UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(e) Notice of Intent to Cancel Flubendiamide Registrations	)	Docket No. FIFRA-HQ-2016-0001

REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS BY BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

STATUTORY PROVISIONS

REGULATORY PROVISIONS

REGULATORY MATERIALS

INTRODUCTION

1. Bayer CropScience LP ("Bayer") and Nichino America, Inc. ("Nichino") hereby object and request a hearing pursuant to Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y, "FIFRA") to contest the cancellation of registrations for pesticide products containing the active ingredient flubendiamide proposed in the Notice of Intent to Cancel Pesticide Registrations issued by the U.S. Environmental Protection Agency ("EPA" or "the Agency") and received by Bayer and Nichino on March 1, 2016. Exhibit 1 (81 Fed. Reg. 11,558 (Mar. 4, 2016)) ("NOIC").

2. The flubendiamide registrations that EPA has proposed to cancel are:

Belt® SC Insecticide (EPA Reg. No. 264-1025)
Flubendiamide Technical (EPA Reg. No. 71711-26)
Vetica® Insecticide (EPA Reg. No. 71711-32)
Tourismo® Insecticide (EPA Reg. No. 71711-33)

Copies of the currently approved labels for these registrations, which identify the currently registered uses for each product, are attached as Exhibits 2 to 5.

3. The NOIC follows a January 29, 2016 determination by EPA asserting that continued registration of flubendiamide does not meet the FIFRA registration standard because of a concern that residues of flubendiamide and a degradate will accumulate in pore water in the sediment of farm ponds and other aquatic environments to levels that pose potential risks to benthic aquatic invertebrates. EPA reached this determination based on the Agency's sudden reversion to a toxicity endpoint that is seventy times lower than what the most relevant data support, and relies on assumptions about accumulation of residues based on overly conservative, theoretical modeling instead of real-world monitoring data that show no accumulation in the environment even approaching a level of concern.

4. EPA's cancellation determination is based solely on this theoretical risk to benthic aquatic invertebrates. Flubendiamide has an outstanding safety profile, both in its own right and compared to alternatives. EPA has repeatedly confirmed that flubendiamide poses no human health or safety concerns and EPA has identified no direct regulatory concerns with respect to mammals, birds, fish, crustaceans, mollusks, beneficial insects, pollinators, and plants.

5. If EPA determines, as it has here, that an existing pesticide product "generally causes unreasonable adverse effects on the environment" and thus no longer meets the registration standard, FIFRA requires EPA to follow the cancellation process detailed in FIFRA § 6(b), 7 U.S.C. § 136d(b). This includes the requirement that EPA submit its cancellation determination for scientific peer review by the Scientific Advisory Panel ("SAP") and solicit comment from the United States Department of Agriculture ("USDA") on the impact of the proposed cancellation before issuing the NOIC. After that independent review and input, FIFRA guarantees registrants and other affected stakeholders the right to request an administrative hearing on the scientific and regulatory merits of the cancellation determination. FIFRA § 6(b). EPA has not fulfilled any of these requirements.

6. Instead, EPA seeks to evade required process and shield its unfounded January 29, 2016 determination from independent scrutiny and challenge by trying to implement an unlawful condition of registration that purported to require Bayer and Nichino to "voluntarily" relinquish all of their flubendiamide registrations upon EPA's simple issuance of an unfavorable determination. EPA devised this condition and approach to bypass required peer review and other aspects of FIFRA § 6(b) cancellation proceedings.

7. EPA's NOIC invokes FIFRA § 6(e), 7 U.S.C. § 136d(e), which in contrast to the substantive scrutiny ensured by FIFRA § 6(b), provides a highly streamlined process for proposed cancellation determinations in cases where there is a purported failure to meet a condition of registration. EPA claims that the narrow focus and 75-day hearing process under Section 6(e) preclude any consideration by an Administrative Law Judge ("ALJ") of whether EPA's cancellation approach is lawful or of the merits of EPA's determination. This cannot be the case. EPA cannot grant itself the right to bypass the cancellation process required by Congress, cannot evade independent scientific peer review and input from other federal agencies, cannot deny registrants, growers, and other stakeholders the due process rights they possess by statute, and cannot preclude the ALJ from reviewing the lawfulness of EPA's approach.

8. For these reasons, Bayer and Nichino respectfully request that the ALJ find that the purported condition of registration requiring forced "voluntary" cancellation is unlawful, deny EPA's proposed cancellation of the flubendiamide registrations under FIFRA § 6(e), and order EPA to follow the FIFRA § 6(b) cancellation process if it wishes to cancel the existing flubendiamide registrations for failure to meet the FIFRA registration standard.

9. While it should not be necessary for the ALJ to reach this issue, Bayer and Nichino also object to and request a hearing on EPA's existing stocks proposal. The NOIC specifies that EPA will allow the use of products in the hands of end-users upon cancellation, but will not allow any sale or distribution of existing stocks in the hands of Bayer, Nichino, or any of the distributors or retailers in the channels of trade. The NOIC includes no findings suggesting any harm from post-cancellation sale and distribution of existing stocks; instead, the sole basis for EPA's proposed ban is Bayer and Nichino's invocation of their statutory rights. Bayer and Nichino have a right to refuse EPA's unlawful "voluntary" cancellation demand and to challenge

the lawfulness of EPA's approach and, ultimately, the merits of EPA's cancellation determination. Should EPA's proposed cancellation be upheld by the ALJ—which it should not be—Bayer and Nichino should not be punished for exercising their statutory hearing rights and seeking administrative review by EPA's unfounded and overly restrictive existing stocks provision.

10. In the NOIC, EPA acknowledges that Bayer, Nichino, and others in the channels of trade have the right to continue selling and distributing flubendiamide during the administrative proceeding. However, EPA claims the right to change its position on use of existing stocks at the hearing if "the quantity of [flubendiamide] products in the hands of end users increases prior to cancellation." This appears to be an implicit effort to halt sales and distribution during the ALJ process that are allowed by statute by threatening to disallow use of products sold while the ALJ is considering the issues and by creating confusion in the marketplace. At a minimum, EPA has not made the imminent hazard finding required under FIFRA § 6(c), 7 U.S.C. § 136d(c), to suspend the products and prohibit sale or distribution during the proceeding.

11. Moreover, FIFRA § 6(e) requires EPA to "specify" in the NOIC the extent and conditions of continued use and sale of the product. EPA cannot amend its specified position on existing stocks "at [the] hearing," as the NOIC can be amended only "prior to the commencement of the public hearing." 40 C.F.R. § 164.21(b). Moreover, consistent with 40 C.F.R. § 164.21, if EPA decides to amend its existing stocks provision before the hearing, the ALJ should stay the hearing, provide an opportunity for all affected stakeholders to file objections to the new existing stocks provision, and then restart the 75-day clock under FIFRA § 6(e).

BACKGROUND

I. FLUBENDIAMIDE

A. Development of Flubendiamide

12. Flubendiamide is the first pesticide in its class of chemistry, known as phthalic acid diamides, to be registered by EPA under FIFRA. Flubendiamide is approved for use on over 200 crops and provides excellent, targeted control of larval lepidopteran pests (caterpillars). Flubendiamide is consistent with and furthers the goals of modern Integrated Pest Management ("IPM") practices and is an important tool for resistance management. Flubendiamide has an excellent safety profile. EPA has repeatedly confirmed that flubendiamide poses no human health or safety concerns and no direct regulatory concerns for mammals, birds, fish, crustaceans, mollusks, beneficial insects, pollinators, and plants. EPA also has determined that flubendiamide has a favorable risk profile compared to alternatives.

13. Flubendiamide was invented by Nihon Nohyaku Co., Ltd. ("NNC"). Bayer has a licensing, product development, and marketing agreement with NNC and Nichino pursuant to which Bayer serves as Nichino's regulatory agent for flubendiamide and sells flubendiamide products under the Belt® brand name. As regulatory agent, Bayer took the lead on engaging in discussions with EPA and generating data required to support the flubendiamide registrations. Nichino sells flubendiamide products under the Vetica® and Tourismo® brand names.

14. Bayer and Nichino are the original and current holders of the flubendiamide registrations that are the subject of EPA's proposed cancellation. Bayer holds the registration for the Belt® SC Insecticide end-use product (EPA Reg. No. 264-1025). Nichino holds the registration for the Flubendiamide Technical product (EPA Reg. No. 71711-26), which consists of nearly pure flubendiamide and is used to manufacture end-use products, and the Vetica®

Insecticide and Tourismo® Insecticide end-use product registrations (EPA Reg. Nos. 71711-32 and 71711-33), which combine flubendiamide with buprofezin, another insecticide.

15. Bayer is a world-leading innovator in the development of newer, more effective, and more sustainable crop protection products. Bayer's mission of Science for a Better Life is to provide products that help farmers feed a growing population and foster healthy environments. This mission is supported by the discovery, development, registration, marketing, and stewardship of safe, effective, and environmentally responsible plant protection technologies. Bayer invests heavily in the expertise needed to design and conduct the complex health and environmental tests and analyses necessary to obtain and maintain EPA pesticide approvals. Bayer has made significant investments to obtain and maintain the flubendiamide registrations. Bayer spent more than $60 million in data and development costs to obtain the initial registrations and to support the expansion and continuation of the registrations.

16. Nichino is a wholly owned subsidiary of NNC. NNC was established in 1928 and is a basic researcher and manufacturer of plant protection products based in Tokyo, Japan. NNC's mission is to meet current needs in global crop protection markets by introducing innovative agrochemicals that can contribute to healthy food production while protecting the environment.

17. NNC has conducted insecticide discovery research at its Research Center near Osaka, Japan since 1990. In the course of this research, in 1993 it discovered a lead compound for a new insecticide from the class of phthalic acid diamides. It synthesized two thousand derivatives from this initial discovery and conducted many studies to improve activity before it finally discovered flubendiamide in 1998. NNC and Nichino have spent more than $65 million

on the initial discovery, data, and development costs to obtain the US registrations and to bring flubendiamide to the US market.

18. Flubendiamide products are sold by Bayer and Nichino throughout the country, with their primary use running across the South and up the West Coast (south of the Mason-Dixon line and from Virginia through California).

19. Flubendiamide was originally labeled for use on broad acre crops (*e.g.*, corn and cotton), pome fruit, tree nuts, vines, and some vegetables. Over time, EPA has expanded the approved uses to cover more than 200 crops.

20. Growers use flubendiamide on a wide range of crops throughout the year. It is used on winter vegetables in Arizona and Florida from January through March, on tree fruits and nuts in California from March through June, on soybeans, cotton, and alfalfa from June through August, and on fall vegetables from September through December.

B. Benefits of Flubendiamide

21. EPA has concluded that flubendiamide poses no risk of concern to humans (either through diet or worker exposure), fish, mammals, crustaceans, mollusks, beneficial insects, and plants. *See, e.g.*, Exhibit 6 at 2-8 (EPA Flubendiamide Pesticide Fact Sheet (Aug. 1, 2008)). It is an alternative to organophosphate insecticides, a class of chemistry that EPA has long made a priority for replacement in light of EPA's conclusions about the human health impacts of pesticides in that class. Flubendiamide has a human health safety profile that is equal to or better than existing alternatives. From a common sense standpoint, flubendiamide's very favorable safety profile provides strong benefits to society, along with the agronomic and economic benefits discussed below.

22. Bayer provided over 300 pages of general and crop-specific benefits information for EPA's review, including detailed comparative health and safety information, use information,

and third-party data, articles, and letters of support establishing flubendiamide's current use and benefits and its important current and future role for IPM and resistance management.

23. In reviewing this extensive benefits information, EPA's Benefits and Economic Analysis Division ("BEAD") noted only "minor" differences with the registrants' assessment of flubendiamide's benefits. It agreed that cancellation of flubendiamide would "reduce[] the ability to manage" insecticide resistance and that likely alternatives, including pyrethroids, "do not fit well with most IPM practices." Exhibit 7 (BEAD Review of Bayer CropScience Flubendiamide Benefits Document (July 24, 2015)).

24. This recent EPA analysis, conducted after seven years of flubendiamide use, is consistent with BEAD's Public Interest Finding from April 15, 2008, in which the Agency described flubendiamide as a "novel chemistry" and predicted that it "can be an important tool as a rotational insecticide to limit or prevent resistance development," with "low toxicity to insect predators and honey bees [that] should make flubendiamide an important component in integrated pest management programs." Exhibit 8 (BEAD Public Interest Finding for Flubendiamide (Apr. 15, 2008)).

25. Flubendiamide is a highly effective selective insecticide that provides outstanding control of lepidopteran insects, such as caterpillar pests. Flubendiamide works by affecting certain receptors in the targeted species, stopping feeding within minutes.

26. As EPA has acknowledged, because flubendiamide is selective, it has minimal impact on beneficial insects, including parasitic and predatory species such as parasitoid wasps, ladybird beetles, and syrphid flies. This encourages natural or biological pest control, and makes flubendiamide an important tool for modern IPM approaches. IPM is an ecosystem-based strategy that focuses on long-term prevention using a range of practices to minimize negative

impacts and resistance issues. Both EPA and USDA have a statutory obligation to encourage and develop IPM techniques. 7 U.S.C. § 136r-1.

27. By contrast, broader-spectrum alternatives like pyrethroids, organophosphates, and carbamates affect a much wider range of insects, including beneficial species. As EPA acknowledges, broad-spectrum pesticides can cause flare-ups when populations of fast-reproducing species, such as aphids and mites, recover and grow unchecked in the absence of slower-reproducing insect predators. These flare-ups can create new pest problems that require additional pesticide applications with additional environmental impacts and increased costs to the growers. Flubendiamide's selectivity and minimal impact on predatory insects help avoid these problems.

28. Flubendiamide products are also an important tool for growers in managing pest resistance. They can be rotated (*i.e.*, alternated) with other pesticides with different modes of action as part of a resistance management program to avoid resistance issues that can arise from the overuse of a single mode of action. As a member of the diamide class of chemistry, flubendiamide has a different mode of action from pyrethroids, carbamates, and organophosphates and is effective at controlling insect populations that have developed resistance to those classes of chemistry.

29. Flubendiamide has an excellent safety profile compared to alternatives such as organophosphates, carbamates, and pyrethroids, and poses no risks of concern to humans. In addition to its safety benefits, flubendiamide's lower risk profile allows for more flexible use because of fewer restrictions on timing of application (*e.g.*, shorter pre-harvest intervals and restricted entry intervals for workers).

30. Unlike many of the other products commonly used to control lepidopteran insects, flubendiamide products are rainfast once spray deposits have dried, providing control for up to two weeks. Flubendiamide's residual effectiveness period can reduce the need for multiple applications, lowering costs and environmental impacts.

31. In its 2015 benefits analysis, EPA acknowledged that flubendiamide's "translaminar characteristic is unique . . . and makes it very suitable for IRM [Insecticide Resistance Management] and IPM strategies in many crops." Exhibit 7 at 4. Therefore, even among the limited subset of pesticides available to growers using IPM to control lepidopteran pests, flubendiamide presents distinct advantages for resistance-avoidance.

II. REGISTRATION UNDER FIFRA

32. All pesticide products sold or distributed in the United States must be registered with EPA under FIFRA § 3(a), 7 U.S.C. § 136a(a). "A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used." *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010) (citing FIFRA §§ 3(a), (c)-(e), 7 U.S.C. §§ 136a(a), (c)-(e)).

33. Registrations are difficult and costly to obtain and valuable assets to hold. Courts have recognized that registrants hold property rights in their registrations. *See, e.g.*, *Reckitt Benckiser*, 613 F.3d at 1133 ("A FIFRA registration is a product-specific license."); *Ctr. for Biological Diversity v. EPA*, No. 11-CV-00293-JCS, 2013 WL 1729573, at *6 (N.D. Cal. Apr. 22, 2013) ("The applicants are owners of the pesticide registrations, and thus have property and financial interests in the registrations.").

A. Registration Process

34. FIFRA § 3 provides that EPA "shall register" a pesticide if EPA determines, among other things, that the product "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." FIFRA § 3(c)(5)(C)-(D), 7 U.S.C. § 136a(c)(5)(C)-(D). "Unreasonable adverse effects on the environment" are defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA § 2(bb), 7 U.S.C. §136(bb).

35. Congress thus established a risk-benefit standard (the "Registration Standard"), requiring EPA to weigh the potential health and environmental risks of a pesticide against its economic, social and environmental benefits. *See, e.g.*, *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) (citing *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 532 (9th Cir. 2001)).

36. The permissible uses of a pesticide product are described in detailed labels that are reviewed and approved by EPA as part of the registration. It is unlawful to distribute or sell a pesticide product that is not registered with EPA, or to use a registered product in a manner inconsistent with its labeling. FIFRA §§ 12(a)(1)(A), (a)(2)(G), 7 U.S.C. §§ 136j(a)(1)(A), (a)(2)(G).

37. Registrants must generate and submit to EPA a broad range of substantial health and safety data regarding the properties and potential effects of a pesticide, which informs EPA's assessment of whether the pesticide meets or continues to meet the Registration Standard. FIFRA § 3(c)(1)(F), 7 U.S.C. § 136a(c)(1)(F) (data required to support an application for registration); 40 C.F.R. Part 158 ("Data Requirements for Pesticides"). EPA has developed standard guidelines for the conduct of required studies and frequently requires additional data to address product-specific or newly arising issues. EPA works with registrants to review and

approve any departure from standard guideline protocols and to develop, review, and approve protocols as needed for additional studies. The data package required to support a new pesticide takes years to develop at costs that can reach $100 million or more.

38. The obligation to submit data continues beyond registration. FIFRA §§ 3(c)(2)(B) ("Additional data"), 3(g) ("Registration review"), 7 U.S.C. §§ 136a(c)(2)(B), 136a(g).

39. EPA has both science and risk management teams. The science teams review data submissions and submit their evaluations to the risk management team for the particular pesticide being evaluated. The risk management team then reviews the science teams' input, applies the FIFRA risk-benefit balancing standard, and determines whether the product as proposed meets the standard for registration or whether steps should be taken to mitigate the risks so that the product can meet the FIFRA standard.

B. Conditional Registrations

40. FIFRA Section 3(c)(7) allows EPA to issue "conditional registrations" under three circumstances. EPA may grant conditional registrations: (1) if "the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof" with the condition that the applicant must submit all pending required data for its registration no later than the time required for similar products; (2) to conditionally amend a registration to allow additional uses even if required data are pending, with the condition that the applicant must submit all pending required data for its registration no later than the time required for similar products; and (3) for "a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since [EPA] first imposed the data requirement)." FIFRA § 3(c)(7)(A)-(C), 7 U.S.C. § 136a(c)(7)(A)-(C).

41. EPA may issue conditional registrations for pesticides containing an active ingredient not contained in any currently registered pesticide under Section 3(c)(7)(C) only if it makes an affirmative determination that "use of the pesticide is in the public interest" and the product "will not cause any unreasonable adverse effect on the environment" during the time period set for generation and submission of the data. FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C).

C. Cancellation and Suspension of Registrations

42. Under FIFRA, Congress provided specific procedures that must be followed if EPA wishes to cancel or suspend an existing pesticide registration. FIFRA § 6 "establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (emphasis in original).

43. These cancellation and suspension provisions not only ensure that registrants receive due process but also that cancellation and suspension decisions are based on consideration of both the risks and the benefits of the registration under the Registration Standard, are subject to scientific and interagency review and input and, if requested, can be tested and challenged through a *de novo* administrative hearing. The procedures and requirements for cancellation of an existing FIFRA registration are set forth in FIFRA § 6, 7 U.S.C. § 136d, and EPA's implementing regulations at 40 C.F.R. Part 164.

44. Many stakeholders have an interest in cancellation proceedings and the continued availability of safe, effective, and beneficial pesticide products, including the registrants, the United States Department of Agriculture, the United States Department of Health and Human Services, the National Institutes of Health, the National Science Foundation, growers,

agricultural workers, food processors, distributors, retailers, and the general public. *See, e.g.,* FIFRA §§ 6(b)-(f), 25(d), 7 U.S.C. §§ 136d(b)-(f), 136w(d).

1. Cancellation Procedures Under FIFRA § 6(b)

45. FIFRA's cancellation provisions include a standard cancellation process under FIFRA § 6(b), and a streamlined process for cancellations that are based on the failure to meet conditions of registration under FIFRA § 6(e).

46. FIFRA § 6(b) applies when cancellation is based on a determination by EPA that an existing registration no longer meets the Registration Standard. "If it appears to the Administrator that a pesticide . . . does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed." FIFRA § 6(b).

47. The cancellation process established by Congress under FIFRA § 6(b) is well-defined and thorough.

48. In deciding whether to issue a notice of intent to cancel, EPA must consider "the impact [of cancellation] on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." FIFRA § 6(b).

49. At least 60 days before providing the notice to the registrant and the public, EPA must provide the notice of intent to cancel and its analysis for review by the Secretary of Agriculture and, if comments are received from the Secretary, publish them and EPA's response in the Federal Register. *See* FIFRA § 6(b). This ensures that EPA's determination is informed

by the USDA's views on and consideration of the role and benefits of the affected pesticides, and that USDA has early notice of any possible cancellation determination by EPA.

50. Under FIFRA Section 25(d), EPA must also provide the notice of intent to cancel to the Scientific Advisory Panel ("SAP"), a multi-disciplinary panel of experts nominated by the National Institutes of Health and the National Science Foundation. The SAP's comments and EPA's response are published in the Federal Register. FIFRA § 25(d). This ensures that the scientific findings underlying any cancellation decision are sound and are subject to open, transparent, and independent scientific review before any administrative hearing that may be requested.

51. Under FIFRA § 6(b), if the proposed cancellation would affect a public health use, EPA must provide similar notice and an opportunity to comment to the Secretary of Health and Human Services ("HHS"). FIFRA § 6(b). This ensures that any cancellation decision is informed by HHS's consideration of and comment on any public health impacts, and that HHS has early notice of any pending cancellation determination by EPA.

52. After these independent reviews and comments, if EPA issues a notice of intent to cancel, registrants and any other adversely affected parties have 30 days to request a public administrative hearing. Such hearings involve a full, *de novo* evidentiary hearing before an ALJ on the merits of the proposed cancellation action, with subpoena power to compel testimony and the production of documents. FIFRA §§ 6(b), (d), 7 U.S.C. §§ 136d(b), (d); 40 C.F.R. Part 164.

53. Any party to the proceeding may request that "relevant questions of scientific fact" be referred to a Committee of the National Academy of Sciences, which will issue a public report that "shall be considered as part of the hearing record." FIFRA § 6(d).

54. Decisions of the ALJ may be appealed to the Environmental Appeals Board. 40 C.F.R. §§ 164.100-111.

55. Under FIFRA § 16(b), after completion of the hearing and any appeal, EPA may issue its final cancellation order which in turn is subject to judicial review by the federal Court of Appeals. FIFRA § 16(b), 7 U.S.C. § 136n(b).

2. Cancellation Procedures Under FIFRA § 6(e)

56. FIFRA § 6(e) provides a much more limited process that applies in carefully limited circumstances to FIFRA § 3(c)(7) conditional registrations. FIFRA § 6(e). It allows EPA to issue a notice of intent to cancel a registration under that section only: (1) if EPA determines "at any time during the period provided for satisfaction of any condition imposed" that "the registrant has failed to initiate and pursue appropriate action toward fulfilling" the condition; or (2) if EPA determines "at the end of the period provided for satisfaction of any condition imposed, that condition has not been met." FIFRA § 6(e)(1), 7 U.S.C. § 136d(e)(1).

57. A FIFRA § 6(e) cancellation notice becomes final unless the registrant or other adversely affected party requests a hearing within 30 days. FIFRA § 6(e)(2), 7 U.S.C. § 136d(e)(2).

58. Any such hearing is conducted as a public hearing under the process described in FIFRA § 6(d), except that the matters for consideration at the hearing are whether the registrant initiated and pursued the actions required to comply with the conditions or whether the conditions were satisfied within the specified time period, and whether the proposed existing stocks determination is consistent with FIFRA. A § 6(e) hearing must be held and the final determination made within 75 days of the request for the hearing. FIFRA § 6(e)(2).

59. To the registrants' knowledge, there has never been a hearing conducted under FIFRA § 6(e).

60. FIFRA § 6(e) does not apply where EPA determines that a registration does not meet the Registration Standard. In such cases, EPA must proceed with full cancellation proceedings under FIFRA §§ 6(b) & (d).

3. Suspension of Registration Under FIFRA § 6(c)

61. If EPA determines immediate action "is necessary to prevent an *imminent hazard*," EPA may issue an order to "suspend the registration of the pesticide immediately." FIFRA § 6(c)(1), 7 U.S.C. § 136d(c)(1) (emphasis added).

62. EPA must provide the registrant a notice of intent to cancel including the "imminent hazard" finding and the registrant can request an expedited hearing before suspension "on the question of whether an imminent hazard exists." FIFRA § 6(c)(1)-(3), 7 U.S.C. § 136d(c)(1)-(3).

63. EPA can proceed without an "imminent hazard" hearing only under emergency conditions, in which case a notice of intent to cancel, initiating full cancellation proceedings, must be issued within 90 days. FIFRA § 6(c)(3), 7 U.S.C. § 136d(c)(3).

D. Existing Stocks Under FIFRA § 6(a)(1)

64. If EPA cancels or suspends a registration, EPA may allow "the continued sale and use of existing stocks of a pesticide." FIFRA § 6(a)(1), 7 U.S.C. § 136d(a)(1). EPA's general policy is to allow for existing stocks to be sold and used if "the benefits associated with such sale, distribution, or use exceed the risks." Exhibit 9 (Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362, 29,362 (June 26, 1991)).

65. Distribution or sale of existing stocks of cancelled or suspended pesticides is unlawful unless expressly authorized in an existing stocks order. The use of existing stocks is permitted, unless "specifically prohibited" by EPA in the cancellation or suspension order. *Id.* at 29,363. In determining whether to allow the distribution, sale, or use of existing stocks, "EPA

must apply the same risk-benefit considerations that are applicable to other Agency actions under FIFRA." *Id.* In situations "where the Agency has identified particular risk concerns," the existing stocks determination will be based on consideration of the quantity of existing stocks, the risks and benefits from use of such stocks, including the existence of alternatives and cost and efficacy of such alternatives, the amount invested in existing stocks, risks and costs of disposal or alternate disposition, and the practicality of implementing restrictions. *Id.* at 29,364.

III. REGULATORY HISTORY

A. Conditional Registration of Flubendiamide

66. EPA registered flubendiamide in 2008 under FIFRA § 3(c)(7)(C) (conditional registration of a new active ingredient), applying FIFRA's risk-benefit Registration Standard.

67. EPA's conditional registration included requirements to generate additional data, as set forth in EPA's July 31, 2008 preliminary acceptance letter. Exhibit 10.

68. At the time of the first approval in 2008, EPA made an affirmative determination, as required under FIFRA, that registration of flubendiamide was in the public interest. It granted FIFRA registration for five years to allow the registrants to generate and submit additional data to address potential persistence, consistent with FIFRA § 3(c)(7)(C). Exhibit 8 (EPA Public Interest Finding), Exhibit 10 (July 31, 2008 Preliminary Acceptance Letter), Exhibit 11 (Aug. 1, 2008 Notices of Registration referring to July 31, 2008 letter).

69. At the same time, EPA established "permanent tolerances" (the limit of residues allowed on food or food crops) for flubendiamide under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-399) ("FFDCA"). Over the years, numerous additional permanent tolerances have been established through rulemakings under the FFDCA as new crops have been registered and added to the flubendiamide labels. The tolerance-setting process is primarily focused on human health impacts through the diet. Given flubendiamide's very favorable human

health profile, EPA has not proposed any changes to flubendiamide's tolerances and none is warranted. However, EPA must take flubendiamide's very favorable human health profile into account in evaluating whether flubendiamide meets FIFRA's risk-benefit standard for registration.

70. The only potential risk of concern identified by EPA was that flubendiamide and its degradate des-iodo may persist and accumulate over time in farm ponds surrounded by treated fields, potentially to a level that may impact freshwater benthic invertebrates. Exhibit 6 at 8-9. EPA issued the flubendiamide registrations while requiring the registrants to develop data to better understand this potential. *Id.* at 10.

71. EPA's July 31, 2008 letter included a schedule for the registrants to submit proposed protocols for the required data, so that EPA could review the study designs and plans and request modifications as appropriate. EPA also committed to review the data generated and submitted by the registrants, and to engage in discussion with the registrants about the data and EPA's conclusions. The letter outlined three potential outcomes, including: (a) unconditional registration; (b) EPA and the registrants agreeing on a path forward, revising or providing additional data under a conditional registration; or (c) EPA accepting voluntary cancellation of the flubendiamide registrations.

72. EPA stated in the July 31, 2008 letter: "No cancellation shall occur if EPA determines, after review of the data, that the flubendiamide technical product registration could meet the standards for registration set forth in section 3(c)(5) of FIFRA" and Bayer and Nichino agree "to comply with any conditions (including, but not limited to, revised label language, use deletions or conditions of registration) that EPA finds necessary in order to make the registration determination." Exhibit 10 at 3.

73. EPA refused to issue the registrations unless the applicants "concur[red]" that if in the future EPA made an affirmative finding that "further registration of the flubendiamide . . . products will result in unreasonable adverse effects on the environment," the companies would request "voluntary" cancellation of the registrations. Exhibit 10 at 1, 3. EPA threatened that, absent this provision, it would not grant the registrations. In other words, EPA claimed the right to require registrants to accept upfront and sight unseen whatever determination EPA might make and to forgo statutorily guaranteed rights no matter what the basis for EPA's finding. EPA threatened to deny issuance of registrations EPA had already determined were in the public interest absent this purported "condition of registration." EPA's insistence on this Hobson's choice approach is reflected in the July 31, 2008 letter.

B. Data Submission, Evaluation, and Registration Extensions

74. Consistent with the July 31, 2008 letter, the registrants generated the required data. EPA and Bayer communicated about study protocols, study conduct, study reports, and interpretation of the study results. Over time, EPA approved expansion of flubendiamide's registrations to over 200 crops.

75. EPA repeatedly extended the original September 1, 2013 "expiration" date, including an initial extension of the deadline for an additional two years to allow for further data generation and review, and a flurry of more recent extensions until the issuance of its January 29, 2016 Decision Memorandum and demand for voluntary cancellation.

76. EPA commonly uses its authority to request additional data to refine its risk assessments and to identify risk mitigation consistent with FIFRA. Particularly in light of flubendiamide's favorable human health and non-target organism safety profile and its value to agriculture, in conjunction with the substantial amount of scientific data supporting its

registration, it is consistent with EPA's fulfillment of its responsibilities under FIFRA that right up until the end of 2015, EPA repeatedly expressed its intention to do so here.

77. EPA often communicates with registrants to evaluate such options and implement them. Sometimes this is done while data are being generated that may allow the mitigation to be refined, removed, or a substitution for such measures made in the future.

78. Consistent with this process and progress, on July 18, 2013, EPA extended the registrations to August 31, 2015 to allow for ongoing review and discussion of the submitted data and continued monitoring. Exhibit 12. In that letter, EPA confirmed that "[a] s of July 31, 2012, [the registrants] . . . ha[ve] submitted all data required by the original conditions of registration for flubendiamide." *Id.*

79. In discussions with the registrants in July and August 2015, EPA presented a plan for continuing the registrations for all crop uses that involved reducing exposure by eliminating aerial applications, limiting use to a single application per growing season for all crops, and conducting additional studies to "address the uncertainties related to flubendiamide." Exhibit 13 (Aug. 4, 2015 email from C. Rodia to N. Delaney). EPA provided a specific list of proposed additional studies, including an expanded stream and pond monitoring program and toxicity studies on additional aquatic species. *Id.* EPA proposed a three-year extension of the registrations to allow the data to be generated and reviewed. *Id.* EPA and the registrants reached an agreement regarding what studies would be performed and work was underway to develop and deliver for EPA's review protocols and scoping documents for the studies.

80. On August 26, 2015, EPA again extended the registrations to December 10, 2015 to "provide time for [the registrants] and the EPA to discuss whether potential additional data requirements and label amendments are necessary to address areas of uncertainty" related to

EPA's ecological risk assessment. Exhibit 14. In its letter, EPA again confirmed that "[a]s of July 31, 2012, [the registrants] ha[ve] submitted all data required by the original conditions of registration for flubendiamide." *Id.*

81. EPA and the registrants continued to have discussions into December 2015. Bayer agreed to eliminate certain uses and to work with EPA to refine limitations on use rates and applications for remaining uses to reduce exposure while meeting commercial needs. Bayer also agreed to conduct additional studies, including the additional ecotoxicity studies and the expansion and continuation of the monitoring program, which was anticipated to cost millions of dollars. EPA indicated that it planned to extend the registrations for three years while the registrants generated the additional data.

82. On December 1, 2015, Bayer and Nichino met with EPA to discuss the path forward and to reiterate the registrants' commitment to generate the additional scientific data EPA had identified.

83. The registrants also provided a comparative assessment with a competitive pesticide, methoxyfenozide, that has nearly the same persistence and risk profile to benthic aquatic invertebrates as flubendiamide. EPA required similar water monitoring studies for that compound, resulting in levels of detection that, like flubendiamide, were below levels of concern at all of the monitoring sites tested. EPA chose to rely on the actual monitoring data showing no levels of concern rather than its modeling which predicted much higher exposures that exceeded levels of concern. EPA's risk assessment for methoxyfenozide explained that the modeling results "likely overestimate concentrations in streams and various other kinds of water bodies" for a number of reasons, including "washout, dispersion, burial of sediment and other dissipative processes that aren't simulated." Exhibit 15 at 21 (Preliminary Environmental Fate and

Ecological Risk Assessment for Methoxyfenozide (Sept. 16, 2015)). EPA also determined that methoxyfenozide concentrations in flowing water bodies are not expected "to accumulate at such a high concentration[] from year to year because of downstream advective removal." *Id.*

84. For methoxyfenozide, EPA properly focused on the higher-tier, actual monitoring data rather than overly conservative modeling and has not taken steps to cancel the methoxyfenozide registrations. Singling out flubendiamide for different, extreme treatment is not consistent with FIFRA nor is it fair in light of how EPA is approaching its overall risk-benefit regulation of pesticides.

85. Up until early December 2015, EPA was consistent in discussing with the registrants EPA's plan to extend the flubendiamide registrations for three years until 2018 and to require additional data. EPA and the registrants also discussed potential mitigation. Consistent with those discussions, the registrants proposed mitigation through changes to the product label and conducted calculations to confirm that the mitigated label would pass EPA's risk assessment, even using a methodology the registrants believe to be more conservative than required.

86. On December 8, 2015, EPA extended the December 10 expiration date to December 18, 2015 "to provide additional time for BCS [Bayer CropScience] and EPA to discuss areas of uncertainties." Exhibit 16. This timing allowed for the scheduling of a high level meeting on December 15, 2015, between the Assistant Administrator of EPA responsible for all pesticides and the CEOs of both Bayer and Nichino.

87. At the December 15 meeting, the Assistant Administrator described his view of flubendiamide, repeatedly using precautionary language and contending that flubendiamide should be cancelled based on its persistence alone, even though no harm had been identified, to eliminate any possibility of future harm. This is contrary to the risk-benefit approach required by

FIFRA. He stated the view that, absent any action by EPA beforehand, the registrations would expire on December 18, 2015. He stated that EPA would consider whether to take action and would inform the registrants of its decision by the end of the day on December 18, 2015.

88. The registrants raised the practical difficulties of that timing and requested that EPA extend the December 18, 2015 date to help ensure an orderly process and that EPA advise the registrants promptly when a decision had been made, with at least a small amount of time remaining before the deadline. EPA committed to respond on the extension and suggested that the registrants submit the best, final mitigation proposal they could develop, as promptly as possible, in light of an internal briefing of the EPA Assistant Administrator the following day. The registrants quickly convened their experts and prepared and submitted a further mitigation proposal later the same day.

C. Change in EPA's Toxicity Endpoint

89. Up to this point, the open scientific question concerned whether the modeling and monitoring data suggested that flubendiamide or the des-iodo metabolite might accumulate to a level of concern based on the toxicity data. These data include a 2010 spiked sediment study Bayer conducted specifically to focus on the area of EPA's concern: the level of toxicity to benthic aquatic invertebrates in pore water and sediment. As EPA confirmed in its May 21, 2008 review of a spiked water study submitted in 2004, the Agency prefers the spiked sediment methodology for this purpose. Exhibit 17 at 2.

90. In a spiked sediment study, the test compound is introduced into the sediment and the system is allowed to equilibrate. In a spiked water study, the chemical is introduced directly into the overlying water. For the reasons discussed below, a spiked sediment study is a higher tier, more relevant study for assessing potential toxicity from accumulation of runoff residues in sediment pore water.

91. On December 16, 2015, EPA's Environmental Fate and Effects Division ("EFED") briefed the EPA Assistant Administrator as planned. In a new development, after years of discussion, the high level meeting the day before, and visibility of the registrants' submission of a "final" mitigation plan that passed even EFED's conservative, theoretical modeling approach, EFED stopped using the directly relevant toxicity endpoint from the des-iodo spiked sediment study that had been the basis of the many discussions, technical evaluations, and mitigation plans of the preceding months. It based the briefing on a different endpoint that appeared to be designed to ensure, after the fact, that the registrants' "final" mitigation proposal would not be sufficient.

92. The spiked sediment study specifically conducted to assess the potential toxicity of des-iodo to benthic aquatic invertebrates in pore water in sediment showed no observable adverse effects at any of the levels tested, supporting a level of concern for des-iodo of 19.5 parts per billion ("ppb") (as calculated by EPA using a time-weighted average approach) or 22 ppb (as calculated in the report based on measured concentrations). Although this is the most appropriate study to measure toxicity from the potential toxicity route of exposure, EPA chose at the eleventh hour to ignore this study and revert to an endpoint derived from the less appropriate, earlier-conducted spiked water study, leading to a toxicity endpoint of 0.28 ppb, 70 times lower than the more environmentally relevant data conducted using EPA's preferred methodology support. This reversion ensured that EPA could continue to "predict" exceedances of levels of concern even after making overdue and necessary corrections to its theoretical modeling.

D. EPA's Cancellation Determination and Notice of Intent to Cancel

93. This dramatic change in the ground rules for an apparently preordained result was shocking to the registrants. Bayer wrote to the Assistant Administrator on December 16 to seek

to confirm whether he was aware of this sudden change in approach and lack of transparency, and to request the underlying science. Exhibit 19.

94. On December 18, 2015, EPA provided a letter "extending the expiration date of December 18, 2015 to January 15, 2016." Exhibit 20. EPA also scheduled a meeting with the registrants for January 6, 2016 at which EPA EFED would present its evaluations.

95. The registrants reviewed the information provided by EPA over the holidays and also submitted two formal reports on environmental fate and ecotoxicology data whose conclusions had previously been previewed with EPA. In particular, one of the studies showed that des-iodo, the flubendiamide metabolite whose potential toxicity forms the basis for EPA's proposed cancellation, degrades when exposed to sunlight. This is helpful to understanding the degree to which it may persist in the environment. Bayer submitted both study reports to EPA on January 5, 2016.

96. At the January 6 meeting, EPA acknowledged that things were "very dynamic" and the timing of its change was "unfortunate." It sought to explain what activities had taken place within the Agency at the end of the year that had not been visible to the registrants.

97. At that meeting, EPA presented its scientific position, relying on the lower toxicity endpoint and flawed theoretical modeling to support its position that flubendiamide is accumulating or will accumulate in vulnerable water bodies above a level of concern.

98. The registrants asked EPA to confirm, if EPA decided the flubendiamide registrations should not continue beyond the January 15, 2016 date, whether the Agency: (1) would pursue "automatic" expiration without further action; (2) would seek to implement the unlawful forced "voluntary" cancellation condition; or (3) would issue a proper notice of intent to cancel and follow the cancellation proceedings required by FIFRA § 6(b). EPA ultimately

confirmed that it would demand "voluntary" cancellation and seek cancellation under FIFRA § 6(e) if Bayer and Nichino refused to request "voluntary" cancellation. On January 14, 2016, EPA again extended the conditional registration for flubendiamide, this time to January 29, 2016.

99. On January 29, 2016, EPA issued a letter, formally notifying Bayer and Nichino that it determined flubendiamide poses unreasonable adverse effects to the environment and requesting that Bayer and Nichino "voluntarily" cancel their registrations for flubendiamide within one week of the letter. Exhibit 21. EPA further stated that the failure to submit the requested voluntary cancellation would cause EPA to initiate a cancellation proceeding consistent with FIFRA § 6(e).

100. On February 5, 2016, Bayer and Nichino responded to EPA's request. The response stated: (1) that the "voluntary" cancellation condition was an unlawful condition of registration; (2) that if EPA determined flubendiamide poses unreasonable adverse effects to the environment, the proper procedure is to issue a Notice of Intent to Cancel pursuant to FIFRA § 6(b); and (3) that the available evidence shows that flubendiamide does not pose unreasonable adverse effects to the environment. Exhibit 22.

101. On March 1, 2016, EPA provided its Notice of Intent to Cancel the flubendiamide registrations to Bayer and Nichino. The NOIC was dated February 29, 2016, and was published in the Federal Register on March 4, 2016. Exhibit 1.

102. Also on March 1, 2016, EPA issued press releases and posted information on its website announcing that EPA was seeking cancellation because flubendiamide products "pose a risk to aquatic invertebrates that are important to the health of aquatic environments."[1] EPA

[1] EPA Moves to Cancel the Insecticide Flubendiamide (Mar. 1, 2016), available at https://www.epa.gov/pesticides/epa-moves-cancel-insecticide-flubendiamide (last visited Mar. 31, 2016).

asserted that "[r]equired studies showed flubendiamide breaks down into a more highly toxic material that is harmful to species that are an important part of aquatic food chains, especially for fish, and is persistent in the environment." EPA "concluded that continued use of the product would result in unreasonable adverse effects on the environment." EPA posted the NOIC and 11 other documents totaling 504 pages regarding the merits of its cancellation decision.[2] The announcement and these documents leave no doubt that EPA's cancellation decision was a substantive decision that the flubendiamide products no longer meet the Registration Standard and thus that the cancellation process under FIFRA § 6(b) should apply.

103. Despite posting this decision and the supporting documents for public review, EPA studiously avoided any discussion in the NOIC of the basis and justification for its substantive cancellation determination. Instead, the NOIC argues that its cancellation determination is a foregone and unchallengeable decision that is beyond review by the SAP, the USDA, or the ALJ, and that Bayer, Nichino, and other affected parties have no right to a hearing on the merits of EPA's decision. EPA's approach is contrary to the process guaranteed by FIFRA § 6(b) and must be rejected by the ALJ.

E. EPA's Cancellation Determination Is Contrary to the Science and the FIFRA Registration Standard.

104. Bayer and Nichino have the right to address the merits of EPA's cancellation determination in the context of a full and proper FIFRA § 6(b) hearing after review by the SAP and USDA. EPA has failed to satisfy statutory prerequisites to the issuance of the NOIC. The 75-day time limit of the FIFRA § 6(e) process EPA has invoked makes a proper hearing on the scientific and regulatory merits of its cancellation decision impossible. EPA lacks the authority

[2] Flubendiamide – Notice of Intent to Cancel and Other Supporting Documents, available at https://www.epa.gov/ingredients-used-pesticide-products/flubendiamide-notice-intent-cancel-and-other-supporting (last visited Mar. 31, 2016).

to proceed under § 6(e) and to impose on registrants, other stakeholders, and the ALJ an unlawful process. The proposed cancellation must be denied and, if EPA wishes to pursue cancellation, it must be required to proceed under the appropriate § 6(b) process to allow full consideration of the merits of its cancellation determination.

105. Nonetheless, if this matter proceeds to a § 6(e) hearing, Bayer and Nichino intend to present evidence and witnesses, to the degree possible within the severe time constraints of the expedited process, challenging the scientific and regulatory merits of EPA's proposed cancellation. Such evidence is relevant to establishing that EPA's existing stocks proposal is inconsistent with FIFRA and EPA's own existing stocks policy. It is also relevant to establish the unsoundness of EPA's decision and EPA's motives in avoiding substantive review of its determination, to demonstrate the harm caused by EPA's unlawful "voluntary" cancellation provision to registrants and all affected stakeholders, and to develop the record for appeal should the ALJ determine – as it should not – that EPA's approach is lawful and the registrations must be cancelled.

1. EPA's Lower Aquatic Endpoint Ignores the Best Available Science.

106. EPA seeks to justify its cancellation based on a toxicity endpoint or level of concern that is derived from the spiked water study that has been superseded by the spiked sediment study that directly addresses the specific potential risk of concern. The spiked sediment study is a "higher-tier" study because it analyzes the specific route by which benthic aquatic invertebrates are exposed to des-iodo in the environment and is thus more environmentally relevant.

107. The risk assessment issued by EPA in 2008 in connection with the first flubendiamide registrations considered the potential impact of flubendiamide and its degradate des-iodo on benthic aquatic invertebrates and included as the most sensitive ecotoxicological

endpoint a No Observable Effect Concentration ("NOEC") of 0.28 ppb of des-iodo in pore water in the sediment. This endpoint was derived from a type of study known as a spiked water study, in which concentrations of flubendiamide or des-iodo were introduced into the water column above a thin layer of pond sediment, and the effects of flubendiamide or des-iodo on a representative benthic aquatic invertebrate species were measured. This type of study is designed to address deposition of flubendiamide or des-iodo directly into the water, for example, through spray drift that can occur as the product is applied.

108. In its May 21, 2008 review of the spiked water study, EPA identified the spiked water methodology as a "major guideline deviation," noting that the "[o]verlying water was spiked," and that EPA "prefer[s] that the sediment is spiked." Exhibit 17 at 2. EPA's 2008 risk assessment noted that the flubendiamide and des-iodo spiked water studies did not "follow[] sediment toxicity guidelines which require the sediment to be spiked as opposed to the overlying water." Exhibit 18 at 3. However, EPA found that the studies provided "sufficient information to reach a risk conclusion for benthic invertebrates" for the 2008 risk assessment. *Id.*

109. Pursuant to EPA's indicated preference, EPA and OECD guidance, and well-accepted toxicological practice, levels of concern for the potential toxicity of residues in pore water in sediment are most appropriately measured using a spiked sediment study, in which flubendiamide or des-iodo is introduced into the sediment and allowed to equilibrate and partition between the sediment and pore water. This test system better represents the manner in which benthic aquatic invertebrates will be exposed to des-iodo in the environment–through agricultural runoff that carries flubendiamide into a farm pond or other water body where it will degrade over time in the sediment into des-iodo. Thus, the spiked sediment study provides higher-tier results with regard to the route of exposure to the benthic organisms.

110. Bayer submitted to EPA in August 2010 precisely such a study. This study tested des-iodo at concentrations higher than the spiked water study and it showed *no observable adverse effects* at any of the concentrations tested, including the maximum level of 22 ppb. Thus, it establishes for regulatory purposes a NOEC of 22 ppb, although the actual level at which adverse effects could occur may be even more favorable. EPA issued its formal review of this study in July 2011, which confirmed the findings. Exhibit 23. Due to methodological differences and the use of time-weighted average rather than measured concentrations, EPA set the NOEC slightly lower, at 19.5 ppb. *Id.* at 2.

111. All subsequent analyses and discussions between the registrants and EPA – until December 2015 – were based on a foundation that the level of concern for des-iodo in sediment pore water was at the 19.5 or 22 ppb level, based on the higher-tier spiked sediment study. For example, in a February 2015 review of the ongoing monitoring data, EFED noted that "[s]ome of these registrant-calculated endpoints *differ slightly* from the Agency determined endpoints" and that the Agency "will use the registrant-calculated endpoints." Exhibit 24 at 17.

112. Nonetheless, at the eleventh hour and after requesting the registrants' final analysis and mitigation proposal, EPA suddenly and remarkably chose to revert to the pore water endpoint of 0.28 ppb from the superseded spiked water study, an endpoint that is 70 times lower than the current science based on the higher-tier spiked sediment study. The timing suggests EPA made this change to offset the drop in predicted exposures that resulted from EPA implementing necessary refinements to its still overly conservative exposure modeling.

113. The documents provided by EPA in support of the January 29, 2016 cancellation determination identify the 22, 19.5, and 0.28 ppb endpoints. Yet EPA provides no discussion, explanation, or justification for its sudden reversion to the superseded and unsound 0.28 ppb

endpoint and its use of that endpoint to guide its cancellation determination. Exhibit 25 (Decision Memorandum).

114. EPA did not provide its 0.28 ppb endpoint determination or any other scientific determination related to the potential environmental toxicity of flubendiamide for review by the SAP before issuing the NOIC.

2. EPA Relies on Theoretical Modeling Rather Than Actual Monitoring Data Showing No Accumulations of Concern.

115. EPA's environmental fate and effects science team, unlike EPA's human health effects science team, relied heavily on overly conservative theoretical modeling, and ultimately based its environmental effects determination on theoretical calculations instead of the actual data.

116. To address concerns regarding potential accumulation in farm ponds and other water bodies, EPA required the registrants to conduct multi-year water monitoring studies assessing the accumulation of flubendiamide and des-iodo in real-world conditions. These monitoring studies were conducted by the registrants at significant expense at the direction of EPA and using test locations and protocols confirmed by the Agency before the testing was initiated. They have continued for almost five years and are ongoing even after the issuance of the NOIC as this monitoring is the best data source available for exposure evaluations.

117. In addition, at EPA's request, the United States Geological Survey ("USGS") generated and provided data on flubendiamide and des-iodo concentrations as part of its nationwide water monitoring that includes key agricultural areas where flubendiamide is used.

118. Both the registrant and USGS data show that if flubendiamide and its degradate des-iodo are found in water bodies, it is in minute quantities.

119. From almost five years of monitoring conducted by the registrants as directed by EPA, all measured concentrations are well below the "no effect" level. For example, the maximum measured concentration of des-iodo in sediment pore water, which EPA has identified as the most critical endpoint of concern, was a 0.17 ppb concentration measured at a single site, which did not increase or reoccur in subsequent samples from the same site. This highest single value is below EPA's incorrect 0.28 ppb level of concern for des-iodo in pore water and 115 times lower than the proper 19.5 ppb des-iodo pore water level of concern based on the more relevant spiked sediment study.

120. After seven years of product use, and three years of monitoring, the USGS data show that concentrations of flubendiamide and des-iodo are found infrequently and only at parts per trillion levels. The results from the USGS data, like the registrant monitoring data, are well below "no effect" levels. The maximum measured concentrations of flubendiamide (0.93 ppb) and des-iodo (0.07 ppb) in the water column were 16 times and 27 times lower than EPA's stated levels of concern of 15.5 ppb for flubendiamide and 1.9 ppb for des-iodo.

121. EPA's theoretical modeling, including updated modeling belatedly disclosed in documents supporting the January 29, 2016 Decision Memorandum, predicts rapid accumulation of flubendiamide and des-iodo to and beyond the level of concern. The real-world monitoring data, which are not depicted in any of the tables in EPA's Decision Memorandum (Exhibit 25) supporting the cancellation determination, show that accumulation is minimal and that EPA's modeling is inaccurate. The monitoring results and all other real-world measures do not include a single exceedance of any level of concern and do not show the rapid accumulation toward exceedance of the level of concern predicted by EPA's modeling.

122. As expected, the monitoring data show some variability in concentrations from year to year. This can be caused, among other things, by product application rates and timing of application, which can vary based on growing conditions and pest pressure, and the weather, which can affect the amount of runoff based on the timing of application and of rainfall events. The monitoring results to date warrant, at most, continued or expanded monitoring to refine and confirm these results.

123. It is not surprising that EPA's theoretical modeling is not consistent with observed results. The potential for accumulation of flubendiamide and des-iodo is constrained by very specific climactic, hydrologic, and agronomic conditions. In most agricultural settings where flubendiamide is used, farm ponds have sufficient flow-through of water that will prevent significant accumulation. In the years leading up to its decision, EPA defended a modeling approach that assumed 30 years of runoff from maximum pesticide applications would accumulate in a farm pond, without any corresponding outflow. In other words, the model assumes that chemicals and sediments that enter the pond never leave. In the real world, residues that enter a pond also may exit a pond through regular or periodic outflow and can be expected to disperse through hydrologic processes rather than accumulate. This is consistent with the USGS data, in which flubendiamide and des-iodo, if detected, are present in minute quantities at concentrations in the parts per trillion, far below any levels of concern.

124. Recognizing its position was untenable, EPA finally modeled ponds with outflow, but did not disclose its updated modeling until the eve of its January 29, 2016 cancellation determination, and only after the Agency reverted to the 0.28 ppb endpoint apparently to ensure predicted exposures still exceeded levels of concern. EPA never conducted a quantitative evaluation of the model performance using an appropriate statistical test. As such, the predictive

power of the model was never established within any measure of sound science. This should have been done before making any decision to cancel based on the modeling.

125. EPA's updated modeling remains overly conservative and is based on unrealistic assumptions that ignore actual agricultural conditions and practice, and thus significantly overstates levels observed in the real world. Among other things, much of EPA's recent modeling assessments assume an initial seven years of flubendiamide use at maximum annual application rates, which is not consistent with actual use. The highest predicted accumulations occur in drier climates, such as California's Central Valley. Theoretical modeling input and outflow in these climates can lead to theoretical accumulations of residues, particularly as the lack of precipitation and evaporation causes farm ponds to periodically dry up. These theoretical accumulations ignore the fact that few, if any, farm ponds exist near agricultural fields in these areas precisely because of the lack of precipitation. Furthermore, careful management of irrigation in arid climates leads to minimal runoff from agricultural fields. Therefore, the theoretical accumulations predicted by EPA's models in drier climates are not evidence of any significant real-world risk. The registrants provided EPA with information related to the lack of ponds in proximity to key areas of commercial agriculture in California, but EPA did not refine its modeling or risk assessment approach to take that fact into account.

126. Moreover, it is contrary to sound science and regulatory principles for EPA to continue to base its registration decision on overly conservative theoretical modeling when there are now years of actual monitoring data that the Agency specifically required to resolve uncertainty in its modeling and ensure that its registration decision was based on actual rather than theoretical concerns. EPA cannot require registrants to generate millions of dollars of

higher-tier monitoring data to resolve the uncertainty created by theoretical modeling and then revert to its models when the actual results do not support its apparent wished-for outcome.

127. EPA did not provide its modeling, the monitoring data, or any of its determinations with respect to potential accumulation and aquatic environmental exposure to flubendiamide and des-iodo for review by the SAP before issuing its NOIC.

3. EPA's Cancellation Determination Discounts or Ignores Significant Benefits EPA Must Consider Under FIFRA.

128. As requested by EPA, on May 20, 2015, the registrants submitted benefits data for EPA to take into account in conducting its risk-benefit analysis. In this submission, the registrants reviewed the substantial available data and showed that continued registration of flubendiamide is in the public interest for the following reasons: (1) it offers unique attributes which make it compatible with and easily incorporated into integrated pest management (IPM) and insecticide resistance management ("IRM") programs in over 200 crops, providing broad-spectrum control of over 95 lepidopteran pests; (2) it offers a mode of action with no known cross resistance to alternative modes of action; (3) it offers superior length of control compared to other classes of chemistry; and (4) it has a favorable human safety and environmental profile, ensuring safety to applicators, field workers, the public, and the environment.

129. The registrants' benefits submission included a discussion of flubendiamide's benefits with respect to fifteen representative crops. Flubendiamide is not a high volume use product, but where it is used, the qualitative benefits are significant. The general and crop-specific benefits of flubendiamide are supported by substantial third-party data, articles, and grower support letters submitted as part of Bayer's benefits analysis.

130. On August 12, 2015, Bayer submitted an additional benefits analysis comparing flubendiamide to two well-known alternative pesticides that are members of the pyrethroid class

of insecticides. Both alternative chemicals pose significantly greater risk to aquatic invertebrates than flubendiamide. This assessment demonstrated that partial or full market share substitution from flubendiamide to these alternative pesticides would increase the immediate risk to aquatic invertebrates. EPA has not provided any specific response to this assessment.

131. EPA's January 29, 2016 Decision Memorandum in support of cancellation addresses the benefits of flubendiamide in a single, dismissive paragraph without actually addressing any of Bayer's benefits analysis. EPA concedes flubendiamide's benefits in promoting IPM and resistance management, its targeted control of lepidopteran pests, its non-systemic properties, and its low impacts to beneficial insects. EPA agrees that pyrethroids are "most likely [to] be the alternative chemistry used by growers." In the end, EPA's entire benefits "analysis" amounts to a single, vague, and unsubstantiated assertion that "there are efficacious alternatives for flubendiamide." Exhibit 25 at 9-10.

132. FIFRA requires EPA to have done more than merely identify whether an efficacious alternative exists. EPA did not but should have assessed whether those alternatives can provide the same benefits to growers and the environment as flubendiamide. In many instances, EPA acknowledges that the most likely replacement for flubendiamide will be pyrethroids, which are IPM- and IRM-disruptive and present their own environmental and safety risks. Even where EPA identifies available IPM alternatives, it fails to consider that growers cannot successfully practice IRM if they cannot rotate through a variety of pesticides with different modes of action. Rather than expanding grower options, EPA would, through this cancellation, narrow grower choices, making it harder for them to continue to practice IPM and counter pest resistance.

133. FIFRA requires EPA to have considered and weighed the economic, environmental, and human safety benefits that flubendiamide provides. FIFRA requires EPA to consider the impact that flubendiamide's removal from the market will have on growers, on human health, and on the environment. EPA's Decision Memorandum neither acknowledges nor discusses the crop-specific data and analysis that Bayer provided for fifteen representative crops.

134. EPA ignores entirely flubendiamide's relative human health and environmental benefits compared to those alternatives, which is so important to farm workers and consumers of the many crops grown with flubendiamide. EPA's Decision Memorandum does not mention or discuss flubendiamide's human health and environmental safety benefits compared to alternatives.

135. Had EPA actually considered the comparative benefits of flubendiamide over IPM and non-IPM alternatives, the Agency would have had to acknowledge that its cancellation would deprive growers of numerous environmental and human health benefits. For example, in EPA's benefits review memorandum, the Agency repeatedly identified chlorantraniliprole as a likely IPM replacement if flubendiamide is cancelled. The Agency drew this conclusion even though chlorantraniliprole costs on average over twice as much as flubendiamide – a price differential that is likely to prompt some growers to abandon IPM in favor of cheaper pyrethroids. EPA also failed to consider that because flubendiamide is non-systemic, growers that wish to apply a treatment window approach that minimizes the opportunities for pest resistance to develop (*e.g.*, waiting to see what pest pressures develop before applying a targeted insecticide) may not simply be able to substitute chlorantraniliprole for flubendiamide.

136. That EPA did not actually consider flubendiamide's benefits is further evidenced by the Agency's cursory treatment of the data Bayer submitted demonstrating flubendiamide's

superior length of control compared to other classes of chemistry used to control lepidopteran pests. In its benefits analysis, EPA acknowledged Bayer's submissions, but noted that EPA "did not conduct a comparative product performance analysis," and that it was therefore "unable to quantify whether multiple applications of alternatives would be necessary to control target pests in the respective crops."

137. EPA had conducted a comparative product performance analysis as part of its Public Interest Finding for flubendiamide in 2008, in which it concluded that "flubendiamide provides Lepidoptera control equivalent or superior to the insecticides currently being used for pest control in the evaluated crops." Exhibit 8 at 5. EPA possessed sufficient data from the registrants to update its analysis in 2015, yet the Agency declined to do so and provided no explanation for that decision. Flubendiamide's superior length of control (thus avoiding, for instance, additional applications and exposures) is never even mentioned, let alone considered, in EPA's Decision Memorandum. Nor does EPA's Decision Memorandum acknowledge that flubendiamide, unlike many of the compounds EPA identifies as alternatives, is rainfast once spray deposits have dried and would therefore not need to be reapplied after it rains.

138. In summary, EPA determined to cancel flubendiamide without "taking into account the economic, social, and environmental . . . benefits of" flubendiamide as required by FIFRA. FIFRA § 2(bb).

139. EPA did not provide USDA with its cancellation determination and benefits analysis for review before issuing the NOIC.

STATEMENT OF OBJECTIONS

I. EPA CANNOT CANCEL THE FLUBENDIAMIDE REGISTRATIONS WITHOUT PROVIDING THE PROCESS REQUIRED BY FIFRA.

A. Cancellation of Existing Registrations for Failure to Meet the Registration Standard Requires the Full Cancellation Process Under FIFRA §§ 6(b) & (d).

140. FIFRA's cancellation requirements are not optional. They "establish[] a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *See Reckitt Benckiser*, 762 F. Supp. 2d at 42 (emphasis in original).

141. Congress has spoken in creating specific cancellation procedures under FIFRA §§ 6(b)-(e), 7 U.S.C. §§ 136d(b)-(e), and determining when they apply. As detailed above, if EPA determines that it wishes to cancel existing registrations based on a determination that use of the registrations "generally causes unreasonable adverse effects on the environment" (the Registration Standard), EPA *must* issue a notice of intent to cancel and provide the right to request a hearing under FIFRA §§ 6(b) & (d), and comply with all accompanying process, including consulting with USDA and HHS, if applicable, before issuing the NOIC, submitting its determination for review by the SAP, and defending the merits of its cancellation decision in a full administrative hearing.

142. EPA's January 29, 2016 Decision Memorandum, its press release and statements issued on March 1, 2016, and the voluminous scientific and regulatory documents EPA has made available in support of its decision render beyond dispute the fact that EPA has made a substantive – albeit incorrect – determination that use of flubendiamide will cause "unreasonable adverse effects." Thus, the only proper process for EPA to cancel the registrations under the plain language of FIFRA is through §§ 6(b) & (d).

143. Due to an apparent unwillingness to subject its positions to peer review and public scrutiny in compliance with FIFRA, EPA has sought to force the cancellation process down a different and inappropriate path. By law, and to ensure that it is not used to shield substantive EPA cancellation decisions from required process and review, the streamlined cancellation process under FIFRA § 6(e) applies only when EPA determines that a registrant "has failed to initiate and pursue appropriate action toward fulfilling any condition imposed" or that "at the end of the period provided . . . that condition has not been met." FIFRA § 6(e)(1). In this case, EPA has repeatedly confirmed that Bayer and Nichino have satisfied the substantive conditions EPA imposed on the flubendiamide registrations. EPA's request for cancellation under § 6(e) is inappropriate on its face.

144. To serve its purposes, EPA devised and imposed an unlawful "condition of registration" that purports to require "voluntary" cancellation upon the mere announcement by EPA that it has reached a negative registration determination. This provision was designed to create a mechanism by which EPA could short circuit the statutory process and claim the right to cancel a product it believes no longer meets the Registration Standard without any outside review or cancellation process. This unlawful approach reveals EPA's wish to shield its scientific and regulatory determinations from rigorous, independent scrutiny. The suggestion by EPA in the NOIC that affected parties cannot challenge, and the ALJ cannot review, the merits and lawfulness of the "voluntary" cancellation provision shows a similar desire to shield from rigorous, independent scrutiny the cancellation approach it has chosen to pursue.

145. EPA cannot invent its own process to bypass statutory rights through forced "voluntary" cancellation. Whatever the scope of EPA's authority under FIFRA § 3(c)(7)(C) may be to impose "such other conditions as the Administrator may prescribe," it must fall well short

of granting itself the authority to preclude the specific cancellation rights and procedures Congress chose to require and cut others – in addition to the registrants – out of the process. Otherwise, EPA could bypass the cancellation requirements in FIFRA § 6 at will, rendering them meaningless.[3]

146. This principle was confirmed in a recent decision rejecting a different attempt by EPA to cancel registrations without cancellation process. *Reckitt Benckiser*, 762 F. Supp. 2d at 49. In that case, EPA concluded that certain rodenticides no longer met the Registration Standard, and that some could be "brought into compliance" while others "will require cancellation." *Id.* at 39. However, EPA refused to initiate cancellation and instead informed registrants that non-complying products would be deemed "misbranded" as of a date certain, making further distribution unlawful and subject to civil and criminal penalties. *Id.*

147. The Court of Appeals for the D.C. Circuit rejected EPA's efforts to shield this unlawful approach from judicial review based on assertions that the Agency had not yet taken "final action" on its misbranding scheme, and characterized the question on the merits as whether EPA could "bypass[] cancellation proceedings." *Reckitt Benckiser*, 613 F.3d at 1136. The answer on remand was a resounding no:

> It is undisputed that plaintiff holds valid registrations for products that EPA believes must be cancelled because they do not comply with the RMD. Yet, if EPA also has the authority to bring misbranding enforcement actions after June 4, 2011 . . . based on non-compliance . . ., it will be able to "bypass[] cancellation proceedings" and "effect[ively] cancel[] the registrations without following the regulatory procedures provided in Section 6." *See Reckitt*, 613 F.3d at 1136. To interpret FIFRA to give EPA that authority not only renders Section 6 superfluous; it also allows EPA to avoid the rigorous cancellation process Congress provided for in the statute.

[3] "It is 'a cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'" *TRW Inc. v. Andrews,* 534 U.S. 19, 31 (2001) (quoting *Duncan v. Walker*, 533 U.S. 167, 174 (2001)).

Reckitt Benckiser, 762 F. Supp. 2d at 43. The statute was "not ambiguous" and EPA's creative "interpretation" was entitled to no deference. *Id.* at 49. EPA did not appeal.

148. The same result applies here. The plain language of FIFRA's cancellation provisions, Congress's intent in establishing robust due process rights for existing registrations, and the logic of the *Reckitt Benckiser* decisions make clear that EPA cannot circumvent required process by seeking to implement a substantive cancellation determination through a forced "voluntary" cancellation condition.

149. In another recent action, the Ninth Circuit denied EPA's efforts to avoid its obligations before cancellation of existing registrations. That action involved a petition for review filed in the Ninth Circuit challenging EPA's issuance of certain registrations. In light of new information received, EPA asked the Court to remand and to grant voluntary vacatur of the registrations. The registrant objected, arguing that EPA's request that the Court summarily vacate the registrations was an attempt to cancel the registrations without providing any of the process required under FIFRA § 6, and that EPA should not be allowed to "short-circuit" the statutory cancellation process in this way.[4]

150. On January 25, 2016, the Ninth Circuit remanded the matter to EPA and summarily denied the motion for vacatur "without prejudice to the rights of either party to litigate that question before the agency."[5] The Ninth Circuit's order confirms that existing registrations cannot be "vacated" without following the prescribed administrative process, and rejects another creative yet unlawful attempt by EPA to achieve cancellation while bypassing required cancellation procedure.

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[4] Exhibit 26 (Intervenor's Response to Respondents' Motion for Voluntary Vacatur and Remand at 3-7, 9-11, Dkt. #122, *NRDC v. EPA*, No. 14-73353 (9th Cir. Dec. 7, 2015)).

[5] Exhibit 27 (*NRDC v. EPA*, No. 14-73353, Dkt. #128 (9th Cir. Jan. 25, 2016) (order remanding registrations)).

B. EPA Previously Confirmed That FIFRA § 6(b) Applies When Proposed Cancellation Is Based on a Determination Under the Registration Standard.

151. In the only other FIFRA cancellation proceeding to have been conducted in at least two decades, EPA drew a sharp distinction between FIFRA §§ 6(b) and 6(e) and confirmed that when EPA makes a cancellation decision based on a Registration Standard determination, the proper process is for EPA to proceed with cancellation under § 6(b).

152. After the *Reckitt Benckiser* decisions rejected EPA's misbranding scheme, EPA issued a notice of intent to cancel Reckitt Benckiser's registrations for certain rodenticides. In the notice of intent to cancel, EPA indicated that its existing stocks determination would not be included in the scope of the § 6(b) hearing. The registrant filed a motion challenging that position. Among other things, CropLife America noted in an amicus brief that § 6(e) grants the right to a hearing on existing stocks, and the § 6(b) process should, if anything, be broader. In defending its approach, EPA distinguished the purposes of a § 6(b) hearing from a § 6(e) hearing in a manner that precludes the approach it has taken here.[6]

153. As EPA explained in the *Reckitt Benckiser* proceeding, the "provisions governing risk-based cancellations" are contained in § 6(b) and pesticides "cancelled pursuant to section 6(b) have been determined to pose unreasonable risks to man or the environment that require that they be removed from commerce."[7] EPA asserted that, in contrast, "a section 6(e) cancellation is about the *registrant's* failure to meet its obligations, and not about a problem with *the pesticide*

[6] Exhibit 28 (EPA's Conditional Opposition to CropLife America's Motion to File an Amicus Curiae Brief at 4-5 & n.2, Dkt. #24, *In re Reckitt Benckiser*, EPA FIFRA Dkt. 661 (May 6, 2013)).

[7] *Id.* at 4 n.2 & 5.

product itself."[8] EPA argued that the scope of the hearings available under §§ 6(b) and 6(e) correctly reflect that distinction.

154. In the flubendiamide NOIC, EPA implicitly disavows its earlier representations to the ALJ and turns that distinction on its head. It is indisputable that EPA seeks to cancel the flubendiamide registrations due to its risk concerns and for failure to meet the Registration Standard. In the NOIC, EPA explicitly acknowledged that it "determined the registrations did not meet the FIFRA standard for registration" on January 29, 2016. Exhibit 1 at 11,559. Its carefully segregated press releases and postings about that determination leave no doubt on this score. Thus, the proper forum for EPA's "risk-based cancellation" is § 6(b). Yet in the NOIC EPA takes the position that it can cancel the registrations under § 6(e) and preclude any consideration or review of its January 29, 2016 Decision Memorandum and its determination under the Registration Standard. This is flatly inconsistent with the statutory language and intent that EPA previously recognized and relied on, when it suited its purpose.

II. THE "VOLUNTARY" CANCELLATION CONDITION IS UNLAWFUL.

A. The Purpose of EPA's Forced "Voluntary" Cancellation Condition Is to Bypass Required Cancellation Process.

155. Rather than follow the § 6(b) process, EPA seeks to force cancellation through its purported "voluntary" cancellation provision. EPA cannot be permitted to avoid its obligations by presenting powerless entities the Hobson's choice of either accepting conditions designed to bypass the cancellation process or receiving no registration at all. The July 31, 2008 letter purported to require Nichino and Bayer to submit irrevocable requests for "voluntary" cancellation of the registrations if EPA later "makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the

[8] *Id.* at 4 n.2 (emphasis in original).

environment." If found lawful, this type of "condition" would allow EPA to obtain cancellation by fiat, without providing any of the required process. EPA cannot circumvent the due process required by FIFRA for its own convenience. As discussed above, courts in the D.C. Circuit and the Ninth Circuit have recently confirmed that EPA cannot invent alternative cancellation mechanisms to avoid the statutory process.[9]

156. In the NOIC, EPA contends that "[w]ithout that condition, the registration would likely not have been approved by EPA." Yet EPA provides no explanation as to why the "voluntary" cancellation condition would be necessary.

157. The "voluntary" cancellation provision serves no valid regulatory purpose. In granting the conditional registrations, EPA necessarily and expressly determined that issuance of the registrations was in the public interest and that the registrations would not pose unreasonable adverse effects on the environment.[10] If Bayer and Nichino refused to generate the data required, EPA could have sought prompt cancellation under FIFRA § 6(e), while FIFRA § 6(b) provides the mechanism for achieving cancellation if EPA subsequently determined that continued registration would not meet the Registration Standard. FIFRA § 6(c) would allow EPA to promptly suspend the registrations during the cancellation process if the Agency identified an "imminent" hazard.

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[9] *See Reckitt Benckiser*, 613 F.3d at 1136 (remanding for determination whether EPA can "bypass[] cancellation" through misbranding scheme); *Reckitt Benckiser*, 762 F. Supp. 2d at 43 (confirming that EPA's misbranding enforcement authority cannot be used to circumvent "the rigorous cancellation process Congress provided for in the statute"); *NRDC v. EPA*, No. 14-73353, Dkt. #128 (9th Cir. Jan. 25, 2016) (order remanding the registrations for further administrative action and denying EPA's request for "voluntary vacatur").

[10] *See* FIFRA § 3(c)(7)(C); Exhibit 8 (Apr. 15, 2008 Public Interest Finding for Flubendiamide); Exhibit 10 (July 31, 2008 Letter re Approval of Registrations Under 3(c)(7)(C), with Public Interest Finding enclosed).

158. In short, there was no need for EPA to invent and impose the "voluntary" cancellation condition, and EPA has no basis to contend that the registrations might not have been issued without that condition. The only purpose it could serve is to allow EPA to evade statutory obligations and deny registrants and other affected parties due process. Allowing EPA to proceed in this fashion would render the cancellation provisions in § 6 meaningless and would deny the cancellation due process protections Congress chose to provide.

B. The "Voluntary" Cancellation Process Eliminates Required Review and Rights Afforded Registrants and Other Stakeholders.

159. The "voluntary" cancellation condition circumvents procedural requirements Congress intended to ensure that cancellation decisions are subject to interagency review by the Secretary of Agriculture and independent scientific peer review by the SAP *before* the cancellation order issues. FIFRA §§ 6(b), 25(d). This review helps to ensure that the benefits of the product to the agricultural community and the potential agricultural and commercial harm cancellation could cause are fully considered, and that the scientific grounds for the proposed cancellation are subject to and can withstand independent scientific peer review *before* the cancellation order issues.

160. This review process ensures that stakeholders considering whether to object to a proposed cancellation have the benefit of independent peer review of complex scientific determinations. It also ensures that a robust and transparent record will be available to the parties and the ALJ in a cancellation hearing.

161. Because EPA did not follow this process, the ALJ is denied such a record in this proceeding, and thus, for example, does not have an independent scientific review to gauge the strength of EPA's scientific conclusions in support of its proposed cancellation. The strength and merits of EPA's cancellation determination are relevant here for two purposes. First, they

are relevant to determining the lawfulness of EPA's approach, because subjecting EPA's determination to critical review will provide insight on EPA's motives in seeking to shield its conclusions from scrutiny and will illustrate the harm that will occur if EPA is allowed to avoid proper process and review. Second, even under the § 6(e) process EPA has wrongly invoked, EPA's overestimation of the risks and discounting of the benefits of the flubendiamide products are relevant to ruling on EPA's existing stocks proposal.

162. By demanding that registrants accept the "voluntary" cancellation condition, the Agency is not only holding registrations that should issue under FIFRA hostage to its demands for powerless entities to waive their due process rights, it is also effectively asking pesticide companies to waive the rights of other important stakeholders to object to any future determination by EPA that the registrations should be cancelled. Setting aside EPA's unlawful coercion, these companies have no authority to waive the important procedural protections Congress created under FIFRA § 6 for USDA, HHS, growers, and other adversely affected parties. By inserting this "voluntary" cancellation provision as a purported condition of registration, EPA eliminates any mechanism for these stakeholders to participate in the evaluation of whether the pesticide meets the Registration Standard. Yet Congress was explicit in including rights and process for these stakeholders in the Act. *See id.* §§ 6(b), 25(d); *see also Envtl. Def. Fund, Inc. v. Costle*, 631 F.2d 922, 936-37 (D.C. Cir. 1980) (noting the Congressional objective in amending FIFRA in 1972 was "to broaden the category of hearing requesters" beyond just registrants).

III. THE REGISTRANTS HAVE SATISFIED ALL THE LAWFUL CONDITIONS OF THE CONDITIONAL REGISTRATION.

163. Beyond the unlawful "voluntary" cancellation condition, the registrants diligently complied with all the lawful conditions of the flubendiamide registrations.

164. The original conditional registrations required the generation of significant data, including a "small-scale run-off/vegetative buffer strip study" and a monitoring program intended to generate additional data to evaluate any remaining risk concerns after the initial study. *See* Exhibit 10. EPA recognized that as of July 31, 2012, Bayer "ha[d] submitted all data required by the original conditions of registration for flubendiamide." *See* Exhibit 12.

165. On July 18, 2013, EPA agreed to extend the registrations for flubendiamide to August 31, 2015. *Id.* This allowed for additional data generation under the monitoring program and for the registrants to submit a report on those data by December 31, 2014. Throughout 2015, scientists from the registrants and EPA engaged in discussions about both the benefits and the risks of flubendiamide. On August 26, 2015, EPA again confirmed that "[a]s of July 31, 2012, BCS [Bayer CropScience] has submitted all data required by the original conditions of registration for flubendiamide." Exhibit 14.

166. EPA has no basis to seek cancellation under § 6(e) for failure to meet any valid condition of registration.

IV. CONTINUED REGISTRATION OF FLUBENDIAMIDE MEETS THE REGISTRATION STANDARD.

A. EPA's Efforts to Show That Flubendiamide No Longer Meets the Registration Standard Demonstrate Why a § 6(b) Cancellation Process Is Necessary.

167. While EPA takes the position in the NOIC that the registrations should be cancelled because the registrants declined to cancel their registrations pursuant to EPA's unlawful "voluntary" cancellation provision, the NOIC itself acknowledges that the actual substantive basis for EPA's proposed cancellation is EPA's January 29, 2016 determination that "continued registration of flubendiamide products will result in unreasonable adverse effects on the environment." Exhibit 1 at 11,559. In its March 1, 2016 press release announcing the NOIC,

EPA asserted that flubendiamide breaks down into a "more highly toxic material," that flubendiamide products "pose a risk to aquatic invertebrates," and that EPA "concluded that continued use of the product would result in unreasonable adverse effects on the environment." The January 29, 2016 Decision Memorandum documents EPA's determination that "the risks of allowing the continued use of flubendiamide outweigh the benefits, and will result in unreasonable adverse effects to the environment." Exhibit 25 at 10.

168. When it announced the NOIC, EPA posted on its website the NOIC, the Decision Memorandum, and 10 other "supporting documents" totaling 504 pages. These documents reflect EPA's scientific and regulatory analysis and conclusions, including a January 28, 2016 Ecological Risk Assessment Addendum that includes previously undisclosed modeling of predicted flubendiamide and des-iodo exposure levels and a January 29, 2016 Addendum to Clarify Invertebrate Terminology that seeks to redefine the term "benthic" aquatic invertebrates to cover all aquatic invertebrates and thus to expand retroactively the scope of EPA's stated ecological concerns.

169. Other than the registrants' letter declining to "voluntarily" cancel the registrations, EPA has not provided for public review any of the documents, white papers, and presentations that the registrants provided in response to EPA's flawed scientific determinations through their years of discussion and scientific exchange on these issues.

170. After making public claims about the risks posed by flubendiamide and its lack of offsetting benefits, determining that the flubendiamide registrations should be cancelled because they do not meet the Registration Standard, and publishing incorrect, eleventh-hour scientific and regulatory determinations in support of that determination, EPA now seeks through its unlawful "voluntary" cancellation scheme to deny everyone – the USDA, the SAP, growers, the

registrants, other interested stakeholders, the general public, and the ALJ – any opportunity to review and challenge EPA's scientific conclusions and regulatory determinations.

171. Congress established that *every* EPA cancellation determination based on the Registration Standard must undergo thorough review subject to FIFRA §§ 6(b) & (d), and 25(d). This is particularly important here, as any rigorous review encompassing EPA's Decision Memorandum, the supporting documents, and the remainder of the record not disclosed by EPA would show that EPA's cancellation determination relies on unsound scientific and regulatory determinations.

172. If afforded a proper FIFRA § 6(b) hearing and after required USDA and SAP review, Bayer and Nichino would present fact and expert evidence and testimony establishing that EPA's cancellation determination: (1) ignores the most recent and definitive data and relies on a toxicity endpoint that is 70 times lower than the current science supports; (2) ignores the real-world monitoring data that show no accumulation to a level of concern and contradict the overly conservative theoretical exposure modeling the Agency relies on; and (3) dismisses without justification the significant benefits of flubendiamide, including the lack of *any* human health concerns, an ecological risk profile that is very favorable and better than many likely alternatives, and its critical and unique role as tool for growers practicing both IPM and IRM.

173. If this matter proceeds to an evidentiary hearing under § 6(e) – even though it should not – the registrants and the ALJ will be denied the benefits of USDA and SAP review and input, but the registrants will nonetheless request the right to present evidence and testimony establishing the unsoundness of EPA's determination. Such evidence and testimony are relevant to EPA's motives in selecting an unlawful cancellation process that shields its determination from required review and to the merits of EPA's existing stocks determination.

174. Without waiving the right to a full and proper hearing on the merits of EPA's cancellation decision *after* USDA consultation and SAP review, the errors in EPA's cancellation determination are summarized below.

B. EPA's Selection of the Lower Endpoint Is Not Consistent with Sound Science and Regulatory Process.

1. The Sudden Switch to the Lower Endpoint Undermined Transparency and Precluded Appropriate Review.

175. As described above, EPA's cancellation determination relies on EPA's sudden reversion in mid-December 2015 to a toxicological endpoint of 0.28 ppb for the flubendiamide degradate des-iodo in pore water in sediment, which is 70 times lower than the 19.5 ppb endpoint based on a more definitive and appropriate 2010 study that EPA had reviewed and approved in 2011. While EPA took the position that the endpoint should be 19.5 ppb rather than the 22 ppb endpoint the registrants calculated due to the Agency's use of time-weighted average rather than measured concentrations, before December 2015 EPA never suggested that it would revert to the superseded and incorrect 0.28 ppb endpoint.[11]

176. As a result, through 2015, EPA's discussions with the registrants focused on whether the modeling and monitoring data suggested that flubendiamide or des-iodo might accumulate to a level of concern, not whether the most critical endpoint should be drastically reduced. Even as EPA changed course and prepared to take action against the registrations, EPA asked the registrants to prepare their final analysis and mitigation proposals, and scheduled and conducted a high level meeting on December 15, 2015, involving EPA's Assistant Administrator

[11] *See, e.g,* Exhibit 24 at 17 (reflecting EFED's position in February 2015 that "[s]ome of these registrant-calculated endpoints *differ slightly* from the Agency-determined endpoints" but that the Agency "will use the registrant-calculated endpoints.") (emphasis added).

and the CEOs of Bayer and Nichino, EPA failed to disclose it was changing the most critical endpoint in this remarkable way.

177. The day after the high level meeting, EPA's EFED briefed the Assistant Administrator on its ecological risk determinations using the lower endpoint which had not been disclosed to the registrants just the day before. This maneuvering by EPA undermined a years-long transparent process of scientific review and exchange between EPA and the registrants, and precluded the registrants from addressing EPA's most critical scientific position before it was presented to the Assistant Administrator in support of the cancellation decision that he apparently desired.

178. In the January 6, 2016 meeting, EPA acknowledged that the timing of its change was "unfortunate," but provided no justification for the lack of disclosure even as it asked the registrants to provide their final mitigation analyses.

179. The January 29, 2016 Decision Memorandum wrongly implies that the only area of dispute between EPA and the registrants was the use of time-weighted average versus nominal or measured concentrations, and does not defend or provide *any* discussion of EPA's reversion to the lower endpoint from the superseded spiked water study.

180. The Decision Memorandum includes a table of the "final suite" of available endpoints that lists both the superseded 0.28 ppb endpoint under the spiked water study and the 19.5 ppb endpoint under the spiked sediment study, both calculated under EPA's time-weighted average approach. Exhibit 25 at 5. Only after examining the underlying data and modeling and comparing them to EPA's statements regarding the exceedances is it clear that EPA selected the superseded 0.28 ppb endpoint as an "Agency LOC" [level of concern] and the basis for its

cancellation determination, while rejecting and incorrectly characterizing the 19.5 ppb endpoint as a "[Bayer/Nichino]-suggested" endpoint with which EPA did not agree.

181. This level of obfuscation is antithetical to scientific and regulatory transparency, let alone accuracy. Scientific peer review by the SAP – which EPA goes to great lengths to avoid – would require EPA to confirm and explain its use of the lower endpoint. The ALJ should deny EPA's proposed cancellation under § 6(e) and require EPA to subject its scientific determinations to the § 6(b) process, which would include review by the SAP of EPA's endpoint selection.

2. EPA's Selection of the Lower Endpoint Was Outcome Driven and Is Not Supported by the Science.

182. If this matter proceeds to a hearing, the registrants will present fact and expert testimony confirming that, as discussed above, the timing of EPA's sudden reversion to a 70 times lower endpoint was necessary in order for EPA's modeling to continue to predict exceedances after EPA made necessary corrections to its overly conservative modeling.

183. As discussed above, throughout EPA's discussions with the registrants, it defended its use of a modeling approach that predicted concentrations based on a model assuming 30 years of agricultural runoff into a farm pond *with no corresponding outflow.* At the final hour, in modeling EPA disclosed only in connection with its cancellation determination, EPA finally addressed this methodological error. However, to ensure that the modeling still "predicted" widespread exceedances, EPA at the same time reverted to the incorrect lower endpoint. EPA asked the registrants to provide their final analysis of the viability of flubendiamide and proposed mitigation measures without informing them of either change.

184. At the hearing, Bayer and Nichino's witnesses will establish that EPA's use of the lower endpoint is contrary to the definitive, spiked sediment study reviewed and approved by

EPA that showed no observable effects at 22 ppb, the highest level tested. The witnesses will testify that EPA's use of an endpoint from the superseded and less applicable spiked water study is contrary to the weight of the evidence and is inconsistent with EPA and OECD guidance and well-accepted toxicological practice.

C. EPA Wrongly Relies on Theoretical Modeling That Is Contradicted by Real-World Data Showing No Accumulation of Concern.

1. EPA's Theoretical Modeling Relies on Highly Unrealistic Assumptions and Has No Predictive Value.

185. The second leg supporting EPA's cancellation determination is equally unsound. If this matter proceeds to a hearing, the registrants will present expert testimony confirming that EPA's theoretical modeling is overly conservative and unrealistic and has no predictive value.

186. EPA's cancellation decision relies wholly on its theoretical modeling predicting rapid accumulation of residues of flubendiamide and des-iodo that are not connected to real-world use conditions and have not been observed in any monitoring and sampling.

187. At the hearing, the registrants' witnesses will establish that even EPA's eleventh-hour, more refined modeling has little to no predictive value, as confirmed when compared to the real-world monitoring data generated at EPA's direction. Among other things, the modeling all proceeds from the assumption that there have been seven years of use with the maximum application rate and number of applications each year. This is not consistent with actual, known historic use rates, data that are available to EPA.

188. EPA's updated modeling also predicts the highest exceedances in drier climates such as California's Central Valley where very few, if any, farm ponds exist due to the arid conditions and where very little runoff will occur due to irrigation practices in those regions.

189. Testimony from the registrants' witnesses will confirm that EPA's decision to cancel flubendiamide based on "predicted" exceedances from the overly conservative theoretical modeling is contrary to sound science and reasonable regulatory practice.

190. The registrants' witnesses will establish that EPA failed to perform any statistical analysis comparing the predicted results of the model to the real-world monitoring data to quantify how well the modeling performed in predicting actual exposures. The registrants' witnesses will show that such analysis reveals, among other things, that the modeling not only significantly overstates the actual results but also that the mean value of the observed data is a better predictor than the modeled values. In other words, simply taking the average of the observed data is a better predictor than EPA's modeling. This unacceptable performance confirms that EPA's modeling is not a sound basis for making regulatory determinations, and that the Agency's registration determination should instead be based on the monitoring data.

2. Real-World Data Show No Accumulation Above a Level of Concern.

191. As discussed above, the registrants were required to conduct monitoring studies to address the uncertainties posed by EPA's theoretical modeling and measure the actual amount of flubendiamide and des-iodo accumulating in aquatic environments. At EPA's direction and at significant expense, the registrants generated almost five years of monitoring data and are continuing to conduct the monitoring. The registrants' witnesses will establish that these data, and additional analysis conducted by USGS at EPA's request, have not uncovered a single sample showing an exceedance of any level of concern.

192. Moreover, the year-over-year monitoring data do not show the rapid accumulation toward a level of concern that EPA's modeling predicted would occur. As the registrants' witnesses will explain, the variability observed in the monitoring results is likely due to factors including different use rates caused by growing conditions and pest pressures, and different

weather patterns and application timing which can result in different amounts of agricultural runoff. The data do not support the conclusion that flubendiamide or des-iodo is accumulating or will accumulate to a level of concern.

193. Finally, the registrants' witnesses will establish that it is unsound scientific and regulatory practice for EPA to require registrants to conduct higher-tier monitoring studies to address and resolve uncertainties in theoretical models, and then ignore the results obtained from the monitoring when they do not show the theoretical accumulation predicted. EPA should not ignore the higher-tier monitoring data and cannot justify the cancellation of a valuable agricultural tool using "predicted" exceedances from theoretical models whose predictive accuracy has been discredited by the very data EPA required to be generated.

D. The Human Health, Environmental, and Economic Benefits of Flubendiamide Outweigh Any Alleged Risks.

194. EPA's determination of whether the continued registration of a product "causes unreasonable adverse risks on the environment" must "tak[e] into account the economic, social, and environmental costs *and benefits* of the use of any pesticide." FIFRA § 2(bb) (emphasis added). Flubendiamide narrowly and effectively targets lepidopteran insects, while posing minimal risk to beneficial insects. It is one of a limited set of IPM options for growers seeking to control lepidopteran insects, and its non-systemic properties render it far less likely to result in resistance than other alternative diamide products having systemic qualities. Flubendiamide has an excellent safety profile, posing no risk to humans, and it is far less costly to growers than identified IPM alternatives. Unlike certain alternative compounds identified by EPA, flubendiamide poses minimal risk to pollinator species, and it is rainfast once spray deposits have dried and therefore less likely to require repeated treatments than alternatives.

195. Had EPA undertaken the analysis required by FIFRA, it would have had to consider the drawbacks of cancelling such a unique compound with a unique array of benefits that render it an essential tool for both IPM and IRM. EPA would have had to consider that while there may be efficacious alternatives to flubendiamide, none present the same array of benefits to growers and to the environment as flubendiamide. EPA would have had to consider that flubendiamide's cancellation will result in the use of alternative products with less favorable human safety profiles. EPA would have had to consider that flubendiamide's cancellation will likely deter growers from applying the very IPM and IRM practices that EPA claims to be promoting, in place of disfavored organophosphates and pyrethroids. EPA would have had to consider the increased likelihood for lepidopteran insects to develop resistance to the remaining compounds available to growers. If EPA had properly weighed flubendiamide's alleged risks against its human health, environmental, and economic benefits, the Agency would have had to conclude that flubendiamide continues to meet the Registration Standard.

V. EPA'S PROPOSED LIMITATIONS ON DISTRIBUTION, SALE, AND USE OF EXISTING STOCKS ARE NOT CONSISTENT WITH FIFRA.

196. For the reasons described above, Bayer requests that the ALJ find unlawful EPA's purported "voluntary" cancellation condition, deny the Agency's attempt to achieve cancellation for purported failure to meet the Registration Standard through FIFRA § 6(e), and deny EPA's proposed cancellation of the flubendiamide registrations. However, should this matter proceed, Bayer and Nichino also object to and request a hearing on the existing stocks provision contained in the NOIC.

197. Under § 6(e), EPA "may permit the continued sale and use of existing stocks" of a cancelled pesticide "under such conditions, and for such uses as the Administrator may specify," so long as EPA determines that "such sale or use is not inconsistent with the purposes [of

FIFRA] and will not have unreasonable adverse effects on the environment." FIFRA § 6(e)(1). Registrants and any other adversely affected party may object to and request a hearing on EPA's existing stocks determination and whether it is "consistent with" FIFRA. *Id.* § 6(e)(2).

198. EPA defines existing stocks as "products that were 'released for shipment' before the effective date of cancellation." Exhibit 1 at 11,560.

199. In the NOIC, EPA acknowledged that, absent a suspension order, Bayer, Nichino, and others in the channels of trade have the right to continue to produce, sell, and distribute flubendiamide products until cancellation occurs. *Id.*

200. In the NOIC, EPA determined that "it would not be appropriate to allow any further sale or distribution, by any person, of existing stocks" as of the cancellation date, "except to the extent that distribution is for purposes of returning material back up the channels of trade, for purposes of disposal, or for purposes of lawful export." *Id.* EPA determined that it would also ban use of flubendiamide technical products as of the cancellation date except for production of products that are "clearly designated solely for lawful export." *Id.* Finally, EPA determined that it would allow end-use products "in the hands of end users to be used until exhausted." *Id.*

201. In the NOIC, EPA noted that it "expected" that the quantity of flubendiamide in the hands of end users would be "sufficiently low that the costs and risks associated with collecting them for disposal would be high compared to those associated with the use of the cancelled product." *Id.* However, EPA threatened that it "may amend its position regarding use of existing stocks at [the] hearing if the quantity of those products in the hands of end users increases prior to cancellation." *Id.*

202. EPA's proposed existing stocks determination is unlawful and inconsistent with the purposes of FIFRA and should be denied.

A. Punishing Bayer and Nichino for Seeking Review of the Lawfulness of EPA's Cancellation Approach Is Not an Appropriate Basis to Ban Distribution and Sale of Existing Stocks.

203. The NOIC does not allege that allowing unrestricted distribution, sale, and use of existing stocks would cause any harm. Instead, EPA justifies its proposed restrictions on the grounds that the registrants refused to comply with the unlawful "voluntary" cancellation provision and that it would be "inappropriate to reward registrants who disregard the terms and conditions of registration, like the condition at issue here, by allowing any distribution or sale of existing stocks." *Id.*

204. The desire to punish the registrants for exercising their statutory right to challenge the basis for and legality of EPA's proposed cancellation is not a proper basis on which to make an existing stocks provision. EPA's proposed ban on sales and distribution and limitation on the use of existing stocks without any substantive basis is presented as punishment for the registrants' invocation of statutory due process and arises from the Agency's dissatisfaction with the fact that FIFRA allows continued sale and use while a proposed cancellation is challenged. This punitive existing stocks provision is thus inconsistent with the purposes of FIFRA and should be rejected.

B. EPA's Approach Is Contrary to the Existing Stocks Policy the Agency Cited.

205. EPA cites a 1991 policy statement in support of its existing stocks provision. Exhibit 1 at 11,560 (citing Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362 (June 26, 1991) (the "Policy"), attached as Exhibit 9). EPA claims the Policy supports the proposed restrictions because it provides that the Agency will generally not allow

sale or distribution of existing stocks where a registrant fails to comply with a "specific" condition of registration. Exhibit 1 at 11,560.

206. However, the language EPA relies on falls under Part III.A.2 of the Policy, which applies to "[c]ancellations where a registrant has failed to comply with an obligation of registration" and "*where the Agency does not have significant risk concerns with respect to the cancelled pesticide*." Exhibit 9 at 29,365 (emphasis added). Part III.A.2.d addresses existing stocks provisions for "[f]ailure to comply with the terms of a conditional registration." *Id.* at 29,366. It explains that "[w]here a conditional registration is cancelled (*and the Agency has not identified significant risk concerns*), the Agency will base its existing stocks decision on the nature of any conditions that have not been met by the registrant," *i.e.*, whether the condition is "general" or "specific." *Id.* (emphasis added). Because EPA has asserted that there are "significant risk concerns" with flubendiamide, Part III.A.2 and III.A.2.d do not apply.

207. Instead, EPA should follow Part III.A.1, which applies to cancellations "where the Agency has identified particular risk concerns." *Id.* at 29,364. In such cases, EPA is to make a "case-by-case" determination focusing on whether "the social, economic, and environmental benefits associated with such distribution, sale, or use exceed the social, economic, and environmental risks." *Id.* The Policy suggests that EPA should consider the "quantity of existing stocks at each level of the market"; the "risks resulting from . . . use," taking into account the limited nature of the use of existing stocks and whether the identified risk is acute; the "benefits resulting from the use of such stocks," including short-term problems from switching to alternatives, availability of alternatives, and economic effects; the "dollar amount users and others have already spent on existing stocks (which would be lost . . .)"; and "the nature, feasibility, and cost of proper disposal." *Id.*

208. The NOIC does not contain any analysis, findings, or conclusions with respect to these factors, and EPA's punitive existing stocks provision is contrary to the case-by-case consideration the Policy requires.

209. If this matter proceeds to a hearing, the registrants will present fact and expert testimony establishing that a case-by-case analysis considering the factors specified under the Policy would not support any limitations on use of existing stocks. For the reasons discussed above, EPA's scientific and regulatory determinations alleging unreasonable risk from the use of flubendiamide are unsound and contrary to the weight of the evidence, while the benefits of flubendiamide are substantial. The potential risk identified by EPA is not acute but relates to potential long-term accumulation over many years of flubendiamide and des-iodo in the environment. The monitoring data and real-world evidence after seven years of registration show no signs of residues approaching a level of concern, and there is no evidence that use of the limited existing stocks as of such cancellation will pose any such threat.

210. For all these reasons, EPA's proposed existing stocks limitations should be denied, the registrants, distributors, and retailers should be allowed to sell and distribute stocks that were released for shipment at the time of cancellation, and users should be permitted to use any remaining stocks consistent with the terms of the label.

C. EPA Does Not Have the Right to Amend Its Provisions on Use of Existing Stocks "At [the] Hearing."

211. EPA's threat to revisit its existing stocks provision "at [the] hearing" if it determines that the stocks in the hands of end users have increased is an unlawful attempt to implicitly ban sale and distribution of flubendiamide during the hearing, despite EPA's acknowledgement that such sales are lawful. This threat is yet another attempt by EPA to achieve a desired result – in this instance, suspension – without following the required process.

212. If EPA wishes to limit or ban sale and distribution while the cancellation proceeding is ongoing, EPA must make an "imminent hazard" finding and provide the process required under FIFRA § 6(c) to support suspension of the registrations. EPA has not done so. Instead, EPA is attempting to discourage sales, sow marketplace confusion, and achieve effective suspension by claiming the right to revisit its determination and render products sold and distributed since the NOIC unusable. The ALJ should find EPA's implicit suspension attempt unlawful and not allow EPA to change retroactively its existing stocks provision.

213. EPA's attempt to reserve the right to change its existing stocks provision "at [the] hearing" is also inconsistent with FIFRA and EPA's implementing regulations. Under EPA's chosen approach pursuant to FIFRA § 6(e), EPA must "specify" in the NOIC the extent and conditions of continued use and sale of the product, and registrants and other adversely affected parties then have the right to object to and challenge that determination in the hearing. EPA does not have the right to change to a far more restrictive existing stocks determination "at [the] hearing," as doing so would undermine notification requirements under § 6(e).

214. Moreover, under EPA's regulations, the NOIC can be amended only "prior to the commencement of the public hearing." 40 C.F.R. § 164.21(b). If the ALJ determines that "additional time is necessary" to allow parties "to prepare for matters raised by such amendments, the commencement of the hearing shall be delayed for an appropriate period." *Id.* FIFRA makes clear that the existing stocks determination is one of two core issues to be addressed at a § 6(e) hearing. Given the limited, 75-day time period to conduct the hearing and reach a final order, any material change to the existing stocks provision made by EPA after the NOIC is issued would be prejudicial. Among other things, parties who might wish to object to

the revised provision may be time-barred from doing so by the 30-day period for submission of objections.

215. Thus, if EPA wishes to change to a more restrictive existing stocks provision, the ALJ should stay the hearing, require EPA to issue an amended NOIC, provide an opportunity for all stakeholders to file objections to the new existing stocks provision, and restart the 75-day clock under FIFRA § 6(e).

CONCLUSION

216. EPA's scheme to achieve cancellation of the flubendiamide registrations through implementation of a purported "voluntary" cancellation condition and improper invocation of FIFRA § 6(e)'s narrow cancellation process is unlawful. EPA cannot give itself the authority to bypass required cancellation process, including the obligation under FIFRA §§ 6(b) and 25(d) to submit its cancellation determination and supporting findings for review by the USDA and SAP, and cannot deny registrants and other stakeholders their rights under FIFRA §§ 6(b) & (d) to contest the merits of EPA's cancellation determination under the Registration Standard in an administrative hearing.

217. While these rights are applicable under FIFRA § 6(b) to every cancellation based on an unreasonable adverse effects determination, they are particularly critical here where EPA has undermined transparency and scientific and regulatory integrity by ignoring the most relevant data on potential toxicity, exposure, and benefits and relying on faulty regulatory and scientific conclusions that were not disclosed until issuance of the final determination, despite years of scientific and regulatory exchange and discussions.

218. If provided the proper cancellation process, including prior consultation with USDA, independent science review by the SAP, and the right to present evidence and testimony challenging EPA's cancellation determination, Bayer and Nichino would establish that continued

registration of flubendiamide would not cause unreasonable adverse effects and is consistent with and required by FIFRA. For these reasons, Bayer and Nichino request that the ALJ deny EPA's proposed cancellation, find that the forced "voluntary" cancellation condition approach is unlawful and contrary to FIFRA, and order EPA to follow the FIFRA § 6(b) cancellation process if it wishes to cancel the flubendiamide registrations for failure to meet the Registration Standard.

219. Should the ALJ nonetheless proceed with the hearing and approve the proposed cancellation, Bayer and Nichino request that the ALJ deny EPA's proposed existing stocks limitations as inconsistent with FIFRA and EPA's Existing Stocks Policy and allow unrestricted distribution, sale, and use of stocks, consistent with label requirements, that have been manufactured and released for shipment as of the cancellation date.

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