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A Closer Look at EPA's Updated Part 152 Subpart E Regulations and Related Guidance

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On February 5, 2014, EPA issued a Final Rule updating its Part 152 subpart E regulations concerning procedures to protect data submitters' compensation and exclusive use rights. (*79 Fed. Reg. 6819*). Among other changes, EPA amended 40 C.F.R. § 152.84 to require submission of all data compensation compliance information and materials, including evidence of any offers to pay, at the time of application, rather than "at any later time prior to EPA's approval of the application," as the regulation had previously provided. In comments on the rulemaking, CPDA had urged the Agency to retain the flexibility provided in the then-existing version of § 152.84. EPA, however, concluded that the amendment was required by FIFRA § 33(f)(4), added by PRIA 2, which directs EPA to ensure that each application include "all the necessary forms." EPA also concluded that requiring all compliance materials, including the offer-to-pay certification, at the time of application would promote the efficient and effective review of applications.

EPA's rejection of CPDA's proposal to retain § 152.84 as written may have been a disappointment to some, but we have a different perspective. While we understand the desire to withhold compensation offers until substantial similarity is determined, we do not consider the elimination of this option a significant loss. In fact, this practice was never widely followed and was being sharply curtailed by EPA as a matter of administrative procedure in any event. Counterbalancing this minor change are several positive features of EPA's Final Rule and related guidance issued at the same time. Overall, EPA's Final Rule and new guidance are welcome developments that should assist post patent applicants to achieve fair and appropriate resolutions of their data compensation obligations.

Timing of Offers-to-Pay

In its comments on the proposed rule, CPDA urged EPA to allow follow-on applicants to withhold their offers to pay at least until EPA has confirmed that the follow-on's proposed product is substantially similar to the basic registrant's product and that therefore the basic registrant's data are relevant. In cases where the follow-on uses the selective method, CPDA further urged EPA to allow offers to be withheld until EPA has accepted the applicant's data

citations. CPDA reasoned that these measures would minimize unnecessary and premature data compensation disputes.

In our experience, it is unusual for serious data compensation negotiations to occur until after the follow-on's registration is granted, whether or not the offer to pay is issued at the time of application. This is because the duty of the follow-on to actually *pay* compensation is not triggered until EPA approves the follow-on's registration. As a consequence, data owners are often willing to defer compensation discussions until EPA has acted on the follow-on's application.

In the case of selective method applications, it is true that it is more likely that a "petition to deny" may be filed by the data owner if the applicant issues its offer at the time of application, rather than after EPA has reviewed its selective citations. But such petitions have not proven to be a significant hindrance. EPA typically approves selective method applications within PRIA deadlines, even if a "petition to deny" is filed. Moreover, to the extent a "petition to deny" identifies studies that legitimately should be cited by the follow-on, it is preferable to have those issues identified and resolved while the application is pending (so that the scope of the applicant's compensation obligations is fixed), rather than in the context of a "petition to cancel" filed after the registration has been approved.

It has been suggested that the change to § 152.84 strengthens the contention that FIFRA's 15-year compensability period should be measured back from the date of application rather than the date EPA approves the registration (or some intermediate date). This concern is not well-founded. FIFRA § 3(c)(1)(F) provides that data submitted within 15 years of EPA's "consider[ation]" of them "in support of" an application are eligible for compensation. In order for EPA to so "consider" data, the applicant must first cite the data and offer compensation for them. Logically, EPA's consideration of data must occur after the applicant has satisfied the preconditions to that consideration (citation/offer). Indeed, at the time the 15-year period was added to the statute in 1978, and in subsequent rulemaking proceedings, EPA repeatedly stated that it "considers" data "in support of" an application at the time of registration approval. Because the timing of the offer to pay is a separate issue from the timing of EPA's consideration of data for purposes of the 15-year compensability period, this regulatory change should not adversely impact the growing body of arbitration decisions holding that the 15-year period is measured from the date of EPA approval of the follow-on's registration.

Not surprisingly, a majority of arbitration decisions adopt this statutory reading. In the most recent ruling (***Bayer v. Albaugh, AmTide and UPI***, Order, December 9, 2013) – which is by far the most thorough and extensively reasoned public decision on the subject – the arbitrators specifically rejected arguments by the data owner that sought to conflate an applicant's *citation* of data with EPA's *consideration* of data in support of an application. The arbitrators found that it is the latter, not the former, that triggers the compensation obligation under FIFRA and, therefore, that the 15-year period is properly measured from the approval date. Following this decision, the data owner asked the arbitrators to reconsider their ruling. Among other things, the data owner argued that EPA's issuance of the Final Rule requiring submission of an offer to pay at the time of the application confirms that the 15-year compensability period should be

measured from the application date. The arbitrators rejected the data owner's request, finding that the Final rule addresses the contents of the application, not EPA's consideration of it.

Other Changes in the Final Rule

With one minor exception, EPA's Part 152 subpart E regulations had not been revised since their promulgation on August 1, 1984. Many of the changes EPA made to these rules were in the nature of updates. While most revisions are minor and neutral to the interests of participants in data compensation matters, EPA made one small but significant change to the regulations. Specifically, EPA changed the *name* of subpart E by adding the phrase, "Satisfaction of Data Requirements;" in front of the existing title, "Procedures to Ensure Protection of Data Submitters' Rights." This name change is important, as it serves to underscore that the purpose of the data reliance procedures is to enable follow-on applicants to satisfy the EPA data requirements applicable to their products. This point is fundamental, but is often ignored by data owners asserting compensation claims – and also is sometimes overlooked by arbitrators adjudicating those claims. Failure to recognize this limitation can open the door to compensation for a wide assortment of additional data, *e.g.*, studies conducted in foreign countries on foreign pests, soils, or crops, § 6(a)(2) submissions, and special studies of all sorts conducted by the basic registrant for product stewardship or other business reasons, but which have nothing to do with satisfying data requirements applicable to the follow-on's registration.

EPA's Preamble to the Final Rule and Response to Comments contain additional provisions helpful to those involved in compensation matters. For example, in explaining why it did not adopt Syngenta's proposal that EPA declare that *all* data submitted under the FFDCA in support of petitions for tolerances/exemptions from tolerance are eligible for compensation, EPA referenced and thus affirmed its 2003 "White Paper" interpreting FFDCA § 408(i), which states that tolerance data are eligible for compensation "to the same extent provided" in FIFRA section 3. The White Paper sets forth the Agency's careful analysis § 408(i) and concludes that Congress intended this provision to extend compensation rights to data concerning inert ingredients, to the extent those data support FIFRA registrations of pesticides containing those inert ingredients. The White Paper also confirms, however, that data submitted to support import tolerances are *not* eligible for compensation, because those data are not submitted or required to support FIFRA registration actions, a point often ignored by data owners and arbitrators alike.

EPA also rejected several other proposals submitted in comments by basic registrants that would have imposed additional burdens on generic applicants or improperly broadened data compensation obligations. For example, EPA (1) rejected Monsanto's proposal that whenever a generic registration is transferred, the transferee be required to issue a new offer to pay to the data owner(s); (2) rejected Syngenta's proposal that generic applicants be required to provide the data owner with a copy of the applicant's proposed label and data matrix along with its offer-to-pay; and (3) rejected in substantial part Bayer's proposal that EPA declare that companies that contribute funds to IR-4 studies are entitled to compensation for those contributions. In rejecting this proposal, EPA made clear that such contributions are compensable *only if* the company, rather than IR-4, submits the study to EPA. Studies submitted by IR-4 are not entitled to compensation.

New EPA Guidance on Data Compensation

On February 4, 2014, EPA also issued a new guidance document entitled "Guidance on Data Compensation Considerations in Connection with Decisions to Waive Typical Data Requirements." Although the Guidance is directed to OPP risk managers, it is of interest to all those involved in compensation matters. In this Guidance, EPA identifies criteria it uses to determine whether a study – particularly non-guideline studies submitted to support a waiver of a standard Part 158 data requirement – is eligible for compensation or exclusive use protection. While EPA does not have any role in deciding the amount and terms of compensation due for reliance on studies, sometimes it must determine whether particular studies are required for registration and thus eligible for compensation. For example, EPA must make such decisions when a follow-on applicant uses the selective method and does not cite certain studies, or when a basic registrant petitions EPA to deny a selective method applicant's registration on the ground that the applicant failed to cite and offer to pay for studies allegedly required for the applicant's registration. In the past, EPA also made these determinations when deciding which studies to include in Appendix B of a Reregistration Eligibility Decision (RED), which lists those data that support the Agency's decision to reregister the pesticide. Frequently at issue in these instances are studies submitted to secure a data waiver, and/or voluntarily submitted studies that EPA subsequently uses to conduct risk assessments. Although EPA has decided the compensability of such (non-guideline) studies on many occasions, EPA's criteria in making these determinations have been less than transparent. This Guidance provides fresh insights into EPA's decision-making criteria and, as such, constitutes an important contribution.

The Guidance also provides examples of studies that, in the normal course, are or are not compensable. Examples of studies that normally are compensable include task force data, data used to waive a data requirement, and data identified by EPA as the basis for a default assumption in lieu of requiring a study. One example deserves particular mention: "Data submitted by a registrant that leads the Agency to the conclusion that a specific assessment is not needed, *but changes the regulatory outcome*; i.e., leads to a *label change*." (Emphasis added.)

In contrast, EPA identifies as non-compensable, "[d]ata submitted by a registrant that leads the Agency to change the conclusions of a risk assessment without resulting in labeling changes or other changes to the FIFRA registration." Similarly, EPA's Guidance confirms that studies that support "a new approach or methodology" but do not support "specific registration actions" are not compensable. Thus, the fact that EPA relies on a data item to conduct a risk assessment or reach a regulatory determination is not sufficient to confer compensability. Rather, to be compensable, the data item must either result in a data waiver or result in a label change or other change in the registration of the pesticide.

Additionally, EPA's Guidance affirms that studies "that were not submitted to support or maintain a registration are not compensable." Again, this places import tolerance data in the non-compensable category, because those data are submitted to establish an FFDCA tolerance, not to add a new use to the label or make any other change to the registration. EPA also confirms that, if two registrants of the same or similar products both submit their own data to satisfy a data requirement, they do not owe compensation to each other, even if the Agency uses only one registrant's data for assessment purposes.

Inaugural CPDA Legislative Policy Conference a Hit

Sandwiched between snow storms that shut down Washington, D.C., attendees of the 2014 CPDA Legislative Policy Conference, held on March 12th, were given a respite from Mother Nature. Phillip Page, Helena Chemical Company, Chairman of the CPDA Legislative Committee opened the conference by welcoming attendees and then introduced the first speaker, Congressman Richard Hudson (R-NC), a rising star in the republican conference.

CPDA President Sue Ferenc and Rep. Richard Hudson

Representative Hudson spoke of his strong support for two of CPDA's top legislative issues – eliminating duplicative NPDES permits for the lawful application of EPA registered pesticides in, over, or near receiving waters of the U.S. and extending the authorization of the Chemical Facility Anti-Terrorism Standards (CFATS) program. Rep. Hudson, who sits on both the House Committee on Agriculture and the House Committee on Homeland Security, provided CPDA members an overview of how important agricultural and small business issues are to his district.

Congresswoman Cheri Bustos is flanked by CPDA members at the Legislative Policy Conference.

Congresswoman Cheri Bustos (D-IL) spoke later in the morning and gave her perspective on life as a freshman Democrat in the minority, as a member of the conservative Blue-Dog Caucus and as part of the "No Labels" group, described as a citizens' movement of Democrats, Republicans, and Independents dedicated to promoting a new politics of problem solving and making government work. The Congresswoman spoke about what motivates her and how the bi-partisan relationships she has developed through playing on the female Members of Congress softball team has aided her in effectively passing legislation. Rep. Bustos, who is a member of the House Committee on Agriculture and the House Committee on Transportation & Infrastructure, also discussed legislation that she has introduced, H.R. 2675, titled the Government Transformation Act. This bill aims to eliminate duplicative government administrative functions where there is jurisdictional overlap.

Attendees of the Conference were also presented with an in-depth report by CPDA Director of Legislative Affairs John Boling on the issues identified as key to CPDA members along with a quick summary of legislation that would reform the Toxic Substances Control Act (TSCA). In addition, Boling provided an overview of what may happen in the 2014 mid-term elections and how this could likely impact the outcome of the 2016 Presidential election.

Over lunch, 15 people participated in the CPDA-PAC fundraiser and were treated to a personal briefing on the status of the Administration's efforts to expand the jurisdiction of the Clean Water Act (CWA). Joe Price, legislative aide to Congressman Bob Gibbs (R-OH), briefed the group on the status of the proposed rulemaking and what opponents of expanding the jurisdiction were doing.

After lunch the group walked to the U.S. Capitol and posed on the steps for a group picture to kick off the *Rally on the Hill* portion of the conference.

The group then headed off for a meeting with Bill Greene, external relations staffer for Speaker of the House John Boehner (R-OH), held in the Montgomery Room, an historical and ornate room of the U.S. Capitol.

The group had the rare honor of being escorted onto the Speaker's balcony, which looks down the Washington Mall where they were able to enjoy the panoramic view and take a picture or two. Mr. Greene then gave the group a quick tour of the Capitol Rotunda resplendent with grandeur, history, paintings and sculptures. While assembled in the hallways of the Capitol Rotunda, CPDA members had the opportunity to meet Representatives Danny Davis (D-IL), Rodney Davis (R-IL), and John Shimkus (R-IL) who, after chatting with a delegation of CPDA members from Illinois, posed for the picture above.

CPDA members and Rep. Stephen Fincher

Later in the afternoon, the CPDA group broke up for team meetings with 20 Members of Congress and staff to educate them on issues important to CPDA and to express the Council's strong support for: 1) legislation that would amend FIFRA and the Clean Water Act to remove the duplicative NPDES permitting requirement; 2) changes that would increase transparency and ensure the use of sound science and technical data in the Federal rulemaking process; 3) a permanent extension of the Research & Development (R&D) tax credit; and 4) a two-year authorization of the Department of Homeland Security CFATS program that would expressly prohibit any requirement calling for the use of "inherently safer technology."

CPDA delegation visits Illinois Congressman Brad Schneider.

The *Rally on the Hill* culminated with the annual Congressional Reception, held once again in the ornate House Agriculture Committee Room. Sponsored by Helena Chemical Company, Precision Laboratories, LLC, Wilbur-Ellis Company, and Winfield Solutions, LLC, attendees munched on Red, Hot & Blue BBQ as they conversed with their colleagues, Members of Congress, and Congressional staff who came by for the camaraderie and excellent view of the Capitol from the balcony.

CPDA Members and Rep. Doug LaMalfa at the Congressional Reception

Attendees accomplished the primary goals of the meeting: first, to remind Congress of our interest in specific legislation; second to reaffirm relationships with select elected officials; and, third, to network and have a bit of fun. The attendees' efforts on behalf of the industry will pay dividends when the issues discussed come up on the House floor and in the future when different issues impacting the industry arise.

CPDA Member Spotlight

FINE AMERICAS, INC.

Fine Americas, Inc. is a wholly owned subsidiary of Fine Holdings Ltd., Worcester, UK. While its parent company was founded in 1983 as a leading supplier of plant growth regulators (PGRs) to world markets, Fine Americas was established 10 years ago to give the company a greater presence in North and South America.

Since then, Fine Americas has expanded its product line and country registrations dramatically to bring new products to the agricultural marketplace, including several proprietary technologies and advanced formulations. Currently, Fine markets 10 products in the greenhouse ornamental sector and another six products in the high-value and row crop agricultural markets, with additional registrations pending.

Headquartered in Walnut Creek, CA, Fine Americas is one of Western Hemisphere's leading suppliers of advanced plant growth regulators for the agricultural markets.

One-of-a-kind products

In terms of exclusive products, Fine Americas was the first company to offer a 2% 6-BA plant growth regulator for greenhouse ornamentals. Two years ago, it launched the world's first and only 4% paclobutrazol PGR in a soluble liquid formulation, providing ornamental growers with unsurpassed performance and convenience. Last year, Fine introduced a new state-of-the-art

ethephon PGR for ornamentals containing six times the active ingredient of traditional ethephon products. And this year, Fine Americas has registered a new active ingredient (5% prohydrojasmon) in the U.S. for enhanced red coloration of Fuji, Gala, Honeycrisp and other bi-color apple varieties.

In addition, Fine Americas is in the process of registering a number of new active ingredients, along with new formulations of existing products to meet market demands and California EPA guidelines regulating volatile organic compound (VOC) emissions. The first of these new formulations will be a low VOC liquid gibberellic acid (GA3) PGR for use in table grapes, cherries and citrus.

A decade of excellence

These new product introductions and continued geographic expansion, combined with outstanding sales, distributor and technical support, have allowed Fine Americas to grow its business significantly over the past 10 years. The company takes great pride in this accomplishment, considering the macroeconomic challenges the industry has faced during that period.

Another source of Fine's success stems from its outstanding manufacturing processes. All of its products are manufactured under strict ISO 9001-2008 quality control standards and the company continually strives to improve plant growth regulator technology to meet the exacting demands of today's quality-conscious growers.

An even brighter future

Looking to the future, Fine Americas will continue to bring innovative new PGR products and technologies to the agricultural markets. Growers in all segments are becoming increasingly sophisticated in their use of plant growth regulators, so the company plans to provide new PGR active ingredients and improved formulations to help drive the PGR market forward. In turn, this will allow growers experienced in the use of PGRs to continue fine-tuning their PGR programs as a cost-effective way to improve crop size, quality, color, yield and harvest efficiency. Plus, it will enable row crop growers to expand their use of PGRs to improve crop performance and yields.

Fine Americas attributes much of its success to its distribution partners throughout the Western Hemisphere. In the U.S. and Canada, the company works closely with distributors to provide outstanding sales and service support in their respective geographic areas. In other regions of the hemisphere, Fine has formed strategic alliances with partners in each country to distribute and support its product line. Furthermore, Fine Americas is proud to be at the forefront of ongoing testing programs with leading university researchers as a means of constantly improving product performance and expanding product registrations.

Finally, Fine Americas relies on targeted marketing communications to reach its key audiences with high-impact sales messages. From print advertising, technical bulletins and public relations to webinars, email marketing and program sponsorships, marketing communications plays an essential role in building brand awareness and preference for Fine's products while positioning the company as a leader in the field of plant growth regulators.

2014 Annual Adjuvants & Inerts Conference

The 2014 Annual Adjuvants & Inerts Conference will be held May 7 at the Sheraton Denver Downtown Hotel in Denver, Colorado. The Annual Adjuvants & Inerts Conference provides a unique forum for the exchange of information on current challenges in agricultural production and opportunities for innovation in agrotechnology to meet those challenges. The program is geared toward the manufacturers, importers, suppliers, and users of adjuvant and inert ingredient products. This year's conference program will include a discussion of the development and effectiveness of drift reduction technologies, biorationals and their uses in agriculture, the use of ammonium sulfate as a water conditioning agent in agricultural chemical tank mixes, the use of adjuvants and other chemistries as a water management tool in draught-stricken agricultural areas, and the environmental and regulatory aspects of water/fertilizer use in agriculture. Preceding the Conference on May 6th will be a number of optional activities including the CPDA-PAC Golf Tournament, a clay shooting event, and an evening baseball game at Coors Field where the Colorado Rockies will take on the Texas Rangers. Registration and hotel information is available on CPDA's web site and may be accessed by clicking here.