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Current and Emerging Issues for Ag Tech

Does GDPR Apply to Ag Data?

With the May 24, 2018 deadline for compliance the European Union's General Data Protection Regulation (GDPR), ag data companies may be wondering whether their privacy policies need to be in compliance with the EU's regulation. This is the first in a series of posts on GDPR and its impacts on north American ag data platforms.

This post will answer the threshold question: Does the GDPR apply to collection of ag data in North America?

To answer this question, two definitions from the GDPR are important: "personal data" and "ag data."

The GDPR applies only to "personal data" collection. Personal data is defined in the GDPR as:

> any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

GDPR, Art. 4, 1. There is lot in that paragraph, so let's break it down into its constituents. The first required element here is that personal data is from a "natural person." This means data generated by tractors, farm equipment, cows, or pigs are not covered by the GDPR--only data related to people.

The second required element is that the data contains "reference to an identifier" tied to that natural person. The definition gives us lots of examples, including name, ID numbers, location data, and other identifiers related to physical, physiological, genetic or cultural characteristics.

Of these, only "location data" potentially applies to ag data since yield data, planting data, machine data, etc. all include location information. Still, I do not think that is enough to bring ag data into the definition of the GDPR's "personal data" since these data streams are not tied to, or related to, a natural person.

My conclusion might be different if an ag data platform recorded location information about specific employees which is cross-referenced to collected ag data. For example, if a platform recorded not only machine location data but also which employee was driving that machine, this might pull "machine data" into GDPR's personal data definition.

In general, however, ag data is not "personal data." GDPR authorizes organizations to create "codes of conduct" for specific data uses. A number of EU farm organizations recently created an EU Code of Conduct on Agricultural Data Sharing by Contractual Agreement. This document defines "ag data" as inclusive of a number of data streams, including: farm operation data, agronomic data, compliance data, livestock data, machine data, service data, agri-supply data, and agri-service provider data. These definitions are different than "personal data" since they are not tied to a natural person.

Back to the question: does the GDPR extend to protect ag data? In general, the answer is "no," ag data is not "personal data." But, there may be examples where ag data does fit within this definition. All ag tech providers should examine this issue for their unique situation.

What Does it Mean to Be "Ag Data Transparent"?

John Deere's announcement that it had certified the John Deere Operations Center as "Ag Data Transparent" this week might have you wondering, what exactly does that mean? This post answers that question. But first, a quick history lesson about how we got here.

Ag Data's Core Principles

In 2014, American Farm Bureau Federation (AFBF) observed that many of its farmer-members were concerned about the variety of new ag data products that were arriving on the market. What would happen to ag data once provided to these platforms? Would the tech providers use this data for their own purposes? Could the farmer ever get this data back? Should they trust these providers, which included legacy companies like John Deere that were developing new cloud-based products, as well as new start ups from Silicon Valley and the Midwest?

To address these concerns, AFBF hosted a series of meetings with representatives of other interested farm groups, such as American Soybean Association, National Corn Growers, National Association of Wheat Growers, National Farmers Union, and National Sorghum Producers. These organizations had similar concerns.

Ag tech providers were also invited. Representatives from the big equipment manufacturers were there: Deere, CNH, AGCO, as well as large seed and chemical companies, Dow, DuPont, and Monsanto. Smaller and start-up ag tech companies were there too. (I was fortunate to attend a couple of these meetings.)

After a series of these meetings, the group drafted *The Privacy and Security Principles for Farm Data*, or what today we call ag data's "***Core Principles***." These Core Principles represented basic guidelines that ag tech providers should following when collecting, using, storing, and transferring farmers' ag data. After publishing, 37 different companies signed onto the Core Principles, pledging to incorporate them into their contracts with farmers.

The Ag Data Transparent Seal

Of course, a pledge to follow non-binding guidelines is good, but incorporating the Core Principles into actual data contracts is much better.

To verify compliance with the Core Principles, AFBF and the other interested organizations and companies formed the Ag Data Transparency Evaluator, Inc., a non-profit organization (ADT) to audit companies' ag data contracts. This organization developed the Ag Data Transparent seal of approval (above). Much like the Good Housekeeping seal of approval verifies compliance with Good Housekeeping's standards, the Ag Data Transparent seal recognizes compliance with the Core Principles.

How do companies get the Ag Data Transparent seal?

Companies that want to be recognized as Ag Data Transparent must submit their contracts with farmers for certification to the ADT. In addition, companies must answer 10 questions about how they collect, store, use, and share farmers' ag data. The contracts and answers to the 10 questions are then reviewed by a third party administrator* for accuracy. If the answers match what the company's contracts say, the Ag Data Transparent seal is awarded. If there is a discrepancy, the company is required to make a change before the seal is awarded.

Each of the 10 questions is based upon one or more of the Core Principles. For example, one principle is *portability*--farmers should be able to move ag data from one platform and use it in another. Accordingly, question 4 asks: *After I upload data to the Ag Tech Provider, will it be possible to retrieve my original complete dataset in an original or equivalent format?*

Participating companies must answer yes or no and provide an explanation. The final results are posted only at the Ag Data Transparent website so that farmers, agronomists, and other ag professionals can review. The results also include hyperlinks to the companies' ag data contracts, in case someone wants to more closely examine a particular answer.

When a participating company changes or updates its ag data contracts, the company's answers must be updated as well if they want to continue to use the Ag Data Transparent seal.

What can you do to help?

Many companies that collect ag data have not yet agreed to follow the ag data Core Principles. (Read: Few Big Ag Companies have yet to follow through on data transparency pledge). This should be step one. Many have signed onto the Core Principles, but not achieved the Ag Data Transparent certification. This should be step two.

Ask your ag tech provider to incorporate the Core Principles into their contracts with farmers. Ask your provider to become Ag Data Transparent. Congratulate those companies that have already taken these steps.

What Does Blockchain Mean for Agriculture?

One of my predictions for 2018 was that we would start hearing about blockchain implications for agriculture. But I did not expect it would be this quick.

On January 22, 2018, Reuters reported that a Louis Dreyfus Co. transported a shipload of soybeans from the US to China using blockchain as to documentation tool. The sales contract, letter of credit and certificates were digitalized on the Easy Trading Connect (ETC) platform.

The US soy shipment did not involve Bitcoin or other cryptocurrency, which often goes hand-in-hand with blockchain, but it is still a big step.

For those new to blockchain, think of it as decentralized ledger recording various transactions in a process. Rather than record transactions in a central, single database, blockchain syncs various databases together creating a digital record that, in theory, is difficult to tamper with or hack. Bitcoin is a blockchain.

Blockchain, as it was used here, simplified the paperwork necessary to transport and transfer a shipload of soybeans.

The real challenge for agriculture will be figuring out how to combine blockchain record keeping with easy to move funds from buyers to sellers.

Still, the US soy transaction is a sign that blockchain has some real potential for transfer of agricultural commodities. Blockchain can help simplify record keeping, documentation of payment, and traceability. Reducing these burdens on agriculture should reduce transaction costs, and as a result, ultimately return more money to the farmer.

Will OSHA be an Obstacle for Robotic Farm Equipment?

The talking points surrounding robotic farm equipment usually focus on the decreased need for humans to interface with machines. We use words like "driverless" and "autonomous" to describe the lack of human involvement with farm equipment. Marketers talk about the shortage of farm labor and the ability to do more with fewer employees. For the most part, as long as driverless machinery stays in the field and off of public roads, there are few regulations that prevent these new technologies.

But what about farm-worker safety around autonomous farm vehicles?

Perhaps this is the question that drove California to add regulations prohibiting driverless machinery unless a person remains at the wheel (somewhat defeating the point). California's OSHA regulations require all "self-propelled equipment" to have an operator "stationed at the vehicular controls" whenever the machine is moving. There is an exception for furrow guided equipment, which allows an operator to control the vehicle remotely provided he or she stays within 10 feet of the controls and the equipment is not moving at greater than 2 mph.

Here is the full text of the California OSHA regulation:

> *All self-propelled equipment shall, when under its own power and in motion, have an operator stationed at the vehicular controls. This shall not prohibit the operator occupying or being stationed at a location on the vehicle other than the normal driving position or cab if controls for starting, accelerating, decelerating and stopping are provided adjacent and convenient to the alternate position. If the machine requires steering other than ground or furrow steering or operates at ground speeds in excess of two miles per hour, steering controls shall also be provided at the alternate location.*

Seedling planters and other similar equipment traveling at a speed of two miles an hour or less where a control that will immediately stop the machine is located at the operator's work station will satisfy this requirement.

Furrow guided self-propelled mobile equipment may be operated by an operator not on the equipment provided that all of the following are complied with:

(A) The operator has a good view of the course of travel of the equipment and any employees in the immediate vicinity.

(B) The steering controls, when provided, and the brake and throttle controls are extended within easy reach of the operator's station.

(C) The operator is not over 10 feet away from such controls and does not have to climb over or onto the equipment or other obstacles to operate the controls.

(D) The equipment is not traveling at over two miles per hour ground speed.

I have not found any other states that have imposed similar restrictions on driverless farm equipment. The federal OSHA regulations, upon which state regulations are based, do not include this driverless prohibition.

I understand that California agriculture includes a number of specialty crops that require slow moving farm equipment saddled with many workers close by on implements or in the field. This regulation appears to be aimed at protecting those workers' safety. However, I can't help but think this is also road block for new driverless farm technologies--at least in California.

If you are aware of other laws or regulations that restrict driverless technologies on the farm, please let me know.

Can an Ag Tech Provider Collect Data without Your Consent?

During a recent webinar, an audience member asked: "Can a machine track and send data to the manufacturer without the owner's consent?" I think you could even broaden this question to ask: "Can a machine can send data to a manufacturer without the owners' knowledge?"

From my research, the general answer to this question is "yes." A manufacturer can track information from their machine and send that data back to the manufacturer without the owner's consent, or even without the owner's knowledge.

There are likely many exceptions to this general answer, however. If the transmission of data includes personally identifiable information, the transmission may be subject to certain state laws protecting personal information.

There are also state statutes and common law that protect person's right to privacy. Unauthorized data sharing from a machine might violate these statutes or case law. For example, a machine that collects video might collect images that would be protected by certain state privacy statutes.

The Privacy and Security Principles for Farm Data provide this guidepost for this issue:

> *An ag tech provider's collection, access and use of farm data should be granted only with the affirmative and explicit consent of the farmer. This will be by contract agreements, whether signed or digital.*

This principle is not legally binding, but a court may look to statements like this as what is commonly accepted practice in the ag tech industry. This could be helpful when determining what is the expected standard of care for an ag tech provider.

Tesla collects data from its drivers' cars. Here is what Tesla asks its customers before collecting video information:

> *We are working hard to improve autonomous safety features and make self-driving a reality for you as soon as possible.*
>
> *In order to do so, we need to collect short video clips using the car's external cameras to learn how to recognize things like lane lines, street signs, and traffic light positions. The more fleet learning of road conditions we are able to do, the better your Tesla's self-driving ability will become.*

We want to be super clear that these short video clips are not linked to your vehicle identification number. In order to protect your privacy, we have ensured that there is no way to search our system for clips that are associated with a specific car.

Please click "I accept" below in order to allow us to collect these clips. You can change or mind at any time. (Quote from Electrek.com)

I think Tesla has the correct approach. It is OK to collect data from your customers, but ask first, anonymize the information, and give customers the option of changing their mind later. Put this in your contract.

As attorneys we often tell clients: Just because something is legal, does not mean it is advisable. The same is true with collecting data without affirmative consent.

What's Old is New Again: What New Holland's Methane Tractor Means for Ag

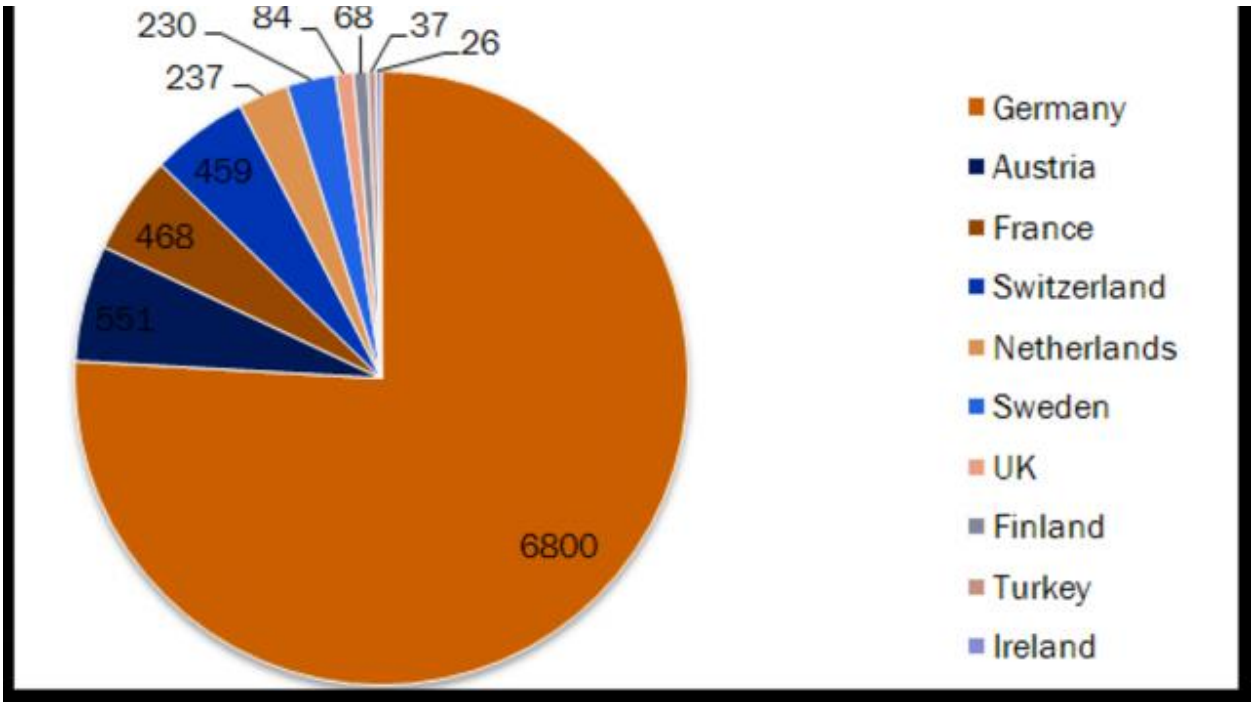
At a recent Farm Progess Show, New Holland rolled out a new concept tractor that appeared mostly conventional but had one stand out feature--it runs on methane rather than diesel. My first impression when seeing this was--*didn't we have this same concept 50 years ago?* Growing up, our farm included an International 504 LP than ran on natural gas (until it spectacularly caught on fire when I was about 10). Is the New Holland concept any different?

The New Holland tractor unveiled at Farm Progress Show is powered by a 180 hp bio-methane engine. New Holland (CNH) claims that it has identical performance to a diesel tractor but produces ultra-low emissions and a "virtually zero CO2 profile." Another benefit is a 50% reduction in drive-by noise levels, making the tractor well suited to livestock operations. Read more about the concept at CNH's website.

This made me think back to the popularity of LP tractors during my childhood. John Deere, Case, IH, Ford, and others all had LP tractors on the market in the decade that proceeded my farming youth. These machines took advantage of low LP prices that made these models more economical in some parts of the US than their diesel or gas equivalents.

New Holland's methane tractor is different because it addresses different problems. Sustainability is the holy grail of farming. If farms can be self-sustaining and energy independent, there is no reason they cannot continue for generations to come. Sustainable farms must produce not only food, but energy too.

There are relatively few farms in the US that generate methane, but other countries have widely embraced construction and use of anaerobic digesters on farms. Here is a graph from 2011 that shows farms in the European Union with anaerobic digesters. Germany had 6800. The entire US at this time had 167. (Indiana had 7). Farmers I've talked to say the cost/benefit does not work in the US unless you are a really large livestock farm.



SOURCE: CENTER FOR CLIMATE AND ENERGY SOLUTIONS

The New Holland methane tractor concept also addresses climate change concerns. If powered by methane generated by a farm, the resulting CO2 emissions are "virtually zero" according to CNH. Many in the US may think climate change irrelevant, but the issue is arriving on US farms whether farmers embrace it or not. I see climate change in contracts between farmers and purchasers of raw farm products more and more. For example, many milk purchasers are starting to require the farms

they purchase milk from to reduce their carbon emissions. How long before certain countries only buy "low-carbon" grain. A methane tractor could help these farms produce products that meet these standards.

When my grandfather purchased an International LP tractor he likely didn't even know that its emissions were less than the diesel equivalent. How ironic that the 1950's technology is new once again, but for entirely different reasons.

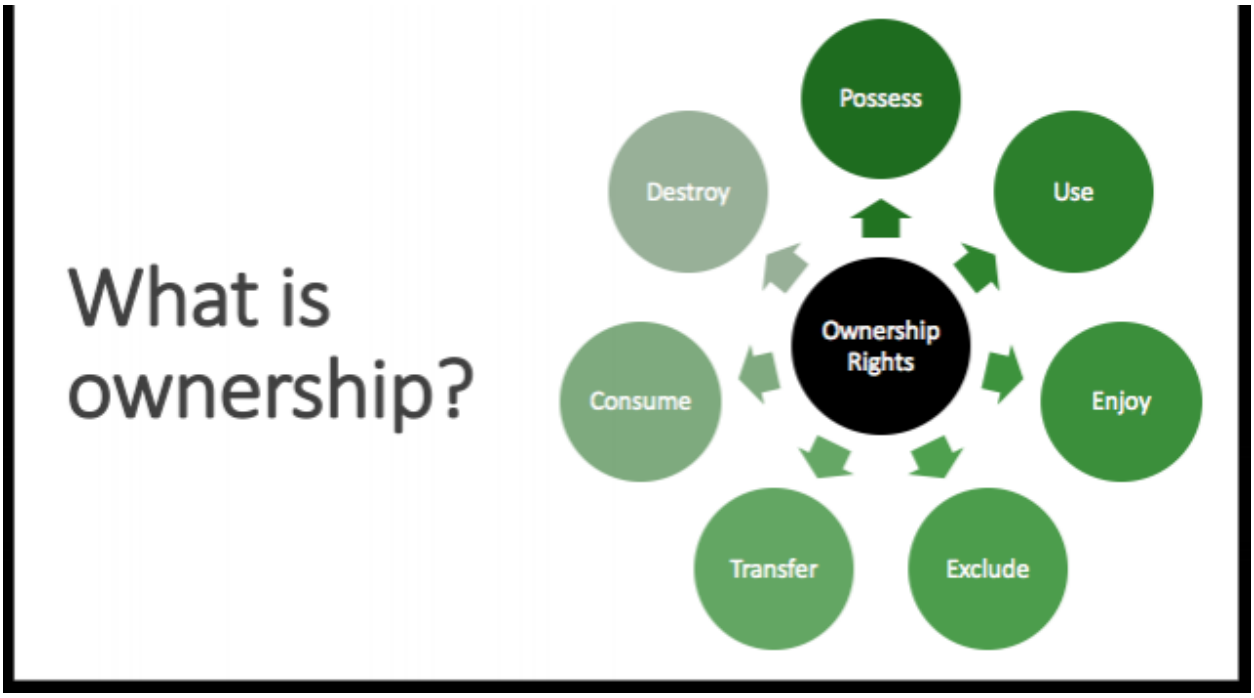
Breaking Down Ag Data Ownership

Over two years has passed since American Farm Bureau Federation (AFBF) led an industry coalition to address issues of surrounding ag data ownership, privacy, and security. When AFBF published the "Privacy and Security Principles for Farm Data"--or as I call them, the ag data's "Core Principles," I expected the industry uptake to be swift. Companies enthusiastically signed on. But here we are, two years later, and many ag tech providers still do not get it--ag data is not just 1s and 0s, but proprietary information that should be grounded in an ownership principle.

The Core Principle's statement on "ownership" was pretty easy to understand:

> ***Ownership:*** *We believe farmers own information generated on their farming operations. However, it is the responsibility of the farmer to agree upon data use and sharing with the other stakeholders with an economic interest, such as the tenant, landowner, cooperative, owner of the precision agriculture system hardware, and/or ATP etc. The farmer contracting with the ATP is responsible for ensuring that only the data they own or have permission to use is included in the account with the ATP.*

You could break this down into a few parts. First, the general principle is **that farmers own the data created on their farms**. Second, there are multiple stakeholders that may have an interest in the farmer's data when using online platforms. Third, farmers are responsible for making sure the data they upload is theirs, or used by permission. This ownership principle is fairly straightforward.



"Ownership" as a legal concept is more complicated. You can only own something if the law recognizes that an ownership right. "Ag Data" is not a traditionally recognized type of property, subject to ownership. In the US, our laws recognize ownership of real property (land), improvements (buildings), personal property (goods), and even animals. Ag data is none of these.

US laws also recognize ownership of "intellectual property" or "IP" in a few instances. You can own a patent on a new invention. You can own a trademark or service mark. You can own a copyright in an original literary, musical, theatrical or other creative work. Ag data doesn't fit into these traditional IP classifications.

That leaves only two options for establishing ownership of ag data. The first option is to view ag data a farmer's "trade secret." The Uniform Trade Secrets Act, which has been adopted in similar forms in most states, defines a trade secret as:

> *Information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.*

In short, a trade secret is something that only the farmer knows, that has economic value to the farmer, and that another person could not easily identify or reverse engineer.

Not all ag data fits this definition. Not all ag data are protected trade secrets. But clearly some ag data is the type of information that a farmer considers his or her trade secret.

The other option for recognizing ownership in ag data is legislative. Congress could enact laws that protects ag data, prohibiting copying or distributing without a farmer's consent. Congress has done this medical data, for example (HIPAA). But nothing like this exists for ag data.

All of this points to one fact. Whether a farmer owns his or her data after transferring it to a cloud-based platform is dependent on the contracts the farmer signs with the provider. If the contracts do not treat ag data as a protected trade secret, saying the farmer owns their data is an empty promise. Ownership means nothing if the farmer has no control.

Before signing up for an ag data platform, farmers should ask what the provider's position is on ag data ownership. Farmers can also look on the Ag Data Transparent website (www.agdatatransparent.com) and see how the provider answered that question when under review. If the provider is not "Ag Data Transparent" certified, farmers should ask why.

Outline for Analyzing Federal Motor Carrier Safety Administration Regulation: Applicability for Agriculture

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Recent regulations written by the Federal Motor Carrier Safety Administration (FMCSA) have led to much concern in the agricultural industry. While a waiver from compliance with the ELD requirements for persons transporting of "agricultural commodities" is in place until June 18, 2018, and another waiver from the ELD requirements exists for persons transporting of livestock and insects is in place until September 30, 2018, once these regulations go into effect they impose requirements on vehicles hauling property, including horses and livestock. The rules are complex and can be confusing, particularly for people involved in agriculture, stock and horse showing, and rodeoing who may have never dealt with this type of regulations before. This outline, focused specifically on agriculture, attempts to assist a hauler in determining whether the requirements of a commercial driver's license, hours of service records, or an electronic logging device may apply. Importantly, this outline **does not** address state-level hauling regulations that may differ from these federal rules. Drivers should consult with their state Department of Transportation with any questions as to state rules and regulations.

1. Am I operating my vehicle in "commerce?"

a. The FMCSA regulations, including ELD, HOS, and CDL requirements, apply only if a person is operating a vehicle "in commerce." State-level requirements, such as the requirement that a driver have a CDL, may apply regardless of whether "commerce" is involved.

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b. Under the federal regulations, the definition of "commerce" is broadly written: "commerce" is "trade, traffic, or transportation in the United States."
c. The FMCSA guidance documents, however, articulate a more narrow definition.
    i. FMCSA states that a vehicle is not traveling "in commerce" and, therefore, is not required to comply with FMCSA regulations if the vehicle is "non-commercial" or is "not business related." They further explain this to be a situation where a driver is not "engaged in an underlying business related to the move" and is not hauling for compensation.
    ii. Scholarship or prize money being offered does not mean that the transportation is necessarily business related.
    iii. Examples of this, taken from FMCSA guidance:
        1. Hauling horses or livestock to shows and events when the transportation in question is not business related;
        2. Transportation unrelated to an agricultural business, such as a cattle rancher that owns horses for personal use, unrelated to that cattle ranch.

2. If I am operating my vehicle in "commerce," am I operating in "interstate" or "intrastate" commerce?

a. Under the FMCSA regulations:
    i. "Interstate commerce" is trade, traffic, or transportation involving the crossing of a state boundary.
    ii. "Intrastate commerce" is trade, traffic, or transportation within a single state.
b. If a person is engaged in <u>interstate commerce</u>, he or she is subject to all federal FMCSA regulations, including each of the ones outlined below.
c. If a person is engaged in <u>intrastate commerce</u>, he or she is subject to the federal CDL requirements, as well as any CDL requirements specific to the state in which the person operates. The person is not subject to the federal FMCSA requirements for ROD and ELD outlined below, but is responsible to comply with any state-level requirements, which may or may not mirror these federal requirements. Please contact your state Department of Transportation or similar department for more information.

Each state establishes its own CDL requirements, but minimum federal standards must be met. The below outline reflects federal standards, including the "covered farm vehicle" exception.

3. What is the "Gross Combination Weight Rating" (GCWR), "Gross Vehicle Weight Rating" (GVWR), and "Gross Vehicle Weight" (GVW) for my vehicle?

a. GCWR is the value specified by the manufacturer of the power unit if displayed on the FMVSS certification label, or the sum of the gross vehicle weight ratings (GVWR) or gross vehicle weights of the power unit and the towed unit, whichever is greater.
b. The GVWR is an amount specified by the manufacturer as the loaded weight

Example*: For a Ford F-250, the GCWR ranges between 19,500-25,700. The GVWR is 10,000. For a 11' x 6 ' x 7' bumper pull stock trailer and for a 12' x 6' x 6'6" gooseneck trailer, the GVWR is 7,000. Thus, the GCWR of 25,700 is greater than the GVWR for the pickup and trailer of 17,000. As a result, you would use the GCWR*

of a single vehicle. This is generally printed on a sticker applied to the trailer, perhaps on the escape door or on the frame.

c. GVW is the actual weight of the vehicle.
d. GCW is the actual weight of the vehicle and towed unit.

4. Do I need a Commercial Driver's License (CDL)?

a. Required for operator of a "commercial motor vehicle" (CMV) in interstate, foreign, or intrastate commerce.
b. What is a "CMV?"
    i. A motor vehicle or combination of motor vehicles used in commerce to transport passengers or property if the vehicle is a:
        1. Combination Vehicle (Class A): Has a GCWR or GCW over 26,001 pounds inclusive of a towed unit with a GVWR or GCW of over 10,000 pounds;
        2. Heavy Straight Vehicle (Class B): Has a GVWR or GVW of more than 26,001 pounds
        3. Small Vehicle (Class C): Does not meet Class A or B, but is designed to transport 16 or more passengers or, regardless of size, is used to transport hazardous materials.
c. Is the vehicle a "covered farm vehicle?"
    i. Drivers of a "covered farm vehicle" are exempt, and not required to obtain a CDL if the vehicle is:
        1. Registered in a State with a license plate or other designation issued by the state that allows law enforcement officials to identify it as a farm vehicle;
        2. Operated by the owner or operator of a farm or ranch, or employee or family member of the farm owner;
        3. Used to transport agricultural commodities, livestock, machinery, or supplies to or from a farm or ranch;
        4. Not used in for-hire motor carrier operations;
        5. Traveling in-state (regardless of weight) or out-of-state and have a GVWR or GVR of less than 26,001 pounds; or if GVWR or GVR of over 26,001 pounds and traveling out of state within 150 air miles of the farm or ranch.

Note: *A state may also waive the required knowledge and skills test and issue restricted CDLs to employees in the following farm-related service industries:*

- *Agri-chemical business*
- *Custom harvester*
- *Farm retail outlet and supplier*
- *Livestock feeders*

5. Am I required to keep paper Records of Duty Status ("RODS")?

a. Required for all "motor carriers," and drivers unless an identified exception applies.
    i. A motor carrier is anyone engaged in transportation of goods or passengers, whether for compensation, in a CMV, or both.
b. Does an exception apply?
    i. Covered farm vehicles (as defined above) are not required to keep RODS.
    ii. "Short-haul operations", as defined below, are not required to keep RODS.
        1. Driver of property-carrying commercial vehicles *for which a CDL is not required*, if::
            a. The driver operates within a 150 air-mile radius of the location where the driver reports to and is released from work;
            b. The driver returns to the normal work reporting location at the end of each duty tour;
            c. The driver does not drive:
                i. After the 14th hour after coming on duty on 5 days of any period of 7 consecutive days; and
                ii. After the 16th hour after coming on duty on 2 days of any period of 7 consecutive days; and
            d. The motor carrier that employs the driver maintains and retains for a period of 6 months accurate and true time records as required
        2. Driver (whether or not a CDL is required) operates within a 100 air-mile radius of the normal work reporting location;
            a. The driver returns to the work reporting location and is released from work within 12 consecutive hours;
            b. The driver has at least 10 consecutive hours off duty separating each 12 hours on duty;
            c. A driver does not exceed the maximum driving time allowed in Section 395.3(a)(3) following 10 consecutive hours off duty; and
            d. The motor carrier that employs the driver maintains and retains for a period of 6 months accurate and true time records as required
    iii. Drivers that fall within the "agricultural operations" exemption are not required to keep RODS if:
        1. It is planting or harvest period as determined by each state;
            a. Both Texas and Arkansas, for example, define this period to include the entire year from January 1st through December 31st.
        2. And drivers are transporting:
            a. Ag commodities from the source of the commodity to a location within 150 air miles; or

b. Farm supplies for ag purposes from a wholesale or retail distribution point of the farm supplies to a farm or other location where the supplies are intended to be used within a 150 air mile radius from the distribution point; or
c. Farm supplies for agricultural purposes from a wholesale distribution point of the farm supplies to a retail distribution point of the farm supplies within a 150 air mile radius from the wholesale distribution point.

iv. Drivers falling under the "occasional transportation" exception, discussed in Section 6 below, are exempt from keeping RODs.

6. Do I need an Electronic Logging Device, or "ELD"?

a. ELDs are required for motor carriers operating "commercial motor vehicles" between multiple states when
   i. Your vehicle has a GCWR, GVWR, GVW, or GCW of 10,001 pounds or more;
   ii. You are traveling in "interstate commerce"; and
   iii. You are hauling property (includes horses and livestock).

> **Note:** *Until June 18, 2018, there is a waiver excluding the transportation of "agricultural commodities" from the new electronic logging device regulations. Drivers operating under this waiver must carry a copy of it to present upon request. A copy of the waiver may be found at* https://bit.ly/2uaFCoo.
>
> *Further, authorities will not enforce the ELD requirement for persons hauling livestock or insects through September 30, 2018. No official waiver paperwork is necessary for this provision to apply.*

b. Are you excluded from the requirement?
   i. Vehicles older than model year 2000 are not required to have an ELD.
   ii. Drivers required to complete RODS for not more than 8 days within any 30 day period are not required to have an ELD.

   Note: Drivers not required to keep RODS at all fall under this exception.

   iii. Drivers of a "covered farm vehicle" are not required to have an ELD if:
      1. Registered in a state with a license plate or other designation issued by the state that allows law enforcement officials to identify it as a farm vehicle;
      2. Operated by the owner or operator of a farm or ranch, or employee or family member of the farm owner;
      3. Used to transport agricultural commodities, livestock, machinery, or supplies to or from a farm or ranch;
      4. Not used in for-hire motor carrier operations; and
      5. Traveling in any state with a GVWR or GVW of less than 26,001 pounds; or if GVWR or GVW of over 26,001 pounds, traveling within the state in

which is registered or out of state within 150 air miles of the owner's farm or ranch.

iv. Drivers engaged in the "occasional transportation of personal property" are not required to have an ELD. This exception applies if:
    1. The transportation is not in return for compensation; and
    2. It is not in the furtherance of a commercial enterprise
        a. Any prize money is declared as ordinary income for taxes;
        b. The cost of underlying activities is not deducted as a business expense for tax purposes;
        c. Corporate sponsorship is not involved.

Summary

The first step is to determine whether a vehicle is being operated in "commerce" and, if so, whether that is intrastate or interstate commerce. If it is a vehicle operated in intrastate commerce, the driver should contact the appropriate state Department of Transportation. If it is operated in interstate commerce, the next step is to determine the gross combination weight rating and the gross vehicle weight rating (whichever is greater). With these initial questions answered, a driver may then continue to analyze which federal statutes apply.

A person must determine if a commercial driver's license ("CDL") is legally required. For anyone operating in commerce with a weight rating or actual weight of more than 26,001, a CDL is required, unless the vehicle qualifies as a covered farm vehicle.

Next, a person must analyze whether installing an electronic logging device ("ELD") is required. ELDs are required for any vehicle hauling property weighing over 10,001 pounds that does not fall under exceptions such as the covered farm vehicle, occasional transportation, or other listed exceptions. As part of analyzing the ELD requirements, a person should consider whether he or she is required to keep paper records of duty status (RODS.)

Many livestock owners will fall under an exception to the rules, such as the covered farm vehicle exemption or an exemption for drivers not required to maintain certain records more than 8 out of a 30 day period. There may be concern, however, for persons with vehicles over 26,001 pounds, who travel more than 8 days out of a 30 day period, who are traveling more than 150 miles out of state.

For example, a rodeo athlete living in San Antonio who is going to travel to Oklahoma City to compete in a rodeo may have to have a CDL, ELD, and be required to keep RODS. The "covered farm vehicle" exception to the CDL requirement would not apply as the athlete would be traveling out of state and more than 150 miles. Thus, a CDL would be required. The "covered farm vehicle" exception to the ELD requirement would not apply for the same reasons. Further, the occasional transportation exception likely would not apply because most athletes in this situation would deduct underlying expenses from taxes and many may have corporate sponsorships. Thus, the only potential exception left would be if the person was not required to keep paper records of duty status "RODS" for more than 8 days during a 30

day period. This would likely depend on how many trips the driver had taken, and where the trip destinations were, within the last month.

Livestock exhibitors would be another example. Assume a person in Amarillo has a vehicle with a GCWR or GVWR over 26,001 pounds headed to a stock show to exhibit cattle. The driver would need to determine if he was traveling in "commerce." If the livestock owner was a ranch and the stock were to be exhibited in an open show as part of the ranch business, that likely would constitute commerce and the federal regulations would be applicable. If, however, the livestock were owned by a 4-H or FFA exhibitor and were not part of an underlying business, the hauling would likely not constitute "commerce" and the federal regulations would not apply.

Assuming a factual scenario where the hauling did constitute commerce, if the exhibitor hauls to Houston, he or she would not be required to have a CDL if the farm vehicle exception applies (farm tags are required on the vehicle) because the travel would be in-state. If the same vehicle was headed to show at Denver, a CDL would be required because that would be out-of-state and more than 150 miles. With regard to an ELD and hours of service requirements, there are likely several exceptions that would apply, including the covered farm vehicle exception, the "occasional transportation exception", or the 8/30 day exception if the driver was not required to keep paper RODS more than 8 out of a 30 day period.

Conclusion

As with most regulations, the FMCSA rules are complicated and determining applicability can be very fact specific. An additional layer of complication exists with regard to state Department of Transportation rules, which may differ from the federal rules discussed in this outline. Anyone concerned should visit with an attorney, Department of Transportation employee, or FMCSA official to determine what, if any, of these rules may apply to their situation.

University of Arkansas Division of Agriculture

An Agricultural Law Research Project

Beef Checkoff Dollars & USDA "Redirection": Compatible with Federal Law?

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INTRODUCTION

Congress enacted the Beef Promotion and Research Act of 1985[1] (Beef Act) to authorize "a coordinated program of promotion and research designed to strengthen the beef industry's position in the marketplace and to maintain and expand domestic and foreign markets and uses for beef and beef products."[2] This program, commonly referred to as the beef checkoff, is funded by a mandatory assessment of one dollar per-head of cattle sold in the United States.[3] Additionally, the Beef Act and Beef Promotion and Research Order[4] (Order) set forth a mandatory three-step process for the payment, collection, and remittance of the assessment that, when complied with, results in a state's Qualified State Beef Council[5] (QSBC) retaining one-half of the assessment and remitting the remaining half to the Cattlemen's Beef Promotion and Research Board (Board).[6]

However, the USDA Agricultural Marketing Service (AMS) implements a "redirection" policy that appears incompatible with the Beef Act and Order, specifically including the three-step process that governs the payment, collection, and remittance of the dollar per-head assessment.[7] The policy at issue allows beef producers in certain states to "redirect" the full dollar per-head assessment to the Board, thereby prohibiting the QSBC from retaining the fifty cents of the assessment it would have otherwise retained. More recently, AMS issued a proposed rule that "is intended to formalize the policy."[8] Outside of redirection, there appears to be no other legal avenue under the Beef Act or Order that allows QSBCs to be "bypassed" such that the assessment they would have collected, retained, and expended is otherwise remitted to the Board. Thus, redirection is very significant because it directly impacts – and challenges – the federal-state relationship Congress envisioned when it enacted the Beef Act more than three decades ago.

The apparent incompatibility between "redirection" and the Beef Act and Order raises questions as to whether, or to what extent, redirection is legally permissible. Additionally, there is a central question as to

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[1] 7 U.S.C. §§ 2901-2911 (2012).

[2] Id. at § 2901(b).

[3] Id. at § 2904(8)(C). The Beef Act requires importers to pay the one dollar per-head assessment "or the equivalent thereof." Id.

[4] 7 C.F.R. Part 1260.

[5] *See* 7 U.S.C. § 2902(14) and 7 C.F.R. § 1260.115 (defining "Qualified State Beef Council"). *See also* 7 C.F.R. § 1260.181 (setting forth requirements for certification as a Qualified State Beef Council).

[6] *See Flow of a Checkoff Dollar*, CATTLEMEN'S BEEF PROMOTION AND RESEARCH BOARD, http://www.beefboard.org/ (follow "Resources +" tab; then follow "Flow of a Checkoff Dollar" hyperlink under "References").

[7] Soybean Promotion, Research, and Consumer Information; Beef Promotion and Research; Amendments to Allow Redirection of State Assessments to the National Program; Technical Amendments; 81 Fed. Reg. 45984, 45986 (proposed July 15, 2016) (to be codified at 7 C.F.R. pt. 1220 and 1260) (hereinafter Redirection Proposed Rule). *See also* Defendants' Objections to Findings and Recommendations of United States Magistrate Judge at 7-8, Ranchers-Cattlemen Action Legal Defense Fund, United Stockgrowers of America v. United States Department of Agriculture, 4:16-cv-00041-BMM, Doc. 45 (D. Mont., Dec. 23, 2016) ("Defendants have now made clear that, in accordance with USDA's longstanding policy, cattle producers in states like Montana may decline to contribute to a QSBC and instead direct the QSBC to forward the full amount of their federal assessment to the Beef Board.").

[8] Redirection Proposed Rule at 45986 ("In States where payments to a QSBC are not required by State law, the opportunity for producers to choose to direct the full assessment is already AMS' current policy; this rule is intended to formalize the policy.").

whether AMS's stated legal basis for its redirection policy is based on an accurate interpretation of the Beef Act and Order. This article briefly addresses these questions.

A. Beef Act & Order: Three-Step Process

The Beef Act and Order establish a mandatory three-step process for the payment, collection, and remittance of the dollar per-head assessment that fuels the beef checkoff at the state and national levels. That process is as follows:

(1) The purchaser "shall" collect the dollar per-head assessment from the producer;[9]
(2) The purchaser "shall" remit to the appropriate QSBC the dollar per-head assessment it collected from the producer;[10] and
(3) The QSBC "shall remit to the Board assessments paid and remitted to the council, *minus authorized credits issued to producers pursuant to § 1260.172(a)(3)* . . . ."[11]

Additionally, if a purchaser fails to collect the assessment from the producer, that failure "shall not relieve the producer of his obligation to pay the assessment to the appropriate qualified State beef council . . . ."[12] A producer, purchaser, or QSBC that fails to comply with these requirements stands in violation of the Beef Act and Order.[13]

Section 1260.172(a)(3) provides that "a producer who is contributing to a qualified State beef council(s) shall receive a credit from the Board for contributions to such council, but not to exceed 50 cents per head of cattle produced."[14] The practical application of the § 1260.172(a)(3) is that QSBCs retain fifty cents of the dollar per-

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[9] 7 U.S.C. § 2904(8)(A) ("The order shall provide that each person making payment to a producer for cattle purchased from the producer shall, in the manner prescribed in the order, collect an assessment . . . ."); 7 C.F.R. §§ 1260.172(a)(1) (". . . each person making payment to a producer for cattle purchased from such producer . . . shall collect an assessment from the producer, and each producer shall pay such assessment . . . ."); and 7 C.F.R. § 1260.311(a) (". . . each person making payment to a producer for cattle purchased . . . shall collect from the producer an assessment at the rate of $1-per-head of cattle. . . .").

[10] 7 U.S.C. § 2904(8)(A); *Id.* at § 2904(8)(B) ("If an appropriate qualified State beef council does not exist to collect an assessment in accordance with paragraph(1), such assessment shall be collected by the Board."); 7 C.F.R. § 1260.172(a)(1) (". . . such collecting person shall remit the assessment to the Board or to a qualified State beef council pursuant to § 1260.172(a)(5)."); 7 C.F.R. § 1260.172(a)(5) ("Each person responsible for the remittance of the assessment pursuant to § 1260.172(a)(1) and (2) shall remit the assessment to the qualified State beef council in the State from which the cattle originated prior to sale, or if there is no qualified State beef council within such State, the assessment shall be remitted directly to the Board."); 7 C.F.R. § 1260.311(a) (". . . each person making payment . . . shall collect . . . an assessment . . . and shall be responsible for remitting assessments to the QSBC or Board as provided in § 1260.312."); 7 C.F.R. § 1260.311 ("Each person responsible for the collection and remittance of assessments shall transmit assessments . . . to the qualified State beef council of the State in which such person resides or if there is not qualified State beef council in such State, then to the Cattlemen's Board as follows . . . ."). *See also* 7 C.F.R. § 1260.310(c) ("Failure of the collecting person to collect the assessment on each head of cattle . . . shall not relieve the producer of his obligation to pay the assessment to the appropriate qualified State beef council or the Cattlemen's Board as required in § 1260.312.").

[11] 7 U.S.C. § 2904(8)(A); 7 C.F.R. § 1260.181(b)(4) (emphasis added).

[12] 7 C.F.R. § 1260.310(c).

[13] *See* 7 U.S.C. § 2908 (Enforcement). *See also* id. at § 2904(2)E).

[14] 7 C.F.R. § 1260.172(a)(3).

head assessment so that the QSBC can "determine how it should be invested in local and state programs."[15] It bears noting that the requirement that the QSBC remit fifty cents to the Board and retain fifty cents is one that a state entity "must" agree to in order to even exist as a QSBC.[16]

B. AMS Redirection Policy & Proposed Rule: An Overview

AMS states that it maintains a "longstanding policy" that allows producers "to decline to contribute to a QSBC and instead direct the QSBC to forward the full amount of their federal assessment to the Beef Board."[17] The redirection policy applies whenever "there is no state law requiring cattle producers to contribute to the QSBC."[18] On July 15, 2016, AMS issued a proposed rule that is "intended to formalize the policy."[19]

AMS's proposed rule encompasses its "longstanding policy" of redirection but also includes a standard that deals with the existence of producer refund provisions "authorized or required" under state law. According to the AMS Press Release that accompanied the issuance of the proposed rule, the rule would apply when (1) "there is no state law requiring assessments to a state . . . council"; or (2) "there is a state law requiring assessments, but the state law allows for refunds."[20]

C. Redirection: Legally Permissible?

1) AMS's Core Legal Basis for Redirection May Be In Fundamental Error

AMS's core legal basis for its "longstanding policy" of redirection appears to be based on an interpretation of the Beef Act and Order that may be precisely the opposite of the meaning given by the plain language of the Beef Act and Order. If true, AMS's stated legal basis for redirection would be in serious error. Similarly, the portion of the proposed rule that applies when "there is no state law requiring assessments to a state . . . council" would stand in equal legal jeopardy.

In explaining its redirection policy, AMS states the following:

> Furthermore, while the Beef Act and Beef Order *authorize* QSBCs to retain up to 50 cents per head of cattle assessed, neither the Beef Act or the Beef Order *require* producers to contribute a portion of the $1.00-per-head assessment to a QSBC. Thus, unless State statutes require the collection of the $1.00-per-head assessment set forth in the Beef Act (the federal assessment) or require producers to contribute a portion of the $1.00-per-head assessment to the State

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[15] *Flow of a Checkoff Dollar*, CATTLEMEN'S BEEF PROMOTION AND RESEARCH BOARD, http://www.beefboard.org/ (follow "Resources +" tab; then follow "Flow of a Checkoff Dollar" hyperlink under "References").

[16] 7 C.F.R. § 1260.181.

[17] Defendants' Objections to Findings and Recommendations of United States Magistrate Judge at 7-8, Ranchers-Cattlemen Action Legal Defense Fund, United Stockgrowers of America v. United States Department of Agriculture, 4:16-cv-00041-BMM, Doc. 45 (D. Mont., Dec. 23, 2016). *See also* Proposed Redirection Rule at 45986.

[18] Id. at 12-13 (citing Proposed Redirection Rule at 45986).

[19] Proposed Redirection Rule at 45986).

[20] Press Release, Sam Jones-Ellard, *USDA Proposes Changes to Beef and Soybean Checkoff Programs,* UNITED STATES DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE (July 15, 2016, 9:30 AM), https://www.ams.usda.gov/press-release/usda-proposes-changes-beef-and-soybean-checkoff-programs.

> beef council, producers may be able to choose not to contribute up to 50 cents per head of the federal assessment to their QSBC. [21]

Here, AMS clearly espouses that the legal foundation of its "longstanding policy" of redirection is predicated upon an interpretation that the Beef Act and Order merely "authorize" – rather than "require" – QSBCs to retain fifty cents per head of cattle assessed. However, as previously detailed, the mandatory three-step process set forth in the Beef Act and Order, when complied with, concludes with the QSBC retaining fifty cents of the assessment and remitting fifty cents to the Board. Thus, it may be that AMS's entire legal foundation for redirection has no basis in law because its interpretation is precisely the opposite of the meaning given to the plain language of the Beef Act and Order.

Additionally, AMS's view that "neither the Beef Act or the Beef Order require producers to contribute *a portion* of the $1.00-per-head assessment to a QSBC"[22] may be expressly contradicted by the Beef Act and Order. Specifically, "[f]ailure of the collecting person to collect the assessment . . . shall not relieve the producer of his obligation to pay the assessment to the appropriate qualified State beef council or Cattlemen's Board as required in §1260.312."[23] The Beef Act and Order require that such payment be made to the QSBC if one exists in that state; the assessment is to be made directly to the Board only if there is no QSBC.[24] Finally, the Beef Act and Order actually characterize such payments to QSBCs – as well as those payments that are remitted to QSBCs when the purchaser does *not* fail to collect the assessment – as "*contributions* to such Council."

AMS asserts that "[t]hus, unless State statutes require *the collection* of the $1.00-per-head assessment set forth in the Beef Act . . . to the State beef council, . . . producers may be able to choose not to contribute up to 50 cents per head of the federal assessment to their QSBC."[25] The Beef Act expressly speaks to this precise issue, which presumably negates the legal relevance of a standard that depends upon the existence of state laws that "require the collection of the $1.00-per-head assessment". Specifically, the Beef Act states as follows: "The Board *shall* use qualified State beef councils *to collect* such assessments."[26] Therefore, this particular basis for redirection appears to be expressly prohibited by the plain language of the Beef Act and Order.

Next, AMS asserts that "[t]]hus, unless State statutes require . . . producers to contribute *a portion* of the $1.00-per-head assessment to the State beef council, producers may be able to choose not to contribute up to 50 cents per head of the federal assessment to their QSBC."[27] As noted, the Beef Act and Order require producers to pay the dollar per-head assessment to the purchaser at the point of sale or, in the event the purchaser fails to collect the assessment, directly to the appropriate QSBC. Once the assessment is remitted to and collected by the QSBC, the fate of the assessment is governed not by the producer or state law. Rather, the fate of the assessment is governed by the Beef Act and Order requirement that the QSBC "*shall* remit to

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[21] Proposed Redirection Rule at 45986 (emphasis added).
[22] Id. (emphasis added).
[23] 7 C.F.R. § 1260.310(c).
[24] 7 U.S.C. § 2904(8)(A); 7 C.F.R. § 1260.312.
[25] Proposed Redirection Rule at 45986 (emphasis added).
[26] 7 U.S.C. § 2904(8)(A) (emphasis added).
[27] Proposed Redirection Rule at 45986 (emphasis added).

the Board assessments paid and remitted to the council, *minus authorized credits issued to producers pursuant to § 1260.172(a)(3).*"[28]

Finally, it bears re-emphasizing that even if AMS's legal basis for redirection is not in error, its reliance on the existence or non-existence of state law requiring assessments to a QSBC remains legally problematic. The Beef Act and the Order – not state law – clearly establish the mandatory three-step process that, when complied with, concludes with the QSBC retaining one-half of the dollar per-head assessment. That mandatory process in no way involves or is otherwise influenced by the existence of a state law. Therefore, AMS's reliance on the existence of state laws that alter the mandatory requirements of the Beef Act and Order appears to be a false standard that falls outside the boundaries prescribed by the Beef Act and Order, even if AMS's legal basis for redirection is somehow based on a proper interpretation of the Beef Act and Order.

2) Preemption or Superseding of States' Producer Refund Provisions

Another key issue regarding redirection is whether states' producer refund provisions are preempted or superseded by the Beef Act and Order. If states' refund provisions are preempted or superseded by federal law, then those state laws are unenforceable or otherwise set aside. Thus, the state law would not be available for a producer to even request the refund that then triggers "redirection". If true, the portion of AMS's redirection policy and proposed rule that applies to QSBCs that are "authorized or required" to provide producer refunds may not even be capable of implementation. Conversely, if states' refund provisions are somehow not preempted or superseded by state law, the question arises as to how a producer's request for a refund under an otherwise valid and operable state law simultaneously results in the producer's loss of a refund *and* the QSBC's loss of funds that the QSBC would have otherwise retained in accordance with the mandatory, three-step process for the payment, collection, and remittance of the full assessment.

CONCLUSION

Redirection is a very unique legal concept that directly impacts the "coordinated" federal-state relationship Congress established when it enacted the Beef Act thirty-two years ago. As such, it warrants scrutiny from any person or entity who pays, collects, expends, or is otherwise impacted by the beef checkoff.

The uniqueness of redirection is amplified when one considers that redirection appears to be the only mechanism in the Beef Act and Order – or USDA policy based on interpretation of the Beef Act and Order – through which assessment funds that would otherwise be collected, retained, and expended by QSBCs are instead collected, retained, and expended by the Board. Stated differently, USDA's "longstanding policy" of redirection appears to be the only way in which a QSBC is deprived of the funding it would otherwise collect and retain as a result of producers', purchasers', and QSBCs' compliance with the mandatory three-step process set forth in the Beef Act and Order. Redirection therefore strikes at the very heart of the federal-state relationship Congress wove into the beef checkoff in 1985.

Yet, the term "redirection" is never defined, discussed, or otherwise mentioned in the Beef Act or Order. Currently, redirection exists only as a policy that is born entirely from AMS's interpretation that "neither the Beef Act or Order require producers to contribute a portion of the $1.00-per-head assessment to a QSBC." As discussed in this brief article, AMS's interpretation may be exactly the opposite of what Congress – and AMS itself – envisioned when beef checkoff launched more than three decades ago. Further, AMS's reliance on the existence or non-existence of state law may be based not only on a faulty interpretation of the Beef Act and

[28] 7 C.F.R. § 1260.181(b)(4) (emphasis added).

Order but also be expressly contradicted by the plain language of the Beef Act and Order. The proposed rule, which incorporates AMS's existing policy as well as a standard that depends on the existence of states' producer refund provisions, may also be legally problematic.

Ironically, redirection requires QSBCs to violate § 1260.181(b)(4) of the Beef Order, one of several criteria state entities "must" agree to comply with in order to even exist as a QSBC. Namely, § 1260.181(b)(4) requires that the state entities that applied to the Board for certification as a QSBC "must" agree that it "shall remit to the Board assessments paid and remitted to the Council, minus authorized credits issued to producers pursuant to § 1260.172(a)(3)." Like redirection itself, § 1260.181(b)(4) strikes at the heart of the federal-state relationship that Congress constructed under the Beef Act. Yet, § 1260.181(b)(4) is effectively suspended in each instance that redirection applies; namely, when (1) "there is no state law requiring assessments to a state . . . council"; or (2) "there is a state law requiring assessments, but the state law allows for refunds."[29]

What's a QSBC to do when it receives a producer's request for redirection or for a refund "authorized or required" under state law? Should the QSBC comply with the mandatory requirements placed upon it by the Beef Act and Order, or comply with AMS's policy of redirection based the agency's interpretation of the Beef Act and Order? The lack of compatibility between redirection and the Beef Act and Order suggests that it is not possible for a QSBC to simultaneously comply with both, thereby setting the stage for legal and political tension between cattle producers, QSBCs, the Board, and USDA that could undermine the vitality of the beef checkoff.[30]

[29] Press Release, Sam Jones-Ellard, *USDA Proposes Changes to Beef and Soybean Checkoff Programs,* UNITED STATES DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE (July 15, 2016, 9:30 AM), https://www.ams.usda.gov/press-release/usda-proposes-changes-beef-and-soybean-checkoff-programs.

[30] Chris Bennett, *Legal Jumble Over Beef, Soybean Checkoff Articles?* AGWEB (POWERED BY FARM JOURNAL), Nov. 6, 2016, available at https://www.agweb.com/article/legal-jumble-over-beef-soybean-checkoff-dollars-naa-chris-bennett/.

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CRS REPORT
Prepared for Members and
Committees of Congress

Summary

The farm bill provides an opportunity for Congress to address agricultural and food issues comprehensively about every five years. Over time, farm bills have tended to become more complicated and politically sensitive. As a result, the timeline for reauthorization has become less certain, and in general recent farm bills have taken longer to enact than in previous decades. Recent farm bills, beginning with the 2008 farm bill (P.L. 110-246), have been subject to various developments that have delayed enactment, such as insufficient votes to pass the House floor, presidential vetoes, and short-term extensions.

The 2014 farm bill took more than 21 months from introduction to enactment and spanned the 112th and 113th Congresses. The House rejected a bill in 2013 and then passed separate farm and nutrition assistance components before procedurally recombining them for conference with the Senate. Somewhat similarly, the 2008 farm bill took more than a year to enact and was complicated by revenue provisions from another committee of jurisdiction, temporary extensions, and vetoes.

Whether the House or Senate proceeds first in committee or on the floor is also not always predictable. Both the 2008 farm bill and the 2002 farm bill were extended before their successors were enacted.

In 2018, a farm bill reauthorization was reported from the House Agriculture Committee on April 18 (H.R. 2). An initial floor vote on passage on May 18 failed in the House 198-213, but floor procedures allowed that vote to be reconsidered (H.Res. 905). The House passed H.R. 2 in a second vote of 213-211 on June 21, 2018. In the Senate, the Agriculture Committee reported its bill (S. 3042) on June 13 by a vote of 20-1. The Senate passed its bill as an amendment to H.R. 2 by a vote of 86-11 on June 28, 2018.

This report examines the major legislative milestones for the last 11 farm bills covering 53 years and illustrates trends that may provide useful background and context as the current farm bill debate proceeds.

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The farm bill provides an opportunity for Congress to address agricultural and food issues comprehensively about every five years.[1] Over time, farm bills have tended to become more complicated and politically sensitive. This has made the timeline for reauthorization less certain. Recent farm bills have been subject to developments that have delayed enactment, such as insufficient votes to pass the House floor, presidential vetoes, and short-term extensions.

For example, the 1973 farm bill was enacted less than three months after being introduced. In contrast, the 2014 farm bill took more than 21 months from introduction to enactment, spanning the 112th and 113th Congresses.[2] The House rejected a bill in 2013 and then passed separate farm and nutrition assistance components—the first time a chamber-passed farm bill reauthorization did not include a nutrition title since nutrition became part of the farm bill in 1973. The House later procedurally recombined them for conference with the Senate.

Both the 2002 and 2008 farm bills had expired for about three months (from October through December in 2007 and 2012) before extensions were enacted. In each case, the fiscal year began under a continuing resolution for appropriations. The extensions of the 2002 farm bill were for relatively short periods totaling about five months during final House-Senate negotiations. However, the extension of the 2008 farm bill in 2013 was for a full year, since the 112th Congress had ended and it was necessary to reintroduce farm bill legislation in the 113th Congress.

In 2018, a farm bill reauthorization was reported from the House Agriculture Committee on April 18 (H.R. 2). An initial floor vote on passage on May 18 failed in the House 198-213, but procedures allowed that vote to be reconsidered (H.Res. 905). The House passed H.R. 2 in a second vote of 213-211 on June 21, 2018. In the Senate, the Agriculture Committee reported its bill (S. 3042) on June 13 by a vote of 20-1. The Senate passed its bill as an amendment to H.R. 2 by a vote of 86-11 on June 28, 2018. This is the first time since at least 1965 that both chambers completed floor action before the end of June.

This report examines the major legislative milestones for the last 11 farm bills over 53 years, a period representing modern farm bills with growing complexity. It discusses trends that may provide historical perspective as the current farm bill debate proceeds. **Table 1** contains a history of major legislative action on farm bills since 1965. **Figure 1** shows the dates on a timeline for each farm bill from introduction to enactment. The consequences of expiration of a farm bill,[3] as well as its content, are discussed in other CRS reports.[4]

Timelines for Enactment, Extension, and Vetoes

Parts of a farm bill are authorized for a period of fiscal years and therefore expire at the end of the fiscal year (September 30) in the year of the farm bill's expiration. Other parts are authorized for crop years or calendar years. The 2014 farm bill (the Agricultural Act of 2014, P.L. 113-79) generally expires at the end of FY2018 and with the 2018 crop year, which for dairy is the end of the calendar year.

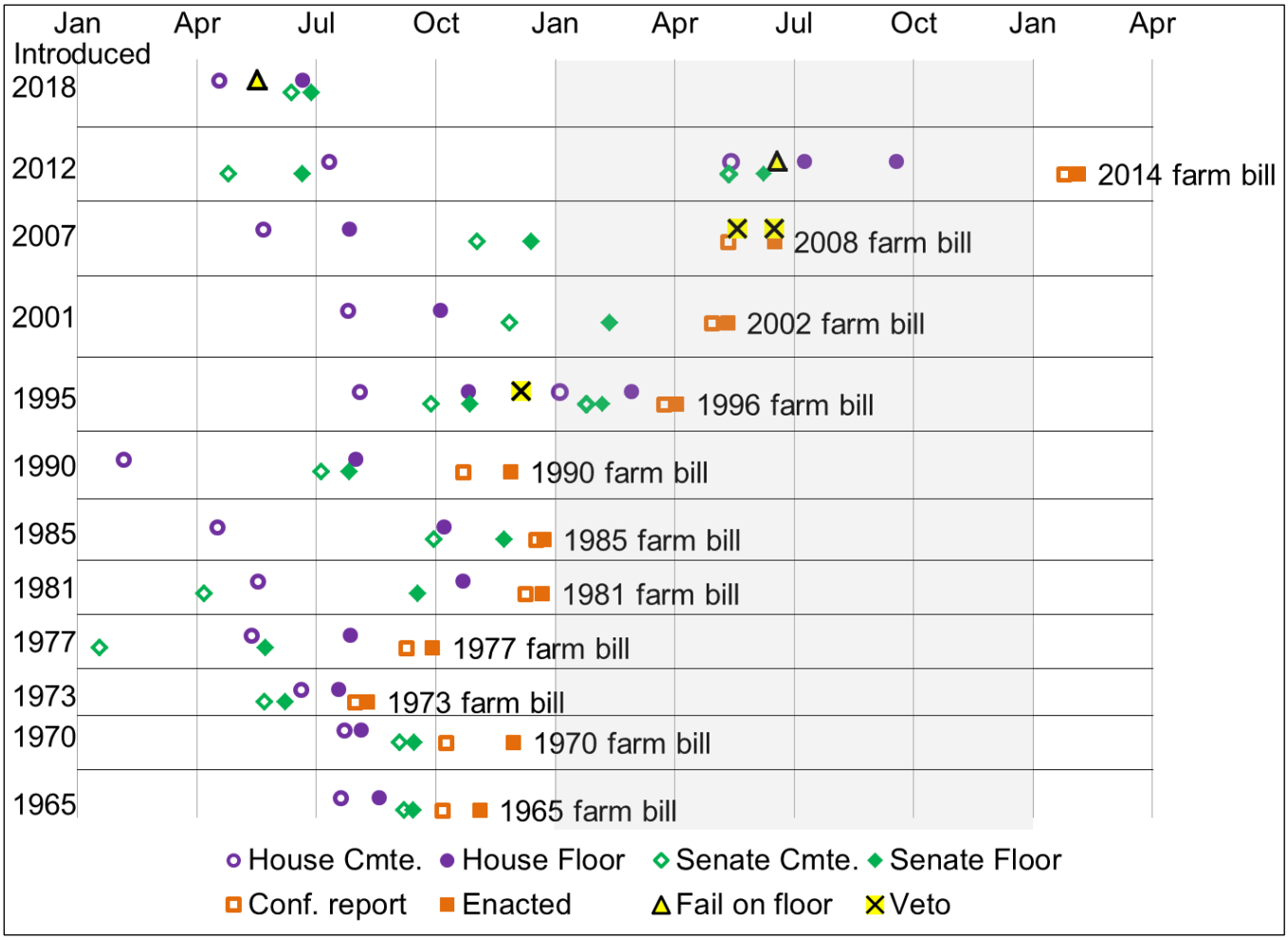
[1] See CRS In Focus IF10187, *Farm Bill Primer: What Is the Farm Bill?*

[2] These dates span only the official introduction of a bill marked up by committee until the President signed the bill. They do not include background hearings before committee markup, which would extend the timeline.

[3] For example, expiration of the 2008 farm bill as the 2014 farm bill was being developed is discussed in CRS Report R42442, *Expiration and Extension of the 2008 Farm Bill*.

[4] See CRS Report R45197, *The House Agriculture Committee's 2018 Farm Bill (H.R. 2): A Side-by-Side Comparison with Current Law*; and CRS Report R44913, *Farm Bill Primer Series: A Guide to Omnibus Legislation on Agriculture and Food Programs*.

Figure 1. Major Legislative Actions on Farm Bills, 2018-1965



Source: CRS, using http://www.congress.gov.

Timeline Relative to Fiscal Years

Enacting farm bills after the end of the fiscal year (in which a farm bill expired) is commonplace. In the past 53 years, only the 1973 and 1977 farm bills were enacted before the September 30 expiration date for most programs.

Timeline Relative to Calendar Years

Farm bills in 1965, 1970, 1981, 1985, and 1990 were enacted by December 31—within three months of the end of the fiscal year but before spring-planted crops that would be covered by the new law were planted. The most recent four farm bills (1996, 2002, 2008, and 2014) have been enacted later in the year—in April (1996), May (2002), June (2008), and February (2014)—but still prior to the first crop covered by the farm bill was harvested.

Timeline Relative to the Two-Year Congress

Since 1965, eight out of 11 enacted farm bills were *introduced* in the first session of a two-year Congress (the odd-numbered year); the exceptions are the 1970, 1990, and 2014 farm bills.[5] The 2014 farm bill, which was introduced in 2012, was the first to start in one Congress, remain unfinished, and require reintroduction in a subsequent Congress. *Enactment* of the past five farm bills (1990-2014) have been in the second session (the even-numbered year), although, except for the 1990 farm bill, some action had occurred in the prior year. Only the 1970 and 1990 farm bills were enacted after an election during a lame duck Congress in late November.

House or Senate Action First

The House and Senate have taken turns in initiating action on a farm bill. Since 1965, the Senate was first to mark up farm bills in 1973, 1977, 1981, 2012, and 2013. The House was first to mark up bills in 1965, 1970, 1985, 1990, 1995 (and 1996), 2001, 2007, and 2018.

Short-Term Extensions

Extensions of a prior farm bill while its successor is being written have been atypical, though the past two reauthorizations have involved extensions. Only the 2002 and 2008 farm bills have required extensions in 2007-2008 and 2013, respectively, as their successors were being written.[6]

When the 2002 farm bill expired, portions of it were extended six times for less than a year total beginning in December 2007. The first of those extensions continued authority for many expiring programs for about three months.[7] Because final agreement was pending, five more extensions—ranging from a week to a month—were needed. With a few exceptions, these extensions continued all 2002 farm bill provisions that were in effect on September 30, 2007. Dairy and sugar programs were included, as were price support loan programs for wool and mohair. But the direct, counter-cyclical, and marketing loan programs for the 2008 crop year for all other supported commodities (i.e., the primary supported commodities such as feed grains, oilseeds, wheat, rice, cotton, and peanuts) were specifically *not* extended.[8] Moreover, the first extension in December 2007 did not address permanent law, but the second and subsequent extensions in 2008 did extend the 2002 farm bill's suspension of permanent law.[9]

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[5] Technically, the bill that became the 2014 farm bill (H.R. 2642) was introduced in 2013 (the first session of the 113th Congress), but many observers consider it a reintroduction of the bills started in 2012.

[6] The 1965 farm bill was extended for one year, but that extension occurred more than a year before expiration and before the reauthorization process had begun in 1970. The 1996 and 2002 farm bills may appear to have been delayed by being reintroduced (1996) or going through the new year into May (2002), but their predecessors did not require extensions. Writing the 1996 farm bill was not pressured by the 1990 farm bill's original expiration date of the 1995 crop year because budget reconciliation in 1993 had extended the farm commodity programs through at least 1996 and, in some cases, the 1997 crops. Writing the 2002 farm bill was not pressured because the 1996 farm bill was to be effective until September 30, 2002, and through the 2002 crop year. In fact, the 2002 farm bill superseded the last year of the 1996 farm bill by beginning with the 2002 crop year.

[7] "Except as otherwise provided in this Act ... authorities provided under the Farm Security and Rural Investment Act of 2002 ... (and for mandatory programs at such funding levels), as in effect on September 30, 2007, shall continue, and the Secretary of Agriculture shall carry out the authorities, until March 15, 2008." P.L. 110-161, §751.

[8] Other programs that were *not* included in the extensions were peanut storage payments, agricultural management assistance, community food projects, the rural broadband program, value-added market development grants, federal procurement of biobased products, the biodiesel fuel education program, and the renewable energy systems program.

[9] Permanent law refers to nonexpiring provisions in Agriculture Adjustment Act of 1938 and the Agriculture Act of (continued...)

When the 2008 farm bill expired on September 30, 2012, the continuing resolution providing appropriations (P.L. 112-175, §§101, 111) continued discretionary programs, the Supplemental Nutrition Assistance Program (SNAP), and certain related nutrition programs. Certain other mandatory programs—such as the Market Assistance Program and the Conservation Reserve Program—ceased to operate insofar as new activity.[10] On January 2, 2013, the entire 2008 farm bill, as it existed on September 30, 2012, was extended for the 2013 fiscal year and the 2013 crop year (P.L. 112-240). This avoided reverting to permanent law for the farm commodity programs, which was imminent for the dairy programs.

The situation from October to December 2013 somewhat repeated the end of 2012. Most of the discretionary parts of the farm bill expired again on October 1, 2013. Some programs ceased new operations, while others were able to continue under appropriations. For SNAP and the discretionary programs, farm bill expiration coupled with the two-week lapse during October 2013 of FY2014 appropriations (the "government shutdown") did create difficulties in operating some farm bill programs. From January 1, 2014, until enactment of the 2014 farm bill on February 7, 2014, the dairy program had technically reverted to permanent law, though federal officials did not implement it, since a conference agreement was imminent.

Presidential Vetoes

Presidential vetoes of farm bills are not common. Since 1965, only the 2008 farm bill has been vetoed as stand-alone measure; it was vetoed twice. A 1995 farm bill was vetoed as part of a larger budget reconciliation package.[11]

President George W. Bush vetoed the 2008 farm bill (H.R. 2419). When Congress overrode the veto to enact P.L. 110-234, it accidentally enrolled the law without Title III (the trade title). Congress immediately reintroduced the same bill with the trade title (H.R. 6124). President Bush vetoed this version as well, and Congress again overrode the veto to enact P.L. 110-246, a complete 2008 farm bill that included the trade title. The overrides in 2008 were the only time that a farm bill was enacted as a result of a veto override.

President Clinton vetoed a 1995 budget reconciliation package that included the first version of what became the 1996 farm bill, but the veto was not due to the farm bill itself but rather the controversial nature of the reconciliation bill in which the farm bill was embedded.

Implications for Congress

As farm bill reauthorization has tended to become more complex and engender greater political sensitivity, the process of enacting a new farm bill prior to the expiration of the existing law has become more difficult. As stakeholders in the farm bill have become more diverse, more people are affected by the legislative uncertainty around this process. This lack of certainty may translate into questions about the availability of future program benefits, some of which may affect agricultural production decisions or market uncertainty for agricultural commodities.

(...continued)

1949 that are temporarily suspended by each modern farm bill. The commodity support provisions of permanent law are inconsistent with today's farming, marketing, and trade agreements and potentially costly to the federal government. See CRS Report RL34154, *Possible Expiration (or Extension) of the 2002 Farm Bill.*

[10] See CRS Report R42442, *Expiration and Extension of the 2008 Farm Bill*.

[11] Prior to 1965, the first veto of a farm bill was in 1956, when President Eisenhower vetoed H.R. 12, the first version of the Agricultural Act of 1956.

Table 1. Major Legislative Actions on Farm Bills, 2018-1965

					Conference Report Approval			
	House Cmte.	House Passage	Senate Cmte.	Senate Passage	Conf. Report	House Passage	Senate Passage	Public Law
2018 farm bill *(115th Congress)* **Agriculture and Nutrition Act of 2018** Would cover 2019-2023 crops or until 9/30/2023	4/18/2018 H.R. 2 Vote of 26-20 5/3/2018 H.Rept. 115-661	5/18/2018 H.R. 2 Initial vote failed by 198-213 Reconsider under H.Res. 905 6/21/2018 Passed by vote of 213-211	6/13/2018 S. 3042 Vote of 20-1	6/28/2018 H.R. 2 Vote of 86-11	—	—	—	—
Agricultural Act of 2014 *(113th Congress)* Covers 2014-2018 crops or until 9/30/2018	5/15/2013 H.R. 1947 Vote of 36-10 5/29/2013 H.Rept. 113-92	6/20/2013 H.R. 1947 Failed by 195-234 7/11/2013 H.R. 2642 Farm part vote of 216-208 9/19/2013 H.R. 3102 Nutrition part vote of 217-210 9/28/2013 H.Res. 361 combines House bills	5/14/2013 S. 954 Vote of 15-5 9/4/2013 S.Rept. 113-88	6/10/2013 S. 954 Vote of 66-27	1/27/2014 H.Rept. 113-333	1/29/2014 H.R. 2642 Vote of 251-166	2/4/2014 H.R. 2642 Vote of 68-32	2/7/2014 P.L. 113-79
Agriculture Reform, Food, and Jobs Act *(112th Congress)*	7/11/2012 H.R. 6083 Vote of 35-11 9/13/2012 H.Rept. 112-669	—	4/26/2012 S. 3240 Vote of 16-5 8/28/2012 S.Rept. 112-203	6/21/2012 S. 3240 Vote of 64-35	—	—	—	—
Early extension:	Extended five conservation programs of the 2008 farm bill through FY2014 (AMA, CSP, EQIP, FPP, and WHIP).							11/18/2011 P.L. 112-55
Extension:	One-year extension of the 2008 farm bill until 9/30/2013 and for the 2013 crop year (dairy price support extended until 12/31/2013, and MILC extended until 9/30/2013). Did not provide funding for programs without mandatory baseline.							1/2/2013 P.L. 112-240 Title VII

					Conference Report Approval			
	House Cmte.	**House Passage**	**Senate Cmte.**	**Senate Passage**	**Conf. Report**	**House Passage**	**Senate Passage**	**Public Law**
2008 farm bill **Food, Conservation, and Energy Act of 2008** Covers 2008-2012 crops or until 9/30/2012	5/22/2007 H.R. 2419 Introduced 7/23/2007 H.Rept. 110-256	7/27/2007 H.R. 2419 Vote of 231-191	11/2/2007 S. 2302 S.Rept. 110-220	12/14/2007 Amdt. to H.R. 2419 Vote of 79-14	5/13/2008 H.Rept. 110-627	5/14/2008 H.R. 2419 Vote of 318-106	5/15/2008 H.R. 2419 Vote of 81-15	5/21/2008 Enrolling error omits Title III Vetoed
						5/21/2008 Passed over veto 316-108	5/22/2008 Passed over veto 82-13	5/22/2008 P.L. 110-234
					Re-passed as new bill w/ Title III	5/22/2008 H.R. 6124 Vote of 306-110	6/5/2008 H.R. 6124 Vote of 77-15	6/18/2008 Vetoed
						6/18/2008 Passed over veto 317-109	6/18/2008 Passed over veto 80-14	6/18/2008 P.L. 110-246
Early extensions:	Extended the early-expiring MILC program of the 2002 farm bill for two years from 9/2005 through 8/2007 and two conservation programs (EQIP and Conservation Security Program) until FY2010.							2/8/2006 P.L. 109-171
Extensions:	Extended parts of the 2002 farm bill until 3/15/2008 but did not extend the direct and counter-cyclical farm commodity programs. See Division A, §751.							12/26/2007 P.L. 110-161
	Continued extension until 4/18/2008 and added extension of suspension of permanent law.							3/14/2008 P.L. 110-196
	Continued extension until 4/25/2008.							4/18/2008 P.L. 110-200
	Continued extension until 5/2/2008.							4/25/2008 P.L. 110-205
	Continued extension until 5/16/2008.							5/2/2008 P.L. 110-208
	Continued extension until 5/23/2008.							5/18/2008 P.L. 110-231
2002 farm bill **Farm Security and Rural Investment Act** Covers 2002-2007 crops or until 9/30/2007	7/26/2001 H.R. 2646 8/2/2001 H.Rept. 107-191	10/5/2001 H.R. 2646 Vote of 291-120	11/27/2001 S. 1731 12/7/2001 S.Rept. 107-117	2/13/2002 Amdt. to H.R. 2646 Vote of 58-40	5/1/2002 H.Rept. 107-424	5/2/2002 H.R. 2646 Vote of 280-141	5/8/2002 H.R. 2646 Vote of 64-35	5/13/2002 P.L. 107-171

					Conference Report Approval			
	House Cmte.	**House Passage**	**Senate Cmte.**	**Senate Passage**	**Conf. Report**	**House Passage**	**Senate Passage**	**Public Law**
1996 farm bill **Federal Agriculture Improvement and Reform Act of 1996** Covers 1996-2002 crops or until 9/30/2002	1/5/1996 H.R. 2854 introduced Vote of 29-17 2/9/1996 H.Rept. 104-462	2/29/1996 H.R. 2854 Vote of 270-155	1/26/1996 S. 1541 introduced	2/7/1996 S. 1541 Vote of 64-32 3/12/1996 Amdt. to H.R. 2854 Voice vote	3/25/1996 H.Rept. 104-494	3/29/1996 H.R. 2854 Vote of 318-89	3/28/1996 H.R. 2854 Vote of 74-26	4/4/1996 P.L. 104-127
Balanced Budget Act of 1995	10/26/1995 H.R. 2491 includes H.R. 2195	10/26/1995 H.R. 2491 Vote of 227-203	10/28/1995 S. 1357 includes Senate bill	10/28/1995 Amdt. to H.R. 2491 Vote of 52-47	11/16/1995 H.Rept. 104-347	11/20/1995 H.R. 2491 Vote of 235-192	11/17/1995 H.R. 2491 Vote of 52-47	12/6/1995 Vetoed
Freedom to Farm Act	8/4/1995 H.R. 2195 introduced 9/20/1995 fails cmte.	—	9/28/1995 unnumber-ed bill	—	—	—	—	—
Extension:	More than a year before expiration, extended the dairy program of the 1990 farm bill until 1996 and extended programs for wheat, feed grains, cotton, rice, peanuts, wool, and mohair until 1997 and honey until 1998.							8/10/1993 P.L. 103-66
1990 farm bill **Food, Agriculture, Conservation, and Trade Act of 1990** Covers 1991-1995 crops or until 9/30/1995	2/5/1990 H.R. 3950 introduced 7/3/1990 H.Rept. 101-569	8/1/1990 H.R. 3950 Vote of 327-91	7/6/1990 S. 2830 S.Rept. 101-357	7/27/1990 S. 2830 Vote of 70-21	10/22/1990 H.Rept. 101-916	10/23/1990 S. 2830 Vote of 318-102	10/25/1990 S. 2830 Vote of 60-36	11/28/1990 P.L. 101-624
1985 farm bill **Food Security Act of 1985** Covers 1986-1990 crops or until 9/30/1990	4/17/1985 H.R. 2100 introduced 9/13/1985 H.Rept. 99-271	10/8/1985 H.R. 2100 Vote of 282-141	9/30/1985 S. 1714 S.Rept. 99-145	11/23/1985 H.R. 2100 Vote of 61-28	12/17/1985 H.Rept. 99-447	12/18/1985 H.R. 2100 Vote of 325-96	12/18/1985 H.R. 2100 Vote of 55-38	12/23/1985 P.L. 99-198
1981 farm bill **Agriculture and Food Act of 1981** Covers 1982-1985 crops or until 9/30/1985	5/18/1981 H.R. 3603 introduced 5/19/1981 H.Rept. 97-106	10/22/1981 S. 884 Vote of 192-160	4/7/1981 S. 884 introduced 5/27/1981 S.Rept. 97-126	9/18/1981 S. 884 Vote of 49-32	12/9/1981 H.Rept. 97-377 12/10/1981 S.Rept. 97-290	12/16/1981 S. 884 Vote of 205-203	12/10/1981 S. 884 Vote of 67-32	12/22/1981 P.L. 97-98
1977 farm bill **Food and Agriculture Act of 1977** Covers 1978-1981 crops or until 9/30/1981	5/13/1977 H.R. 7171 introduced 5/16/1977 H.Rept. 95-348	7/28/1977 Amdt. to S. 275 Vote of 294-114	1/18/1977 S. 275 introduced 5/16/1977 S.Rept. 95-180	5/24/1977 S. 275 Vote of 69-18	9/9/1977 S.Rept. 95-418	9/16/1977 S. 275 Vote of 283-107	9/9/1977 S. 275 Vote of 63-8	9/29/1977 P.L. 95-113

					Conference Report Approval			
	House Cmte.	House Passage	Senate Cmte.	Senate Passage	Conf. Report	House Passage	Senate Passage	Public Law
1973 farm bill **Agriculture and Consumer Protection Act** Covers 1974-1977 crops or until 6/30/1977	6/20/1973 H.R. 8860 introduced 6/27/1973 H.Rept. 93-337	7/19/1973 Amdt. to S. 1888 Vote of 226-182	5/23/1973 S. 1888 introduced S.Rept. 93-173	6/8/1973 S. 1888 Vote of 78-9	7/31/1973 H.Rept. 93-427	8/3/1973 S. 1888 Vote of 252-151	7/31/1973 S. 1888 Vote of 85-7	8/10/1973 P.L. 93-86
1970 farm bill **Agricultural Act of 1970** Covers 1971-1973 crops	7/23/1970 H.R. 18546 H.Rept. 91-1329	8/5/1970 H.R. 18546 Vote of 212-171	9/4/1970 Amdt. to H.R. 18546 S.Rept. 91-1154	9/15/1970 Amdt. to H.R. 18546 Vote of 65-7	10/9/1970 H.Rept. 91-1594	10/13/1970 H.R. 18546 Vote of 191-145	11/19/1970 H.R. 18546 Vote of 48-35	11/30/1970 P.L. 91-524
Extension:	More than a year before expiration, extended the 1965 farm bill for one-year until 12/31/1970.							10/11/1968 P.L. 90-559
1965 farm bill **Food and Agricultural Act** Covers 1966-1969 crops	7/20/1965 H.R. 9811 H.Rept. 89-631	8/19/1965 H.R. 9811 Vote of 221-172	9/7/1965 Amdt. to H.R. 9811 S.Rept. 89-687	9/14/1965 Amdt. to H.R. 9811 Vote of 72-22	10/6/1965 H.Rept. 89-1123	10/8/1965 H.R. 9811 Vote of 219-150	10/12/1965 H.R. 9811 Voice vote	11/4/1965 P.L. 89-321

Source: CRS, using http://www.congress.gov. Includes only major legislative actions. Excludes subsequent revisions, such as in budget reconciliation, except for extensions as noted.

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All Data Big and Small: Legal Issues Surrounding Agricultural Data

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I. INTRODUCTION

A. Abstract

Drones and advanced sensing equipment on agricultural machinery can provide farmers and ranchers unprecedented insights to their own operations. Uploading, aggregating, and analyzing data across multiple operations (a process often referred to as "Big Data") also holds the potential to generate knowledge beneficial not only to producers but numerous other segments of the agricultural industry. However, many producers have numerous concerns about their rights with respect to the data generated by them or, in some cases, about them. This article addresses some of the legal concerns involved both with data acquisition and with data rights. Regardless of how data about their operations is acquired, though, producers should work with their attorneys to craft data use agreements to protect their interests, as few existing laws deal with these issues.

B. The Brave New World of Farm Data

"Big Data" is one of the biggest buzzwords in the arena of agricultural technology right now and may receive almost as much discussion in agriculture as the weather and commodity prices. But what is Big Data anyway, and why should farmers care? This article aims to define both "Small" and "Big" Data, and to reveal its advantages and disadvantages for farmers. The discussion then turns to the concerns farmers express about disclosing farm data, and provides concrete solutions for what they can do individually and collectively to address those concerns.

1. Drones and Other Data Acquisition Tools

As many in Generation X learned from School House Rock, "knowledge is power!" Increasingly, agricultural producers rely on advanced analytics for their operations to optimize their operations and stay "in the black" in an era of increased volatility for input prices and production conditions. These analytics are only as good as the data that drives them, though, and producers have more tools than ever to acquire that data.

One important potential source of this data is the Unmanned Aerial Vehicle (UAV), more commonly called a "drone." Though there are numerous definitions of "UAV" or "drone," the FAA Modernization and Reform Act of 2012 defines the term "unmanned aircraft system" (sufficiently synonymous with UAV for the purposes of this discussion) as "an unmanned aircraft and associated elements (including communication links and the components that control the unmanned aircraft) that are required for the pilot in command to operate safely and efficiently in the national airspace system." P. Law 112-95 (H.R. 658-62), § 331(9).

The opportunity for producers to fly over their operations for relatively little cost and virtually no risk to life (at least their own) opens a number of doors for them to gain much better data of crop and pasture conditions through both visual and non-visual spectrum (such as infrared) data that can look at entire parcels at once. Imagery from drones can even be orthorectified through relatively inexpensive software to provide detailed measurements of land. Additionally, drones can be used to check on livestock, proving particularly useful on large operations and/or those with rugged, inaccessible terrain. Indeed, the potential uses of drone technology are almost innumerable.

At the same time, though, any new technology comes with risks and fears of misuse. Privacy and safety concerns are perhaps two of the largest issues swirling around agricultural drone use. When flying at any appreciable altitude, a camera-equipped drone can see not only the property over which it flies, but adjoining parcels. Naturally, this raises concerns of privacy, with those concerns drastically exacerbated by public proclamations of groups critical of standard agricultural practices that they will deploy drones to overfly agricultural operations in circumvention of "ag-gag" laws and to surveil livestock operations for potential environmental and animal well-being violations. *See* Lowe, P., "Drone to Fly Over Livestock Operations and 'Ag-Gag' Laws," Nebraska Educational Telecommunications Commission / Harvest Public Media, August 25, 2014. *Available at* http://www.netnebraska.org/article/news/933744/drone-fly-over-livestock-operations-and-ag-gag-laws. Pilots flying at low altitudes are also concerned about potential mid-air collisions with drones, as noted by a number of near-misses. *See* "Drone Sightings," Wall Street Journal, November 26, 2014, *available at* http://graphics.wsj.com/faa-drones/ .

2. "Small" and Big Data" on the Farm

The evolution and revolution in agricultural Big Data comes from the expansion of "Small Data" in agriculture. Recent years have seen remarkable growth in producers' ability to collect data pertaining to their own operation through the growth of techniques and technologies such as grid soil sampling, telematics systems for farm equipment, Global Navigation Satellite Systems (GNSS), farm aerial imagery acquired via small unmanned aerial systems (sUAS), and the like. In simplest terms, "Small Data" consists of data isolated to the fields or farms where the data originated. Farmers who use information technology to conduct their own

on-farm experiments, document yield penalties from poor drainage, or negotiate crop share agreements are using data that is considered "small." Coble, Keith *et al*, 2017. *Big Data in Agriculture: A Challenge for the Future*, APPPLIED ECONOMIC PERSPECTIVES AND POLICY, 40(1):79-96.

Drones represent only one of a myriad of tools now available to help producers accumulate data about their agricultural operations. Machinery-based and even hand-held sensors provide mountains of information about the operation of farm equipment as well as the inputs they apply, the crops they harvest, and even the ground over which they run. This data can be wirelessly uploaded to consultants and cloud-based data storage warehouses, sometimes even without any intervention on the part of the operator. The ability to aggregate data over hundreds or even thousands of farms creates the power to conduct analyses more powerful than ever-before imagined.

These capabilities give rise to the issue of "Big Data." While the term Big Data is relatively new, it refers to a concept that is not. There are many definitions for the term, but a straight-forward one might be "a collection of data from traditional and digital sources inside and outside your company that represents a source for ongoing discovery and analysis." Arthur, Lisa. 2013. What is Big Data? Forbes, CMO Network blog entry, *available at* http://www.forbes.com/sites/lisaarthur/2013/08/15/what-is-big-data/. While this definition sounds much like traditional data analysis (and it is), recent advances in both data collection and transmission increase the analytical power of datasets by orders of magnitude. Not only do companies now have access to data from every link in their supply and marketing chain from sensors on the factory equipment to GPS on delivery trucks and bar code scanners in the store; they can now track search engine inquiries for their product and listen directly to conversations about their products in social media. This profusion of data creates an enormous dataset, the analysis of which can do everything from predict the hot toy for Christmas this year to tell the Centers for Disease Control ground zero in the next influenza outbreak. Google.org. 2011. "Google Flu Trends: How Does it Work?" *available at* http://www.google.org/flutrends/intl/en_gb/about/how.html).

Given these considerations, a more complete definition of "Big Data" requires data considered truly "big" possess the following traits (Coble, Keith *et al*, 2016." Advancing U.S. Agricultural Competitiveness with Big Data and Agricultural Economic Market Information. Council on Food, Agricultural, and Resource Economics report):

Volume: The amount of data is so large it cannot be stored on one physical volume such as a hard drive; put another way, the analytical software must "go to" the data rather than the data being "brought to" it.

Velocity: The data comes at higher rates than can be handled by a single computer.

Variety: The data comes from a broad array of sources including data automatically gathered by sensors and software as well as data manually entered by users. This also means the data may come in a variety of formats with a lack of structure or design to it.

Veracity: The data analytics are required to consider the accuracy and credibility of the data, especially considering the "variety" considerations mentioned above and the potential for mis-calibration of automated data collection systems or user error (and bias) coming from manually-entered data.

The agricultural industry stands on the front line with other industries in the Big Data revolution. In agriculture, tremendous leaps in data acquisition equipment on everything from tractors to granaries coupled with instantaneous and continuous transmission of that data through cellular modems creates a dataset soon to rival that of any industry. In a farm context, Big Data means farmers can not only analyze their own production data in ways never before possible; they can also aggregate their data with other producers to drastically increase their ability to detect trends in everything from seed variety performance to the comparative economics of cultivation practices. As anyone who has taken a statistics class knows, the predictive power of a dataset grows with its size. The exponential growth of farm data means farmers will soon have analytic tools to rival those of any industry.

3. The Promise and Peril of Big Data on the Farm

If Big Data posed nothing but advantages, its discussion would not have the fevered pitch currently seen across virtually every agricultural media source. As with any tool, Big Data is neither inherently good nor evil – it is simply a tool. As with any tool, its benefits and dangers lie in how one uses it. Following is a discussion of these potential advantages and disadvantages.

Many a farm management teacher has proclaimed "you can't manage what you can't measure," and today's farmer lives in an era where almost everything on the farm can be measured, giving him or her the power to manage elements of agricultural production heretofore unimaginable. Improvements in farm equipment diagnostic and data acquisition systems alone provide the potential to diagnose equipment issues before they manifest themselves in downtime and to monitor a crop at literally every step of the production process from planting through cultivation and to harvest. One need only watch John Deere's "Farm

Forward" video to see a host of innovations made possible by these technologies and to realize that these possibilities are not as far away as one might think. John Deere, Inc. "Farm Forward (video) *available at* https://www.youtube.com/watch?v=jEh5-zZ9jUg.

Looking one step up the data ladder from the farm, cellular modem technology means producers can instantly and continuously share data with crop advisors and other consultants. These consultants can analyze this data (using their own Big Data tools), prepare recommendations, and even create prescriptions that can be uploaded to the producer's equipment to make on-the-fly adjustments to seeding, fertilizer, pesticide, and cultivation practices.

While these advantages alone make the prospects of Big Data tantalizing, the power of Big Data only comes to full force when it is truly big. What if equipment companies, consultants, and input suppliers combined the data from thousands of farmers into one massive dataset? Seed trials could be conducted in a fraction of the time as varieties could be compared across hundreds or even thousands of farms representing dozens of soil types, microclimates, and production systems simultaneously. The costs and benefits of various production systems and cultivation practices could be analyzed with similar speed. Plant disorders could be isolated and eradicated before costing producers their entire crops.

Lest one think any of these prospects to be far-fetched, many of them are (or soon will be) a reality. John Deere already uses real-time telematics data to analyze potential equipment failures to dispatch service technicians, and has partnered with Pioneer to provide near-real-time crop recommendations that can be uploaded to the farmer's equipment (Eckelkamp, 2013). Eckelkamp, Margy. 2013. John Deere Partners with Open Platform. Agweb.com, *available at* http://www.agweb.com/article/john_deere_partners_with_open_platform_NAA_Margy_Eckelkamp/. Monsanto's work through The Climate Corporation looks to create massive datasets to analyze a host of issues from plant variety protection to the impacts of climate change on crop production systems (Upbin, 2013). Just as the constantly increasing speed and decreasing size of processors continues to yield evermore-powerful computers, so too may one expect new applications of Big Data to farm issues.

Any new technology carries potential harms, whether real or imagined. In the realm of Big Data, recent history suggests many of the real threats come from insufficient controls to prevent the disclosure of personally identifiable information ("PII") to outside parties and inadequate agreements on the uses of data by parties to whom it is disclosed.

One need not look far into the past to find numerous examples of the disclosure of PII, whether merely inadvertent or the result of targeted hacker attacks. Attacks on companies' payment systems have resulted in the credit card information of hundreds of millions of customers from Adobe Systems (150 million customers), Heartland Payment Systems (130 million customers), TJX (parent company of TJ Maxx and Marshalls, 94 million customers), TRW Information Systems (credit reporting company, 90 million customers), Sony (70 million customers) all of which dwarf breaches attracting more media attention such as Home Depot (56 million customers) and Target (40 million customers). Pepitone, Julianne. 2013. "5 of the Biggest-ever Credit Card Hacks." CNN Money. *available at* http://money.cnn.com/gallery/technology/security/2013/12/19/biggest-credit-card-hacks/. Credit card theft may be the most direct form of PII theft, but theft of other individual pieces of information such as Social Security Numbers, addresses, and birthdays may allow a criminal to fabricate an identity as well. Farmers are understandably concerned that PII may be stolen if that information is disclosed to an outside party such as a financial consultant. However, most data disclosed to a crop production consultant will be in the form of raw data regarding crop production, GIS information about the farm, and the like. This significantly reduces the risk of identity theft by someone obtaining the data by illicit means. Nevertheless, farmers should still be aware of the data they are disclosing to providers as discussed later in this paper.

The theft of PII by criminals is one threat posed by data transfers, but so too is the inadvertent, or perhaps intentional but misinformed, disclosure of data by the party receiving that data. Take, for example, the disclosure of thousands of "farmers' and ranchers' names, home addresses, GPS coordinates and personal contact information" by EPA in response to a Freedom of Information Act (FOIA) request regarding concentrated animal feeding operations (CAFOs) which prompted a lawsuit from the American Farm Bureau Federation and National Pork Producers Council alleging that the agency overstepped its authority in doing so (Wyant, 2013). Wyant, Sara. 2013. "Farm Groups File Lawsuit to Stop EPA Release of Farmers' Personal Data." Agri-Pulse, available at http://www.agri-pulse.com/Farm-groups-file-lawsuit-to-stop-EPA-release-of-farmers-personal-data-07082013.asp. While this event represents the disclosure of information by an enforcement agency, many farmers fear the converse - that an enforcement agency could compel a data-receiving party to disclose information even if such disclosure were not legally required. Another concern is whether an adverse party in litigation (or even a party contemplating litigation) could persuade a party holding a farmer's data to disclose the data as an aid to their case, again even if such disclosure was not legally required.

All Data, Big and Small

Still another issue of concern for farmers, but clearly not limited to farmers, is how data – some willingly disclosed via social media platforms such as Facebook, Twitter, Instagram, and others – can be used for purposes well beyond those conceived when the user agrees to participate in such platforms. The myriad uses of data to psycometrically analyze and potentially manipulate users were highlighted in the Cambridge Analytica controversy. *See* Granville, Kevin, 2018. "Facebook and Cambridge Analytica: What you Need to Know as Fallout Widens," New York Times, March 19, 2018.

Indeed, a number of potential data uses lie within a gray area of conduct. These uses may seem wrong or at least uncomfortable at an intuitive level, but are not illegal at this point in time. The first such use – highly targeted or "laser" marketing – is encountered almost every day as one sees online ads through Google search results or Facebook selected based on a user's online profile. In some cases, this marketing can become uncomfortably precise and predictive, as was recently publicized by a recent story showing now Target's retail analytics could predict shoppers were pregnant (Duhigg, 2012). Duhigg, Charles. 2012. "How Companies Learn Your Secrets." The New York Times Magazine, available at http://www.nytimes.com/2012/02/19/magazine/shopping-habits.html?pagewanted=1&_r=2&hp&. In the agricultural realm, many of the consulting service providers to whom farmers are disclosing data are the same companies (or affiliates of companies) providing a number of other inputs such as seed, fertilizer, pesticide, and equipment. At a minimum, one could see a potential conflict of interest in such companies recommending products their affiliate provide, and at a maximum a customer could be barraged by solicitations for products based on their production patterns. Taken one step further, could such companies manipulate commodity markets themselves? If one thinks about it, equipment companies already have fleets of combines and other harvesters continuously uploading harvest data to their servers – what better market intelligence could one have? Although such behavior could arguably fit into some legally-prohibited practices, it is also arguably outside the reach of those prohibitions in that "really good intelligence" might not be regarded by courts as price manipulation. 17 C.F.R. § 180.1 (2015).

Salon.com summarized many of these fears in its article "Monsanto's Scary New Scheme: Why Does it Really Want All This Data?" Khan, Lina. 2013. "Monsanto's Scary New Scheme: Why Does It Really Want All This Data?" Salon.com, *available at* http://www.salon.com/2013/12/29/monsantos_scary_new_scheme_why_does_it_really_want_all_this_data/. Although the story may be speculative in some of the prospective problems it outlines, the old adage "perception is reality" bears some weight in the Big Data discussion. Although many argue that the potential advantages of Big Data on the farm will significantly outweigh the potential disadvantages (pointing out that any firms abusing the data relationship with producers will soon find themselves out of business), the perceptions of those concerns prevent many producers from exploring Big Data applications.

II. PROTECTING FARM DATA

A. Where does farm data fit in the current intellectual property framework?

The United States of America has one of the most robust systems of property rights in the world, empowered by a legal system making it (relatively) easy to enforce those rights. Thus, the first place many look for a means of protecting one's data from misappropriation and/or misuse is the property rights system. This requires one to examine who "owns" farm data. The answer to the question is not easy, though, as traditional notions of property ownership find challenge in their application to pure information.

The notion of property ownership typically involves some form of six interests, including the right to possess (occupy or hold), use (interact with, alter, or manipulate), enjoy (in this context, profit from), exclude others from, transfer, and consume or destroy. Some of these interests do not fit, or at least do not fit well, with data ownership. Excluding others from data, for example, is difficult, particularly when it is possible for many people to "possess" the property without diminishing its value to the others, just as the value of a book to one person may not be diminished by the fact other people own the same book. Smith, Lars. 2006. "RFID and other embedded technologies: who owns the data?" SANTA CLARA COMPUTER AND HIGH TECHNOLOGY LAW JOURNAL 22:4, 695. Thus, the better question may be "what are the rights and responsibilities of the parties in a data disclosure relationship with respect to that data?" (Petersen, 2013). Peterson, Rodney. 2013. "Can Data Governance Address the Conundrum of Who Owns Data?" Educause blog, http://www.educause.edu/blogs/rodney/can-data-governance-address-conundrum-who-owns-data.

Data is difficult to define under traditional notions of tangible property, but the intellectual property framework serves as a useful starting point to define what rights a farmer might have to their farm data. Intellectual property can be divided into four categories: (1) trademark, (2) patent, (3) copyright, and (4) trade secret. The first three areas compose the realm of federal intellectual property law as they are defined by the Constitution as areas in which Congress has legislative authority. U.S. Constitution, Article I, §8,

clause 8. For the purposes of the following discussion, "farm data" will include the types of data typically uploaded automatically by the farmer's equipment, such as diagnostic and use data, input application data, harvest data, and global positioning system (GPS) and geographic information system (GIS) data.

1. Trademark

One of the easiest intellectual property models to discard as a viable farm data protection tool is trademark. The Federal Trademark Act (sometimes called the Lanham Act) defines trademark as "any word, name, symbol, or device, or any combination thereof...to identify and distinguish his or her goods, including a unique product, from those manufactured or sold by others and to indicate the source of the goods, even if that source is unknown." 15 U.S.C. § 1127. Examples of trademark include product names, such as Coca-Cola® or the design of its contoured bottle. One quickly realizes trademark fits poorly as a model for defining farm data ownership, as trademark addresses intellectual property used for branding purposes rather than information.

2. Patent

The U.S. Patent Act states "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor." 35 U.S.C. § 101. Generally, for an invention to be patentable, it must be useful (capable of performing its intended purpose), novel (different from existing knowledge in the field), and non-obvious (somewhat difficult to define, but as set forth in the Patent Act, "a patent may not be obtained… if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains"). 35 U.S.C. §§ 102, 103. Patent serves as a poor fit for a model of farm data ownership since it protects "inventions." Raw data, such as farm data, would not satisfy the definition of invention.

It should be noted patentable inventions could be derived from the analysis of farm data. While this does not mean the data itself is patentable, it does suggest that the agreement governing the disclosure of farm data by the farmer should address who holds the rights to inventions so derived (as discussed below).

3. Copyright

The federal Copyright Act states the following:

> Copyright protection subsists, in accordance with this title, in original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device. Works of authorship include the following categories:
> literary works;
> musical works, including any accompanying words;
> dramatic works, including any accompanying music;
> pantomimes and choreographic works;
> pictorial, graphic, and sculptural works;
> motion pictures and other audiovisual works;
> sound recordings; and
> architectural works.

17 U.S.C. § 102(a). More so than trademark and patent, the copyright model at least resembles a model applicable to farm data. At the same time, however, the model also has numerous problems in addressing agricultural data. First, the list of "works of authorship" provided in the statue strongly suggests a creative component is important to the copyrightable material. Second, the term "original works of authorship" also has been interpreted to require some element of creative input by the author of the copyrighted material. This requirement was highlighted in the case of *Fiest Publications Inc. v. Rural Telephone Service Company*, 499 U.S. 340 (1991), where the U.S. Supreme Court held that the Copyright Act does not protect individual facts.

In *Fiest Publications*, the question was whether a pure telephone directory (consisting solely of a list of telephone numbers, organized alphabetically by the holder's last name) was copyrightable. Since the directory consisted solely of pure data and was organized in the only practical way to organize such data, the Supreme Court held the work did not satisfy the creative requirements of the Copyright Act. This ruling affirmed the principle that raw facts and data, in and of themselves, are not copyrightable. However, an author can add creative components to facts and data such as illustrations, commentary, or alternative organization systems and can copyright the creative components even if they cannot copyright the underlying facts and data. Put another way, the facts that hydrogen has an atomic number of 1 or that the number of ABC Plumbing is 555-1234 are not copyrightable, but an article about hydrogen in an encyclopedia or a Yellow Pages® ad with ABC Plumbing's number along with a graphic and description of their services are.

As with patent, farm data can lead to copyrightable works even if the underlying data is not protected itself. For example, farm data may not be copyrightable, but a

report summarizing the data and adding recommendations for action might be. Again, then, it is incumbent upon those disclosing farm data to include language in their agreements with the receiving party to define the rights to such works derived from the data.

4. Why trade secret might work as a farm data framework

While trademark, patent, and copyright do not appear to fit as models for farm data ownership, trade secret has the potential to fit the bill. Importantly, trade secret is a function of state law (unlike trademark, patent, and copyright, which are all creatures of federal law). As of this writing, all but three states have adopted the Uniform Trade Secrets Act, providing a significant degree of consistency in trade secret law across most states.

Under the Uniform Trade Secrets Act, a "trade secret" is defined as:

> …information, including a formula, pattern, compilation, program, device, method, technique, or process, that:
> (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
> (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Uniform Trade Secret Act, § 1. Importantly, this definition makes clear that "information… pattern[s], [and] compilation[s]" can be protected as trade secret. This, at last, affords hope of a protective model for farm data. This is not to say that trade secret is a "slam dunk" for protecting farm data, however. Note the two additional requirements of trade secret: first, that the information has actual or potential economic value from not being known to other parties, and second, that it is the subject of reasonable efforts to maintain the secret.

The first provision requires that to be protected as a trade secret, farm data such as planting rates, harvest yields, or outlines of fields and machinery paths must have economic value because such information is not generally known. While a farmer may (or may not) have a privacy interest in this information, the question remains as to whether the economic value of that information derives, at least in part, from being a secret. The counterargument to that point is that the economic value of the information comes from the farmer's analysis of that information and the application of that analysis to his or her own operation – a value completely independent of what anyone else does with that information – and that the information for that farm, standing alone, has no economic value to anyone else since that information is useless to anyone not farming that particular farm. One can see then this first element poses problems for the trade secret model. It should be noted here that there is a clear economic benefit to the collection of farm data; otherwise Monsanto would not spend nearly $1 billion in acquiring a company to aggregate such data. This represents a question yet to be answered clearly by the body of trade secret law: whether one can have trade secret protection in information that standing alone has no economic value to other parties, but does have such value when aggregated with similar data from other parties.

The second provision – that the data be subject to reasonable efforts to maintain its secrecy – also finds problems in an environment where the data is continuously uploaded to another party without the intervention of the disclosing party. The fact that data is disclosed to another party does not mean it cannot be protected as a trade secret; if that were the case, there would be little need for much of trade secret law. Rather, the question is how and to whom the information is disclosed. As noted in the Restatement (Third) of Unfair Competition's comments on the Uniform Trade Secret Act, "…the owner is not required to go to extraordinary lengths to maintain secrecy; all that is needed is that he or she takes reasonable steps to ensure that the information does not become generally known." (Smith, 2006, *citing* Restatement, 1995). The question becomes what constitutes "reasonable steps" to keep continuously uploaded data protected. Almost certainly this means there must be some form of agreement in place between the disclosing party and the receiving party regarding how the receiving party must treat the received information, including to whom (if anyone) the receiving party may disclose that information.

While an explicit written agreement is not necessary to claim trade secret protection, such an agreement is almost certainly a good idea. Not only can such an agreement clarify a number of issues unique to the relationship between the disclosing and receiving parties; it can also address numerous novel issues in the current information environment that trade secret law has not yet reached.

B. The Importance of Non-Disclosure Agreements

As the reader can see from the preceding discussion, there is not an intellectual property model presenting a spot-on fit for the protection of agricultural data. Trade secret comes closest, and if indeed a farmer can prove their data is protectable information (with the burden of such proof resting on the farmer), no agreement is needed to provide such protection. However, this scenario poses a tremendous amount of uncertainty and requires costly, time-consuming litigation.

Conversely, farmers disclosing their data, and service providers receiving it, proactively could enter a non-disclosure agreement (NDA) in which both parties

agree in advance to hold the information confidential and agree to what uses can and cannot be made of the data. Such an agreement may be entered even if the information would not be regarded as a trade secret, since the parties covenant to treat the information as secret independently; the obligations of the party derive from the contract itself and not another legal doctrine. The following discussion addresses attempts to address some NDA issues by corporate policies, and the provisions that should be considered by farmers when negotiating an NDA with a party to whom they will be disclosing farm data.

Many companies offering consulting or data analysis services have company policies addressing various concerns such as confidentiality of the information, specifying to whom the data may be disclosed, and uses that may be made of the data. Examples of such policies can be found in the Climate Corporation (2014) and John Deere (2014) data privacy statements. As an example of these policies, below is an excerpt from the John Deere Privacy and Data Statement:

> John Deere understands that you may not want us to provide Personal Information and Machine Data to third parties for their own marketing purposes. We limit our sharing of Personal Information and Machine Data as follows:
>
> We may share Personal Information and Machine Data with our affiliated companies, suppliers, authorized John Deere dealers and distributors, and business partners, which may use it for the Purposes listed above.
>
> We may also share Personal Information and Machine Data with our service providers to fulfill the Purposes on our behalf. Our service providers are bound by law or contract to protect the information and data, and to only use it in accordance with our instructions.
>
> We may disclose Personal Information and Machine Data where needed to affect the sale or transfer of business assets, to enforce our rights, protect our property, or protect the rights, property or safety of others, or as needed to support external auditing, compliance and corporate governance functions.
>
> We will also disclose Personal Information and Machine Data when required to do so by law, such as in response to a subpoena, including to law enforcement agencies and courts in the United States and other countries where we operate.

John Deere, Inc. 2014. Privacy and Data, *available at* https://www.deere.com/privacy_and_data/privacy_and_data_us.page. Policy statements can have value, but they are only legally enforceable if their text is incorporated by reference into a binding agreement between the farmer and the service provider. This underscores the need for some form of NDA. However, the relative bargaining power between the farmer and the service provider will obviously vary. Negotiating the terms of "boilerplate" agreements large corporations will provide to their customers will likely require high-level collective discussions between industry groups and corporate service providers (see the Epilogue). This discussion presumes at least some parity in bargaining power between the farmer and the service provider receiving the farm data.

The following is a list of items the farmer and his or her attorney should consider in drafting an NDA for the disclosure of farm data to a service provider. These considerations are compiled from the works of Bowden (1995) and Fishman and Stim (2001). Bowden, Brian. 1995. Drafting and Negotiating Effective Confidentiality Agreements (with forms). The Practical Lawyer, 41:7, pp. 39-56.. Fishman, Stephen and Richard Stim (2001). Nondisclosure Agreements: Protecting Your Trade Secrets and More. Nolo Press.

1) Execute the agreement prior to data disclosure: Trade secret law will not protect information voluntarily disclosed or publicly available (see Uniform Trade Secret Act, § 1 above). Thus, it is critical the NDA be executed before the disclosure of any data.
2) Define who is disclosing and receiving the information: In most cases, the farmer will be the disclosing party, and the service provider will be the receiving party, though this is not necessarily always the case. In many cases, the obligations of the agreement will be defined the role of the party, so defining when those roles are triggered is important.
3) Define what information will be regarded as confidential: Blanket statements that all information disclosed by the farmer to the service provider may be ineffective as the protection of all information may be impractical or counterproductive to the services provided. As a result, the agreement should define what information is, and is not, to be kept confidential, whether by category of information or the channel by which such information is transmitted.
4) Exclude information that will not be regarded as confidential: By the same token, it may be useful to define what categories of information are not to be treated as confidential and may be disclosed without further consent from the parties. Other information may be discloseable, but only with the express written consent of the party providing the information.
5) Establish a duty to keep the information secret: Perhaps the most important portion of the agreement, an affirmative contractual duty should be established that the party receiving the information must keep it secret. On the

other side of the same coin, this portion of the agreement should also explicitly prohibit the disclosure of the information, and should also define the measures the receiving party must take to maintain the secrecy of the information. This portion of the agreement may also be accompanied by a time limit on its enforceability, which is usually defined by an event (such as execution of a release by the party providing the information, or the public disclosure of the information by that party) rather than a period of time.

6) Specifically allowed/prohibited uses of information: This section of the agreement can spell out what uses of the information are specifically allowed, and which are specifically prohibited. The farmer and his or her attorney will wish to use care in making sure that the beneficial uses of the data motivating the farmer to seek the service provider's services are not blocked by these terms.
7) Data destruction requirements: The farmer may wish to require the destruction of all data transmitted to the service provider in the event of a breach of the agreement by the service provider or some other event terminating the agreement. While there may be merit in such provisions, it should also be noted that data destruction in today's highly-interconnected computing environment may be a practical impossibility. The most one may be able to achieve is the destruction of any hardcopies of the information and the complete erasure of physical drives where the data is stored.
8) Provision for injunctive relief: Without boring the reader with a discussion of civil procedure rules, suffice it to say that proving the case for "injunctive relief" (that is, an order from a court commanding an offending party to immediately cease a harmful activity such as releasing data, as opposed to the much more common remedy of ordering the offending party to pay monetary damages to the injured party) can be both costly and time-consuming, permitting the farmer to suffer continuing damages from data disclosure until it is stopped. A provision stating that the parties both agree that injunctive relief is appropriate in the specified circumstances can drastically shorten this process and limit the expenses in securing such relief.
9) Indemnity clause: The farmer may desire a clause stating the service provider will indemnify the farmer for any of his or her expenses (or the expenses of third parties asserting a claim against the farmer) caused by the wrongful disclosure of data.
10) Integration clause: An integration clause will state the entire agreement between the parties has been reduced to writing through the NDA. The effect of the integration clause is to exclude evidence of the parties' discussions in the negotiation of the agreement and to limit the resolution of any disputes to the language in the agreement itself. If the parties agree to an integration clause, it is critical all of their concerns be addressed in the text of the agreement.
11) Attorney's fees: The "American Rule" in most civil litigation is the parties pay for their own attorney's fees, unless a statute or other legal rule overrides this presumption. Frequently, contracts override this rule and require the losing party pay the prevailing party's costs; this is usually an attempt to minimize the chance of frivolous claims by one party. Farmers should use care in the inclusion of such language since it may result in the payment of significant legal fees if they should initiate what is eventually proven to be an unsuccessful claim against the service provider.
12) Alternative Dispute Resolution (ADR) and venue provisions: The parties may want to require any dispute among them be first submitted to ADR (arbitration or mediation) before the claim may be litigated. Large corporations often prefer arbitration as it may be faster and less expensive than litigation, but a growing body of research suggests arbitration may favor the corporation over other plaintiffs. The farmer may wish to specify mediation as a first line of ADR. At the same time, many large corporations fear they will be treated unfairly at the hands of local juries, where the opponent will have "home field advantage." This may or may not be true; by the same token, if there is to be such an advantage, does the farmer wish to relinquish it?
13) Disclosure under legal process: One situation in which the receiving party may have little choice in disclosing information is when they are legally compelled to do so. However, there may be disagreement about when a party is "legally compelled" to disclose information. To provide the best possible opportunity for both parties to determine is such disclosure is indeed legally required, many attorneys recommend a fourfold approach: (a) disclosure of the information is prohibited unless the receiving party is subpoenaed or otherwise compelled by some form of legal process; (b) the disclosing party must be given as much notice as possible, allowing them to contest the legal process; (c) the receiving party must use best efforts to

cooperate with the disclosing party; and (d) the receiving party may disclose only information which, in the written opinion of its legal counsel, it is required to disclose.

14) Liquidated damages: It may be difficult (or even impossible) to determine the amount of damages that the farmer has sustained from the disclosure of protected information. As a result, the farmer may wish to define an amount of liquidated damages in advance. Liquidated damages are simply an amount, agreed to in advance of a contractual breach, to be paid if a breach is proven to have occurred. The counterpoint to liquidated damages is that they serve as both a floor and ceiling to claimed damages; even if a farmer sustained greater damages than those negotiated in the liquidated damages provision, he or she will likely be deemed to have waived any claim to a greater damage amount.

III. CONCLUSIONS

Acquiring farm data via the use of drones currently poses a number of regulatory challenges, although continued pressure on the FAA to open up more avenues for drone use may eventually ease those restrictions.

Regardless of how farm data is acquired, though, Big Data on the farm holds the promise for tools heretofore undreamt of – tools necessary for the American farmer to meet the challenges of feeding a world population of 9 billion by the end of the 21st Century. At the same time, there are many concerns about the potential misuses of Big Data. Some of these concerns may prove to be more imagination than fact, but recent history is replete with reasons for those disclosing data to have legitimate reasons for seeking the assurance of data security. At the individual level, thoughtful consideration of the advantages and disadvantages of data use and the negotiation of thorough and balanced NDAs can do much to protect farmers' data interests. At the industry level, continued discussion of these issues can lead to proactive, negotiated solutions between large service providers and the agriculture industry.

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LEGAL CHALLENGES FACING UNMANNED AERIAL SYSTEMS AND COMMERCIAL AGRICULTURE

I. INTRODUCTION

Unmanned aircraft have existed for many years, but recent advancements in technology have prompted a rapid increase in their use. [1] By 2020, over 2.7 million small unmanned aircraft systems (UAS) could be navigating the nation's airspace for commercial purposes. [2] If estimates are accurate, agriculture will be one of the top industries employing UAS technology [3] and will represent approximately 80% of the worldwide UAS market. [4] The usefulness of UAS technology for agriculture leads some to predict that every farm or ranch will soon have one or two UAS. [5] Conversely, UAS also present risks and liabilities for commercial agricultural businesses and landowners. UAS offers a surveillance tool that may infringe upon perceived property and privacy rights and that, in the hands of those opposed to agricultural production or desiring to cause public harm, could be used to mischaracterize agricultural practices or harm agricultural property and goods.

***390** UAS technology has evolved much more quickly than a corresponding legal framework for UAS use. At the federal level, the surge in small UAS activity caught the FAA off guard and without a clear Congressional man-date for regulating UAS until Congress enacted the Federal Aviation Administration Modernization and Reform Act of 2012 (FMRA). [6] The FAA took a rigid approach for those seeking to use UAS for "commercial" purposes such as farming and ranching. Drawing a clear regulatory boundary between recreational and non-recreational uses, the agency declared the need for commercial, non-recreational operators of UAS to have certified aircrafts, certified pilots, and operating approval from the FAA. [7] The agency's interpretation required agricultural operators to pursue flight authorization from the FAA through its Section 333 exemption process [8] while the FAA developed specific regulations for the commercial operation of UAS. The specific regulations arrived several years later in 2016, when the FAA published its Final Rule to regulate small UAS used for commercial purposes. [9]

The lack of federal regulations to address airspace safety issues coupled with concerns over the potential misuse of UAS for surveillance, harassment, and personal or property harm has compelled many states to confront UAS issues. [10] As a result, state UAS legislation has swept the nation. [11] ***391** Undoubtedly, the new state laws will affect agriculture, either because they place additional operating requirements on agricultural UAS users or because they provide rights and remedies for potential UAS misuse by or against agricultural users and businesses.

This article examines the evolving federal and state legal landscapes that will impact agriculture's legal relationship with UAS technology. Part Two begins with an explanation of the FAA's new regulations for small UAS that now govern

commercial agricultural operators. In Part Three, we review recently enacted state laws that address issues of importance to agricultural businesses. Part Four presents problems and challenges facing agriculture as it navigates the legal UAS landscape.

II. FAA'S FINAL RULE FOR SMALL UNMANNED AIRCRAFT SYSTEMS

The final rule for the *Operation and Certification of Small Unmanned Aircraft Systems* (Small UAS Rule) was published on June 28, 2016, a direct outcome of FMRA. [12] In FMRA, Congress confirmed its intent to safely integrate UAS technology into the national airspace and directed the Secretary of Transportation to develop a comprehensive plan for doing so. [13] The Small UAS Rule largely replaced the burdensome Section 333 process to allow for routine civil operation of small UAS in the national airspace. [14] Following a notice of proposed rulemaking that generated over 4,600 comments, the Small UAS Rule became effective on August 29, 2016. [15]

Part 107 of the Small UAS Rule regulates the commercial use of UAS weighing less than 55 pounds by establishing a remote pilot certification ***392** process, a Remote Pilot in Command position, operational limitations, and a waiver process. [16] We explain each of these provisions in the following sections.

A. Remote Pilot Certification

Under the Small UAS Rule, no person may act as a pilot in command of a small UAS unless the person has a remote pilot certificate with a small UAS rating (RPC). [17] To obtain an RPC, an applicant must meet eligibility requirements, pass a knowledge test, and complete an application process.

1. Eligibility Requirements

An applicant for a RPC must be at least 16 years old; able to read, speak, write, and understand the English language; not know or have reason to know that he or she is in a physical or mental condition that would interfere with the safe operation of a small UAS; and be able to demonstrate aeronautical knowledge. [18] The applicant may demonstrate such knowledge either by passing an aeronautical knowledge test or completing a training course for small UAS if the person already holds a pilot certificate issued under 14 C.F.R. part 61 other than a student pilot certificate. [19]

***393** *2. Knowledge Test*

An applicant for a RPC who doesn't already hold a pilot certificate must pass the unmanned aircraft general (UAG) knowledge test in person through an FAA-approved Knowledge Testing Center. [20]

The test is an objective, 60-question, multiple-choice examination that covers the following areas as they relate to small UAS: (1) regulations regarding rating privileges; (2) limitations and flight operation; (3) airspace classification, operating requirements, and flight restrictions; (4) aviation weather sources and effects of weather on aircraft performance; (5) aircraft loading emergency procedures; (6) crew resource management; (7) radio communication procedures; (8) determining aircraft performance effects of drugs and alcohol; (9) aeronautical decision-making and judgment; (10) airport operations; and (11) maintenance and preflight inspection procedures. [21]

The FAA allows two hours to complete the test and requires a 70 percent passing score. [22] If an applicant fails, he or she may apply to retake the test after a period of 14 days. [23]

3. Remote Pilot Application

An eligible applicant who passes the UAG knowledge test must complete an application for the RPC.[24] The FAA administers the application online through its Integrated Airmen Certificate Rating Application System (IACRA)[25] and in paper form.[26] The application triggers a security threat assessment of the applicant by the Transportation Security Administration (TSA) to determine if the applicant poses a threat to transportation or national security, a risk of air piracy or terrorism, a threat to airline or passenger ***394** safety, or a threat to civil aviation security.[27] A successful security screening results in the issuance of the RPC, and an applicant who applied through IACRA may print a temporary certificate immediately upon receiving the security confirmation.[28] If TSA believes an applicant presents a security threat, TSA will not approve the application and will advise the applicant of its action in a written Initial Determination of Threat Assessment.[29] The applicant may appeal the determination to the TSA within 60 days.[30] Once certified, a remote pilot must pass a recurrent knowledge test every 24 months to maintain certification.[31]

B. The Remote Pilot in Command Role

The final Small UAS Rule varies from the earlier proposed rule, which recommended creating an "operator" role for small UAS flight control but did not establish a "pilot in command" position similar to airmen regulations for other types of aircraft.[32] To the contrary, in the final rule, the remote pilot certification allows a person to function as the pilot in command (Remote PIC) for a small UAS.[33] The new role expands the operator role from that envisioned in the proposed rule and recognizes the need to assign flight responsibilities to one of several "crewmembers" that may be involved in a small UAS flight.[34]

The Small UAS Rule sets out a number of general responsibilities for Remote PICs. A Remote PIC must be designated before or during any non-recreational, small UAS flight and is directly responsible for the operation of the small UAS.[35] The Remote PIC must ensure that the aircraft does not pose a hazard to people, aircraft, or property in the event of a loss of control of the aircraft; ensure compliance with all applicable regulations; and have ***395** the ability to direct the small UAS to ensure such regulatory compliance.[36] Importantly, the FAA grants a Remote PIC the discretion to vary from the Small UAS Rule's provisions in the event of an in-flight emergency that requires immediate action to the extent necessary to address the emergency.[37] Upon request, a Remote PIC who deviates from the rules in an emergency situation must provide a written report to the FAA.[38] Similar to other airmen certification rules, the Small UAS Rule allows a Remote PIC to supervise a small UAS flight by a person who does not have a RPC.[39] Such a person may manipulate the flight controls of a small UAS as long as a Remote PIC is able to directly and immediately take control of the flight.[40]

The Small UAS Rule also contains specific directives for the Remote PIC in addition to the general operating limitations for small UAS flights. A Remote PIC must conduct an inspection of a small UAS prior to its flight.[41] The rule specifies the components of a pre-flight inspection.[42] An accident-reporting provision requires the Remote PIC to report to the FAA within ten days any operation of a small UAS that caused serious injury to a person, loss of consciousness, or damage of at least $500 to any property other than the small UAS.[43]

***396** C. Aircraft Requirements

There are several provisions in the Small UAS Rule that pertain to the aircraft used in a UAS flight. The small UAS must be in compliance with the FAA's registration requirements, which apply to unmanned vehicles weighing more than .55 pounds. [44] A small UAS must also be in a condition for safe operation, [45] a mandate that corresponds with the Small UAS Rule's emphasis on pre-flight inspections. The Small UAS Rule calls for discontinuation of a flight if the person operating the small UAS knows or should know that the aircraft is no longer in a condition for safe operation. [46] Upon request, a small UAS must be made available to the FAA for testing or inspection. [47]

D. Operational Limitations

The rest of the Small UAS Rule lays out the constraints on where and how Remote PICs may operate small UAS. The limitations are intended to address the remainder of FAA's safety concerns and include see and avoid principles, contain and control provisions, flight-area restrictions, and prohibitions against hazardous operation.

1. See and Avoid Provisions

The FAA included several sections in the Small UAS Rule that aim to incorporate "see and avoid" principles for airspace collision avoidance. The visual line of sight (VLOS) rule states that the Remote PIC or person manipulating the flight controls of the small UAS must be able to see the aircraft throughout its entire flight without the aid of a visual device other than glasses or contact lenses. [48] This VLOS relationship with the aircraft requires that the operators be able to know the aircraft's location; determine its attitude, altitude, and flight direction; observe the airspace for air traffic and hazards; and ensure that the aircraft is not endangering another's life or property. [49]

***397** The Remote PIC may rely upon a visual observer to help maintain the VLOS. [50] The FAA describes a visual observer as an optional crewmember who can augment the small UAS operation but who does not have to hold a RPC. [51] A visual observer is subject to the VLOS conditions and must have direct communication with the Remote PIC and any other person manipulating the flight controls. [52] The Small UAS Rule requires coordination between a visual observer, Remote PIC, and the person operating a small UAS to ensure continuous scanning and awareness of the aircraft and airspace through direct visual observation. [53]

Other provisions in the rule also relate to see-and-avoid principles and collision avoidance. The rule requires a small UAS to yield the right of way to all other aircraft. [54] In doing so, a small UAS must give way to the other aircraft and cannot pass over, under, or ahead of the aircraft unless well clear. [55] Additionally, a small UAS must maintain a distance from any other aircraft that is sufficient to prevent a collision hazard. [56] The rule prohibits nighttime operation of a small UAS but allows operation during civil twilight with specified anti-collision lighting. [57] The minimum flight visibility required for operation is three miles, determined from the location of the small UAS controls. [58] A small UAS must be no less than 500 feet below and 2,000 feet horizontally from clouds. [59]

***398** *2. Contain and Control Provisions*

The Small UAS Rule includes several other restrictions intended to contain the area of operation to address the risk that a Remote PIC could lose the direct connection with a small UAS. The rule establishes a vertical boundary for a small UAS flight by limiting flight altitude to 400 feet above ground level, except when a small UAS is within a 400-foot radius of a structure and doesn't fly higher than 400 feet above the structure's highest point. [60] Horizontal boundaries arise with the VLOS requirement and prohibitions against operating a small UAS from a moving aircraft, although the rule

allows operation from a moving land or water vehicle if over a sparsely populated area. [61] The rule aims to mitigate the risks of losing positive control of a small UAS within its contained area of operation by limiting small UAS speed to 100 miles per hour, [62] prohibiting a person from operating the controls of, or serving as a Remote PIC or visual observer for, more than one small UAS at a time, [63] and not allowing flights of a small UAS over people who are not under the cover of a structure or vehicle unless the people are participating in the aircraft's operation. [64]

3. Flight Area Restrictions

The Small UAS Rule allows small UAS flights in Class G's uncontrolled airspace, while flights under the control of an Air Traffic Control facility--Class B, Class C, Class D, and certain Class E airspace--require permission from the appropriate Air Traffic Control prior to flight. [65] A small ***399** UAS cannot be operated near an airport, heliport, or seaplane base in a way that interferes with operations and traffic patterns. [66] Additionally, the Small UAS Rule incorporates typical flight-area restrictions for small UAS, such as prohibitions against flights in areas identified by the FAA as temporary disaster areas or major sporting events. [67]

4. Hazardous Operation Prohibitions

Careless or reckless operation of a small UAS in a manner that could cause danger for the life or property of another is prohibited by the Small UAS Rule. [68] A person may not create an undue hazard to people or property by dropping an object from a small UAS [69] and cannot use a small UAS to transport hazardous materials. [70] The rule prohibits manipulating small UAS flight controls or acting as a Remote PIC, visual observer, or participant in small UAS operations with the knowledge of a mental or physical condition that could interfere with the safe operation of the small UAS [71] or while under the influence of drugs or alcohol. [72]

E. The Waiver Process

The FAA decided to add a waiver process to the Small UAS Rule to address the possibility of emerging new technologies that could alleviate some of the risk concerns underlying the Small UAS Rule and to recognize ***400** unique operating conditions for some small UAS applications. [73] The waiver mechanism allows a small UAS operation to deviate from operational restrictions in the rule if the FAA finds that the proposed operation can be safely conducted. [74] An applicant may request a waiver from nine sections of the rule: VLOS; visual observer; operation from a moving aircraft or vehicle; daylight operation; operation of multiple aircraft; yielding the right of way; operation over people; operation in airspace other than Class G airspace; and limitations on speed, altitude, visibility, and cloud distance. [75]

A person requesting a certificate of waiver must complete an online application that describes the proposed operation and justifies that the operation can be safely conducted under the terms of the waiver. [76] The FAA may place additional restrictions in the certificate of waiver. [77] If issued, a certificate of waiver requires the operator to deviate as stated in the waiver and in accordance with conditions and limitations. [78]

III. STATE LAWS AFFECTING UAS AND AGRICULTURE

The Small UAS Rule offers a federal regulatory framework for managing the safety risks of UAS flights in the national airspace, but intensified UAS activity also requires attention to other legal issues such as potential infringements on privacy rights, conflicts between private and public rights to airspace, and use of UAS for unlawful or harmful activities.

Since 2013, state lawmakers have introduced hundreds of bills and resolutions, with every state except Colorado enacting one or multiple laws or resolutions regarding UAS. [79]

Federal preemption is a frequent point of debate in matters concerning our country's navigable airspace, and state legislative activity on UAS adds new complexities to the discussion. [80] Courts have consistently looked to ***401** federal aviation laws as indicators of congressional intent to occupy the entire field of aviation safety. [81] Some argue that unmanned aircraft regulation fits squarely within the field of "aviation safety," [82] including the FAA's Office of the Chief Counsel, which provided guidance on state and local authority to regulate UAS in the midst of heightened state UAS legislative activity in 2015. [83] The guidance described the federal regulatory framework for UAS and cautioned state and local governments against attempting to regulate the operation of UAS in a way that would create fractionalized control of the navigable airspace. [84] The FAA also explained that UAS issues related to surveillance and search warrants, voyeurism, harassment of hunters and fishermen, and weaponizing UAS are not subject to federal regulation because they relate to state and local police power. [85]

The U.S. Senate attempted to codify federal preemption for UAS regulation with specific language in the FAA Extension, Safety and Security Act of 2016. [86] The Senate's language clarified that state and local governments would not be limited in their authority to create and enforce laws relating to "nuisance, voyeurism, privacy, data security, harassment, reckless endangerment, wrongful death, personal injury, property damage, or other illegal acts" arising from the use of UAS. [87] However, Congress did not include the Senate's preemption language in the final version of the law, [88] despite concerns from the UAS industry that a patchwork of state and local laws could hamper UAS development. [89] Such interests assert that, at some point in the ***402** near future, there will be preemption challenges to state and local UAS laws that aren't clear extensions of state and local police powers. [90]

Many of the new state laws for UAS that may affect agriculture provide remedies for contending with potentially harmful UAS impacts such as privacy interference, harassment, and trespass--issues that we can easily classify as extensions of state police power. But a handful of states have enacted legislation that arguably strays into the realm of aviation safety; actions that may lead to preemption challenges. In the following, we discuss laws that establish state regulatory programs for commercial UAS operators and state laws that address important concerns for agriculture--privacy, harassment, and trespass.

A. State UAS Regulatory Programs

Louisiana and North Carolina have enacted state UAS operating requirements, two laws that appear to collide with the FAA's charge to regulate the field of "aviation safety." [91] To date, however, neither state law is the source of a federal preemption challenge. Notably, Louisiana's law affects only commercial agricultural UAS operators, [92] while North Carolina's operating requirements apply to all commercial and governmental UAS users. [93]

In 2015, Louisiana's legislature directed its Department of Agriculture and Forestry (LDAF) to establish a registration and licensing process for agricultural commercial operations using UAS. [94] The law evolved a year before the FAA proposed its Small UAS Rule and a year after the Louisiana legislature tasked a stakeholder group to study the use of UAS for agricultural purposes and recommend actions or legislation. [95] A provision allowing agricultural commercial operators who obtain a license to use UAS over ***403** their properties [96] is of questionable value in the wake of the Small UAS Rule. [97] Additional provisions in the law require license applicants to complete a safety training course [98] and authorize LDAF to prohibit violators from continued UAS operations. [99] LDAF filed its proposed regulations for

agricultural commercial operation of UAS in February of 2016, [100] but the regulations are not yet final as of the date of this publication, likely due to the intervening finalization of the Small UAS Rule.

North Carolina's 2015 law established a state UAS permit process for commercial and governmental UAS operators that is currently in effect. [101] UAS permit applicants must be at least 16 years old, hold a valid driver's license, and pass the state's own UAS knowledge test; [102] prerequisites that duplicate the now effective Small UAS Rule. Given the state's explanation of a "commercial operator" as one who uses UAS technology for business purposes, agricultural businesses using UAS are subject to North Carolina's permit requirement. [103] Permitted commercial operators must agree to terms and conditions that include holding appropriate authorization from the FAA for UAS operations; abiding by all federal, state, and local laws; and assuming all risks and liabilities associated with UAS operation. [104]

*404 B. State Privacy and Surveillance Laws

1. Federal Background

A major issue surrounding the rise of UAS has been the technology's potential impact on the privacy rights and security of citizens and landowners throughout the United States. [105] Small, affordable UAS with fairly sophisticated cameras provide an easy way to covertly view and capture images and data of people and property. The technology can raise fears of privacy invasions, such as those reported by citizens who believe they will suffer a loss of privacy if agencies use UAS for criminal investigations. [106]

While the FAA recognizes that UAS pose a new set of challenges over privacy rights, the agency determined that it lacked authority to address privacy within the Small UAS Rule. [107] As an alternative, President Obama ordered federal departments and agencies in 2015 to take steps to safeguard privacy, civil rights, and civil liberties in the face of UAS integration into ***405** the national airspace. [108] The President's memorandum also established a multi-stakeholder, public-private process to develop best practices for privacy, accountability, and transparency issues associated with UAS use in the national airspace. [109] The stakeholder process yielded a report in 2016 of recommended best practices for commercial, non-commercial, and news-reporting users of UAS, [110] while noting that the practices would not replace or take precedence over any local, state, or federal laws. [111]

In Congress, Senator Rand Paul unsuccessfully advocated legislation as early as 2012 to circumscribe governmental UAS intrusion into the private affairs of citizens. [112] Senator Edward J. Markey has proposed the Drone Aircraft Privacy and Transparency Act without success four times since 2012. [113] The proposed legislation would direct the FAA to identify threats to privacy from UAS, require data collection statements from licensed UAS operators, make UAS certificates and licenses available in a searchable format on FAA's website, instill privacy protections for law enforcement and intelligence use of UAS, and provide civil remedies for prohibited acts. [114]

*406 *2. State Approaches to Privacy and Surveillance*

Given growing apprehensions about UAS and privacy, and the limited federal role in confronting such concerns, many states hastened to devise parameters for UAS surveillance activities and provide remedies for privacy invasions. [115] A common thread of debate over privacy legislation in the states has been whether the Fourth Amendment [116] or the traditional tort laws of false light, appropriation, intrusion of seclusion, and public disclosure of private facts [117] already

provide adequate remedies for UAS privacy situations. In spite of potential duplication with existing legal remedies, nearly half of the states have enacted legislation that provides specific privacy protections from UAS activities. [118]

A number of "Freedom from Unwarranted Surveillance" acts modelled after Senator Paul's federal proposals began trending the states in 2013, and several states enacted the law in some form. [119] Three approaches emerge from these laws: (1) establishing new civil and criminal actions for unauthorized governmental or private surveillance activities; (2) prohibiting surveillance of critical infrastructure; and (3) instituting policies and procedures for law enforcement and other governmental users planning to conduct searches and gather evidence with UAS. While recognizing that governmental ***407** surveillance activities and threats to critical infrastructure are important issues, we summarize below only the laws that address unauthorized UAS surveillance by civilians because they most directly relate to surveillance and privacy concerns for farms and ranches. Within our identified subset of laws, we decline to discuss laws that relate to voyeurism as those would not likely apply to agricultural situations.

3. Approaches that Target Surveillance of Agricultural Property

Idaho's Preserving Freedom from Unwanted Surveillance Act [120] is the only state law that specifically includes farms, ranches, and the agricultural industry within the scope of its surveillance protection. [121] The law states that no person, entity, or state agency shall use a UAS to photograph or record a person without that person's consent and shall not, absent a search warrant, use a UAS to:

> "... intentionally conduct surveillance of, gather evidence or collect information about, or photographically or electronically record specifically targeted persons or specifically targeted private property including, but not limited to:
>
> i. An individual or a dwelling owned by an individual and such dwelling's curtilage, without such individual's written consent;
>
> ii. A farm, dairy, ranch or other agricultural industry without the written consent of the owner of such farm, dairy, ranch or other agricultural industry." [122]

The statute creates a civil cause of action for a person who is the subject of the prohibited UAS conduct and entitles the person to at least $1,000 or actual damages plus attorney fees and litigation costs. [123] Legislators in New Mexico and Missouri unsuccessfully proposed laws similar to Idaho's restriction against UAS surveillance of agricultural settings. [124]

The introduced version of an unsuccessful 2013 bill in North Carolina [125] contained a prohibition regarding agricultural surveillance but the ***408** House Judiciary Committee substituted the bill's application to "farms, ranches, and agricultural industry" with a broad reference to "private real property." [126]

4. Reasonable Expectation of Privacy Approaches

In its Freedom from Unwarranted Surveillance Act, [127] Florida codified a "reasonable expectation of privacy test" [128] for UAS surveillance conducted by any person, state agency, or political subdivision. [129] UAS surveillance of private

property or a person on private property in violation of the person's "reasonable expectation of privacy" is prohibited. [130] The statute explains that a person is presumed to have a reasonable expectation of privacy on his or her privately owned real property if "he or she is not observable by persons located at ground level in a place where they have a legal right to be, regardless of whether he or she is observable from the air with the use of a drone." [131] An injured party may initiate a civil action for injunctive relief or compensatory damages, including attorney fees, and may also seek punitive damages. [132] Michigan, South Dakota, and Utah have also adopted a "reasonable expectation of privacy" approach for circumscribing UAS surveillance. Michigan's 2016 law prohibits intentional capture of photographs, video, or audio recordings by UAS in a manner that would invade a person's reasonable expectation of privacy. [133] Violation can lead to criminal misdemeanor charges. [134] In its 2017 legislation, South Dakota amended its statute that prohibits trespassing with intent to eavesdrop. [135] The amendment established misdemeanor penalties for intentionally using a drone to photograph, record, or otherwise observe another person in a "private place" where the person has a "reasonable expectation of privacy" or landing a drone on the lands or ***409** waters of another resident without the owner's consent. [136] Unlike Florida, neither Michigan nor South Dakota's law provides guidance for determining when a "reasonable expectation of privacy" exists. Utah devised a slightly different approach when it amended its privacy violation offense to include a prohibition against using a device to observe or photograph a person in a private place where the person may reasonably expect to be safe from casual or hostile intrusion or surveillance. [137] Both South Dakota and Utah exempt persons operating UAS in compliance with FAA regulations for commercial, educational, or agricultural purposes from privacy offenses. [138]

5. Other State Approaches to Privacy and Surveillance

The North Carolina Legislature successfully added UAS surveillance protection language and other UAS provisions to North Carolina's Appropriations Act of 2014. [139] With certain exceptions for law enforcement, newsgathering, or general public events, North Carolina's law states that no person, entity, or State agency shall use a UAS to:

1) Conduct surveillance of:

a) A person or a dwelling occupied by a person and that dwelling's curtilage without the person's consent.

b) Private real property without the consent of the owner, easement holder, or lessee of the property.

2) Photograph an individual, without the individual's consent, for the purpose of publishing or otherwise publicly disseminating the photo-graph. [140]

As with Idaho's law, North Carolina affords aggrieved parties a civil cause of action that may include damages, attorney fees, and injunctive relief, including recovery of $5,000 for each photograph or video published or disseminated. [141]

Tennessee's General Assembly passed its Freedom from Unwarranted Surveillance Act in 2013 [142] and, within a year, passed a second and more ***410** comprehensive bill that establishes misdemeanor criminal offenses for any person who uses a UAS to capture images of individuals or privately owned real property with the intent to conduct surveillance

on the individual or property. [143] A person who possesses, displays, or distributes images captured by an unauthorized surveillance is subject to criminal misdemeanor charges, but the law provides a defense if the person destroys or stops displaying images upon gaining knowledge that the images were captured un-lawfully. [144]

Although titled differently than similar laws, the Texas Privacy Act, [145] adopted in 2013, also establishes a criminal offense for illegal use of a UAS to capture images of an individual or private property with the intent to conduct surveillance. [146] Texas couples the criminal offense with considerable civil remedies. An owner or tenant of property may seek injunctive relief or damages against a person who illegally captures images of the property, the owner, or a tenant on the property. [147] Damage awards are $5,000 for images captured in an unauthorized surveillance and $10,000 for disclosure, display, or distribution of the images, plus actual damages if a person disseminates images with malice. [148]

Louisiana addressed UAS surveillance by amending its criminal trespass statute in 2016. The Legislature established a criminal trespass offense for the unauthorized operation of a UAS "in the air space over immovable property owned by another with the intent to conduct surveillance of the property or of any individual lawfully on the property." [149] The law excludes the operation of a UAS in compliance with federal law or FAA regulations. [150] Violation of the statute can result in fines and imprisonment. [151]

*411 C. State UAS Harassment Laws

Concerns over UAS as mechanisms for harassment activities arose quickly when animal-rights organizations began encouraging the use of UAS to identify individuals in the act of violating hunting laws and regulations. [152] Outdoorsmen claimed the actual purpose of such efforts was to impede hunting activities and intentionally harass hunters engaged in lawful hunting. [153] Several states responded by creating criminal offenses for using a UAS to interfere with lawful hunting, fishing, or trapping. [154] Similar concerns about UAS harassment have emerged in the agricultural community.

In addition to the potential of using UAS to harass agricultural producers who raise animals or use certain production practices, producers also face harm to livestock resulting from general pranks that involve using UAS to chase or frighten livestock in open fields. [155] Utah, the only state to specifically address UAS harassment, established a criminal offense for the use of UAS to harm or intentionally, knowingly, or recklessly chase livestock with the intent of causing distress. [156] A first-time offender who forces displacement of the animals or doesn't cause serious injury or death to the livestock is guilty of a Class B misdemeanor and subject to a $1,000 fine. [157] A repeat offense causing serious injury or death to livestock, or damaging property in excess of $1,000, leads to a Class A misdemeanor and a $2,500 penalty. [158]

In 2016, Kansas expanded the definition of harassment in its Protection from Stalking Act to include "any course of conduct carried out through the use of an unmanned aerial system over or near any dwelling, occupied vehicle ***412** or other place where one may reasonably expect to be safe from uninvited intrusion or surveillance." [159] The law offers judicial protection from UAS harassment activities. [160] Michigan's legislature took similar action the same year. [161] Its Unmanned Aircraft Systems Act prohibits a person from knowingly and intentionally operating a UAS to subject an individual to harassment. [162] A violation results in misdemeanor charges. [163]

D. State UAS Trespass Laws

UAS technology sets up an inevitable conflict between UAS flight operators and the owners and possessors of property who may believe a UAS is committing a trespass by flying too close to private property. Shortly after the invention

of the airplane, the *ad coelum* doctrine's holding that the owner of land also owned the skies above the land created the possibility of committing trespass when using airspace for aviation. [164] The Air Commerce Act of 1926 diluted the conflict between land and air rights by recognizing a public right of transit through the nation's navigable airspace, [165] set for safety reasons at a minimum height of 1000 feet over populated areas and 500 feet elsewhere. [166] At the same time, courts rejected the breadth of the *ad coelum* doctrine, holding instead that a landowner possesses rights in the air space immediately over the land surface in relation to uses taking place on the land surface, described as "a dominant right of occupancy for purposes incident to his use and enjoyment of the surface ...." [167] and "at least as much of the space above the ground as [the landowner] can occupy or use in connection with the land." [168] Accordingly, the extent of a private property owner's rights in airspace varies according to the owner's surface uses.

***413** These historical attempts to separate private property rights and aircraft navigability rights are further muddied by the entrance of UAS into the skies. The Small UAS Rule requires UAS to operate beneath 400 feet, an altitude that could lead to claims of trespass due to alleged interference with an owner's legal right of occupancy in airspace that is "incidental" to the owner's use of the land surface. Perhaps equally relevant is the perception that a trespass is occurring, prompted by the physical presence of UAS at much lower altitudes than property owners experience with other types of aircraft. [169] Such conflicts have driven states to attempt further clarification of the boundary between public navigable airspace and private property, [170] although few have navigated the challenge successfully. As holders of a significant portion of the nation's private lands, agricultural landowners will undoubtedly encounter UAS trespass issues on their properties. Conversely, as primary users of UAS technology, agricultural UAS operators may be subject to trespass claims by other landowners.

Several early laws attempted to establish a minimum elevation for UAS flights. Oregon's 2013 UAS trespass law allows an owner or occupier of property to bring a trespass action against a UAS operator who later repeats a UAS flight at less than 400 feet over the owner or occupier's property after being notified that the owner or occupier does not authorize the flight. [171] The Legislature twice amended the law in 2015; first, removing the requirement that the UAS be operating at less than 400 feet [172] and next, disallowing a trespass action against a UAS operated for commercial purposes in compliance with FAA rules. [173] Nevada passed a nearly identical law in 2015 for flights under 250 feet in elevation. [174] Both states permit a plaintiff to ***414** recover treble damages for any injuries resulting from the trespass, in addition to attorney fees. [175]

Although California's legislature passed a UAS trespass bill in 2015, [176] Governor Brown vetoed the measure because the law would "expose the occasional hobbyist and the FAA-approved commercial user alike to burdensome litigation and new causes of action." [177] The bill would have extended liability for wrongful occupation of real property to a person who operates a UAS at an elevation less than 350 feet without express permission. [178]

South Dakota failed to enact similar legislation in 2017. The legislation would have prohibited low altitude UAS flights that interfere with existing land and water uses, the space over land and water, or that are imminently dangerous or damaging to a person or property lawfully on the land or water beneath the flight. [179] The legislature removed that provision and instead amended its trespass with intent to eavesdrop statute to prohibit landing a UAS on lands or waters of another resident without the owner's consent; a class one misdemeanor. [180]

Utah also employed the criminal trespass approach in its 2017 UAS bill. [181] Criminal trespass in Utah now includes causing a UAS to enter and remain unlawfully over property, for which notice against the entering has been given, [182] or entering and remaining unlawfully over property with intent to cause annoyance or injury, with intent to commit

a crime, or with reckless disregard for the fear for safety caused by the UAS. [183] Violation of the statute can lead to misdemeanor charges. [184]

*415 IV. CHALLENGES AND IMPLICATIONS FOR AGRICULTURE

A. The Small UAS Rule

As FAA developed its plan and proposed rule, the agency required operators desiring to fly UAS for commercial, work, or business purposes to seek authorization from the FAA on a case-by-case basis through FMRA's Section 333 process, [185] claimed by many to be burdensome and time consuming. [186] Many applaud the Small UAS Rule for providing greater regulatory certainty than the alternative Section 333 regulatory process, an improvement that will ultimately accelerate UAS technology development. [187] The Small UAS Rule is not without its critics, however. In the agricultural sector, dissatisfaction with the rule centers in three key areas: certification standards, the VLOS requirement, and restrictions on nighttime flying. The rule's waiver provisions may diminish some of these concerns.

In the agricultural arena, we would expect criticism of the Small UAS Rule certification standards to come from those who must meet the standards, [188] but the strongest criticism arises from other users of the zero to 400 foot airspace who claim that the standards are too lenient given the risks of collision presented by small UAS. [189] The agricultural aerial applicator industry, [190] concerned with collision avoidance in shared airspace with UAS, argues that visibility test results indicate that UAS operators should be subject ***416** to the more demanding FAA airman certification standards and should be required to pass an actual skills test. [191] The FAA responded to these concerns by stating that a more stringent approach would impose significant cost burdens with little corresponding safety benefits. [192]

Additional disapproval of the Small UAS Rule centers on its VLOS restriction. Some claim that maintaining an unassisted line of sight will be difficult for agricultural UAS operators [193] and will impede the usefulness of UAS technology when used over sizable agricultural acreages. [194] Many argue that UAS technology is capable of safe operation "beyond visual line of sight" (BVLOS) but are willing to accept the FAA's incremental approach to the issue until more UAS possess avoidance protection technology. [195] FAA Administrator Huerta recently suggested that BVLOS regulations would be under development in 2017. [196] For now, the FAA prefers to address VLOS complaints by allowing operators who are hampered by the restriction to seek a waiver of the provision. [197] Congress may choose to direct the issue, ***417** however, as indicated by language included in the recently proposed FAA reauthorization bill that would require the FAA to develop regulations for BVLOS flights. [198]

The agricultural industry asserts that the Small UAS Rule's daylight-only restriction also hinders the potential benefits of UAS technology for agricultural uses. Many UAS flights over agricultural crops are best conducted at night due to temperatures, weather conditions, or imaging capabilities. [199] In the final rule, the FAA did not eliminate the proposed rule's daylight-only restrictions but did expand the rule to allow operation during "civil twilight" with appropriate lighting. [200] Consistent with its handling of other operating restrictions, the FAA proposed the waiver process as the mechanism for accommodating nighttime flight need, stating that the agency would allow a small, nighttime UAS operation "if an applicant can demonstrate sufficient mitigation such that operating at night would not reduce the level of safety of the operation." [201]

UAS operators have indeed utilized the Small UAS Rule's waiver process. In the rule's first five months, the FAA approved 318 waivers. [202] By far, the daylight operation restriction is the most common waiver request, with only 14 of

the 318 requests seeking to waive a provision other than the daylight operation restriction. [203] Nine applications asked the FAA to set aside the restriction on multiple UAS operations, and two requested waivers of the VLOS restriction. [204] The visual observer, weather visibility, and operation from a moving vehicle provisions were each the subject of one waiver request. [205]

***418 B. State Regulation of UAS**

Few states have appeared anxious to implement a state regulatory program for UAS operators since the FAA devised its Small UAS Rule. [206] North Carolina's state-level permitting program, enacted prior to the Small UAS Rule, does establish additional steps and a state-based knowledge test for commercial UAS operators who are now also subject to certification by the FAA. Louisiana's regulatory program for commercial agricultural UAS users may have intended to enable UAS operations on farms when originally drafted prior to the Small UAS Rule, but if implemented, the program will duplicate the FAA's Small UAS Rule. Both state laws create regulatory burdens for commercial agricultural UAS operators and contribute to the potential of "fractionalized control of the navigable airspace" against which the FAA warned states that were considering UAS legislation. [207] Whether there will be a preemption challenge alleging that the state regulations interfere with the federal government's intent to occupy the entire field of aviation safety is an important question for commercial agricultural UAS users in North Carolina and Louisiana.

Equally important is the question of the utility of UAS surveillance and privacy protection laws for agricultural situations. For farmers and ranchers, UAS technology raises unique privacy and security problems. Animal rights advocates and environmental interests have published threats to use UAS to "pull back the curtain" on the agricultural industry [208] and see what is "invisible and hidden" from the public. [209] Internet sites already host photographs and videos gathered through UAS surveillance activities. [210] While some private surveillance might legitimately disclose regulatory violations on farms, it is equally possible that images and data obtained by UAS surveillance could be misrepresented, misused, or misunderstood. As the agricultural community has already experienced, dissemination of skewed or untruthful ***419** information by interests opposed to agriculture can result in negative publicity, sales losses, and personal threats. [211]

Only Idaho's law specifically references unauthorized surveillance of farms, ranches, and dairies, but criticism of Idaho's law as another type of "ag-gag" [212] law that shields farmers from criminal exposure [213] raises the possibility of legal challenges. Idaho and several other states enacted ag-gag laws to punish undercover video surveillance of livestock and poultry facilities by animal welfare advocates posing as employees. [214] Proponents of ag-gag claim that the laws protect farmers from skewed or misleading depictions of farm practices that are obtained unlawfully, [215] an argument that also applies to UAS surveillance protection laws for farms. A federal district court has struck down Idaho's ag-gag law for violating freedom of speech and equal protection rights based upon the law's intent to "limit and punish" those who would speak out against agriculture and its "animus to animal welfare groups." [216] Most of the other ag-gag laws face similar constitutional challenges. [217] Meanwhile, animal welfare advocates have publicly announced ***420** UAS as a tool for side-stepping ag-gag laws, [218] suggesting the possibility that state laws circumscribing UAS surveillance could also see constitutional challenges. Would a court interpret Idaho's law and its specific reference to farms as another hostile attempt to "limit and punish" those who would speak out against agriculture? An important distinction to note is that Idaho's UAS surveillance law shields all individuals, their dwellings, and their curtilage from UAS surveillance along with its protection of agricultural properties, rather than targeting only agricultural properties. [219]

Other state laws that generally prohibit UAS surveillance of any private real property can apply to farms and ranches that experience unauthorized UAS surveillance. Laws in Florida, Michigan, South Dakota, and Utah include a "reasonable

expectation of privacy" standard for surveillance interferences, which some claim will "inspire a new wave of litigation" for invasion of privacy claims.[220] To utilize such remedies, agriculture would be forced to argue that a reasonable expectation of privacy or a reasonable expectation to be safe from private aircraft surveillance should exist for open agricultural fields, curtilage, and agricultural structures, areas that don't fare well under judicial scrutiny of privacy rights in relation to Fourth Amendment governmental searches.[221]

Further complications with these UAS surveillance protection laws stem from the nature of UAS surveillance technology. In its landmark *Dow Chemical* decision, the Supreme Court ruled that for purposes of aerial surveillance by governmental agencies, a property owner does not have a reasonable expectation of privacy when 'publicly available' technology such as photographic equipment is used to collect images from an aircraft flying at a legal altitude, as opposed to surveillance by highly sophisticated surveil ***421** lance equipment that is not publicly available.[222] A critical question for purposes of the reasonable expectation of privacy is whether privacy spaces will narrow as UAS technology becomes more common and publicly available. Should this evolution occur, it will logically become more difficult for farmers and ranchers to establish privacy spaces that are safe from UAS surveillance.

Perhaps to combat this possibility, Florida's statute establishes a "ground level" standard of privacy for aerial UAS surveillance,[223] an approach that conflicts with *Dow Chemical's* allowance of a technologically-driven standard for privacy and governmental searches.[224] For agricultural landowners in Florida, the law could result in an expansive definition of privacy rights, since many agricultural spaces are not easily observable from ground-level places such as a public road. Agricultural landowners under Michigan and South Dakota's laws,[225] which also incorporate a reasonable expectation of privacy standard, may face an aerial standard of privacy that could diminish the value of the statute for prohibiting aerial surveillance of farms and ranches.

Several of the state UAS privacy and surveillance laws include exceptions for claims against persons operating UAS in compliance with FAA regulations for commercial, educational, or agricultural purposes.[226] These exceptions can buffer agricultural UAS operators from privacy or surveillance claims resulting from unintended or accidental surveillance that may occur in the course of conducting UAS operations for agricultural purposes. Conversely, the exceptions could create a loophole by allowing a UAS operator holding Small UAS Rule certification to conduct otherwise prohibited surveillance and be free from privacy claims as long as the operator is in compliance with the Small UAS Rule, which consequently does not include regulations that affect privacy or property rights. Senator Markey's proposed Drone Aircraft Privacy and Transparency Act[227] could alter this scenario. The proposal advocates requiring data-collection statements that establish privacy guidelines for the collection of data and information by UAS ***422** operators.[228] An operator who failed to follow the provisions would not be in compliance with FAA and thus could not utilize the exception from the surveillance protection statute.[229]

Of the handful of state UAS harassment laws, Utah's livestock harassment statute[230] is most useful for agriculture. While the law criminalizes actions against livestock,[231] it doesn't establish clear civil remedies for resulting harm to livestock from UAS harassment. The UAS harassment statutes in Kansas and Michigan could conceivably apply to repeated intrusions of UAS near persons engaged in an agricultural operation, but the required causation of fear or emotional distress as a result of the UAS harassment[232] may limit the law's relevance to all potential harassment activities. Perhaps also applicable to potential agricultural situations would be laws modeled after UAS hunter harassment statutes, which penalize UAS operations that attempt to impede or interfere with lawful activities.[233]

Surprisingly, only a few states have enacted UAS trespass laws. Of those, Nevada's setting of a 250-foot elevation boundary[234] establishes a new class of airspace for UAS navigation in the space between 250 feet and the FAA's

maximum elevation of 400 feet for UAS users.[235] It also gives landowners a well-defined legal right to exclude unauthorized UAS from the resulting "private" airspace. Governor Brown's rejection of California's proposed 350-foot elevation for creating burdensome litigation and new causes of action[236] fails to recognize that such an approach simplifies the case-by-case determination of airspace rights employed for existing trespass claims, in which the court must establish the extent of airspace that is "incident to [a landowner's] use and enjoyment of the surface."[237]

Both Nevada and Oregon's trespass laws apply only to UAS flights repeated after a landowner previously gave notice that a UAS flight was not authorized.[238] This requirement may diminish the law's effectiveness for agricultural landowners, who must be prepared to establish property boundaries that are discernable to UAS operators, identify unauthorized UAS, and provide notice to the unauthorized UAS operators. Technological tools such as "geofencing" and "airmapping" can alert a UAS operator to "restricted" airspace, but such tools must be incorporated into the operating UAS's ***423** software and currently only notify UAS operators of government-restricted airspace such as airport zones.[239] Agricultural landowners will need to stay abreast of advancements in technology that could allow a landowner to alert a UAS of private property boundaries.

A pressing concern for agricultural landowners not addressed in any state or federal laws regards threats to agricultural security. Much attention is given to the benefits UAS offer for agriculture, but it is equally plausible that UAS could intentionally harm agriculture and food supplies. Concerns about "weaponizing" UAS highlight the possibility of misuse of UAS in destructive ways,[240] apprehensions that can also apply to the agricultural production setting. For agricultural operators and food consumers, harmful actions could include introducing pests, disease, or bacteria to destroy or infect crops or livestock. Considerable deliberation would be required for developing legislative strategies to minimize such risks, but efforts to prohibit UAS flights over "critical infrastructure" such as electric, transportation, and energy systems provide a model.[241] Could agricultural systems fall within the category of "critical infrastructure" that warrants legislative protection? Given that agricultural products meet basic human needs, a strong argument exists for special protection of agriculture from potentially destructive UAS activities.

V. CONCLUSION

Agricultural landowners and operators will undoubtedly gain from UAS technology and the improvements it offers for agricultural production. Now that the FAA has finalized the Small UAS Rule, agricultural operators using UAS for commercial purposes will benefit from more efficient regulatory oversight intended to ensure safety while integrating UAS into the nation's airspace. Shortfalls in the Small UAS Rule exist for agriculture, but some issues such as restrictions on nighttime flights can be resolved through the rule's waiver process. Other concerns, such as the rule's visual line of sight provisions, suggest needs for future legislative or regulatory revisions. An additional burden for UAS users in North Carolina, and possibly Louisiana, is a duplicative oversight process at the state level that may violate the federal government's authority over airspace safety.

***424** Other state laws regarding UAS operations may help agriculture navigate the privacy, harassment, and property rights issues posed by UAS. Several states have attempted to circumscribe UAS surveillance activities that can interfere with privacy rights of farmers, ranchers, and other persons. These laws may provide civil and criminal remedies when agriculture suffers harm from misinformation based upon UAS surveillance activities. Several states have also developed legislative solutions for delineating private property rights from UAS airspace navigation rights. Trespass statutes may reduce UAS interferences with agricultural property and also offer remedial measures for farmers and ranchers. Absent from any legislative discussions, however, is the possibility of "terrorism" type UAS activities that could destroy or disease agricultural products and threaten the security of agricultural operations and consumers of agricultural products. The evolution of UAS technology and its use in agriculture should continue with an eye toward addressing the legal landscape UAS creates for agricultural landowners and operators.

Footnotes

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1 *See, e.g.*, Sean Hogan et al., *Unmanned Aerial Systems for Agriculture and Natural Resources*, 71 CAL. AGRIC. 5, 5-6 (2017). The authors explain that, in the past decade, technology has improved UAS flight longevity, reliability, ease of use, and utilization of cameras and sensors. *Id.* at 5.

2 FED. AVIATION ADMIN., FAA AEROSPACE FORECAST FISCAL YEARS 2016-2036 31 (2016) [hereinafter FORECAST]. The forecast shows a quadrupling of sales in the year following implementation of the new FAA rule for small UAS. The 2016 forecast is 600,000 small UAS; the number jumps to 2.5 million in 2017. *Id.* at 31.

3 *Id.* at 33.

4 DARRYL JENKINS & DR. BIJAN VASIGH, THE ECONOMIC IMPACT OF UNMANNED AIRCRAFT SYSTEMS INTEGRATION IN THE UNITED STATES 6 (2013).

5 Lauren Manning, *What do the New FAA Regulations Actually Mean for Ag Drone Startups?,* AGFUNDER NEWS (July 1, 2016), https://agfundernews.com/what-do-the-new-faa-regulations-actually-mean-for-ag-drone-startups.html. "It will be the fastest growing segment of commercialized drones," says [AgEagle's Tom] Nichol. "We think every farm will not only have one but maybe two drones. A fixed wing to fly a lot of acreage and a rotary to spot check cattle, water systems, and other things." *Id.*

6 Federal Aviation Administration Modernization and Reform Act of 2012, Pub. L. No. 112-95, 126 Stat. 11 (codified at 49 U.S.C. § 40101 note) [hereinafter FMRA]. For thorough reviews of the history of FAA's regulation of UAS prior to the Small UAS Rule, *see* Douglas Marshall, *"What a Long Strange Trip It's Been": A Journey Through the FAA's Drone Policies and Regulations,* 65 DEPAUL L. REV. 123 (2015); Joshua Kohler, Note, *The Sky is the Limit: FAA Regulations and the Future of Drones*, 15 COLO. TECH. L. J. 151 (2017).

7 *Busting Myths about the FAA and Unmanned Aircraft*, FED. AVIATION ADMIN., https://www.faa.gov/news/updates/?newsId=76240 (last modified Mar. 07, 2014). The FAA also stated that a user may not fly a UAS for commercial purposes by following the guidelines for model aircraft flown for recreational purposes (below 400 feet, 3 miles from an airport, away from populated areas) because Congress exempted model aircraft from regulations in FMRA. This distinction between "flying for work" and "flying for fun" was understandably difficult for those seeking to use UAS for agricultural purposes to conduct flights that appeared remarkably similar to recreational flights of model aircraft.

8 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. 42064, 42069-70 (June 28, 2016) (codified at 14 C.F.R. § 107).

9 *Id.*

10 Stateline, *States Issue Their Own Drone Rules*, GOVERNING MAG. (Sept. 14, 2015), http://www.governing.com/topics/public-justice-safety/states-rush-to-regulate-drones-ahead-of-federal-guidelines2.html.

11 *See Current Unmanned Aircraft State Law Landscape,* NAT'L CONF. STATE LEG. (NCSL) (Nov. 30, 2017), http://www.ncsl.org/research/transportation/current-unmanned-aircraft-state-law-landscape.aspx [hereinafter NCSL]. NCSL has compiled year-by-year reports on UAS legislation since 2013 and also provides a report with all UAS legislation and federal law and policy on UAS. *See* Amanda Essex, *Taking Off: State Unmanned Aircraft Systems Policies*, NAT'L CONF. STATE LEG. (2016), http://www.ncsl.org/Portals/1/Documents/transportation/TAKING_OFF-STATE_%20UNMANNED_%20AIRCRAFT_SYSTEMS_%20POLICIES_%20%28004%29.pdf.

12 FMRA, *supra* note 6.

13 *Id.* Section 332(a)(2) of FMRA required that the comprehensive plan for UAS integration include nine components, the first concerning rulemaking. The rulemaking recommendations were to define acceptable standards for operation and certification of UAS; standards and requirements for operators and pilots of UAS, including registration and licensing; and were to ensure that UAS include sense and avoid capabilities. Congress set September 30, 2015 as the date by which the plan should provide for the safe integration of civil UAS. Section 332(b) directed that a final rule to allow for civil operation of UAS and to implement the plan required by Section 332(a) be published no later than 18 months after completion of the plan.

14 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. 42064, 42066 (June 28, 2016) (codified at 14 C.F.R. § 107). In the rule, the FAA explains that the new framework allows small UAS operations without requiring airworthiness certification, an exemption or a Certificate of Authorization from the FAA.

15 *Id. See generally* Comments to *Operation and Certification of Small Unmanned Aircraft Systems,* REGULATIONS.GOV, https://www.regulations.gov/docket?D=FAA-2015-0150 (last visited Dec. 28, 2017).

16 *See* 14 C.F.R. § 107.3 (2017) (defining a small unmanned aircraft as "an unmanned aircraft weighing less than 55 pounds on takeoff, including everything that is on board or otherwise attached to the aircraft."); *Id.* ("small unmanned aircraft system (small UAS) means a small unmanned aircraft and its associated elements (including communication links and the components that control the small unmanned aircraft) that are required for the safe and efficient operation of the small unmanned aircraft in the national airspace system."). *See generally* 14 C.F.R. § 101 (2017). The Small UAS Rule does not apply to unmanned aircraft regulated by 14 C.F.R. § 101, which includes model aircraft flown for recreational or hobby purposes, moored balloons, kits, amateur rockets, and unmanned free balloons.

17 14 C.F.R. § 107.12 (2017). An exception exists for international operators. The Small UAS Rule allows the FAA Administrator to authorize an airman without a RPC to operate a civil foreign-registered small UAS, consistent with international standards. *Id.* The FAA notes, however, that global remote pilot standards do not yet exist, so non-U.S. citizens must currently obtain an FAA-issued RPC through the foreign air carrier licensing process contained in 14 C.F.R. § 375. *See Unmanned Aircraft Systems (UAS) Frequently Asked Questions*, FED. AVIATION ADMIN, https://www.faa.gov/uas/faqs/ (last modified July 11, 2017) [hereinafter *UAS FAQs*].

18 14 C.F.R. § 107.61 (2017). The rule provides that for safety reasons, the FAA may place operating restrictions on a person who cannot meet one of the English language requirements because of medical reasons. *Id.*

19 *Id.* Applicants who possess a current pilot certificate, other than a student pilot certificate, may complete the required "Part 107 small Unmanned Aircraft Systems (sUAS) ALC-451" online training course. *See Part 107 Small UAS Course Introduction*, FED. AVIATION ADMIN., https://www.faasafety.gov/gslac/ALC/course_content.aspx?cID=451&sID=726&crID=1437198 (last visited Dec. 28, 2017).

20 14 C.F.R. § 107.7 (2017). According to the FAA, Knowledge Testing Centers charge applicants approximately $150 to take the test. *See UAS FAQs, supra* note 17.

21 *Id.* For more detail on the knowledge standards expected for certification, *see* FED. AVIATION ADMIN., REMOTE PILOT KNOWLEDGE TEST GUIDE (2017), https://www.faa.gov/training_testing/testing/test_guides/media/remote_pilot_ktg.pdf [hereinafter TEST GUIDE].

22 TEST GUIDE, *supra* note 21, at 2.

23 14 C.F.R. § 107.71 (2017).

24 14 C.F.R. § 107.63 (2017). The application is the FAA Airman Certificate and/or Rating Application, FAA Form 8710-13.

25 *See Integrated Airman Certification and Rating Application (IACRA)*, FED. AVIATION ADMIN., https://iacra.faa.gov/IACRA (last visited Dec. 28, 2017).

26 The FAA reports that processing time is longer for paper applications and those who use the paper application do not have the option of receiving a temporary RPC as provided through the online IACRA system. *See Becoming a Pilot*, FED. AVIATION ADMIN., https://www.faa.gov/uas/getting_started/fly_for_work_business/becoming_a_pilot/ (last modified Feb. 10, 2017).

27 U.S. DEPT. OF HOMELAND SECURITY, PRIVACY IMPACT ASSESSMENT UPDATE FOR THE AIRMEN CERTIFICATION VETTING PROGRAM 2 (2016).

28 FED. AVIATION ADMIN., ADVISORY CIRCULAR 107-2, SMALL UNMANNED AIRCRAFT SYSTEMS at 6-2 (2016) [hereinafter FAA ADVISORY CIRCULAR]. A temporary RPC is valid for 120 calendar days. 14 C.F.R. § 107.64 (2017). The FAA states that applications through IACRA should be validated within ten days. *See UAS FAQs, supra* note 17.

29 FAA ADVISORY CIRCULAR, *supra* note 28, at 6.5.

30 49 C.F.R. § 1515.5 (2017) and 40 C.F.R. § 1515.9 (2017) outline the grounds for appeal and appeals process for an Initial Determination of Threat Assessment.

31 14 C.F.R. § 107.65 (2017).

32 Operation and Certification of Small Unmanned Aircraft Systems, 80 Fed. Reg. 9544, 9558 (proposed Feb. 23, 2015). In the Notice of Proposed Rulemaking, the FAA sought comments on whether to establish a pilot in command role for small UAS flights. *Id.*

33 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. 42064, 42099-100 (June 28, 2016) (codified at 14 C.F.R. § 107).

34 *Id.*

35 14 C.F.R. § 107.19 (2017).

36 *Id.*

37 14 C.F.R. § 107.21 (2017). The authority to make emergency decisions equates the Remote PIC role with that of pilots in command for other types of aircraft.

38 *Id.*

39 14 C.F.R. § 107.12 (2017).

40 *Id.*

41 14 C.F.R. § 107.49 (2017).

42 *Id.* The rule specifies that a pre-flight inspection should include assessing risks in the immediate vicinity, such as local weather conditions; airspace and flight restrictions; location of persons, property, and ground hazards; ensuring that persons directly involved in operation of the small UAS are informed of operating conditions, emergency and contingency procedures, roles and responsibilities, and potential hazards; ensuring that control links between the aircraft and ground control are operational; ensuring sufficient power to operate for the intended time period; and ensuring that objects attached to or carried by the small UAS are secure and will not adversely affect flight characteristics or controllability of the aircraft. *Id.* Another section of the Small UAS Rule reiterates the importance of inspection, stating that a Remote PIC must check the small UAS to determine whether it is in a condition for safe operation. 14 C.F.R. § 107.15 (2017). The FAA advises the Remote PIC to conduct a preflight inspection in accordance with the small UAS manufacturer's owner or maintenance manual. *See* FAA ADVISORY CIRCULAR, *supra* note 28, at 7-2.

43 14 C.F.R. § 107.9 (2017). In regards to property damage, the rule specifies that the $500 property damage amount includes materials and labor for repairs or is based upon the fair market value of a property. The FAA provides an online portal for accident reporting at *Report an Accident*, FED. AVIATION ADMIN., https://www.faa.gov/uas/report_accident/ (last modified Aug. 25, 2016). Alternatively, accident reports may be directed to the nearest FAA Flight Standards District Office. *Id.*

44 14 C.F.R. § 107.13 (2017) (referring to registration requirements in 14 C.F.R. § 91.203(a)(2) (2017)). Note that the D.C. Circuit Court of Appeals recently held that the FAA does not have the legal authority to require registration for recreational UAS operators. *See* Taylor v. Huerta, 856 F.3d 1089 (D.C. Cir. 2017).

45 14 C.F.R. § 107.15(b) (2017).

46 *Id.*

47 14 C.F.R. § 107.7(b) (2017).

48 14 C.F.R. § 107.31 (2017).

49 *Id.*

50 14 C.F.R. § 107.33.

51 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. 42064, 42099-100 (June 28, 2016) (codified at 14 C.F.R. § 107).

52 *Id.* The Small UAS Rule charges the Remote PIC with ensuring that the visual observer meets the VLOS provisions. *Id.*

53 *Id.*

54 14 C.F.R. § 107.37 (2017) (stating that a small UAS must yield the right of way to "all aircraft, airborne vehicles, and launch and reentry vehicles).

55 *Id.* § 107.37(a).

56 *Id.* § 107.37(b).

57 14 C.F.R. § 107.29 (2017). "Civil twilight" refers to 30 minutes before and after official sunrise and sunset, except in Alaska, where civil twilight is defined by the Dept. of Defense's Air Almanac. *Id.* Anti-collision lighting must be visible for at least three statute miles, but the Remote PIC may alter the lighting intensity in the interest of safety. *Id.* § 107.29 (c).

58 14 C.F.R. § 107.51(c) (2017). "Flight visibility" is the "average slant distance from the control station at which prominent unlighted objects may be seen and identified by day and prominent lighted objects may be seen and identified by night." *Id.* A person must be able to see the diagonal distance of three miles into the sky in order to detect other aircraft that may be approaching and maintain sight of the small UAS. Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. at 42107.

59 14 C.F.R. § 107.51(d) (2017). Cloud clearance provisions attempt to address the speed differential between manned and unmanned aircraft so that a small UAS can respond at its lesser speed to avoid a manned aircraft exiting from clouds at a higher speed. Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. at 42106.

60 14 C.F.R. § 107.51 (2017). The proposed rule established a flight ceiling of 500 feet, lowered to 400 feet in the final rule after the FAA considered comments by groups such as the National Agricultural Aviation Association (whose members conduct aerial applications of pesticides, herbicides, and other crop protection products). The comments asked the FAA to increase the buffer zone between manned and unmanned aircraft to further prevent collision risk. Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. at 42116-118.

61 14 C.F.R. § 107.25 (2017). The FAA explains that the term "sparsely populated area" will be determined on a case-by-case basis, but points to Mickalich v. United States, No. 05-72276, 2007 WL 1041202, at *9-11 (E.D. Mich. Apr. 5, 2007) for its determination that twenty people on a ten-acre site constitutes sparsely populated as that term is used in FAA general operating and flight rules in 14 C.F.R. § 91.119 (2017). Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. at 42115. *Mickalich* suggests that many agricultural areas would likely qualify as "sparsely populated." 2007 WL 1041202 at *11.

62 14 C.F.R. § 107.51 (2017).

63 14 C.F.R. § 107.35 (2017).

64 14 C.F.R. § 107.39 (2017).

65 14 C.F.R. § 107.41 (2017). The rule does not expressly permit small UAS flights in Class G airspace but allows the flights by omission when stating that flights in other airspace require permission. The FAA defines Class G airspace as that portion of airspace that has not been designated as Class A, Class B, Class D, or Class E airspace. FED. AVIATION ADMIN., AERONAUTICAL INFORMATION MANUAL 139 (2017), https://www.faa.gov/air_traffic/publications/media/AIM_Basic_dtd_10-12-17.pdf. FAA relies on its Aeronautical Knowledge Test to guide operators in determining airspace classifications and developed its B4UFLY app to help UAS flyers know if they are in controlled airspace. A request to fly in controlled airspace may only be made through an online portal at https://www.faa.gov/uas/request_waiver/. *See UAS FAQs, supra* note 17.

66 14 C.F.R. § 107.43 (2017).

67 14 C.F.R. § 107.45 (2017). The provision requires compliance with 14 C.F.R. §§ 91.137-145, which also prohibits flights in the vicinity of public figures such as the President of the United States, near space flight operations, or in areas declared by FAA as emergency or aerial flight demonstration areas. 14 C.F.R. § 107.45 (2017).

68 14 C.F.R. § 107.23 (2017).

69 *Id.*

70 14 C.F.R. § 107.36 (2017). The Small UAS Rule references transportation regulations in 49 C.F.R. § 171.8 (2017) for the definition of hazardous material. Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. 42064, 42064 (June 28, 2016) (codified at 14 C.F.R. § 107).

71 14 C.F.R. § 107.17 (2017).

72 14 C.F.R. § 107.27 (requiring compliance with FAA's general operating and flight rules for aircraft in 14 C.F.R. §§91.17-19 (2017)).

73 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. at 42071. The proposed rule for Small UAS invited comments on adding a waiver mechanism to accommodate new technologies and unique operational circumstances, to which representatives of agriculture replied that its unique operating environments would call for deviation from the rule's operating limitations. *Id.*

74 *Id.* at 40166.

75 14 C.F.R. § 107.205 (2017). For waiver requests regarding VLOS and operation from a moving vehicle or aircraft, the FAA will not issue a waiver to allow the carriage of property of another by aircraft for compensation or hire. *Id.*

76 14 C.F.R. § 107.200 (2017). The application appears to be available only online at *Request a Part 107 Waiver or Operation in Controlled Airspace*, FED. AVIATION ADMIN., https://www.faa.gov/uas/request_waiver/ (last visited Dec. 28, 2017).

77 *Id.*

78 *Id.*

79 *See generally* NCSL, *supra* note 11.

80 *See, e.g.*, Margot E. Kaminski, *Drone Federalism: Civilian Drones and the Things They Carry*, 4 CAL. L. REV. 57 (2013); Troy A. Rule, *Airspace in an Age of Drones*, 95 B. U. L. REV. 155 (2015); Ray Carver, *State Drone Laws: A Legitimate Answer to State Concerns or a Violation of Federal Sovereignty*, 31 GA. ST. U. L. REV. 377 (2014-2015).

81 *See* Goodspeed Airport, LLC v. East Haddam Inland Wetlands & Watercourses Comm'n, 634 F.3d 206, 210 (2d Cir. 2011); U.S. Airways, Inc. v. O'Donnell, 627 F.3d 1318, 1326 (10th Cir. 2010); Montalvo v. Spirit Airlines, 508 F.3d 464 (9th Cir. 2007).

82 Andrew Zimmitti, *A Look at Federal Preemption of State Drone Laws*, LAW 360 (Oct. 25, 2016), https://www.law360.com/media/articles/854886/a-look-at-federal-preemption-of-state-drone-laws.

83 *See* FED. AVIATION ADMIN., STATE AND LOCAL REGULATION OF UNMANNED AIRCRAFT SYSTEMS (UAS) FACT SHEET (2015), https://www.faa.gov/uas/resources/uas_regulations_policy/media/UAS_Fact_Sheet_Final.pdf.

84 *Id.* at 2.

85 *Id.* at 3.

86 FAA Extension, Safety and Security Act of 2016, Pub. L. No. 114-190 (proposing preemption of state or political subdivision actions related to design, manufacture, testing, licensing, registration, certification, operation, or maintenance of unmanned aircraft systems).

87 H.R. 636, 114th Cong. § 2152 (2015). The Senate's Engrossed Amendment to the bill contained the preemption provisions.

88 *Id.* The House amendments to the Senate's amended version of the bill removed the preemption sections along with several other sections of the Senate's amendments. 162 CONG. REC. H4624-41 (daily ed. July 11, 2016).

89 Essex, *supra* note 11, at 14.

90 *See, e.g.*, Zimmitti, *supra* note 82 ("[w]hile there are scant, if any, reported opinions on the federal preemption of state laws concerning unmanned aircraft, it is simply a question of when, not if, such cases will appear."); Gregory M. Palmer & Katherine Abigail Roberts, *Preemptive Effect of Federal Aviation Regulations on State and Local Laws*, FOR THE DEFENSE (Dec. 2016), http://m.rumberger.com/90F6E0/assets/files/lawarticles/DRI%20Article.pdf.

91 *See supra* notes 80-82.

92 LA. REV. STAT. ANN. § 3:41-47.

93 N.C. GEN. STAT. § 63-96.

94 LA. REV. STAT. ANN. § 3:41-47. "Agricultural commercial operation" means any agricultural facility or agricultural land used for agricultural production or agricultural processing. *Id.*

95 S. Con. Res. 124, 2014 Reg. Sess. (La. 2014). The resolution states that 80% of the commercial market for UAS will be for agricultural uses, forecasts the economic impact of UAS, recognizes the benefits of UAS for agriculture, and notes that further study of concerns about UAS in agriculture is essential to continued development and success of Louisiana's UAS agricultural economy.

96 LA. REV. STAT. ANN. § 3:44.

97 The stakeholder Unmanned Aerial Vehicle Study Group formed by the Louisiana legislature clearly disagreed with the FAA's handling of agricultural UAS prior to the Small UAS Rule. The group provided comments in 2014 to the FAA's Special Rule for Model Aircraft that focused on commercial agricultural operations and asserted that such operations should be allowed to use UAS within their properties, that agricultural uses of UAS required new and completely separate sections of policy, and that states should be allowed to develop regulatory policies for UAS beyond FAA's guidelines. Letter from Francis C. Thompson, Chairman, Louisiana Unmanned Aerial Vehicle Study Group, to U.S. Dep't of Transp. Docket Operations (Sept. 23, 2014), http://www.agandruralleaders.org/sites/default/files/resource/2015/12_LA_FAA_resolution.pdf.

98 LA. REV. STAT. ANN. § 3:43.

99 LA. REV. STAT. ANN. § 3:46.

100 Unmanned Aerial Systems, 42 La. Reg. 297 (proposed Feb. 20, 2016). The proposed regulations share several similarities with the FAA Rule and require registration of UAS, licensure of operators following completion of an educational and safety training course, and operating rules.

101 N.C. GEN. STAT. § 63-96.

102 *Id.*

103 *See Commercial Operators*, N.C. DEP'T TRANSP., https://www.ncdot.gov/aviation/uas/operators/ (last visited Dec. 28, 2017).

104 *See Commercial Terms & Conditions*, N.C. DEP'T TRANSP., https://www.ncdot.gov/aviation/uas/terms/#comm_terms (last visited Oct. 25, 2017).

105 A growing body of scholarship analyzes privacy rights as applied to UAS operations by governmental users and private citizens, which we don't attempt to address fully in this article. *See, e.g.,* Joseph J. Vacek, *Big Brother Will Soon Be Watching--Or Will He? Constitutional, Regulatory, and Operational Issues Surrounding the Use of Unmanned Aerial Vehicles in Law Enforcement*, 85 N. D. L. REV. 673 (2009); M. Ryan Calo, *The Drone as Privacy Catalyst*, 64 Stan. L. Rev. Online 29 (2011), https://www.stanfordlawreview.org/online/the-drone-as-privacy-catalyst/; Chris Schlag, *The New Privacy Battle: How the Expanding Use of Drones Continues to Erode Our Concept of Privacy and Privacy Rights*, 13 PITT. J. TECH. L. & POL'Y 1 (2013), http://tlp.law.pitt.edu/ojs/index.php/tlp/article/view/123/126; David C. Ison et al., *Privacy, Restriction, and Regulation Involving Federal, State and Local Legislation: More Hurdles for Unmanned Aerial Systems (UAS) Integration?* 24 J. AVIATION/AEROSPACE EDUC. & RES. 40 (2014).

106 A poll conducted by GfK Roper Public Affairs & Corporate Communications in 2012 indicated that 35% of the 1,006 adults polled were "extremely" or "very" concerned that police department use of UAS would cause them to lose privacy, and 24% were "some-what" concerned. Joan Lowy, *AP-NCC Poll: A Third of the Public Fears Police Use of Drones Will Erode Their Privacy*, AP-GFK (Sept. 27, 2012), http://ap-gfkpoll.com/uncategorized/our-latest-poll-findings-13. *But see* Gregory McNeal, *Drones and Aerial Surveillance: Considerations for Legislators,* BROOKINGS INST. (Nov. 2014), https://www.brookings.edu/research/drones-and-aerial-surveillance-considerations-for-legislatures/ (arguing that it is premature to conclude that widespread privacy violations by unmanned aircraft are imminent).

107 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. 42064, 42191-92 (June 28, 2016) (codified at 14 C.F.R. § 107). There is considerable debate over whether the FAA can or should regulate UAS privacy issues. Some criticize the FAA for its position on privacy, asserting that the agency has "skirted, avoided, and delayed involvement in the privacy quandary by placing the burden on operators." Ison et al., *supra* note 105, at 41. Conversely, others claim that the FAA is not equipped to regulate UAS privacy invasions. Schlag, *supra* note 105, at 2.

108 Promoting Economic Competitiveness While Safeguarding Privacy, Civil Rights, and Civil Liberties in Domestic Use of Unmanned Aircraft Systems, 80 Fed. Reg. 9355 (Feb. 15, 2015). President Obama stated, "[a]lthough these [UAS] opportunities will enhance American economic competitiveness, our Nation must be mindful of the potential implications for privacy, civil rights, and civil liberties. The Federal Government is committed to promoting the responsible use of this technology in a way that does not diminish rights and freedoms." *Id.* at 9357.

109 *Id.*

110 NAT'L TELECOMM. & INFO. ADMIN., VOLUNTARY BEST PRACTICES FOR UAS PRIVACY, TRANSPARENCY, AND ACCOUNTABILITY: CONSENSUS, STAKEHOLDER-DRAFTED BEST PRACTICES CREATED IN THE NTIA-CONVENED MULTISTAKEHOLDER PROCESS (2016), https://www.ntia.doc.gov/files/ntia/publications/uas_privacy_best_practices_6-21-16.pdf.

111 *Id.* at 3.

112 Senator Paul's "Preserving Freedom from Unwanted Surveillance Act of 2012" was not enacted. S. 3287, 112th Cong. (2012). Sen. Paul later used the dangers of governmental UAS activity as the topic of a 12-hour filibuster to delay a vote on President Obama's nomination of John Brennan to head the CIA earning him both criticism and praise for bringing "drone policy" into the national spotlight. *See* Carrie Johnson, *When Rand Paul Ended Filibuster, He Left Drones on National Stage*, NATIONAL PUBLIC RADIO (Mar. 8, 2013), http://www.npr.org/2013/03/10/173864536/when-rand-paul-ended-filibuster-he-left-drones-on-national-stage.

113 H.R. 6676, 112th Cong. (2012); H.R. 1262, 113th Cong. (2013); S. 635, 114th Cong. (2014); S. 631, 115th Cong. (2017).

114 *See supra* note 112. The mandated data collection statements would require a UAS operator to state whether the unmanned aircraft system would collect information or data about individuals or groups of individuals.

115 Kaminski, *supra* note 80, at 66 (arguing (with qualifications) that states should take the lead on privacy regulations governing private UAS use). Privacy rights impacted by law enforcement use, however, require a federal or mixed state and federal approach. *Id.* at 65. Others assert that "the best course of action would be to adopt a carefully constructed federal privacy act governing drones." Robert H. Gruber, *Commercial Drones and Privacy: Can We Trust States with 'Drone Federalism'?*, 21 RICH. J. L. & TECH. 14, 42 (2015), http://scholarship.richmond.edu/cgi/viewcontent.cgi?article=1419&context=jolt.

116 *See* Florida v. Riley, 488 U.S. 445 (1989) (naked eye surveillance from a helicopter operating in public airspace at 400-foot altitude does not require a search warrant); Dow Chem. Co. v. United States, 476 U.S. 227 (1986) (use of photographic equipment from an aircraft flying at a legal altitude over "open fields" is not an unconstitutional search under the Fourth Amendment); California v. Ciraolo, 476 U.S. 207 (1986) (aerial observation over property from airplane at 1,000-foot altitude does not violate the Fourth Amendment); Katz v. United States, 389 U.S. 347 (1967) (physical intrusion is not necessary for Fourth Amendment protection, which extends to a person in a place where that person has a "reasonable expectation of privacy").

117 *See, e.g.,* Kaminski, *supra* note 80, at 65 and Essex, *supra* note 11, at 15.

118 *See* Essex and NCSL, *supra* note 11.

119 *See, e.g.*, Freedom from Unwarranted Surveillance Act, S.B. 92, 115th Reg. Sess. (Fla. 2013) (UAS use by law enforcement); Preserving Freedom from Unwanted Surveillance Act, S.B. 1067, 62d Leg. (Idaho 2013) (UAS use by governmental and private users); Freedom from Drone Surveillance Act, S.B. 1587, 98th Gen. Assemb. (Ill. 2013) (UAS use by law enforcement); S.B. 744, 2013-2014 Sess. (N.C. 2014) (UAS use by private and governmental users); Freedom from Unwarranted Surveillance Act, S.B. 796, 108th Gen. Assemb. (Tenn. 2013) (UAS use by law enforcement); Texas Privacy Act, H.B. 912, 83d Leg. (Tex. 2013) (private UAS use).

120 S.B. 1067, 62d Leg., 1st Reg. Sess. (Idaho 2013).

121 IDAHO CODE § 21-213.

122 IDAHO CODE § 21-213.

123 *Id.*

124 S.B. 167, 2017 Reg. Sess. (N.M. 2017) (including protection for farms and agricultural operations). The bill's sponsor, Sen. Pino, also introduced the bill in 2013 as S.B. 556 and in 2015 as S.B. 303. Missouri's H.B. 46, 97th Gen. Assemb. (Mo. 2013), also closely resembled Idaho's law.

125 H.B. 1099, 2013-2014 Sess. (N.C. 2014).

126 *Id.* The committee's substitute, Edition 2 of H.B. 1099, is available at http://www.ncleg.net/gascripts/BillLookUp/BillLookUp.pl?Session=2013&BillID=H1099.

127 S.B. 766, 2015 Leg., 24th Sess. (Fla. 2015).

128 Katz v. United States, 389 U.S. 347 (1967) advanced the concept of the "reasonable expectation of privacy test" for purposes of governmental searches pursuant to the Fourth Amendment. The reasonable expectation of privacy test now extends beyond Fourth Amendment challenges and permeates state common law and statutes. *See* Peter Winn, *Katz and the Origins of the "Reasonable Expectation of Privacy" Test*, 40 MCGEORGE L. REV. 1 (2009).

129 FLA. STAT. § 934.50.

130 FLA. STAT. § 934.50(3)(b).

131 FLA. STAT. § 934.50(2)(b).

132 FLA. STAT. § 934.50(5).

133 MICH. COMP. LAWS § 259.322(3).

134 MICH. COMP. LAWS § 259.323. The misdemeanor is punishable by imprisonment for not more than 90 days or a fine of not more than $500, or both. *Id.*

135 S.D. CODIFIED LAWS §22-21-1.

136 *Id.* While the prohibition against landing a UAS on another's land or water appears in the invasion of privacy of South Dakota's criminal laws, the provision does not include any reference to surveillance or intent to observe. *Id.*

137 UTAH CODE ANN. § 76-9-402(1).

138 UTAH CODE ANN. § 76-9-402(2); S.D. CODIFIED LAWS § 22-21-1.

139 N.C. GEN. STAT. § 15A-300.1.

140 N.C. GEN. STAT. § 15A-300.1(b).

141 N.C. GEN. STAT. § 15A-300.1(e).

142 TENN. CODE ANN. § 39-13-609. The original version of the law prohibits a law enforcement agency from using a UAS to gather evidence or other information except in specified circumstances such as with a search warrant, and a party harmed by such use may bring a civil action for "all appropriate relief." *Id.*

143 TENN. CODE ANN. § 39-13-904(a).

144 TENN. CODE ANN. § 39-13-904(d). Each image capture constitutes a separate offense. *Id.*

145 TEX. BUS. & COM. CODE ANN. § 423.003.

146 TEX. BUS. & COM. CODE ANN. § 423.006. The definition of "images" is broadly defined to include "any capturing of sound waves, thermal, infrared, ultraviolet, visible light, or other electromagnetic waves, odor, or other conditions existing on or about real property in this state or an individual located on that property." TEX. BUS. & COM. CODE ANN. § 423.001.

147 TEX. BUS. & COM. CODE ANN. § 423.006. The statute lists 21 separate exceptions to the offense in § 423.002.

148 TEX. BUS. & COM. CODE ANN. §§ 423.001-004. "Malice" means a specific intent by the defendant to cause substantial injury or harm to the claimant. Tex. Gov't Code Ann. § 41.001.

149 LA. STAT. ANN. §14:63(B).

150 *Id.* §14:63(b)(3).

151 *Id.* §14:63(G). A first offense can result in a $100-$500 fine and imprisonment up to 30 days, a second offense ranges from $300-$700 in fines and up to 90 days in jail, and repeated offenses thereafter could lead to $500-$1,000 in fines and imprisonment up to six months.

152 Jason Koebler, *PETA Plans to Fly Drones That Would 'Stalk Hunters',* U.S. NEWS AND WORLD REP. (Apr. 8, 2013), https://www.usnews.com/news/articles/2013/04/08/peta-plans-to-fly-drones-that-would-stalk-hunters.

153 Kathleen Gray, *Drones About to be Banned for Hunting, Harassing Hunters*, LANSING ST. J. (Dec. 2, 2014), http://www.lansingstatejournal.com/story/news/local/2014/12/02/drones-banned-hunting-harassing-hunters/19780325/.

154 *See* 720 ILL. COMP. STAT. ANN. 5/48-3 (b)(10); MICH. COMP. LAWS ANN. § 324.40112(2)(c); N.H. REV. STAT. ANN. § 207:57(1); N.C. GEN. STAT. ANN. § 113-295(a1); OR. REV. STAT. ANN. § 498.128; TENN. CODE ANN. § 70-4-302(a)(6); WIS. STAT. ANN. § 29.079.

155 *See* Ching Lee, *New CFBF Policy Reflects Changes in Use of Drones*, AGALERT (Dec. 16, 2015), http://www.agalert.com/story/?id=9099; Kelly Weill, *Cows Have a New Enemy: Drones*, DAILY BEAST (Feb. 28, 2017), https://www.thedailybeast.com/cows-have-a-new-enemy-drones.

156 H.B. 217, 62nd Gen. Sess. (Utah 2017). The bill also prohibits livestock harassment using a motor vehicle, all-terrain vehicle, or dog.

157 *Id.*

158 *Id.*

159 S.B. 319, 2015-2016 Gen. Sess. (Kan. 2016).

160 KANS. STAT. ANN. § 60-31a01.

161 MICH. COMP. LAWS ANN. § 259.322.

162 *Id.* "Harassment" means conduct directed toward a victim that includes, but is not limited to, repeated or continuing unconsented contact that would cause a reasonable individual to suffer emotional distress and that actually causes the victim to suffer emotional distress. Harassment does not include constitutionally protected activity or conduct that serves a legitimate purpose. MICH. COMP. LAWS § 750.411(h).

163 MICH. COMP. LAWS ANN. § 750.411(h). Punishment for misdemeanor can include not more than one year imprisonment and/or a fine of not more $1,000. *Id.*

164 *See* Roderick B. Anderson, *Some Aspects of Airspace Trespass*, 27 J. AIR L. & COM. 341 (1961).

165 49 U.S.C. § 40103(a)(2) (2012).

166 14 C.F.R. § 91.119.

167 Swetland v. Curtiss Airports Corp., 55 F.2d 201, 203 (6th Cir. 1932).

168 United States v. Causby, 328 U.S. 256, 264 (1946). The landmark case involved a farm property in North Carolina located near a military airport. The farmer alleged that aircraft flying as low as 83 feet over his property so frightened his chickens that they flew into the walls and died. The court explicitly rejected the *ad coelum* doctrine, stating that "[c]ommon sense revolts at the idea" of an aircraft operator being subject to countless trespass suits, while recognizing that a landowner must have "exclusive control of the immediate reaches of the enveloping atmosphere." *Id.* at 264.

169 Based upon anecdotal observations from dozens of meetings between the authors and landowners during which consistent comments by landowners suggest a belief that a UAS is trespassing simply if it is visible to a landowner when flying over the owner's property.

170 *See, e.g.,* STAFF OF S. JUDICIARY COMM., S. 142, 2015-2016 REG. SESS., Bill Analysis at 4 (Ca. 2015).

171 H.R. 2710, 2013 Reg. Sess. (Or. 2013). The law does not allow an action against a UAS that is lawfully in the flight path of an airport or runway and in the process of taking off or landing.

172 H.R. 2354A, 2015 Reg. Sess. (Or. 2015).

173 OR. REV. STAT. ANN. § 837.380(3).

174 NEV. REV. STAT. 493.103(1). Nevada's statute also provides that a property owner or occupier may give notification verbally, in writing, or by marking the property with fluorescent orange paint. *See* NEV. REV. STAT. 207.200(2). Nevada

also prevents a trespass claim against a business registered in the State and authorized to operate under FAA regulations, as long as the UAS flight does not reasonably interfere with the use of the property. NEV. REV. STAT. 493.103(2)(d).

175 OR. REV. STAT. ANN. § 837.380(4); Nev. Rev. Stat. 493.103(3).

176 S. 142, 2015-2016 Reg. Sess. (Ca. 2015).

177 Letter from Governor Edmund G. Brown to Members of the California State Senate (Sept. 9, 2015), https://www.gov.ca.gov/docs/SB_142_Veto_Message.pdf.

178 S.B. 142, 2015-2016 Reg. Sess. (Ca. 2015). California law allows damages for wrongful occupation of real property to include the value of the use of the property for the time of the wrongful occupation, the reasonable cost of repair or restoration of the property, and the costs of recovering possession of the property. CA. CIV. CODE §3334.

179 S. 80, 92nd Sess. (S.D. 2017).

180 *Id.* The statute reads like an ordinary trespass offense and doesn't require either actual or intended eavesdropping. The provision excepts forced landings from trespass but states that the UAS owner will be liable for any damages resulting from a forced landing.

181 S. 111, 62nd Leg. Gen. Sess. (Utah 2017).

182 *Id.* Notice may be given by personal communication, fencing or other enclosure, or posting of signs. UTAH CODE ANN. § 76-6-206.

183 *Id.*

184 UTAH CODE ANN. §§ 76-3-204 and 76-3-301. UTAH CODE ANN.§ 76-3-301 (establishing misdemeanor penalties of up to $1,000 and imprisonment for up to six months).

185 Unmanned Aircraft Operations in the National Airspace System, 72 Fed. Reg. 6689, 6689-90 (Feb. 13, 2007) (stating that UAS flown for business purposes must obtain an FAA airworthiness certificate the same as other types of aircraft).

186 *Id.*

187 *See, e.g.*, Jonathan Knutson, *New UAV Rules Should Help Farmers, Ag Businesses*, AGWEEK (July 25, 2016), http://www.agweek.com/news/business-and-technology/4080630-new-uav-rules-should-help-farmers-ag-businesses; Elizabeth A. Tennyson, *Small UAS Rules Take Effect*, AIRCRAFT OWNERS AND PILOTS ASSOCIATION (Aug. 29, 2016), https://www.aopa.org/news-and-media/all-news/2016/august/29/small-uas-rules-take-effect; Kristine A. Tidgren, *Ground Control, We Have a Rule*, IOWA ST. U. CTR. FOR AGRIC. L. AND TAX'N (June 30, 2016), https://www.calt.iastate.edu/article/ground-control-we-have-rule.

188 A number of applicants have shared their test taking experiences online and raised concerns about the application process and difficult or unexpected knowledge test questions. *See, e.g.*, Matt Gunn, *My Experience Taking the FAA 107 Test* (Aug. 29, 2016, 10:37 PM), https://www.rcgroups.com/forums/showthread.php?2729603-My-Experience-Taking-the-FAA-107-Test; Miriam McNabb, *How to Pass the Part 107 Test, Part 1: Interview With a Success Story* (Aug. 30, 2016), http://dronelife.com/2016/08/30/how-to-pass-the-part-107-test-part-1/.

189 Knutson, *supra* note 187. In addition to the agricultural aerial applicators discussed by Knutson, the Aviation Insurance Association, Aircraft Owners and Pilots Association, and National Association of Realtors advocated for stricter airman certification for UAS operators.

190 Agricultural aerial application involves the spraying of crop protection products on agricultural and forest lands from an altitude of 400 feet or less.

191 *Id.* Visibility tests conducted by the "Think Before You Launch" campaign in 2015 confirmed the industry's belief that aerial applicators could not spot small UAS in mid-air quickly enough to avoid collision. *See NAAA UAS Safety Concerns and Recommendations*, NAT'L AGRIC. AVIATION ASS'N (Feb. 2016), http://www.agaviation.org/uasnaaaaction; Jim Moore,

Drones Prove Difficult for Ag Pilots to See, AOPA (Oct. 8, 2015), https://www.aopa.org/news-and-media/all-news/2015/october/08/unseen-drones (referring to preliminary test results that, according to a spokesman, indicated that "in flight visual acquisition of a drone also in flight over agricultural land is much more difficult than originally anticipated."); Jessica Freeman, *Think Before You Launch Executes Drone Visibility Testing at the CoAAA Operation S.A.F.E. Fly-In,* UAS IN AGRIC. LEARNING NETWORK (Nov. 23, 2015), http://www.learnuasag.org/2015/11/23/think-before-you-launch-executes-drone-visibility-testing-at-the-coaaa-operation-s-a-f-e-fly-in/.

192 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. 42064, 42089 (June 28, 2016) (codified at 14 C.F.R. § 107).

193 *See* Kohler, *supra* note 6; (citing Larry Downes, *What's Wrong with the FAA's New Drone Rules*, HARV. BUS. REV. (Mar. 2, 2015), https://hbr.org/2015/03/whats-wrong-with-the-faas-new-drone-rules#.

194 Brooks Lindsay, *Drone Drain: How the FAA Can Avoid Draining (and Instead Spur) the American Drone Industry by Adding Nuisance to Its Draft Small UAS Rules*, 10 WASH. J. L. TECH. & ARTS 343, 346-47 (2015) (suggesting that VLOS would cut off a substantial portion of the predicted $75 billion contribution UAS will make to the U.S. agriculture industry in the first decade of use).

195 *See, e.g.*, Jacqui Fatka, *Drones Rules Don't Include All Ag Wanted*, FARMFUTURES (June 24, 2016), http://www.farmfutures.com/blogs-drone-rules-dont-include-ag-wanted-11068; Manning, *supra* note 5 ("[e]ven though the technology on these small unmanned systems is capable of going way beyond the line of sight, until we get avoidance protection set up on all these devices, it's going to be a little down the road ... The point is that we've started.").

196 Juan Plaza, *Beyond Visual Line of Sight Operations: The Next Target for FAA Regulation*, COM. UAV NEWS (Jan. 30, 2017), http://www.expouav.com/news/latest/beyond-visual-line-sight-operations-next-target-faa-regulation/.

197 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. at 42094-95; 14 C.F.R. § 107.205 (addressing VLOS waivers).

198 A Bill to Amend Title 49, United States Code, to Authorize Appropriations for the Federal Aviation Administration, and for Other Purposes, S. 1405, 115th Congress (2017).

199 *See* David Morgan, *Farm Groups Fight for Drone Freedom*, HUFFINGTON POST (Mar. 25, 2015), http://www.huffingtonpost.com/2015/03/25/farmers-drone-regulations_n_6941692.html; Janelle Atyeo, *South Dakota Ag Groups Call for Flexibility in Drone Rules*, TRI-STATE NEWS (May 13, 2015), http://www.tristateneighbor.com/news/agri-tech/south-dakota-ag-groups-call-for-flexibility-in-drone-rules/article_7a8faea0-f818-11e4-af50-ff20919c23d1.html.

200 *See supra* note 57.

201 Operation and Certification of Small Unmanned Aircraft Systems, 81 Fed. Reg. at 42104.

202 *Part 107 Waivers Granted*, FED. AVIATION ADMIN., https://www.faa.gov/uas/request_waiver/waivers_granted/ (last visited Mar. 21, 2017). The FAA does not report any of the waiver requests as denied. *Id.*

203 *Id.*

204 *Id.*

205 *Id.*

206 While UAS legislative activity has remained steady in the states since the Small UAS Rule's August 29, 2016 effective date, the proposals do not address state regulatory programs. Several bills, however, propose a prohibition of local regulation of UAS. *See* NCSL, *supra* note 11.

207 *See supra* note 84.

208 *See* Lauren Russell, *PETA Eyes Drones to Watch Hunters, Farmers*, CNN (Apr. 12, 2013), http://www.cnn.com/2013/04/11/us/animal-rights-drones/; Michael D'Estries, *Will Potter's Drone Army Sets Its Sights on Factory Farms*, MNN (Oct. 29, 2014), http://www.mnn.com/your-home/organic-farming-gardening/blogs/will-potters-drone-army-sets-its-sights-on-factory-farms.

209 *See* Peggy Lowe, *Deploying Drones to get an Overview of Factory Farms*, SALT (July 19, 2014), http://www.npr.org/sections/thesalt/2014/07/19/332344201/deploying-drones-to-get-big-picture-of-factory-farms-from-above.

210 *See, e.g., Factory Food from Above: Satellite Images of Industrial Farms*, WIRED (Sept. 16, 2017), https://www.wired.com/2013/09/mishka-henner-factory-farms/.

211 *See, e.g.,* Dairy Herd News Source, *Gary Conklin Speaks Out*, DAIRY HERD MGMT. (Jan. 17, 2011), https://www.dairyherd.com/article/gary-conklin-speaks-out (describing the impact of a video released by Mercy for Animals showing acts of animal abuse by a farm employee). The footage was captured by an undercover videographer who did not report the abuse to the farm owner. The employee pleaded guilty to six counts of cruelty to animals and was ordered to undergo psychological counseling, but no charges were brought against the farm owner. Chris Kick, *Conklin Dairy Farm: NO Additional Charges*, FARM AND DAIRY (July 6, 2010), http://www.farmanddairy.com/news/conklin-dairy-farm-no-additional-charges/15283.html.

212 "Ag-gag" is a controversial term used by animal welfare advocates. The term can provoke negative reactions from both the agricultural community and those who oppose agricultural production practices. We use the term only for lack of a less controversial term to describe statutes that address exposé strategies against farm operations.

213 *See* Gregory S. McNeal, *Poorly Drafted Drone Laws May Shield Crimes from View*, FORBES (July 8, 2014), https://www.forbes.com/sites/gregorymcneal/2014/07/08/anti-dron-elegislation-protects-animal-abuses-and-other-crimes/#4f9a0ca05d18.

214 *See, e.g.,* IDAHO CODE ANN. § 18-7042. The law establishes criminal penalties for a person who enters an agricultural production facility that is not open to the public and, without the facility owner's express consent or pursuant to judicial process or statutory authorization, makes audio or video recordings of the conduct of an agricultural production facility's operations. *Id.*

215 Alicia Prygoski, *Detailed Discussion of Ag-gag Laws*, ANIMAL LEGAL & HIST. CTR., https://www.animallaw.info/article/detailed-discussion-ag-gag-laws (last visited Mar. 30, 2017).

216 Animal Legal Def. Fund v. Otter, 118 F. Supp. 3d 1195 (D. Idaho 2015). The court found that the Idaho legislature intended to "limit and punish" those who would speak out against agriculture and was motivated in part by an "animus to animal welfare groups." *Id.* at 1201.

217 For a critical review of "ag-gag" litigation, *see* Dan Flynn, *Letter from the Editor: 'Ag-gag' End Game in Hands of Many*, FOOD SAFETY NEWS (Mar. 27, 2017) http://www.foodsafetynews.com/2017/03/letter-from-the-editor-ag-gag-end-game-in-hands-of-many/#.WOGbIWnysvA.

218 *See* Cori Capik, *Drones to Be Used to Side-Step "Ag Gag" Laws, Photographing Animal Cruelty,* AGFUNDER NEWS (July 9, 2014), https://agfundernews.com/drones-used-side-step-ag-gag-laws-photographing-animal-cruelty.html; Russell, *supra* note 208; D'Estries, *supra* note 208; Lowe, *supra* note 209.

219 IDAHO CODE ANN. § 21-213.

220 *See* Amy O'Connor, *Insurers Warned to 'Think Before You Snap' as Florida Drone Privacy Law Takes Flight*, INS. J. (July 29, 2015), http://www.insurancejournal.com/news/southeast/2015/07/29/376560.htm.

221 In Donovan v. Dewey, 452 U.S. 227, 237 (1981), the U.S. Supreme Court held that "the expectation of privacy that the owner of commercial property enjoys in such property differs significantly from the sanctity accorded an individual's home" in regards to warrantless inspections of commercial property. The Court later added in Oliver v. United States, 466 U.S. 170, 179 (1984) that "open fields do not provide the setting for those intimate activities that the [Fourth] Amendment is intended

to shelter from governmental interference or surveillance" and held that "an individual may not legitimately demand privacy for activities out of doors in fields, except in the area immediately surrounding the home." *Id.* at 179.

222 Dow Chem. Co. v. United States, 476 U.S. 227, 239 (1986).

223 Under Florida's law, an individual is presumed to have a reasonable expectation of privacy if he or she is not observable by a person at "ground level" from a place where that person has a legal right to be, regardless of whether the individual could be observed from the air with a UAS. FLA. STAT. ANN. § 934.50(3)(b).

224 *Dow Chem. Co., supra* note 222, at 234 (stating that "EPA, as a regulatory and enforcement agency, needs no explicit statutory provision to employ methods of observation commonly available to the public at large ...").

225 *See supra* notes 133-36.

226 Louisiana, South Dakota, and Utah provide exceptions for persons operating UAS in compliance with FAA regulations. *See supra* notes 138 and 150.

227 *See supra* note 113.

228 *Id.*

229 *Id.*

230 *See supra* note 156.

231 *Id.*

232 *See supra* notes 161-62.

233 *See supra* note 155.

234 *See supra* note 175.

235 *See supra* note 61.

236 *See supra* note 179.

237 *See supra* note 168.

238 *See supra* notes 172 and 175.

239 See Tim Moynihan, *Things Will Get Messy If We Don't Start Wrangling Drones Now*, WIRED (Jan. 30, 2016), https://www.wired.com/2016/01/things-will-get-messy-if-we-dont-start-wrangling-drones-now/.

240 *See, e.g.,* Robert J. Bunker, *Terrorist and Insurgent Unmanned Aerial Vehicles: Use, Potentials, and Military Implications*, U.S. ARM Y WAR C. STRATEGIC STUD. INST. (Aug. 2015), https://ssi.armywarcollege.edu/pdffiles/PUB1287.pdf.

241 *See* Dan Shea et al., *Drones and Critical Infrastructure*, NAT'L CONF. ST. LEG. (Sept. 12, 2016), http://www.ncsl.org/research/energy/drones-and-critical-infrastructure.aspx.

39 UARLRLR 389

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Agricultural Credit: Institutions and Issues

(name redacted)
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Prepared for Members and
Committees of Congress

Summary

The federal government provides credit assistance to farmers to help assure adequate and reliable lending in rural areas, particularly for farmers who cannot obtain loans elsewhere. Federal farm loan programs also target credit to beginning farmers and socially disadvantaged groups.

The primary federal lender to farmers, though with a small share of the market, is the Farm Service Agency (FSA) in the U.S. Department of Agriculture (USDA). Congress funds FSA loans with annual discretionary appropriations—about $90 million of budget authority and $317 million for salaries—to support $8 billion of new direct loans and guarantees. FSA issues direct loans to farmers who cannot qualify for regular credit and guarantees the repayment of loans made by other lenders. FSA thus is called a lender of last resort. Of about $374 billion in total farm debt, FSA provides about 2.6% through direct loans and guarantees about another 4%-5% of loans.

Another federally related lender is the Farm Credit System (FCS)—cooperatively owned and funded by the sale of bonds in the financial markets. Congress sets the statutes that govern the FCS banks and lending associations, mandating that they serve agriculture-related borrowers. FCS makes loans to creditworthy farmers and is not a lender of last resort. FCS accounts for 41% of farm debt and is the largest lender for farm real estate.

Commercial banks are the other primary agricultural lender, holding slightly more than FCS with 42% of total farm debt. Commercial banks are the largest lender for farm production loans.

Generally speaking, the farm sector's balance sheet has remained strong in recent years. While delinquency rates on farm loans increased from 2008 into 2010 during the global financial crisis, farmers and agricultural lenders did not face credit problems as severe as those of other economic sectors. Since 2010, loan repayment rates have improved, but recent weakness in farm income has begun to put pressure on some farmers' loan repayment capacity.

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Current Situation

Major Players and Market Shares

The federal government has a long history of assisting farmers with obtaining loans for farming. This intervention has been justified at one time or another by many factors, including the presence of asymmetric information among lenders, asymmetric information between lenders and farmers, lack of competition in some rural lending markets, insufficient lending resources in rural areas compared to more populated areas, and the desire for targeted lending to disadvantaged groups (such as small farms or socially disadvantaged farmers).[1]

Several types of lenders make loans to farmers. Some are government entities or have a statutory mandate to serve agriculture. The one most controlled by the federal government is the Farm Service Agency (FSA) in the U.S. Department of Agriculture (USDA). It receives federal appropriations to make direct loans to farmers and to issue guarantees on loans made by commercial lenders to farmers who do not qualify for regular credit. FSA is a lender of last resort but also of first opportunity, because it targets loans or reserves funds for disadvantaged groups.

The lender with the next-largest amount of government intervention is the Farm Credit System (FCS). It is a cooperatively owned and funded—but federally chartered—private lender with a statutory mandate to serve agriculture-related borrowers only. FCS makes loans to creditworthy farmers and is *not* a lender of last resort but is a government-sponsored enterprise (GSE). Third is Farmer Mac, another GSE that is privately held and provides a secondary market for agricultural loans. FSA, FCS, and Farmer Mac are described in more detail later in this report.

Other lenders do not have direct government involvement in their funding or existence. These include commercial banks, life insurance companies, individuals, merchants, and dealers.

Figure 1 shows that the FCS and commercial banks provide most of the farm credit (41% and 42%, respectively) followed by individuals and others (9.2%) and life insurance companies (3.5%; based on 2016 USDA data, the most recent year with such detail).[2] FSA provides about 2.6% of the debt through direct loans. FSA also guarantees about another 4%-5% of the market through loans that are made by commercial banks and the FCS.

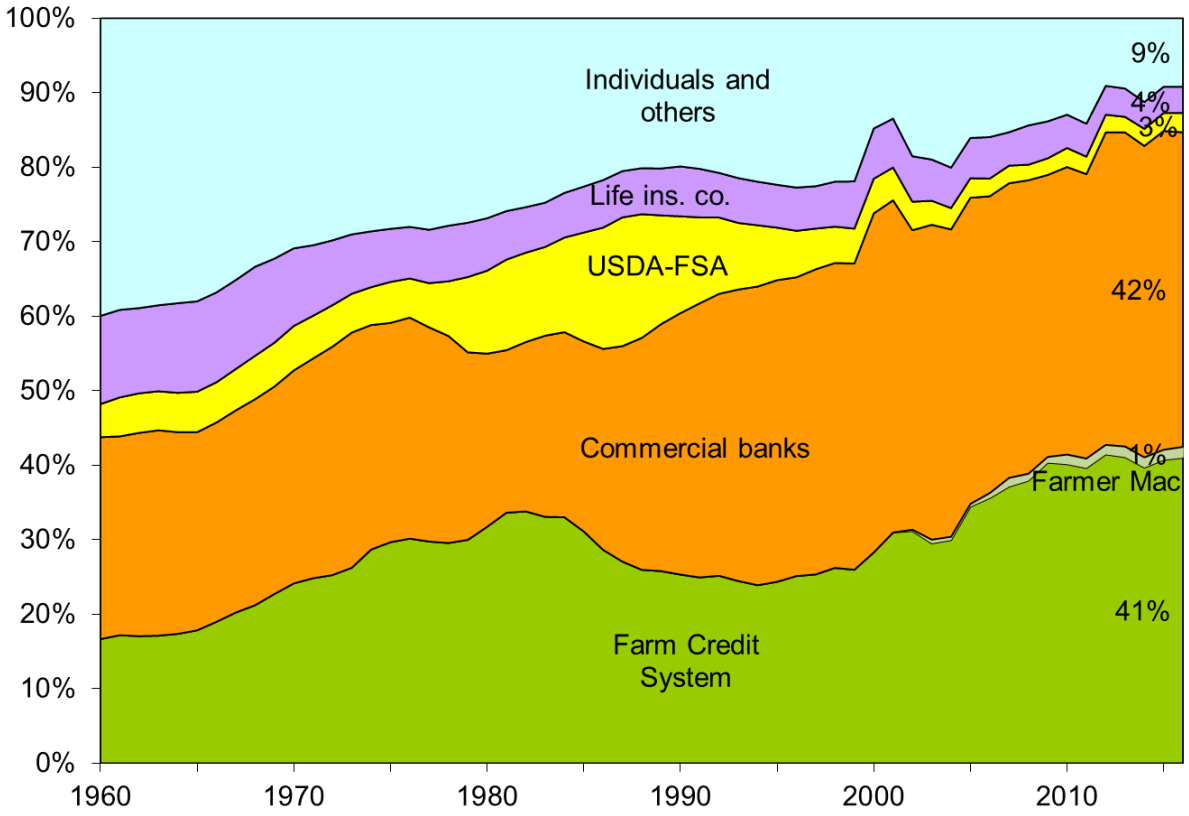
The total amount of farm debt ($374 billion at the end of 2016) is concentrated relatively more in real estate debt (60%) than in non-real estate debt (40%). FCS is the largest lender for real estate (46%), and both commercial banks' and FCS's shares have grown as others' shares have decreased (**Figure 2**). Commercial banks are the largest lender for non-real estate loans (49%), although FCS has gained share in recent years as the shares by others have decreased (**Figure 3**).

As the figures show, market shares among these lenders have changed over time. Commercial banks held relatively little farm real estate debt through 1985 but now hold a sizeable amount (**Figure 2**). The share of loans from "individuals and others" has steadily decreased over time, with fewer private contracts for farm real estate and relatively less dealer financing in operating credits. FSA held a much larger share of farm debt during the farm financial crisis of the 1980s, but that ratio declined as the farm economy improved through the 1990s (**Figure 3**).

[1] USDA, Farm Service Agency, *Evaluating the Relative Cost Effectiveness of the Farm Service Agency's Farm Loan Programs*, report to Congress, August 2006, pp. 11-17, http://www.fsa.usda.gov/Internet/FSA_File/farm_loan_study_august_06.pdf.

[2] USDA, Economic Research Service (ERS), http://www.ers.usda.gov/data-products/farm-income-and-wealth-statistics.aspx.

Figure 1. Market Shares by Lender of Total Farm Debt, 1960-2016

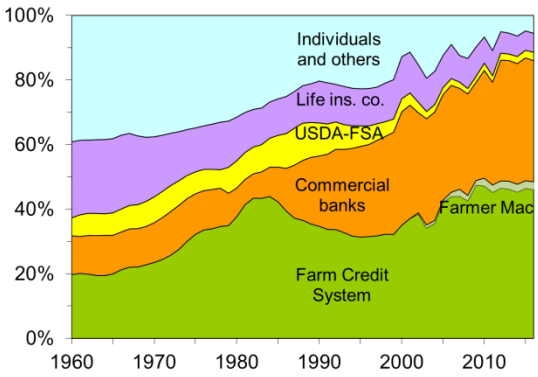


Source: CRS, using USDA Economic Research Service (ERS) year-end data at http://www.ers.usda.gov/data-products/farm-income-and-wealth-statistics.aspx.

Notes: Shares in the graph are for direct loans. Guarantees issued on other lenders' loans are not shown. FSA issued guarantees on about 4%-5% of farm loans that are not shown separately but are included in the shares of commercial banks and the Farm Credit System. ERS began publishing data on Farmer Mac in 2002.

Figure 2. Market Shares of Real Estate Farm Debt, 1960-2016

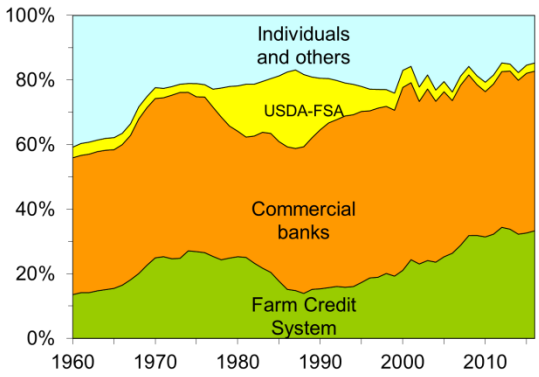
(60% of total farm debt in 2016)



Source: CRS, using ERS data.

Figure 3. Market Shares of Non-Real Estate Farm Debt, 1960-2016

(40% of total farm debt in 2016)



Source: CRS, using ERS data.

The Farm Balance Sheet

As a whole, farm sector assets have remained strong despite pressure on other real estate sectors. The value of farm assets has grown steadily since the end of the 1980s, particularly since 2003. At the end of 2017, farm sector assets totaled $3.04 trillion. In 2018, USDA forecasts that farm assets will increase 1.6% (**Figure 4**). The Federal Reserve has found declining land values in recent years but a small recovery through 2017.[3] Total farm assets now exceed the previous peak from 1980 in inflation-adjusted terms. Real estate is about 83% of the total amount of farm assets; machinery and vehicles are the next-largest category at about 8% of the total.[4]

Farm debt reached a historic high of $385 billion at the end of 2017 (**Figure 5**). USDA forecasts that debt will increase 1% in 2018. In inflation-adjusted terms, however, this level of debt is still well below the peak debt levels of the 1980s.

Debts and assets can be compared in a single measure by dividing debts by assets—the debt-to-asset ratio. A lower debt-to-asset ratio generally implies less financial risk to the sector than a higher ratio. Farm debt-to-asset ratio levels have declined fairly steadily since the late 1980s after the farm financial crisis and reached a historic low of 11.3% in 2006. When farm asset growth paused in 2009-2010, the debt-to-asset ratio rose slightly to 12.9% (**Figure 6**). After returning to a historic low in 2012, the debt-to-asset ratio rose to 12.7 in 2017 and is forecasted to remain steady in 2018. But as a whole, farms are not as highly leveraged as they were in the 1980s.

Net farm income has become more variable, especially since 2000. After reaching then-historic highs in 2004, net farm income fell by a third in two years (**Figure 7**). After peaking again in 2008, net farm income fell by 25% in 2009. New net farm income highs were set in 2011 and 2013, but USDA's February 2018 forecast of $60 billion would be a 52% decline from 2013.[5] The relatively low net farm income forecasted for 2018 is 29% below the 10-year average.[6]

Government payments to farmers have also risen from decades ago but do not always offset the variability in net farm income. Fixed direct payments that were not tied to prices or revenue were the primary form of government payments in recent years. These payments supported farm income but did not necessarily help farmers manage risks. **Figure 8** shows that more of net farm income is coming from the market rather than the government compared to the 1980s.

Another indicator of leverage compares debt to net farm income. A lower debt-to-income ratio (with the ratio expressing the number of years of current income that debt represents) implies less financial risk. The farm-debt-to-net-farm-income ratio is more variable than the debt-to-asset ratio. It reached a 35-year low of 2.3 in 2004 and rose to 4.3 in 2009 before falling again to 2.5 in 2013. However, the decline in net farm income into 2018 has caused it to rise to a ratio of over 6, not seen since the 1980s. This is outside the typical range of 2-4 over the past 50-years and is leading to an observed rise in repayment risk[7] (**Figure 9**).

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[3] Federal Reserve Bank of Kansas City, "Farm Economy Seeks Footing," *Main Street Views*, November 2017, https://www.kansascityfed.org/research/indicatorsdata/agcreditsurvey/articles/2017/11-9-2017/farm-economy-seeks-footing.

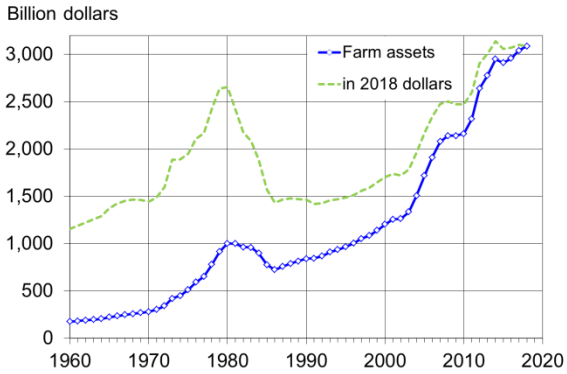
[4] ERS, *Farm Income and Wealth Statistics*, http://www.ers.usda.gov/data-products/farm-income-and-wealth-statistics.aspx.

[5] ERS, "Highlights From the February 2018 Farm Income Forecast," February 2018, https://www.ers.usda.gov/topics/farm-economy/farm-sector-income-finances/highlights-from-the-farm-income-forecast.

[6] CRS Report R45117, *U.S. Farm Income Outlook for 2018*.

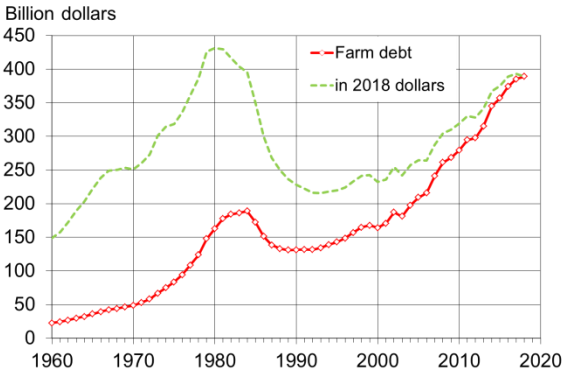
[7] Federal Reserve Bank of Chicago, *AgConditions*, February 2018, https://www.chicagofed.org/research/data/ag-conditions/index.

Figure 4. Farm Assets, 1960-2018



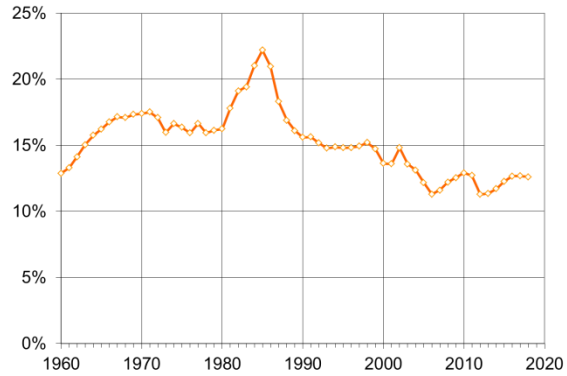
Source: CRS, using ERS data.
Notes: 2018 forecast.

Figure 5. Farm Debt, 1960-2018



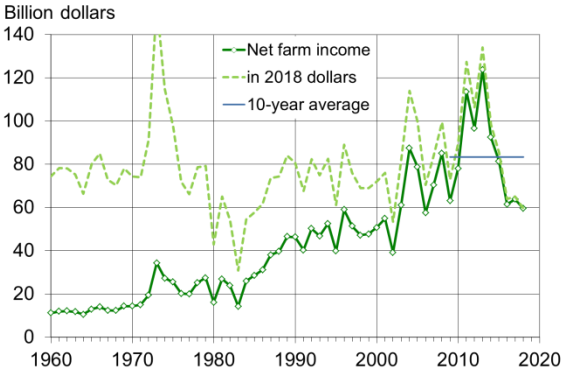
Source: CRS, using ERS data.
Notes: 2018 forecast.

Figure 6. Debt-to-Asset Ratio, 1960-2018



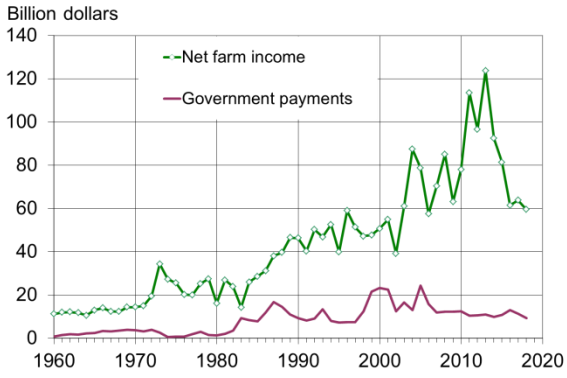
Source: CRS, using ERS data.
Notes: 2018 forecast.

Figure 7. Net Farm Income, 1960-2018



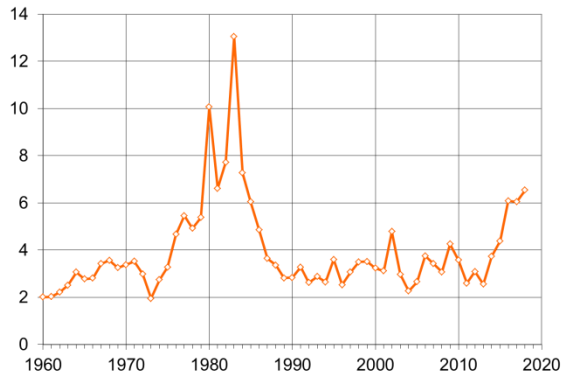
Source: CRS, using ERS data.
Notes: 2018 forecast.

Figure 8. Net Farm Income and Government Payments, 1960-2018



Source: CRS, using ERS data.
Notes: 2018 forecast.

Figure 9. Debt-to-Income Ratio, 1960-2018



Source: CRS, using ERS data.
Notes: 2018 forecast.

Delinquency Rates on Farm Loans

While the global financial crisis in 2008-2009 was slower to affect the balance sheets of farmers and agricultural lenders than the housing market, its presence was observed in agricultural lending. Credit standards were tightened (more documentation and oversight of loans was required), and lenders sometimes made less credit available to producers. As the lender of last resort, the FSA experienced significantly higher demand for its direct loans and guarantees.

In 2007, 2008, and 2010, farm commodity prices were particularly high, supporting farm income at above-average levels. But in 2006 and 2009, net farm income fell by about one-third (**Figure 7**), reducing some farmers' ability to repay loans, particularly in some farm sectors such as dairy, hogs, and poultry. Strong farm income from 2011 to 2013 improved most farmers' ability to repay loans. But weakness in farm income since 2014 has increased pressure on some farmers' repayment capacity.

Delinquency rates include loans that are 30 days or more past due and still accruing interest, as well as those in nonaccrual status. The delinquency rates on residential mortgages and all loans appear to have reached a recent peak in mid-2010 (11.5% for residential mortgages and 7.4% for all commercial bank loans, **Figure 10**). The delinquency rates for agricultural loans did not begin to rise until mid-2008 after continuing to fall to historic lows while delinquencies were rising in residential mortgages and other loans. Moreover, the rate of increase in delinquencies on farm production loans at commercial banks was not as sharp as in the non-farm sectors and peaked in June 2010 at 3.3%. Delinquency rates on farm production loans at commercial banks returned to historic lows below 1% but have risen slightly since 2015 and appear to have stabilized in 2017.[8]

A more severe measure of loan performance is nonperforming loans. Nonperforming loans include nonaccrual loans and accruing loans 90 days or more past due. These loans are more in jeopardy than delinquent loans and represent a smaller subset of loans. Within the agricultural loan portfolio, the FCS nonperforming loan rate has maintained the levels of the mid-2000s that indicated that the system had recovered from the farm financial crisis of the 1980s. FCS nonperforming loans rose from 0.5% at the beginning of 2008 to a near-term peak of 2.8% on September 30, 2009, before decreasing to 0.73% at the end of 2015. While FCS nonperforming loans have risen slightly in 2016 and 2017, they remain below 0.85% into 2018 (**Figure 11**).[9]

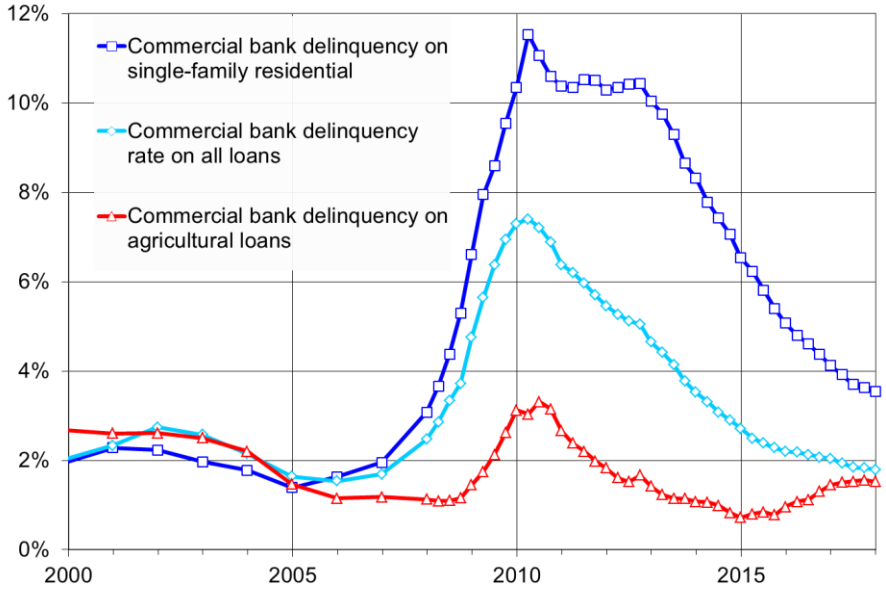
At commercial banks, nonperforming farm loans rose during the 2008-2010 financial crisis, recovered into 2015, but have risen again as declining farm income has stressed repayment. Nonperforming farm real estate loans at commercial banks rose from a low of 0.7% in December 2006 to 2.9% in March 2011 before declining to 1% as of December 31, 2015. Nonperforming farm production loans rose from a low of 0.6% in December 2006 to 2.4% in March 2010 before declining again to 0.4% as of December 31, 2014 (**Figure 11**). Nonperforming loan rates at commercial banks have risen for farm real estate loans and farm production loans to about 1.5% and 1.3%, respectively, at the end of 2017.[10]

[8] Federal Reserve Bank, "Delinquency Rates on Loans at Commercial Banks" (seasonally adjusted), http://www.federalreserve.gov/releases/chargeoff.

[9] FCS, Annual and Quarterly Information Statements, http://www.farmcreditfunding.com/ffcb_live/financialInformation.html?tab=statements.

[10] Federal Reserve Bank, *Agricultural Finance Data Book*, Tables B.2 and B.4, http://www.kansascityfed.org/research/indicatorsdata/agfinance/index.cfm.

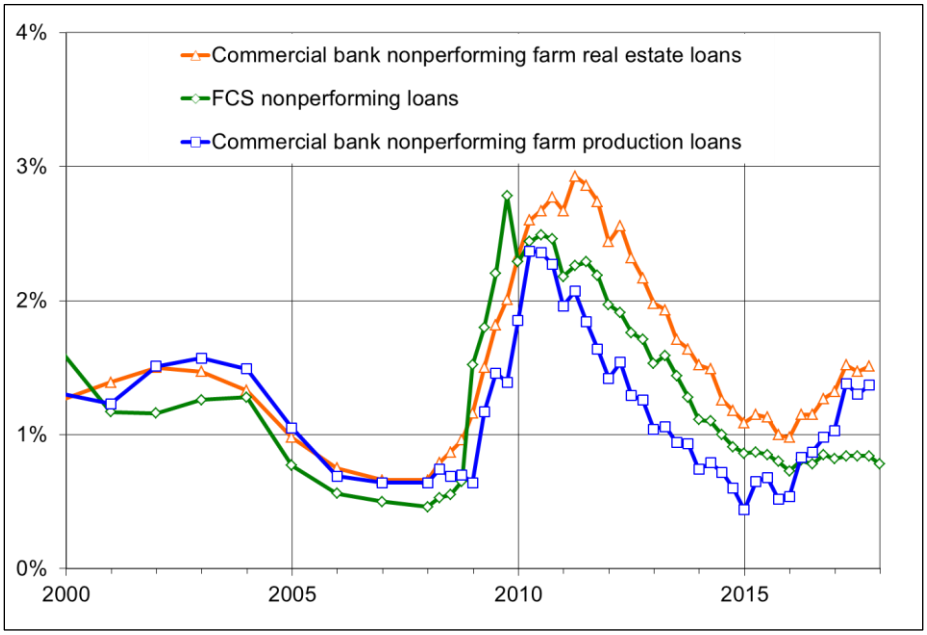
Figure 10. Delinquency Rates on Commercial Bank Loans, 2000-2017Q4



Source: Compiled by CRS. Data through December 31, 2017, using Federal Reserve Bank, "Delinquency Rates on Loans at Commercial Banks" (seasonally adjusted), http://www.federalreserve.gov/releases/chargeoff.

Notes: Delinquencies include loans that are 30 days or more past due and still accruing interest, as well as those in nonaccrual status. The amounts are percentages of end-of-period loans.

Figure 11. Nonperforming Farm Loans, 2000-2017Q4



Source: Compiled by CRS. Federal Farm Credit Banks Funding Corporation data through December 31, 2017, http://www.farmcredit-ffcb.com. Federal Reserve Bank, *Agricultural Finance Data Book*, Tables B.2 and B.4, through September 30, 2017, https://www.kansascityfed.org/research/indicatorsdata/agfinancedatabook.

Notes: Nonperforming loans include nonaccrual loans and accruing loans 90 days or more past due. The amounts are percentages of total loans.

Description of Government-Related Farm Lenders

USDA Farm Service Agency (FSA)

FSA is considered a lender of last resort because it makes direct farm ownership and operating loans to family-sized farms that are unable to obtain credit elsewhere. FSA also guarantees timely payment of principal and interest on qualified loans made by commercial banks and the FCS. Farm bills modify the permanent authority in 7 U.S.C. 1921.

In FY2017, an appropriation of $90 million in budget authority (plus $317 million for salaries and expenses) supported $8 billion of new direct loans and guarantees.[11] Direct loans are limited to $300,000 per borrower ($50,000 for microloans), and guaranteed loans to $1,399,000 (adjusted for inflation). Direct emergency loans are available for disasters.[12]

Part of the FSA loan program is reserved for beginning farmers and ranchers (7 U.S.C. 1994 (b)(2)). For direct loans, 75% of the funding for farm ownership loans and 50% of operating loans are reserved for the first 11 months of the fiscal year. For guaranteed loans, 40% is reserved for ownership loans and farm operating loans for the first half of the fiscal year. Funds are also targeted to "socially disadvantaged" farmers by race, gender, and ethnicity (7 U.S.C. 2003). Using these provisions, FSA is also known as lender of first opportunity for many borrowers.[13]

Farm Credit System (FCS)

Congress established the FCS in 1916 to provide a dependable and affordable source of credit to rural areas at a time when commercial lenders avoided farm loans. The FCS is neither a government agency nor guaranteed by the U.S. government but is a network of borrower-owned lending institutions operating as a GSE. It is not a lender of last resort; it is a for-profit lender with a statutory mandate to serve agriculture. Funds are raised through the sale of bonds on Wall Street. Four large banks allocate these funds to 69 credit associations that, in turn, make loans to eligible creditworthy borrowers.

Statutes and oversight by the House and Senate Agriculture Committees determine the scope of FCS activity (Farm Credit Act of 1971, as amended; 12 U.S.C. 2001 *et seq.*). Benefits such as tax exemptions are also provided. Eligibility is limited to farmers, certain farm-related agribusinesses, rural homeowners in towns under 2,500 population, and cooperatives.[14] The federal regulator is the Farm Credit Administration (FCA).[15]

Farmer Mac

Farmer Mac is a separate GSE that is a secondary market for agricultural loans. Some consider it related to the FCS in that FCA is its regulator and that it was created by the same legislation, but it is financially and organizationally a separate entity. Farmer Mac purchases mortgages from lenders and guarantees mortgage-backed securities that are bought by investors.

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[11] CRS Report R44588, *Agriculture and Related Agencies: FY2017 Appropriations*.

[12] FSA, "Farm Loan Program," http://www.fsa.usda.gov/dafl.

[13] CRS In Focus IF10641, *Farm Bill Primer: Federal Programs Supporting New Farmers*.

[14] CRS Report RS21278, *Farm Credit System*.

[15] CRS In Focus IF10767, *Farm Credit Administration Board Members*.

Recent Congressional Issues for Agricultural Credit

Competition Between Farm Credit System and Commercial Banks

The FCS is unique among the GSEs because it is a retail lender making loans directly to farmers and thus is in direct competition with commercial banks. Because of this direct competition for creditworthy borrowers, the FCS and commercial banks often have an adversarial relationship in the policy realm. Commercial banks assert unfair competition from the FCS for borrowers because of tax advantages that can lower the relative cost of funds for the FCS.[16] They often call for increased congressional oversight. The FCS counters by citing its statutory mandate (and limitations) to serve agricultural borrowers in good times and bad times.[17]

In contrast, FSA's loan programs are supported by both the FCS and commercial banks. FSA is not regarded as a competitor since it serves farmers who otherwise may not be able to obtain credit. Commercial banks and the FCS particularly support the FSA loan guarantee program because it allows them to make and service loans that otherwise might not be possible or at reduced risk.

Credit Title in the Farm Bill

Credit issues are not expected to be a major part of a farm bill in 2018 or to be particularly significant in the overall scope of the permanent agricultural credit statutes. Nonetheless, several issues could arise, such as (1) further targeting of FSA lending resources to beginning, socially disadvantaged, and/or veteran farmers and (2) raising the maximum loan size per borrower.

The enacted 2014 farm bill (P.L. 113-79) made relatively small policy changes to USDA's permanently authorized farm loan programs. It gave USDA discretion to recognize alternative legal entities and allowed alternatives to meet a farming experience requirement. It increased the maximum size of down-payment loans and eliminated term limits on guaranteed operating loans, among other changes.[18]

Maximum Loan Size per Borrower

For the FSA farm loan program, the maximum loan size per borrower for direct loans is $300,000 (7 U.S.C. 1925(a)(2) for farm ownership loans, and 7 U.S.C. 1943(a)(1) for farm operating loans). It was last increased in the 2008 farm bill from $200,000. For FSA guaranteed loans, the maximum size per borrower is presently $1,399,000, which is a $700,000 base amount in statute increased annually by an inflation factor (same U.S. Code sections as for direct loans). It was last updated in statute in 1998, when the inflation factor was added.

As the average size of farms has increased and farms have become more capital intensive, these loan limits may increasingly be seen as limiting opportunities for some farmers. Two bills in the 115th Congress would raise these limits:

[16] For example, American Bankers Association, letter to House and Senate Agriculture Committees, February 2, 2015, http://www.aba.com/Advocacy/LetterstoCongress/Documents/LetterSenateAgCommreFCS-Oversight020215.pdf.

[17] For example, Farm Credit Council, letter to House and Senate Agriculture Committees, February 5, 2015, http://www.fccouncil.com/files/FCC_Letters_in_Response_to_ABA_5Feb2015.pdf.

[18] For details, see Title V in CRS Report R43076, *The 2014 Farm Bill (P.L. 113-79): Summary and Side-by-Side*.

- S. 1736 would raise the maximum size of direct loans to $600,000. It would raise the maximum size of guaranteed loans to $2.5 million, indexed for inflation.
- S. 1921 would similarly raise the maximum size of direct loans to $600,000. It would raise the maximum size of guaranteed loans to $3 million, indexed for inflation. The bill would also update and increase the overall program authorization levels and provide mandatory funding. The FSA farm loan program has historically been funded with discretionary appropriations.

Term Limits on USDA Farm Loans

Congress added "term limits" to the USDA farm loan program in 1992 and 1996 to restrict eligibility for government farm loans and encourage farmers to "graduate" to commercial loans. The term limits place a maximum number of years that farmers are eligible for certain types of FSA loans or guarantees. However, until the end of 2010, Congress had suspended enforcement of term limits on guaranteed operating loans to prevent some farmers from being denied credit, and the 2014 farm bill eliminated that term limit (**Table 1**).

Table 1. Term Limits on Farm Service Agency Loans

Maximum number of years that farmers are eligible for loans

Type of FSA Loan	Direct loans term limits	Guaranteed loans term limits
Farm Operating Loans	6 years, plus possible 2-year extension[a]	No term limit[b]
Farm Ownership Loans	10 years[c]	No term limit[d]

Source: CRS, based on statute and unpublished USDA data.

Note: Term limits are separate from the maximum maturity or duration of an individual loan, which may be as long as 40 years for a farm ownership loan or as short as one year for a farm operating loan.

a. Direct operating loans are limited to a six-year period. In certain cases, borrowers may qualify for a one-time, two-year extension (7 U.S.C. 1941(c)(1)(C) and (c)(4)). In June 2009, USDA said that about 4,800 FSA borrowers were limited to one more year, and another 7,800 borrowers were limited to two more years. USDA did not expect many to graduate to commercial credit (FSA Administrator, testimony to the House Agriculture Subcommittee on Conservation, Credit, Energy and Research, June 11, 2009).

b. Prior to the 2014 farm bill, guaranteed operating loans were limited to a 15-year period (former 7 U.S.C. 1949(b)(1)). However, enforcement of that term limit was suspended by statute until December 31, 2010. Upon expiration of the suspension, the 15-year term limit was enforced from 2011 to 2013. In December 2010, USDA had said that about 1,600 borrowers had reached the guaranteed term limit. The 2014 farm bill permanently removed this term limit (P.L. 113-79 §5107).

c. A borrower is eligible for direct farm ownership (real estate) loans for a maximum of 10 years after the first loan is made (7 U.S.C. 1922(b)(1)(C)).

d. FSA, *Evaluating the Relative Cost Effectiveness of the Farm Service Agency's Farm Loan Programs*, report to Congress, August 2006, p. 76, http://www.fsa.usda.gov/Internet/FSA_File/farm_loan_study_august_06.pdf.

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GENE EDITING: BIOTECHNOLOGY BREAKTHROUGHS AND CHALLENGES

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CRISPR, an acronym for Clustered Regularly Interspaced Short Palindromic Repeats, is a novel gene editing technology that has been called one of the greatest scientific discoveries in the last century.[1] The CRISPR system, also known as the "CRISPR-Cas9" system, is a simple and inexpensive method to identify an "unhealthy" genetic sequence in an organism, cut the sequence out, and then replace the removed "unhealthy" sequence with a "healthy" version.[2] This amazing process results in an organism with a corrected genetic sequence. In some cases, the organism with corrected genetic sequence is made up entirely of its own native genes and is indistinguishable from an organism that has undergone natural breeding selection.[3]

The instances in which the CRISPR system can use an organism's own genetic library to correct damaged DNA results in a far different outcome than some methods that have been historically used to create GMOs.[4] Using CRISPR in this capacity, the corrected genetic system is not a "hybrid" mishmash of DNA obtained from different organisms. Instead, the corrected DNA in a CRISPR-modified organism comes from the organism itself.[5] In other words, although an organism does in fact undergo genetic editing using CRISPR, the resulting CRISPR-modified organism is indistinguishable from a normal organism in nature that is free of the ailment that was fixed by the CRISPR process.[6]

In particular, the agricultural community is struggling to understand how the CRISPR system will affect current procedures, processes, and products. In this regard, Maywa Montenegro, a food systems researcher and a PhD candidate in Environmental Science, Policy and Management at the University of California, Berkeley, may have said it best:

> CRISPR is giving us a rare opportunity, then, to escape GMO definitions stuck in the 1980s and begin treating agriculture and food as the complex systems they are. It invites us to update biotech governance to include expertise from a wider public and range of sciences. We'll need to consult not just geneticists but also ecologists. Not just natural scientists but social scientists. Not just scientists, but farmers, consumers, seed producers and workers across the food chain.[7]

In summary, CRISPR is a game changer for defining what is and what is not a genetically modified organism. This paper will explain the science of using the CRISPR system as a genetic editing

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[1] *See* Antonio Regalado, *Who Owns the Biggest Biotech Discovery of the Century?*, MIT TECH. REV. (Dec. 4, 2014), https://www.technologyreview.com/s/532796/who-owns-the-biggest-biotech-discovery-of-the-century/.
[2] *Id*.
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] https://www.sciencedaily.com/releases/2015/10/151019123744.htm
[7] Maywa Montenegro, *CRISPR is Coming to Agriculture – with Big Implications for Food, Farmers, Consumers and Nature*, ENSIA (Jan. 28, 2016), https://ensia.com/voices/crispr-is-coming-to-agriculture-with-big-implications-for-food-farmers-consumers-and-nature/.

tool,[8] the current and potential applications of CRISPR in animals and plants,[9] the important battle over the inventorship of the CRISPR process that will ultimately determine the true owner of the technology,[10] and the growing regulatory quandary faced by various countries on how to classify organisms modified by CRISPR.[11]

THE CRISPR SYSTEM AND ITS USE AS A GENETIC EDITING TOOL

Modifying organisms via genetic manipulation has been the foundation of biotechnology research for several decades.[12] For most organisms, deoxyribonucleic acid (DNA) is the main genetic material and is made of nucleotide bases adenosine (A), thymidine (T), cytidine (C), and guanosine (G).[13] Nearly all advances in biotechnology research and innovation are developed from this basic framework.

In 1984, CRISPR was first identified during a study of the bacterial genome.[14] CRISPR is represented by short DNA sequences followed by the same DNA sequence in reverse, also known as the "palindromic sequence."[15] This is followed by about thirty base pairs of DNA, known as "spacer" DNA, which then is followed by a repeat of the palindromic sequence.[16] These DNA sequences represent a significant portion of the bacterial genome and almost all archaea, a domain and kingdom of single-celled microorganisms.[17] For many years, the scientific community assumed that these sequences were nothing more than "junk" DNA due to the frequency of seemingly unimportant repetition in the sequences.[18] This assumption, however, fell by the wayside as more and more genomic information became available to scientists in the 1990s and 2000s.[19]

In 2005, researchers discovered that the spacer DNA sequences in the bacterial genome actually matched the DNA sequences known to be present in viruses.[20] This breakthrough indicated that that the spacer DNA sequences may not be junk DNA after all and ultimately suggested a role in microbial immunity.[21] Bacteria are commonly infected by viruses, so scientists hypothesized that bacteria may actually integrate the viral DNA into their own DNA as a sort of defense mechanism to quickly identify and disable viruses upon infection.[22] In other words, bacteria appeared to be able to take up invading viral DNA and make it part of the bacteria's own genetic code to form a sort of "catalog" of viral DNA. If a virus infects the bacteria in the future, the bacteria can reference the catalog of viral DNA and readily identify the virus as an invading, non-bacterial organism.

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[8] See *infra* Part II.
[9] *See infra* Part III.
[10] *See infra* Part IV.
[11] *See infra* Part V.
[12] *See, e.g.*, Asude Alpman Durmaz et al., *Evolution of Genetic Techniques: Past, Present, and Beyond*, BIOMED RES. INT'L 1, 1 (2014).
[13] https://ghr.nlm.nih.gov/primer/basics/dna
[14] Michael J. Stern et al., *Repetitive Extragenic Palindromic Sequences: A Major Component of the Bacterial Genome*, 37 CELL 1015, 1015 (1984) (the conserved nucleotide sequence identified as the REP (repetitive extragenic palindromic) sequence in *E. coli* and *S. typhimurium* is now recognized as the first description of the machinery now known as CRISPR technology).
[15] Elizabeth E. Pennisi, *The CRISPR Craze*, 341 SCI. 833, 834 (2013).
[16] Stern et al., *supra* note 18, at 1015.
[17] *Id.*
[18] *Id.* (due to the repetitive nature of REP sequences, it was assumed that DNA only reflected nonsense "junk" sequences in the genome).
[19] *See* Carl Zimmer, *Breakthrough DNA Editor Born of Bacteria*, QUANTA MAG., Feb. 6, 2015, https://www.quantamagazine.org/20150206-CRISPR-dna-editor-bacteria.
[20] *Id.*
[21] *Id.*
[22] *Id.*

Dr. Jennifer A. Doudna, a researcher at the University of California, Berkeley, discovered how bacteria utilize CRISPR spacer DNA (crDNA) as a defense mechanism.[23] Bacteria use a single-sided section of crDNA (crRNA) as a guide mechanism, in tandem with an enzyme known as Cas9, to identify a virus that had invaded the bacteria.[24] Cas9 is an enzyme that cuts the identified viral DNA at the end of the crRNA complementary sequence, thus inactivating the virus.[25] This simple mechanism is very effective at identifying specific genetic sequences and quickly inactivating them to prevent damage. Essentially, the Cas9 enzyme cuts the DNA like scissors, and CRISPR is the guide mechanism that tells Cas9 where to cut.

After realizing the power of CRISPR as a defense system in organisms, scientists began working on how to adapt the process as a genetic editing tool.[26] Dr. Doudna and her team modified the system to create a single guide RNA (sgRNA) that could include *any* RNA sequence to direct the Cas9 protein to cut DNA at a specific point.[27] The innovative aspect of the CRISPR-Cas9 system is that it uses a RNA-based recognition of DNA instead of a protein-based recognition.[28] The result is that the CRISPR-Cas9 system is more effective and simpler than having to produce an individual protein for every desired genetic cleavage, which had been the gold standard in the genetic world.[29]

Scientists developed several competing genetic-editing technologies before CRISPR, including meganucleases,[30] zinc finger nucleases (ZFNs),[31] and transcription activator-like effector nucleases (TALENs).[32] However, CRISPR is seen to be advantageous over the competing systems due to its accessibility, its inexpensive cost, and the ease with which it can be made and used.

To utilize the CRISPR system, scientists first create a CRISPR "guide" molecule that matches a specific DNA sequence of interest.[33] In this regard, CRISPR is used as a kind of GPS device to find its intended target on the DNA double helix where genetic editing is desired.[34] Once it arrives at the precise position in the DNA, CRISPR cuts and splices the DNA with Cas9 enzyme in order to remove the sequence from the genome.[35] The CRISPR system then incorporates a corrected sequence into the genome provided by scientists to "fix" the cut DNA sequence.

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[23] *See* Dipali G. Sashital et al., *Mechanism of Foreign DNA Selection in a Bacterial Adaptive Immune System*, 46 MOLECULAR CELL 606, 606 (2012).
[24] Jennifer A. Doudna & Emmanuelle Charpentier, *The New Frontier of Genome Engineering with CRISPR-Cas9*, 346 SCIENCE 1258096-1, 1258096-2-1258096-3, 1258096-5 fig. 4 (2014).
[25] *Id*. at 1258096-2.
[26] *Id*. at 1258096-1to -5.
[27] Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCI. 816, 819–20 (2012).
[28] *Id.*
[29] Pennisi, *supra* note 19, at 835.
[30] Maria Jasin & Rodney Rothstein, *Repair of Strand Breaks by Homologous Recombination*, 5 COLD SPRING HARBOR PERSP. BIOLOGY 1, 5 (2013).
[31] Mattew H. Porteus & David Baltimore, *Chimeric Nucleases Stimulate Gene Targeting in Human Cells*, 300 SCI. 763, 763 (2003).
[32] Matthew J. Moscou & Adam J. Bogdanove, *A Simple Cipher Governs DNA Recognition by TAL Effectors*, 326 SCI. 1501, 1501 (2009).
[33] *See* Amy Maxmen, *The Genesis Engine*, WIRED, Aug. 2015, http://www.wired.com/2015/07/crispr-dna-editing-2/.
[34] *Id.*
[35] *Id.*

However, in 2018, research demonstrated that changes in DNA can be introduced by CRISPR edits at a farther distance from the target location to be edited than was previously known.[36] Further, in a somewhat concerning revelation, standard DNA tests may not normally detect this damage. Previous identification of damage from CRISPR-induced edits was conducted relatively close to the original edit and did not generally find any signs of harm. The research determined that in some cases, the newly identified changes introduced fairly large deletions or insertions, possibly leading to DNA being either switched on or off at inappropriate times as a result of the edits. Although these new findings do not necessarily invalidate the CRISPR approach to gene editing, they certainly represent a good reason for scientists to pay attention to their data in order to address the concerns.

As discussed in Part III of this paper, the CRISPR-Cas9 process has been harnessed into a powerful system that can edit specific sites of DNA in virtually any organism.[37] Genetic modifications using CRISPR can be used to activate, add, delete, or suppress genes. In this way, CRISPR acts as a sort of "cut and paste" mechanism for genetic content within targeted regions of an organism's genome. At this early stage of development, the possibilities for CRISPR appear to be nearly endless.

APPLICATIONS OF CRISPR

As with any newly developing technology, the advancement of the CRISPR system is still in its infancy. However, given the simplicity and the low cost of using CRISPR, researchers have already utilized CRISPR to create improved livestock and plants.[38] Targeted gene therapies for humans and animals will also likely be forthcoming.[39] The estimates of the economic impact of CRISPR are staggering for such a newly developed technology, with one estimate predicting a market of more than $5.54 billion by 2021.[40] This section will discuss a few of the recent CRISPR developments for animals and plants.

A. Animal Applications of CRISPR

As CRISPR can be used to genetically edit virtually any germline cell, animals are also at the forefront of the technological applications. CRISPR has the potential to impact not only agriculturally important livestock animals, but also companion animals throughout the world.

Of course, CRISPR modification of animals can also be targeted to impact human health. For instance, researchers are exploring the possibility of altering the pig genome so that pigs could, in theory, grow human organs for transplant.[41] CRISPR can also repair defective DNA in mice and cure them of genetic disorders, which in turn could influence the cure of related human disorders.[42]

Other animals can benefit from the CRISPR platform, for example by instituting disease resistance into the genome. To combat the depletion of honeybees around the world due to disease and parasites, researcher Brian Gillis is investigating the genomes of "hygienic" honeybees for potential

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[36] https://www.extremetech.com/extreme/274110-study-suggests-crispr-gene-editing-could-have-unanticipated-side-effects

[37] *See infra* Part III.

[38] *See* Heidi Ledford, *CRISPR, The Disruptor*, NATURE (June 3, 2015), http://www.nature.com/news/crispr-thedisruptor-1.17673.

[39] *Id.*

[40] *See Genome Editing/Genome Engineering Market Worth 5.54 Billion USD by 2021*, MARKETSANDMARKETS, http://www.marketsandmarkets.com/PressReleases/genome-editing-engineering.asp (last visited Aug. 28, 2017).

[41] *See* Kristen V. Brown, *Inside the Garage Labs of DIY Gene Hackers*, *Whose Hobby May Terrify You*, FUSION (Mar. 29, 2016, 7:00 AM), http://projectearth.us/inside-the-garage-labs-of-diy-gene-hackers-whose-hobby-1796423884.

[42] *See* Zimmer, *supra* note 23.

CRISPR application.[43] These hygienic bees are known to compulsively clean their hives in order to remove sick and infested bee larvae, and are shown to be less susceptible to mites, fungi, and other pathogens compared to other strains.[44] Identification of honeybee genomics associated with this hygienic behavior may lead to genomic editing via CRISPR to improve hive heath and to stem the worldwide honeybee depletion.

In addition, researchers at the University of Missouri have used CRISPR to modify cell surface proteins in pigs to make them virtually resistant to the deadly swine disease porcine reproductive and respiratory syndrome (PRRS).[45] According to estimates, PRRS costs producers in North America more than $600 million on an annual basis,[46] and there is no cure.[47] However, using CRISPR, the pig genome was edited to disable the protein responsible for entry of the virus into swine cells, and the modification actually resulted in protection from the deadly disease.[48]

CRISPR could also be used to make agriculture more humane. For example, long horns on cattle can cause injuries, so farmers generally remove the horns via burning, cutting, or chemical techniques.[49] Although polled cattle varieties exist, crossing these animals with more "elite" meat or dairy cattle breeds may reduce the quality of the resultant offspring.[50] CRISPR gene editing has been used to eliminate horns from cattle by transferring the non-horn gene from one species into an "elite" breed.[51]

Furthermore, CRISPR technology could result in a more fantastical application – reviving species of extinct animals.[52] Although talk of bringing back the wooly mammoth (*Mammuthus primigenius*) has existed for years, CRISPR may facilitate this undertaking by editing the genome of existing elephant species, such as the Indian elephant.[53] Such an application will require several more years of research, but could result in a Jurassic Park-like plotline becoming reality.

In summary, animal applications of CRISPR are far-reaching, but within the purview of researchers around the globe. Generally, given lower regulatory thresholds and fewer social morality issues, applications resulting from CRISPR editing of animal germlines may be more plentiful and faster to market than their human counterparts.

B. Plant Applications of CRISPR

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[43] Sara Reardon, *Welcome to the CRISPR Zoo,* NATURE (Mar. 9, 2016), http://www.nature.com/news/welcome-to-the-crispr-zoo-1.19537.
[44] *Id.*
[45] Monique Brouillette, *You Can Edit a Pig, but it Will Still Be a Pig,* SCI. AM., Mar. 2016, at A22, *subsequently published as,* Monique Brouillette, *Scientists Breed Pigs Resistant to a Devastating Infection Using CRIPSR*, SCI. AM. (Mar. 1, 2016), https://www.scientificamerican.com/article/scientists-breed-pigs-resistant-to-a-devastating-infection-using-crispr/.
[46] *See* Derald J. Holtkamp et al., *Assessment of the Economic Impact of Porcine Reproductive and Respiratory Syndrome Virus on United States Pork Producers*, 21 J. OF SWINE HEALTH AND PROD. (2013).
[47] *See Porcine Reproductive and Respiratory Syndrome (PRRS)*, THE PIG SITE, http://www.thepigsite.com/pighealth/article/142/porcine-reproductive-and-respiratory-syndrome-prrs/ (last visited Dec. 14, 2017).
[48] Brouillette*, supra* note 59.
[49] Reardon, *supra* note 57.
[50] *Id*.
[51] Wenfang Tan et al., *Efficient Nonmeiotic Allele Introgression in Livestock Using Custom Endonucleases*, 110 PROC. NAT'L. ACAD. SCI. U.S.16526–27 (2013).
[52] Reardon, *supra* note 57.
[53] *Id*.; *See also* Zimmer, *supra* note 23.

Applications of CRISPR to the plant world have also flourished.[54] Published research demonstrates that plant modification via CRISPR is more successful, and also more efficient, than previously developed genetic engineering methods.[55] Importantly, thanks to CRISPR, curing crop diseases and creating crops that are immune to disease may soon become the normal course for genetically modified plants.[56]

The use of CRISPR for agriculturally important crops is of great significance given the rapidly growing global population. Although the global population has increased by approximately 60% over the past twenty years, grain production per capita has actually decreased worldwide.[57] If population growth rates continue according to the current pace, the world population will double again within fifty years, and estimates show that food production must also double by the year 2050 in order to keep up with demands.[58] Therefore, creating new ways to feed a growing population must be explored by any means necessary.

Several success stories of using CRISPR to modify crops have already emerged. For example, Chinese researchers using CRISPR developed a strain of wheat that is resistant to powdery mildew, a destructive fungal pathogen.[59] The Chinese researchers edited the wheat genome to delete certain genes that encode proteins that repress defenses against the mildew.[60] Thus, simple genetic editing via CRISPR can stop mildew in its tracks, rather than using heavy doses of fungicides to control the disease.[61] The results are more effective and environmentally friendly compared to current methods.

Researchers have also successfully created tomatoes with prolonged life via CRISPR by turning off the genes that control how quickly the tomatoes ripen.[62] Furthermore, using CRISPR methods, researchers are working on engineering vegetables that possess enhanced nutrition.[63] Because vegetables can make their nutrients more available, such as lycopine and glucosinolates in broccoli, humans can benefit even more from eating their vegetables.[64]

In June 2018, Dr. Michael Gomez, working with partners at the Innovative Genomics Institute, announced that he had succeeded in removing genes from cassava (known in North America as the tapioca product). Cassava is an important crop in Africa and many countries in the southern hemisphere due to its drought resistant properties. Removal of the genes that are responsible for excessive cyanide production in cassava could result in a huge increase in the usefulness of the crop as a food source in these regions.

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[54] Doudna & Charpentier, *supra* note 28, at 1258096-5.
[55] *Id.*
[56] *See, e.g.*, Khaoula Belhaj et al., *Plant Genome Editing Made Easy: Targeted Mutagenesis in Model and Crop Plant Using The CRISPR/Cas System*, PLANT METHODS, Oct. 11, 2013, at 1, https://plantmethods.biomedcentral.com/articles/10.1186/1746-4811-9-39.
[57] Samir Suweis et al., *Resilience and Reactivity of Global Food Security*, 112 PROC. NAT'L. ACAD. SCI. U.S. 6902, 6902, 6905 (2015).
[58] *Id.* at 6902.
[59] David Talbot, *Chinese Researchers Stop Wheat Disease with Gene Editing*, MIT TECH. REV. (Jul. 21, 2014), https://www.technologyreview.com/s/529181/chinese-researchers-stop-wheat-disease-with-gene-editing/.
[60] *Id.*
[61] *Id.*
[62] *See* Michael Specter, *The Gene Hackers*, THE NEW YORKER (Nov. 16, 2015), http://www.newyorker.com/magazine/2015/11/16/the-gene-hackers.
[63] Jeannine Otto, *More Nutritious and Tastier Vegetables? CRISPR Gene Editing Could Dramatically Boost Consumption,* GENETIC LITERACY PROJECT (Feb. 16, 2017), https://www.geneticliteracyproject.org/2017/02/16/nutritious-tastier-vegetables-crispr-gene-editing-dramatically-boost-consumption/.
[64] Specter, *supra* note 76.

There appears to be a myriad of CRISPR applications in the plant world, and agricultural companies are already on board.[65] For example, DuPont Pioneer has invested in Caribou Biosciences, the startup co-founded by CRISPR co-inventor Jennifer Doudna, which explores the use of genome editing on corn, soybeans, wheat, and rice.[66] DuPont Pioneer has announced plans to begin selling seeds made with CRISPR technology within five years.[67]

INVENTORSHIP OF CRISPR

The CRISPR system's multitude of applications, both real and theoretical, is developing at a breakneck pace. But what was the first group to invest in CRISPR's function for gene editing? And, perhaps more importantly, which group owns the intellectual property rights to use CRISPR for gene editing? The final answer is yet to be determined, but is currently playing out in the U.S. Patent Office and perhaps in the federal court system.[68]

The story of who invented the use of CRISPR for gene editing focuses on two research groups.[69] One research group was led by Dr. Jennifer Doudna at the University of California, Berkeley.[70] Dr. Doudna and French researcher, Emmanuelle Charpentier, were the first scientists to demonstrate that CRISPR could edit purified DNA, and published these findings in the journal *Science* in the summer of 2012.[71] The second research group was led by the laboratory of Dr. Feng Zhang of The Broad Institute of MIT and Harvard.[72] In early 2013, Dr. Zhang published research demonstrating that CRISPR could be used to modify human genes.[73]

The history of the patent applications arising from both Dr. Doudna's group and from Dr. Zhang's group is more complicated.[74] In March 2013, Dr. Doudna filed a patent application regarding the general CRISPR-Cas9 system, which included a whopping 155 claims.[75] In October 2013, Dr. Zhang filed a patent application and requested that the application be placed on the accelerated examination track by the United States Patent and Trademark Office (USPTO).[76]

Because of Dr. Zhang's request for his patent to be placed on the accelerated track, Dr. Zhang's patent was first issued on April 15, 2014.[77] Specifically, the patent granted Dr. Zhang the right to exclude others from implementing the commercial use of CRISPR technology for eukaryotic cells (e.g., cells of humans and other animals).[78] As a result, Dr. Zhang was granted control over CRISPR applications for use in humans, monkeys, pigs, and mice, which represent the majority of test models that can be used for

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[65] Talbot, *supra* note 73.
[66] *Id.*
[67] Specter, *supra* note 76.
[68] Otto, *supra* note 77.
[69] Specter, *supra* note 76.
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] Le Cong et al., *Multiplex Genome Engineering Using CRISPR/Cas Systems*, 339 SCI. 819, 822 (2013); *see also* Specter, *supra* note 76.
[74] *See generally* Jacob S. Sherkow, *The CRISPR Patent Interference Showdown Is On: How Did We Get Here and What Comes Next*?, STAN L. SCH.: L. & BIOSCIENCES BLOG (Dec. 29, 2015), https://law.stanford.edu/2015/12/29/the-crispr-patent-interference-showdown-is-on-how-did-we-get-here-and-what-comes-next/.
[75] U.S. Patent Application No. 13/842,859 (filed Mar. 15, 2013) (priority date May 25, 2012).
[76] U.S. Patent No. 8,697,359 (filed Oct. 15, 2013) (issued Apr. 15, 2014).
[77] Sherkow, *supra* note 88.
[78] *Id.*

advancement of human disease therapeutics.[79] In other words, with the grant of the patent, Dr. Zhang was given the keys to the vehicle that undoubtedly represents the possibility of generating the most profitable uses of CRISPR technology.

As filed, the two patent applications can seemingly be distinguished.[80] Dr. Doudna's patent application contained language that could be interpreted to limit the claims to apply CRISPR only to *prokaryotic* cells.[81] In contrast, Dr. Zhang's application claimed a method of performing CRISPR editing in *eukaryotic* cells.[82] In light of the patent grant to Dr. Zhang, Dr. Doudna's group amended the claims of their patent application to remove the suggestion that the claims are limited to prokaryotic cells.[83] This amendment provided Dr. Doudna the opportunity to request that the USPTO determine which competing party is truly entitled to a patent on CRISPR technology.[84]

Clearly, Dr. Doudna's patent application was filed first and thus was given an earlier priority date than Dr. Zhang's patent application. As a result, Dr. Doudna petitioned the USPTO to institute an interference proceeding in order to argue that Dr. Zhang's already issued patent "interfere[ed]" with Dr. Doudna's ability to obtain a patent on her earlier filed application.[85] The purpose of an interference proceeding is to determine which party was actually the first to invent a particular claimed technology.[86]

On January 11, 2016, the USPTO granted Dr. Doudna's request for an interference proceeding of the two patent filings, and a number of disputed claims between the two patent filings became at issue.[87] The interference proceeding was thereafter argued before a panel of judges in order to determine who was the true inventor. Several motions and oral proceedings were undertaken before the USPTO issued its decision.

During the interference proceeding, Dr. Zhang's group argued that the two competing patent filings actually represented different claims—Zhang's patent claiming CRISPR for use on eukaryotic cells, and Doudna's patent claiming CRISPR for use on prokaryotic cells like bacteria.[88] In contrast, Dr. Doudna's group argued that their patent filing dominated the later patent filing by Dr. Zhang because Dr. Doudna's patent application covered all aspects of CRISPR, not just prokaryotes.[89] In other words, Dr. Doudna asserted that her group was the rightful owner of the patent issued to Dr. Zhang because they, in fact, invented the technology first.

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[79] *Id.*
[80] *Id.*
[81] '859 Patent Application ("The present disclosure provides genetically modified cells that produce Cas9; and Cas9 transgenic non-human multi-cellular organisms.").
[82] '359 Patent.
[83] Suggestion of Interference Pursuant to 37 C.F.R. § 41.202 at 7, In re Patent Application of Jennifer Doudna et al., U.S. Patent Application Serial No. 13/842,859 (Apr. 13, 2015).
[84] *Id.* at 1.
[85] *Id.*
[86] *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 35 U.S.C.); Mark Summerfield, *CRISPR--Will This Be the Last Great US Patent Interference?*, PATENTOLOGY (July 11, 2015, 8:08 PM), http://blog.patentology.com.au/2015/07/crispr-will-this-be-last-great-us.html.
[87] Declaration – 37 C.F.R. § 41.203(b) at 2, Broad Inst. Inc. v. Regents of the Univ. of Cal., No. 106,048 (P.T.A.B. Jan. 11, 2016); Heidi Ledford, *Bitter Fight Over CRISPR Patent Heats Up*, NATURE (Jan. 12, 2016), http://www.nature.com/news/bitter-fightover-crispr-patent-heats-up-1.17961.
[88] Heidi Ledford, *Broad Institute Wins Bitter Battle Over CRISPR Patents*, NATURE (Feb. 15, 2017), http://www.nature.com/news/broad-institute-wins-bitter-battle-over-crispr-patents-1.21502.
[89] *Id.*

In a decision rendered in February 2017, the USPTO upheld the patents issued to Dr. Zhang's group, stating that the patents were valid because they were distinguishable from the patent filings of Dr. Doudna's group.[90] As a result, the USPTO found that the most lucrative applications of CRISPR technology, the editing of eukaryotic cells such as humans, animals, and plants, belong to Dr. Zhang and The Broad Institute.[91] The decision was immediately reflected in the business world, as stock in Editas Medicine, a biotechnology company that licensed the CRISPR patents owned by The Broad Institute, surged following announcement of the USPTO verdict.[92]

However, the battle over CRISPR patent rights is far from over. The decision was appealed to the Federal Circuit and remains pending on appeal at the current time. Moreover, the patent rights outside the United States are still up for grabs and a patent battle may be forthcoming in other jurisdictions, such as Europe.[93]

In the wake of the USPTO's decision, both Dr. Doudna and Dr. Zhang were allowed to maintain ownership of their respective patents.[94] However, the USPTO interim decision has created a cloud of uncertainty for entities that desire to use CRISPR gene editing in eukaryotic cells. For example, it is unclear if a license for using CRISPR on eukaryotic cells must be obtained from the University of California, Berkeley (the owner of the Doudna patents), The Broad Institute (the owner of the Zhang patents), or both.[95] If researchers are compelled to obtain a license from both entities, the cost of commercializing CRISPR technology may ultimately increase. However, it does not appear that the ongoing patent rights battle has slowed down research on utilizing CRISPR; in fact, many groups have developed new methods that may be outside the scope of the claims of *both* the Doudna and Zhang patents.[96]

In summary, The Broad Institute won an important early victory in the battle for ownership of CRISPR applications. However, the jury is still out on who will be the ultimate victor in the war. In the meantime, the science surrounding CRISPR continues to march on by exploring even more innovative pathways.

REGULATORY ASPECTS OF CRISPR-EDITED PRODUCTS

As discussed previously, the phrase "genetically modified organism" evokes strong feelings and beliefs from both proponents and opponents of GMOs.[97] However, the unique mechanism of the CRISPR system presents an opportunity to redefine how "gene edited" animals and plants are viewed by scientists, regulators, and consumers. Before exploring CRISPR's varied regulatory aspects in human, animal, and plant organisms, it is informative to understand the scope of how "traditionally viewed" GMOs are regulated.

A. Current Regulation of GMOs

Generally, there are two processes by which GMOs are regulated by worldwide agencies. The first view is a *product-focused* approach that evaluates the final genetically modified product compared to

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[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] Heidi Ledford, *Why the CRISPR Patent Verdict Isn't the End of the Story*, NATURE (Feb. 17, 2017), http://www.nature.com/news/why-the-crispr-patent-verdict-isn-t-the-end-of-the-story-1.21510.
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *See infra* Part I.

the natural, unmodified product.[98] Alternatively, the second view is a *process-focused* approach that emphasizes review of the actual process by which the GMO is produced.[99] The biotechnology industry prefers regulation that is product-focused because the genetic modification process itself is not stigmatized during evaluation of a GMO. However, in the end, both product *and* process focused regulatory reviews consider the method that is used to produce the GMO, although method of production is considered less in the product-focused review.[100]

In the United States, there is no federal legislation specifically directed to review GMOs.[101] Instead, GMOs are regulated by various existing government agencies that are set up to evaluate the health, safety, and environmental impact of the products under the Coordinated Framework for Regulation of Biotechnology, published in 1986.[102] According to this regulation, there are three tenets: "(1) U.S. policy would focus on the product of genetic modification (GM) techniques, not the process itself, (2) only regulation grounded in verifiable scientific risks would be tolerated, and (3) GM products are on a continuum with existing products and, therefore, existing statutes are sufficient to review the products."[103]

The process of regulatory review and approval varies depending on the type of GMO.[104] For example, "food, drug, and biological product GMOs are regulated under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act . . . by the Food and Drug Administration (FDA)."[105] Plant GMOs are regulated according to the "Animal and Plant Health Inspection Service by the U.S. Department of Agriculture (USDA) under the Plant Protection Act."[106] Pesticide and microorganism GMOs are regulated pursuant to the "Federal Insecticide, Fungicide and Rodenticide Act and the Toxic Substances Control Act by the Environmental Protection Agency (EPA)."[107]

Compared to other countries, regulation on GMO development in the United States is relatively favorable. For the U.S., GMOs are very important to the biotechnology industry from an economic standpoint. For example, the U.S. leads the world in producing genetically modified crops. In 2012, there were 420.8 acres of biotech crops worldwide, and the U.S. accounted for over 40% of this production (171.7 acres).[108] Furthermore, the majority of several different types of crops grown in the U.S. are now comprised of genetically engineered varieties.[109] For instance, in 2013, 93% of the soybeans, 90% of the cotton, and 90% of the corn grown in the U.S. were genetically engineered crops, due to either herbicide tolerance or an insect resistance.[110]

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[98] S.J. Mayer, *The Regulation of Genetically Modified Food*, *in* 13 BIOTECHNOLOGY 91 (Horst Werner Doelle et al., eds., 2009).
[99] *Id.*
[100] *Id.*
[101] *Restrictions on Genetically Modified Organisms: United States*, LIBR. OF CONGRESS (Jun. 9, 2015), https://www.loc.gov/law/help/restrictions-on-gmos/usa.php.
[102] *Id.*
[103] Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 738 (2003).
[104] LIBR. OF CONGRESS, *supra* note 115.
[105] *Id.*
[106] *Id.*
[107] *Id.*
[108] CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, BRIEF 44: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS 7 (2012). https://www.loc.gov/law/help/restrictions-on-gmos/usa.php
[109] *See Recent Trends in GE Adoption*, U.S. DEP'T OF AGRIC., ECON. RES. SERV., http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx#.UobvBXL92Dk (last updated July 12, 2017).
[110] *Id.*

On the other side of the spectrum, the regulation of GMOs in the European Union (EU) is vastly different. Regulatory laws passed in 2003 caused the EU to have possibly the most stringent GMO regulations in the world, which primarily utilize the process-based approach to regulatory review.[111]

As of 2010, the EU considers all GMO crops to be "new foods."[112] As a result, each GMO crop is subjected to an extensive, scientific-based evaluation by the European Food Safety Authority (EFSA) on a case-by-case basis.[113] In turn, the EFSA agency reports to the European Commission (EC), which proceeds to draft proposals to either grant or refuse authorization of the GMO crop for submission to the "Section on GM Food and Feed of the Standing Committee on the Food Chain and Animal Health."[114] If accepted, the proposal is then either adopted by the European Commission or is passed on to the Council of Agricultural Ministers.[115] Thereafter, the Council has a three-month window to either vote for or against the proposal, and if a majority vote is not achieved, the proposal returns to the EC, which then adopts it.[116] The extreme amount of regulatory review and oversight over GMO crops, divided between multiple agencies within the EU, can result in tremendous delays in garnering approval.

The role of the EFSA is to use independent scientific research to advise the EU in order to protect not only consumers but also the environment.[117] This risk assessment includes evaluations to the molecular characterization of the GMO crop, its potential toxicity, and also its potential to impact the environment**.**[118] Each GMO that is approved must be reassessed every 10 years.[119] Moreover, applicants desiring to cultivate or to process the GMOs must further deliver a detailed surveillance plan outlining the steps to be taken after GMO authorization.[120] In other words, even after garnering an approval in the EU, the GMO crop is still subject to multiple layers of regulatory review.

B. Regulation of CRISPR Animal Applications

Like human applications of CRISPR, the use of gene editing on animals intended for food would be governed in the United States by the FDA.[121] This process appears to be relatively straightforward, given that the FDA currently regulates genetically engineered animals.

On January 18, 2017, two days before President Obama left office, the FDA released three proposed regulations addressing different categories of products.[122] In particular, one proposal was directed to regulation of "intentionally altered" DNA in animals.[123] According to this draft proposal, the

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[111] John Davison, *GM plants: Science, Politics and EC regulations*, 178 PLANT SCI. 94, 94 (2010).
[112] *Id.*
[113] *Id.* at 95.
[114] *Id.*
[115] *Id.*
[116] *Id.*
[117] EFSA, http://www.efsa.europa.eu/ (last visited Mar. 4, 2017).
[118] *Genetically Modified Organisms,* EFSA, https://www.efsa.europa.eu/en/topics/topic/genetically-modified-organisms (last visited Mar. 4, 2017).
[119] *Id.*
[120] *Monitoring Plans and Reports*, EFSA, http://ec.europa.eu/food/plant/gmo/post_authorisation/plans_reports_opinions_en (last visited Mar. 4, 2017).
[121] Amy Maxmen, *Gene-Edited Animals Face US Regulatory Crackdown,* NATURE (Jan. 19, 2017), http://www.nature.com/news/gene-edited-animals-face-us-regulatory-crackdown-1.21331.
[122] *Id.*
[123] *Guidance for Industry – Regulation of Intentionally Altered Genomic DNA in Animals*, FDA (Jan. 2017), *available at*

review of *all* animals with an "intentionally altered" genome would be subject to evaluation for safety and efficacy in a manner similar to the review process for new drugs.[124]

This proposed regulation was immediately met with criticism from CRISPR researchers. Given the accuracy and precision of the CRIPSR process to edit an animal's genome without the introduction of nonnative DNA, researchers were hopeful that these gene-editing products would be regulated less stringently than animals that are genetically engineered by introducing foreign DNA.[125] Furthermore, the inclusion of an "'intent"' element in the proposed regulation was also questioned.[126] Because the U.S. has generally followed a product-based approach to regulating genetically-altered animals, many researchers were baffled as to why animals with an "intentionally altered" genome would be subjected to increased scrutiny.[127] "The trigger for their regulation is whether the animal was intended to be made, and what does intention have to do with risk," commented Alison van Eenennaam, an animal geneticist at the University of California, Davis. "The risk has to do with the attributes of the product."[128]

In particular, many people are concerned that, if implemented, the proposed regulations would result in the development of CRISPR-edited animals to slow down or to be abandoned completely by researchers.[129] In other words, the increased regulation of the animals via FDA review may cause businesses and universities to think twice before investing the time and effort to create improved animals via gene editing. Those who cannot remember the past are condemned to repeat it, and such companies undoubtedly recall the development of genetically engineered salmon by AquaBounty Technologies.[130]

In 1995, AquaBounty began the approval process for the development of an Atlantic salmon (*Salmo salar*) engineered with genes from Chinook salmon (*Oncorhynchus tshawytscha*) in order to promote rapid growth of the genetically modified fish.[131] However, the path to regulatory approval was lengthy and laborious. AquaBounty had to perform over 50 studies to demonstrate that the genetically modified salmon posed no unusual risks before the FDA finally approved the fish for sale in November 2015.[132] In total, AquaBounty spent approximately $60 million on the development of the fish. Even after gaining approval, the FDA later determined that the salmon cannot be sold in the United States until a final determination is made on whether the fish must be labeled as genetically modified.[133]

The FDA's proposed regulation in January 2017 was a setback to scientists currently engaged in the development of CRISPR-edited animals. For example, the gene editing company Recombinetics, located in St Paul, Minnesota, has developed hornless dairy cattle by using gene editing.[134] The gene editing to create the polled animal inserts a gene from naturally hornless beef cattle into a breed of the

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https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf.

[124] *Id.*

[125] Maxmen, *supra* note 143.

[126] *Id.*

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *Id.*

[131] Amy Maxmen, *Transgenic Fish Wins US Regulatory Backing*, NATURE (Dec. 22, 2012), http://www.nature.com/news/transgenic-fish-wins-us-regulatory-backing-1.12130.

[132] Maxmen, *supra* note 143.

[133] *Id.*

[134] *Id.*

same species used in milk production.[135] As discussed previously, this process could ease animal welfare concerns associated with the removal of horns via burning, cutting, or chemical techniques.[136]

In December 2016, Recombinetics informed the FDA that it intended to sell food from the genetically edited cattle without receiving FDA approval, which is allowable if the food label states that the product is "generally recognized as safe."[137] However, with the uncertainty surrounding the newly proposed FDA regulation, this decision has been thrown into jeopardy.

It is important to note that the January 2017 documents published by the FDA are simply proposals, and full implementation of the proposed procedures will take time, if they happen at all. The draft regulations are subject to receive public comments until April 2017; based on feedback, the regulatory approach may be further modified by the FDA.[138] Moreover, it is uncertain how the new administration under President Trump will oversee the proposed regulations. In the end, the proposed regulations have been the subject of many discussions for the future of CRISPR's animal editing, and it remains to be seen whether they represent a speed bump or a roadblock for future developments.

C. Regulation of CRISPR Plant Applications

In the U.S., plants with genetic modifications or genetic editing are regulated by the USDA.[139] In contrast to human and animal applications of CRISPR, the regulatory pathway for CRISPR-edited plants has already been assessed, both in the United States and abroad.

In April 2016, the USDA determined that a CRISPR-edited mushroom developed by scientists at Penn State University did not have to undergo regulation in the United States prior to being placed on sale.[140] Dr. Yinong Yang, the plant pathologist credited with the creation, used CRISPR to edit the common white button mushroom (*Agaricus bisporus*) so that it would resist browning.[141] By editing the mushroom to knock out one gene from the enzyme family that leads to browning, Dr. Yang successfully reduced the enzyme's activity by 30%.[142] In its evaluation, the USDA determined that since the edited mushroom did not contain any foreign genetic material, and did not represent "a plant pest or weed," regulation by the agency was unnecessary.[143]

Furthermore, the USDA has also determined that other gene-edited plants (including corn, potatoes, and soybeans that have been edited using TALENs instead of CRIPSR) do not require evaluation, according to existing regulations.[144] This decision offers hope to companies and researchers

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[135] *Gene-editing Options,* THE CATTLE BUSINESS WEEKLY (Jan. 25. 2017), http://cbw60.1upprelaunch.com/Content/Headlines/-Headlines/Article/Gene-editing-options/1/1/8660.
[136] *See supra* Part III B.
[137] Maxmen, *supra* note 143.
[138] *Id.*
[139] http://www.businessinsider.com/the-us-government-says-crop-edited-with-crispr-wont-be-regulated-2016-4
[140] Emily Waltz, *Gene-edited CRISPR Mushroom Escapes US Regulation,* NATURE (Apr. 14. 2016), http://www.nature.com/news/gene-edited-crispr-mushroom-escapes-us-regulation-1.19754.
[141] *Id.*
[142] *Id.*
[143] Julienne Isaacs, *CRISPR-Cas9: A Promising Tool for Plant Breeding*, TOP CROP MANAGER (Oct. 3. 2016), http://www.topcropmanager.com/plant-breeding/crispr-cas9-a-promising-tool-for-plant-breeding-19611.
[144] Talbot, *supra* note 73.

pursuing gene-edited crops using CRISPR technology. However, the current regulations are under review and may change in the future.

In March 2018, U.S. Secretary of Agriculture Sonny Perdue issued a statement clarify the USDA's oversight of plants produced via CRISPR.[145] In the statement, Perdue indicated that the USDA has no plans to regulate genome editing when used to produce new plant varieties that are indistinguishable from those bred through traditional breeding methods. This important announcement brought some clarification to parties currently using CRISPR to edit plants.

The review of CRISPR applications to plants is also being conducted abroad. Similar to the United States, countries such as Argentina have indicated that genetically edited plants using CRISPR or TALENs are outside of the scope of existing GMO legislation.[146] In Canada, products are evaluated according to the new "trait" introduced in the plant instead of the process by which the plant was developed.[147] Moreover, the Canadian Food Inspection Agency (CFIA) must assess the environmental safety profile of plants comprising novel traits before the associated product can be released.[148] The jury is still out in China, where authorities have not yet decided whether CRISPR-edited crops will be able to be planted.[149]

But the biggest domino yet to fall is if the EU will ultimately decide to regulate CRISPR-edited plants. As discussed previously, the EU has some of the strictest regulations in the world with respect to GMO crops. However, given the differences in CRISPR technology with older methods for genetically modifying plants, the EU may follow the lead of the USDA and determine that CRISPR editing falls outside of the scope of current GMO regulations.

A promising development for proponents of CRISPR in the EU came in late 2015, when the Swedish Board of Agriculture determined that some plants edited using CRISPR technology did not fall under the rigorous EU definition of a GMO.[150] The Board issued its decision following an inquiry from researchers in Umeå and Uppsala in Sweden, and rendered an opinion that although some Arabidopsis plants modified using CRISPR fall within the scope of the EU's GMO definition, other plants do not.[151]

However, in July 2018, the Court of Justice of the European Union (Europe's highest court) held that that crops created by gene editing would fall under the strict laws restricting the use of GMOs in Europe.[152] The decision represents a tremendous setback for scientists that are interested in the European market. In the decision, the Court stated that the "risks linked to the use of these new mutagenesis techniques might prove to be similar to those that result from the production and release of a GMO through transgenesis (standard genetic modification)."[153]

The court's decision was met with derision by many scientists. Sarah Schmidt, project coordinator at the Institute for Molecular Physiology in the Heinrich Heine University Düsseldorf, called

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145 https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation

146 *"Green Light in the Tunnel"! Swedish Board of Agriculture: a CRISPR-Cas9-mutant but Not a GMO*, UMEÅ PLANT SCI. CENTRE (Dec. 19, 2016), https://www.upsc.se/about-upsc/news/4815-green-light-in-the-tunnel-swedish-board-of-agriculture-a-crispr-cas9-mutant-but-not-a-gmo.html.

147 Isaacs, *supra* note 164.

148 *Id.*

149 Talbot, *supra* note 73.

150 *CRISPR-Cas9-edited Plant Genomes May Not Be Classified as GMOs*, PHYS. ORG. (Nov. 17, 2015), https://phys.org/news/2015-11-crispr-cas9-edited-genomes-gmos.html.

151 *Id.*

152 https://www.agri-pulse.com/articles/11274-eu-court-rules-gene-editing-technique-falls-under-gmo-laws

153 Id.

the decision “the deathblow for plant biotech in Europe,” that “could slam the door shut on this revolutionary technology.”[154] Likewise, Maurice Moloney, CEO at the Global Institute for Food Security in Canada said that the decision represented “a real step backwards for the EU, for innovation and in the wider context, for global food security,” he said. “It will have the consequence of further disrupting world trade in agricultural products at a critical time for world trading policy.”[155]

CONCLUSION

CRISPR technology is moving at a breakneck pace. Although regulatory concerns are certainly valid, the benefits offered by the new technology are also significant for the medical and agricultural world. Thus, it will be imperative for researchers and regulators to find common ground so that these valuable innovations can be brought to market for the benefit of mankind.

[154] https://sciencebusiness.net/news/ruling-gene-editing-crops-threat-innovation-and-future-food-security-scientists-say

[155] Id.

SYNGENTA CASE SETS BARRIERS & BOUNDARIES FOR GENETICALLY EDITED CROP & ANIMAL PIPELINES

Thomas P. Redick[1]

This article addresses the challenges that lie ahead for the latest ground-breaking innovation in agriculture – genetic editing.

I will also outline the current status of and potential impacts from the lawsuits tried and settled against Syngenta for its allegedly negligent disruption the U.S. corn export market to China. While some of those cases against Syngenta are still pending, I will chart the potential barriers that these court decisions and settlements could create for biotech crops down the road. With new tools for plant breeding arriving in the form of genetic editing, the threat of liability could undermine innovation for years to come.

The Syngenta case requires a biotech seed company to seek overseas approvals in a newly broadened, court-defined "major" market for the crop in question. The European Union is a major market for most US crops, and it recently decided to regulate genetic editing as if it were a "GMO" (i.e., a recombinant DNA crop of the first generation of biotech plant breeding).

It is clear that the outcome of this case, which creates a duty of care (under the law of negligence) to seek overseas approval before marketing a new biotech crop, along with the expected steady stream of new laws requiring overseas approval, could create barriers to entry to the future use of all agricultural biotechnology in the United States, including new genetically edited crops and animals.

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I. Agricultural Biotechnology Enters a New Era

Genetic editing has come to agriculture promising new traits created with more speed, lower cost and greater precision than any plant breeding tool to date.

Each past transition in breeding, from hybrids to mutagenesis to recombination and now gene-editing, has had challenges in acceptance. You cannot save the seeds from hybrids and replant them – some growers resented this at first, and there are still corners of the world where hybrid corn is shunned for open-pollinating varieties (often sacrificing higher yields for the "Right to Save Seed"[2]). Some proponents of traditional and organic agriculture,[3] particularly in Europe, continue to promote this outdated, lower productivity approach to plant breeding, sometimes using amusing videos decrying payments of royalties to seed breeders.[4] Concerns expressed about safety and the environment appear overblown, with the possible exception of the resistant crop treadmill that must be managed to maintain the benefits of many crops, insects and other biotech organisms.

In the final analysis, however, there is no denying that patenting gives a company the right to own and license a living thing. As a result, there is no reason to believe that the organic industry will ever drop its objections to the patents and "industrial" biocides that may be associated with genetic editing in agriculture.[5] Using this patenting practice as ground to distinguish genetic

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[2] Janak Rhans Ghose, The Right to Save Seed, Rural Poverty and Environment Working Paper Series, Academia.edu (2005) www.academia.edu/2434248/The_Right_to_Save_Seed . (last visited July 20, 2018)

[3] Seed Sharing Deemed Illegal in the United States, https://www.youtube.com/watch?v=txRUeuuKex4 . (last visited July 20, 2018)

[4] The Right to Save Seed, https://www.youtube.com/watch?v=33DwBp2QTgg

[5] The pipeline of genetically edited crops includes many that will resist commonly used herbicides, for example. See, e.g., Cibus Products, https://www.**cibus**.com/**products**.php (**Cibus** is a growth stage company that is currently in the commercialization phase or late-stage development in sulfonylurea (SU) herbicide tolerant **Canola**, glyphosate tolerant Flax, etc.) . (last visited July 20, 2018)

editing in agriculture from past breeding tools that changed DNA (but only used lesser varietal plant patents), it is now clear, after the EU decision discussed below, that nations around the world may raise trade barriers to genetic editing in agriculture, as they become more familiar with genetic editing and the American way of agriculture.

Many more nations are banning biotech crops while endorsing hybrids and mutagenesis breeding, which means that mid-20th Century innovation is finally being accepted in some corners of the world that missed the "Green Revolution". Such tools account for expanding food production exponentially over the past 100 years, and genetic editing will take its place in further expanding food production as the human population stretches its resource limits in the mid-21st Century.

II. Regulatory Barriers to Entry

Gene editing is new enough to the world that many nations are still working on the issue of whether to require pre-market approval.

a. U.S. Regulation

In the U.S., the 1986 Coordinated Framework for the Regulation of Biotechnology ("Coordinated Framework") focuses on regulating the process of recombinant DNA ("rDNA") plant and animal breeding. At the USDA, however, gene editing of crops, however, falls under a "Am I Regulated" website.[6] USDA has decided not to regulate genetic editing crops unless they carry DNA of a plant pest and since most crops do not carry such DNA sequences, there is no

[6] United State Department of Agriculture, Biotechnology Regulatory Services, Am I Regulated Under 7 CFR part 340? (Jun 30, 2017) https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated. (last visited July 20, 2018)

regulatory hook for USDA to regulate.[7] USDA maintains a list of those crops consulted upon, in its

The biotech crop approval process falls under the jurisdiction of USDA's Biotechnology Regulatory Services ("BRS"), which assesses the environmental impacts of biotech crops. If BRS finds no significant impact after a review of the public comments under NEPA and BRS grants the deregulation petition, the way will be cleared for the developer to commercialize the biotech crop.

The EPA has roles in crops that resist herbicides (to approve herbicide uses and warnings) or pests covered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The FDA, however, issued proposed guidelines to regulate genetically edited animals under its veterinary drug approval process.[8] This same process was used to approve the Aquabounty® AquAdvantage® Salmon, which encountered many delays before approval (and saw an import ban crop up in the US after approval which prevented sale to Americans).[9] There

[7] Isasi1, Keiderman & Knoppers, Editing policy to fit the genome? 22 Science 351 at 337-339 (Jan 2016) Vol. Issue 6271, DOI: 10.1126/science.aad6778

[8] Sarah Zhang, The FDA Wants to Regulate Gene-Editing That Makes Cows Less Horny: What happens when new technology meets old laws, The Atlantic (January 20, 2017) https://www.theatlantic.com/science/archive/2017/01/the-fda-wants-to-regulate-gene-edited-animals-as-drugs/513686/; See Also, U.S. Department of Health and Human Services Food and Drug Administration Center for Veterinary Medicine, Draft Guidance for Industry Regulation of Intentionally Altered Genomic DNA in Animal #187, (January 2017) available at https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf (last visited July 25, 2018)

[9] Brady Dennis, FDA bans imports of genetically engineered salmon — for now, Washington Post (January 29, 2016) online at https://www.washingtonpost.com/news/to-your-health/wp/2016/01/29/fda-bans-imports-of-genetically-engineered-salmon-for-now/?noredirect=on&utm_term=.9f04108d071d (last visited July 31, 2018)

may be some apparent disagreement between USDA and FDA over who should regulate gene-edited animals.[10]

b. International Regulation

The European Union's High Court of Justice in July 2018 decided to regulate crops and other organisms produced through genetic editing as if they were a "GMO" under its long-standing "precautionary approach" to regulatory approval. This means that approval times will take several years, sometime longer, for crops to be approved in the EU after being okayed in by North American nations.

The EU's 'precautionary approach" is the law followed by the 171 nations that are parties to the Cartagena Protocol on Biosafety ("CPB"). These parties will meet again for the ninth time (COP-MOP 9) in November 2018 in Egypt, and they will address how to develop their unified approach to genetic editing, which falls under a "synthetic biology" descriptor in this international multilateral environmental agreement. Since the US, Canada, Australia, Argentina and other grain exporting nations are not signatories to the CPB, they cannot block consensus on any attempt by these parties to follow the lead of the EU, which is in many instances a key trading partner and source of foreign aid (e.g., in parts of Africa, where the EU's influence on GMO policy is notably strong).

Canada regulate all "novel foods " and includes genetic editing in that category. This encompasses those crops created using non-rDNA methods. For example, both herbicide-resistant crops created using older (chemical-radiation) or newer (genetic editing) forms of mutagenesis would be regulated. It is worth noting that those older forms of plant and animal

[10] Marc Heller, Agencies clash over biotech livestock, E&E News, (April 19, 2018) available at http://www.sciencemag.org/news/2018/04/us-agencies-clash-over-who-should-regulate-genetically-engineered-livestock (last visited August 7, 2018)

"mutagenesis" breeding arguably carry greater risks of the "pleiotropic" sort raised by activists, who see risks in off-target effects in genes (the adverse nature of which remain unlinked to health concerns). Since many of these crops have similar ecological effects (e.g., there are mutagenic, r-DNA and genetically edited crops with herbicide resistance, all of which can outcross to wild relatives or cause problematic herbicide-resistant weeds to develop after widespread use), Canada's regime at least has a consistent approach to similar risks.

Europe has recently decided to apply its "precautionary" regulatory test to these newer forms of mutagenesis plant breeding.[11] Sweden, Finland, Belgium and the UK had pre-empted the European Court of Justice ruling by greenlighting field trials of gene-edited plants outside the scope of EU GMO law. "these field trials are now illegal." [12] and many other nations in Asia and Africa are likely to follow its lead. Notwithstanding the lack of any scientific theory to suggest serious health threat from crops and animals created using this technology, activists have nevertheless asserted that "the behavior of synthetic biological systems is inherently uncertain and unpredictable, yet the precautionary principle is not guiding research and development of synthetic organisms. Risk assessment protocols have not yet been developed to assess the potential ecological risks associated with synthetic biology."

The international regulatory treaty that allows nations to follow the EU is the Cartagena Protocol on Biosafety ("Biosafety Protocol"), which regulates the release and use of "living modified organisms," also known as genetically modified organisms ("GMOs"). Gene-edited

[11] Jeff Cronin & Ariana Stone, European Union Issues Crucial Ruling on Regulating Gene-Edited Organisms as GMOs (July 26, 2018) https://cspinet.org/news/european-union-issues-crucial-ruling-regulating-gene-edited-organisms-gmos-20180726 (last visited July 20, 2018)

[12] Press release, New GMOs cannot escape testing and labelling under EU law, EU court rules, Greenpeace (July 25, 2018) http://www.greenpeace.org/eu-unit/en/News/2018/New-GMOs-cannot-escape-testing-labelling-under-EU-law-EU-court-rules/

crops would be considered products of "synthetic biology". The parties to the Biosafety Protocol are calling genetic editing a form of "synthetic biology" and will certainly take up the question of how to regulate genetic editing when they hold their next meeting in 2020, now that the EU (a key party) has decided to regulate genetic editing in agriculture as if it were "GMO" technology. NGOs in opposition to old biotech breeding consider these new plant breeding methods to be "GMOS" like their predecessors, not mere "mutagenesis" (which the organic industry embraces form of chemical or radiation mutagenesis, but shuns more precise genetic editing with its relatively minimal off-target effects to target plant DNA).[13]

As part of the implementation of this law, nations that are parties to the Biosafety Protocol enact legislation, such as the European Traceability Directive, that impose zero-tolerance for the import of any GMO that lacks regulatory approval. More nations are imposing regulatory approval requirements as the Biosafety Protocol is implemented. Any biotech crop that could be exported may also require approval in many of these overseas markets. See Appendix A for a chart compiled from various online regulatory sources, listing approaches being taken in various nations for various types of genetic editing (e.g., Oligo-directed mutagenesis or ODM is the tool used by Cibus San Diego for its genetically edited canola, which is widely marketed in the US and Canada).

For innovators in agricultural biotechnology, these approval requirements for overseas markets can create a barrier to their entry. For example, the new biotech potato that the USDA approved for J.R. Simplot Company, known as the Innate™ potato, may require market approval for export to Japan to avoid causing another costly recall of potato chips in Japan, where regulatory approval and genetically-modified ("GM") food labeling could complicate the

[13] Stratfor, How the EU's Stance on Gene Editing May Evolve, (Jan 29, 2018) https://worldview.stratfor.com/article/how-eus-stance-gene-editing-may-evolve (last visited July 23, 2018)

marketing of any foods containing a biotech potato. Simplot's Innate™ potatoes are "cisgenic," meaning that the genes used to transform are from the same species—wild and commercial potatoes. Simplot applied for approval in China, South Korea, Taiwan, Malaysia, Singapore and Mexico, and plans to apply in the Philippines for its first-generation disease-resistant Innate™ potato.[14]

Other genetic editing companies, like Cibus with its genetically edited canola, are getting Canadian and US approval and waiting to see what the Biosafety Protocol will do next, in terms of precautionary regulation.

At the Annual meeting of the Agricultural & Applied Economics Association, the speakers discussed the economic impacts of the EU's decision to regulate, which may spread to up to 100 export markets for soybeans. The entire cost of seeking compliance for a biotech crop was estimated at a range from $7,060,000 to $15,440,000 [15]and most or all of that cost may now be placed upon genetic editing companies who want to market their crops without undue liability risk.

These overseas regulatory approvals, moratoria and other trade barriers to agricultural biotechnology, including genetic editing in agriculture, have demonstrated their power to cause the common law courts in the United States to wake up, take notice, and impose liability on aspects of marketing crops that are fully approved for sale in the US with no federally-imposed restrictions regarding their potential impact on exports.

[14] John O'Connell, Simplot's Innate GMO bruise-resistant potatoes approved for sale in Japan Capital Press, (September 12, 2017) https://geneticliteracyproject.org/2017/09/12/simplots-innate-gmo-bruise-resistant-potatoes-approved-sale-japan/ (last visited July 23, 2018).

[15] Nicholas Kalaitzandonakes, Julian M Alston & Kent J Bradford, Compliance costs for regulatory approval of new biotech crops, Nature Biotech (2007) available at http://www.plantsciences.ucdavis.edu/bradford/Kalaitzandonakes-Compliance%20costs-NBT-2007.pdf (last visited August 9, 2018).

It is worth noting that the USDA has considered such economic impacts, as the National Environmental Policy Act requires of all federal agencies. It has not, however, managed to have "occupied the field" enough to preempt state tort law awarding growers damages for such economic impacts.

III. Liability Precedents to Syngenta's Case

This section briefly addresses the mass tort cases that lead up to a finding that export-related trade disruption can be grounds for a negligence trial. In all of these preceding cases, the questions arose from releases of crops that lacked (or had revoked) approval in the U.S.

The scope of liability for biotech crops has been determined in three stages over the past 15 years. After Starlink® corn recognized a claim for nuisance and negligence arising from a physical injury and regulatory violation that led to a U.S. recall, Liberty Link® rice trials awarded damages based on that precedent for disruption of major markets overseas (mainly the EU) from a rice crop lacking US approval at time of commingling. Syngenta's China case would impose liability for failing to foresee the emergence of a major market and get approval there before allowing Viptera, pending China approval, to commingle in the US corn market.

a. Starlink Corn

The Starlink corn precedent took the first step towards creating biotech seed company liability for failing to foresee the emergence of a major market and get approval there. The court decisions and settlements arising from the sale of Starlink corn by Aventis Crop Sciences USA's predecessor, AgrEvo USA, established that economic injuries could be recovered after commingling of corn that was deemed a "physical injury" to property, including growers' lost

profits. Since the EPA revoked approval for this crop and declared Starlink corn a potential health risk, it was subject to a nationwide and international recalls, with significant disruption of trade.

Starlink corn set the stage for biotech seed company liability by recognizing claims for nuisance and negligence arising from a company's failure to obtain regulatory approval in overseas markets. Damages paid in settlement were calculated based on the price impacts to commodity corn on the Chicago Board of Trade.

b. Liberty Link Rice

This liability risk was expanded to include economic impact from lack of overseas approval in the LL Rice cases. In December 2011, Bayer AG (the German parent company of Bayer Cropsciences) announced that enough growers had signed its proposed $750 million settlement with U.S. rice farmers to confirm that it will compensate them for loss of export rice markets. The decision in LL601 Rice established that negligence could apply to crops that the US had eventually approved--but the EU and other major markets had not. This finding of "contamination" from economic impacts was reinforced by language used in a 2010 Supreme Court decision, as is discussed in more detail below at Section II.G.

Bayer failed to prove that farmers should have simply avoided the brief dip in rice prices and suffered no harm. Bayer also lost its argument that prompt U.S. planting approval after years of unauthorized release (commingling across six states in the rice seed supply) would allow Bayer to bar claims for nuisance or negligence using a federal preemption defense. This ground-breaking court decision, LL601 Rice, is the first decision in the U.S. to follow Starlink and allow mass tort plaintiffs to recover their "economic loss" from the "physical injury" that occurs

from commingling a biotech crop (or other crop, like treated seed) where the crop's only flaw -- or material fact, for consumer fraud claims -- is that it was not approved for export to major markets overseas. The settlements Bayer is entering into in LL601 Rice exceed $1.2 billion, more than the amount reportedly paid in Starlink corn settlements by Bayer's corporate predecessor Aventis. More recent "bellwether" trials raise risks of liability approaching $1.5 billion in the litigation against Bayer Cropscience USA and its parent, Bayer AG, which deemed to be the legal successor to Aventis (despite the efforts of corporate attorneys to structure the sale of Aventis to Bayer as a sale of assets only, leaving liabilities behind).

Commentators have warned that growers may also be liable for disrupting trade if the law evolves in that direction. This negligence-based liability, however, may not stop only with the large biotechnology firm. Farmers or other operators within the broader agricultural supply chain could face similar claims if they were to be found negligent in any future crop commingling litigation. Therefore, farmers should follow basic precautionary strategies, including reading all the fine print listing various crop planting or marketing restrictions. To date, however, this author has not heard of any biotech crops growers in the US being targeted with claims for disrupting trade.

IV. The Liability Bullseye Expands – US & NCGA Approvals Not Preemptive

As counsel to the American Soybean Association and related entities (United Soybean Board, US Soybean Export Council), I assisted in the creation and maintenance of a "Major Market Approval" policy from 1998 to 2016. This policy was created in close consultation with key grain traders, including Archer Daniels Midland, Bunge North America, Cargill, the International Grain Trade Coalition and others. In confidential gatherings held twice a year

(going by various names, e.g., ASA Biotech Working Group), more recently including the NCGA, the policy on major market approval was applied to establish the markets that seed companies had to get regulatory approval in, before they would market new biotech soybeans or corn to growers.

While this might mean 15-20 markets met the "major" designation for soybean exports, the NCGA only required approval in Japan, while also suggesting that approvals be obtained in other major markets. The grain trade adopted its own policies that went beyond both ASA and NCGA, to require approval in major markets one year before planting.

ASA's major market approval policy was intended to set a common law duty of reasonable care in protecting exports to major markets for U.S. soybeans. NCGA, in contrast, would not impose a duty for maintaining regulatory approval in any other markets than Japan.

Syngenta hoped to use, as evidence of its due care, the USDA approval of Viptera and NCGA's request that it be sold without overseas approval in various corn markets. The court denied a procedural motion argument seeking preemption of tort claims due to USDA approval; such preemption of tort claims is getting rarer in US litigation after the Supreme Court rejected FIFRA preemption in Bates v. Dow, 8) 544 U.S. 431 (2005), 332 F.3d 323, vacated and remanded (2005) making federal preemption unlikely in the Syngenta cases.

V. Factual Background – Syngenta Pays for its Misleading Messages on China Approval

Syngenta commercialized its biotech corn trait, Agrisure Viptera® MIR162 ("Viptera") in the United States starting in 2011. Although Syngenta had obtained regulatory approval for the sale of Viptera in the United States, Argentina, Japan, Canada, and the European Union,

Syngenta's application for importation and cultivation approval from the Chinese Ministry of Agriculture was submitted in March 2010.

Nevertheless, Syngenta told growers that it expected approval from China in March 2012, when it should have known, based on feedback from regulatory agencies in China, that approval would still take a year or two more.[16] Like most nations imposing regulatory approval for biotech crops, China had a zero-tolerance policy on the import of biotech corn traits that had not been approved by the Chinese government. Nevertheless, there is no disputing that China had not made any signals of an intent to buy significant shipments of U.S. corn as of spring 2011 when nationwide planting of Viptera began in the United States.[17]

In late 2011, citing ""market signals" coming from China about its corn needs and anticipated selling corn to China., several major grain trading companies (Bunge and Consolidated Grain & Barge (CGB)) told growers that they would not buy Viptera corn. They cited potential sales of US corn to China.

Despite the concerns of the grain trade and China's increasing need for imported corn, Syngenta continued to market Viptera in the United States in 2012. Syngenta's decision not to wait for Chinese approval had the support of the NCGA and was consistent with industry precedent. For instance, Monsanto launched several new corn traits (MON89034 in the Genuity VT Triple PRO stack and SmartStax with Dow) without waiting for Chinese approvals in 2010, and these traits were grown on more acres than Syngenta's Viptera traits were grown in 2011.

In late 2011, Syngenta sued Bunge in response to the grain trader's decision to reject Viptera by for allegedly attempting to illegally block the sale of the Agrisure Viptera trait. Since

[16] Paul Christensen, Chinese Approval of Syngenta Agrisure Viptera, Seed in Context Blog (February 21, 2012), http://www.intlcorn.com/seedsiteblog/?p=268 (last visited April 28, 2017).
[17] Fisher at 5, supra n. 3. (China imports of US corn dipped below one million metric tons ("1 MMT") from 1.2 MMT in 2009-10 (6th largest) to 980 in 2010-11 (5th largest).

Viptera was sold in compliance with all U.S. regulatory requirements and longstanding industry guidance in the U.S., Syngenta felt it had a legitimate right to sell Viptera corn to willing farmers. After a federal court in Iowa denied Syngenta's request for an injunction and dismissed most of Syngenta's claims, Syngenta dismissed the case in December 2014 following approval of Viptera in China.[18]

Over two years later, China stopped accepting all U.S. corn imports in November 2013 and did not begin importing U.S. corn again until late 2014 after China approved Viptera. Although the adverse economic impact of the 13-month trade disruption is debatable given increase in corn yields over the past few years, in April 2014, a grain trade association issued a report suggesting several billions of dollars in adverse economic impacts had been caused by Syngenta's decision to market corn that lacked approval from China.[19]

VI. Summary of Litigation Against Syngenta

In late 2014 and early 2015, grain traders sued Syngenta seeking compensation for lost export markets (measured in millions of dollars) and growers filed class actions seeking billions of dollars for alleged impacts to corn prices quickly thereafter. The plaintiffs claimed that Syngenta failed to follow industry standards for stewardship to keep Viptera out of the export

[18] Syngenta's decision to ultimately dismiss the case was likely due to the fact that its event was approved in China, and that it would have been hard to prove that a buyer does not have the right to choose not to spend money on crops or other products based on their international regulatory status. Despite the outcome of the case, one should wonder whether Syngenta's decision to sue Bunge made it easier for grain traders to decide to sue Syngenta over trade disruption.

[19] *See* Max Fisher, Lack of Chinese Approval for Import of U.S. Agricultural Products Containing Agrisure Viptera™ MIR 162: A Case Study on Economic Impacts in Marketing Year 2013/14, NAT'L GRAIN & FEED ASS'N (April 16, 2014), http://ngfa.org/wp-content/uploads/Agrisure-Viptera-MIR-162-Case-Study-An-Economic-Impact-Analysis.pdf (last visited July 20, 2018).

distribution channel and falsely told growers that China would approve the trait in 2012.[20] The growers asserted claims based primarily on negligence while the grain traders brought negligence claims and claims under consumer protection statutes. The federal cases ultimately were consolidated in the U.S. District Court for the District of Kansas in Kansas City. Syngenta sought and received a motion to dismiss punitive damages in the Kansas class action before trial.[21]

After dismissing some extraneous claims on summary judgment motions, the MDL court certified the class action. Syngenta's interlocutory appeal of the class certification order was denied.[22] A grower[23] wanting to opt out had to send a letter postmarked by April 1, 2017 to be excluded from the class. The first MDL case against Syngenta went to trial in June 2017,[24] and the jury returned a unanimous verdict for Plaintiffs (i.e., 7,343 Kansas farmers). The jury awarded full damages in the amount of $217,700,000 ($217.7 Million).[25] Syngenta filed post-trial motions to dismiss and appeal the verdict after these motions were denied.[26] Syngenta had

[20] *See, e.g.*, Hadden Farms Inc. v. Syngenta Corp., No. 3:14-cv-03302-SEM-TSH (C.D. Ill. filed Oct. 3, 2014) (class action complaint for damages and injunctive relief), http://www.fien.com/pdfs/IllinoisvSyngenta.pdf ("Syngenta Corn Class Action"). (last visited April 28, 2017).
[21] Todd Neeley, Viptera Trial Ongoing: Ruling Could Limit Punitive Damages, (June 19, 2017) available at https://www.dtnpf.com/agriculture/web/ag/news/article/2017/06/19/ruling-limit-punitive-damages (last visited August 26, 2017).
[22] Tenth Circuit denied Syngenta's Attempt to Appeal the Order on Certification, Syngenta Corn Litigation, (December 8, 2016), available at http://www.syngentacornlitigation.com/2016/12/08/tenth-circuit-denies-syngentas-attempt-appeal-order-granting-class-certification/ (last visited August 26, 2017).
[23] Thomas Capehart, USDA estimates around 440,000 farmers grow corn in the United States. (August 16, 2017) available at https://www.ers.usda.gov/topics/crops/corn/background.aspx (last visited August 26, 2017).
[24] U.S District Judge Certifies Syngenta Corn Case Class Action (Sept. 27, 2016), available at http://www.syngentacornlitigation.com/2016/09/26/u-s-district-judge-certifies-syngenta-corn-case-class-action/; Order and notice at www.syngentacornlitigation.com/wp-content/uploads/2016/12/Syngenta2016_Notice_v5.pdf. (last visited April 28, 2017).
[25] AP newswire, The Latest: Syngenta to Appeal $218M Verdict in Seed Case, U.S. News & World Report (June 23, 2017) available at https://www.usnews.com/news/business/articles/2017-06-23/the-latest-syngenta-to-appeal-218m-verdict-in-seed-case. (last visited August 26, 2017).
[26] Id.

been acquired by China National Chemical Corp ("ChemChina") which recently finalized its $43 billion takeover.

The verdicts and settlements piled up. A jury trial for one Nebraska farmer in April, 2017 settled out for a confidential amount. .[27]

Syngenta has also won a case; a defense verdict for Syngenta was awarded by a state court in Ohio based on the economic loss doctrine defense. As that court explained its verdict, while it found that Syngenta had a duty to prevent "physical harm" to growers, it ruled that the economic loss sought by this class of growers (who did not allege pollen drift) was barred by the "economic loss doctrine" ("ELD"), because "[t]here has been no case from any court in Ohio…to show that Syngenta's duty should extend to economic harm caused by the intended use of its products, and this court declines to invent such a duty."[28] In its post-trial motion to dismiss, Syngenta cites this ELD holding and 'submits that there is a substantial basis for rejecting the conclusion that it was "appropriate for the Court to conclude that a [state] court would apply [the ELD] only . . . when the doctrine's purposes would be served."[29]

Syngenta argued that the very nature of this litigation over the ELD precluded a federal court from reaching decisions on such ELD issues.

> The majority rule holds that an integral part of the ELD is the principle that the doctrine should be applied as bright-line rule without case-by-case inquiries into whether the policies behind the doctrine apply on the facts of a particular case. By predicting that the States at issue here would apply the ELD "only . . . when the doctrine's purposes would be served," Order 24 n. 10, the Order effectively predicts that all twenty-two States would reject the rule of the Restatement, which does not permit "case-by-case inquiry

[27] Margaret Cronin Fisk and Jef Feeley, Syngenta Settles Farmer's Contamination Suit Ahead of Trial, Bloomberg, July 7, 2017, available at https://www.bloomberg.com/news/articles/2017-07-07/syngenta-settles-farmer-s-corn-contamination-suit-before-trial. (last visited August 26, 2017).

[28] Fostoria Ethanol, LLC vs. Syngenta Seeds, Inc., Ohio Court of Common Please, Judgment Awarding Motion to Dismiss, Case No. 15 CV 0323 (June 28, 2017)

[29] In re Syngenta AG MIR162 Corn Litigation, Sygenta's Memorandum in Support of Motion to Certify Order on Motions to Dismiss for Interlocutory Appeal Under U.S. Code, §1292(b),Case 2:14-md-02591-JWL-JPO Document 1082 Filed 10/13/15. (last visited August 26, 2017).

into the policies at issue." Restatement (Third) § 7 cmt. b. At a minimum, such a holding raises substantial grounds for a difference of opinion."[30]

Parallel actions by Cargill, a grain trader, are proceeding to trial state court in Louisiana in September 2018.

Non-class cases are also pending – some growers opted out of the class, perhaps remembering resentment of the "gift card" settlements in the StarLink™ ("StarLink") corn litigation.[31]

Syngenta may choose to wait for various statutes of limitations in key corn belt states to expire to reach a complete settlement of all pending cases. This process could take several years.

III. Can These Syngenta Cases be "Distinguished" and Isolated in Legal Precedential Effect?

Rulings made in this case will define the future boundaries for industry stewardship in all commodity crops, with potential negligence for failing to foresee future disruption of a potentially major export market for corn, soy or other exported agricultural products. For the first time in the history of litigation over biotech crops, a claim for negligence has succeeded against conduct in marketing a crop that had full approval for marketing in the United States disrupted an overseas market causing compensable damages in the form of economic impact. Given the history of similar litigation involving StarLink corn and LibertyLink® ("LL") rice, the pending Syngenta litigation may expand the boundary of common law negligence. While the NCGA did not consider China to be a "major market" that would have required approval before an unrestricted U.S. launch, this Kansas court found that Syngenta had a duty to seek major

[30] Id.
[31] AP Newswire, Modified-Corn Lawsuit Is Settled, N. Y. Times (March 8, 2002) http://www.nytimes.com/2002/03/08/business/modified-corn-lawsuit-is-settled.html (last visited August 26, 2017).

market approval (e.g., China, a major market as defined by the grain trade and this court). While courts have traditionally adapted common law claims to address novel challenges and economic harms occurring in society, this case could cause a seismic shift in biotech crop innovation, shutting down some product lines and limiting others to carefully contained production that does not disrupt trade.

As a result, attorneys will be trying to determine where the line of negligence toward export risks will be drawn in future cases. Given the role of underlying factual scenarios in giving rise to precedent, attorney wondering how to advise genetic editing clients of future liability risk should seek to distinguish their clients behavior from Syngenta's behavior, as recorded in the legal opinions arising from this case.

The conduct of Syngenta involved both erroneous predictions about dates of probable approval and the subsequent failure to get approval.[32] A future biotech seed company that does not overpromise and underdeliver may have better facts than the Syngenta case, and find safe harbor in a duty that has been approved widely in the industry by growers, grain trades and other major stakeholders.

While Syngenta followed the NCGA's guidance in selling Viptera, it also sued a grain trader that dared to post signs at elevators informing growers it would not purchase corn containing any trace of Viptera (Bunge North America cited "market signals" from Chinese buyers and the lack of Chinese approval for its decision to bar Viptera sales to it.)

[32] See, e.g., Syngenta Corn Lawsuit: MIR162 Corn (2018) ("Syngenta misinformed farmers, exporters, and the general public about the potential approval of MIR162 in China. These lawsuits further allege that Syngenta led farmers to believe that approval in China was imminent and that China's failure to approve MIR162 would not impact corn farmers.") https://stromlaw.com/syngenta-corn-lawsuit/ (last visited July 30, 2018)

By following a more widely recognized duty, the company selling something not approved in some overseas markets cannot be held liable for negligence. This will allow the Syngenta cases to be distinguished on their facts, and thereby limit their legal precedential effect.

Plaintiffs' core claim of negligence[33] has survived all motions and could provide the best route to recovery. To prevail on their negligence claim against Syngenta, the plaintiffs will have to prove that Syngenta had a legal duty to avoid disrupting exports to China and that its failure to exercise due care caused plaintiffs to incur actual damages.

In response, Syngenta will argue that it owed no duty to growers or grain traders to wait for approval from China and that segregation for export interests is the growers' challenge, depending on the buyers' needs. In support of its position, Syngenta will likely cite to the National Corn Growers Association's ("NCGA") policy which did not require such approvals before launching Viptera.[34] Syngenta may also seek to rely upon the Biotechnology Industry Association's ("BIO") published standards for stewardship, which discuss the need to seek approval in "major" markets with "functioning" regulatory systems.[35] However, it may be an open question whether the 2011 China export corn market was so minimal that it was not "major" and hence the applicable standard of care would only require approval from Japan.

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[33] *See* Non-Producer Plaintiffs' Third Amended Master Complaint at 93-108, *In re* Syngenta Corn Litig., No. 2:14-md-02591-JWL-JPO (D. Kan. Sept. 19, 2016). Available at http://www.ksd.uscourts.gov/non-producer-plaintiffs-third-amended-master-complaint-doc-2530/.(last visited April 28, 2017).

[34] *See*, NCGA, *Know Before You Grow*, (2015), http://www.ncga.com/for-farmers/know-before-you-grow (last visited May 16, 2015); Biotechnology Industry Organization, EXCELLENCE THROUGH STEWARDSHIP, http://excellencethroughstewardship.org/ (last visited April 28, 2017).

[35] Biotechnology Innovation Organization, Excellence Through Stewardship (2015), http://www.excellencethroughstewardship.org/ (last visited April 28, 2017). (last visited July 30, 2018)

While Syngenta stopped being a member of BIO, it has been a member of BIO's Excellence Through Stewardship (ETS) program since 2008.[36] ETS is a program that BIO members sign up for, which requires companies to engage in stewardship for exports, including analyses of market acceptance. Syngenta allegedly failed to implement stewardship to protect exports to China by segregating Viptera to domestic uses.

As Plaintiffs' counsel attests, it Syngenta recognized the harm threatened by irresponsible commercialization, quoting it as saying: "There have been a number of high-profile cases involving genetically modified varieties . . . and disruption of international shipments of commodity grains such as corn, wheat, and rice."[37]

To defeat negligence claims, Syngenta will also argue that the benefits of getting corn traits into production outweighed the alleged adverse economic impacts. Its experts may claim that lower corn prices in the U.S. were due to high U.S. corn production and were not caused by Chinese rejection of U.S. corn.

B. Voluntary Undertaking

As an alternative basis for a duty, plaintiffs alleged that Syngenta owed a duty to them under the voluntary undertaking doctrine. Many states recognize that a duty can arise when a defendant offers to take action to prevent some harm, but negligently fails to fulfill its "voluntary undertaking" (like a "Good Samaritan"). *See McGee v. Chalfant*, 248 Kan. 434 (1991). If Syngenta offered to render stewardship services but failed to exercise due care in the

[36] Syngenta Corn Allegation, Factual Allegations, http://www.syngentacorncase.com/about-the-case/case-updates-documents/class-action/factual-allegations/ (last visited August 9, 2018)
[37] Id. Citing http://www.syngentafoundation.org/index.cfm?pageID=703.

performance of its stewardship program, it could be liable for the harm caused to the growers and grain traders.

Syngenta has cited its relationship with its seed buyers to reject this duty, stating: "[F]armers don't have any exposure whatsoever to Chinese corn rejection. . .. they sell their corn to the elevator" who sells into a grain trader. Willing growers must decide which buyer gets their corn."[38] Growers who bought Viptera are excluded from the class, and while they may be the ones whose corn commingled, they have not been sued for causing trade disruption.

Syngenta alleges that growers who know of buyers' export-related expectations arguably have a duty to protect their own economic interests. A grower can call Syngenta or check NCGA's "Know Before You Grow" webpage or the International Service for the Acquisition of Agri-biotech Applications ("ISAAA") database for export approval information.

Syngenta's failed efforts to contain its corn could give rise to liability under this "voluntary undertaking" basis for imposing a duty of care. In *McGee v. Chalfant*, the Kansas Supreme Court held that, even in the absence of a special relationship, "the actor may still be liable to third persons when he negligently performs an undertaking to render services to another which he should recognize as necessary for the protection of third persons," as set forth in Section 324A of the Restatement of Torts. *See McGee*, 248 Kan. at 438. Plaintiffs argue that Syngenta voluntarily undertook compliance with the BIO Policy concerning the commercialization of new GM products but failed to protect the China export market.

[38] SYNGENTA, FIRST QUARTER 2014 SALES TRANSCRIPT 28 (2014), available at https://www.syngenta.com/global/corporate/SiteCollectionDocuments/pdf/transcripts/q1-2014-transcript-syngenta.pdf (quoting Michael Mack, Syngenta CEO). (last visited April 28, 2017)

In rejecting this argument, the Court in the Syngenta Corn Class Action agreed with Syngenta, finding that Section 324A cannot apply here. Plaintiffs have not sought to recover for "physical" harm and the Restatement section provides for liability "for physical harm resulting from [the actor's] failure to exercise reasonable care to protect his undertaking," *see* Restatement (Second) of Torts § 324A. Since the Kansas Supreme Court has specifically held that Section 324A "has application only in cases involving physical harm," *Barber v. Williams*, 244 Kan. 318, 324 (1989), and the court found no "physical harm" from the decline in prices (as opposed to actual commingling with particular corn), the Court granted Syngenta's motion for summary judgment with respect to any claim of negligence in which liability is based on any alleged misrepresentation, a voluntary undertaking, a failure to warn, or a duty to recall.[39]

D. Damages

Lastly, Syngenta's experts surely claimed, to no avail, that the lower corn prices were not impacted by loss of the Chinese market for around a year during a time of high U.S. corn production. Syngenta could also say that it had permission to market Viptera, and cite NCGA's policy of only requiring approval from Japan and other markets with functioning regulatory systems and BIO's policy of only requiring approval from Japan and Canada.[40]

As was noted above, on June 23, 2017, the jury rendered a verdict against Syngenta for $217.77 million finding negligence in failing to prevent disruption of the export market for US corn to China.

[39] In Re Syngenta AG MIR 162 Corn Litigation, MDL No. 2591 Case No. 14-md-2591-JWL (Apr. 5, 2017), https://ecf.ksd.uscourts.gov/cgi-bin/show_public_doc?2014md2591-3051 (last visited April 28, 2017).
[40] Todd Neeley, Syngenta Trial Set: Viptera Class-Action Case in June, (Feb. 2, 2017), available at ,https://www.dtnpf.com/agriculture/web/ag/news/article/2017/02/02/viptera-class-action-case-summer. (last visited Apr. 28, 2017).

E. Settlement of Grower Class Actions

In September 2017, Syngenta reached a settlement in pending grower class action cases, ending pending trials in those cases. The terms are not fully disclosed and require court approval, but the amount is reported at up to $1.5 billion. Other pending cases outside the Multi-District Litigation do not appear to be included –for example, pending cases filed by grain traders Cargill and ADM are reportedly outside the scope of this settlement. The settlement awards in this litigation could define the boundaries of tort law in agricultural biotechnology for years to come.

III. Impact on the Biotech Innovation Pipeline

The proliferation of small start-up companies in genetic editing appears to have parallels with the long-standing innovation pipeline for biotech-derived pharmaceuticals. Small companies that lack the massive regulatory staffs and capacity for submitting data of a big biotech seed company (after consolidating, we have Bayer merging with Monsanto to emerge as Bayer, Dow absorbing Dupont to become Corteva®, and ChemChina taking over Syngenta. These "big 3" companies all have access to top-rated germplasm in agriculture, as well as regulatory expertise to offer smaller innovators in genetic editing.

As a result, the EU regulatory move will likely serve as a catalyst for moving products of little genetic editing companies into the hands of big biotech seed companies. This would parallel the biotech pharmaceutical industry, where smaller start-up innovators partnered with larger companies to ensure that the high cost of FDA and any overseas national approvals were paid for by the company with more cash on hand.

IV. Conclusion

The court decisions in these Syngenta cases many send the message that any grower or grain trader seeking a specialized market (e.g., the benefits of export markets) should maintain their own identity preserved production to avoid liability. Any failure to implement such self-imposed measures may lead to economic loss, unless a court decide for the seed company (as the court in Ohio did) and finds this loss cannot be recovered in tort against the seller of a U.S.-approved biotech crop that lacked approval in certain export markets. The decisions in cases to come from various U.S. courts will define the boundaries of tort law in agricultural biotechnology for years to come.

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APPENDIX A

Global Genetic Editing Regulatory Approaches

Country	Status	Case-by-Case	Comments
South America			
Argentina	Final	yes	Consultation required, depends on whether there is any new combination of DNA (transgene)
Chile	Final	yes	Consultation required, depends on whether there is any new combination of DNA (transgene)
Brazil	Final	yes	Consultation required, depends on whether there is any new combination of DNA (transgene)
Colombia	Proposed	yes	Consultation required, depends on whether there is any foreign genetic material
North America			
Canada	product based	yes	Canada does not have "GMO" laws - Uses existing regulatory framework based on novelty as trigger for pre-market assessment - no method itself is regulated; 'Novel' products of biotechnology have traits that are new, absent or outside the range for the organism.
US	In progress	yes (am I regulated?)	The U.S. does not have "GMO" laws but a coordinated framework; USDA has made a number of "Am I Regulated?" decisions.
Other			
Australia	Proposed		Not final. Based on proposed changes to legislation (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/amendment+proposals-1). Categorization may change in final amendments to legislation. The proposals are intended to provide an interim solution whist broader policy considerations associated with new technologies are being progressed through a policy review (http://health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review).

New Zealand	Uncertain		Currently taking a wait and see approach; previous High Court decision ruled that as currently written, gene editing techniques were not excluded from "new organisms provisions."
FSANZ	Code under review		Food Safety agency for Australia and NZ
Israel	Final	yes	
Europe			
EU	Final	yes, *(EJC) decision SDN, & ODM= "GMOs"*	*Opinion of Advocate General for EJC (1-18-2018); said genetic editing introduces foreign DNA (transgene)*
Spain		Yes	*Dutch proposal before EJC; no other genetic material is introduced into the resulting plant than genetic material from the same plant species or from a plant species with which it can exchange genetic material through traditional breeding methods or rDNA used no longer present.*
Netherlands		Yes	*High Council for Biotechnology Opinion. Depends on whether there is any new combination of DNA (transgene).*
France		Yes	*Federal Office of Consumer Protection and Food Safety (BVL) opinion citing a Central Commission for biological safety (ZKBS) evaluation, since it is a targeted mutation rather than an insertion of foreign DNA.*
Germany		Yes	*Agriculture Committee of Chamber of Deputies opinion*
Italy		yes	*Swedish Board of Agriculture; depends on whether there is any new combination of DNA (transgene)*
Sweden		yes	
Norway	*Proposed*		*Norwegian Biotechnology Advisory Board proposed 3-tiered system: notification, expedited, standard assessment Opinion of Advocate General for EJC (1-18-2018); Depends on whether they introduce foreign DNA (transgene)*

Class Action Ethics Materials

The following excerpts are from the American Bar Association's Model Rules of Professional Conduct.

Rule 5.5 Unauthorized Practice Of Law; Multijurisdictional Practice Of Law

(a) A lawyer shall not practice law in a jurisdiction in violation of the regulation of the legal profession in that jurisdiction, or assist another in doing so.

(b) A lawyer who is not admitted to practice in this jurisdiction shall not:

> (1) except as authorized by these Rules or other law, establish an office or other systematic and continuous presence in this jurisdiction for the practice of law; or
>
> (2) hold out to the public or otherwise represent that the lawyer is admitted to practice law in this jurisdiction.

(c) A lawyer admitted in another United States jurisdiction, and not disbarred or suspended from practice in any jurisdiction, may provide legal services on a temporary basis in this jurisdiction that:

> (1) are undertaken in association with a lawyer who is admitted to practice in this jurisdiction and who actively participates in the matter;
>
> (2) are in or reasonably related to a pending or potential proceeding before a tribunal in this or another jurisdiction, if the lawyer, or a person the lawyer is assisting, is authorized by law or order to appear in such proceeding or reasonably expects to be so authorized;
>
> (3) are in or reasonably related to a pending or potential arbitration, mediation, or other alternative resolution proceeding in this or another jurisdiction, if the services arise out of or are reasonably related to the lawyer's practice in a jurisdiction in which the lawyer is admitted to practice and are not services for which the forum requires pro hac vice admission; or
>
> (4) are not within paragraphs (c) (2) or (c)(3) and arise out of or are reasonably related to the lawyer's practice in a jurisdiction in which the lawyer is admitted to practice.

(d) A lawyer admitted in another United States jurisdiction or in a foreign jurisdiction, and not disbarred or suspended from practice in any jurisdiction or the equivalent thereof, or a person otherwise lawfully practicing as an in-house counsel under the laws of a foreign jurisdiction, may provide legal services through an office or other systematic and continuous presence in this jurisdiction that:

> (1) are provided to the lawyer's employer or its organizational affiliates, are not services for which the forum requires pro hac vice admission; and when performed by a foreign lawyer and requires advice on the law of this or another U.S. jurisdiction or of the United States, such advice shall be based upon the advice of a lawyer who is duly licensed and authorized by the jurisdiction to provide such advice; or

(2) are services that the lawyer is authorized by federal or other law or rule to provide in this jurisdiction.

(e) For purposes of paragraph (d):

(1) the foreign lawyer must be a member in good standing of a recognized legal profession in a foreign jurisdiction, the members of which are admitted to practice as lawyers or counselors at law or the equivalent, and subject to effective regulation and discipline by a duly constituted professional body or a public authority; or,

(2) the person otherwise lawfully practicing as an in-house counsel under the laws of a foreign jurisdiction must be authorized to practice under this rule by, in the exercise of its discretion, [the highest court of this jurisdiction].

Rule 5.5 Unauthorized Practice Of Law; Multijurisdictional Practice Of Law - Comment

[1] A lawyer may practice law only in a jurisdiction in which the lawyer is authorized to practice. A lawyer may be admitted to practice law in a jurisdiction on a regular basis or may be authorized by court rule or order or by law to practice for a limited purpose or on a restricted basis. Paragraph (a) applies to unauthorized practice of law by a lawyer, whether through the lawyer's direct action or by the lawyer assisting another person. For example, a lawyer may not assist a person in practicing law in violation of the rules governing professional conduct in that person's jurisdiction.

[2] The definition of the practice of law is established by law and varies from one jurisdiction to another. Whatever the definition, limiting the practice of law to members of the bar protects the public against rendition of legal services by unqualified persons. This Rule does not prohibit a lawyer from employing the services of paraprofessionals and delegating functions to them, so long as the lawyer supervises the delegated work and retains responsibility for their work. See Rule 5.3.

[3] A lawyer may provide professional advice and instruction to nonlawyers whose employment requires knowledge of the law; for example, claims adjusters, employees of financial or commercial institutions, social workers, accountants and persons employed in government agencies. Lawyers also may assist independent nonlawyers, such as paraprofessionals, who are authorized by the law of a jurisdiction to provide particular law-related services. In addition, a lawyer may counsel nonlawyers who wish to proceed pro se.

[4] Other than as authorized by law or this Rule, a lawyer who is not admitted to practice generally in this jurisdiction violates paragraph (b)(1) if the lawyer establishes an office or other systematic and continuous presence in this jurisdiction for the practice of law. Presence may be systematic and continuous even if the lawyer is not physically present here. Such a lawyer must not hold out to the public or otherwise represent that the lawyer is admitted to practice law in this jurisdiction. See also Rules 7.1(a) and 7.5(b).

[5] There are occasions in which a lawyer admitted to practice in another United States jurisdiction, and not disbarred or suspended from practice in any jurisdiction, may provide legal services on a temporary

basis in this jurisdiction under circumstances that do not create an unreasonable risk to the interests of their clients, the public or the courts. Paragraph (c) identifies four such circumstances. The fact that conduct is not so identified does not imply that the conduct is or is not authorized. With the exception of paragraphs (d)(1) and (d)(2), this Rule does not authorize a U.S. or foreign lawyer to establish an office or other systematic and continuous presence in this jurisdiction without being admitted to practice generally here.

[6] There is no single test to determine whether a lawyer's services are provided on a "temporary basis" in this jurisdiction, and may therefore be permissible under paragraph (c). Services may be "temporary" even though the lawyer provides services in this jurisdiction on a recurring basis, or for an extended period of time, as when the lawyer is representing a client in a single lengthy negotiation or litigation.

[7] Paragraphs (c) and (d) apply to lawyers who are admitted to practice law in any United States jurisdiction, which includes the District of Columbia and any state, territory or commonwealth of the United States. Paragraph (d) also applies to lawyers admitted in a foreign jurisdiction. The word "admitted" in paragraphs (c), (d) and (e) contemplates that the lawyer is authorized to practice in the jurisdiction in which the lawyer is admitted and excludes a lawyer who while technically admitted is not authorized to practice, because, for example, the lawyer is on inactive status.

[8] Paragraph (c)(1) recognizes that the interests of clients and the public are protected if a lawyer admitted only in another jurisdiction associates with a lawyer licensed to practice in this jurisdiction. For this paragraph to apply, however, the lawyer admitted to practice in this jurisdiction must actively participate in and share responsibility for the representation of the client.

[9] Lawyers not admitted to practice generally in a jurisdiction may be authorized by law or order of a tribunal or an administrative agency to appear before the tribunal or agency. This authority may be granted pursuant to formal rules governing admission pro hac vice or pursuant to informal practice of the tribunal or agency. Under paragraph (c)(2), a lawyer does not violate this Rule when the lawyer appears before a tribunal or agency pursuant to such authority. To the extent that a court rule or other law of this jurisdiction requires a lawyer who is not admitted to practice in this jurisdiction to obtain admission pro hac vice before appearing before a tribunal or administrative agency, this Rule requires the lawyer to obtain that authority.

[10] Paragraph (c)(2) also provides that a lawyer rendering services in this jurisdiction on a temporary basis does not violate this Rule when the lawyer engages in conduct in anticipation of a proceeding or hearing in a jurisdiction in which the lawyer is authorized to practice law or in which the lawyer reasonably expects to be admitted pro hac vice. Examples of such conduct include meetings with the client, interviews of potential witnesses, and the review of documents. Similarly, a lawyer admitted only in another jurisdiction may engage in conduct temporarily in this jurisdiction in connection with pending litigation in another jurisdiction in which the lawyer is or reasonably expects to be authorized to appear, including taking depositions in this jurisdiction.

[11] When a lawyer has been or reasonably expects to be admitted to appear before a court or administrative agency, paragraph (c)(2) also permits conduct by lawyers who are associated with that lawyer in the matter, but who do not expect to appear before the court or administrative agency. For example, subordinate lawyers may conduct research, review documents, and attend meetings with witnesses in support of the lawyer responsible for the litigation.

[12] Paragraph (c)(3) permits a lawyer admitted to practice law in another jurisdiction to perform services on a temporary basis in this jurisdiction if those services are in or reasonably related to a pending or potential arbitration, mediation, or other alternative dispute resolution proceeding in this or another jurisdiction, if the services arise out of or are reasonably related to the lawyer's practice in a jurisdiction in which the lawyer is admitted to practice. The lawyer, however, must obtain admission pro hac vice in the case of a court-annexed arbitration or mediation or otherwise if court rules or law so require.

[13] Paragraph (c)(4) permits a lawyer admitted in another jurisdiction to provide certain legal services on a temporary basis in this jurisdiction that arise out of or are reasonably related to the lawyer's practice in a jurisdiction in which the lawyer is admitted but are not within paragraphs (c)(2) or (c)(3). These services include both legal services and services that nonlawyers may perform but that are considered the practice of law when performed by lawyers.

[14] Paragraphs (c)(3) and (c)(4) require that the services arise out of or be reasonably related to the lawyer's practice in a jurisdiction in which the lawyer is admitted. A variety of factors evidence such a relationship. The lawyer's client may have been previously represented by the lawyer, or may be resident in or have substantial contacts with the jurisdiction in which the lawyer is admitted. The matter, although involving other jurisdictions, may have a significant connection with that jurisdiction. In other cases, significant aspects of the lawyer's work might be conducted in that jurisdiction or a significant aspect of the matter may involve the law of that jurisdiction. The necessary relationship might arise when the client's activities or the legal issues involve multiple jurisdictions, such as when the officers of a multinational corporation survey potential business sites and seek the services of their lawyer in assessing the relative merits of each. In addition, the services may draw on the lawyer's recognized expertise developed through the regular practice of law on behalf of clients in matters involving a particular body of federal, nationally-uniform, foreign, or international law. Lawyers desiring to provide pro bono legal services on a temporary basis in a jurisdiction that has been affected by a major disaster, but in which they are not otherwise authorized to practice law, as well as lawyers from the affected jurisdiction who seek to practice law temporarily in another jurisdiction, but in which they are not otherwise authorized to practice law, should consult the [Model Court Rule on Provision of Legal Services Following Determination of Major Disaster].

[15] Paragraph (d) identifies two circumstances in which a lawyer who is admitted to practice in another United States or a foreign jurisdiction, and is not disbarred or suspended from practice in any jurisdiction, or the equivalent thereof, may establish an office or other systematic and continuous presence in this jurisdiction for the practice of law. Pursuant to paragraph (c) of this Rule, a lawyer admitted in any U.S. jurisdiction may also provide legal services in this jurisdiction on a temporary basis. See also Model Rule on Temporary Practice by Foreign Lawyers. Except as provided in paragraphs (d)(1) and (d)(2), a lawyer who is admitted to practice law in another United States or foreign jurisdiction and who establishes an office or other systematic or continuous presence in this jurisdiction must become admitted to practice law generally in this jurisdiction.

[16] Paragraph (d)(1) applies to a U.S. or foreign lawyer who is employed by a client to provide legal services to the client or its organizational affiliates, i.e., entities that control, are controlled by, or are under common control with the employer. This paragraph does not authorize the provision of personal legal services to the employer's officers or employees. The paragraph applies to in-house corporate

lawyers, government lawyers and others who are employed to render legal services to the employer. The lawyer's ability to represent the employer outside the jurisdiction in which the lawyer is licensed generally serves the interests of the employer and does not create an unreasonable risk to the client and others because the employer is well situated to assess the lawyer's qualifications and the quality of the lawyer's work. To further decrease any risk to the client, when advising on the domestic law of a United States jurisdiction or on the law of the United States, the foreign lawyer authorized to practice under paragraph (d)(1) of this Rule needs to base that advice on the advice of a lawyer licensed and authorized by the jurisdiction to provide it.

[17] If an employed lawyer establishes an office or other systematic presence in this jurisdiction for the purpose of rendering legal services to the employer, the lawyer may be subject to registration or other requirements, including assessments for client protection funds and mandatory continuing legal education. See Model Rule for Registration of In-House Counsel.

[18] Paragraph (d)(2) recognizes that a U.S. or foreign lawyer may provide legal services in a jurisdiction in which the lawyer is not licensed when authorized to do so by federal or other law, which includes statute, court rule, executive regulation or judicial precedent. See, e.g., Model Rule on Practice Pending Admission.

[19] A lawyer who practices law in this jurisdiction pursuant to paragraphs (c) or (d) or otherwise is subject to the disciplinary authority of this jurisdiction. See Rule 8.5(a).

[20] In some circumstances, a lawyer who practices law in this jurisdiction pursuant to paragraphs (c) or (d) may have to inform the client that the lawyer is not licensed to practice law in this jurisdiction. For example, that may be required when the representation occurs primarily in this jurisdiction and requires knowledge of the law of this jurisdiction. See Rule 1.4(b).

[21] Paragraphs (c) and (d) do not authorize communications advertising legal services in this jurisdiction by lawyers who are admitted to practice in other jurisdictions. Whether and how lawyers may communicate the availability of their services in this jurisdiction is governed by Rules 7.1 to 7.5.

Rule 7.3 Solicitation of Clients

(a) A lawyer shall not by in-person, live telephone or real-time electronic contact solicit professional employment when a significant motive for the lawyer's doing so is the lawyer's pecuniary gain, unless the person contacted:

(1) is a lawyer; or

(2) has a family, close personal, or prior professional relationship with the lawyer.

(b) A lawyer shall not solicit professional employment by written, recorded or electronic communication or by in-person, telephone or real-time electronic contact even when not otherwise prohibited by paragraph (a), if:

(1) the target of the solicitation has made known to the lawyer a desire not to be solicited by the lawyer; or

(2) the solicitation involves coercion, duress or harassment.

(c) Every written, recorded or electronic communication from a lawyer soliciting professional employment from anyone known to be in need of legal services in a particular matter shall include the words "Advertising Material" on the outside envelope, if any, and at the beginning and ending of any recorded or electronic communication, unless the recipient of the communication is a person specified in paragraphs (a)(1) or (a)(2).

(d) Notwithstanding the prohibitions in paragraph (a), a lawyer may participate with a prepaid or group legal service plan operated by an organization not owned or directed by the lawyer that uses in-person or telephone contact to solicit memberships or subscriptions for the plan from persons who are not known to need legal services in a particular matter covered by the plan.

Rule 7.3 Solicitation of Clients - Comment

[1] A solicitation is a targeted communication initiated by the lawyer that is directed to a specific person and that offers to provide, or can reasonably be understood as offering to provide, legal services. In contrast, a lawyer's communication typically does not constitute a solicitation if it is directed to the general public, such as through a billboard, an Internet banner advertisement, a website or a television commercial, or if it is in response to a request for information or is automatically generated in response to Internet searches.

[2] There is a potential for abuse when a solicitation involves direct in-person, live telephone or real-time electronic contact by a lawyer with someone known to need legal services. These forms of contact subject a person to the private importuning of the trained advocate in a direct interpersonal encounter. The person, who may already feel overwhelmed by the circumstances giving rise to the need for legal services, may find it difficult fully to evaluate all available alternatives with reasoned judgment and appropriate self-interest in the face of the lawyer's presence and insistence upon being retained immediately. The situation is fraught with the possibility of undue influence, intimidation, and over-reaching.

[3] This potential for abuse inherent in direct in-person, live telephone or real-time electronic solicitation justifies its prohibition, particularly since lawyers have alternative means of conveying necessary information to those who may be in need of legal services. In particular, communications can be mailed or transmitted by email or other electronic means that do not involve real-time contact and do not violate other laws governing solicitations. These forms of communications and solicitations make it possible for the public to be informed about the need for legal services, and about the qualifications of available lawyers and law firms, without subjecting the public to direct in-person, telephone or real-time electronic persuasion that may overwhelm a person's judgment.

[4] The use of general advertising and written, recorded or electronic communications to transmit information from lawyer to the public, rather than direct in-person, live telephone or real-time electronic contact, will help to assure that the information flows cleanly as well as freely. The contents of advertisements and communications permitted under Rule 7.2 can be permanently recorded so that they cannot be disputed and may be shared with others who know the lawyer. This potential for informal review is itself likely to help guard against statements and claims that might constitute false

and misleading communications, in violation of Rule 7.1. The contents of direct in-person, live telephone or real-time electronic contact can be disputed and may not be subject to third-party scrutiny. Consequently, they are much more likely to approach (and occasionally cross) the dividing line between accurate representations and those that are false and misleading.

[5] There is far less likelihood that a lawyer would engage in abusive practices against a former client, or a person with whom the lawyer has a close personal or family relationship, or in situations in which the lawyer is motivated by considerations other than the lawyer's pecuniary gain. Nor is there a serious potential for abuse when the person contacted is a lawyer. Consequently, the general prohibition in Rule 7.3(a) and the requirements of Rule 7.3(c) are not applicable in those situations. Also, paragraph (a) is not intended to prohibit a lawyer from participating in constitutionally protected activities of public or charitable legal- service organizations or bona fide political, social, civic, fraternal, employee or trade organizations whose purposes include providing or recommending legal services to their members or beneficiaries.

[6] But even permitted forms of solicitation can be abused. Thus, any solicitation which contains information which is false or misleading within the meaning of Rule 7.1, which involves coercion, duress or harassment within the meaning of Rule 7.3(b)(2), or which involves contact with someone who has made known to the lawyer a desire not to be solicited by the lawyer within the meaning of Rule 7.3(b)(1) is prohibited. Moreover, if after sending a letter or other communication as permitted by Rule 7.2 the lawyer receives no response, any further effort to communicate with the recipient of the communication may violate the provisions of Rule 7.3(b).

[7] This Rule is not intended to prohibit a lawyer from contacting representatives of organizations or groups that may be interested in establishing a group or prepaid legal plan for their members, insureds, beneficiaries or other third parties for the purpose of informing such entities of the availability of and details concerning the plan or arrangement which the lawyer or lawyer's firm is willing to offer. This form of communication is not directed to people who are seeking legal services for themselves. Rather, it is usually addressed to an individual acting in a fiduciary capacity seeking a supplier of legal services for others who may, if they choose, become prospective clients of the lawyer. Under these circumstances, the activity which the lawyer undertakes in communicating with such representatives and the type of information transmitted to the individual are functionally similar to and serve the same purpose as advertising permitted under Rule 7.2.

[8] The requirement in Rule 7.3(c) that certain communications be marked "Advertising Material" does not apply to communications sent in response to requests of potential clients or their spokespersons or sponsors. General announcements by lawyers, including changes in personnel or office location, do not constitute communications soliciting professional employment from a client known to be in need of legal services within the meaning of this Rule.

[9] Paragraph (d) of this Rule permits a lawyer to participate with an organization which uses personal contact to solicit members for its group or prepaid legal service plan, provided that the personal contact is not undertaken by any lawyer who would be a provider of legal services through the plan. The organization must not be owned by or directed (whether as manager or otherwise) by any lawyer or law firm that participates in the plan. For example, paragraph (d) would not permit a lawyer to create an organization controlled directly or indirectly by the lawyer and use the organization for the in-person or telephone solicitation of legal employment of the lawyer through memberships in the plan or otherwise.

The communication permitted by these organizations also must not be directed to a person known to need legal services in a particular matter, but is to be designed to inform potential plan members generally of another means of affordable legal services. Lawyers who participate in a legal service plan must reasonably assure that the plan sponsors are in compliance with Rules 7.1, 7.2 and 7.3(b). See 8.4(a).

Rule 4.2 Communication With Person Represented By Counsel

In representing a client, a lawyer shall not communicate about the subject of the representation with a person the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the consent of the other lawyer or is authorized to do so by law or a court order.

Rule 4.2 Communication With Person Represented By Counsel - Comment

[1] This Rule contributes to the proper functioning of the legal system by protecting a person who has chosen to be represented by a lawyer in a matter against possible overreaching by other lawyers who are participating in the matter, interference by those lawyers with the client-lawyer relationship and the uncounselled disclosure of information relating to the representation.

[2] This Rule applies to communications with any person who is represented by counsel concerning the matter to which the communication relates.

[3] The Rule applies even though the represented person initiates or consents to the communication. A lawyer must immediately terminate communication with a person if, after commencing communication, the lawyer learns that the person is one with whom communication is not permitted by this Rule.

[4] This Rule does not prohibit communication with a represented person, or an employee or agent of such a person, concerning matters outside the representation. For example, the existence of a controversy between a government agency and a private party, or between two organizations, does not prohibit a lawyer for either from communicating with nonlawyer representatives of the other regarding a separate matter. Nor does this Rule preclude communication with a represented person who is seeking advice from a lawyer who is not otherwise representing a client in the matter. A lawyer may not make a communication prohibited by this Rule through the acts of another. See Rule 8.4(a). Parties to a matter may communicate directly with each other, and a lawyer is not prohibited from advising a client concerning a communication that the client is legally entitled to make. Also, a lawyer having independent justification or legal authorization for communicating with a represented person is permitted to do so.

[5] Communications authorized by law may include communications by a lawyer on behalf of a client who is exercising a constitutional or other legal right to communicate with the government. Communications authorized by law may also include investigative activities of lawyers representing governmental entities, directly or through investigative agents, prior to the commencement of criminal or civil enforcement proceedings. When communicating with the accused in a criminal matter, a government lawyer must comply with this Rule in addition to honoring the constitutional rights of the

accused. The fact that a communication does not violate a state or federal constitutional right is insufficient to establish that the communication is permissible under this Rule.

[6] A lawyer who is uncertain whether a communication with a represented person is permissible may seek a court order. A lawyer may also seek a court order in exceptional circumstances to authorize a communication that would otherwise be prohibited by this Rule, for example, where communication with a person represented by counsel is necessary to avoid reasonably certain injury.

[7] In the case of a represented organization, this Rule prohibits communications with a constituent of the organization who supervises, directs or regularly consults with the organization's lawyer concerning the matter or has authority to obligate the organization with respect to the matter or whose act or omission in connection with the matter may be imputed to the organization for purposes of civil or criminal liability. Consent of the organization's lawyer is not required for communication with a former constituent. If a constituent of the organization is represented in the matter by his or her own counsel, the consent by that counsel to a communication will be sufficient for purposes of this Rule. Compare Rule 3.4(f). In communicating with a current or former constituent of an organization, a lawyer must not use methods of obtaining evidence that violate the legal rights of the organization. See Rule 4.4.

[8] The prohibition on communications with a represented person only applies in circumstances where the lawyer knows that the person is in fact represented in the matter to be discussed. This means that the lawyer has actual knowledge of the fact of the representation; but such actual knowledge may be inferred from the circumstances. See Rule 1.0(f). Thus, the lawyer cannot evade the requirement of obtaining the consent of counsel by closing eyes to the obvious.

[9] In the event the person with whom the lawyer communicates is not known to be represented by counsel in the matter, the lawyer's communications are subject to Rule 4.3.

Rule 1.8 Conflict Of Interest: Current Clients: Specific Rules

(g) A lawyer who represents two or more clients shall not participate in making an aggregate settlement of the claims of or against the clients, or in a criminal case an aggregated agreement as to guilty or nolo contendere pleas, unless each client gives informed consent, in a writing signed by the client. The lawyer's disclosure shall include the existence and nature of all the claims or pleas involved and of the participation of each person in the settlement.

Rule 1.8 Conflict Of Interest: Current Clients: Specific Rules - Comment

Aggregate Settlements

[13] Differences in willingness to make or accept an offer of settlement are among the risks of common representation of multiple clients by a single lawyer. Under Rule 1.7, this is one of the risks that should be discussed before undertaking the representation, as part of the process of obtaining the clients' informed consent. In addition, Rule 1.2(a) protects each client's right to have the final say in deciding whether to accept or reject an offer of settlement and in deciding whether to enter a guilty or nolo contendere plea in a criminal case. The rule stated in this paragraph is a corollary of both these Rules

and provides that, before any settlement offer or plea bargain is made or accepted on behalf of multiple clients, the lawyer must inform each of them about all the material terms of the settlement, including what the other clients will receive or pay if the settlement or plea offer is accepted. See also Rule 1.0(e) (definition of informed consent). Lawyers representing a class of plaintiffs or defendants, or those proceeding derivatively, may not have a full client-lawyer relationship with each member of the class; nevertheless, such lawyers must comply with applicable rules regulating notification of class members and other procedural requirements designed to ensure adequate protection of the entire class.

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

JEFF ANDERSON, BRET ADEE, DAVID HACKENBERG, LUCAS CRISWELL, GAIL FULLER, CENTER FOR FOOD SAFETY, AMERICAN BIRD CONSERVANCY, PESTICIDE ACTION NETWORK NORTH AMERICA, and POLLINATOR STEWARDSHIP COUNCIL,

Plaintiffs,

v.

GINA MCCARTHY and ENVIRONMENTAL PROTECTION AGENCY,

Defendants,

and

CROPLIFE AMERICA, AMERICAN SEED TRADE ASSOCIATION, AGRICULTURAL RETAILERS ASSOCIATION, AMERICAN SOYBEAN ASSOCIATION, NATIONAL COTTON COUNCIL OF AMERICA, NATIONAL ASSOCIATION OF WHEAT GROWERS, and NATIONAL CORN GROWERS ASSOCIATION,

Defendant-Intervenors.
_____/

No. C 16-00068 WHA

ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, DENYING AS MOOT DEFENDANT-INTERVENORS' MOTION FOR SUMMARY JUDGMENT, AND DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

In this challenge to federal agency action, all parties move for summary judgment. For the reasons discussed below, the agency's motion is **GRANTED**, defendant-intervenors' motion is **DENIED AS MOOT**, and plaintiffs' motion is **DENIED**.

STATEMENT

Plaintiffs are beekeepers, farmers, and organizations concerned about the effect of pesticide-treated seeds on bees and other pollinators. They brought this action to challenge the alleged failure of the Environmental Protection Agency and its Administrator, Gina McCarthy, to enforce the Federal Insecticide, Fungicide, and Rodenticide Act with respect to such seeds. According to plaintiffs, many seeds planted in the United States are coated with neonicotinoids, a type of pesticide that distributes throughout the resultant plant and thus kills insects both by direct contact and via the plants they ingest. Additionally, these seeds, when planted, can release pesticidal "dust-off" that further spreads neonicotinoids beyond the seeds themselves (Dkt. No. 90-1 at 4). Thus, plaintiffs allege, the practice of coating seeds with neonicotinoids has had a systematic and catastrophic impact on bees and the beekeeping industry throughout the United States (*id.* at 1).

Under FIFRA, pesticides must be registered with the EPA prior to use. 7 U.S.C. 136a. The Administrator, however, may exempt from registration requirements "any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." 7 U.S.C. 136w(b). In 1988, pursuant to this authority, the EPA created an exemption from FIFRA registration requirements for "articles or substances . . . treated with, or containing, a pesticide to protect the article or substance itself . . . if the pesticide is registered for such use." 40 C.F.R. 152.25(a).

In 2003, in a publication titled "Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States" (Dkt. No. 88-3), the EPA clarified the 1988 "treated articles or substances" exemption applied to "pesticide-treated seeds" as long as the pesticide is registered for such use under FIFRA and "the pesticidal protection imparted to the treated seed does not extend beyond the seed itself to offer pesticidal benefits or value attributable to the treated seed." Subject to those two conditions, "[s]eeds for planting which are treated with pesticides registered in the U.S. are exempt from registration as pesticides" (*id.* at 1–2).

In 2013, the EPA issued to FIFRA compliance and enforcement managers a document titled "Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents." The cover memorandum stated, "This guidance is a supplement to the [FIFRA] Inspection Manual . . . I request that you distribute this guidance to your state lead agencies and tribal pesticide programs and encourage you to discuss implementation of this guidance with them." A disclaimer at the beginning of the document cautioned (Dkt. No. 88-2):

> This guidance represents EPA's recommended procedures for [FIFRA] inspectors when they are conducting FIFRA inspections as a result of an incident involving bee deaths. This guidance is not a regulation and, therefore, does not add, eliminate or change any existing regulatory requirements. The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. EPA, state and tribal officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on analysis of site-specific circumstances.

The focal point of our lawsuit is a single passage within the guidance itself, which stated (*id.* at 7–8 & n.17):

> Note: Treated seed (and any resulting dust-off from treated seed) may be exempted from registration under FIFRA [pursuant to 40 C.F.R. 152.25(a)] as a treated article and as such its planting is not considered a "pesticide use." However, if the inspector suspects or has reason to believe a treated seed is subject to registration (*i.e.*, the seed is not in compliance with the treated article exemption), plantings of that treated seed may nonetheless be investigated.

Plaintiffs filed this lawsuit in 2016, claiming the 2013 Guidance is reviewable under the Administrative Procedure Act. Their complaint asserted four claims for relief. The first, third, and fourth claims for relief asserted that the 2013 Guidance exceeded the EPA's statutory authority, failed to comply with the APA's rulemaking requirements, and was arbitrary and capricious (Dkt. No. 1 at 22–29). The second claim for relief asserted that the EPA's "non-enforcement policy" regarding neonicotinoid-coated seeds, as embodied in the 2013 Guidance, was an unlawful "abdication" of its responsibilities under FIFRA (*id.* at 25–26).

The EPA moved to dismiss for lack of subject-matter jurisdiction (Dkt. No. 21) and several trade organizations that would be affected by the outcome of this case moved to intervene (Dkt. No. 26). A previous order granted the motion to intervene and denied the EPA's

motion to dismiss, finding that "the factual dispute between the parties — whether the 2013 Guidance constituted final agency action — is 'so intertwined' with the merits that a 'jurisdictional finding of genuinely disputed facts is inappropriate.'" The order acknowledged the EPA "put forth a strong argument in support of dismissal of the lawsuit at the Rule 12 stage" but noted that, in our circuit, "essentially all environmental cases concerning subject-matter jurisdiction are decided only after reviewing the administrative record, typically at the summary judgment stage" (Dkt. No. 62 at 4–6).

The EPA now moves for summary judgment on plaintiffs' first, third, and fourth claims for relief on the basis that the 2013 Guidance was not a reviewable final agency action, and on plaintiffs' second claim for relief on the basis that plaintiffs have failed to identify any nondiscretionary action that has been unlawfully withheld (Dkt. No. 88). Defendant-intervenors join in the motion and separately move for summary judgment on the basis that plaintiffs' lawsuit constitutes an improper programmatic challenge to the EPA's regulation of pesticides (Dkt. No. 89). Plaintiffs also move for summary judgment on their first, third, and fourth claims for relief on the basis that the 2013 Guidance was a reviewable final agency action, and on their second claim for relief on the basis that the EPA's policy of non-enforcement as to neonicotinoid-coated seeds is an unlawful "abdication" of its responsibilities under FIFRA subject to judicial review (Dkt. No. 90-1).

ANALYSIS

1. LEGAL STANDARD.

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. F.R.C.P. 56(a); *Conservation Congress v. Finley*, 774 F.3d 611, 617 (9th Cir. 2014). When a court reviews a government agency's action, however, the standard for summary judgment is amplified by the APA, which provides the applicable standard of review. *Finley*, *supra*, at 617; *Good Samaritan Hosp., Corvallis v. Matthews*, 609 F.2d 949, 951 (9th Cir. 1979). The APA requires the reviewing court to "decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action." The reviewing court shall "compel

agency action unlawfully withheld or unreasonably delayed" and "hold unlawful and set aside agency action, findings, and conclusions" found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. 706(1)–(2). Thus, in considering motions for summary judgment, "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. I.N.S.*, 753 F.2d 766, 769–70 (9th Cir. 1985).

2. NATURE OF PLAINTIFFS' CLAIMS.

As a preliminary matter, this order clarifies the current status of plaintiffs' four claims for relief. Plaintiffs' theory underlying their first, third, and fourth claims is that the 2013 Guidance constituted an unlawful "final agency action" under Section 706(2) (*e.g.*, Dkt. Nos. 90-1 at 16–25, 95 at 2–8). Plaintiffs' second claim for relief started out as a claim for "failure to act" under Section 706(1) (*see, e.g.*, Dkt. No. 81 at 4–5) but then evolved into claim under Section 706(2) instead. *See Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 62 (2004) (Section 706(1) provides relief for an agency's failure to act). Plaintiffs commit to this change in their opposition brief where they say their second claim for relief "should properly be regarded as a claim under § 706(2), *not § 706(1)*, despite Plaintiffs having cited both in their Complaint and in briefing" (Dkt. No. 95 at 9) (emphasis added).

In attempting to defuse various arguments leveled by the EPA and defendant-intervenors against their second claim for relief, plaintiffs repeatedly emphasize that they are *not* bringing any claim under Section 706(1) (Dkt. No. 103 at 7, 11–12). Plaintiffs' counsel also reaffirmed this position at oral argument. Thus, despite plaintiffs' repeated use of the phrase "failure to act," this order construes all four of plaintiffs' claims for relief as challenging, *under Section 706(2) only*, the 2013 Guidance's alleged promulgation of a new policy applying the "treated articles and substances" exemption to pesticide-treated seeds and their dust-off. This order first addresses plaintiffs' first, third, and fourth claims for relief within the framework of final agency

action analysis, reserving for later the nettlesome question of whether plaintiffs' "failure to act" claim can survive summary judgment.

3. FINAL AGENCY ACTION?

The APA permits judicial review of "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. Since plaintiffs seek review under the general provisions of the APA, they must challenge a "final agency action." *Ibid.*; *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990); *Or. Nat. Desert Ass'n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006). An "agency action" includes "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. 551(13); *Norton*, *supra*, at 62. Moreover, to be final, an agency action must satisfy two conditions. *First*, "the action must mark the consummation of the agency's decisionmaking process — it must not be of a merely tentative or interlocutory nature." *Second*, "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (quotations omitted); *Fairbanks North Star Borough v. U.S. Army Corps of Eng'rs.*, 543 F.3d 586, 591 (9th Cir. 2008).[1]

A. Agency Action.

Having ruled out the possibility that plaintiffs claim a "failure to act" under Section 706(1), the next step of the inquiry is to determine whether the challenged 2013 Guidance is "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof" so as to constitute "agency action." 5 U.S.C. 551(13); *Norton*, *supra*, at 62. To repeat, the relevant passage from the Guidance reads in its entirety (Dkt. No. 88-2 at 7–8):

> Inspectors may also take into account any locations of treated seed planting when identifying locations of potential pesticide sources. Note: Treated seed (and any resulting dust-off from treated seed)

[1] In their complaint and opposition to defendants' motion to dismiss, plaintiffs had previously argued that FIFRA, 7 U.S.C. 136n(a), also authorizes judicial review (Dkt. Nos. 1 at 1–2, 57 at 24–25). In their motion for summary judgment, defendants contend "a cause of action may exist under either the APA or another judicial review provision, but not both" (Dkt. No. 88 at 10). Plaintiffs' briefs on summary judgment do not revive their contention that 7 U.S.C. 136n(a) authorizes judicial review.

> may be exempted from registration under FIFRA [pursuant to 40 C.F.R. 152.25(a)] as a treated article and as such its planting is not considered a "pesticide use." However, if the inspector suspects or has reason to believe a treated seed is subject to registration (*i.e.*, the seed is not in compliance with the treated article exemption), plantings of that treated seed may nonetheless be investigated.

The EPA characterizes this passage, and the 2013 Guidance as a whole, as "a set of non-binding recommendations for the use of federal, state, and tribal inspectors" rather than an agency action (Dkt. Nos. 88 at 11, 96 at 3, 100 at 5–6). The plain language of the 2013 Guidance supports the EPA's position in three ways.

First, the key passage quoted above reads like a recommendation, not a mandate. The first sentence discusses what inspectors "may" take into account during investigations. The customary meaning of "may" is permissive. *Sierra Club v. Johnson*, 614 F. Supp. 2d 998, 1003 (N.D. Cal. July 23, 2008). The "Note" about pesticide-treated seed states that both the seeds and resultant dust-off "*may* be exempted from registration under FIFRA," indicating that applicability of the "treated articles and substances" exemption is not a foregone conclusion but a mere possibility, *i.e.*, the exemption *may or may not apply*. This interpretation fits with the rest of the passage, which sets forth a corresponding scenario for each possibility: *If* the inspector finds pesticide-treated seed (and resultant dust-off) exempt, *then* "as [a treated article] its planting is not considered a 'pesticide use.'" But *if* "the inspector suspects or has reason to believe a treated seed is subject to registration (*i.e.*, the seed is not in compliance with the treated article exemption), plantings of that treated seed may nonetheless be investigated."

Plaintiffs reply that this passage represents a "definitive statement" despite its permissive language because the phrase "its planting is not considered a 'pesticide use'" is "definitive" (Dkt. No. 95 at 4). That phrase would be definitive if it were its own sentence, but it is not. It is merely a fragment within a sentence. Plaintiffs' interpretation would completely omit not only the surrounding permissive language in the rest of that sentence and the rest of the passage, but also the *two immediately preceding words*, namely, "*as such* its planting is not considered a 'pesticide use'" (emphasis added) — with "as such" meaning "as a treated article." In other words, the planting of a seed is not considered a pesticide use *if* the seed is a treated article covered by the "treated articles or substances" exemption (*see* Dkt. No. 96 at 14–15). This order

declines to interpret a single incomplete phrase inconsistently with the plain meaning of the rest of the relevant passage.

Plaintiffs further reply that it would make "no sense" to interpret this passage as making permissive and conditional statements because "a treated seed that has resulting dust-off" can *never* qualify for the "treated articles or substances" exemption, since "'[r]esulting dust-off from treated seed' necessarily includes the pesticidal coating and necessarily has pesticidal effects that extend beyond the seed itself" (Dkt. Nos. 95 at 4, 103 at 14–15). The premise is plaintiffs' interpretation of the 2003 Harmonization Document as applying the "treated articles or substances" exemption only to pesticide-treated seeds that cause no pesticidal effect beyond the seed itself. This argument would carry some weight if the 2003 Harmonization Document had interpreted the exemption to be inapplicable whenever a pesticide-treated seed's pesticidal effect extends in *any* way beyond the seed itself. The 2003 Harmonization Document, however, did not impose such a strict limitation. That document set forth two conditions for exemption, the second of which is that "the treatment is for the protection of the article or substance itself" (Dkt. No. 88-3 at 1).

Plaintiffs point out that the 2003 Harmonization Document explained the second condition for exemption as follows: "The term 'for the protection of the [seed] itself' means that the pesticidal protection imparted to the pesticide-treated seed does not extend beyond the seed itself to offer pesticidal benefits or value attributable to the treated seed" (*id.* at 2). Plaintiffs read this sentence as rendering ineligible for exemption any "treated seed that has resulting dust-off" (Dkt. No. 103 at 14). Again, plaintiffs gloss over informing context and fail to read the phrase as a whole, *i.e.*, "*the treatment is for* the protection of the article or substance itself" (emphasis added) — wherein the words "the treatment is for" contemplate the pesticidal treatment's intended purpose rather than its entire range of potential but unintended effects. The plain meaning of these excerpts from the 2003 Harmonization Document, read together, is that the pesticidal treatment used on the seed must be for — *i.e.*, intended for — the protection of the seed itself as opposed to protection that extends beyond the seed to offer other pesticidal benefits or value.

This interpretation is consistent with the 2003 Harmonization Document's use of the phrase "pesticidal *benefits or value*" — as opposed to, *e.g.*, "pesticidal *effects*" — and with the immediately following sentence, which states, "Unless claims of pesticidal benefit or value attributable to the treated seed and extending beyond the treated seed are made in conjunction with the distribution or sale of the treated seed within the U.S., the EPA will presume that the seed will have been treated 'for the protection of the seed itself'" (Dkt. No. 88-3 at 2). This sentence highlights the distinction contemplated by the 2003 Harmonization Document between exempt pesticide-treated seeds and non-exempt pesticide-treated seeds — the latter would be distributed or sold with "claims of pesticidal benefit or value attributable to the treated seed and extending beyond the treated seed," while the former would ostensibly be distributed or sold with claims of pesticidal benefit or value *only* for the seed itself. In other words, the focus of the second condition for exemption described in the 2003 Harmonization Document is on the pesticidal treatment's intended purpose rather than on all its potential effects.

Nothing in the plain language of the 2003 Harmonization Document strictly limits the "treated articles and substances" exemption to pesticide-treated seeds that can never cause a pesticidal effect beyond the seed itself. Plaintiffs' claim that "treated seed that has resulting dust-off *cannot be exempted*" (Dkt. No. 103 at 14) (emphasis in original) is thus unsupported and fails to rebut the EPA's position that, as described by the plain language of the 2013 Guidance, "[t]reated seed (and any resulting dust-off from treated seed)" may or may not be exempt from FIFRA registration requirements (*e.g.*, Dkt. No. 96 at 15). *See Sierra Club*, *supra*, at 1003 (customary meaning of "may" is permissive).

Second, the EPA's position that the 2013 Guidance is "a set of non-binding recommendations for the use of federal, state, and tribal inspectors" is consistent with its cover memorandum. The cover memorandum, addressed to FIFRA Compliance and Enforcement Managers by the Office of Compliance, described the 2013 Guidance as a "guidance for inspecting alleged cases of pesticide-related bee incidents." Moreover, the cover memorandum stated, "I *request* that you distribute this guidance to your state lead agencies and tribal pesticide programs and *encourage* you to discuss implementation of this guidance with them" (Dkt. No.

88-2) (emphasis added). This sort of permissive language is consistent with the EPA's position, but inconsistent with plaintiffs' claim that the 2013 Guidance was a "rule" or equivalent thereof with the force of law (*e.g.*, Dkt. No. 103 at 13–15).

Third, the 2013 Guidance included an explicit disclaimer that stated in relevant part (Dkt. No. 88-2) (emphasis added):

> This guidance is an *inspection support tool* provided by the U.S. Environmental Protection Agency (EPA), for use by EPA regions, states and tribes conducting inspections under [FIFRA]. This guidance represents EPA's *recommended* procedures for these inspectors when they are conducting FIFRA inspections as a result of an incident involving bee deaths. *This guidance is not a regulation and, therefore, does not add, eliminate or change any existing regulatory requirements. The statements in this document are intended solely as guidance.* This document is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. EPA, state and tribal officials may decide to follow the guidance provided in this document, *or to act at variance with the guidance*, based on analysis of site-specific circumstances. This guidance may be revised without public notice to reflect changes in EPA's policy.

Plaintiffs offer two responses to this disclaimer. The first is that the disclaimer is "boilerplate" language, and the Court is not obliged to accept it at face value (Dkt. No. 90-1 at 23). As this order explains, however, the disclaimer — boilerplate or not — is consistent with the EPA's position and with the rest of the 2013 Guidance. Plaintiffs are correct that the disclaimer is not *dispositive* of the true nature of the 2013 Guidance, but that does not mean the disclaimer is not *relevant*.

In their reply brief, plaintiffs raise a second argument against the disclaimer, claiming it is "directly contradict[ed]" by the following page in the 2013 Guidance (Dkt. No. 103 at 3–4). That page stated in relevant part (Dkt. No. 88-2 at 1): "This guidance will aid in standardizing bee incident inspections across federal, state and tribal agencies when trying to determine if the deaths are related to the use of a pesticide in violation of FIFRA. The data gathered in these types of inspections will help determine if the death of the bees was associated with the legal or illegal use of a pesticide." Plaintiffs point out that if "the purpose of the 2013 Guidance is to help determine whether the particular use of a pesticide was legal or illegal under FIFRA," then it also helps determine "whether EPA should take enforcement action or not." Thus, plaintiffs

argue, this language "reveal[ed] the true purpose of the document to be something much more substantive" than the disclaimer would suggest (Dkt. No. 103 at 3–4).

It does not follow that the disclaimer is "directly contradict[ed]" by the language quoted above. A disclaimer that essentially states the 2013 Guidance is non-binding does not contradict an acknowledgment that it will nonetheless be *helpful* to inspectors in conducting investigations and making determinations that may lead to discrete agency action. Moreover, plaintiffs' reasoning would lead to the untenable conclusion that virtually any guidance — no matter how non-binding or advisory — could be subject to judicial review on the vague theory that it informs some day-to-day activity that may somehow affect discrete agency action somewhere down the line. At best, plaintiffs possibly have shown a speculative degree of tension between the EPA's characterization of the 2013 Guidance's overall significance and the practical reality of its influence on the EPA's FIFRA enforcement efforts — but this falls well short of a direct contradiction that would completely discredit the disclaimer.

In summary, considering together the disclaimer, cover memorandum, and key passage that is the subject of plaintiffs' challenge, this order concludes the plain language of the 2013 Guidance supports the EPA's position that it was not an agency action.

Plaintiffs attempt to discredit the EPA's position by pointing out that "[a] reviewing court does not have to rubber stamp an agency's own characterization of its action (Dkt. No. 90-1 at 17). The foregoing analysis, however, is not a rubber stamp.

Plaintiffs cite *CropLife Am. v. E.P.A.*, 329 F.3d 876, 883 (D.C. Cir. 2003), for the proposition that "the agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the 'force of law,' but the record indicates otherwise." *CropLife*, however, is distinguishable from this case. In *CropLife*, the EPA issued a press release stating "the Agency will not consider or rely on [third-party] human studies in its regulatory decision making, whether previously or newly submitted." *CropLife*, *supra*, at 878. The EPA claimed the statement was "nothing more than a 'policy statement,' and thus [was] not subject to judicial review." The reviewing court rejected the EPA's self-serving characterization of its own action as "not controlling" because "there [was] little

doubt that the . . . Press Release [bound] private parties and the agency itself with the force of law, and thus constitute[d] a regulation rather than a policy statement. The directive clearly establishe[d] a substantive rule declaring that third-party human studies [were] deemed immaterial in EPA regulatory decisionmaking." *Id.* at 883. In other words, in *CropLife* the record clearly contradicted the agency's characterization of its own action.

No comparable facts present in this case. Here, as discussed above, the plain language of the 2013 Guidance supports the EPA's position that it is "a set of non-binding recommendations for the use of federal, state, and tribal inspectors" (Dkt. Nos. 88 at 11, 96 at 3, 100 at 5–6), not a rule with the force of law.

Plaintiffs also cite *Siskiyou Reg'l Educ. Project v. U.S. Forest Serv.*, 565 F.3d 545, 553–54 (9th Cir. 2009), as an example of when "[t]he Ninth Circuit has found that statements within memoranda are final agency actions actionable under the APA." *Siskiyou* is also distinguishable from this case. In *Siskiyou*, the agency memorandum at issue interpreted "*binding* standards and guidelines [restricting] certain activities within areas designated as riparian reserves or key watersheds." *Siskiyou*, *supra*, at 551–53. The jurisdictional question addressed by the court was whether the lawsuit constituted an improper "programmatic attack." The court found the plaintiff's allegations challenged "specific instances of the [agency's] actions taken pursuant to its interpretation of [the memorandum], and therefore constitute[d] more than a programmatic attack or a vague reference to [agency] action or inaction." *Id.* at 554. There was no dispute as to whether the memorandum was a non-binding recommendation or a binding document with the force of law. *Siskiyou* is thus unhelpful to plaintiffs' position that mere issuance of a non-binding guidance is agency action for purposes of APA review.

Plaintiffs further contend the 2013 Guidance is an agency action because it effectively amended the "treated articles or substances" exemption as interpreted by the 2003 Harmonization Document (Dkt. No. 103 at 13). Specifically, plaintiffs claim the 2013 Guidance (1) "expand[ed] the . . . exemption from seeds to dust-off," (2) "stat[ed] definitively that the planting of treated seeds and dust-off is not considered a pesticide use," and (3) omitted the condition that "the pesticidal protection imparted to the treated seed does not extend beyond the

seed itself to offer pesticidal benefits or value attributable to the treated seed" (*e.g.*, Dkt. Nos. 90-1 at 13–14, 95 at 4–5, 103 at 14). Plaintiffs cite *Hemp Indus. Ass'n v. D.E.A.*, 333 F.3d 1082, 1087 (9th Cir. 2003), as the "key Ninth Circuit precedent" (Dkt. No. 103 at 13) for the proposition that an agency guidance has the "force of law" when it "effectively amends a prior legislative rule."

It is important to note that *Hemp* is distinguishable from this case because the challenged agency in *Hemp* had actually issued a *rule* banning naturally occurring THC. *Hemp*, *supra*, at 1084. The issue before that court was whether that rule was "legislative," in which case the agency needed to follow certain procedures described in the APA, or "interpretive," in which case the agency did not. Within that context, the court concluded "a rule has the 'force of law' [*i.e.*, is legislative] . . . when [it] effectively amends a prior legislative rule." *Id.* at 1087.

Here, in contrast, the challenged 2013 Guidance was not a rule (*see* Dkt. No. 100 at 5). A "rule," as defined by the APA, is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." 5 U.S.C. 551(4). Here, as discussed above, the 2013 Guidance did not "implement, interpret, or prescribe law or policy," nor did it describe any *requirements* of the EPA, since it comprised of recommendations with which compliance is permissive, not mandatory. There is thus no reason to conclude the 2013 Guidance was a "rule" — or rule "equivalent," as plaintiffs suggest (Dkt. No. 1 at 23) — of the sort contemplated by *Hemp*.

Plaintiffs attempt to overcome this distinction by claiming "an agency's interpretive rule or statement of policy can be a reviewable 'rule' within the meaning of the APA," citing *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1021 (D.C. Cir. 2000), which stated:

> If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes "binding."

Plaintiffs provide no analysis as to why *Appalachian Power* applies in this case (Dkt. No. 90-1 at 19). Their bald statement that "an agency's interpretive rule or statement of policy *can* be a reviewable 'rule' within the meaning of the APA" (emphasis added) does not demonstrate that such is the situation here. As discussed above, the EPA did not act as if the 2013 Guidance was controlling in the field or a "legislative rule." In fact, an explicit disclaimer in the 2013 Guidance and the plain language of the document itself indicated otherwise. The EPA may base enforcement actions on the results of investigations conducted according to the 2013 Guidance, but nothing in the record indicates the EPA has taken discrete enforcement actions based directly on the 2013 Guidance itself. Finally, as discussed above, the 2013 Guidance would not lead its recipients to believe the EPA will "declare permits invalid," or take any action, "unless they comply with the terms of the document." In fact, the cover memorandum, disclaimer, and plain language of the 2013 Guidance all indicated compliance was voluntary because the document offered a set of recommendations, not rules or mandates. *Appalachian Power* is thus unhelpful to show that the 2013 Guidance "is for all practical purposes 'binding.'"

Even assuming for the sake of argument that *Hemp*'s reasoning applies, not only to actual rules issued by an agency, but also to non-binding guidance documents, *Hemp* would still not support plaintiffs' position. As discussed above, the 2013 Guidance did not amend the "treated articles or substances" exemption as interpreted by the 2003 Harmonization Document. The 2013 Guidance did not contradict the 2003 Harmonization Document, nor did the passage plaintiffs rely on definitively direct mandatory application or withholding of the "treated articles or substances" exemption.

B. Finality.

The 2013 Guidance, moreover, lacked the finality required for judicial review under the APA. To be "final" for purposes of the APA, an action must (1) "mark the 'consummation' of the agency's decisionmaking process," *i.e.*, "it must not be of a merely tentative or interlocutory nature," and (2) "be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett*, *supra*, at 177–78 (citations omitted). Neither requirement is satisfied here.

First, the 2013 Guidance did not mark the "consummation" of the EPA's decisionmaking process with respect to applying the "treated articles or substances" exemption to pesticide-treated seeds. As explained, the 2013 Guidance recommended that inspectors investigating bee deaths consider *if* the exemption should apply on a case-by-case basis. It did not mandate the investigations, much less direct their outcomes. Insofar as the resulting determinations from these investigations potentially influence the EPA's enforcement decisions further down the line, they are necessarily "tentative" or "interlocutory" in nature. Thus, the 2013 Guidance, which merely assisted investigations that are themselves only "tentative" or "interlocutory," could not be the "consummation" of the EPA's decisionmaking process.

Second, and for similar reasons, the 2013 Guidance could not have been an action "by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Based on the 2013 Guidance alone it would be impossible to determine if a particular investigator would conclude a particular pesticide-treated seed qualifies for the "treated articles or substances" exemption, if the seed would therefore be subject to FIFRA's registration requirements, or if the EPA would take further enforcement action. Thus the 2013 Guidance — the alleged agency action in this case — was not a final agency action that determined rights or obligations, or triggered legal consequences.

Plaintiffs' other arguments that the 2013 Guidance was sufficiently final for purposes of APA review are similarly unpersuasive. *First*, plaintiffs claim the 2013 Guidance "represents the final word by EPA on its decision to exempt neonicotinoid-coated seeds and pesticidal dust-off from the requirements of FIFRA" (Dkt. No. 90-1 at 19). Thus, plaintiffs contend, the legal consequence flows that "planting of treated seeds and any resulting dust-off are not considered pesticidal uses under FIFRA" (*id.* at 21–22). But as stated, the 2013 Guidance conveyed no such decision. Contrary to plaintiffs' bald assertions that "sellers and users of . . . treated seed with associated pesticidal dust-off . . . do not have to comply with [FIFRA]," and that the "EPA does not and will not enforce FIFRA against the sale or use of neonicotinoid-coated seeds" (*id.* at 19–20), the 2013 Guidance expressly contemplated scenarios in which pesticide-treated seeds could be subject to FIFRA's registration requirements and necessitate enforcement (Dkt.

No. 88-2 at 7). The 2013 Guidance thus did not represent the EPA's "final word" as to any non-enforcement policy.

Second, plaintiffs claim the 2013 Guidance "is clearly the consummation of EPA's decisionmaking process" because "it is explicitly 'a supplement to the national [FIFRA] Inspection Manual,' . . . which is described as 'an important element of the [EPA's] Pollinator Protection Strategic Plan.'" Plaintiffs also point out the 2013 Guidance "is not a draft or preliminary document, but rather a final document published by the agency" (Dkt. No. 90-1 at 20). These are non sequiturs. A "supplement" to an inspection manual is not necessarily a "consummation" of the decisionmaking process aided by that manual. An "important element" of the EPA's plan to protect pollinators is not necessarily a "consummation" of its decisionmaking process as to a specific exemption relevant to that plan. And it would be absurd to conclude that a document is "final" for purposes of judicial review under the APA just because it is a final published document, as opposed to a preliminary draft. It is the document's nature, not the stage of its drafting, that is germane to the finality inquiry.[2]

4. FAILURE TO ACT?

As discussed, plaintiffs' second claim for relief is essentially a "failure to act" claim now brought under Section 706(2) instead of Section 706(1). At oral argument, plaintiffs focused solely on this claim, insisting they never abandoned their "failure to act" allegations and glossing over their previous flip-flopping from Section 706(1) to Section 706(2). Plaintiffs now stake their second claim for relief on an "exception" articulated in a footnote in *Heckler v. Chaney*, 470 U.S. 821 (1985).

A. *Heckler* Exception.

At oral argument, plaintiffs repeatedly emphasized that the "*Heckler* exception" authorizes judicial review of their second claim for relief. This begs the question: Exception to

[2] Plaintiffs also claim the 2013 Guidance "represents EPA's last word for the purposes of the *Bennett* test even though the agency *could* take some other action in the future" (Dkt. No. 90-1 at 20) (emphasis in original), ostensibly attempting to preempt an argument by the EPA that the 2013 Guidance lacked finality because the agency could take future action on the guidance's subject matter. Since neither the EPA nor this order relies on the possibility of future agency action in concluding the 2013 Guidance lacked finality, plaintiffs' point does not affect the analysis herein.

what? To answer this question, it is necessary to take a step back and clarify the context and holding of *Heckler*.

As stated, judicial review of claims like the ones in this case requires a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. Where there is no such final agency action, judicial review is not available and the inquiry ends. *If* final agency action exists, however, then such action is nonetheless unreviewable unless it *also* clears the hurdle imposed by Section 701(a)(2), *i.e.*, that it is not agency action "committed to agency discretion by law." *F.T.C. v. Standard Oil Co. of Cal.*, 449 U.S. 232, 238 & n.7, 246–47 (1980); *Aguayo v. Jewell*, 827 F.3d 1213, 1223 (9th Cir. 2016). In other words, Section 701 functions *in addition to*, but does not *replace*, Section 704. This is evident both in the case law applying these provisions and in the plain language of Section 701(a), which states, "This chapter applies, *according to the provisions thereof*, except to the extent that – (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." The *Heckler* decision, applying Section 701(a)(2), held that in situations where an agency "refus[es] to take enforcement steps . . . the presumption is that judicial review is not available" because "an agency's decision not to prosecute or enforce . . . is a decision generally committed to an agency's absolute discretion." *Heckler*, *supra*, at 831–33. In short, an agency's refusal to take enforcement action is generally unreviewable under Section 701(a)(2). The exception to this general rule — *i.e.*, the "*Heckler* exception" plaintiffs rely on — is in a footnote to the aforementioned analysis, wherein *Heckler* stated the Court "express[ed] no opinion" on whether an agency's decision to "consciously and expressly adopt[] a general policy that is so extreme as to amount to an abdication of its statutory responsibilities" would similarly be "unreviewable under § 701(a)(2)." *Id.* at 833 & n.4 (quotations omitted).

That expression of "no opinion" left open the possibility that "[a] decision that is committed to agency discretion by law may nonetheless be reviewable where the agency has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities." *Garcia v. McCarthy*, 649 F. App'x 589, 592 (9th

Cir. 2016) (quotations omitted). Plaintiffs' application of this exception to their second claim for relief, however, suffers from two fatal flaws.

First, application of the *Heckler* exception requires an agency decision to "consciously and expressly" adopt a general policy. Plaintiffs claim the "EPA's failure to enforce FIFRA against neonicotinoid-coated seeds and pesticidal dust-off is a 'consciously and expressly adopted general policy,' which 'amounts to an abdication of [the EPA's] statutory responsibilities,'" but this is mere recitation of the *Heckler* exception coupled with a bald assertion that it is on point in this case. Plaintiffs have not identified a single document that contains such a decision. The administrative record and the Court's *in camera* review of additional documents submitted by the EPA also revealed nothing that would qualify as a decision "consciously and expressly" adopting any general policy, much less one "so extreme as to amount to an abdication of [the EPA's] statutory responsibilities." The bulk of those documents included multiple drafts, often attached to multiple email chains, of the 2013 Guidance as its contents were repeatedly and painstakingly discussed, reviewed, and edited in the long road to publication.

In their reply brief, plaintiffs argue judicial review is available for the EPA's "policy of non-enforcement [as to pesticide-treated seeds] . . . expressed in [the] EPA's 2013 Guidance" (Dkt. No. 103 at 8). This argument is unavailing. As stated, the 2013 Guidance — which plaintiffs characterize as the "focal point" that "expressed" the alleged policy — contained no language indicating the EPA took a definitive stand on the applicability of the "treated articles or substances" exemption to any pesticide-treated seeds. Indeed, the very fact that the relevant passage acknowledged two possibilities — either pesticide-treated seed qualifies for the exemption or it does not — indicated the EPA had no standing policy on the matter.

To this end, the 2013 Guidance specifically informed investigators "plantings of . . . treated seed may . . . be investigated" if the pesticide-treated seed "is subject to registration (*i.e.*, the seed is not in compliance with the treated article exemption)" (Dkt. No. 88-2 at 7). This language indicated that the EPA in issuing the 2013 Guidance expressly contemplated *potential enforcement* of FIFRA requirements as to pesticide-treated seeds, which directly

contradicts plaintiffs' allegations of a "policy of non-enforcement" and "abdication of duties." Thus, even assuming for the sake of argument that a blanket-exemption policy as to pesticide-treated seeds would constitute an abdication of the EPA's responsibilities under FIFRA as to such seeds, there is no basis for finding the EPA "consciously and expressly adopted a general policy" abdicating its statutory responsibilities here.

Second, plaintiffs' framing of their second claim for relief within the *Heckler* exception is predicated on flagrant mischaracterization of how the exception functions. At oral argument, plaintiffs' counsel repeatedly stated the *Heckler* exception dispenses with the APA's final agency action requirement for judicial review. That was and remains wrong. Plaintiffs could properly raise the *Heckler* exception to defend their second claim for relief *if* they had first alleged a final agency action that defendants had argued was nonetheless unreviewable because of the hurdle imposed by Section 701(a)(2). As explained, however, plaintiffs cannot even clear the initial Section 704 hurdle of identifying a final agency action. Thus, their claim cannot reach the additional requirements of Section 701(a)(2), let alone raise *Heckler* as a defense against said requirements. In short, the *Heckler* exception might save plaintiffs' claim from Section 701(a)(2) but does nothing to circumvent Section 704.[3]

What plaintiffs need here is not an exception to Section 701(a)(2), but an exception to the "final agency requirement" of Section 704. Such an exception exists — in Section 706(1). "A court's review of an agency's failure to act [under Section 706(1)] has been referred to as an exception to the final agency action requirement." *ONRC Action v. Bureau of Land Mgmt.*, 150 F.3d 1132, 1137 (9th Cir. 1998); *Indep. Min. Co., Inc. v. Babbitt*, 105 F.3d 502, 511 (9th Cir. 1997). Plaintiffs, however, have unequivocally foresworn any reliance on Section 706(1) (*e.g.*, Dkt. No. 95 at 9). The final agency action requirement for judicial review under the APA thus applies squarely to their second claim for relief under Section 706(2). As stated, plaintiffs

[3] Plaintiffs' briefing indicates they understood how to apply *Heckler* correctly, *i.e.*, to rebut the EPA's argument that any alleged decision to not enforce FIFRA would generally be unreviewable pursuant to Section 701(a)(2) as a decision committed to agency discretion (*see* Dkt. Nos. 95 at 8–13, 103 at 8). If so, plaintiffs' representation at oral argument that they relied on *Heckler* all along as an exception to the "final agency action" requirement of Section 704 was disingenuous.

cannot meet this requirement. Thus, their second claim for relief — like their first, third, and fourth claims — is unreviewable under the APA.

B. Administrative Record.

Finally, this order must address the parties' fight over the administrative record. Plaintiffs had previously moved to compel "completion and supplementation" of the administrative record, and to conduct limited discovery in support of their second claim for relief (Dkt. No. 81). A prior order instructed the EPA to submit under seal for *in camera* review "documents that relate to the development of the guidance that are *not* a part of the administrative record, including pre-decisional and deliberative documents," instructed plaintiffs to "lay out any alleged shortfalls in the administrative record" in their summary judgment briefs, and denied plaintiffs' request for limited discovery without prejudice (Dkt. No. 86). Plaintiffs now renew their request for limited discovery relevant to their second claim for relief (Dkt. No. 90-1 at 11). The original basis for this request was that, unlike plaintiffs' other claims for relief, a claim for failure to act under Section 706(1) is not predicated on an agency action for which there can be a clearly demarcated administrative record. Thus, plaintiffs argued, they should be allowed to take extra-record discovery (Dkt. No. 81 at 4–5). As stated, plaintiffs have since abandoned their claim under Section 706(1) and are proceeding on the theory that all four claims for relief challenge a final agency action under Section 706(2). The premise of their request for limited discovery is now defunct (*see* Dkt. No. 100 at 8 & n.4). Accordingly, the request is **DENIED**.

Plaintiffs also renew their request to compel the EPA to supplement the administrative record with additional materials. The prior order directing the EPA to lodge the administrative record stated, "The administrative record shall include all emails and memoranda discussing whether the agency should proceed by guidance versus some other procedure and/or discussing whether the guidance would constitute final agency action" (Dkt. No. 62 at 8–9). In claiming the EPA has failed to comply with that order, plaintiffs highlight the importance of three documents: (1) "Pros and Cons of Issues Surrounding Review and Release of the Guidance," (2) an email

from the Chief Division of Plant Health, Ohio Department of Agriculture, and (3) a PowerPoint presentation titled "2012 Indiana Bee Kill Investigations" (Dkt. No. 90-1 at 14–15).

The Court's *in camera* review of these unredacted documents, and others submitted by the EPA, revealed nothing that would weigh in plaintiffs' favor on the issue of "whether the agency should proceed by guidance versus some other procedure" or "whether the guidance would constitute final agency action." Nor did any document submitted for *in camera* review support application of the *Heckler* exception to this case. There is thus no reason to compel additional production. Plaintiffs also seek documents that would be relevant to the *merits* of their claims (*e.g.*, *id.* at 16; Dkt. No. 103 at 1–2) but, as discussed, have not satisfied the requirements for judicial review under the APA. Their request to supplement the administrative record is therefore **DENIED**.

CONCLUSION

The Court is most sympathetic to the plight of our bee population and beekeepers. Perhaps the EPA should have done more to protect them, but such policy decisions are for the agency to make. A district judge's role is limited to judicial review of final agency actions, which do not include the type of guidance involved here.

For the foregoing reasons, defendants' motion for summary judgment, in which defendant-intervenors join, is **GRANTED**. Defendant-intervenors' separate motion for summary judgment is **DENIED AS MOOT**. Plaintiffs' motion for summary judgment is **DENIED**. Plaintiffs' request for judicial notice (Dkt. No. 93) of documents not relied upon in this order is **DENIED AS MOOT**.

IT IS SO ORDERED.

Dated: November 21, 2016.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE

CITIZEN PETITION TO THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BRET ADEE, AMERICAN BEEKEEPING FEDERATION, AMERICAN BIRD CONSERVANCY, AMERICAN HONEY PRODUCERS ASSOCIATION, JEFF ANDERSON, LUCAS CRISWELL, GAIL FULLER, DAVID HACKENBERG, PESTICIDE ACTION NETWORK OF NORTH AMERICA and POLLINATOR STEWARDSHIP COUNCIL including and represented by **CENTER FOR FOOD SAFETY** 660 Pennsylvania Ave., SE, Suite 302 Washington, D.C. 20003, *Petitioners,*	Docket Number _____
Filed With:	
SCOTT PRUITT, ADMINISTRATOR Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460**)**	

EXECUTIVE SUMMARY

This Citizen Petition seeks to end an existing regulatory loophole for seeds coated with systemic pesticides. The Environmental Protection Agency (EPA) is tasked with regulating pesticides in the United States, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 et seq. However, a class of pesticides made up of crop seeds coated with systemic insecticides ("coated seeds") that are intended to kill pests of the plants are not regulated by EPA under FIFRA. Although these seeds fit the definition of "pesticide" and have devastating impacts to the environment and Petitioners' interests, EPA exempts the coated seeds

from FIFRA's registration and labeling requirements, improperly relying on the Treated Article Exemption, 40 C.F.R. §152.25(a).

Petitioners are commercial beekeepers, farmers, and environmental and agriculture public interest groups, all with a keen interest in ending this loophole for these pesticide-coated seeds. These seeds are used on nearly 150 million acres across the country, representing the vast majority of systemic insecticide use, where they cause both acute and chronic bee kills, contribute to pollinator decline, pollute soil and water, and harm wildlife, including threatened and endangered invertebrate and bird species. Excessive honey bee mortality and wild pollinator declines are a major crisis for American agriculture as so many of our food crops require pollination. Because the coated crop seeds are not treated primarily to protect the seed itself, but rather to protect the growing plant, and have vast adverse impacts beyond the seed, they cannot be properly exempted as "treated articles." Nor can EPA continue to allow the coated seeds to avoid compliance with FIFRA's mandatory safety standards and enforceable labeling requirements.

This Petition seeks an amendment to, or a formal re-interpretation of, the Treated Article Exemption, 40 C.F.R. §152.25(a), to clearly communicate to the regulated community that systemic pesticidal seeds intended to kill insect pests of the plants are not included under the Treated Article Exemption and are therefore subject to FIFRA's requirements. Petitioners also request that EPA aggressively enforce FIFRA's registration and labeling requirements for each separate seed product coated with a systemic insecticide.

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CITIZEN PETITION TO THE U.S. ENVIRONMENTAL PROTECTION AGENCY SEEKING RULEMAKING OR A FORMAL AGENCY INTERPRETATION FOR PLANT SEEDS COATED WITH SYSTEMIC INSECTICIDES

INTRODUCTION

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 *et seq.*, the Environmental Protection Agency (EPA) regulates pesticide use in the United States. Currently, EPA does not enforce FIFRA's requirements as to a class of pesticides that includes crop seeds coated with systemic insecticides intended to kill pests of the plants. EPA improperly interprets the Treated Article Exemption, 40 C.F.R. §152.25(a), to exempt these pesticidal seeds from FIFRA's registration and labeling requirements. However, this class of pesticides causes widespread adverse effects on the environment and its exemption violates FIFRA for the reasons detailed herein. This Petition seeks an amendment to, or a formal re-interpretation of, that EPA regulation, 40 C.F.R. §152.25(a), to clearly communicate to the regulated community that systemic pestidical seeds intended to kill pests of the plants are not included under the Treated Article Exemption and are therefore subject to FIFRA's requirements for registration and labeling. To continue this unlawful exemption would be severely detrimental to Petitioners' interests. Petitioners also request that EPA aggressively enforce FIFRA's registration and labeling requirements for each separate seed product coated in systemic insecticides.

EPA has allowed millions of pounds of crop seeds, such as corn, soybean, and sunflower seeds, planted on almost 150 million acres each year, to be coated with four systemic insecticide active ingredients: acetamiprid, clothianidin, imidacloprid, and thiamethoxam (hereinafter "neonicotinoids").[1] These seeds coated with neonicotinoids and other systemic insecticides

[1] Brassard, D. 2012. Memorandum - Estimated Incremental Increase in Clothianidin Usage from Pending Registrations. EPA Biological Analysis Branch, Biological and Economic Analysis Division, Office of Chemical Safety and Pollution Prevention; *See* Answer ¶ 2, *Anderson v. McCarthy,* No. 3:16-cv-00068-WHA, ECF No.67 (N.D. Cal. May 27, 2016) ("between 2010 and 2014, approximately 142 million acres on average were planted with

intended to protect the plant will be referred to throughout as "coated seeds." Approximately ninety-five percent of the land area in the United States that is treated with any neonicotinoid insecticide is treated via planting coated seeds.[2] In the vast majority of cases, the coatings are not intended to protect the seed itself from any disease, pest, or predator. Rather, the coating chemicals are *systemic*, meaning they are absorbed into the plant's circulatory system as the plant grows and are predominately intended to have an external pesticidal effect on pests and predators of the growing plant. That effect is exerted not only on plant pests, but also on beneficial insects, valuable pollinators, and birds, including threatened and endangered species protected under the Endangered Species Act (ESA).[3] For many coated crop seeds, the coatings are abraded off of the seed as dust or are sloughed off the seed into the surrounding soil. Indeed, more than eighty to ninety percent of the chemical coating can move off of the seed to contaminate the air, soil, marginal vegetation, and waters.[4]

Over the past decade the increasing use of seeds coated with neonicotinoid insecticides has coincided with mass die-offs of honey bees and wild native bees. If left unchecked, these losses could precipitate an economic and ecological disaster impacting the Petitioners and the United States as a whole at a time when the nation can ill afford it. Honey bees not only produce nutritious honey, but are also of enormous economic importance to American agriculture as pollinators. About ninety percent of all flowering plants require pollinators to reproduce and nearly a third of pollination is performed by bees in American agriculture.[5] Honey bee

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seeds treated with [neonicotinoid] pesticides."). Note: after the initial filing of this Petition, copies of the footnoted supporting documents will be subsequently provided or their location will be indicated to EPA.

[2] Thomas Steeger, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA. *Bee health in the USA and the debate about Neonicotinoids*. Powerpoint dated April 11, 2014. Slide 8.

[3] 16 U.S.C. 1531 *et seq.*

[4] Goulson, D., 2014. Pesticides linked to bird declines. *Nature* 511:295-296; doi:10.1038/nature13642.

[5] United Nations, Food and Agriculture Organization. *Global Action on Pollination Services for Sustainable Agriculture*. Undated background report, *at* http://www.fao.org/pollination/background/en/; Johnson, R. and Corn,

pollination adds tens of billions of dollars annually in crop value. Healthy populations of all pollinators are essential for the future of American agriculture.

EPA has allowed this threat to pollinators to transpire without requiring the seeds to be registered under FIFRA or for the seed bags or tags to bear mandatory or enforceable labeling under FIFRA. The Agency has failed to adequately assess the risks of the unregulated seeds, instead exempting them from registration or labeling requirements and only registering the liquid coating products. EPA has never provided the public with any justification for its exemption. EPA's actions and inactions have led to excess bee colony mortality, declines in native bees, increased bird mortality, nationwide soil and water contamination, contaminated marginal vegetation and other environmental and economic harms, thereby severely damaging the Beekeeper Petitioners' businesses, while also damaging the land and welfare of the Farmer Petitioners and damaging the interests of the Public Interest Organization Petitioners.

EPA has approved other non-neonicotinoid systemic insecticides and appears poised to register additional systemic seed coatings. If additional systemic seed coatings are registered, the resulting seeds will present the same potential damage to Petitioners as the unregulated and unlabeled neonicotinoid-coated seeds. Thus, they also are subject to Petitioners' requests herein.

PETITION REQUESTS

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution[6] and the Administrative Procedure Act (APA),[7] Petitioners

L. 2015 *Bee Health: Background and Issues for Congress.* Congressional Research Service, No. 7-5700, at https://fas.org/sgp/crs/misc/R43191.pdf.

[6] U.S. CONST. amend. I.

[7] 5 U.S.C. § 553(e).

request the Administrator of EPA to take the following actions (please note Requests No. 1 and 2 are in the alternative):[8]

1. **Amend 40 C.F.R. § 152.25(a) to clarify that it does not apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself (shown in red):**

> **Treated articles or substances**. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation, but excluding seeds for planting coated with a systemic pesticide intended to kill pests of the plant) if the pesticide is registered for such use.

2. ***Alternatively*, publish a final, formal, agency interpretation in the Federal Register stating that EPA interprets the exemption in 40 C.F.R. § 152.25(a) not to apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself.**

3. **Aggressively enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic insecticidal chemical.**

Failure by the Administrator to take the requested actions would severely harm Petitioners' interests. It also would violate the mandates of FIFRA and would be arbitrary and capricious. In view of the severity of the impacts the Petitioners are suffering and EPA's excessive delays in resolving the concerns over its past application of the Treated Article

[8] EPA's lacks regulations for handling public petitions related to pesticides, a problem it has been urged by its Inspector General (IG) to cure. *EPA Needs Policies and Procedures to Manage Public Pesticide Petitions in a Transparent and Efficient Manner*. 2015. IG Report No. 16-P-0019, Washington, D.C., *at* www.epa.gov/sites/production/files/2015-10/documents/20151027-16-p-0019.pdf.

Exemption to seeds coated with systemic insecticides, the agency is urged to grant the requests in this Petition within **180 days** of its filing date.[9]

PETITIONERS

The eleven Petitioners are listed below by three groups: 1) Beekeepers, 2) Farmers and 3) Public Interest Organizations. The Appendix, incorporated herein, describes their particularized interests.

BEEKEEPER PETITIONERS: Bret Adee, American Beekeeping Federation, American Honey Producers Association, Jeff Anderson, David Hackenberg, Pollinator Stewardship Council

FARMER PETITIONERS: Lucas Criswell, Gail Fuller

PUBLIC INTEREST ORGANIZATION PETITIONERS: American Bird Conservancy, Center for Food Safety (CFS), Pesticide Action Network of North America

LEGAL BACKGROUND

FIFRA governs pesticide commercialization and application in the United States. The definition of "pesticide" is (in pertinent part), a "mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C. § 136(u)(1). FIFRA makes it unlawful, with a few minor exceptions, for any "person in any State [to] distribute or sell to any person any pesticide that is not registered" under the Act. 7 U.S.C. § 136a(a); *see also* 7 U.S.C. § 136j(a)(1).

FIFRA prohibits EPA from registering a pesticide if its widespread and commonly recognized use would have "unreasonable adverse effects on the environment." 7 U.S.C § 136a(c)(5). EPA has broad discretion to require all data necessary to support the registration (including the conclusion that the pesticide will not have unreasonable adverse environmental effects), including testing of the product for effects on pollinators. *Id.* § 136a(c)(2)(A); *see e.g.,* 40 C.F.R. § 158.630.

[9] EPA has refused to correct these failures regarding its exemption of systemic coated seeds despite prior oral and written requests to do so made by many of the Petitioners since at least 2015.

The Administrator is required to provide public notice and comment opportunities for registrations under 7 U.S.C. § 136a(c)(4):

> Notice of application. The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

EPA's FIFRA-implementing regulations also contain procedural requirements for product registration, including, but not limited to, requiring publication of two classes of notices in the Federal Register. Under 40 C.F.R. § 152.102:

> The Agency will issue in the Federal Register a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the Federal Register a notice of issuance. The notice of issuance will describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application.

The culmination of the registration process, if followed, is EPA's official approval of a label for the pesticide product, including use directions and appropriate warnings on safety and environmental risks. It is a violation of FIFRA for any person to sell or distribute a "misbranded" pesticide product. 7 U.S.C. § 136j(a)(1)(E). FIFRA is explicit in requiring EPA to find a product misbranded and, under 7 U.S.C. § 136(q)(1), may not be used, if:

> (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment; [or]
>
> (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment.

With regard to exemptions from FIFRA, the "Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." 7 U.S.C. § 136w(b). EPA's implementing regulation for such exemptions, at 40 C.F.R. § 152.25, provides (in pertinent part; this is known as the Treated Article Exemption):

> **Exemptions for pesticides of a character not requiring FIFRA regulation**. The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.
>
> (a) Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

FACTS

I. Characteristics of Neonicotinoid-Coated Seeds.

The systemic nature of neonicotinoid-coated seeds renders them qualitatively and quantitatively different from other seeds. Seeds coated with liquid formulations of these chemicals are pesticide delivery devices. The purpose of this technology is to carry the active ingredient via the growing plants' circulatory systems into the tissues of the plants, which ultimately are typically hundreds or even thousands of times larger in dimension and mass than the seed itself. Common crops with neonicotinoid-coated seeds include, but are not limited to:

canola, field and sweet corn, cotton, cucurbits, legume vegetables, potatoes, soybean, sunflowers, and wheat.[10]

Given the lack of pesticide usage data collected by EPA, comprehensive data on the usage of clothianidin (most common product is Bayer CropScience's Poncho®), thiamethoxam (most common product is Syngenta's Cruiser®), and imidacloprid (most common product is Bayer and Valent USA's Gaucho®) have been scarce. However, EPA's preliminary risk assessments on those three neonicotinoid active ingredients released in January of 2017 revealed that 42 million to 61 million acres of corn are treated with clothianidin via seed coatings annually (45% to 65% of all U.S. corn acres) and 24 million to 42 million acres of corn are treated with thiamethoxam (26% to 45% of all U.S. corn acres).[11] That means close to 100% of U.S. corn acres are likely treated with one of these two neonicotinoid insecticides.

In soybeans, 13 million to 21 million acres are treated with thiamethoxam (16% to 25% of all U.S. soybean acres), and 2.1 million acres are treated with clothianidin each year (3% of all U.S. soybean acres).[12] Although the acreage of imidacloprid-treated soybean was not reported, EPA did report that 36% of all imidacloprid use is on soybeans as seed treatment, representing the largest increase in imidacloprid use from 2004-2013, from 300,000 to 400,000 pounds annually.[13] EPA also included the usage data on imidacloprid from U.S. Geological Survey, indicating that over 800,000 pounds of imidacloprid were applied to soybeans in 2014.[14] For comparison, that is nearly three times the amount of thiamethoxam applied to soybeans each

[10] K. Stoner, Conn. Ag. Expt. Station, *Best Management Practices for Farmers Using Seeds Treated With Neonicotinoid Insecticides*. Unpublished report, *at* www.dem.ri.gov/programs/agriculture/documents/pwg_docs_seeds_neonicotinoids.pdf.
[11] EPA, *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam,* pp. 33-35, Tables 2.4 and 2.6 (Released Jan. 5, 2017), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0865-0173.
[12] *Id.*
[13] EPA, *Preliminary Aquatic Risk Assessment to Support Registration Review of Imidacloprid*, pp. 21-24 (Released Jan. 12, 2017), https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-1086.
[14] *Id.*, p. 23, Fig. 3-3.

year, which accounted for 13 million to 21 million acres. Thus, likely nearly 50% of soybean fields were planted with one of the neonicotinoid coatings.

While even less use data is publicly available for the other crops, EPA has stated in documents and legal filings that the estimated acreage planted with coated seeds amounts to at least 140 million acres nationally.[15] That is close to one-fifteenth of the entire land surface of the lower forty-eight states.[16]

The dried-on insecticidal coatings do not, in the vast majority of their uses, protect the seed itself against any disease or other risk to the seed. The neonicotinoid ingredients are predominately aimed at protecting the growing crop plants, later in time, as demonstrated by the EPA-approved labels placed on the bottles/containers of the liquid coating products. EPA is known to have approved fifteen new coating product registrations and their label language since January 1, 2010.[17] (See Table 1, *infra*.) All but two of those products (i.e., thirteen out of fifteen)

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[15] See n.1, ***supra.***

[16] U.S. land total from *Land and Water Area of States*, www.infoplease.com/ipa/A0108355.html.

[17] The 15 coating products and initial labels are listed below; note that most of these products are labeled for more than one crop use (see Table 1, below): **1**. Prosper Evergol (date of first EPA label approval—May 11, 2012), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01121-20120511.pdf; **2**. Poncho Votivo (date of first label approval—Mar. 16, 2010), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01109-20100316.pdf; **3**. Emesto Quantum (date of first label approval—May 11, 2012), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01125-20120511.pdf; **4**. INOVATE Seed Protectant (date of first label approval—June 21, 2011), *at* https://www3.epa.gov/pesticides/chem_search/ppls/059639-00176-20110621.pdf; **5**. Sepresto 75 WS (date of first label approval—Apr. 28, 2010), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01081-20100428.pdf; **6**. NipsIt SUITE Cereals of Seed Protectant (date of first label approval—Dec. 21, 2011), *at* https://www3.epa.gov/pesticides/chem_search/ppls/059639-00183-20111221.pdf; **7.** PONCHO/GB126 (date of first label approval—Apr. 29, 2011), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000264-01132-20110429.pdf; **8**. Helix Vibrance (date of first label approval—June 3, 2014), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01528-20140603.pdf; **9**. CruiserMaxx Potato Extreme (date of first label approval—June 12, 2013), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01444-20130612.pdf; **10**. CruiserMaxx Vibrance (date of first label approval—Feb. 27, 2014), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01508-20140227.pdf; **11**: Avicta Complete Beans 500 (date of first label approval—Jan. 15, 2013), at https://www3.epa.gov/pesticides/chem_search/ppls/000100-01457-20130115.pdf; **12**: SYT0511 (date of first label approval—Jan. 30, 2013), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01460-20130130.pdf; **13**: SYT0113 (date of first label approval—Jan. 30, 2013), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01459-20130130.pdf; **14**: Cruiser Vibrance Quattro (date of first label approval—May 29, 2014), *at* https://www3.epa.gov/pesticides/chem_search/ppls/000100-01527-20140529.pdf; **15**: Dyna-shield Foothold Virock

lack a clear label claim that the neonicotinoid ingredient protects the planted seed itself; the labels generally state that the neonicotinoids are to kill "chewing and sucking insect pests" of the growing *plants*, not of the seeds.[18] (Several of the labels have unclear claims.) Moreover, the label warnings frequently indicate that the neonicotinoids actually may *harm* the seeds and result in reduced germination and/or reduction of seed and seedling vigor.[19] Depending on the crop, up to ninety percent of the insecticide is either scraped off the seeds and blown away as dust during machine planting, or sloughed off into the surrounding soil and groundwater.[20] In short, the alleged neonicotinoid "treatment" is predominately not "for the protection of the article itself"—the seed.

II. The Treated Article Exemption.

The Treated Article Exemption, 40 C.F.R. § 152.25(a), was first promulgated in 1988. Pesticide-coated seeds were neither mentioned in the regulation text nor in the Federal Register notice accompanying the exemption.[21] In 2003, EPA publicly stated a view on the Treated Article Exemption and pesticide-coated seeds in a paper issued jointly by EPA and the Pest Management Regulatory Agency of Canada, *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States* (hereinafter "Harmonization Paper").[22] The Harmonization Paper mentions pesticide-coated seeds, but it provides no coverage or analysis of systemic insecticide or neonicotinoid-coated seeds. Rather than supporting an interpretation that

(date of first label approval—Apr. 30, 2014), *at* https://www3.epa.gov/pesticides/chem_search/ppls/034704-01090-20140430.pdf.

[18] The exceptions are No. 1, Prosper Evergol, and No. 5 Sepresto 75 WS, above, the labels for which include at least one explicit *seed* protection claim for the neonicotinoid ingredient(s). Several other labels have unclear claims with respect to whether protection of the seed is provided by the neonicotinoid ingredients or other ingredients. Typically it is the *non*-neonicotinoid active ingredients that are claimed to protect the seed *per se*.

[19] *Id.*

[20] Goulson 2014, *supra,* n.4.

[21] EPA, Pesticide Registration Procedures; Pesticide Data Requirements. Final Rule. 53 Fed. Reg. 15,977, May 4, 1988.

[22] *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United* States April 11, 2003, pp. 1-2, (Joint Regulatory Directive of EPA and the Pest Management Regulatory Agency of Canada), perma.cc/3MUH-B9VQ.

systemic, neonicotinoid-coated seeds properly fit within the Treated Article Exemption described in 40 C.F.R. §152.25(a), the Harmonization Paper instead indicates that such coated seeds actually should be *excluded* from the exemption:

> The term "for the protection of the [seed] itself" means that the pesticidal protection imparted to the treated seed *does not extend beyond the seed itself*. . . .[23]

Clear and convincing evidence shows that the pesticidal "protective" effect of the scraped, blown, and sloughed-off neonicotinoid coatings "extends beyond the seed itself," and extends far beyond the full-grown plants. As explained more fully below, these harms stem from both the effects of the coatings that come off the seed and from the gross overuse of this systemic class of insecticides. Uncontained dust and contamination from these coatings is killing honey bees by the many millions and imposing a potentially catastrophic hazard to aquatic systems across the nation.[24] Both freshwater and marine systems and the invertebrate and vertebrate wildlife—such as fish and waterfowl—that they contain are being harmed. In addition to direct mortality to birds from ingesting neonicotinoid-coated seeds, indirect mortality is resulting from the destruction of rural invertebrate life across a vast portion of the United States.[25] Coated seeds are planted year after year and the active ingredients have long half-lives in most soils, exceeding the planting intervals. Thus, the contamination has swiftly built up to, and past, harmful levels in America's lands and waters.

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[23] *Id.* at 2 (emphasis added).

[24] Morrissey, CA, Mineau, P., Devries, JH, Sanchez-Bayo, F., Liess, M, Cavallaro, MC, and Liber, K. 2015. Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review. *Environment International*, 74: 291-303; Sánchez-Bayo, F., Goka, K., and Hayasaka, D. 2016 Contamination of the Aquatic Environment with Neonicotinoids and its Implication for Ecosystems. *Front. Environ. Sci. 4:71.* doi: 10.3389/fenvs.2016.00071, *at*: http://journal.frontiersin.org/article/10.3389/fenvs.2016.00071/full; Carnemark, M., Jenkins, P., and Walker, L. 2015. *Water Hazard: Aquatic Contamination by Neonicotinoid Insecticides in The United States*. Unpublished report, CFS, Washington, D.C., *at* www.centerforfoodsafety.org/files/neonic-water-report-final-242016_web_33288.pdf and Carnemark, M. *Water Hazard 2.0,* CFS, 2017.

[25] *Id.*

The risks of the systemic insecticides appear to have not been foreseen by the registrants of the neonicotinoid liquid coating products or by EPA in applying its Treated Article Exemption to the coated seeds. The exemption has allowed these unregistered, unlabeled insecticides to outcompete and displace other *FIFRA-registered* insecticides and other less risky crop protection methods in U.S. agricultural markets. Their aggressive marketing has directly led to vastly more use of insecticides on crops for which no insecticides were needed or used by farmers in the years before these products were sold. This prophylactic use of coated seeds is incompatible with the principles of Integrated Pest Management.[26]

III. EPA's Coating Product Approvals.

While exempting the various neonicotinoid-coated crop seeds themselves, EPA has approved and registered the liquid coating products to be applied to seeds in a facility before sale or in limited cases by farmers themselves. However, EPA has failed to fully assess the adverse effects, described in this Petition, of the systemic insecticide beyond the seed coating process. Table 1 indicates unregistered pesticidal crop seeds with fifteen coating products that EPA approved since January 1, 2010.[27]

[26] Iowa State University, et al. 2015. *The Effectiveness of Neonicotinoid Seed Treatments in Soybean*. Unpublished extension report, *at* www.extension.umn.edu/agriculture/soybean/pest/docs/effectiveness-of-neonicotinoid-seed-treatments-in-soybean.pdf.

[27] See labels listed in n.17, *supra.*

Table 1: Unregistered Pesticidal Crop Seeds Approved Since 2010.

Active Ingredient	Coating Product	Pesticidal Crop Seeds
Clothianidin		
	Prosper Evergol	Canola, rapeseed and mustard
	Poncho Votivo/ Poncho 1250 Votivo	Corn, cotton, sorghum, soybean and sugarbeet
	Ernesto Quantum	Cotton
	Inovate	Soybean
	Sepresto 75 WS	Barley, buckwheat, corn, millet, oats, popcorn, rye, sorghum, teosinte, triticale, wheat, potato seed pieces, carrot, onion bulbs, leek, bunching onion, and broccoli
	NipsIt Suite Cereals Seed Protectant	Barley, oat and wheat
	Poncho/GB126	Sugarbeet, barley, buckwheat, millet, oats, rye, teosinte, triticale and wheat
Thiamethoxam		
	Helix Vibrance	Canola
	CruiserMAXX Potato Extreme	Potato
	CruiserMAXX Vibrance	Soybean
	Avicta Complete Beans	Soybean
	SYT0511 and SYT0113	Soybean
	Cruiser Vibrance Quattro	Small grain cereals
Imidacloprid		
	Dynashield Foothold Virock	Barley and wheat

Source: EPA Pesticide Product and Label System database, *at* https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

This Petition addresses all such pesticidal seeds, including both those listed in Table 1 and other older or newer pesticidal seeds products not listed in Table 1. The number of different crops in Table 1 totals at least twenty-five. The seeds are sold by various marketers under a large variety of product line names or numbers that typically, but not always, include the seed coatings.[28]

EPA's Risk Assessments (RAs) for the coating products ignore numerous risks of planting the resulting seeds, such as the toxic abraded dust-off, due to EPA's inclusion of the

[28] A non-exhaustive sample list includes: 1) Wyffels Hybrid corn lines W1526RIB; 1528RIB; and W1690, shipped coated with Poncho, *see* perma.cc/9N92-QAC5; and 2) the Pioneer Brand T Series of soybean seeds coated with Pioneer Premium Seed Treatment, *see* perma.cc/R8X8-FV9A.

coated seeds themselves under the Treated Article Exemption. This is most vividly illustrated in EPA's 2016 *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid*.[29] It discloses that: "Mitigation of risks from abraded seed coating are addressed *outside* of this process." The identical assertion that EPA's risk assessors are not actually analyzing the external effects and risks of the abraded coatings is repeated in the Preliminary RAs for both thiamethoxam and clothianidin.[30] The Agency's claims that the risks are addressed "outside of" the formal RA process are not supported by any evidence.

Further, the large majority of the coating products listed in Table 1 were "conditionally registered" under FIFRA, indicating that key information needed for their full risk evaluation was not produced by the registrants to allow an unconditional registration.[31] Extensive information gaps remain for the resulting coated seeds.

IV. Major Reviews and Studies on Harms of Coated Seeds.

The full scope of harms have been revealed by extensive scientific monitoring and analysis, including an authoritative 2014 global review of over 800 published studies conducted under the auspices of the International Union for the Conservation of Nature (IUCN).[32] That expert review determined that neonicotinoids were dangerously overused and should be restricted. Based on detailed assessments by the European Food Safety Agency (EFSA), the European Union (EU) voted to prohibit their use on seeds of most crops largely due to dust-off

[29] EPA-HQ-OPP-2008-0844-0140, p. 36, lower left corner of Fig. 2-5 "Tiered approach for assessing risk to honey bees from soil/seed applications," (Released Jan. 6, 2016), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-0140.

[30] EPA, *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam*, p. 46, lower left corner of Fig. 2-5 "Tiered approach for assessing risk to honey bees from soil/seed applications," (Released Jan. 5, 2017), *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0865-0173 .

[31] Conditional registration requires the registrants to meet EPA's conditions regarding missing data, such as to conduct studies to fill specific data gaps, within a set timeframe. 7 U.S.C. § 136a(c)(7)(C).

[32] Van der Sluijs J.P., *et al*., 2014. *Conclusions of the Worldwide Integrated Assessment on the risks of neonicotinoids and fipronil to biodiversity and ecosystem functioning*, Environ. Sci. Pollut. Res. 22 (1), 148-154, *at* perma.cc/7RVA-FMA7.

and other harmful effects on bees.[33] That prohibition has been in effect since the EU vote in 2013.

In a 2017 review and update of the evidence that EFSA considered, Wood and Goulson published the comprehensive *Environmental Risks of neonicotinoid pesticides: a review of the evidence post-2013*.[34] Examining eight risk topics, the authors sought "to summarize how the new evidence has changed our understanding of the likely risks to bees; is it lower, similar or greater than the risk perceived in 2013"? The study vindicated the EU's 2013 prohibition, finding no decreased risk for any topics. For six risk topics they found them to be "Risk Unchanged." Evidence for the two topics connected with seed coatings pointed to a "Greater Risk."[35] Wood and Goulson also found extensive new evidence of what they labeled "broader risks to environmental health" that were not fully understood in 2013. They concluded:

> Field-realistic laboratory experiments and field trials continue to demonstrate that traces of residual neonicotinoids can have a mixture of lethal and sublethal effects on a wide range of taxa. . . . Relative to the risk assessments produced in 2013 for clothianidin, imidacloprid and thiamethoxam which focused on their effects on bees, new research strengthens arguments for the imposition of a moratorium, in particular because it has become evident that they pose significant risks to many non-target organisms, not just bees.

Acting to protect wildlife on Refuges, the U.S. Fish and Wildlife Service (FWS) prohibited all neonicotinoids from use in all National Wildlife Refuges as of January 1, 2016, because the Service: [36]

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[33] Official Journal of the European Union, Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013, amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances, L 139/12; 25.5.2013, *at* http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:139:0012:0026:EN:PDF.

[34] Wood, T.J. and Goulson, D. 2017. *The Environmental Risks of neonicotinoid pesticides: a review of the evidence post-2013***.** Unpublished report for Greenpeace. Paris, France, *available at* http://www.greenpeace.org/international/Global/international/publications/agriculture/2017/neonicotinoid-pesticides.pdf.

[35] Wood and Goulson 2017, *supra*, p. 8. The two "Greater Risk" findings are for these topic areas: "Risk of exposure from and uptake of neonicotinoids in non-crop plants" and "Sublethal effects of neonicotinoids on wild bees."

[36] Memorandum from James W. Kurth, Chief, National Wildlife Refuge System, U.S. Department of the Interior, Fish and Wildlife Service, *Use of Agricultural Practices in Wildlife Management in the National Wildlife Refuge*

> . . . determined . . . prophylactic use, such as a seed treatment, of the neonicotinoid pesticides that can distribute systematically in a plant and can potentially affect a broad spectrum of non-target species.

The FWS also has found that these seeds are among the neonicotinoid uses that are "strongly implicated" as a factor in the "endangered" classification under the ESA that the agency gave to the once-common Rusty Patched Bumble Bee.[37] The agency stated (citations omitted; emphasis added):[38]

> Neonicotinoids are a class of insecticides used to target pests of agricultural crops, forests (for example, emerald ash borer), turf, gardens, and pets and *have been strongly implicated as the cause of the decline of bees in, and specifically for rusty patched bumble bees,* due to the contemporaneous introduction of neonicotinoid use and the precipitous decline of the specie. . . . The use of *neonicotinoids rapidly increased as seed-applied products were introduced* in field crops, marking a shift toward large-scale, preemptive insecticide use.

A major review by the American Bird Conservancy stated that a *single* corn kernel treated with any of the common neonicotinoids could kill a songbird and just one-tenth of a treated corn kernel is enough to adversely affect a songbird's reproduction.[39]

Peer-reviewed, published studies from just the last two years further illustrate harmful effects from these coated seeds, effects that EPA's RAs for the coating chemicals have failed to assess. A list of the studies and excerpts of their abstracts follows:

1) Alburaki et al. 2015.[40] Indicating that neonicotinoid exposures increase pathogen risks

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System 1 (July 17, 2014), *at* www.centerforfoodsafety.com/files/agricultural-practices-in-wildlife-management_20849.pdf.

[37] Department of the Interior, U.S. Fish and Wildlife Service. Final rule, Endangered Species Status for Rusty Patched Bumble Bee, 82 Fed. Reg. 3,186, January 11, 2017, *at* https://www.fws.gov/midwest/endangered/insects/rpbb/pdf/FRFinalListingRuleRPBB11Jan2017.pdf

[38] *Id.,* at p. 3,190; *see also* p. 3,201.

[39] Mineau, P. and Palmer, C. 2013. *The Impact of the Nation's Most Widely Used Insecticides on Birds.* American Bird Conservancy, *at*: www.abcbirds.org/abcprograms/policy/toxins/Neonic_FINAL.pdf.

and weaken honey bee colonies:

> Thirty-two honeybee (Apis mellifera) colonies were studied in order to detect and measure potential in vivo effects of neonicotinoid pesticides used in cornfields (Zea mays spp) on honeybee health . . . Hives were extensively monitored for their performance and health traits over a period of two years. Honeybee viruses (brood queen cell virus BQCV, deformed wing virus DWV, and Israeli acute paralysis virus IAPV) and the brain specific expression of a biomarker of host physiological stress, the Acetylcholinesterase gene AChE, were investigated using RT-qPCR . . . In addition, general hive conditions were assessed by monitoring colony weight and brood development. Neonicotinoids were only identified in corn flowers at low concentrations. However, honeybee colonies located in neonicotinoid treated cornfields expressed significantly higher pathogen infection than those located in untreated cornfields. AChE levels showed elevated levels among honeybees that collected corn pollen from treated fields. *Positive correlations were recorded between pathogens and the treated locations. Our data suggests that neonicotinoids indirectly weaken honeybee health by inducing physiological stress and increasing pathogen loads*.

2) **Botias et al. 2016.**[41] Seed-coating of canola with neonicotinoids in the UK led to frequently high-level contamination of marginal vegetation:

> …we analysed samples of foliage collected from neonicotinoid seed-treated oilseed rape plants and also compared the levels of neonicotinoid residues in foliage (range: 1.4–11 ng/g) with the levels found in pollen collected from the same plants (range: 1.4–22 ng/g). We then analysed residue levels in foliage from non-target plants growing in the crop field margins (range: ≤0.02–106 ng/g). Finally, in order to assess the possible risk posed by the peak levels of neonicotinoids that we detected in foliage for farmland phytophagous and predatory insects, we compared the maximum concentrations found against the LC50 values reported in the literature for a set of relevant insect species. *Our results suggest that neonicotinoid seed dressings lead to widespread contamination of the foliage of field margin plants with mixtures of neonicotinoid residues, where levels are very variable and*

[40] Alburaki, M., Boutin, S., Mercier, PL, Loublier, Y., Chagnon, M., and Derome, N. 2015. Neonicotinoid-coated *Zea mays* seeds indirectly affect honeybee performance and pathogen susceptibility in field trials. *Plos One*, 10(5): p.e0125790, doi:10.1371/journal.pone.012579 (emphasis added).

[41] Botías, C., David, A., Hill, EM, and Goulson, D., 2016. Contamination of wild plants near neonicotinoid seed-treated crops, and implications for non-target insects. *Science of the Total Environment*, 566: 269-278 (emphasis added).

> *discontinuous, but sometimes overlap with lethal concentrations reported for some insect species*.

3) **David et al. 2016.**[42] Marginal vegetation near treated-seed canola fields was contaminated with high levels of neonicotinoids and other chemicals with synergistic effects:

> Here, we quantify concentrations of neonicotinoid insecticides and fungicides in the pollen of oilseed rape, and in pollen of wildflowers growing near arable fields. We then compare this to concentrations of these pesticides found in pollen collected by honey bees and in pollen and adult bees sampled from bumble bee colonies placed on arable farms. We also compared this with levels found in bumble bee colonies placed in urban areas. Pollen of oilseed rape was heavily contaminated with a broad range of pesticides, as was the pollen of wildflowers growing nearby. Consequently, pollen collected by both bee species also contained a wide range of pesticides, notably including the fungicides carbendazim, boscalid, flusilazole, metconazole, tebuconazole and trifloxystrobin and the neonicotinoids thiamethoxam, thiacloprid and imidacloprid. . . *It is notable that pollen collected by bumble bees in rural areas contained high levels of the neonicotinoids thiamethoxam (mean 18 ng/g) and thiacloprid (mean 2.9 ng/g), along with a range of fungicides, some of which are known to act synergistically with neonicotinoids*.

4) **Millot et al.**[43] Review of bird mortalities in France documented a high proportion resulted from common farmland birds consuming neonicotinoid-coated seeds:

> The large-scale use of neonicotinoid insecticides has raised growing concerns about their potential adverse effects on farmland birds, and more generally on biodiversity. Imidacloprid, the first neonicotinoid commercialized, has been identified as posing a risk for seed-eating birds when it is used as seed treatment of some crops since the consumption of a few dressed seeds could cause mortality. But evidence of direct effects in the field is lacking. Here, we reviewed the 103 wildlife mortality incidents reported by

[42] David, A., Botías, C., Abdul-Sada, A., Nicholls, E., Rotheray, EL, Hill, EM, and Goulson, D., 2016. Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops. *Environment International*, 88: 169-178 (emphasis added).

[43] Millot, F., Decours, A. *et al.*, 2016. Field evidence of bird poisonings by imidacloprid-treated seeds: a review of incidents reported by the French SAGIR network from 1995 to 2014 Environ *Sci Pollut Res* DOI 10.1007/s11356-016-8272-y (emphasis added).

> the French SAGIR Network from 1995 to 2014, for which toxicological analyses detected imidacloprid residues. One hundred and one incidents totalling at least 734 dead animals were consistent with an agricultural use as seed treatment. Grey partridges (Perdix perdix) and "pigeons" (Columba palumbus, Columba livia and Columba oenas) were the main species found. More than 70% of incidents occurred during autumn cereal sowings. Furthermore, since there is no biomarker for diagnosing neonicotinoid poisonings, we developed a diagnostic approach to estimate the degree of certainty that these mortalities were due to imidacloprid poisoning. By this way, *the probability that mortality was due to poisoning by imidacloprid treated seeds was ranked as at least "likely" in 70% of incidents. As a result, this work provides clear evidence to risk managers that lethal effects due to the consumption by birds of imidacloprid-treated seeds regularly occur in the field*. This in turn raises the question of the effectiveness of the two main factors (seed burying and imidacloprid-treated seeds avoidance) that are supposed to make the risk to birds negligible.

5) Mogren and Lundgren. 2016.[44] Set-aside vegetation strips near farms did not protect bees from nutritional harms caused by adjacent corn fields planted with clothianidin-coated seeds:

> Pollinator strips were tested for clothianidin contamination in plant tissues, and the risks to honey bees assessed. An enzyme-linked immunosorbent assay (ELISA) quantified clothianidin in leaf, nectar, honey, and bee bread at organic and seed-treated farms. Total glycogen, lipids, and protein from honey bee workers were quantified. The proportion of plants testing positive for clothianidin were the same between treatments. Leaf tissue and honey had similar concentrations of clothianidin between organic and seed-treated farms. Honey (mean ±SE: 6.61 ± 0.88 ppb clothianidin per hive) had seven times greater concentrations than nectar collected by bees (0.94 ± 0.09 ppb). Bee bread collected from organic sites (25.8 ± 3.0 ppb) had significantly less clothianidin than those at seed treated locations (41.6 ± 2.9 ppb). Increasing concentrations of clothianidin in bee bread were correlated with decreased glycogen, lipid, and protein in workers. *This study shows that small, isolated areas set aside for conservation do not provide spatial or temporal relief from*

[44] Mogren, CL and Lundgren, JG, 2016. Neonicotinoid-contaminated pollinator strips adjacent to cropland reduce honey bee nutritional status. *Scientific Reports*, 6:29608; DOI: 10.1038/srep29608 (emphasis added).

> *neonicotinoid exposures in agricultural regions where their use is largely prophylactic*.

6) **Rundlof et al**. **2015.**[45] Harm to wild bumblebees and other wild bees (which mostly are solitary) from clothianidin-coated canola seeds in a major field study in Sweden, published in *Nature*:

> Here we show that a commonly used insecticide seed coating in a flowering crop can have serious consequences for wild bees. In a study with replicated and matched landscapes, we found that *seed coating with Elado, an insecticide containing a combination of the neonicotinoid clothianidin and the non-systemic pyrethroid b-cyfluthrin, applied to oilseed rape seeds, reduced wild bee density, solitary bee nesting, and bumblebee colony growth and reproduction under field conditions. Hence, such insecticidal use can pose a substantial risk to wild bees in agricultural landscapes, and the contribution of pesticides to the global decline of wild bees may have been underestimated*. The lack of a significant response in honeybee colonies suggests that reported pesticide effects on honeybees cannot always be extrapolated to wild bees.

7) **Woodcock et al**. **2016.**[46] Planting neonicotinoid-treated canola seed is an important factor in the *extinction* of wild bee species in Britain:

> *We relate 18 years of UK national wild bee distribution data for 62 species to amounts of neonicotinoid use in oilseed rape. Using a multi-species dynamic Bayesian occupancy analysis, we find evidence of increased population extinction rates in response to neonicotinoid seed treatment use on oilseed rape*. Species foraging on oilseed rape benefit from the cover of this crop, but were on average three times more negatively affected by exposure to neonicotinoids than non-crop foragers. Our results suggest that sub-lethal effects of neonicotinoids could scale up to cause losses of bee biodiversity. *Restrictions on neonicotinoid use may reduce population declines*.

[45] Rundlöf, M., Andersson, GK, Bommarco, R., Fries, I., Hederström, V., Herbertsson, L., Jonsson, O., Klatt, BK, Pedersen, TR, Yourstone, J., and Smith, HG, 2015. Seed coating with a neonicotinoid insecticide negatively affects wild bees. *Nature*, 521(7550): 77-80. (emphasis added).

[46] Woodcock, BA, NJ Isaac, JM Bullock, DB Roy, DG Garthwaite, A Crowe, and RF Pywell. 2016. Impacts of neonicotinoid use on long-term population changes in wild bees in England. *Nature Communications*, 7: 12459 (emphasis added).

V. Honey Bee Kills and Other Costs.

Pervasive use of these chemicals, particularly on corn and soybeans, is resulting in pesticide contamination of vast areas extending far beyond the planted fields. Many beekeepers have observed toxic dust clouds billowing from seed planting machines, spreading the insecticides far and wide: to neighboring farms, onto marginal vegetation visited by their bees, into waterways, and even directly onto their beehives. Honey bee kill incidents caused by neonicotinoid-coated seeds have numbered in the hundreds and likely many more.[47] These incidents have likely killed hundreds of millions of individual bees due to acute dust-off kills and chronic damage to bee hives. As a result, for Beekeeper Petitioners Anderson, Adee, and Hackenberg and other beekeepers represented by Petitioners American Beekeeping Federation, American Honey Producers Association and Pollinator Stewardship Council, their honey production and the overall profitability of their business have drastically declined, while their workloads and personal stress have multiplied.

A recent scientific study from England showed high and unexpected contamination in honey bee hives resulting from seed coatings, originating with contaminated marginal vegetation near the canola fields rather than from the canola pollen.[48] Honey bees examined in the study were collecting enough neonicotinoids to damage their productivity and reproduction rate. Similarly, a Canadian study found unexpectedly high levels of neonicotinoids in the surface dust of arable fields and evidence that this dust blows into adjoining fields, contaminating them and

[47] For a source on beekills that is not comprehensive but is illustrative of the problem, see Pollinator Stewardship Council, Reported Bee Kills, at http://pollinatorstewardship.org/?page_id=1428. Beekeepers typically do not report their dust-off kills systematically as there are no Federal or State enforcement responses due to the exemption that is the focus of this Petition.

[48] Botias, *et al*., 2015. Neonicotinoid rresidues in wwildflowers, a ppotential rroute of cchronic cexposure for bees, *Environ. Sci. Technol.* 49(21): 12731-12740, *available at* perma.cc/G2PY-UF25.

putting surface-living beneficial species at risk.[49] Sublethal doses can result in honey bee colony damage through chronic effects, including compromising the behavior, health, and immunity of colonies, thus causing them to collapse under the additional stress of pathogens and parasites.[50]

The costs of neonicotinoid-coated seeds and their resulting contamination include, at a minimum, these foreseeable categories: 1) harmful honey bee colony effects and resulting reduced yields of pollinated crops; 2) reduced production of honey and other bee products; 3) financial harm to beekeepers and consumers; 4) loss of ecosystem services; and 5) market damage from contamination events.[51] Estimated cumulative, direct, and indirect costs of this contamination to date across these five categories are in the tens of *billions* of dollars.[52] The Beekeeper Petitioners have personally experienced many of the economic harms associated with bee kills and the decline of pollinators, as stated in the Interests of the Petitioners in the Appendix.

The harm to native bees, which are essential pollinators but that lack commercial valuation, is nationwide and incalculable. Unmanaged and often living in contaminated soil, species such as bumblebees, ground-nesting mining bees, alkali bees, squash bees, and long-horned sunflower bees are harmed by repeated, persistent use of the coated seeds. Adverse impacts to other species of native bees that are not ground nesters also has been identified, particularly due to the high toxicity of neonicotinoids to blue orchard bees and alfalfa leafcutter

[49] Victor Limay-Rios, *et al*., 2015. Neonicotinoid insecticide residues in soil dust and associated parent soil in fields with a history of seed treatment use on crops in Southwestern Ontario, *Environ. Toxicol. Chem.* 35(2):303-10. doi: 10.1002/etc.3257, *available at* perma.cc/4PTA-HQRN.

[50] Dussaubat, C., Maisonnasse, A., Crauser, D., Tchamitchian, S., Bonnet, M., Cousin, M., Kretzschmar, A., Brunet, JL, and Le Conte, Y., 2016. Combined neonicotinoid pesticide and parasite stress alter honeybee queens' physiology and survival. *Scientific Reports*, 6:31430; DOI: 10.1038/srep31430; Sánchez-Bayo, F., Goulson, D., Pennacchio, F., Nazzi, F., Goka, K., and Desneux, N., 2016. Are bee diseases linked to pesticides?—a brief review. *Environment International*, 89:7-11.

[51] Stevens S., and Jenkins, P., 2014. *Heavy Costs: Weighing the Value of Neonicotinoid Insecticides in Agriculture.* Unpublished report, CFS, Washington, D.C., pp. 12-15, *at* http://www.centerforfoodsafety.org/files/neonic-efficacy_digital_29226.pdf.

[52] *Id.*

bees.[53] While blue orchard and leafcutter bees do not nest in the soil, they rely on plant materials and mud for building their brood cells and can be contaminated through those nesting materials and other exposure routes. None of the risks to native bees are captured in EPA's Pollinator RAs issued in 2016 and 2017 for the three main active ingredients in the seed coating products: imidacloprid, clothianidin and thiamethoxam.

VI. Harm to Threatened and Endangered Species.

The sum lesson of the voluminous science cited throughout this Petition is that the pesticidal coated-seeds may affect broad groups of non-target animals. These range from direct harm to both managed and wild bees and other beneficial terrestrial insects, to contaminated run-off decimating aquatic invertebrates, to both acute and chronic effects on birds that ingest the seeds. Within each of those animal groups are many threatened and endangered species protected under the ESA. The 2017 listing of the rusty patched bumble bee, mentioned above, is one example of species listed partially because it is directly affected by the use of neonicotinoid coated seeds. Two butterflies listed in 2014 also had neonicotinoid-coated seeds explicitly singled out by the FWS as a significant factor that led to their listings: Dakota skipper (*Hesperia dacotae*) and Poweshiek skipperling (*Oarisma poweshiek*).[54]

Nationally and internationally recognized experts, Drs. John Stark of Washington State University, John Losey of Cornell University, and Pierre Mineau, a consultant formerly with Environment Canada, have submitted formal expert opinions identifying at least these five

[53] Hopwood, J., Code, A., Vaughan, M., Biddinger, D., Shepherd, M., Black, S.H., Mader, E., and Mazzacano, C., 2016 *How Neonicotinoids Can Kill Bees* 2d Ed., Unpublished report, Xerces Society for Invertebrate Conservation, Portland, OR, *at* www.xerces.org/wp-content/uploads/2016/10/HowNeonicsCanKillBees_XercesSociety_Nov2016.pdf.

[54] 79 Fed. Reg. 63,672 (Oct. 24, 2014)(codified at 50 C.F.R. pt. 17), *available at* https://www.fws.gov/midwest/endangered/insects/dask/pdf/FRButterflyFinalListing24Oct2014.pdf.

additional ESA-protected species, beyond the two butterflies above (which they also identified), as potentially affected by coated seed use:[55]

> **Invertebrates:** Hine's emerald dragonfly (*Somatochlora hineana*); Salt Creek tiger beetle (*Cicindela nevadica lincolniana*).
>
> **Birds:** Mississippi sandhill crane (*Grus canadensis pulla*), whooping crane (*Grus Americana*), Attwater's prairie chicken (*Tympanuchus cupido attwateri*).

The analyses by Drs. Stark, Losey, and Mineau focused just on a small number of case study species (three species per expert). They stated in their opinions that likely many other similarly-exposed ESA-listed species could be affected.[56] The following is an illustrative, non-exhaustive, list of ten threatened and endangered terrestrial insects that EPA should consider as an additional starting point:[57]

> 1) American burying beetle (*Nicrophorus americanus*); 2) Behren's fritillary (or Behren's silverspot) (*Speyeria zerene behrensii*); 3) Callippe silverspot (*Speyeria callippe callippe*); Fender's blue (*Icaricia icarioides fender*); 4) Karner blue (*Plebejus melissa samuelis*); 5) Lange's metalmark (*Apodemia mormo langei*); 6) Mitchell's satyr butterfly *Neonympha mitchellii mitchelli*; 7) Myrtle's silverspot (*Speyeria zerene myrtleae*); 8) Quino checkerspot butterfly (*Euphydryas editha quino*); 9) San Bruno elfin (*Callophrys mossii bayensis*); and 10) Schaus swallowtail (*Papilio aristodemus ponceanus*).

As discussed in the Argument section, below, EPA has never once consulted with the expert agencies—the FWS or National Marine Fisheries Service (NMFS)—on any neonicotinoid insecticide product registration or on the exempted coated seeds as required under the ESA when

[55] Expert Declarations of Drs. John Stark, John Losey, and Pierre Mineau, filed with this Petition; these were originally prepared in support of Plaintiffs' Memorandum of Points and Authorities in Support of Motion for Summary Judgment, *Ellis v. Housenger,* No. 3:13-cv-01266-MMC, ECF No. 215-1 (N.D. Cal. Apr. 14, 2016).
[56] Decl. Mineau ¶¶ 9, 23, 43, 45; Decl. Stark ¶¶ 17, 49; Decl. Losey ¶ 8, 10, 12, 14.
[57] *See* listings in FWS ECOS Environmental Conservation Online System, http://ecos.fws.gov/ecp0/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&mapstatus=3&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals. This list will need updating as more species are regularly added and numerous "Candidate" species await further action.

"effects" on any listed species or their critical habitats are foreseeable. Since ninety-five percent of the land area in the country that is affected by any neonicotinoid product is affected by the coated seeds, obviously consultation on the seeds' effects is required. The more than 140 million acres planted across the country overlaps the habitats of, or otherwise affects, literally *hundreds* of listed species. EPA's own internal risk assessments for various seed treatment uses of clothianidin and thiamethoxam going back at least seventeen years explicitly reveal that the agency is fully aware that likely many hundreds of species may be affected.[58]

The *obvious* failures to date are the three ESA-listed species for which the planting of neonicotinoid-coated seeds already are labeled by the FWS as significant factors in their listings, again, the rusty patched bumble bee, Dakota skipper and Poweshiek skipperling. EPA's ongoing

[58] The following 13 risk assessments and similar documents are illustrative of numerous documents in EPA's own files just for clothianidin and thiamethoxam that show foreseeable effects of the coated seeds on hundreds of ESA-listed species nationwide. This is not exhaustive. As EPA has copies of its own very lengthy assessments, copies are not being attached with this Petition:

1) Clothianidin Pesticide Fact Sheet, dated May 30, 2003.
2) EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola, dated Feb. 20, 2003.
3) "Addendum" to the above-referenced EFED Risk Assessment, dated Apr. 10, 2003.
4) EFED Registration Chapter for Clothianidin for Use on Potatoes and Grapes as a spray treatment and as a Seed Treatment for Sorghum and Cotton, dated Sept. 28, 2005.
5) Revised Assessment for Clothianidin Registration of Prosper T400 Seed Treatment on Mustard Seed and Poncho/Votivo Seed Treatment on Cotton, dated Dec. 2, 2010.
6) Environmental Fate and Ecological Risk Assessment for the Use of Thiamethoxam as a Seed Treatment to Control Grape Colapsis on Arkansas Rice, dated Feb. 26, 2009.
7) Ecological Risk Assessment for the Proposed New Uses of Thiamethoxam Seed Treatment for Dry Bulb Onions and Peanuts and Registered Seed Treatment for Corn, Carrots, Leafy Vegetables, and Brassica (Cole) Leafy Vegetables, dated May 18, 2010.
8) Ecological Risk Assessment for the Proposed New Uses of Thiamethoxam Seed Treatment on Alfalfa, dated Dec. 28, 2010.
9) Environmental Fate and Ecological Risk Assessment for the Registration of Thiamethoxam On Ornamentals, Brassica (Cole) and Non-Brassica Leafy Vegetables, Pecans, Succulent Beans, Sunflower, and Stone fruit, dated June 1, 2009.
10) Section 3 Registration Request for Use of Thiamethoxam on Multiple Crops, dated June 11, 2001.
11) Section 3 Registration Request for Thiamethoxam (Chemical #060109, DP Barcode D251956) Use as a Seed Treatment, dated Dec. 14, 2000.
12) Ecological Risk Assessment for the Proposed New Use of Thiamethoxam as a Seed Treatment for Cereal Grains, dated Aug. 30, 2011.
13) Ecological Risk Assessment for the Section 3 New Use Registration of Thiamethoxam on Tropical Fruits, Sugar Beet Seed, Rice Seed, Cranberry, Bushberry Subgroup 13-07B, Low Growing Berry Subgroup 13-07G, Caneberry Subgroup 13-07A, and Small Fruit Vine Climbing Subgroup 13, dated May 18, 2009.

refusal to consult under the ESA must change or else these—and other—valued, irreplaceable, native species may face severe jeopardy of extinction now directly under the agency's watch.

VII. Lack of Yield Benefits.

Two thorough reviews of the published science on crop yields by Petitioner Center for Food Safety (CFS), first in 2014 and then updated in 2016, show that use of neonicotinoid-coated seeds actually provides no net yield benefit to farmers across the majority of crop-planting contexts.[59] The 2016 report *Net Loss* report summarizes the current knowledge**:**

> [T]he broad lack of independent data showing economic justification for [neonicotinoids] use on seeds indicates that they are grossly over-used. In the European Union (EU), there is no evidence that crop production declined due to the 2013 prohibition on most crop-seed uses of neonicotinoids, which was adopted across the continent despite extremely dire industry predictions made at the time. In fact, on average, production to date has risen for major crops. Thus, prohibiting use of the neonicotinoid seed coatings did not deny European farmers any significant economic benefits.
>
> Further, agricultural scientists and other experts in the United States and the United Kingdom have issued extensive new studies and reviews on the lack of overall efficacy of this technology. The lack of economic justification for the prophylactic use of neonicotinoid-coated seeds for soybeans (the second most extensively planted U.S. crop after corn), is virtually uncontested based on the overwhelming weight of independent reviews. Published evidence on weak or non-existent benefits exists for other crops as well, although it is more sporadic.

The most detailed report on the "efficacy" question for soybeans came from EPA itself, issued in 2015.[60] The Agency's Biological and Economic Analysis Division (BEAD) stated:

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[59] Stevens and Jenkins, 2014, *supra*; Jenkins, P., *Net Loss—Economic Efficacy and Costs of Neonicotinoid Insecticides Used as Seed Coatings: Updates from the United States and Europe* (2016), unpublished report, CFS, Washington, D.C., *at* www.centerforfoodsafety.org/files/efficacy-netloss12616_38208.pdf.

[60] Myers, C., Hill, E., *Memorandum: Benefits of Neonicotinoid Seed Treatments to Soybean Production* at 9, United States Environmental Protection Agency (Oct. 15, 2014), *at* www.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf.

> This analysis provides evidence that U.S. soybean growers derive limited to no benefit from neonicotinoid seed treatments in most instances. Published data indicate that most usage of neonicotinoid seed treatments does not protect soybean yield any better than doing no pest control. Given that much of the reported seed treatment usage in the U.S. on soybeans is not associated with a target pest, BEAD concludes that much of the observed use is preventative and may not be currently providing any actual pest management benefits.

BEAD went on to observe, based on EPA's survey of agriculture extension experts nationwide, that when asked how the use of neonicotinoid-treated seeds affected soybean yields, *seventy-four percent* of respondents stated that *yield either stayed the same or decreased.*[61] EPA must heed its own analysis. The lack of yield benefits in most cases, and actual yield *reductions* in many cases, reinforces the experience of the Farmer Petitioners Criswell and Fuller. Despite paying for the seed coating protections when they bought seeds in the past, the farmers' yields did not benefit. And the beneficial insects in or near their farms and other aspects of their soil health were harmed.[62]

VIII. Aquatic Contamination.

Recent studies address the severe aquatic contamination associated with neonicotinoids, which are water soluble.[63] Their increasing contamination of ditches, streams, groundwater, lakes, rivers, and marine areas is now being documented. Researchers across the United States are finding high levels, exceeding vital standards set by experts to protect aquatic life. The coatings applied to crop seeds are a primary source of the contamination. The 2015 CFS report, *Water Hazard—Aquatic Contamination by Neonicotinoid Insecticides in the United States,* describes numerous exceedances of safe levels, including many findings exceeding EPA

[61] *Id*., pp. 9-10 (emphasis added).
[62] *See* Petitioners' Interests in Appendix, Section II.
[63] Morrissey, C.A., *et al*. 2015, *supra,* n.24, Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review.

benchmarks.[64] It documents contamination caused by coated seeds in a wide variety of rural habitats nationwide, typically via pathways that EPA failed to consider adequately when it approved the coating products.

Water concerns were clearly illuminated in late 2016 in another review paper by Sanchez-Bayo, *et al*.[65] The implications, partly attributable to coated seeds, are extremely alarming, summed in the Conclusion as:

> Negative impacts of neonicotinoids in aquatic environments are a reality. Initial assessments that considered these insecticides harmless to aquatic organisms may have led to a relaxation of monitoring efforts, resulting in the worldwide contamination of many aquatic ecosystems with neonicotinoids.
>
> The decline of many populations of invertebrates, due mostly to the widespread presence of waterborne residues and the extreme chronic toxicity of neonicotinoids, is affecting the structure and function of aquatic ecosystems. Consequently, vertebrates that depend on insects and other aquatic invertebrates as their sole or main food resource are being affected. Declines of insectivore bird species are quite evident so far, but many other terrestrial and amphibian species may be at risk.
>
> *Solutions must be found soon if we are to save the biodiversity not only of aquatic ecosystems, but all other ecosystems linked by the food web*.

On January 12, 2017, EPA released its *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid.*[66] While containing many conservative assumptions and admitted uncertainties, for seed treatment uses EPA found ongoing *chronic* effects for many aquatic invertebrates and some group likely to suffer *acute* effects. As discussed above, *supra* Section VI, while EPA failed to do the required ESA Section 7 analysis, it is transparent that

[64] Carnemark, M., Jenkins, P., and Walker, L., *Water Hazard—Aquatic Contamination by Neonicotinoid Insecticides in the United States*, CFS, Washington, D.C., 2015, *at* www.centerforfoodsafety.org/files/neonic-water-report-final-242016_web_33288.pdf and Carnemark, M. *Water Hazard 2.0,* CFS, 2017.
[65] Sánchez-Bayo F., Goka K., Hayasaka, D., *Contamination of the aquatic environment with neonicotinoids and its implication for ecosystems,* Front. Environ. Sci. 4:71 (2016) doi: 10.3389/fenvs.2016.00071, *at* http://journal.frontiersin.org/article/10.3389/fenvs.2016.00071/full (emphasis added).
[66] EPA-HQ-OPP-2008-0844-1086, *at* www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-1086.

listed threatened and endangered aquatic invertebrates may be adversely affected by the same chronic and/or acute effects. Despite its own findings the agency has failed to take—or even propose—any solutions needed to alleviate these effects on those species or those essential aquatic ecosystems as urged by Sanchez-Bayo, *et al*., *supra*.

IX. Labels on Neonicotinoid-Coated Seed Bags and Tags.

EPA requires labels to be placed onto the bags or other containers, or onto the affixed tags, of the unregistered pesticidal seeds, which include some sparse warnings superficially aimed at protecting pollinators and other environmental values.[67] While these amount to admissions of the seeds' pesticidal effects, the label language itself is unenforceable by EPA's own statements and its inactions.[68]

Even were it enforceable, the seed bag or tag language is utterly inadequate to reduce or mitigate the harm caused by contaminated neonicotinoid dust and talc, or the grown plants themselves, to honey bees—including those owned by the Beekeeper Petitioners. Further, the bag labels are inadequate to protect against the vast spectrum of other environmental and economic impacts, including, but not limited to, damage to soil health, harm to ESA-protected species and the extensive water contamination described above.

On the inadequacy of the labels, Petitioner Bret Adee (representing the nation's largest commercial beekeeping company) has stated:

> …[a]s shown in our massive 2015 bee kill, the exemption of toxic dust coming off of the neonicotinoid-coated corn seeds means there are no legal consequences for the seed coaters or pesticide manufacturers whose chemicals killed our bees. Neither the state enforcement agents nor EPA's enforcement agents will take any action to stop or mitigate the harms. There are no enforceable labels on the seed bags that the farmer must follow to not cause

[67] *See* n.17, *supra.*
[68] *See* EPA, Sulfoxaflor—Final Cancellation Order, dated Nov. 12, 2015, p.2, *at* https://www.epa.gov/sites/production/files/2015-11/documents/final_cancellation_order-sulfoxaflor.pdf.

> dust-off that will kill honeybees. My direct experience is that whatever language EPA asks to be put on those seed bags is inadequate to protect bees. From my perspective, my right as a beekeeper to obtain pesticide law enforcement for such dust-off kills has become non-existent. That reduces not only my ability to protect my valuable livestock, but also my ability to make any civil or other claim that I might seek to bring against those in the chain of production and use of these pesticides.[69]

The seed coating companies that apply the liquid chemicals to the various crop seeds are not the applicators of the ultimate pesticidal products—the seeds. Rather, the crop farmers who plant the seeds are, including the Petitioner farmers herein. The farmers are the "users" who need—and in many cases, desire—clear label warnings and strong directions in order to protect their own surrounding environment. EPA misuses its labeling authority and arbitrarily assumes that the seed coating companies—applying the liquid coatings mostly in industrial buildings—can be given warnings and use directions adequate to ensure that FIFRA's safety standards will be met during the actual use of the pesticidal seeds in the environment.

X. Past Statements by EPA, USDA Officials and Others.

Extensive statements by EPA and USDA officials, and in documents before the agencies, underscore their awareness of the harms of the coated seeds and the associated dust-off. Below is a non-exhaustive example of such statements:

A) EPA's Pesticide Fact Sheet—Clothianidin:[70]

> …assessments show that exposure to treated seeds through ingestion may result in chronic toxic risk to non-endangered and endangered small birds (e.g., songbirds) and acute/chronic toxicity risk to non-endangered and endangered mammals. Clothianidin has the potential for toxic chronic exposure to honey bees, as well as other nontarget pollinators, through the translocation of clothianidin residues in nectar and pollen … [It] is

[69] Decl. Adee p.2, *Anderson v. McCarthy,* No. 3:16-cv-00068-WHA, ECF No. 58 (N.D. Cal. Apr. 14, 2016).
[70] EPA, Office of Prevention, Pesticides and Toxic Substances. Pesticide Fact Sheet—Clothianidin (May 30, 2003), *at* https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-044309_30-May-03.pdf.

a systemic insecticide that is persistent and mobile, stable to hydrolysis, and has potential to leach to ground water, as well as runoff to surface waters.

B) Report on the National Stakeholders Conference on Honey Bee Health:[71]

It is clear, however, that in some instances honey bee colonies can be severely harmed by exposure to high doses of insecticides when these compounds are used on crops, or via drift onto flowers in areas adjacent to crops that are attractive to bees. For example, dust produced in the process of planting pesticide-coated seeds has been shown to contain high levels of insecticide with the potential to harm bees.

C) EPA's Team Preparing the 2013 *Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents*:[72]

Keen interest has been expressed by outside groups in contributing to the bee guidance, which has been under development since mid-2012, following a spring with an unusual number of bee mortality incidents either unexplained or which appeared to be associated with treated seed.

D) Evidence EPA Collected from Non-Federal Experts in the Preparation of its 2013 Guidance:

For background on its Bee Incident Guidance, above, EPA convened a panel of experts, several of whom highlighted the role of neonicotinoid-coated seeds. Commercial beekeeper Randy Oliver identified: "dust from fields . . . dust from corn seeding . . . transport of systemic pesticides into crops or exposed weeds" as routes of pesticide exposure to his hives. Oliver also stated to EPA: "Exposure to planting dust kills the 'pollen hogs'—newly-emerged workers and drones that are feeding heavily on beebread. Next would be effects upon the nurse bees, who also consume the bulk of pollen in the hive."[73] The most devastating effect of exposure by bees to neonicotinoid pesticides is a large number of dead bees appearing in front of and surrounding a hive. Other sub-lethal effects can be just as devastating, including "queen failure,

[71] USDA, October 2012 Report on the National Stakeholders Conference on Honey Bee Health, p. 16, *at* http://www.usda.gov/documents/ReportHoneyBee Health.pdf.

[72] EPA, undated memorandum (likely 2013). Draft Guidance for Investigation of Alleged Cases of Pesticide-Related Bee Mortality: Pros and Cons of Issues Surrounding Review and Release of the Guidance, *available at* perma.cc/P5VX-JS6T.

[73] EPA, Undated survey responses. *Responses From Bee Experts* (collected in preparation for EPA's 2013 *Guidance for Inspecting Alleged Cases of Pesticide Related Bee Incidents*); Randy Oliver responses, pp. 1, 6.

> [inability] to navigate correctly, inability to supersede during queen failure, sterile drones and/or inability to successfully copulate with virgin queens," and "loss of vigor by foragers, lack of veteran foragers that harvest proposes, [and] shortened lifespan of foragers."[74] Dr. Eric Mussen of University of California, Davis, stated, "bees exposed to neonicotinoids looked 'anemic'; the bee colony is not necessarily killed; there seems to be 'downstream sickness' and the bees tend to be sluggish."[75]

E) EPA's Scientific Advisory Panel (SAP), Pollinator Risk Assessment Framework:

> During that SAP in 2012, Purdue University Professor of Entomology Dr. Greg Hunt stated:
>
> Well, I'll just speak to the seed treatment. Neonicotinoid seed treatments in particular, in the conceptual model, this is modeled—the EPA White Paper is only looking primarily at systemic movement plant parts**.** But clearly, we're seeing a problem with dust, particularly with corn planting and in regards to the soil. We see at least twice the concentrations of Clothianidin that we find in corn pollen. We're seeing a lot of reports, many of which apparently aren't getting transmitted to the EPA, and I think there is a lag in that also because, for example, in Indiana, the office of the state chemist has looked at 14 incident reports and they all came up positive for Clothianidin. In Ohio, there was something like 50 reports, incident reports, which again have not gotten their way to the EPA. In Ontario and Quebec, there are a lot of positive reports—over 130 of them, I understand—just from this year.[76]

XI. Other Systemic Seed Coating Chemicals.

The same factual concerns discussed above apply to other non-neonicotinoid, systemic seed coating products that EPA has already approved or has indicated its intent to approve, including, but not limited to, Fipronil, Sulfoxaflor, Cyantraniloprole and Flupyradifurone. Some of these may not yet be registered for seed coating use; however, based on EPA's practices with the neonicotinoids, it is foreseeable EPA will approve them for that use. If so approved they are likely to present the same class of harms to Petitioners as do neonicotinoid-coated seeds.

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[74] *Id.,* Randy Verhoek response, p. 5.
[75] EPA, 2013. Meeting Minutes Teleconference: EPA and 'Bee Experts.' Tues. Feb. 26, Eric Mussen ("EMu") response, p. 2.
[76] FIFRA Scientific Advisory Panel, 2012, Open meeting, Pollinator Risk Assessment Framework, Docket number: EPA-HQ-OPP-2012-0543 p.411, *at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0543-0039.

ARGUMENT

I. EPA Has the Authority and Duty To Regulate Coated Seeds Under FIFRA.

Systemic neonicotinoid-coated seeds clearly fit within FIFRA's definition of "pesticide" because they are a "mixture of substances that are intended to prevent, destroy, repel or mitigate a pest," and would otherwise require registration prior to sale. 7 U.S.C. § 136(u)(1). Under FIFRA, EPA is charged with regulating pesticides, absent an exemption, including directing what data will support registration and evaluating whether a given pesticide meets FIFRA's safety standard. *Id.* § 136a. Specifically, EPA may not register a pesticide unless it determines that "it will perform its intended function without unreasonable adverse effects on the environment; and when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 36a(c)(5)(C), (D).

EPA is authorized under FIFRA to exempt certain pesticides from FIFRA's requirements. Namely, under 7 U.S.C. § 136w(b), the "Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." Given that EPA is not allowed to *register* a pesticide which will cause unreasonable adverse effects on the environment, it follows that EPA may not *exempt* pesticides that would cause unreasonable adverse effects on the environment. Put another way, EPA could not lawfully determine that a pesticide that causes "unreasonable adverse effects on the environment" is "of a character which is unnecessary to be subject to" FIFRA.

Pursuant to its authority under 7 U.S.C. § 136w(b)(2), EPA promulgated the Treated

Article Exemption, for "[a]n article or substance treated with, or containing, a pesticide to protect the article or substance itself." 40 C.F.R. §152.25(a). As currently written, the plain language of that exemption does not include systemic insecticide-coated seeds. Coated seeds do not fit within 40 C.F.R. §152.25(a) (which lacks any mention of "seeds"), because they are not intended "to protect the article or substance itself" as the regulation requires. First, the actual intent behind coating crop seeds with neonicotinoids and other systemic insecticides predominately is to protect the growing plant from pests that prey on living plant tissues, not to protect the seed "itself." As indicated, reviewing the fifteen coating product labels that EPA has registered since 2010 reveals that on thirteen of those labels the neonicotinoid ingredients are intended to protect the growing crop plants.[77] Only two of those labels explicitly claim protection of the planted seed itself by the neonicotinoid ingredient. Second, the coatings of these seeds do not remain on the seed, but instead "dust-off" into the air during planting, or slough off into the soil. The fact that 80% to 90% of the coating chemicals move off the seed and plant into the surrounding air, soil, marginal vegetation and waters, illustrates that the bulk of the treatment does not remain in or on the "treated article." Because the Treated Article Exemption requires that the treatment be for the protection of the article itself, it should be a necessary condition that the treatment largely remains *on the treated article.*

However, EPA's current interpretation of the Treated Article Exemption includes systemic coated seeds under this exemption, despite the intended and actual pesticidal effects beyond the articles (seeds) themselves.[78] While the Agency has not made this interpretation clear in any regulation or formal interpretation, EPA's practice of neither requiring registration of the seeds nor imposing enforceable labeling on their bags or tags speaks clearly. EPA can and must

[77] *See* n.17, *supra.*
[78] EPA, 2013 *Guidance for Inspecting Alleged Cases of Pesticide Related Bee Incidents*, p. 7, *at* https://www.epa.gov/sites/production/files/2013-09/documents/bee-inspection-guide.pdf.

correct this interpretation and practice of exempting coated seeds from registration and labeling by clarifying that the Treated Article Exemption does not include systemic coated seeds.

Not only does the extension of the Treated Article Exemption to these pesticidal seeds violate its plain language, it violates the basic FIFRA safety standard. EPA cannot exempt a pesticide that violates this safety standard, i.e., that the pesticides as commonly used will not cause unreasonable adverse effects to the environment. 7 U.S.C. § 136a(c)(5). As shown above, these seeds *do* cause unreasonable adverse effects to the environment, including to the pollinators that support U.S. agriculture and make up the livelihoods of the Beekeeper Petitioners. EPA has failed to fully evaluate the harms from coated seeds in its approvals of the liquid coating products alone. EPA's own pollinator RAs for imidacloprid, clothianidin, and thiamethoxam do not fully examine their risks when used as seed treatments, due to EPA's exemption for the seeds. Most explicitly, the RAs *exclude* any risk assessment or mitigation for the abraded seed coatings and the associated "dust-off," despite EPA's awareness that these insecticides are spread far from where the exempted seeds were planted.[79] Even though agency officials are aware of harm occurring as a result of these seeds, their exemption blinds them to the full magnitude of the damage. Many incidents of damage from coated seeds simply go uninvestigated. Even reports of massive honey bee colony kills due to coated seeds may never lead to enforcement because they are not caused by registered "pesticides" covered under FIFRA. Petitioner beekeepers have no incentive to report such kills to the agency due to its well-known lack of enforcement.

By approving only the liquid coating products applied to the seeds indoors, EPA allows manufacturers of systemic seeds of the various crops (>24) to avoid a comprehensive EPA

[79] EPA's Preliminary Pollinator/Bee Risk Assessments for Imidacloprid, Clothianidin and Thiamethoxam cited in n.29 and n.30, *supra*.

determination of whether those particular crop seeds and their associated dust-off, soil and water contamination and other externalized effects constitute "unreasonable adverse effects on the environment" as required under 7 U.S.C § 136a(c) (5). Further, EPA's exemption allows manufacturers of the various pesticidal seeds to evade the two classes of EPA notices that must go in the Federal Register under FIFRA and EPA's regulations. 7 U.S.C. § 136a(c)(4); 40 C.F.R. § 152.102. This evasion denies Petitioners and the public essential notice by which they could be allowed to comment to EPA on proposed registrations. The lack of the required published notices also denies Petitioner beekeepers the information needed to protect their bees from fields planted with the numerous exempted crop seeds.

If EPA had followed the FIFRA-mandated registration process for the pesticidal seeds at issue, many of them likely would not have been registered, not been heavily advertised and sold, and they would not have inflicted the damages the Petitioners that they now inflict. Other regulators (in Europe and on our own U.S. wildlife refuges) are taking action to restrict or stop the use of these dangerous pesticides.[80] EPA cannot continue to exempt them from FIFRA. Without the requested action, EPA will allow the continued destruction of the nation's commercial and wild pollinators, damage to agricultural soils, and harm to non-target wildlife including ESA-protected species, to the severe detriment of U.S. agriculture and contrary to EPA's duty to regulate pesticides to protect the public and the environment.

II. EPA's Exemption of Coated Seeds Is Unlawful.

EPA does not have the authority to continue its wholesale exemption of coated seeds from FIFRA's requirements, because FIFRA does not authorize exemptions of pesticides that require regulation, especially not those pesticides that cause unreasonable adverse effects to the environment. Accordingly, EPA's current interpretation of the Treated Article Exemption and

[80] *See* EU and U.S. National Wildlife Refuge System measures cited in n.33 and n.36, *supra*.

practice of exempting coated seeds from registration and labeling is *ultra vires.* 5 U.S.C. § 706(2)(C).

EPA's exemption of coated seeds is also arbitrary and capricious under the APA. *Id.* § 706(2)(A). First, EPA's actions are arbitrary and capricious because they are counter to the available evidence that coated seeds cause significant adverse effects on the environment. *Motor Vehicle Manufacturers Assoc. v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 (1983). Second, EPA's interpretation of the Treated Article Exemption as to coated seeds is inconsistent with its other interpretations in comparable situations where the agency found a treated article not to be exempted due to adverse pesticidal effects beyond the article itself, including its non-exemption of anti-fouling boat paint and other articles.[81]

Finally, EPA's exemption of these coated seeds violates its duty under ESA to ensure that its actions do not jeopardize the continued existence of any protected species. 16 U.S.C. § 1536(a). As shown above, among the impacts from these pesticidal seeds are harms to threatened and endangered species, including invertebrates and birds. Despite the fact that the pesticidal seeds unregulated by EPA "may affect" many protected species either directly or indirectly, EPA has never consulted with the expert Services to determine whether its exemption of coated seeds is likely to jeopardize these species. Moreover, this assessment is missing from EPA's registration of the liquid coating products and active ingredients. As noted above, even if EPA were to consult under the ESA on these products, to date the agency has ignored the full effects of the use of the coated seeds in the field due to its exemption.

Because EPA's ongoing exemption of coated seeds violates FIFRA and the APA and poses adverse effects to a large number of threatened and endangered species protected under the

[81] *See* sample boat hull paint label for *Pro-Line 1080 H Hard Vinyl Anti-Fouling Paint*, EPA registration number 577-549, *at* https://www3.epa.gov/pesticides/chem_search/ppls/000577-00549-20031002.pdf.

ESA, EPA must take the requested actions.

CONCLUSION

For the reasons stated herein Petitioners request that EPA either amend or formally re-interpret the Treated Article Exemption, 40 C.F.R. §152.25(a), to clearly communicate to the regulated community that systemic pesticidal seeds intended to kill pests of the plants are not included under the Treated Article Exemption and are therefore subject to FIFRA's requirements for registration and labeling. Petitioners also request EPA to aggressively enforce FIFRA's registration and labeling requirements for each separate seed product coated in systemic insecticides, in order to properly discharge its duty to protect the public and environment.

DATED this 26th day of April, 2017.

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APPENDIX

PETITIONERS' INTERESTS

The eleven Petitioners are nationally-representative beekeepers, farmers, and public interest organizations harmed by EPA's actions and inactions described, *supra*.

Beekeeper Petitioners

Petitioner **Bret Adee** is a resident of Bruce, South Dakota. He is a third-generation commercial beekeeper and a co-owner of Adee Honey Farms. Founded in 1957, Adee Honey Farms is the nation's largest beekeeping operation. It manages some 90,000 honey bee colonies and has about fifty full-time employees. Its operations have been harmed over several years by the neonicotinoid seed coatings. The colonies, in many cases, cannot be placed so that the free-ranging bees will be able to avoid contaminated crops, dust, soil, marginal vegetation, and water that results from the seed coatings, which are overused. Adee Honey Farms has experienced abnormally high incidences of hive failure in recent years. Prior to 2005, they would expect to lose between three to eight percent of their colonies over the winter. Now, they consider it a good year if they lose only twenty percent. In 2012, for example, they lost forty-two percent of their hives over winter, but by the time they came around to pollinate almonds in the early spring, their losses were at fifty-five percent. For the summer of 2015, the Adees had a massive exposure to clothianidin dust-off that resulted in an estimated 10,000 severely weakened honey bee colonies. The results to the company include lost income, increased expenses and work overload, and emotional distress from seeing their animals killed or weakened. Mr. Adee and his family fear for the future of their business—and commercial beekeeping in general—if the current overuse of neonicotinoids and other pesticides continues. Mr. Adee is the President of the Pollinator Stewardship Council and co-Chair of the National Honey Bee Advisory Board. He also is a member of the American Honey Producers Association, the South Dakota Beekeepers Association, and the California State Beekeepers Association.

Petitioner **American Beekeeping Federation** (ABF) is a 501(c)(5) organization founded in 1943, headquartered in Atlanta, Georgia. ABF is dedicated to advancing the interests of all beekeepers, large or small, and other interests associated with the industry to ensure the future of the honey bee. ABF currently has approximately 1,500 members, making it the largest beekeeping organization in the United States. Approximately twenty-five percent of the commercial beekeepers in the United States are members of ABF. ABF members harvest roughly thirty percent of the honey produced in the United States each year, a lot of that from smaller producers.

Petitioner **American Honey Producers Association** (AHPA) is a non-profit agricultural association incorporated in Oklahoma in 1969. The organization is dedicated to promoting the common interest and general welfare of the American honey producer. AHPA currently has about 400 members who make their living from the production of honey. Collectively, AHPA members produce as much as fifty percent of the United States' honey.

Petitioner **Jeff Anderson** has been the owner of California Minnesota Honey Farms for nineteen years. It is a migratory beekeeping operation based in Eagle Bend, Minnesota; and Oakdale, California. In addition to Mr. Anderson, the business employs one full-time employee, as well as three seasonal employees. He has been a commercial beekeeper since 1976. Mr. Anderson is a member of the Minnesota Honey Producers Association, the California State Beekeepers Association, the American Honey Producers Association, the National Honey Bee Advisory Board, and the Pollinator Stewardship Council. Since about 2004-05, his percentage of hives lost each year has increased dramatically. In 2012, for example, he had 3,150 hives in April, but by February 2013, he was down to just 998 hives, meaning he lost almost 70% of hives that year. Not only is Mr. Anderson losing hives at rates that are unprecedented, but remaining hives are far less robust. It is plain from recent years that he is getting significant *summer* mortality—a time when bee populations should be healthy due to warm weather, long days, and food abundance—from the dominant Minnesota crops: corn and soybeans. It is virtually impossible for honey bees to avoid these crops in central Minnesota; nearly all of them are seed-treated with a combination of two neonicotinoid pesticides, clothianidin and thiamethoxam. There are other consequences of this hive health pattern which adversely affect his business and livelihood. First, sick or poorly-populated hives cannot produce much honey. This is apparent when observing his annual honey production records. Prior to 2005, he would expect to harvest an average eighty pounds of honey per live hive annually. In recent seasons, Mr. Anderson's hives have averaged only about forty pounds of honey. His income has drastically suffered as a result and his expenses to keep his remaining hives alive have dramatically increased. The workload and personal stress are intense. His experience and observations are that the exempted neonicotinoid seed coatings, toxic dust, and other contamination from them have played a major role. Test results for some incidents confirm this.

Petitioner **David Hackenberg** is a commercial beekeeper residing in Lewisburg, Pennsylvania. He has been keeping bees for fifty-four years, through his family business Hackenberg Apiaries. His experience includes serving twelve years on the National Honey Board, has served as President of the American Beekeeping Federation, and as Chair and co-Chair of the National Honey Bee Advisory Board. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged his operation. In 2006, he saw huge losses and was the first beekeeper known to suffer what was described by scientists as Colony Collapse Disorder. These disappearances coincided with the exempted neonicotinoid pesticidal seeds coming on the market in large numbers. This damage at least partly resulted from the use of neonicotinoid seed coatings in row crops nationwide. This is compounded by the lack of labels on the seed bags adequate to inform the crop farmers how to avoid harm to bees, and the lack of any enforcement when bees are harmed by these seed coating. Mr. Hackenberg has about 2,000 hives now. His annual losses have run seventy-five to eighty percent or with continual protein feeding, they can be held closer to sixty percent losses, but both these levels are excessive. The economic damage to his business, increased expenses and work demand, and personal stress from seeing huge numbers of his bees die have all directly harmed him. His experience and direct observations are that the seed coatings, dust, and other contamination from them have played a major role.

Petitioner **Pollinator Stewardship Council (PSC)** is a nonprofit organization incorporated in Kansas in 2012. The mission of PSC is to defend managed and native pollinators

vital to a sustainable and affordable food supply from the adverse impacts of pesticides. As pollination is required for one-third of the nation's food supply, PSC accomplishes it mission by: (1) ensuring that state agencies and EPA enforce laws to protect pollinators from pesticides; (2) providing advocacy, guidance, and tools for beekeepers to defend their bees from the detrimental effects of pesticides; and (3) raising awareness about the adverse impacts of pesticides on pollinators. PSC has previously stated its position in opposition to the "treated article" exemption being applied to neonicotinoid-coated seeds because it leads to excessive and unnecessary use of these insecticides. Beekeepers that PSC represents typically cannot escape many harmful effects of this overuse, nor will EPA or the state agencies enforce against misapplication of the exempted seed coatings, even when major bee kills result. Additionally, the losses inflicted on native pollinators, which lack any management, in many cases may be more severe than the damage to managed pollinators. On the whole, the damages resulting from the exemption EPA has given to the pesticidal coated seeds are unacceptable to PSC.

Farmer Petitioners

Petitioner **Lucas Criswell** resides near Lewisburg, in central Pennsylvania. He farms about 1,800 acres total of mostly corn, soybeans, and small grains. He has been doing this for twenty years, and is familiar with the seed choices for these crops and the effects of using different seeds as well as the effects of neonicotinoid coatings. He is very concerned about the non-availability of uncoated corn seeds of the high-quality hybrid varieties. He also is concerned because he has seen that the exempted neonicotinoid-coated seeds are used as a form of "insurance," when in most situations farmers do not need coated seeds. As a result of their overuse, he has observed harm to beneficial insects and the overall health of the soil. In the case of soybeans, Mr. Criswell planted coated seeds for several years and then quit. Unlike corn, there are many good uncoated soybean varieties available from seed dealers. When he switched, he saw no decrease in overall average yields or profitability from his soybean acreage. He switched because it was clear that the coated seeds he used in the past were causing an increase in slugs in the fields, a harmful and hard-to-control crop pest. There were slug outbreaks because the neonicotinoid killed beetles that kept the slugs under control. Mr. Criswell also quit because he was concerned the unnecessary overuse of the chemicals violated Integrated Pest Management, an important principle for his farming. He switched away from neonicotinoid-coated corn seeds more recently, but it is challenging due to their near complete domination of the available corn seed market. Mr. Criswell is concerned that too many farmers, including him at times, have been using them unnecessarily and paying unnecessary costs for the pesticidal coating. He is concerned that the overall effect harms the soil and farmers themselves in the long run.

Petitioner **Gail Fuller** is a farmer residing near Emporia, Kansas. He farms about 1,000 acres of mixed grains, including sorghum, corn, barley, soybeans, and wheat. He regularly used neonicotinoid-coated seeds in the past on some of his crops. He has switched to non-coated seeds for all the crops where it was feasible based on seed availability. Mr. Fuller is an active proponent for soil health and he has noticed that the neonicotinoids can damage soil health and beneficial insects. He is concerned that he used these chemicals unnecessarily as that is not consistent with good soil health or good farming. He is concerned about how the exempted neonicotinoids appear to put monarch butterflies, honey bees, and other beneficial insects at risk.

Since cutting back on coated seeds, he has observed more biologically diverse and sustainable ecosystems on and around his farmland, without reducing his typical yields.

Public Interest Organization Petitioners

Petitioner **American Bird Conservancy (ABC)** is a national, nonprofit membership organization, headquartered in The Plains, Virginia, dedicated to conserving native birds and their habitat throughout the Americas. With more than 10,000 members nationwide, ABC works to innovate and build on sound science to halt extinctions, protect habitats, eliminate threats, and build capacity for bird conservation. ABC has had a long-standing program to address the significant threat that pesticides pose to birds. It works to cancel or restrict the registrations of the most dangerous products, to improve the evaluation and monitoring of pesticides and their effects on birds, to spearhead scientific research, and to engage the public in protecting birds and other wildlife. The 2013 ABC report, *The Impact of the Nation's Most Widely Used Insecticides on Birds*, concluded that neonicotinoid-coated seeds are lethal to birds and to the aquatic biological diversity upon which they depend. The nation's birds, and ABC's members, are directly and indirectly harmed by the neonicotinoid seed coating chemicals that are blanketing croplands, contaminating watersheds, and poisoning birds, bees, butterflies, and other organisms. ABC has advocated for more than three years to EPA and other federal agencies to curb the overuse of coated seeds. ABC also has urged the Agency to eliminate the coated seeds' exemption from registration as pesticides under FIFRA.

Petitioner **Center for Food Safety (CFS)** is a Washington, D.C.-based, public interest, nonprofit membership organization with offices in San Francisco, CA; Portland, OR; Honolulu, HI; and Washington, D.C. CFS's mission is to empower people, support farmers and protect the earth from the harmful impacts of industrial agriculture. Through legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment. CFS has more than 830,000 consumer and farmer supporters across the country. It seeks to protect human health and the environment by advocating for thorough, science-based safety testing of new agricultural products prior to any marketing and cultivation of crops in a manner that minimizes negative impacts such as increased use of pesticides and evolution of resistant pests and weeds. A foundational part of CFS's mission is to further the public's and its members' fundamental right to know what is in their food and food production methods and technologies.

Petitioner **Pesticide Action Network of North America (PANNA)** is an Oakland, California-based, nonprofit corporation that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than ninety countries. For nearly thirty years, PANNA has worked to replace the use of hazardous pesticides with healthier, ecologically sound pest management across the United States and around the world. PANNA provides scientific expertise, public education and access to pesticide data and analysis, and policy development and coalition support to more than 100 affiliated organizations in North America. PANNA has more than 125,000 members across the United States. PANNA's members live, work, farm, and recreate in areas of the country where pesticides such as the neonicotinoid insecticides are applied, and in which the pesticides and contaminated dust drift and transport occurs, and thus have a strong interest in ensuring that EPA protect public health and the environment from this contamination. PANNA's members are highly concerned by the

effects of the unregulated neonicotinoid-coated seeds on honey bees, bumble bees, butterflies, beneficial invertebrates, wild pollinators, water, aquatic invertebrates, food chains, ecosystem sustainability generally, and ultimately on humans via food and water consumption. The lack of enforceable labeling on these pesticidal seeds, and their prophylactic overuse, violate bedrock principles PANNA seeks to protect as far as only using pesticides as a last resort, and then only when they have strong and clear warnings and enforceable use directions. PANNA has urged EPA to eliminate the coated seeds' exemption from registration as pesticides. PANNA has also urged EPA (as well as the United States Department of Agriculture and Department of Justice) to address issues around the lack of fairness, transparency, and farmer choice in the seed marketplace.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Mitchell Yergert, Director
Division of Plant Industry
Colorado Department of Agriculture
305 Interlocken Parkway
Broomfield, Colorado 80021

MAY 19 2015

Subject: Special Local Needs Registration for pesticide uses for legal marijuana production in Colorado

Dear Mr. Yergert:

Thank you for your inquiry regarding the utilization of Special Local Need (SLN) registrations of pesticides under FIFRA section 24(c) for use on cannabis. As you are aware, EPA's regulations, 40 CFR 162.152(a)(4), state that any SLN registration must be in accord with the purposes of FIFRA, which authorizes the registration of a pesticide only on a finding that it will not lead to "unreasonable adverse effects on the environment." In order to facilitate this finding, EPA strongly encourages a State to pursue SLN authorizations only where a federally registered pesticide is approved for use(s) similar to the manner in which the SLN pesticide would be used. EPA expects that a showing of such similarity would provide the best support for making the necessary determinations. Given our understanding of how cannabis is cultivated and the intended way cannabis plant materials may be consumed by humans, we anticipate that a federally registered pesticide would be regarded as having similar use patterns if the federally registered pesticide is approved for use:

1. on food (in order to have a complete toxicity database to evaluate the potential toxicity of acute, short-term, intermediate, and chronic exposure);
2. on tobacco (in order to have a pyrolysis study to determine the breakdown products formed when the treated plant material is burned);
3. by the same type(s) of application methods (in order to assess the exposure of workers who mix, load, and apply the pesticides);
4. on crops with agronomic characteristics similar to cannabis (in order to adequately protect workers reentering areas following application of the pesticide); and
5. in the same kind of structure (e.g., greenhouses/shadehouses) or on the same kind of site (e.g., outdoor dryland site) as the proposed SLN use (in order to ensure that workers handling the pesticide are adequately protected when applying the pesticide – for example, ensuring that the adequate personal protective equipment is required – and that the environmental fate and effects of the SLN use are adequately understood and that any appropriate measures are in place to protect non-target organisms and water resources).

In addition, EPA encourages the State to consider pesticides for which the agency's aggregate and cumulative risk assessment indicate that some modest additional exposure would not approach a risk of concern, i.e., that there is "room in the human health risk cup."

If the State decides to pursue a SLN registration for use of a pesticide on cannabis, it could meet its responsibility for showing that a proposed SLN registration would be appropriate by identifying a federally registered pesticide with similar use(s) and relying on the agency's most recent risk assessments showing that the pesticide meets the no "unreasonable adverse effects on the environment" standard. In addition, please be certain that any submission contains the information described in 40 CFR part 162 and characterized at the following website: http://www.epa.gov/opprd001/24c/. Like other SLN registrations, the State would need to submit a full label that describes the use pattern and associated mitigation for protecting human health and the environment.

EPA agrees with the State's assessment that pesticides considered for an SLN use on cannabis should have an appropriate dataset for use in assessing the potential for use of the pesticide and for residues on treated plant material to cause human health and environmental risks. In the event that the State cannot identify a federally registered pesticide with use(s) similar to the proposed SLN use, EPA would expect the requesting State to take responsibility for providing information and analysis to support the SLN registration for cannabis. To aid the State in preparing these assessments, an overview of the human and ecological risk assessment methodologies used by the Office of Pesticide Programs (OPP) is presented in the attachment. OPP is available to provide further guidance or answer any questions as to how to ensure the safety of a use under an SLN on cannabis.

Sincerely,

Jack E. Housenger, Director
Office of Pesticide Programs

Attachment

cc: Mr. John Scott, Pesticides Section Chief, Colorado Department of Agriculture
Ms. Laura Quakenbush, Pesticide Registration Coordinator, Colorado Department of Agriculture
Mr. Eric Johansen, Washington State Department of Agriculture
Ms. Melanie Wood, Division Director, Pesticides Program, EPA Region 8
Ms. Jennifer Schuller, Pesticides Team Leader, EPA Region 8
Ms. Rebecca Perrin, Agriculture Advisor, EPA Region 8
Mr. Ed Kowalski, Division Director, Pesticides Program, EPA Region 10
Ms. Kelly McFadden, Section Chief, Pesticides Program, EPA Region 10

ATTACHMENT

The following sections describe how EPA assesses the risks to human health and the environment resulting from use of pesticides.

I. HUMAN HEALTH ASSESSMENT

OPP evaluates pesticide chemicals prior to registration, and reevaluates older pesticides already on the market, to ensure that they can be used without causing unreasonable adverse effects on the environment. OPP employs the National Research Council's four-step process for human health risk assessment: hazard assessment; exposure assessment; risk characterization; and risk assessment. Details are available at http://www.epa.gov/pesticides/factsheets/riskassess.htm

1. Hazard Assessment

In evaluating toxicity or hazard, OPP reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test animals. Where available and appropriate, OPP will also take into account studies involving humans, including human epidemiological studies. An extensive battery of toxicological studies are required for full pesticide registration. Toxicology data requirements are described in 40 CFR §158 subpart F http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm. Toxicology data requirements for a food-use chemical are presented in Table 1.

Once a pesticide's potential hazards are identified, OPP determines a toxicological endpoint of concern for evaluating the risk posed by human exposure to the pesticide. Two critical parts of this evaluation involve identification of a quantitative dose level(s) from these studies to be used in assessing the pesticide's safety to humans, referred to as the Point of Departure (POD), and selection of appropriate uncertainty/safety factors for translating the results of toxicity studies in relatively small groups of animals or humans to the overall human population, including major identifiable subgroups of consumers.

A POD is the dose serving as the 'starting point' in extrapolating a risk to the human population. The POD can be a no observed adverse effect level (NOAEL), the lowest-observed adverse effect level (LOAEL) or an extrapolated benchmark dose (BMD). For details refer to http://www.epa.gov/raf/publications/pdfs/rfd-final.pdf.

For threshold effects, risk assessments are normally conducted using the Reference Dose (RfD) approach. The RfD is calculated by dividing the POD by the appropriate uncertainty/safety factors. OPP's safety/uncertainty factor practice with regard to pesticides was altered to a degree by the Food Quality Protection Act (FQPA). FQPA requires EPA to use an additional safety factor of 10X to protect infants and children, unless EPA determines, based on reliable data, that use of another safety factor would protect infants and children. For pesticides, a Population Adjusted Dose (PAD) is derived by dividing the RfD by the FQPA Safety Factor. For complete details, refer to http://www.epa.gov/pesticides/trac/science/determ.pdf. An example of the toxicity endpoint selection is presented in Table 2.

For compounds causing non-threshold effects, such as carcinogens, an RfD approach is not used. Instead, a cancer risk assessment is conducted which provides an estimate (expressed as a probability) of the excess cancer risk resulting from exposure to a pesticide chemical. http://www.epa.gov/raf/publications/pdfs/

As an unreasonable adverse effects finding is developed for any prospective SLN, EPA encourages you to use the assessment endpoints that have been identified by EPA for that chemical.

2. Dietary Exposure Assessment

Acute, chronic, and cancer dietary exposure and risk assessments are conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID). This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The Agency is in the process of transitioning from the 2003-2008 NHANES/WWEIA consumption data to the 2005-2010 NHANES/WWEIA consumption data. The DEEM model that incorporates the 2005-2010 consumption data can be downloaded from http://www.epa.gov/pesticides/science/deem/

Generally, it would not be expected that the requesting State would have the residue and consumption data needed to perform a quantitative assessment of oral exposure for a SLN on cannabis. In the absence of such data, however, the State could estimate potential dietary exposure by making reasonable assumptions about high end consumption and residue levels. In addition, the State's risk assessment should address, at least qualitatively, why the additional exposure from the use of SLN on cannabis would not result in exposure exceeding the remaining room in the "human health risk cup." We expect that such an assessment will be more straight-forward if the active ingredient being proposed for the SLN registration has ample room in the risk cup for the new use.

3. Occupational and Residential Exposure Assessment

Occupational and residential exposure data requirements are described in 40 CFR part 158 subpart H available at http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series875.htm

In general, the data needed for a human health risk assessment for an agricultural crop, outdoor residential use, and a greenhouse use are similar; however, the exposure scenarios assessed may differ. A typical exposure assessment is divided into two parts. The handler assessment addresses potential exposure from the individuals who mix, load, and apply a pesticide, and the post-application assessment addresses the potential exposure of individuals who enter into previously treated areas and engage in activities that bring them into contact with pesticide residues. An overview of the residential human health risk assessment methodology and corresponding data for the various residential handler and post-application scenarios can be found at http://www.epa.gov/pesticides/science/residential-exposure-sop.html.

Occupational handler scenarios are assessed for the dermal and inhalation exposure pathways. (http://www.epa.gov/pesticides/science/handler-exposure-data.html) OPP uses non-chemical specific unit exposures and information from the labels about application type, site, formulation, rates, and personal protective equipment (PPE) to define each scenario. The resulting risk estimates from the handler assessment inform the risk management decisions on whether additional PPE requirements or other mitigation measures are necessary. PPE requirements on the label also fall under the Worker Protection Standard (WPS) related to the acute toxicity of the end-use product.

The occupational post-application scenarios are assessed for the dermal exposure pathway. OPP uses non-chemical specific transfer coefficients to capture the potential dermal exposure from different crop and activity combinations (http://www.epa.gov/opp00001/science/post-app-exposure-data.html).

OPP also uses chemical-specific data to inform the potential pesticide residue that is available on a foliar surface after an application; these data are referred to as dislodgeable foliar residue (DFR) and turf transferable residue (TTR) studies. When these data are not available, OPP currently uses default assumptions of 25% for DFR and 1% and 0.2% for TTR for the liquid and granular formulations, respectively. The post-application risk estimates determine how many days after treatment an individual may safely reenter the treated area for routine post-application activities. The more protective Restricted Entry Interval value is typically required on the labels. In addition, specifically for greenhouse uses, the WPS provides information on proper ventilation requirements to protect workers from post-application inhalation exposure.

If the pesticide proposed for a SLN use has no federally registered indoor uses, the State should specifically address whether handlers applying the pesticide indoors or others who would contact the pesticide treated plants would be adequately protected without additional PPE, and if not, what additional PPE would be needed to prevent unacceptable exposures from the anticipated application and post-application scenarios.

4. Risk Characterization and Risk Assessment

(i) Dietary Exposure Risk Assessment

The State's risk assessment should provide a general characterization of risk for the general population and should take into account both potential acute and chronic exposures.

(ii) Occupational Exposure Risk Assessment

- Occupational Handlers

In this section, the State's risk assessment should identify the occupational handler exposure scenarios based on the proposed use (list representative scenarios only). Briefly describe the data sources used such as an existing EPA risk assessment or, if a new assessment is being conducted, PHED, biomonitoring studies, or chemical specific data. Summarize the risks assessed. If there are no risks at baseline PPE, simply state the lowest Margin of Exposures (MOEs). If there are scenarios with risks of concern at baseline and additional personal protective equipment (PPE) will be needed to

achieve MOEs greater than the level of concern (LOC), summarize the MOEs at different PPE levels. The summary can be in tabular or paragraph form. As noted earlier, we encourage the State to use existing risk assessments to prepare this information.

- Occupational Post-Application

In this section, identify the occupational post application exposure scenarios based on the proposed use in a general manner. Briefly describe the data sources used such as an existing EPA risk assessment or, if a new assessment is being conducted, biomonitoring studies or chemical-specific data. Indicate whether or not dislodgeable foliar residue (DFR) studies are available. Indicate whether or not the most recent transfer coefficients were used to determine post-application exposure and risk. Summarize the scenarios with risks of concern, and provide a summary of the MOEs. Data can be in tabular or text form.

- Inhalation Exposure Assessment

It is OPP's policy to assess risk following short-term exposure to pesticide residues in tobacco products as the chronic health effects from tobacco use are well documented. OPP uses data from a pyrolysis study (Test Guideline 860.1000) and a magnitude of residue study (Test Guideline 860.1500) for this assessment. This assessment assumes: (1) 100% of the inhaled residue is absorbed; (2) the average U.S. smoker smokes 15 cigarettes per day (Pierce, J. P., *et al.* (1989), Tobacco use in 1986 – Methods and Basic Tabulations from Adult Use of Tobacco Survey, U.S. Dept. of Health and Human Services Publication Number OM90-2004, Office on Smoking and Health, Rockville, Maryland); (3) 1 gram of tobacco per cigarette; and (4) male/female body weight of 70/60 Kg. The POD established for short-term exposure is used to derive a MOE for expressing risk via this exposure scenario. If there is no federally registered tobacco use of the proposed SLN pesticide, the State's risk assessment should assess the potential acute risk from inhaling residues from smoking treated plant material; the assessment should use the above assumptions or justify the use of different assumptions.

II. ECOLOGICAL EFFECTS AND ENVIRONMENTAL FATE

In general, the types of data used to support an ecological risk assessment for a SLN pesticide registration should be comparable to the ecological effects and environmental fate data required for a Section 3 pesticide registration (see 40 CFR part158, subpart G and subpart N). Note the data requirements for outdoor terrestrial uses and greenhouse/indoor uses are substantially different in regards to the number and types of studies required for registration. Outdoor terrestrial uses are also subject to the data requirements for pollinators (see Guidance for Assessing Pesticide Risks to Bees). Tables 3 and 4 provide an overview of the data requirements for ecological effects and environmental fate respectively. An overview of the ecological risk assessment framework and supporting documentation can be found at: http://www.epa.gov/oppefed1/ecorisk_ders/.

The ecological risk assessment should consist of a problem formulation, an analysis characterizing the exposure and effects of the chemical stressor and a risk characterization.

1. Problem Formulation

Problem formulation provides the foundation for the ecological risk assessment. It is an iterative process for generating hypotheses concerning whether ecological effects could occur from human activities. The problem formulation articulates the purpose and objectives of the risk assessment and defines the problem and regulatory action. The quality of the assessment depends on rigorous development of the following products of problem formulation: 1) assessment endpoints that reflect management goals and the ecosystem they represent; 2) conceptual model(s) that represents predicted key relationships between stressor(s) and assessment endpoint(s); and 3) a plan for analyzing the risk.

2. Analysis of Exposure and Effects

For a pesticide risk assessment, the exposure characterization describes the potential or actual contact of a pesticide with a plant, animal, or media. The objective is to describe exposure in terms of intensity, space, and time and to describe the exposure pathway(s). A complete picture of how, when, and where exposure occurs or has occurred is developed by evaluating sources and releases of the pesticide, distribution of the pesticide in the environment, and extent and pattern of contact with the pesticide.

For greenhouse/indoor uses there are several factors the State will need to consider. First there is a difference between a greenhouse and a shadehouse. A greenhouse is defined as "operations that produce agricultural plants indoors in an area that is enclosed with nonporous covering and that is large enough to allow a person to enter." Shadehouses are defined as "a roof made of fencing or fabric to provide shade on plants (no walls)." Growing operations in a shadehouses are typically considered an outdoor terrestrial use.

The other factor to consider in the risk assessment for greenhouse/indoor use is the potential for "Down the Drain" release to publically owned treatment works or in some cases direct discharge to the environment. The "Down the Drain" assessment accounts for the normal use of a pesticide in a greenhouse, not the illegal disposal of a pesticide.

An ecological effects characterization describes how toxic a pesticide is to different organisms and/or to other ecological entities (e.g., community), what effects it produces, how the effects relate to the assessment endpoints, and how these effects change with varying levels of pesticide exposure. This characterization is based on a stressor-response profile that describes how toxic a pesticide is to various plants and animals, the cause-and-effect relationships, how fast the organism(s) recovers, relationships between the assessment endpoints and measures of effect, and the uncertainties and assumptions associated with the analysis. The stressor-response profile is the final product of the ecological effects characterization.

3. Risk Characterization

The risk characterization integrates the analyses from the exposure characterization and ecological effects characterization; describes the uncertainties, assumptions, and strengths and limitations of the analyses; and synthesizes the overall conclusion about risk that is used by risk managers in making risk management decisions.

Risk characterization has two major components: risk estimation and risk description. Risk estimation compares exposure and effects data, considers integrated exposure and effects data in context of Levels of Concern (LOCs), and states the potential for risk. The risk description interprets risks based on assessment endpoints. In interpreting the risk, the risk assessor evaluates the lines of evidence supporting or refuting risk estimates in terms of the following factors: adequacy and quality of data; degree and type of uncertainty; and the relationship of evidence to risk assessment questions.

As noted above for the human health risk assessment, EPA encourages the State to consider and use EPA's existing ecological risk assessments. where appropriate, to assess the environmental fate and ecological effects of any proposed SLN on cannabis.

Table 1. Toxicology Data Requirements

The requirements (40 CFR 158.340) for a typical food-use chemical are listed below:

Study Type		Requirement
870.1100	Acute Oral Toxicity	yes
870.1200	Acute Dermal Toxicity	yes
870.1300	Acute Inhalation Toxicity	yes
870.2400	Primary Eye Irritation	yes
870.2500	Primary Dermal Irritation	yes
870.2600	Dermal Sensitization	yes
870.3100	Oral Subchronic (rodent)	yes
870.3150	Oral Subchronic (nonrodent)	yes
870.3200	21-Day Dermal	yes
870.3250	90-Day Dermal	No
870.3465	90-Day Inhalation	**CR**
870.3700a	Developmental Toxicity (rodent)	yes
870.3700b	Developmental Toxicity (nonrodent)	yes
870.3800	Reproduction toxicity	yes
870.4100a	Chronic Toxicity (rodent)	yes
870.4100b	Chronic Toxicity (nonrodent)	yes
870.4200a	Carcinogenicity (rat)	yes
870.4200b	Carcinogenicity (mouse)	yes
870.4300	Combined chronic toxicity/carcinogenicity	yes
870.5100	Mutagenicity—Gene Mutation - bacterial	yes
870.5300	Mutagenicity—Gene Mutation - mammalian	yes
870.5xxx	Mutagenicity—Structural Chromosomal Aberrations	yes
870.5xxx	Mutagenicity—Other Genotoxic Effects	yes
870.6100a	Acute Delayed Neurotoxicity (hen)	no
870.6100b	90-Day Neurotoxicity (hen)	no
870.6200a	Acute Neurotoxicity Screening Battery (rat)	yes
870.6200b	90-Day Neurotoxicity Screening Battery (rat)	yes
870.6300	Develop. Neurotoxicity	**CR**
870.7485	General Metabolism	yes
870.7600	Dermal Penetration	yes
870.7800	Immunotoxicity	yes

CR= Conditionally Required. See footnotes in Part 158 Table.

Table 2. Summary of Points of Departure and Toxicity Endpoints Used in Human Risk Assessment

Summary of Toxicological Doses and Endpoints for [Chemical] for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (General Population, including Infants and Children)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Acute RfD = [ ] mg/kg/day aPAD =[ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Acute Dietary (Females 13-49 years of age)	NOAEL = [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Acute RfD = [ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Chronic Dietary (All Populations)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Chronic RfD = [ ] mg/kg/day cPAD = [ ] mg/kg/day	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Incidental Oral Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Incidental Oral Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A= [ ]x UF_H=[ ]x FQPA SF= [ ]x	Residential LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]

Summary of Toxicological Doses and Endpoints for [Chemical] for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Cancer (oral, dermal, inhalation)	Classification: This should be consistent with section 4.5.3 and the CARC document.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Summary of Toxicological Doses and Endpoints for [*Chemical*] for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Dermal Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Dermal Intermediate-Term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Short-Term (1-30 days)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Inhalation Intermediate-term (1-6 months)	NOAEL= [ ] mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = [ ]	[insert study name] LOAEL = [ ] mg/kg/day based on [ ]
Cancer (oral, dermal, inhalation)	Classification: This should be consistent with section 4.5.3 and the CARC document.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Table 3. Ecotoxicology Studies[1]

Guideline	Study Type	Comments
850.2100	Avian acute oral	Data required for a passerine species and either a waterfowl or upland game species
850.2200	Avian sub-acute dietary	Data required for a waterfowl and upland game species
850.2300	Avian reproduction study	Data required for a waterfowl and upland game species
850.1075	Acute freshwater fish	Data required for a cold water species and a warm water species
850.1075	Acute estuarine/marine fish	
850.1010	Acute freshwater invertebrates	
850.1025 850.1035 850.1045 850.1055	Acute toxicity to estuarine/marine invertebrates	Data required for one mollusk and one invertebrate
850.1300	Chronic freshwater invertebrate	
850.1350	Chronic estuarine/marine invertebrate	Conditionally required depending on exposure and toxicity (see CFR 158 for more details)
850.1400 or 850.1500	Chronic freshwater fish	
850.1400 or 850.1500	Chronic estuarine/marine fish	Conditionally required depending on exposure and toxicity (see CFR 158 for more details)
850.1735	Acute sediment toxicity to freshwater benthic organisms	Conditionally required depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
850.1740	Acute sediment toxicity to estuarine/marine benthic organisms	Conditionally required if chemical is applied directly to estuarine/marine water bodies or expected to enter them in significant amounts. Also depends depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
Non-guideline	Chronic sediment toxicity	Conditionally required depending on the physical properties of the chemical and toxicity to non-benthic organisms (see CFR 158 for more details)
850.3020	Acute contact toxicity to honeybee	
OECD 213	Acute oral toxicity to adult honeybee	Pollinator Guidance Document requirement (not in CFR 158)
Non-guideline	Subchronic 10-day toxicity to adult honeybees	Pollinator Guidance Document requirement (not in CFR 158)

[1] With the exception of non-guideline data requirements, the studies listed in this table were compiled from tables in the CFR "Terrestrial and aquatic nontarget organisms data requirements table" in 40 CFR §158.630 and "Nontarget plant protection data requirements table" in 40 CFR §158.660. Please see the CFR for the full tables, all applicable footnotes, and several additional studies which are not typically required but may be required in specific instances.

Guideline	Study Type	Comments
Non-guideline	Acute and chronic larval honeybee toxicity	Pollinator Guidance Document requirement (not in CFR 158)
Non-guideline	Pesticide residues in pollen and nectar	Conditionally required if honeybee concerns are identified from the laboratory tests. Pollinator Guidance Document requirement (not in CFR 158)
850.3040	Field testing for pollinators	Conditionally required if honeybee concerns are identified from the laboratory tests.
850.4100	Seedling emergence	
850.4150	Vegetative vigor	
850.4400	Vascular aquatic plant testing	
850.4500	Non-vascular aquatic plant testing	Testing is required for one freshwater algal species, freshwater diatom, and estuarine/marine diatom
850.4550	Cyanobacteria toxicity	
870.1100	Acute mammalian oral toxicity	
870.3800	Two-generation rat reproduction study	

Table 4. Environmental Fate Studies[2]

Guideline	Study Type	Comments
835.2120	Hydrolysis	
835.2240	Photodegradation in water	
835.2410	Photodegradation in soil	
835.2370	Photodegradation in air	Conditionally required for terrestrial and greenhouse use patterns depending on Henry's law constant and other chemical factors. (See CFR 158 for more details.)
835.4100	Aerobic soil metabolism	
835.4200	Anaerobic soil metabolism	
835.4300	Aerobic aquatic metabolism	
835.4400	Anaerobic aquatic metabolism	
835.1230 835.1240	Leaching and adsorption / desorption	
835.1410	Volatility – laboratory	Conditionally required. (See CFR 158 for more details.)
835.8100	Volatility - field	Conditionally required. (See CFR 158 for more details.)
835.6100	Terrestrial field dissipation	
835.6200	Aquatic field dissipation	Conditionally required. (See CFR 158 for more details.)
835.7100	Ground water monitoring	Conditionally required. (See CFR 158 for more details.)

[2] The studies listed in this table were compiled from the "Environmental fate data requirements table" in 40 CFR §158.1300. Please see the CFR for the full table, all applicable footnotes, and several additional studies which are not typically required but may be required in specific instances.

E. SCOTT PRUITT
ADMINISTRATOR

July 3, 2017

Mr. James R. Barbee
Director
Nevada Department of Agriculture
405 South 21st Street
Sparks, Nevada 89431

SUBJECT: **NOTICE OF DISAPPROVAL**
SLN No. NV170003 – General Hydroponics Prevasyn (EPA Reg. No. 91865-1)
SLN No. NV170004 – General Hydroponics Exile (EPA Reg. No. 91865-2)
SLN No. NV170005 – General Hydroponics Defguard (EPA Reg. No. 91865-3)
SLN No. NV170006 – General Hydroponics Azamax (EPA Reg. No. 91865-4)

Dear Mr. Barbee:

On April 5, 2017, the Nevada Department of Agriculture issued Special Local Need registrations under Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act as amended, to Hawthorne Hydroponics LLC d/b/a General Hydroponics. These state registrations, submitted to the U.S. Environmental Protection Agency by Jian (Jim) Zhang of NDA, were issued for the application of the following chemicals: capsicum oleoresin extract, garlic oil and soybean oil (NV170003), potassium salts of fatty acids (NV170004), *Bacillus amyloliquefaciens* strain D747 (NV170005) and azadirachtin (NV170006) to control various insect pests, mites and/or diseases on cannabis. The aforementioned chemicals are not registered by the EPA for use on cannabis. On June 22, 2017, the agency sent the NDA a Notice of Intent to Disapprove the four SLN registrations. On June 29, 2017, the NDA consulted with the agency about the SLN registrations.

Decision: The EPA concludes that SLN Nos. NV170003, NV170004, NV170005 and NV170006 are disapproved, effective immediately, for the reasons provided below.

Reasons for Disapproval: During the consultation on June 29, 2017, the NDA expressed their interest in pesticide use for the marijuana industry in Nevada. However, pursuant to FIFRA section 24(c), the EPA's regulations pertaining to state registrations of pesticides to meet special local needs state that "the Administrator may disapprove, on any reasonable grounds, any state registration which, when compared to a federally registered product, does not have . . . a similar

use pattern . . .." 40 C.F.R. § 162.154(a)(1). The regulations define "similar use pattern" to mean "a use of a pesticide product . . . which is [among other things] substantially the same as the federally registered use." 40 C.F.R. § 162.151. Under federal law, cultivation (along with sale and use) of cannabis is generally unlawful as a schedule I controlled substance under the Controlled Substances Act.[1] The EPA finds that the general illegality of cannabis cultivation makes pesticide use on cannabis a fundamentally different use pattern.

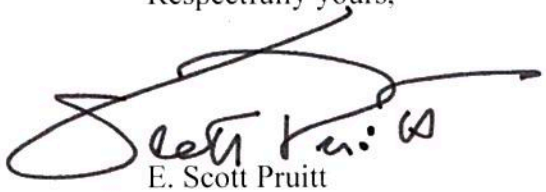
The Administrator may disapprove a different use pattern "on any reasonable grounds." Here, in accordance with 40 C.F.R. section 162.154, the Administrator has determined disapproval is reasonable because the EPA does not believe that Congress intended the process under section 24(c) of FIFRA to be used for the purpose of facilitating activities that are generally in violation of federal law. While the EPA believes that it is not required to consider the general cost-benefit standard applicable to FIFRA registrations when disapproving a registration that is inextricably linked with violations of federal law, application of the cost-benefit standard would not yield a different result – any economic, social or environmental costs associated with pesticide use on cannabis would not be reasonable or justified in light of the fact that such use is in furtherance of an illegal act. The EPA has reviewed the SLN registrations submitted by the state and has not identified any significant risks associated with the SLN registrations; the EPA would not have been inclined to disapprove these registrations were cultivation and sale of marijuana generally lawful in the United States.

Disposition of Existing Stocks: The disapprovals of SLN Nos. NV170003, NV170004, NV170005 and NV170006 are effective immediately. You must take steps to halt any further sale or distribution of products under these SLN registrations. For uses subject to the disapproval, distribution or sale of existing stocks of all disapproved products listed above is prohibited. Sale or distribution of the EPA-registered products is still permitted, as long as the products are still properly labeled and the SLN labeling does not accompany the product.

Per 40 CFR § 162.154(c), a notice of the disapproval of these SLN registrations will be published in the Federal Register. However, this disapproval is effective immediately, as of the date of this letter.

If you have any questions, please contact Nancy Beck at (202) 564-2910 or beck.nancy@epa.gov.

Respectfully yours,



E. Scott Pruitt

Cc: Jian (Jim) Zhang, Nevada Department of Agriculture
Alexis Strauss, Acting Regional Administrator, EPA Region 9

[1] Marihuana, an older spelling of marijuana, and tetrahydrocannabinols are listed under schedule 1 in 21 U.S.C section 812(c).

Legal Ethics Considerations in the Agriculture Tech World

ROSE LAW FIRM

Mark Murphey Henry

OF COUNSEL

Mark is rated as AV-Preeminent™ in both legal ability and ethics, and he serves as counsel in complex federal litigation representing universities, agricultural companies, software development companies, retail vendors, and multi-national corporations having intellectual property rights in the United States. He is a registered patent attorney and earned a Master of Laws (LL.M.) in agricultural law.

ROSE LAW FIRM

Presentation Overview

I. Federal Litigation e-Discovery

There are several ethical considerations surrounding updates in the Federal Rules of Civil Procedure. Attorney Client Privilege and Electronically Stored Information (ESI).

a. Civil Procedure Rule 26(b)(1) – Proportionality Factors Restored
b. Civil Procedure Rule 26(f)(3) – Electronically Stored Information
c. Civil Procedure Rule 16(b)(3)(B) – ESI and Federal Rule of Evidence 502
d. Federal Rule of Evidence 502 – Attorney-Client Privilege and Work Product
e. Civil Procedure Rule 37(e) – Test for balancing interests for "lost" ESI
f. Helpful Guidance on Scheduling Orders for claw-back provisions.
g. Case Study – *Cuker v. Walmart Stores, Inc*. 5:14-cv-05262-TLB (Western District Arkansas)

    Sanction - $400,299.96 for "vexatious, oppressive, and abusive" discovery tactics involving ESI and computer coding.

II. Enforcement of Intellectual Property Rights for public institutions.

Universities develop new seed varieties and have in place a recovery of those costs regimen for licensing. An attorney may need to balance the public disclosure requirements potentially tied to state Freedom of Information Act laws with the ability to enforce intellectual property rights in an effective manner across an array of jurisdictions.

South Dakota Board of Regents v. Fevold Farm Services, 3:18-cv-3005 (N.D. Iowa)

a. Professional Conduct Rule 4.3 – Dealing with unrepresented persons
b. Model Rule 8.4 – "professional misconduct for a lawyer to . . engage in conduct involving dishonesty, fraud, deceit or misrepresentation."
    a. 1974 - ABA Formal Opinion 337 – prohibiting secret recordings
    b. 2001- ABA withdrew it in favor of Formal Opinion 01-422
    c. 2/3 of state statutes permit taping of conversations (one-party consent)
    d. 2012 – Congressional Research Service – Tape Recordings and Legal Ethics.

RULES CITED - FEDERAL LITIGATION E-DISCOVERY

There are several ethical considerations surrounding updates in the Federal Rules of Civil Procedure. Attorney Client Privilege and Electronically Stored Information (ESI).

A. Civil Procedure Rule 26(b)(1) – *Proportionality Factors Restored*

(b) DISCOVERY SCOPE AND LIMITS.

(1) Scope in General. Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

B. Civil Procedure Rule 26(f)(3) Civil Procedure Rule 16(b)(3)(C) and (D) – *connection to FRE 502 and Scheduling Orders.*

(f) CONFERENCE OF THE PARTIES; PLANNING FOR DISCOVERY.

(3) Discovery Plan. A discovery plan must state the parties' views and proposals on:

(C) any issues about disclosure, discovery, or preservation of electronically stored information, including the form or forms in which it should be produced;

(D) any issues about claims of privilege or of protection as trial-preparation materials, including—if the parties agree on a procedure to assert these claims after production—whether to ask the court to include their agreement in an order under Federal Rule of Evidence 502;

C. Federal Rule of Evidence 502 – *Attorney-Client Privilege and Work Product*

RULE 502. ATTORNEY-CLIENT PRIVILEGE AND WORK PRODUCT; LIMITATIONS ON WAIVER

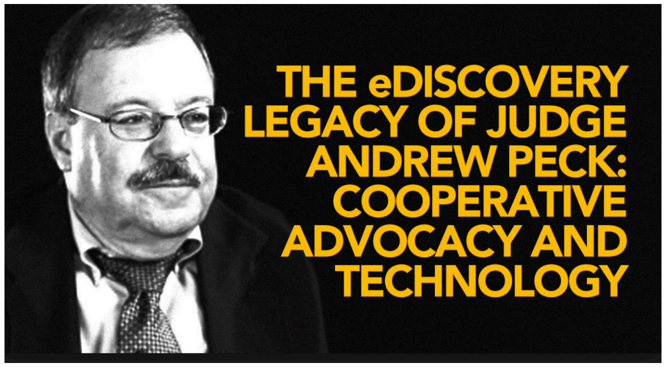
The following provisions apply, in the circumstances set out, to disclosure of a communication or information covered by the attorney-client privilege or work-product protection.

(b) Inadvertent Disclosure. When made in a federal proceeding or to a federal office or agency, the disclosure does not operate as a waiver in a federal or state proceeding if:

(1) the disclosure is inadvertent;

(2) the holder of the privilege or protection took reasonable steps to prevent disclosure; and

(3) the holder promptly took reasonable steps to rectify the error, including (if applicable) following Federal Rule of Civil Procedure 26(b)(5)(B).



Judge Andrew J. Peck, 1 of E-Discovery's Most Influential Figures, Retires From the Bench

: **<u>RULE 502(d) ORDER</u>**

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:

- x

ANDREW J. PECK, United States Magistrate Judge:

1. The production of privileged or work-product protected documents, electronically stored information ("ESI") or information, whether inadvertent or otherwise, is not a waiver of the privilege or protection from discovery in this case or in any other federal or state proceeding. This Order shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d).

2. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of documents, ESI or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production.

D. Civil Procedure Rule 37(e) – *Test for balancing interests for "lost" ESI*

RULE 37. FAILURE TO MAKE DISCLOSURES OR TO COOPERATE IN DISCOVERY; SANCTIONS

(e) **Failure to Preserve Electronically Stored Information.** If electronically stored information that should have been preserved in the anticipation or conduct of litigation is lost because a party failed to take reasonable steps to preserve it, and it cannot be restored or replaced through additional discovery, the court:

(1) upon finding prejudice to another party from loss of the information, may order measures no greater than necessary to cure the prejudice; or

(2) only upon finding that the party acted with the intent to deprive another party of the information's use in the litigation may:

(A) presume that the lost information was unfavorable to the party;

(B) instruct the jury that it may or must presume the information was unfavorable to the party; or

(C) dismiss the action or enter a default judgment.

E. Case Study – *Cuker v. Walmart Stores, Inc*. 5:14-cv-05262-TLB (Western District Arkansas)

Sanction - $400,299.96 for "vexatious, oppressive, and abusive" discovery tactics involving ESI and computer coding.

MULTI-JURISDICTIONAL ENFORCEMENT OF UNIVERSITY-DEVELOPED INTELLECTUAL PROPERTY

Where nonconsensual recording of conversations is permitted by the law of the jurisdiction where the recording occurs, a lawyer does not violate the Model Rules merely by recording a conversation without the consent of the other parties to the conversation.

Where nonconsensual recording of private conversations is prohibited by law in a particular jurisdiction, a lawyer who engages in such conduct in violation of that law may violate Model Rule 8.4, and if the purpose of the recording is to obtain evidence, also may violate Model Rule 4.4.

A lawyer who records a conversation without the consent of a party to that conversation may not represent that the conversation is not being recorded.

Recording requires the consent of all parties in 10 states: California, Florida, Illinois, Massachusetts, Michigan, Montana, New Hampshire, Oregon, Pennsylvania, and Washington.

While illegality and false statements exist as exceptions to a general rule that permits surreptitious recording, evidence gathering is an exception to a general rule that prohibits such recordings. The earlier ABA opinion conceded a possible exception when prosecuting attorneys engaged in surreptitious recording pursuant to court order. Various jurisdictions have expanded the exception to include defense attorneys as well as prosecutors. Some have included use in the connection with other investigations as well. https://fas.org/sgp/crs/misc/R42650.pdf

“The value of secret tape recordings in ferreting out truth is beyond question, and this Court has observed that the admission of such recordings into evidence is sometimes "fully justified." *Miller*, 484 So. 2d at 338; *see also Wilkins v. Bancroft*, 248 Miss. 622, 160 So. 2d 93 (1964) (surreptitious recording properly admitted into evidence to impeach adverse party).” *Attorney M. v. Mississippi Bar*, 621 So. 2d 220 (1992)(Mississippi Supreme Court).

Tyson

Strong today. Leading for tomorrow.

Kevin Igli, SVP & Chief Environmental Officer

August 16, 2018

ESTABLISHED
1935

BORN OF
Necessity
and Opportunity

GROWN THROUGH
Innovation
and Core Values

OUR STRATEGY

Sustainably feed the world with the fastest growing protein brands.

HOW WE WILL ACHIEVE OUR STRATEGY

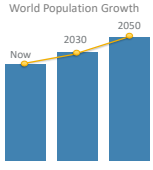
Grow.
Our businesses through differentiated capabilities

Deliver.
Ongoing financial fitness through continuous improvement

Sustain.
Our company and our world for future generations

Sustainability is integral to feeding the world

There are **7.6 Billion** people in the world today.
By 2030, there will be **8.6 Billion.**
By 2050, there will be **9.8 Billion**



That means approximately
2 Billion
more people will need daily nourishment

Activating M&A to Shape our Portfolio

We will evaluate opportunities through four consistent lenses.

Hillshire Brands	AdvancePierre Foods	Original Philly Cheesesteaks
New Brands	New Brands	New Brands
New Capabilities	New Capabilities	New Capabilities
Scale/ Synergy	Scale/ Synergy	Scale/ Synergy
New Geographies/ Markets	New Geographies/ Markets	New Geographies/ Markets

7

8

We continue to focus on our thoughtful 3 step approach to our holistic sustainability strategy

Listen to stakeholders

That means farmers and ranchers, NGOs, policymakers and others in our industry. This is the only way to truly understand what we need to accomplish – and more importantly, how we can do it together.

Identify groundbreaking opportunities

We're looking across our five key pillars – food, animals, environment, workplace and communities – for ways to transform how we work.

Tell Our Story

We're sharing our vision publicly. We're investing. And most importantly, we're holding ourselves accountable for progress.

9

We're taking a holistically approach as all parts of sustainability are interconnected

Food | Animal Well-Being | Environment | Workplace | Community

10

Tyson Confidential

Reduce our environmental impact as we feed the world.

Environment

Achieve a **12%** reduction in water use intensity by 2020 (H_2O)

Achieve a **30%** reduction in greenhouse gases by 2030 (CO_2)

Increase sustainable land stewardship practices on **2M Acres** by 2020

WRI

Collaboration to perform water risk assessment and to set science-based reduction goals

Renewable Fuels

6 of our production locations recapture biogas from wastewater treatment and use it in plant boilers at 4 of the 6 plants – reducing our use of natural gas

8 Million LB

Fiber reduction from corrugated boxes and paperboard cartons in 2017 and our boxes are produced from 100% renewable materials with 30% post-consumer recyclable packaging

11

Tyson Confidential

12

The Seam®

www.theseam.com

Mark Pryor

Chief Executive Officer

Mark Pryor

mark.pryor@theseam.com

- "**The**" Mark Pryor
- Native Memphian
- 18 years "Agtech"
- 12 years "Fintech"

Chairman, CEO

Technical Advisor

Technical Advisor

Board Member

Technical Advisor

Technical Advisor

The Seam®

- Based in Memphis
- Founded year 2000
- Agribusiness Software
- Trading/Clearing
- Blockchain

The Seam Cotton Platform Stats

2017 Crop

Transacting Buyers	Transacting Sellers	Recaps Sold	Bales Sold
50	195	9,150	1.9M

Clearing

$580M

A *growing* need for change…

Data that can be "trusted"

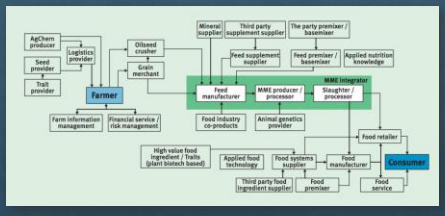
Traceability/Transparency

Digitization

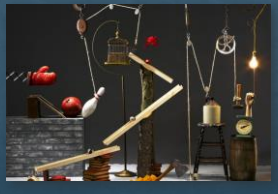
Integration with others

Operational Efficiency

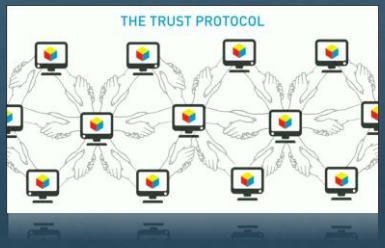
Prove it!

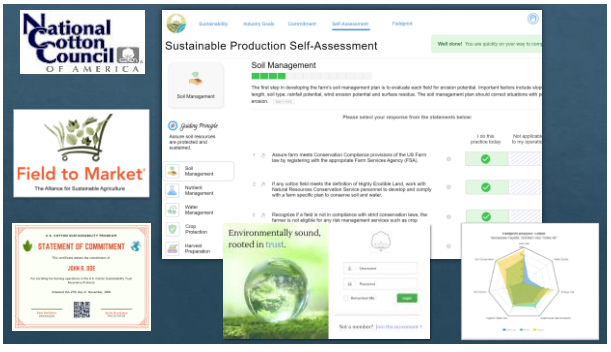


Agriculture is one of the <u>least</u> digitized sectors.



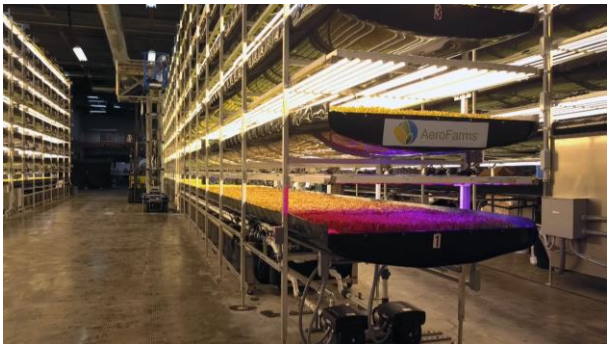
Blockchain: A shared source of "truth".

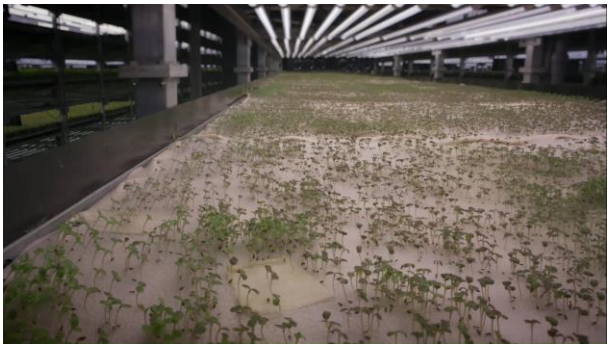


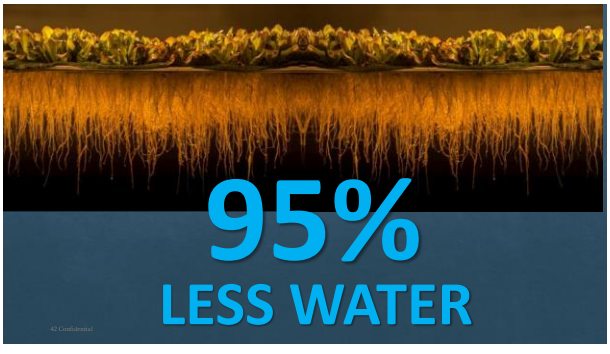


Financial Backers


39 CONFIDENTIAL


AeroFarms




95%
LESS WATER
42 Confidential

390 x More Productive

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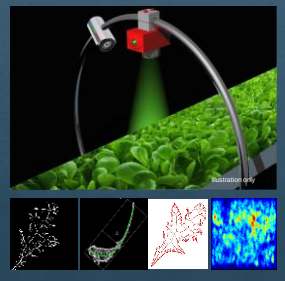
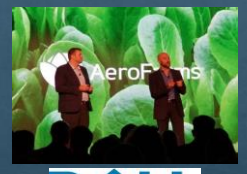
AeroFarms

95% Less Water	Pesticide Free Produce
Taste Texture Nutrition	24 Million Data Points

Smart Data + Machine Learning





DELL Technologies

AeroFarms

Five Pillars

Community Engagement

- High quality jobs
- Local production at scale
- Healthy food access
- Partnerships with schools
- Donations

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Brought to you by the community of

Certified B Corporations

Media and Awards

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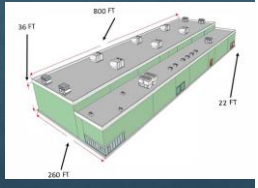
Project Summary

- Creation of 100-150 FTE jobs
- Approximately $100 million capital investment
- 15 MVA electrical; attractive load profile
- Sustainable, resilient and local year-round production of healthy food
- Commitment to community



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General Layout

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Agriculture Law and Technology
State Agriculture Departments and Regulation of Technology
NAAG – Little Rock, Arkansas

I. State Departments of Agriculture Vary Considerably

A. Each state has regulatory and in most cases some promotional and economic development functions vested somewhere in state government. While often housed in a state department of agriculture, other locations include state commerce / economic development agencies, public health agencies, and even university programs.

B. Depending on the state constitution, legislative history of creation of programs, and the ability of a governor to reorganize state functions and transfer programs and authorities, state agriculture departments evolve over time. Many have become something more than "department of agriculture" by adding other responsibilities including areas like forestry, rural development, and consumer protection.

Very few programs exist in every state department of agriculture. Animal health and the position of the state veterinarian may be in the department, but in other cases are vested in an independent state agency, board, or commission. Plant health, including pesticide and fertilizer regulation, may be in the department but could also be part of an environmental or natural resource agency. Food safety may be housed in the department, or a shared responsibility with the public health or commerce departments. Horse racing could be inside or be part of a gaming control function. Regulation of grain sales and elevators may be part of state commerce. Other variables include:

1. The degree to which local units of government have primary or secondary authority, and whether some functions are delegated through the state constitution and statutes from the state to local units. This includes a wide range of areas from food inspection to enforcing dog laws.

2. The size, scope, and relative economic and social power of the food and agriculture sector in a state, and what kinds of laws and regulations the sector has encouraged over time to regulate and protect itself. This includes areas like nuisance lawsuit protection for farms and hiring dairy inspectors to ensure that milk can go into interstate commerce.

3. The nature of the head of the department. Whether called Commissioner, Secretary, or Director, the head of the agency may be created in the state constitution, elected on a statewide basis, appointed by the Governor for a fixed term, or appointed by and serving at the pleasure of the Governor. There may also be limitations on how many at will or politically appointed deputies and assistants are available to help the head of the agency. The in-house counsel type position may be an at-will position appointed by the head of the agency or may be a career civil service position.

The majority of state departments of agriculture contain the following programs: state apiary (bees), feed, seed, pesticide, fertilizer, plant health, dairy inspection, weights and measures, state organics programs, aquaculture, and some animal health components.

II. Legal Duties and Roles of Attorneys in State Agencies Also Vary Considerably

A. There are three main forms:

1. State agencies where there is an in-house counsel and legal staff to represent the agency in legal matters.

2. State agencies where all legal matters are addressed by staff from the state attorney general.

3. State agencies with a hybrid situation, where attorneys within the department may review and write documents, particularly in areas such as drafting of regulations and responses to freedom of information requests, but who defer to the attorney general's office for representation.

B. For attorneys working in state government with and for state departments of agriculture, the practice area can be very specialized, such as working only on matters relating to horse racing or to grain dealers. It can also be incredibly varied, with any given day including:

1. Administrative law – includes things like promulgation of rules, questions on open meetings, freedom of information act responses, and overseeing the process for appeals of agency licensing and enforcement decisions. This may also include hearing contested cases on behalf of the head of the agency or drafting of final orders for the head of the agency. The legal office may also serve as the department's legislative liaison representing the agency in front of legislative committees, drafting legislation, and reviewing proposed legislation.

2. Environmental law – reviewing standards, applications, and enforcement particular to permits on everything from manure lagoons to pesticide drift cases.

3. Commercial law – reviewing contracts, bids, grant agreements, and other financial matters to ensure compliance with state standards. Depending on the state, this could also include oversight of a state fairgrounds / expo center and all that comes with managing that type of facility, including tort cases. Legal offices may also be involved in intellectual property matters for state developed advertising and promotional efforts.

4. Civil rights and Privacy – the legal office may include a liaison role to federally recognized Tribes and oversee compliance with state and federal civil rights requirements. They may also oversee compliance with personal privacy standards, including security of cyber information.

5. Emergency management, safety, and security – in some states, the food and agriculture sector and the state agriculture department are a key part of homeland security efforts. Even if not, the state agency has some functions related to the emergency management areas of prevention, preparedness, mitigation, response, and recovery, and the legal office is likely to be involved in assisting the head of the agency in declaring disasters, issuing quarantines, and related needs. The legal office may also be tasked with ensuring compliance with safety and other worker protection efforts, as well as conducting internal investigations.

III. Some Other Areas That Also Vary Considerably

A. Some states may adopt federal laws and regulations, or handbooks by reference, while other states are required to reproduce all language word by word into their state statutes and rules.

B. In some states, a state agency decision or action can be challenged in a local court anywhere in the state. Other states limit lawsuits against the state to a specific court, like the Court of Claims.

C. Some state agencies have staff that are sworn law enforcement officers who have arrest powers.