



MEMORANDUM

Via E-Mail

DATE: May 17, 2004

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: Tolerance Reassessment Advisory Committee

On May 14, 2004, the U.S. Environmental Protection Agency (EPA) announced revisions to the public participation process it uses for its pesticide tolerance reassessment and reregistration process. 69 Fed. Reg. 26819. The notice announces four significant changes and/or additions to the “pilot” public participation process EPA adopted for the reassessment and reregistration of organophosphate pesticides, developed in 1998 with the Tolerance Reassessment Advisory Committee (TRAC). First, EPA has decided to apply either the full, “updated” public participation process or one of the modified versions described in the notice to all pesticides undergoing tolerance reassessment and reregistration eligibility decision making. Second, EPA has created a modified and shorter public participation process consisting of four (as opposed to six) phases for pesticides with “highly refined risk assessments and other factors.” Third, EPA announced in the notice that it may decide to truncate the process and opt for the shorter four-phase version if “EPA finds that issues can be resolved without a second comment period.” This change presumably could be made for pesticides that originally were destined to go through the full six-phase public participation process. Fourth, EPA has developed a much abbreviated “low risk” public process in which the decision document offered for public comment contains the risk assessment and any regulatory determination.

The Pilot Public Participation Process

The public participation process that EPA has used since 1998 to reassess tolerances and reregister pesticides is known as the “TRAC process” because it was developed in consultation with the TRAC. Over the past six years, EPA reports in the notice that it has gained considerable experience and the revisions to the process in public participation reflect that experience. EPA’s notice makes clear that it remains “strongly committed to public participation” and believes that the TRAC process has served the public well. EPA’s confidence



Memorandum to Firm Clients and Friends
May 17, 2004
Page 2

in the process is evidenced by its decision to extend an updated version of the organophosphate pilot process to all pesticides still to be reviewed for reregistration and tolerance reassessment.

The “updated” and “full” TRAC process consists of a Pre-Phase 1 phase and six succeeding phases. During the Pre-Phase 1 stage (which ideally begins, according to EPA, one year before initiation of the public participation process), EPA, the United States Department of Agriculture (USDA), and other federal agencies work to organize a meeting or meetings with interested stakeholders who possess key information on a pesticide’s use and usage. This meeting is often referred to as the Smart meeting. Following the Smart meeting, EPA uses the information made available to it and prepares a draft risk assessment. The six phases of the full TRAC process are:

■ **Phase 1 -- Registrant “Error Only” Review (30 Days)**

EPA sends its preliminary human health and ecological risk assessments to technical pesticide registrant(s) for a 30-day review. They are asked to identify any computational or other errors that EPA may have made in developing its preliminary assessment of the pesticide’s risks, and asked about due dates for the submission of data that may change the assessments. After sending the assessments to registrants, EPA also sends the assessments to the USDA and other federal agencies.

■ **Phase 2 -- EPA Considers Registrants’ Error Comments (up to 30 Days)**

EPA summarizes and considers comments from registrants as well as those from USDA and other agencies. As appropriate, EPA incorporates comments or makes changes in the preliminary risk assessment to correct any errors identified. EPA also transmits an overview to USDA and other federal agencies that summarizes the risk assessments. By the end of this phase, EPA prepares the assessments for public release.

■ **Phase 3 -- Public Comment on Preliminary Risk Assessment (60 to 90 Days)**

EPA publishes a *Federal Register* notice announcing the availability of its preliminary risk assessment and opening a 60- to 90-day public review and comment period. Registrants, grower groups, other stakeholders, and the public are encouraged to submit data and other information to revise EPA’s preliminary risk assessment. EPA specifically will request information on any population segments with atypical, unusually high exposure to the pesticide, in order to identify environmental justice issues. EPA will initiate among federal government agencies an effort to engage stakeholders in a dialogue on the risk assessments and risk characterization. EPA will keep its state and



Memorandum to Firm Clients and Friends
May 17, 2004
Page 3

Tribal partners informed and will bring them into the dialogue as appropriate. During Phase 3, EPA (and USDA) also may begin to solicit input from stakeholders (and, for public health pesticides, the Centers for Disease Control and Prevention (CDC)) on the role and importance of the pesticide in pest management for particular crops and/or uses.

■ **Phase 4 -- EPA Revises Risk Assessments and Develops Preliminary Risk Reduction Options (up to 90 days + USDA Review and Public Meetings/Briefings)**

EPA summarizes and considers comments received during Phase 3 and develops a revised risk assessment and preliminary risk reduction options. EPA may truncate the process: “If as a result of comments received during Phase 3 EPA finds that issues can be resolved without a second comment period, the Agency may proceed directly to Phase 6 and develop a risk management decision, which the Agency will issue for public review and comment.” When potential risk reduction measures include changes that significantly affect a pesticide’s use, EPA may prepare and release an initial characterization of the benefits of the pesticide for particular uses. When agricultural uses are affected, EPA will consult with USDA and stakeholders as needed, regarding the potential benefits and risk reduction proposals, and may consult with CDC, other federal agencies, states, and Tribes. USDA may hold stakeholder teleconferences, and EPA may hold technical briefing and/or smaller stakeholder meeting(s) at the end of Phase 4 to share with the public the revised risk assessments and begin discussing the range of possible risk reduction options.

■ **Phase 5 -- Public Comment on Risk Reduction (60+ days)**

EPA publishes a *Federal Register* notice announcing the availability of the revised risk assessment and response to public comments, as well as EPA’s preliminary risk reduction options, “EPA’s initial assessment of the impacts of risk reduction options, and/or EPA’s preliminary assessment of benefits in cases where the Agency has identified risks of concern, and a discussion of any potential transition issues identified by USDA, CDC, and other agencies as appropriate.” The notice will open a 60-day or longer comment period, and the public is encouraged to propose risk management proposals. EPA will work closely with other appropriate federal agencies.

■ **Phase 6 -- EPA Develops Final Risk Management (up to 60 days)**

EPA considers all comments and risk management proposals received. EPA continues to solicit input from USDA, other agencies, and stakeholders. EPA develops the risk management documents, and a revised impacts assessment and/or benefits assessment, if



Memorandum to Firm Clients and Friends
May 17, 2004
Page 4

needed. EPA releases to the public the risk management decisions for the pesticide, including the revised impacts and/or benefits assessment. USDA may prepare a transition strategy, if needed, that could include time frames in which EPA expects to make decisions regarding registration of new pesticides/uses.

The Updated Public Processes

The notice announces EPA's decision to employ a modified public participation process. This process is shorter based on the expectation that there are fewer stakeholders and the pesticide being considered has a "highly refined risk assessment" among other factors. Phases 1 and 2 are the same as the full public participation process except that, in Phase 2, in addition to preparing the risk assessments for public comment, EPA also develops preliminary risk reduction options. EPA notes that meetings, conference calls, and other discussions with stakeholders on issues and risk reduction measures "will continue through Phases 3 and 4, as needed." In Phase 3 of the modified process, public participation is invited and public comment on the risk assessment and risk reduction options is solicited for 60 to 90 days. In Phase 4, EPA develops final risk assessments and risk management decisions, and considers comments for up to 90 days. EPA may decide to lengthen the process and include a second comment period if issues warranting further discussion are raised in Phase 3.

The Low Risk Process

The notice announces an entirely new process called the "low risk" process. According to EPA, if its initial screening of a pesticide "indicates that it has low use/usage, affects few if any stakeholders or members of the public, and/or poses low risk and requires little or no risk mitigation, the Agency may determine that neither the full 6-phase process nor the modified 4-phase process is needed." If EPA determines this, EPA would go straight to a regulatory determination and prepare a decision document concluding the review process. Public comment would be solicited on the decision document.

Implications/Issues

The notice is important and has many mixed implications for the pesticide industry. The notice plainly reflects EPA's deep commitment to the TRAC, and now "TRAC-lite" process, when assessing tolerances and reregistering pesticides. That EPA has extended the process to all pesticides beyond organophosphates is clear evidence of its commitment to its multi-phase public participation process.



Memorandum to Firm Clients and Friends
May 17, 2004
Page 5

With the menu of process options made available through this notice, there can be expected some jockeying to be placed in the “low risk” category for several obvious reasons. The name of the category itself is desirable, and it is unclear at this point if third party activists would ever agree any pesticide is deserving of this title, let alone a drastically abbreviated review process. Similarly, manufacturers of pesticides who believe their product satisfies EPA’s somewhat general criteria for qualifying as “low risk” but to whom EPA decides not to offer this process may be understandably concerned with the implications that flow from being subjected to a more protracted and necessarily “non-low risk” public process.

Likewise, the modified public participation process could be good news or not, depending upon the pesticide. If the registrants largely concur with the risk assessment EPA has prepared, a more streamlined public process could be desirable. Alternatively, if the risk assessment EPA prepares is believed to be flawed, a long process may be more desirable from the registrants’ perspective. While arguably it would seem to follow that a controverted tolerance reassessment or reregistration process would seem an unlikely candidate for the modified public participation process, it remains to be seen how EPA will apply this process, what category of pesticides will be deemed deserving of this process, and how participatory the process will be in selecting the process due a particular pesticide. Importantly, there is no discussion in the notice suggesting that anyone other than EPA decides what process is due.

A final point relates to the decision to convert from a full TRAC process to a modified four-phase process. The notice suggests that this decision could be made “mid-process” if events merit. The notice states that if “as a result of comments received during Phase 3 EPA finds that issues can be resolved without a second comment period, the Agency may proceed directly to Phase 6 and develop a risk management decision, which the Agency will issue for public review and comment.” Noticeably absent from this discussion is the notion that the registrants’ views will be solicited, or even considered, in this decision. This is not to say EPA will not do so. It is troubling, however, that the decision appears to be made unilaterally by EPA.

The notice suggests at a minimum that registrants will need to work with EPA to understand upfront what public participation process will be used for a pesticide reregistration and/or tolerance reassessment decision. Failure to agree on a process could result in a decision-making process that does not give full expression to the complexities of the reregistration and tolerance reassessment process. Care thus should be taken to ensure that the public participation process selected for a pesticide is very much a consensus decision between EPA and the registrants.

As always, we hope this is useful. Please call with questions.