Attachment D

Consultations Summary for the Renewal ICR, entitled "Labeling Requirements for Certain Minimum Risk Pesticides under FIFRA Section 25(b) Information Collection Request"

OMB No. 2070-0187; EPA No. 2475.04; Docket No. EPA-HQ-OPP-2021-0346

Representatives contacted from the following companies:

- W. Neudorff GmbH KG - Authorized Agent
- Bonide Products, Inc. - Audra Star
- Central Pet & Garden - Cathy Elmi
- Rockwell Labs - Cisse Spragins
- S.C. Johnson - Jodie Thrune
- Spectrum Brands - Dana Thomas
- W.S. Badger Company - Jamie White

Questionnaire and Responses:

(1) Frequency of Collection

Products entering the market that are fully compliant with the minimum risk exemption at 40 CFR 152.25(f), including the labeling requirements, are exempt from federal registration requirements. The Agency does not collect information on products that meet all of the minimum risk exemption requirements. However, this collection contains third-party disclosures in the form of product labeling, which is mandated under regulation. Therefore, the frequency of the collection (i.e., labeling requirements) cannot be reduced while maintaining an exemption status.

- EPA assumes this is a one-time burden for labeling new products entering the minimum risk pesticide market. Do you believe that EPA's assumption is correct? If not, please provide an explanation.

Rockwell Labs: Generally, labeling a new product is a one-time burden. However, any amendment which would be initiated by the registrants or mandated by one or more States would add additional burden. States are increasingly requiring label changes.

(2) Clarity of Instructions

This ICR is intended to account specifically for the labeling burdens associated with complying with the minimum risk exemption requirements. In particular, the exemption requires respondents to provide certain information on the label so that the Agency, other regulatory agencies (i.e., the States), and consumers can utilize them.

Based on the instructions (regulations, PR Notices, guidances, websites, etc.), is it clear what you are

required to do and how to label products in order to comply with the federal exemption requirements? If not, what suggestions do you have to clarify the instructions to help reduce labeling burdens associated with minimum risk exemption compliance?

- Considering that there is no required labeling format, is it difficult to label products in ways that are clear, logical, and easy to complete?
  Would examples of labels or labeling formats be useful in helping you comply with the labeling requirements of the exemption?

Rockwell Labs: We think EPA's published requirements on what information must be included on a minimum risk product label are clear, and it is not difficult to label products in a manner that is clear and logical. There are many examples of mass-marketed pesticide labels readily available on the market to examine for formatting ideas and guidance, if needed.
With respect to claims that cannot be made on the label, the requirements are generally clear. However, the term "misleading", as with EPA registered pesticides, is too subjective, and in many instances is used by regulators, in the minimum risk case by State regulators, to disallow any claim they personally don't like, even if it is a true statement. Certain States are increasingly targeting and scrutinizing minimum risk product labels, and disallowing claims they had previously accepted, which is adding to the burden of time required to label minimum risk products.

(3) Burden and Costs

Since EPA does not register minimum risk products, the Agency has assumed that the paperwork burdens for labeling new products in this renewal ICR will be similar to those approved in the currently approved ICR.

- Are there other labeling paperwork activities that the Agency has not taken into account for new minimum risk products? If so, what other activities should EPA consider in renewing this ICR?

Rockwell Labs: The principle change that has occurred since 2015 is that certain States are increasingly scrutinizing minimum risk labels and requiring changes to currently registered (in their State) labels, and making it difficult to register new products either by requiring revisions to labeling that would have previously been considered acceptable, additional data, or by simply refusing to evaluate registration applications at all.

- Are the labor wage rates accurate? If you disagree, please provide information to support an alternative estimate.

Rockwell Labs: The average rates appear to be pretty accurate based on our experience.

- The Agency assumes there is no capital cost associated with this activity. Is that correct? If not, please provide an explanation of the capital costs the Agency has missed in this ICR.

Rockwell Labs: There are capital costs associated with the physical production of product labels,

namely cutting dies and printing plates, which can range from a few hundred to a few thousand dollars per label, depending on the physical nature of the label. These are generally one-time costs, unless an amendment is required. For example, a label copy change would require new printing plates. There are no capital costs incurred for producing the copy and artwork for a label, other than computers and software generally used by a business for other purposes as well.

- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the labeling activities described in this ICR (e.g., the ICR does not include estimated burden hours and costs for conducting studies since this information is not required to be submitted to EPA), are the estimated burden hours and costs per response accurate? If you provide burden and cost estimates that are substantially different from EPA's estimates, please provide an explanation of how you arrived at your estimates.

Rockwell Labs: There are many more companies than those listed above marketing minimum risk products. The total number of products is probably difficult to estimate, because many of them likely forego State registrations. The estimate of burden per product appears reasonably accurate, again, unless there are additional requirements mandated by States, which can add considerably to the time required.

- Are there other costs that should be accounted for that may have been missed?

Rockwell Labs: None other than already noted.