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October 22, 2012

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Subject: **Docket ID Number EPA-HQ-OPP-2012-0442**
Comments in Response to *FIFRA Pesticide Registration Review and ESA Consultation Processes; Proposal Regarding Stakeholder Input; Request for Comment*

The following comments are being submitted in response to the August 17, 2012 *Federal Register* notice regarding EPA's request for public comment on a proposal to enhance opportunities for stakeholders to provide input during its review of pesticide registrations and associated consultations under Section 7 of the Endangered Species Act (ESA). These comments are being submitted on behalf of the Western Integrated Pest Management Center and provide input on the process of providing pesticide use information for Hawai'i.

We are in agreement with the spirit of the joint proposal, that, "Because stakeholders, including state governments, universities and growers/users, have significant of relevant information and are the ultimate implementers of pesticide labels in the field, it is critical that they have a seat at the table during the development of any needed risk reduction measures to ensure that such measures are technologically and economically feasible." And we share the goal "to improve the respective agencies' understanding through greater engagement of affected stakeholders, of how pesticides are used, the ways in which they may affect listed species, and how any risks can be effectively mitigated, while preserving the beneficial uses of the pesticides to the extent possible." However, the proposal does not provide a sufficiently detailed schematic to determine if that goal is likely to be achieved.

Because Hawai'i is home to a large number and variety of endangered and threatened species and because many of our farms are very small[1], the implementation of risk mitigation measures has great potential to impact individual growers or even the production of entire commodities in Hawai'i

During the reregistration process, Hawai'i's conduit for information has been the Western Integrated Pest Management (IPM) Center with support and input from USDA's Office of Pest Management Policy (OPMP). This relationship exists because, among their current activities,

> ". . . OPMP is actively working with EPA on pesticide registration review issues resulting from implementation of the 1996 Food Quality Protection Act (FQPA); . . . . Within these current activities, (OPMP) will: . . .
>
> - "Provide the EPA and other regulatory agencies with the most accurate data available to help assure that pesticide regulatory decisions are based on modern, realistic agricultural practices . . .
>   - "Coordinate with the Regional IPM Centers in collection and interpretation of local level IPM practice information." [2]

These comments assume that this relationship will remain an important vehicle through which Hawai'i's growers and other pest management stakeholders can participate in the registration review process.

[1] The 2007 Census of Agriculture reported that 90.2% of Hawai'i's farms were less than 50 acres in size. 64% were 1-9 acres in size and, within this group, the average farm size was 4 acres.
[2] USDA, Agriculture Research Service. 2010. Office of Pest Management Policy Home Page. http://www.ars.usda.gov/Research/docs.htm?docid=12430.

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EPA proposes several changes to the registration review process.

Earlier involvement of stakeholders in the Registration Review Process

1. EPA proposes to increase the value of the 4-year outlook schedule by including information on the specific timeframe within any fiscal year when the pesticide will begin its review.

   This new information is of limited utility. For the enhanced timeframe to be more valuable, it would be helpful if EPA provided guidance about specific information likely to be needed at the beginning of the review for each pesticide. For example:

   - Are there questions that EPA asks for each registration review? If so, data providers can attempt to gather needed data and prepare the answers in advance.
   - Can EPA direct questions to the desired source of the data? (For example, a very common request in a Preliminary Work Plan is for "Confirmation of the following label information: sites of application; formulations application methods and equipment," etc. The best—i.e., most accurate—source of this information would seem to be registrants, sub-registrants or distributors. Another example, "median and 90th percentile reported use rates," would have to be provided by someone who has reports of use rates for each requested level—"national, state, and county".)

2. "EPA could begin to hold 'Focus' meetings during the early stage of registration review." These meetings would be "similar to the 'SMART' meetings that were held during reregistration. . . "

   While it seems that the targeted participants of the SMART meetings have been registrants, other stakeholders could benefit from these meetings because, early in the registration review process, stakeholders:

   - (Purpose #1). Would learn for which uses the registrants intend to continue to seek registration. This would be very helpful because risk mitigation measures cannot be viewed in isolation. A particular mitigation measure may result in the need for another pesticide or pest control tactic. (Consider the very possible scenario where a mitigation measure would reduce the maximum number of applications of 'pesticide A' per year. As a result, 'pesticide B' might be considered as an alternative or a supplement for 'pesticide A'. However, if the registrant indicates they do not intend to support 'pesticide B' for that particular use, the discussion about mitigation measures for 'pesticide A' might change--to allow, perhaps, a lower single application rate instead of fewer applications, or to consider other options for resistance management for 'pesticide A.')
   - (Purpose #2). Growers (and even local regulators), can, and do, encounter sources of confusion on pesticide labels. For example, Hawai'i grows many crops which are planted, grown, and harvested throughout the year. Under such circumstances, it is unclear exactly how to interpret label directions which indicate a maximum number applications or amount to be applied during a "growing season" or "crop cycle".

3. "It would be EPA's goal to have any early risk reduction incorporated onto product labels before the pesticide reaches the preliminary risk assessment stage."

   This item sounds like EPA wants to amend labels BEFORE notification and seeking comments. As such, this action would seem to run counter to the stated objective to get "earlier involvement" of stakeholders.

Consideration of pesticide use and usage data

1. "During the intervening 2-3 years after completion of the final workplan, . . . if needed, EPA would also solicit updated use and usage information from a variety of reliable sources, including USDA and grower organizations. . . . These data, such as application methods, application rates, frequency of application and application timing. are critical pieces of information in developing the ecological risk assessment and effects determination. . . .
   "EPA would incorporate these data as 'best available data' in developing its ecological risk assessment and biological evaluation. These data, which may be national and/or local in scope can also serve to help

further refine the label, the uses that will be supported for registration review, and adoption of any additional needed risk reduction, with the possibility of reducing or eliminating the number of "may effect" determinations under the ESA. These data can also be used to describe the situations in which rates higher than "typical" rates are needed and under what conditions, allowing more prescriptive label language to be developed."

Presumably, the "USDA" referred to above includes OPMP and, by extension, involves the Regional IPM Centers. Again, from OPMP Policy Home Page, OPMP will:

- Review and respond to proposed risk mitigation strategies developed by EPA as part of the pesticide registration review process
  - Meet regularly with the Pesticide Re-Evaluation Division (PRD) and Registration Division (RD) of EPA to gain insight into issues of interest and concern to agriculture related to pesticide registration
  - Provide input to EPA regarding pesticide use and usage information early in the registration review process

Thus, OPMP serves as the conduit, bringing "insight into issues of interest and concern to agriculture related to pesticide registration" from EPA, Coordinat(ing) with the Regional IPM Centers in collection and interpretation of local level IPM practice information" and, then, "Provid(ing) input to EPA regarding pesticide use and usage information early in the registration review process." By doing so, OPMP will "Provide the EPA and other regulatory agencies with the most accurate data available to help assure that pesticide regulatory decisions are based on modern, realistic agricultural practices."

The question arises: how are OPMP and, therefore, the IPM Centers, supposed to collect "critical pieces of information" "such as application methods, application rates, frequency of application and application timing"? Very few states routinely collect this information. The National Agricultural Statistics Service (NASS) does not collect chemical use data for all states (it does not for Hawai'i), nor for all crops. Likewise, the Pesticide Data Program (PDP) of USDA's Agricultural Marketing Service (ARS) collects pesticide residue data, but not in all states (Hawai'i is among the excluded states) and not for all crops. Therefore, for Hawai'i (and for other states as well), it is not correct that "these data can be used to help refine the biological evaluation and, perhaps, the pesticide label" because they do not provide "use patterns on a more local or regional basis." Therefore, these data would not be applicable to "develop additional risk reduction (as necessary) to further reduce concerns for listed species."

For states which do not have such data collections systems in place, implementing them is expensive and may require legislative action. Correct implementation of such a system is difficult to accomplish and involves considerations such as safeguards for grower confidentiality and definitions of reportable pesticide applications.

Even informal mechanisms to collect these "critical pieces of information" can be expensive (probably prohibitively so) to develop and maintain, especially if they strive to be comprehensive. In an informal type of data gathering mechanism, grower participation would be voluntary; more likely the information would be obtained indirectly from sources like knowledgeable Extension Agents. (Grower groups or commodity associations may be able to provide some information. In states like Hawai'i or for small acreage crops, grower groups either do not exist at all or they do not have the resources needed to collect these data.)

If these data are not available, what would EPA use as the "best available data"? Maximum application rates? Would risk mitigation measures for "under-represented" commodities (or growing regions) be the same as those for large commodities? This would not "allow more prescriptive label language" to be developed and ignores the fact that endangered species issues are often local.

2. ". . . EPA proposes to make two significant changes to its registration review process: 1) hold "Focus" meetings at the start of the registration review for each active ingredient and . . . The purpose of the 'Focus' meetings will be. . . :
    a. "to clarify existing label directions."

"As mentioned above, obtaining clarification of existing labels would be very helpful. How will EPA determine what needs clarification? Will there be a request for questions for each pesticide? To whom would such a request be directed?

b. "To provide clarification of pesticide usage for the active ingredient"

Does this mean that EPA will be requesting clarification of usage in the "field"? How does EPA (or OPMP) propose to collect this information for areas and commodities not covered by NASS, or in states which do not have data collection systems or large commodity groups?

3. "One major end result of these process changes is that through public involvement, particularly with growers who are responsible for 'on the ground' implementation of labels, risk reduction measures that. . . . are technologically and economically feasible can be achieved, possibly through changes to labels. The involvement of growers will insure that the protection measures are workable."

How does EPA propose that those "on the ground" be brought into the process?

Again, small growers or growers of very minor commodities are unlikely to participate directly. Their likely representatives, Extension agents, are, in many instances already over-burdened and over-stretched and unable to provide input and follow-up for each and every pesticide. Private consultants, where they exist, would need compensation.

4. "If the Services believe that changes to the pesticide label may be necessary to avoid or reduce the extent of adverse effects to listed species or critical habitat, they would work with EPA, the applicant, and with the consent of the applicant and EPA, product users, to discuss possible label changes needed to avoid jeopardizing the continued existence of any listed species or adversely modifying critical habitat."

Again, this is another instance where, or given current resource constraints, it would be difficult for small producers or producers of minor crops, or (more likely) their representatives such as Extension Agents or crop consultants, to participate.

5. "During this (draft Biological Opinion) public comment period, EPA and the Services would specifically reach out to growers to engage in what technologically and economically feasible approaches could be implemented that minimize the impact on growers and allow them to meet their pest control needs while achieving the necessary protection goals to avoid jeopardy to threatened and/or endangered species. In particular, this process should offer affected stakeholders an opportunity to provide real world data to identify practical considerations that affect the viability of different options for mitigating risks to species. EPA will provide a key role by focusing affected entities on the availability of the draft document and timeframes for submission of input."

For practical purposes, the draft Biological Opinion stage appears to be the first realistic (not "another") "opportunity for the public to provide invaluable input on the RPAs (Reasonable and Prudent Alternatives) as well as to provide/suggest/propose alternate risk reduction measures that accomplish the same protection goals that are easier/less costly for the grower/user community to implement."

Presumably, this means EPA will contact OPMP, who will then contact the Regional IPM Centers with relevant inquiries. It is important to keep in mind that state representation to the Centers (or, for that matter, the Centers themselves) is not funded in ways to ensure continuity or rapid responses, especially if one state has several commodities or pesticides "in play" either simultaneously or within close or overlapping timeframes. Recall that OPMP "will provide EPA . . . with the most accurate data available to help assure that pesticide regulatory decisions are based on modern, realistic agricultural practices . . . (by) Coordinate(ing) with the Regional IPM Centers in collection and interpretation of local level IPM practice information." OPMP will need to determine how it will coordinate and obtain feedback during the comment period for the draft Biological Opinion.

Increased use of the informal consultation process

Recent developments in Hawai'i have raised concerns about the practical implications of endangered species listings and critical habitat determinations. On September 10, a comment period closed regarding the proposed rule which would list 38 endangered and threatened species on the islands of Moloka'i, Lāna'i and Maui and the designatie critical habitat on Moloka'i, Lāna'i, Maui and Kaho'olawe (Docket ID FWS-R1-ES-2011-0098). A public hearing is scheduled for later this year. However, stakeholders, have expressed concerns that FWS has not performed sufficient outreach to inform land owners or lease holders that their land is being proposed as new critical habitat. Privately owned, active farms and ranches are included in the critical habitat designations. While FWS contacted large land owners, holders of small parcels were not so informed; some, no doubt, remain unaware of the potential change and the implications for their homes or businesses.

It seems quite possible that there is a nexus between these designations and the registration review process. If so, the association of endangered species issues for specific chemicals would be identified at this stage because the proposed informal consultation process "would allow EPA to verify any draft conclusions regarding the potential risk to listed species and their habitats and. . . .to begin discussing potential risk reduction measures with the pesticide registrant," The proposal does not specify how—or if—EPA (or OPMP) would reach out to stakeholders whose operations are in areas designated as critical habitat.

In general

- Registration review issues can be important and have unique effects on Hawai'i's grower community because of our wide variety of crops, year-round growing season (for both crops and pests), predominance of very small farms, and vulnerability to pest introductions.
- Hawai'i is the endangered species capital of the country (and, maybe, the world) and so, it is likely that pesticide label changes will be required to protect endangered and threatened species.
- There may be a conflict between the goals of protecting endangered and threatened species and increasing food self-sufficiency for Hawai'i.
- Hawai'i's islands are small and many of our farms are very small. Some mitigation measures—like large buffer zones—may mean the pesticide cannot be used at all on our farms, or on so few farms that vendors may not stock the product locally.
- The National Agricultural Pesticide Impact Assessment Program (NAPIAP) was formed to implement a 1975 amendment to FIFRA which required EPA to notify the Secretary of Agriculture in advance of regulatory decisions affecting pesticides and to consider the impact of pesticide cancellations on the production and costs of agricultural commodities[3]. NAPIAP no longer exists. However, its funds were used to implement and support the regional Pest Management Centers (the predecessors of the Regional IPM Centers) "as a means of strengthening its connection with production agriculture, research and extension programs, and agricultural stakeholders throughout the United States. . . .Pest Management Centers also will bring together and help focus the institutional and individual expertise needed to successfully address a range of pest management issues confronting farmers and other pest manager (e.g., regulatory restrictions. . .)"[4] . The Regional IPM Centers continue to include NAPIAP responsibilites—in combination with the charge of promoting adoption and implementation of IPM. Therefore, the imperative of NAPIAP is not a major component of the IPM Centers, however there is no other project which has assumed this function and, as this proposal indicates, the information is still needed.
- USDA . . . "created the Office of Pest Management Policy (OPMP) to coordinate how the Department meets the needs of both EPA and agricultural producers, as well as other constituents, throughout the regulatory process."[5] OPMP has never enjoyed NAPIAP resources to provide data at the state level. However, in order to follow the recommendations of this document, which "calls for a greater role for USDA" OPMP would now

[3] Toth, S. J. 1996. The National Agricultural Pesticide Impact Assessment Program. North Carolina Cooperative Extension Service, North Carolina State University. http://ipm.ncsu.edu/safety/notes/pfact4.htm.

[4] USDA. 2000. Integrated research, education, and extension competitive grants program—pest management: request for proposals and request for input. Federal register Vol. 65, No. 68, pp18822-1835,

[5] Rominger, R. 1999. Pesticide Regulatory Actions under the FQPA. EPA/USDA press briefing. http://www.usda.gov/news/releases/1999/08/0314. USDA.

need to consider how to "provide the EPA . . . with the most accurate data available to help assure that pesticide regulatory decisions are based on modern, realistic agricultural practices."

Thank you for the opportunity to comment on the registration review process.

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