UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer Crop Science LP and	)	FIFRA-HQ-2016-0001
Nichino America, Inc.	)	
	)	
Petitioners.	)	

RESPONDENT'S PREHEARING EXCHANGE OF PRIMARY DISCOVERY

In response to Judge Biro's April 4, 2016 Order Scheduling Hearing and Prehearing Procedures, Respondent is providing the following responses to the prehearing exchange of primary discovery materials.

(A) Witness

Respondent will provide Susan Lewis, Director of the Registration Division. Ms. Lewis will be called primarily as a fact witness, however, because regulatory agency staff are not neatly classifiable as "fact" or "expert" witnesses, she may be considered as an expert witness for the pesticide registration process and EPA decision-making related to that process. Her curriculum vitae is attached.

(B) Verified Written Statement

Susan Lewis's Written Statement will serve as her direct testimony and is attached.

(C) Exhibits

Respondent's list and copies of all documents and exhibits intended to be introduced into evidence are attached.

(D) Any Objections to Scope of Hearing

Respondent objects to any testimony in this proceeding not related to the only two issues for resolution in this proceeding convened under section 6(e): whether Registrants complied with the relevant condition of registration and the disposition of existing stocks. While Respondent does not know what testimony Registrants will seek to proffer, Respondents will object to any testimony related to the legality or scientific appropriateness of the condition at issue in this proceeding, or whether Registrants' acceptance of the condition was voluntary or "coerced", as being outside the proper scope of this proceeding. Further, as set forth in Respondent's Motion to Limit Scope of Testimony filed on April 18, 2016, Respondent does not believe testimony related to the costs and benefits of sale, distribution, or use of existing stocks is material to resolution of any factual matter at issue in this proceeding, and therefore objects to such testimony for that reason.

(E) Official Notice

At this time, Respondent is unaware of any matters which the Tribunal should take official notice. Respondent reserves the right to move for official notice of matters as appropriate.

(F) Translation Services

No translation services will be required for Respondent's witness.

Dated: April 22, 2016

Respectfully Submitted,

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Curriculum vitae

Susan Torregrosa Lewis

Senior Executive Service

Education

Virginia Polytechnic Institute and State University, B.S. Business/Finance

Experience – United States Environmental Protection Agency

Division Director **October 2014 - Present**
Registration Division, Office of Pesticide Programs, EPA

I am responsible for the management, leadership and oversight of a diverse division responsible for the regulatory review and risk management for new pesticides, new uses, amendments to existing uses, State initiated actions, and inert ingredient evaluations under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). The division's mission is to ensure that the proposed pesticide actions meet the statutory standards for protecting human health and the environment.

Division Director & Acting Division Director **January 2013 – October 2014**
Antimicrobial Division, Office of Pesticide Programs, EPA

I was responsible for the management, leadership and oversight of four branches and an administrative team with a staff of 67 employees responsible for regulating all antimicrobial pesticide products. I managed the registration and registration review programs for all antimicrobial pesticide products under the authorities of FIFRA)and the FFDCA.

Acting Division Director **September 2012 – January 2013**
Biological and Economic Analysis Division, Office of Pesticide Programs, EPA

I was responsible for the management, leadership and oversight of 65 staff and the activities of three branches and four remote laboratories that support all the pesticide regulatory programs as well as other EPA offices. I managed operational responsibilities across a full range of programmatic issues including the development of critical "real-world" pesticide use information, and assessments of the benefits of pesticide uses in support of registration and registration review activities under FIFRA and FFDCA. I managed the economic analyses on the impact of cancellation of a pesticide and cost analyses for pesticide regulations. I managed laboratory activities that support Office of Pesticide Programs (OPP) scientific and regulatory initiatives as well as the Office of Toxic Substances, Office of Water, Office of Enforcement and Compliance Assurance and international governments.

Associate Director **April 2009 – September 2012**
Biological and Economic Analysis Division, Office of Pesticide Programs, EPA

As Associate Director, I was responsible for providing senior level day-to-day oversight and leadership of work in the Division. I also co-managed the Division alongside the Division Director. I oversaw the development of biological pesticide use patterns, evaluations of alternative pesticides and of pest control practices, regulatory impact analyses and analyses of pesticide benefits in support of OPP rulemaking activities, minor use pesticide registrations, emergency exemptions, review of existing registrations and rule-making.

Branch Chief **1998 - 2009**
Special Review and Reregistration Division, Reregistration Branch 1, Office of Pesticide Programs, EPA

I served as the Branch Chief of the Reregistration Branch 1. The branch was responsible for coordinating the reassessment of pesticides under FIFRA to ensure that they meet current scientific and regulatory standards. I managed the development of risk mitigation measures to address both human health and ecological risks using a public participation process, ensuring transparency and input from stakeholders. I provided guidance and direction to staff on technical, policy and administrative issues related to pesticide reregistration and tolerance reassessment, risk assessment, risk management, risk communication, policy development and pesticide statutes. Additionally, I managed the tolerance reassessments to ensure that they meet the new safety standard established by the Food Quality Protection Act of 1996. I oversaw the risk management decision and the development of the Agency's decisions in the issuance of numerous Reregistration Eligibility Decisions. I conducted or arranged for training of the staff on many aspects of pesticide laws, risk assessment and risk management. I negotiated, on behalf of the Division, with pesticide manufacturers to secure agreements for registration changes for pesticides undergoing reregistration and tolerance reassessment.

Acting Branch Chief **2003 (8 month detail)**
Registration Division, Minor Use, Inerts & Emergency Response Branch, Office of Pesticide Programs, EPA

As acting Branch Chief, I provided day-to-day supervision and leadership for all Branch activities including management of all aspects of the minor use program including pesticide registration decisions under FIFRA and establishing residue tolerances under the FFDCA, reviewing and clearing pesticide inert ingredients, and responding to state requests for emergency exemptions from the registration requirements of FIFRA. The branch was responsible for coordinating the scientific reviews, analyzing the risks and benefits of the proposed uses, and recommending Agency risk management decisions. The scientific reviews included human health, ecological risk and economic impacts.

Branch Chief **1997-1998**
Registration Division, Insecticide Branch, Office of Pesticide Programs, EPA

As Branch Chief I managed the regulatory activities associated with the registration of insecticide products. The branch was divided into two product management teams, each led by a Product manager. I managed the coordination of the review, analysis and decision to grant or reject applications for new and amended registrations of insecticide products. I represented the Agency's position at national and international meetings, requiring a comprehensive knowledge of pesticide regulations and an understanding of risk assessment and Agency policies.

Branch Chief **1993 - 1997**
Registration Division, Insecticide/ Rodenticide Branch, Office of Pesticide Programs, EPA

As Branch Chief, I managed a branch consisting of five Product Manager Teams and a Deputy Branch Chief. I was responsible for managing the final decision-making concerning all registration and tolerance setting activities for pesticide products used to control insects, mites, vertebrate pests, such as rats and mice, animal repellents and biochemicals. I developed plans and managed the coordination of the review, analysis and decision to grant or reject pesticide applications in accordance with FIFRA, the FFDCA, and Agency policy. The applications were for new registrations, changes to existing registrations, product

reregistration, and tolerance setting for the allowable residues of pesticides on food. Specifically, Federal law requires that the pesticide, when used according to label directions, will not cause unreasonable risk to human health or the environment, and with a reasonable certainty of no harm from dietary residues.

Supervisory Product Manager Fungicides **1989-1993**
Registration Division, Fungicide/Herbicide Branch, Office of Pesticide Programs, EPA

As Product Manager, I was responsible for managing the coordination of scientific reviews and the performance of regulatory reviews of all applications for registration, amended registration, special local needs, reregistration, experimental use permits and petitions for tolerances for fungicide products. I ensured all regulatory decisions were consistent with applicable laws and policies, timely and accurate. This included the coordination of scientific reviews and risk assessments, labeling requirements, legal opinions and benefits analysis. I coordinated with the Office of General Counsel and Office of Enforcement and Compliance Assurance on legal matters. I communicated pesticide regulations, policies, procedures and Agency's position to a wide range of stakeholders and served as point of contact to the public for all fungicide products.

Environmental Protection Specialist, Fungicides
Fungicide/Herbicide Branch, Registration Division **1987-1989**

I was a staff member on the Fungicide Team. I coordinated the scientific and regulatory assessments in support of registration and reregistration actions and proposed the regulatory decisions.

Environmental Protection Specialist, Immediate Office
Registration Division **1980-1987**

I was a staff member with the Data Call In Team. The purpose of this team was to identify missing human health data requirements for older pesticides which were necessary for a risk assessment and issued Data Call In Notices as authorized under 3(c)(2)(B) of FIFRA. I evaluated responses from the registrants and prepared the Agency's decision concerning data requirements. Registrants' responses included commitments to generate the data and requests for low volume/minor use waivers, amended use profiles, time extensions, and cancellations.

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Written Testimony of Susan T. Lewis, Director of the Registration Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency

I am currently the Director of the Registration Division (RD) in the Office of Pesticide Programs (OPP), Office of Chemical Safety and Pollution Prevention (OCSPP) with the U.S. Environmental Protection Agency (EPA). I have been the Director of RD since October 2014 and previously was the Division Director and Acting Director of the Antimicrobials Division (over 1.5 years), Acting Division Director and Associate Director of the Biological and Economic Analysis Division (3.5 years), and Branch Chief in the Special Review and Reregistration Division (10 years) (renamed the Pesticide Re-evaluation Division). I have spent 35 plus years of my EPA career with OPP; I have worked for approximately 20 of those years in either staff or managerial positions within RD.

My division is the regulatory component of OPP responsible for the product registration for conventional chemical pesticides, including flubendiamide. The other OPP divisions that had a role in analyzing flubendiamide were the Health Effects Division (HED), responsible for assessing pesticide exposure and risks to humans; the Environmental Fate and Effects Division (EFED), responsible for assessing ecological risks of pesticides; and the Biological and

Economic Analysis Division (BEAD), responsible for pesticide use-related information and economic analysis in support of pesticide regulatory activities.

In my capacity as Director of RD, my staff and I are responsible for risk management and regulatory decisions related to new and existing registrations. One of RD's principal responsibilities is responding to applications for new registrations and amendments to existing registrations involving conventional pesticides. In that capacity, RD reviews labels and applications submitted by registrants or applicants for registration; considers risk and benefits assessments and other input from HED, EFED and BEAD; considers whether risk mitigation is necessary or appropriate for a particular product; considers whether additional data are needed; discusses with applicants modifications to the license or labeling that are needed to mitigate any identified risks; and ultimately either rejects or grants a registration based on the relevant statutory factors, including whether use of the registered product as labeled and under the terms of the registration will cause unreasonable adverse effects on the environment.

I have extensive experience in the evaluation and registration of pesticides and a thorough understanding of the registration of flubendiamide. I have developed this knowledge through discussions with my staff, staff in EFED and BEAD, and reviewing all of the exhibits I reference in my written testimony.

Background on Conventional Pesticide Registration Decision-Making

Much of the decision-making on registration applications centers on whether use of the product under the terms of the proposed registration will result in unreasonable adverse effects to man or the environment. The unreasonable adverse effects determination is (with the exception of dietary risk issues) primarily a comparison of the expected risks and benefits. Our determinations on whether use of a product will result in unreasonable adverse effects on the

environment are complicated ones, requiring the consideration of numerous studies on the pesticide at issue, as well as consideration of likely alternative pesticides.

When making a registration decision, RD considers, among other things, the potential toxicity of a pesticide to humans, other mammals, birds, insects, a variety of forms of aquatic life, and non-target plants; the environmental fate characteristics of the pesticide, including its persistence and mobility; the possible routes of exposure of humans and other animal and plant species, and the likelihood and potential extent of exposure; the extent of pesticide residues that could be available on food; and the potential economic and/or health benefits that use of the pesticide could provide, including a comparison of the pesticide with likely alternative pesticides.

In our analysis, RD considers both what we know about the pesticide and what we don't know; how we deal with uncertainties in the analysis can play an important role in the overall unreasonable adverse effects determinations. Through label requirements and other terms and conditions of registration, we require risk mitigation measures as necessary in order to prevent unreasonable adverse effects on the environment, or, if no such measures are feasible, we do not proceed with registration (typically registrants then withdraw their application rather than ask for a denial hearing that is available to them under FIFRA).

When OPP makes a no unreasonable effects determination, we use all available data, including the most current scientific information, policies and methodologies. We also consider the most current information about alternatives, including, but not limited to, the development of resistance to older pesticides and the availability of newer alternatives.

Uncertainties in OPP's assessments can affect our unreasonable adverse effects determinations in a number of ways. For instance, we need a certain level of confidence in the

appropriateness of our determinations in order to issue a registration under FIFRA; in some cases, the existence of significant uncertainties can deprive us of that confidence and oblige us to issue a denial instead. In other circumstances, uncertainties can be resolved without having to deny an application by including more protective license conditions instead. These conditions are agreed upon before EPA can issue the license. Uncertainties can also lead to more mitigation measures to reduce risks of concern, as well as requirements to generate additional studies, conduct monitoring, or submit additional information about incidents related to use of the pesticide. Sometimes, the nature of EPA's analysis and any attendant uncertainties allows OPP to make a no unreasonable adverse effect finding for a limited period of time, but not for an indefinite period of time.

In considering possible risk mitigation measures when reviewing applications, EPA typically considers a wide array of options. Depending upon the particular risk at issue for a pesticide, mitigation measures could include, just to name a few of the possibilities: label requirements to utilize engineering controls or additional protective equipment; limiting the timing of applications; limiting the amount of pesticide that can be applied at a particular site; requiring the use of buffer zones between the application and sources of water or neighboring locations; restricting particular methods of application; restricting who can apply the pesticide; requiring specific training for applicators; prohibiting use on specific sites or crops; requiring changes in the formulation of a pesticide product; or limiting the overall amount of product that can be used, through limits on the quantity allowed to be produced. Another possible risk mitigation measure is limiting the duration of the registration.

Whenever EPA's review suggests that license conditions or risk mitigation measures may be necessary in order for OPP to grant an application, we typically have discussions with the

applicants on the need for the conditions or measures; what conditions or measures may be practicable or appropriate; and, where applicable, an applicant's preference where, as is often the case, a number of alternative options could address EPA's concerns. Our ultimate goal is to come up with conditions and mitigation measures that resolve our concerns and enable us to make the regulatory findings necessary to allow the product to become registered for use, while allowing applicants wide latitude in identifying the particular suite of conditions and mitigation measures that if incorporated into their licenses would enable us to make those necessary findings.

Initial Registration for Flubendiamide

I was not Director of RD in 2008 when the initial registrations of flubendiamide were issued. But I have discussed the matter with my staff who were involved in the review of the initial application, and I have reviewed many of the key decision documents from 2008 as well as email traffic between EPA staff and employees of the flubendiamide registrants pertinent to the 2008 flubendiamide registration decision.

On April 6, 2006, Bayer CropScience LP and Nichino America, Inc. (hereafter identified as BCS/NAI) jointly submitted an application for registration of the flubendiamide technical product and BCS submitted an application for registration of two flubendiamide end-use products. Flubendiamide is an insecticide which targets lepidoptera pests and acts against the larvae of the target pests (Lepidoptera spp.) via oral ingestion of toxic residues on plants.

Flubendiamide was a new active ingredient, not previously registered by EPA. When OPP receives an application for a new active ingredient pesticide registration, we evaluate a variety of potential human health and environmental effects associated with use of the product. The company that wants to sell and distribute the pesticide must provide data from studies that

comply with our testing guidelines, found in EPA Regulations at 40 CFR Part 158. In order to approve a registration, EPA must make a determination that there are no unreasonable adverse effects to human health and the environment.

Flubendiamide has an attractive toxicity profile in many respects, particularly with regard to its relatively low toxicity to humans and many non-target animals. But the EPA reviewers of flubendiamide identified some troubling aspects with the application as well. Flubendiamide is a very persistent compound, especially in aquatic systems. Flubendiamide itself is toxic to freshwater benthic invertebrates, and it breaks down in water into a degradate (des-iodo) that is even more toxic than flubendiamide to freshwater benthic organisms. While the applicants argued that flubendiamide levels in water were not likely to exceed levels where toxicity could be expected, EPA was uncertain about whether this would in fact be the case.

From what I know about flubendiamide, EPA could have resolved the concerns with the application in a number of ways. Because EPA could not definitively conclude that flubendiamide would not get into water or aquatic sediment in concentrations that could have harmful effects on freshwater benthic organisms, and because the persistent characteristics of flubendiamide could mean that any such harm to the aquatic environment could be long-lasting, EPA could have denied the application. That could well have precluded flubendiamide from ever coming to market. But EPA was also mindful of flubendiamide's relatively low toxicity to humans and most other taxa. In the end, EPA determined that it was appropriate under FIFRA to give a time-limited registration for flubendiamide with a requirement that vegetative buffers be used, during which time the registrants would be required to generate data to try and resolve the uncertainty over whether flubendiamide caused unreasonable adverse effects.

Including a time-limitation on the flubendiamide registration was an important part of the decision to issue the initial registrations. Considering the persistence of flubendiamide and its potential toxicity in water, the EPA decision-makers on flubendiamide at the time seemed to be very concerned that the long-term use of flubendiamide may result in unreasonable adverse effects of the environment. At the same time, those decision-makers appear to have concluded that it would be appropriate to grant a short-term registration and acquire more information, in order to not unnecessarily prevent a potentially attractive replacement insecticide from reaching the market. Accordingly, EPA proposed to the applicants to grant a time-limited registration to allow registrants to conduct additional studies based on the actual use of flubendiamide, and that registration would have expired five years after its issuance unless EPA determined that further use of flubendiamide would not cause unreasonable adverse effects on the environment.

The applicants were well aware of EPA's concerns. The issue of whether the registration should include terms that would allow the product to be quickly removed from the market-place if EPA's concerns were unresolved five years later was the topic of much discussion between EPA and the applicants. That the ability to quickly cancel the registration was an important factor in EPA's decision to grant the registration is reflected in the Registration Division's 2008 memorandum recommending that the Director of the Office of Pesticide Programs approve the FIFRA section 3(c)(7) registrations: "If there are risk concerns [after review of data, consideration of uncertainties, and mitigation measures] that result in the Agency being unable to determine that there are no unreasonable adverse effects to the environment, the registrants have agreed that the pesticide will be voluntarily cancelled." (Respondent Exhibit 1). This clearly shows that EPA relied upon the mutually agreed-upon conditions in the registration in order to grant the registration.

After much deliberation over the two years between application and approval, EPA and BCS/NAI discussed the final conditions to be included on the requested registration, and on August 1, 2008, EPA granted a conditional registration under section 3(c)(7)(C) of FIFRA for flubendiamide. EPA issued the registration conditionally, due to the initial concerns regarding flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the extremely toxic nature of the primary degradate NNI-001-des-iodo (des-iodo) to freshwater benthic invertebrates. Because of the uncertainties of how flubendiamide and its degradate des-iodo would accumulate in the aquatic environment and potentially pose risk to freshwater benthic invertebrates, EPA determined that certain conditions were necessary in order for EPA to be able to make a no unreasonable adverse effects determination.

One condition of the flubendiamide registrations required that if the Agency makes a determination that further registration of the flubendiamide technical and end-use products would result in unreasonable adverse effects on the environment, within one week of this finding, the Registrants must submit a voluntary cancellation of the flubendiamide technical and all end-use products. These conditions were agreed to by the Registrants and RD and memorialized in the Preliminary Acceptance Letter (PAL). (Respondent Exhibit 2) The PAL memorialized the conditions that had been negotiated between EPA and the Registrants. The Registrants signed the PAL, concurring on the proposed conditions on July 31, 2008, and the PAL was subsequently incorporated by reference into each of the flubendiamide registrations. Per the Agency's Notice of Registration the Registrants' original release for shipment of the flubendiamide products constituted acceptance of the conditions of registration expressly including those specified in the PAL. (Respondent Exhibit 3)

The terms of flubendiamide's registration were negotiated by staff in the Registration Division and the previous Director of the Registration Division. EPA and the Registrants worked out the conditions to be included in the final registration and I have reviewed emails between EPA staff and the Registrants that support my belief that Registrants understood and agreed with the voluntary cancellation provision. EPA's initial proposal stated that the registration would automatically expire in July 2013 unless EPA, at its sole discretion, extended the registration. (Respondent Exhibit 4) This condition would have been equivalent to an expiration date condition that we have used on other registrations. The Registrants' counterproposal objected to the language concerning automatic cancellation, but appears to have still presumed that registration would end on September 1, 2013 unless EPA approved an unconditional registration or the parties agree to another path forward.

Subsequent discussions shifted away from the initial plan for the registrations to expire on a date certain to the situation where if after review of the new studies and discussions with the Registrants, EPA concluded that the products still did not meet the registration criteria for an unconditional registration, the Registrants would be required to submit a request for voluntary cancellation within one week of EPA informing them of a finding of unreasonable adverse effects. The Registrants' comments on a draft of the PAL illustrate both the Registrants' engagement in the negotiations regarding the process for cancellation and their acquiescence to the process ultimately specified in the PAL.

In an email exchange between EPA and Bayer concerning the negotiations on the conditions for the registration, the Bayer representative, Clive Halder, described the status of the negotiations two days before EPA issued the first flubendiamide registration:

> Basically, there is only one remaining 'sore point', … it appears to allow EPA to demand cancellation without any due process from us. My take is that the Agency

would like to avoid having to go through Section 6 cancellation proceedings. We understand this, so have little problem with fitting in the 'fast death' approach, i.e., voluntary cancellation within a week of the decision. From our side, we expect that a fair cancellation demand can only occur after the conditions of part 5(b) and 7(b) have been met, specifically, that all the submitted data have been reviewed [by EPA] alongside all voluntary data submitted by Bayer, plus following a measured dialogue between the scientists.

Mr. Halder's email goes on to propose alternative language that is almost identical to the final language incorporated in the final PAL as paragraphs 6(d) and 8(d). His rewrite of the paragraphs, which he stated "hopefully addressed our collective needs…", offered the following language for EPA's consideration:

5(c) If after review of the data, as set forth in 5(b) above, the Agency makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, within one (1) week of this finding, Nichino will submit a request for voluntary cancellation of the registration of the flubendiamide technical product. That request shall include a statement that Nichino recognizes and agrees that the cancellation request is irrevocable.

7(c) If after review of the data, as set forth in 7(b) above, the Agency makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment, within one (1) week of this finding, Bayer will submit a request for voluntary cancellation of the registration of the flubendiamide end-use products. That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.

Taken together, the discussions between Registrants and EPA demonstrate that the Registrants were well aware of the cancellation provisions, were materially engaged in shaping those provisions, and ultimately acceded to the cancellation provisions included in the PAL. This exchange not only shows the Registrants involvement in the discussions, it also demonstrates their willing acceptance of the conditions, and negates their notion that they were coerced or threatened into acceptance. I am not aware of any objection Registrants may have

had to the cancellation conditions until late in 2015, when it appeared likely that EPA would invoke the voluntary cancellation condition.

Failure to Comply with the Voluntary Cancellation Provision

The Registration included a condition that if, after EPA review of the referenced conditional data, EPA were to make a determination that continued registration of flubendiamide products will result in unreasonable adverse effects on the environment, EPA would notify the Registrants, and within one week of notification of this finding, the Registrants would submit a request for voluntary cancellation of all the flubendiamide registrations. The specific language:

> 6.(d) If, after EPA's review of the data as set forth in 6(b) above, the Agency makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Nichino will submit a request for voluntary cancellation of the flubendiamide technical product registration. That request shall include a statement that Nichino recognizes and agrees that the cancellation request is irrevocable.

> 8.(d) If, after EPA's review of the data as set forth in 8(b) above, the Agency makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Bayer will submit a request for voluntary cancellation of the flubendiamide technical product registration. That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.

The PAL was designed so that the conditional registrations for flubendiamide would end July 31, 2013, either through amendment or voluntary cancellation. Registrants requested, and EPA agreed to, several extensions to the conditional registration expiration date, to facilitate submission and review of the 3-year farm pond water monitoring study (submitted December 22, 2014). The final extension to January 29, 2016 allowed EPA to host a final technical discussion between its scientists and the Registrants' scientists on January 6, 2016, related to the conditional

data and the EPA's conclusions related to flubendiamide. This extension also allowed additional time for EPA to review two newly submitted studies and to consider the most recent label proposal submitted by the Registrants on January 8, 2016.

On January 29, 2016, I submitted a Decision Memorandum to Jack Housenger, the Director of OPP, which recommended the cancellation of all flubendiamide registrations because the risks of allowing the continued use of flubendiamide outweigh the benefits and continued use will result in unreasonable adverse effects to the environment. (Respondent Exhibit 5) The Registrants were notified on January 29 of our finding, and that the condition of their registration was triggered that required their submission of a voluntary cancellation. (Respondent Exhibit 6) On February 5, 2016, Bayer on its own behalf and as a regulatory agency for Nichino, submitted to EPA a letter informing EPA that neither Registrant would comply with the condition to submit voluntary requests for cancellation of the flubendiamide registrations. (Respondent Exhibit 7) We did not receive a voluntary cancellation request by February 5 or thereafter, and subsequently informed Registrants that because the Registrants have not submitted requests for voluntary cancellation and failed to comply with the condition of registration, the flubendiamide products identified in the Notice of Intent to Cancel (NOIC) are subject to cancellation under FIFRA section 6(e). (Respondent Exhibit 8)

Existing Stocks

Existing stocks are those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment before the effective date of cancellation. FIFRA allows the Agency to permit the continued sale and use of existing stocks of pesticides that have been cancelled, to the extent that the Administrator determines that such sale or use would not be inconsistent with FIFRA's purposes. EPA

published in the Federal Register a Statement of Policy for Existing Stocks of Pesticide Products which is a guide that assists with decisions concerning whether and under what conditions the Agency will allow continued sale, distribution and use of existing stocks of pesticide products. (Respondent Exhibit 9)

I made the determination for how to handle the existing stocks of flubendiamide with the OCSSP management team. The Agency does not intend to allow any further sale or distribution, by Registrants or any other person, of existing stocks of their products, except to the extent that distribution is for the purposes of returning material back up the channels of trade, for purposes of disposal, or for purposes of lawful export. Among the reasons we determined not to allow any further sale or distribution of existing stocks were our belief that registrants should not benefit from failing to follow through with commitments they make to obtain registrations; that much of the existing stocks at the time of a delayed cancellation may well never have entered the channels of trade if the flubendiamide Registrants had complied with the cancellation condition; and the impact that failure of registrants to comply with conditions could have on the registration program in the future.

The Registrants' refusal to comply with the voluntary cancellation provision of their registrations will likely delay a cancellation by a minimum of 3 months. If Registrants had submitted their voluntary cancellation request on February 5, 2016 as required in their registrations, we would have moved quickly to have published the voluntary cancellation request in the Federal Register as required by FIFRA 6(f), with a 30 day comment period. Assuming all comments were received by mid to late March, EPA could have issued the cancellation notice by the end of March or early April 2016. Instead, Registrants may continue to manufacture and sell flubendiamide until at least August 1, 2016, the scheduled end of this hearing process (the

hearing was requested on March 31, 2016 and the hearing must be concluded under FIFRA in 75 days plus the additional 22 days requested by the parties due to scheduling). If Registrants do not prevail before the ALJ and EAB, they could seek Court of Appeals review and a stay of any cancellation order, which could take many more months, and possibly years. So, Registrants may continue to put material in the channels of trade for many months after the cancellation should have taken place, and the release of new existing stocks should have ceased.

EPA's existing stocks policy states that registrants who fail to satisfy a general condition (*i.e.*, a condition which requires a registrant to submit required data when all other registrants of a similar product are required to do so) would typically be allowed to distribute and sell existing stocks of the pesticide for one year. However, the existing stocks policy states that if a registrant fails to comply with a specific condition identified at the time the registration was issued, the Agency does not believe it is generally appropriate to allow any further sale and distribution by the registrant after the registration is canceled. In this case, because Registrants intentionally reneged on a commitment to cancel their registrations, and as a result of their actions much of the existing stocks in the channels of trade when these registrations are finally cancelled could be material that should never have entered the channels of trade in the first place, we believe it appropriate to not allow sale and distribution by others as well.

Existing stocks can be analogized to the material left in a pipeline or garden hose when the tap is turned off. EPA believes it inappropriate to delay closing the tap in order to deliberate extensively on what should be done with material still in the pipeline. EPA's position on existing stocks was set forth in the Notice of Intent to Cancel, where we stated our determination not to allow any further sale or distribution of existing stocks because the registrants in this proceeding should not benefit from failing to comply with a specific term of their conditional

registrations. Specifically, they should not benefit from delaying the cancellation of the flubendiamide registrations for a number of months, potentially longer, during which time they could produce and release additional stocks that they would not have been able to lawfully release into commerce had Registrants complied with the terms of their conditional registrations.

Our rationale for the determination on how to handle the existing stocks for flubendiamide was based on the fact that the Registrants willingly decided to disregard the agreed upon voluntary cancellation provisions of their registration and the OCSPP management team and I agreed that Registrants should not benefit from violating this specific condition, especially where the condition was not only important to the Agency, but where the Registrants were clearly aware of how important that condition was to us in approving their registrations.

OCSPP considers it inappropriate to permit registrants who disregard the terms and conditions of registration, like the condition at issue for flubendiamide, to benefit by allowing any distribution or sale of existing stocks. In this case, the Registrants did not make a diligent effort to comply with a condition of registration; but instead, refused to comply with a condition they knowingly accepted to obtain a registration in 2008.

If registrants are allowed to ignore a condition of registration without consequences, EPA would have to reconsider whether its current practice of approving conditional registrations is adequate to prevent unreasonable adverse effects. If EPA is unable to rely on registrants' compliance with the terms and conditions of registration, EPA will, at least in some circumstances, become less able to make the finding that the terms and conditions of a pesticide's registration are sufficient to conclude that the pesticide will not cause unreasonable adverse effects. Such a scenario could impact many companies and applications not involved in this proceeding, and slow the introduction of promising new pesticide products into the market.

The existing stocks determination in the NOIC relies solely upon the conclusion that continued sale or distribution of existing stocks of the cancelled pesticides would be inconsistent with the purposes of FIFRA because the Registrants have reneged on commitments they made to comply with a specific condition of registration that was material to EPA's approval of the registration. Conditions of registration and the associated commitments by registrants to fulfill those conditions are vitally important to the registration process.

To continue to allow conditional registrations, we must be able to trust that registrants will comply with those conditions of registration. I am disappointed and troubled that the flubendiamide registrants accepted a registration with specific conditions and later elected not to comply with those conditions. While this is hopefully an isolated example, if it is not, OCSPP will need to seriously examine whether we can continue to issue conditional registrations for pesticide products with ostensibly promising new benefits. We do not want to encourage other registrants to ignore conditions of registration. We are concerned that if we do not take a strong position on existing stocks of flubendiamide that may have entered the channels of trade because the Registrants reneged on their commitments, other registrants may be encouraged to ignore their commitments in the future.

EPA has made a determination that the risks posed by the quantities of existing stocks expected to be in end users' hands are reasonable compared to the burdens and risks associated with recovering those existing stocks. Users can continue to use existing stocks of flubendiamide products until their supply of the product is exhausted. It is difficult to track existing stocks of end-use products to user's hands, and notifying end users about and supervising disposal activities would impose significant and unnecessary costs to government authorities. Additionally, users may have open containers which can present additional

challenges for disposal or return. As part of the process of packaging a pesticide, the registrant must apply the closure so it will be leakproof, secured against loosening, and applied according to the packaging manufacturer's instructions. It is unlikely that an end user would be able to apply a closure in the same way and would not have access to the packaging manufacturer's instructions. Therefore, we would not want containers that had already been opened by the end user to be shipped because of the potential for leaks during transportation.

Dated April 22, 2016

Susan T. Lewis

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