UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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In the Matter of:	)	
	)	
Reckitt Benckiser LLC, et al.	)	FIFRA Docket No. 661
	)	
EPA Reg. Nos. 3282-3, 3282-4, 3282-9, 3282-15, 3282-65, 3282-66, 3282-74, 3282-81, 3282-85, 3282-86, 3282-87, and 3282-88	)	

RESPONDENT'S CONDITIONAL OPPOSITION TO CROPLIFE AMERICA'S MOTION TO FILE AN AMICUS CURIAE BRIEF REGARDING EXISTING STOCKS OF CANCELLED PRODUCTS

On April 26, 2013, CropLife America ("CropLife"), as amicus curiae, filed a brief in support of the April 12, 2013, Reckitt Benckiser LLC ("Reckitt") Motion for an Expedited Determination That EPA's Existing Stocks Decision Is Within The Scope of The Hearing ("Reckitt's Motion"). The Assistant Administrator for Chemical Safety and Pollution Prevention ("Respondent") consented to the filing of CropLife's amicus brief conditioned upon Respondent being allowed the opportunity to reply. It is unclear whether the rules governing this proceeding, 40 C.F.R part 164, allow parties to respond to amicus briefs as a matter of right. Accordingly, Respondent files herewith its reply to CropLife's amicus brief, or, in the alternative, Respondent's opposition to CropLife's motion for leave to file an amicus brief.

I. CropLife's Substantive Contentions Are Mistaken And Provide No Support For Reckitt's Motion

CropLife does not address the cases cited in the Notice of Intent To Cancel giving rise to this proceeding that hold that the disposition of existing stocks of cancelled products are not required to be issues for a cancellation proceeding (78 Fed. Reg. 8123, 8126), but instead presents two legislative history arguments in support of its contention "that Congress in 1972 intended to include existing stocks issues within the scope of section 6(b) cancellation hearings." CropLife Brief at 8. Neither has merit.

First, CropLife identifies a letter from an EPA Assistant Administrator to a member of the Senate Committee on Agriculture and Forestry, attached to a report of that Committee regarding proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), and extracts from it the following nugget:

> I believe our present authority under [a House bill that did not include the existing stocks language ultimately included in FIFRA section 6(a)(1)] is sufficiently flexible to permit an orderly phase-out where farmers have relied on a pesticide for use during an upcoming growing season. It is open to registrants and user groups to raise at the hearing any question bearing on the benefits of using a product. Any showing of need for a pesticide during an upcoming season would be relevant and the statute would permit us to issue an order that would result in a label use for a given season or period of time or indeed a certain geographical location. It would be our policy to invoke this flexibility on a showing by affected groups that the particular chemical were needed for the growing season.

S. Rep. No. 92-838 at 13-14 (June 7, 1972).

CropLife represents this as evidence of a Congressional intent that the disposition of existing stocks should be decided in section 6(b) cancellation proceedings, but the text says nothing of the sort. The purpose of a FIFRA section 6(b) cancellation proceeding is to determine whether "a pesticide or its labeling or other material required to be submitted does not comply

with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, [such that] the Administrator [should] cancel its registration or change its classification..." *Id.* The pesticide product is cancelled without a hearing if no person files a timely request for hearing and states particular objections. FIFRA section 6(b); 40 C.F.R. § 164.22. Therefore, persons opposing cancellation necessarily must present evidence of the product's benefits in their efforts to demonstrate that the product satisfies the risk-benefit balancing required by FIFRA. So it is wholly unremarkable to observe that "[i]t is open to registrants and user groups to raise at the hearing any question bearing on the benefits of using a product" (S. Rep. at 13-14) as they must do so in order to oppose cancellation. But it is only the benefits *of continued registration* that are relevant to the question of whether the pesticide registration may continue or must be cancelled; the benefits and risks associated with whatever post-cancellation use that might subsequently be allowed are not germane to the purpose of the proceeding. Nevertheless, testimony at the hearing introduced for the purpose of showing the need for continued registration (the decision before the Administrative Law Judge) may also be relevant to the separate and independent decision of the Assistant Administrator for Chemical Safety and Pollution Prevention concerning whether, and under what conditions, to allow the sale, distribution or use of existing stocks of cancelled product. Hence "[a]ny showing of need for a pesticide during an upcoming season would be relevant and the statute would permit us to issue an order [concerning disposition of existing stocks of cancelled product]." *Id.* Finally, the circumstances-based decision rubric of the Agency's existing stocks policy (Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29362 (June 26, 1991)) stands as evidence of the continuing validity of the 1972 assertion that "[i]t would be our policy to invoke this flexibility [regarding disposition of existing

stocks] on a showing by affected groups that the particular chemical were needed for the growing season." S. Rep. at 14.[1]

CropLife's second contention is that it would be "ironic" for Congress to have established a broader scope for cancellation hearings pursuant to FIFRA section 6(e) and suspension hearings pursuant to FIFRA section 3(c)(2)(B) than it did for section 6(b) cancellation hearings. Respondent finds that Congressional choice eminently reasonable. Unlike the d-CON rodenticides at issue in this proceeding, products cancelled pursuant to FIFRA section 6(e) or suspended pursuant to FIFRA section 3(c)(2)(B) are generally not expected to pose unreasonable risks to health or the environment.[2] A section 6(e) cancellation or section

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[1] For example, regarding cancellations where the Agency has identified particular risk concerns, the Existing Stocks Policy calls for consideration of: (a) the quantity of existing stocks at each level of the market, (b) the risks resulting from the use of such stocks, (c) the benefits resulting from the use of such stocks, (d) the dollar amount users and others have already spent on existing stocks (which would be lost if distribution, sale, or use were not permitted), (e) the risks and costs of disposal or alternative disposition of the pesticide, and (f) the practicality of implementing restrictions on distribution, sale, or use of existing stocks. 56 Fed. Reg. at 29364.

[2] Section 6(e) applies only to conditional registrations (often referred to as "me-too" or "follow-on" registrations) issued pursuant to section 3(c)(7), where a person is granted a registration for a product "substantially similar" to another product already on the market, conditioned upon the new registrant satisfying certain data requirements in the future. If that new registrant subsequently fails to satisfy those outstanding data requirements, the conditional registration is subject to cancellation under Section 6(e), where "[t]he only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or 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 this Act." Thus a section 6(e) cancellation is about the *registrant's* failure to meet its obligations, and not about a problem with *the pesticide product itself.* A pesticide cancelled pursuant to section 6(e) is not being cancelled on account of risks, and, despite cancellation, remains "a pesticide and proposed use [that] are identical or substantially similar to [a] currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment..." Section 3(c)(7)(A).

Similarly, suspensions pursuant to section 3(c)(2)(B) are on account to the *registrant's* failure to comply with new data requirements imposed after registration, rather than any known problem with *the pesticide product itself.* Section 3(c)(2)(B)(iv) likewise provides that "[t]he only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act." Thus Congress expressly provided that the disposition of existing stocks would be within the scopes of the two adverse registration actions that are not directly related to the risks associated with the product itself.

In contrast, the provisions governing risk-based cancellations and suspensions (sections 6(b) and 6(c)) say nothing about disposition of existing stocks. The Agency's authority over existing stocks of products cancelled or suspended pursuant to sections 6(b) and 6(c) comes instead from section 6(a)(1): "The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 3 or 4, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this Act."

3(c)(2)(B) suspension does not result in an adjudicated determination that a product poses unreasonable risks to health or the environment. Instead, section 6(e) cancellations and section 3(c)(2)(B) suspensions result from a registrant's failure to generate data or acquire rights to use the data of others, for products that in most cases are very much like other products that will remain registered. In contrast, products 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. Inasmuch as a pesticide product cancelled pursuant to section 6(e) or suspended pursuant to section 3(c)(2)(B) would not be presumed to pose any unreasonable risk, it seems reasonable that Congress would provide different treatment for existing stocks of such products and for existing stocks of products cancelled owing to unreasonable risks pursuant to section 6(b).

In summation, CropLife's substantive contentions are mistaken and provide no support for Reckitt's Motion. Respondent has shown that the plain language of the legislative history CropLife cites does not support its contention that Congress intended that the question of existing stocks should be at issue in cancellation proceedings. The cited text is instead fully harmonious with Respondent's position that FIFRA does not create any right to hearing on the disposition of existing stocks of product cancelled pursuant to section 6(b). Respondent has shown that Congress's express inclusion of existing stocks in the scope of section 6(e) cancellation proceedings and section 3(c)(2)(B) suspension proceedings does not imply that that existing stocks must therefore be within the scope of section 6(b) cancellation proceedings. The fundamental difference between the risks associated with products cancelled on account of unreasonable risk (section 6(b) cancellations) and products cancelled or suspended on account of registrants failing to meet data requirements (section 6(e) cancellations and section 3(c)(2)(B)

suspensions) fully warrants a statutory scheme where (1) existing stocks of products cancelled owing to unreasonable risk will not be allowed to be distributed or sold, except pursuant to the Administrator's discretionary authority pursuant to section 6(b)(1), and (2) the disposition of existing stocks of products cancelled or suspended for procedural reasons unrelated to risk will be determined by an Administrative Law Judge, or the Environmental Appeals Board on appeal. Accordingly, CropLife's substantive contentions should be disregarded and Reckitt's Motion should be denied.

II. In The Alternative, Respondent Opposes CropLife's Motion For Leave To File An Amicus Brief

Respondent consented to the filing of CropLife's amicus brief conditioned upon Respondent being allowed the opportunity to reply, however, such an agreement does not bind the Administrative Law Judge. The procedural rules governing this proceeding, 40 C.F.R. part 164, do not expressly provide parties a right to respond to briefs of adverse amici, however, § 164.31 does require that "an amicus curiae shall file its brief within the time allowed the party whose position the brief will support." It is reasonable to presume that part of the rationale for that provision was to allow a party to respond to both opposing briefs simultaneously, and to infer from it a general right to respond to amicus briefs. Although it is not directly applicable to this proceeding, the fairness of allowing parties to respond to amicus briefs is acknowledged in 40 C.F.R. § 22.11(b): "Any party to the proceeding may file a response to a non-party brief within 15 days after service of the non-party brief." It would not be fair if an amicus were allowed to make arguments on behalf of one party, and the opposing party were not permitted the opportunity to respond, as this would give amicii a power beyond those enjoyed by full

parties to the proceeding.[3] Accordingly, in the event that the Administrative Law Judge determines that part 164 does not allow the response presented above, Respondent opposes CropLife's motion for leave to file an amicus brief.

Respectfully submitted,

5/6/2013
Date

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[3] Respondent's position here differs from its position in *Respondent's Response To Motion For Leave To File A Reply Concerning Reckitt's Motion For An Expedited Determination That EPA's Existing Stocks Decision Is Within The Scope Of The Hearing* in two major respects. First, Respondent here seeks to establish the rights of full parties to respond to amicus briefs. Second, Respondent opposed Reckitt's request for leave to file a reply because Reckitt was a moving party that simply failed to write the brief it wished it had written the first time, whereas here, Respondent was not the movant and has not had a first opportunity to address Amicus' arguments.

CERTIFICATE OF SERVICE

I hereby certify that the original and one copy of *Respondent's Conditional Opposition To Croplife America's Motion To File An Amicus Curiae Brief Regarding Existing Stocks Of Cancelled Products* were filed with the Headquarters Hearing Clerk, and a copy hand delivered to the office of:

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