federal and state laws, including the Farm Bill and California's own laws.[69] Plaintiffs moved for a temporary restraining order, arguing they would suffer lost revenue if the ban were to be enforced.[70] On October 11, 2024, Judge Goorvitch in the Superior Court of California, Los Angeles County, denied the request for a temporary restraining order, finding a lack of showing of irreparable harm to their business operations, noting that the state's interest in the protection of consumers outweighed the parties' interests in selling hemp products.[71]

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60. CAL. DEP'T OF PUB. HEALTH, Finding of Emergency, *supra* note 55.

61. CAL. DEP'T OF PUB. HEALTH, *California's Ban on Intoxicating Hemp Products Now in Effect*, (Sept. 24, 2024), at https://www.cdph.ca.gov/Programs/OPA/Pages/NR24-26.aspx [https://perma.cc/VA2P-QPFT].

62. CAL. DEP'T OF PUB. HEALTH, Finding of Emergency, *supra* note 55.

63. *Id.*

64. *Id.*

65. *Id.*; CAL. GOVERNMENT CODE § 11018.5.

66. CAL. DEP'T OF PUB. HEALTH, Finding of Emergency, *supra* note 55.

67. CAL. DEP'T OF PUB. HEALTH, *California's Ban, supra* note 61.

68. U.S. Hemp Roundtable, Inc., et al., v. California Department of Public Health, et al., Order Denying Ex Parte Application for TRO, Case No. 24STCPO3095 (Cal. Super. Ct. Oct. 10, 2024).

69. *Id.*

70. *Id.*

71. *Id.*

In his order denying the temporary restraining order, Judge Goorvitch also interpreted the California law. He concluded that the language exempting industrial hemp from the Administrative Procedure Act does not apply to regulations adopted pursuant to other sections of the Health and Safety Code expressly cited.[72] Those sections cited authorize the Department of Health and Safety to adopt regulations pertaining to "active cannabinoid concentration per serving size"[73] and "imposing an age requirement for the sale of certain industrial hemp products upon a finding of a threat to public health.[74] Judge Goorvitch determined that the state administrative procedure act further provides that for emergency regulations adopted by the Department of Health, any finding of emergency must be presented in written form and contain specific facts demonstrating the existence of that emergency and the need for immediate action.[75] The department must also "demonstrate, by substantial evidence, the need for the proposed regulation to effectuate the statute being implemented, interpreted, or made specific and to address only the demonstrated emergency."[76] Judge Goorvitch concluded that the state seemed to have complied with all of the requirements, leaving a genuine question as to whether the petitioners would prevail on the merits.[77]

California has begun enforcement activities under the new regulations. A February 2024 study authored by the Pew Research Center reports that over one thousand illegal cannabis stores operate in Los Angeles County alone, many of which carry the newly prohibited food and beverage items.[78] The state's Department of Alcoholic Beverage Control, along with the Department of Cannabis Control, has announced that they "will enforce all California laws and regulations" through the work of "cannabis and tobacco inspectors."[79]

III. STATE AND INTERNATIONAL ACTIVITIES TO BAN OR RESTRICT INTOXICATING HEMP PRODUCTS

In addition to California, at least ten other states have adopted laws somehow restricting sales or access to products containing hemp-derived cannabinoids, though California's is regarded as one of the most restrictive of

72. *Id.*

73. CAL. HEALTH AND SAFETY CODE § 111922.

74. CAL. HEALTH AND SAFETY CODE § 111921.3.

75. CAL. GOVERNMENT CODE § 11346.1(b)(2).

76. *Id.*

77. U.S. Hemp Roundtable, Inc., et al., v. California Department of Public Health, et al., Order Denying Ex Parte Application for TRO, Case No. 24STCPO3095, at 7 (Cal. Super. Ct. Oct. 10, 2024).

78. Connor Sheets, *Why Did California "Kill" Its Booming Heal-derived THC Industry*?, LA TIMES (Nov. 25, 2024), https://www.latimes.com/california/story/2024-11-25/california-thc-ban-hemp-industry-fallout [https://perma.cc/2AYJ-3DEQ].

79. Governor Gavin Newsom, *Governor Newsome Issues Regulations To Protect Kids From Dangerous and Intoxicating Hemp Products*, (Sept. 6, 2024), https://www.gov.ca.gov/2024/09/06/governor-newsom-issues-regulations-to-protect-kids-from-dangerous-and-intoxicating-hemp-products/ [https://perma.cc/TE2L-J2GH].

the state laws. [80] A comparative analysis of these laws is outside the scope of this article, though there are useful practitioner materials that summarize the legislation.[81] Other states with current relevant laws in effect are Connecticut, Florida, Georgia, Iowa, Kentucky, Oregon, South Dakota, Tennessee, Utah, West Virginia, and Wyoming.[82] Governor Mike Parson of Missouri also signed an Executive Order to remove all hemp-derived THC beverages and edibles on August 1, 2024, which was subsequently challenged in court.[83] The outcome of the order's legality is pending, and the state has not been enforcing the prohibitions.[84] Three additional states (Illinois, Louisiana, and Ohio) have also proposed legislation that would impose various elements of THC limits, age restrictions, label requirements, and marketing restrictions.[85]

International frameworks regarding regulation also vary. On the issue of hemp and hemp-derived cannabinoids in food products, some regions and countries have enacted specific regulations and guidance for legally allowable conditions for marketing and sale, while others have highly restricted use in beverages and food.[86] For example, although hemp has been long recognized for medicinal effects in China, it is unclear how hemp-derived food products containing CBD will be characterized by authorities.[87] Likewise, efforts in Europe by the European Commission to determine whether CBD in food is within the scope of the United Nations Convention have proven challenging, and products not falling within the scope of the convention are subject to the European Union's novel food regulation scheme that requires premarket approval.[88] This regulatory scheme is similar to the GRAS listing process implemented by the FDA. One example of supporting regulatory action is that of Thailand, a country that has affirmatively allowed CBD from hemp seeds in

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80. *See* Andrea Golan, *Newly Enacted Hemp Laws in 2024: Key Regulatory Updates Across the US,* VINCENTE LLP INSIGHTS (May 28, 2024), https://vicentellp.com/insights/newly-enacted-hemp-laws-in-2024-key-regulatory-updates-across-the-us/ [https://perma.cc/2LGT-SZ29perma].

81. *Id.*

82. *Id.*

83. *See* Rebecca Rivas, *Missouri Hemp Leaders File Suit to Halt Governor's Ban on Hemp THC Products*, MISSOURI INDEPENDENT (Aug. 20, 2024), https://missouriindependent.com/2024/08/30/missouri-hemp-leaders-set-to-file-suit-to-halt-governors-ban-on-hemp-thc-products/ [https://perma.cc/VR56-4UUZ]; Stephen L. Bartlett, *Showdown in the Show Me State: New Hemp Executive Order Sparks Litigation and Subsequent Clarification from MO DHSS*, FOLEY HOAG (Sept. 18, 2024), https://foleyhoag.com/news-and-insights/blogs/cannabis-and-the-law/2024/september/showdown-in-the-show-me-state-new-hemp-executive-order-sparks-litigation-and-subsequent-clarificat/ [https://perma.cc/ZNK8-E8E6].

84. Rebecca Rivas, *"Hemp Sales are Back On": Missouri Regulators Pare Down Ban on Intoxicating Hemp Products*, MISSOURI INDEPENDENT (Sept. 18, 2024), https://missouriindependent.com/2024/09/18/hemp-sales-are-back-on-missouri-regulators-pare-down-ban-on-intoxicating-hemp-products/ [https://perma.cc/8VSE-KM2F].

85. Golan, *supra* note 80.

86. David Pineda Eneño, *Global Regulatory Trends in CBD Use in Food and Food Supplements*, REGULATORY FOCUS (Jun. 2021), https://rapsprod.blob.core.windows.net/rapsk13/raps/media/news-images/feature%20pdf%20files/21-6_pineda.pdf [https://perma.cc/E9XL-B8T4].

87. *Id.*

88. *Id.*

food, including express conditions of use and limits on CBD and THC levels.[89]

CONCLUSION

State, federal, and global efforts to develop hemp regulation for food products are in the early stages, with the loopholes in legislation and innovations in synthetic derivatives causing increasing concern about public health. California's approach offers insights on how states may utilize their own administrative law and public health laws to effectuate change in the absence of federal policy.

89. *Id.*