UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

RESPONDENT's MOTION TO LIMIT SCOPE OF TESTIMONY

As noted by the Presiding Officer in the Order Scheduling Hearing and Prehearing Procedures dated April 4, 2016 (at p. 3), it appears that the only factual issue to be resolved in this proceeding is whether the Administrator's determination with respect to the disposition of existing stocks is consistent with FIFRA.[1] Respondent EPA's (hereafter "Respondent" or "EPA" or "the Agency") position on existing stocks in this proceeding is quite simple: as set forth in the Notice of Intent to Cancel published in the Federal Register on March 4, 2016 (81 Fed. Reg. 11558 *et seq.*), the Administrator's determination to not allow any further sale or distribution of existing stocks is appropriate, and certainly is consistent with FIFRA, because the registrants in this proceeding (hereafter "Registrants") should not benefit from failing to comply with a specific term of their conditional registrations, and specifically should not benefit from delaying the cancellation of the flubendiamide registrations for a number of months during which time the

[1] As described in the Notice of Intent to Cancel giving rise to this proceeding, existing stocks of cancelled pesticides are those products that were released for shipment before the effective date of cancellation. A product is considered "released for shipment" when the product has been placed in the container that will be introduced into commerce, and the product and container have passed any final quality assurance/quality control procedures used by the manufacturer before allowing the product to be introduced into commerce.

Registrants can be expected to produce and release additional stocks that they would not have been able to lawfully release into commerce had Registrants complied with the terms of their conditional registrations. 81 Fed. Reg. at 11560. Registrants have made clear in their Motion for Accelerated Decision (at p. 59) that they intend to offer direct testimony at the evidentiary hearing in this proceeding related to whether flubendiamide causes unreasonable adverse effects on the environment. Registrants assert that "[s]uch evidence and testimony are relevant to EPA's motives in shielding its cancelation determination from required review, which bears on the lawfulness of EPA's 'voluntary cancellation' scheme…, and also will be relevant to the merits of EPA's existing stocks determination." *Id.* EPA hereby moves that the Tribunal bar any testimony at hearing related to the issue of whether flubendiamide causes unreasonable adverse effects on the environment because such testimony is not material to any permissible issue of fact that will be raised in the proceeding.

EPA is filing today its Opposition to Registrants' Motion for Accelerated Decision, and in that Opposition the Agency addresses Registrants' meritless arguments related to the legality of the condition they knowingly accepted nearly eight years ago. But for purposes of the evidentiary hearing in this case, the short and absolute answer is that the appropriateness or lawfulness of the condition is not a subject for hearing. FIFRA is quite clear on this point; the only matters for resolution at this hearing under section 6(e) are whether the "condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [FIFRA]." FIFRA section 6(e)(2). While EPA is confident in both the legality and appropriateness of the cancellation conditions, testimony related to the legality and appropriateness of a condition has no place in a proceeding convened under section 6(e).

EPA has made a determination that the risks posed by the quantities of existing stocks expected to be in end users' hands are reasonable compared to the burdens and risks associated with recovering those existing stocks. EPA has made no determination in regard to the risks posed by existing stocks held by the registrants, distributors, and retailers; instead EPA has determined that allowing sale and distribution of those products (except for disposal) would be inconsistent with the purposes of FIFRA because it would financially reward registrants who have refused to comply with a condition of their registrations. EPA concedes that scientific and economic testimony related to whether flubendiamide causes unreasonable adverse effects on the environment could be relevant to the issue of whether the Administrator's determination with respect to the disposition of existing stocks in the hands of end users is consistent with FIFRA. But in this case, the Registrants have given no indication that they dispute EPA's determination in regard to end users. However, there is no scientific or economic testimony that could reasonably bear upon the question of whether it would be inconsistent with the purposes of FIFRA to allow the Registrants to reap the financial rewards of their refusal to comply with a condition of their registrations through the further sale and distribution of existing stocks held by the registrants, distributors, and retailers.

Although Respondent believes that use of flubendiamide causes unreasonable adverse effects on the environment and that sale and distribution of existing stocks would not pass the risk-benefit test under FIFRA, in the interest of simplifying the issues for the abbreviated FIFRA section 6(e) cancellation process, Respondent did not base the existing stocks determination in the Notice of Intent to Cancel on risk-benefit or scientific issues, and will not be offering any testimony in this proceeding on whether the sale and distribution of existing stocks would cause unreasonable adverse effects on the environment. If the Presiding Officer and Environmental

Appeals Board do not agree with Respondent that it is consistent with FIFRA that registrants should not benefit from unlawfully refusing to comply with conditions of their registrations, EPA will not make any further arguments with respect to the sale and distribution of existing stocks. Because Respondent will not be contesting in this proceeding any factual issues with respect to whether flubendiamide causes unreasonable adverse effects on the environment, testimony addressing that issue would not be material to any factual issue in dispute and should not be allowed.

Respondent is not taking this position because it agrees with Registrants' position on the costs and benefits associated with flubendiamide; neither is Respondent taking this position because it is hesitant to engage Registrants on whether flubendiamide causes unreasonable adverse effects on the environment. As is discussed in more detail in Respondent's Opposition to Registrants' Motion for Accelerated Decision, Registrants could have obtained a factual hearing on whether flubendiamide products are eligible for registration without the cancellation conditions that led to this proceeding at any time in the past eight years, either by refusing to accept the initial registrations with the conditions or by subsequently applying for amended or new registrations without the voluntary cancellation condition, and the last of these options remains open to the Registrants today. But while Respondent is prepared to litigate the broader scientific and economic issues related to flubendiamide in an appropriate hearing, Respondent opposes any attempt to pervert the purpose of FIFRA section 6(e). Respondent does not believe it appropriate to further delay the cancellation of flubendiamide, which should have been initiated by the Petitioners in February of this year, in order to prepare for and litigate complicated risk-benefit issues in the context of an existing stocks determination in this proceeding.

Existing stocks can be analogized to the material left in a pipeline when the tap is turned off. Preparation of the Notice of Intent to Cancel and hearing preparation generally would have required significantly more time and resources if Respondent had included risk-benefit issues in its Notice of Intent to Cancel. Further, it is highly doubtful that the 75-day limitation in section 6(e) of FIFRA could accommodate a full and fair hearing on risk-benefit issues; cancellation hearings under section 6(b), which focus on risk-benefit issues, typically require significantly more hearing preparation, witnesses, and hearing days, than can fit into an expedited hearing such as is required under section 6(e). Respondent believes it inappropriate to delay closing the tap in order to deliberate extensively on what should be done with material still in the pipeline.

For these reasons, Respondent elected not to rely on risk-benefit issues to support its existing stocks determination in the Notice of Intent to Cancel, and will not present any factual testimony on risk-benefit issues in this section 6(e) proceeding to support its position that declining to allow sale and distribution is existing stocks in consistent with FIFRA. Instead, EPA will assert a much simpler, but still compelling, position. The conditions at issue in this proceeding were included in the initial registrations because of EPA's concerns with the environmental risks posed by flubendiamide. The conditions were discussed extensively by the parties prior to the issuance of the registration, and Registrants were well aware of the conditions when they accepted the registrations. Their failure to comply with important conditions that they knowingly and willingly accepted, and taken no steps to challenge in more than seven years, is appropriate grounds for both cancellation and for disallowing any further sale or distribution of existing stocks after cancellation. Without regard to risk-benefit issues, Registrants' decision to fail to comply with the commitments they made almost eight years ago and instead to delay cancellation, and introduce new material into the stream of commerce for months after the

registrations should have been cancelled (and the tap turned off), is appropriate grounds to prevent further sale and distribution of material that should never have entered the stream of commerce in the first place.

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

Because Respondent will neither raise nor contest in this proceeding scientific or economic issues related to whether flubendiamide causes unreasonable adverse effects on the environment, the Presiding Officer should limit the scope of testimony at the hearing and not permit the introduction of testimony addressing whether flubendiamide causes unreasonable adverse effects on the environment.

Counsel for Respondent has contacted counsel for the Registrants to discuss the substance of this motion, and counsel for the Registrants has advised that Registrants oppose this Motion and believe this Motion is more properly viewed as a statement identifying an objection to the scope of hearing that, pursuant to the April 4, 2016 Scheduling Order, should be filed as part of the prehearing exchange on April 22, 2016. While EPA does not believe that the Scheduling Order precludes the filing of this Motion at this time, the Agency is not filing this

Motion to distract Registrants from their time to respond to EPA's Opposition to Registrants' Motion for Accelerated Decision that is being filed today. Accordingly, Respondent has no objection to the Tribunal allowing Registrants to file their response to this Motion three business days after Thursday, April 21, 2016 (the day their response to EPA's Opposition is due).

Respectfully submitted,

April 18, 2016
Date

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 18th day of April, 2016, a true and correct copy of *Respondent's Motion to Limit Scope of Testimony* was filed electronically using the EPA OALJ e-filing system and served in the following manner to the below addresses:

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