MCFA

Minor Crop Farmer Alliance

MCFA Work Plan 2023

Background: MCFA has consistently supported the establishment and maintenance of an effective and credible, rationally-based pesticide regulatory program. Such regulatory program must meet certain minimum standards, namely that it is transparent, predictable, based on sound science, and provides a meaningful opportunity for interested stakeholders to participate in important regulatory decisions before they are finalized. We believe that regulatory actions that reflect these minimum standards are much more robust than those that fail to meet these standards. The following areas are intended to be the focus of the MCFA during the year.

I. Implementation of Endangered Species Act (ESA)

For many years, a tension has existed between the Environmental Protection Agency (EPA) and the US Fish and Wildlife Service and the Department of Commerce National Marine Fisheries Service (both collectively referred to as the "Services") in the implementation of the ESA. This tension was based on a variety of factors including lack of resources by the Services to conduct appropriate reviews of pesticide products and the differences in regulatory approach between EPA and the Services. In reviewing the potential ecological impacts of pesticide products, EPA typically considers what is likely to occur as well as the potential economic impact on the user community arising from potential restrictions. The Services adopt a more absolutist, highly conservative approach. Briefly stated, under the ESA, the Services operate on the principle that restrictions on the use of a pesticide are necessary in any circumstance where there may be a theoretical adverse impact to an endangered or threatened species. This approach is reflected in the Services reliance on modeling information in formulating Biological Opinions (BiOps) regarding the potential for pesticides to affect Endangered and Threatened species. Such an approach can significantly overestimate the risk to species. Actual pesticide use information is not generally incorporated into the Services BiOps.

Additionally, litigation involving implementation of the ESA provisions has been increasing such that courts have been more actively engaged in the development of the regulatory program. This litigation generally has focused on process issues, most notably the failure of EPA to consult with the Services as registration related decisions are made. The settlement agreements have not focused on biologically relevant aspects of the resulting actions, i.e., exposure, that would provide meaningful protection for the species involved. This litigation also presents a potential for courts to vacate a challenged registration.

As a result, the Services and EPA are pressured to truncate their ESA assessments to meet court-imposed deadlines. This has resulted in limiting the ability of stakeholders including the agricultural community to fully participate in the ESA evaluation process.

MCFA is working with EPA and the Services to put on an eco-risk Workshop with Stakeholders. The multi-day Workshop is intended to review and analyze regulatory processes and potential responses to pesticide use and potential impacts to listed species.

In addition to the Workshop, MCFA will continue to be involved in the ongoing evaluation of various proposed mitigation measures to reduce the potential for adverse impacts on listed species and their habitats and the potential extension of the Agency's policy regarding ESA assessments for the registration of new active ingredients for conventional pesticides to other registration actions. This includes advocating for increased grower participation in pesticide label mitigation decisions. Further, consideration should be given to the identification of potential new approaches, such as establishing refuges for endangered and threatened species as alternative ways in which the maintenance of endangered and threatened species can be enhanced. Efforts would continue to encourage EPA and the Services to incorporate the use of probabilistic risk assessment as well as using pesticide usage data (e.g., information regarding typical application rates, number of applications, geographic area treated and timing of treatment) in pesticide biological evaluations and BiOps. The Services would also be encouraged to refine their maps regarding listed species habitats to a sub-county level to help assure that any resulting additional pesticide restrictions are not required beyond the area necessary.

II. The role of epidemiological studies/reports in human health pesticide risk assessments

The Agency is charged with assessing the risk that may be present from the potential use of a pesticide. That involves consideration of the hazard of the product and the potential exposure to it. Historically, the Agency relied heavily on the results from animal toxicity studies to guide those assessments. The toxicity testing requirements are specified in the pesticide regulations and typically reflect well controlled, Good Laboratory Practice (GLP) studies in which the test animals are exposed to compounds at multiple dose levels, generally many times greater than the levels that humans may be exposed to. The results of those controlled animal studies have served to provide the Agency with a strong scientific basis for determining the risks associated with potential exposure to a pesticide.

For the past several years, environmental NGOs have been advocating both before the Agency and in the courts that conclusions reflected in epidemiological studies/reports in which the authors may associate various adverse health effects with exposure to pesticide compounds should form the basis for evaluating pesticide impacts rather than the animal toxicity testing data. In a number of these instances, the underlying data on which the authors base their conclusions may not be available. In addition, basic information that establishes that the study population was actually exposed to a particular chemical or product may be lacking, let alone the levels at which such exposure may have occurred. There appears to be a need for additional consideration and guidance by the Agency regarding how epidemiological information should be incorporated into the pesticide risk assessment process. This includes how that information should be considered in the Agency's application of uncertainty factors as required by the FQPA. An unwarranted application can materially impact the standard that a pesticide must meet to establish or maintain a use.

MCFA will continue to work with EPA and USDA to address the rigor, role, and use of epidemiological information in the risk assessment process.

III. The use of actual water monitoring data in conducting drinking water assessments

As part of the tolerance and ecological risk assessment process, the Agency must assess the risks from potential pesticide residues in water including drinking water. Despite the availability of substantial water monitoring data developed by various federal, state, and water agencies for several chemicals, historically, the Agency has relied almost exclusively on modeling data to assess the potential risks to human health. The outputs from these models often substantially overstate the potential risk of exposure. That is understandable because they typically are based on a cascade of worst-case assumptions. At a minimum, the Agency should also assess the potential risk based on reasonable case assumptions as opposed to worst-case assumptions.

The Agency needs to conduct robust reliable pesticide water assessments. It needs to be fully transparent in how its models work, including identifying all assumptions that may influence the model's output. It needs to strive to continue to refine these models wherever possible, including developing probabilistic assessments as is done for evaluating dietary exposure from pesticide residues in food. It should do this in the context of an open notice and comment processes, objectively reviewing all substantive comments submitted, and where appropriate make the necessary changes in the model based on those comments. Finally, the output of the model should be compared with the results of actual water sampling programs. If the model output varies significantly from the water sampling results, a further detailed examination should be made to confirm the reliability of the model before regulatory decisions are made predicated on it.

IV. Evaluating the potential impacts on various pollinators from potential exposure to pesticides

In response to increased media attention on the yearly fluctuations in pollinator populations, particularly in commercial honeybees, registrants have had to change their pesticide labels, initiate expensive additional pesticide pollinator testing regimes as well as moving to have users develop Managed Pollinator Protection Plans. The Agency, in conjunction with USDA, should initiate a research program to better understand the potential impacts, if any, of various potential factors, including but not limited to pesticides, on pollinator colony health. Such information should be a critical pre-requisite to determining what, if any, additional restrictions are needed on the use of crop protection tools.

V. Support for harmonizing pesticide registration requirements including the establishment of maximum residue limits (MRLs)

Often, pesticides are first registered in the United States before they are registered in another country. Additionally, unless a particular pest is present in a foreign country, registering the pesticide in that foreign country may not make economic sense. Also, in several instances, the foreign registration requirements differ from U.S. registration requirements such that the studies may need substantial reformatting or additional supplemental or replacement studies to secure a registration. This situation may influence a company's decision regarding whether to pursue a registration and establish associated MRLs in countries outside the U.S.

Without an established MRL, U.S. growers who use the U.S.-registered product may face significant challenges trying to export their treated crop because of potential pesticide residues on or in their crop. In the absence of applicable MRLs in the importing country, the treated crop may be subject to adverse enforcement action in the receiving country (e.g., denial of entry, re-exported or destroyed).

The Administration should clearly re-affirm that part of EPA's and the USDA's Foreign Agricultural Service's (FAS) mission includes the need to support efforts to minimize adverse trade effects on U.S. food producers associated with the use of pesticides applied in accordance with EPA-approved labels. This includes EPA and FAS actively participating in the WTO and CODEX committees, among other organizations. Increased use of joint reviews between EPA and their foreign counterparts should also be examined. Support for maintaining the MRL data base should also be reaffirmed.

VI. Support the funding of IR-4 and Office of Pest Management Policy (OPMP) at the U.S. Department of Agriculture

The IR-4 program had demonstrated its importance to the agriculture community and the public. It conducts research aimed at supporting new pesticide uses and their associated tolerances, particularly focused on specialty crops. The work IR-4 performs greatly helps get minor pesticide uses established, as well as their associated tolerances. There have been numerous studies establishing the significant cost-benefit value provided by the IR-4 program. That program needs to be retained and expanded.

Further, the USDA Office of Pest Management Policy (OPMP) has been invaluable as a reviewer of EPA-proposed and final regulations, guidance, etc. associated with pesticide use in the United States. The size of the office (~ 10 professionals) pales in comparison to the several hundreds of individuals employed in the EPA's Office of Pesticide Programs. Yet OPMP has been involved in a substantive way in almost all the significant EPA pesticide regulatory actions that may affect the agricultural community. OPMP has been a vigorous advocate, pressing EPA to have substantial evidence when it wants to implement a regulation or guidance document. OPMP serves as an invaluable resource in addressing EPA actions before they are finalized. That role needs to be supported and expanded to meet the challenges of future workloads.

VII. The use of antimicrobial products in horticulture.

Various groups are examining the role of antimicrobial products, including antibiotics in horticulture. A Task Force on Antimicrobial Resistance Management (TFAMR) has been established by Codex to review this issue to determine whether among other things, there should be additional regulation of these products used in the horticulture area. Resistance involving use in animal production is established. However, use in the horticulture sector is significantly different from the use of these products in animal production. MCFA has been participating with US government representatives on the TFAMR to help assure that the use of these products in horticulture is not adversely impact by the Codex review.

VIII. Pesticide Use Surveys

The extent of pesticide use on a particular crop can influence the Agency's risk assessment. From time to time, USDA will conduct pesticide use surveys aimed at growers to get more refined information regarding actual use practices. MCFA believes these surveys are an excellent source of information regarding actual pesticide use, and they should be supported.

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