



PPC

PESTICIDE POLICY COALITION

A Coalition Working for Sound Pest Management Policies

September 7, 2005

Mr. James J. Jones
Director, Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Federal Building
1200 Pennsylvania Ave. N.W.
Washington, D.C. 20460

Dear Mr. Jones:

The Pesticide Policy Coalition has just submitted comments on EPA's proposed revisions to 40 CFR Part 158, the comprehensive listing of data requirements for registration of pesticides. While we applaud the Agency for the progress on this most important regulation, we are concerned about the limitations that have been placed on dialog between EPA staff and stakeholders during the comments process. In a number of forums, discussion of the regulation has been pretty much limited to one-way disbursement of information from the Agency, and questions and comments from stakeholders have largely been deflected to "written comments." We have received this message at all stages of the comments process and from all levels within the Office of Pesticide Programs.

This regulation has a profound and far-reaching influence on the availability of pesticide products to American society for protection of crops, public health, property, and products in commerce. Its complexity raises numerous questions about meaning, interpretation, and nuance that cannot be answered satisfactorily, efficiently, or in a timely manner through formal exchange of written proposals from government and comments from stakeholders over months or years. A truly open dialog is needed to satisfy the need for understanding, and to fully inform stakeholders so they can comment meaningfully. Without a dialog, the resolution of significant regulatory issues is either avoided or prolonged unnecessarily for years. We need to talk to each other.

We understand and fully support the need for the Agency to be open with all stakeholders regarding the deliberations over the content of regulations. We are not asking for nor suggesting *ex parte* communications outside the comment period that might appear to give one or another group disproportionate influence over the content of the regulation. We also realize that stakeholders can pose some mind-boggling questions that resist “spur-of-the-moment” responses, but rather require thoughtful consideration by multiple Agency personnel. But, again, we need to talk to each other.

Below we have excerpted from the PPC comments several issues that we feel must have an open discussion in order to allow stakeholders to comment meaningfully on the content of the proposed regulation, and ultimately to strengthen the regulation. Other stakeholder groups and individuals may have identified additional important issues for dialog.

- While some of the triggering conditions (in footnotes to the data tables) that determine whether particular studies are required are quite specific and objective, others are very subjective. There is no obvious reason why there are such vast differences, particularly with regard to similar studies. It would seem that OPP should be able to describe more precisely the triggers it uses, at least for studies it has been requiring for many years. Has EPA attempted without success to make the triggers more precise, or has it simply not tried?
- At places in the proposed rule’s preamble and in the May 2005 presentation, OPP has indicated that the new data requirements will be applied primarily in the context of applications for new registrations. The extent to which newly required studies will be applied to already-registered products is of great importance in assessing the burden of new studies, as is information on how and when any new studies will be required.
- It would be useful to know why the requirements for various kinds of dermal and inhalation toxicity studies depend on the intended food or nonfood use of a product, when the studies relate primarily to occupational exposure and seemingly the requirements should depend on length and nature of exposure.
- From what we can tell, some new requirements are for studies for which protocols either do not exist or have not been the subject of validation. In preparing comments, it would be useful to know whether OPP is expecting applicants to perform these studies as part of a research project at industry’s expense to determine whether the studies have value, or whether OPP plans to provide protocols and conduct validations before the requirements are implemented.
- Better information on the extent to which newly required studies have already affected regulatory outcomes would be useful in commenting on whether it is worthwhile to require the test. An interim summary table regarding OPP’s experience with the developmental neurotoxicity test (edocket item OPP-2005-0190-0065), released in the context of OPP’s recent ruling on certain tolerance objections, indicates that only a small number of the total tests affected the regulatory outcome, but does not reveal what types of toxicity were responsible. A more complete description of the DNT results to date

would be extremely helpful to commenters. Similarly, we would be interested in the experience to date with immunotoxicity testing.

The dialog could take one or more of several possible forms:

- One or more public workshops conducted by EPA on the significant issues identified; and/or
- Dedication of significant blocks of time in meetings of appropriate federal advisory committees (e.g., the Pesticide Program Dialog Committee) to address issues in the proposed rule; and/or
- An expressed willingness of Agency personnel to accept invitations from stakeholder groups to openly discuss specific issues from the proposed rule, in venues such as
 - Association committee meetings;
 - Stakeholder-sponsored meetings or workshops;
 - Sessions of professional society meetings;
 And/or
- The Agency could consider the comments now received (say, over several months), then –
 - re-open the comment period on a number of specific issues, offering additional background and information, as necessary; and/or
 - revise the proposed regulation based on the initial comments received and repropose for an additional comment period;

We urge your intervention on behalf of stakeholders to institute such a dialog with Agency personnel on this most important regulation. Stakeholders must have an better opportunity to engage in dialog and direct discussion with Agency personnel on structuring the Part 158 rule.

Very Sincerely,



Rebeckah Freeman Adcock
Chairperson, Pesticide Policy Coalition

cc: EPA (Jon Scholl)
USDA (Chuck Connor)
USDA (Burlison Smith)
OMB (Paul Noe)
CEQ (James Connaughton)

**Comments of
PESTICIDE POLICY COALITION
on
PROPOSED RULE TO MODIFY 40 CFR PART 158,
DATA REQUIREMENTS FOR CONVENTIONAL CHEMICALS**

**EPA Docket # OPP-2004-0387,
70 Fed. Reg. 12276 (March 11, 2005)**

The Pesticide Policy Coalition (PPC) submits these comments on the proposal by the Office of Pesticide Programs (OPP) to modify the 40 CFR Part 158. The Part 158 regulations specify the data that EPA ordinarily requires be submitted in support of new or continued registration of pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and petitions for tolerances and exemptions under the Federal Food, Drug, and Cosmetic Act (FFDCA).

The PPC represents food, agriculture, pest management, and related organizations that support transparent, fair, and science-based regulation of pest management. PPC members include: nationwide and regional farm, commodity, specialty crop, and silviculture organizations; cooperatives; food processors and marketers; pesticide manufacturers; pest- and vector-control operators; research organizations; and other interested parties. PPC serves as a forum for the review, discussion, development and advocacy of pest management policies and issues important to our members.

The PPC and its members are vitally interested in Part 158. The cost and difficulty of the testing required by Part 158 are major factors in decisions by pesticide developers and manufacturers about whether particular new compounds should be brought to market and whether current compounds should be defended for some or all uses. Because of that, Part 158 has a major influence on the range of products that are available to growers and other users. PPC members want pesticide products to be well tested and to meet demonstrably the statutory standards under the FIFRA and the FFDCA. At the same time, our members oppose testing that is unnecessarily expensive or that is unlikely to contribute meaningfully to product evaluations.

Accordingly, we are pleased to see that OPP finally has published its proposed changes to Part 158. Applicants, registrants, and other interested members of the public should be able to determine without undue difficulty what kinds of data are required to register various kinds of pesticide products. It has been frustrating to know since 1988—when OPP began to work on this proposed rule—that Part 158 was outmoded and did not set forth the real data requirements that OPP was applying routinely.

It also is important to our members that EPA's regulations be clear, not only on what data OPP feels it needs, but also when data to satisfy new requirements must be submitted. Both FIFRA and FFDCA contain provisions about the timing of data submission for both

new and existing products, including FIFRA §§3(c)(2) and 3(c)(7) and FFDCA §408(f), and these provisions should be reflected in regulations dealing with data requirements.

The PPC believes that there a number of areas in the proposed modification of Part 158 that can and should be improved. In the comments that follow we have not attempted to address each aspect of the proposed changes in detail; for such detailed comments we urge OPP to pay careful attention to the comments that are being filed by PPC members including CropLife America, the American Chemistry Council–Biocides Panel, Consumer Specialty Products Association, Chemical Producers and Distributors Association, and Responsible Industry for a Sound Environment. Our focus instead is more on the overall design and workability of the regulations in the context of reviews of new and existing products. We have looked closely at Subparts A and B and at the new requirements in Subparts C, K, and U.

NEED FOR DIALOGUE WITH STAKEHOLDERS

In May 2005 OPP held a public meeting at which OPP employees gave presentations about the changes proposed for Part 158. At the meeting, although some questions from members of the public were addressed by the OPP panelists, attendees were repeatedly discouraged from making oral comments or engaging in in-depth discussions and were told to put all comments in writing. Thereafter, CropLife America and others wrote OPP to suggest that it would be profitable to hold one or more meetings at which ideas were exchanged, in order to encourage clarification in several areas. OPP responded by saying there was no need for further dialogue:

[Y]ou indicated a desire for more opportunities to interact with EPA to gain an understanding of the contents of the proposal. EPA has taken numerous steps to explain the contents of the proposal. The preamble itself is lengthy primarily to give full and clear explanations of the proposed changes. Particular attention was paid to writing in Plain English as a further means to promote understanding. Extensive documentation is available in the record to support the proposal. Most of the changes are codifying longstanding practices that registrants are extremely familiar with and understand.

Docket item OPP-2004-0387-0060

Many of the explanations of the proposed changes are very clear, but a number of them are not, as our comments and those of our member organizations will show. It is difficult to fashion useful comments when the proposed change or the reasons for it are not clear to us. This proposal has been in preparation for 17 years, and we do not understand why OPP is unwilling to take a bit of time to discuss publicly the areas where our members are having problems understanding OPP's intentions or reasoning. It leaves the impression that in these areas there are no answers available and that accordingly the questions are not wanted.

We think our comments could be more useful to the process if we knew more about several important issues, including these:

- While some of the triggering conditions (in footnotes to the data tables) that determine whether particular studies are required are quite specific and objective, others are very subjective. There is no obvious reason why there are such vast differences, particularly with regard to similar studies. It would seem that OPP should be able to describe more precisely the triggers it uses, at least for studies it has been requiring for many years. Has EPA attempted without success to make the triggers more precise, or has it simply not tried?
- At places in the proposed rule's preamble and in the May 2005 presentation, OPP has indicated that the new data requirements will be applied primarily in the context of applications for new registrations. The extent to which newly required studies will be applied to already-registered products is of great importance in assessing the burden of new studies, as is information on how and when any new studies will be required.
- It would be useful to know why the requirements for various kinds of dermal and inhalation toxicity studies depend on the intended food or nonfood use of a product, when the studies relate primarily to occupational exposure and seemingly the requirements should depend on length and nature of exposure.
- From what we can tell, some new requirements are for studies for which protocols either do not exist or have not been the subject of validation. In preparing comments, it would be useful to know whether OPP is expecting applicants to perform these studies as part of a research project at industry's expense to determine whether the studies have value, or whether OPP plans to provide protocols and conduct validations before the requirements are implemented.
- Better information on the extent to which newly required studies have already affected regulatory outcomes would be useful in commenting on whether it is worthwhile to require the test. An interim summary table regarding OPP's experience with the developmental neurotoxicity test (edocket item OPP-2005-0190-0065), released in the context of OPP's recent ruling on certain tolerance objections, indicates that only a small number of the total tests affected the regulatory outcome, but does not reveal what types of toxicity were responsible. A more complete description of the DNT results to date would be extremely helpful to commenters. Similarly, we would be interested in the experience to date with immunotoxicity testing.

SUBPARTS SHOULD BE PRESENTED IN A LOGICAL ORDER

We start with the request that the readability of the rule be improved. For one thing, instead of retaining the current random order of subparts after B, EPA should group related subparts in some logical manner. There is no reason to follow the numbering system of the

1982 Guidelines, which themselves were in random order and mostly have been replaced by the OPPTS Harmonized Guidelines. A logical structure might be something like this:

Conventional Pesticides

- *Chemistry topics* (product chemistry, residue chemistry, environmental fate),
- *Toxicity topics* (mammalian, nontarget terrestrial and aquatic, nontarget plants),
- *Exposure topics*(applicator, post-application, spray drift, pesticide management and disposal)

Other substances

- Microbial pesticides
- Biochemical pesticides
- Antimicrobial pesticides
- Inert ingredients

SUBPART A—GENERAL PROVISIONS

Unwarranted Removal of Useful Provisions in Current Regulations

Current Subpart A contains a number of provisions that explain how the data requirements interface with FIFRA registration provisions and OPP procedures and practices concerning such topics as conditional registration, reregistration, the formulator exemption, and minor uses. These have all been stripped out of the new proposed rule because OPP wishes to have Part 158 deal entirely and only with data requirements. We believe that some of the provisions should be returned in the final version or that at a minimum Subpart A should incorporate clear references to other OPP regulations where the topics are treated. Otherwise, someone who is unfamiliar with these areas may be misled about what data requirements actually apply and when data must be submitted.

Current §158.30 deals with the timing of the imposition of data requirements. OPP proposes to delete it, saying only that it is considered “unnecessary and not relevant,” 70 FR at 12283. This section should be retained, although it can be modified to shorten it if OPP deems that to be important. The two-sentence lead-in to the current section is as true today as when it was first included in Part 158, and is vital to understanding how the Part is applied in practice; it should be retained as is. Current §158.30(a) is only two sentences long, and discusses the timing of satisfying new data requirements that apply to existing registrations. The OPP regulations do not otherwise deal with this subject; the provision should be retained. Current §158.30(b) discusses the data needed to support applications for conditional registration of “me-too” products, products with new uses, and products with new active ingredients. While 40 CFR §§152.113 through 152.115 also discuss the topic of conditional registrations, they focus on the *findings* that must be made by OPP; §158.30(b) is helpful because it spells out the *kinds of data* needed for those findings. If OPP does not wish to retain §158.30(b) as is, the first two sentences of §158.30(b) should be retained, the cross-reference in the second sentence should be expanded to read “§§152.111 through 152.115”, and the remainder should be moved to and integrated into §§152.113 through 152.115, as appropriate.

Current 40 CFR §158.50 deals with the FIFRA §3(c)(2)(D) “formulator’s exemption.” The current language is out of date in one respect: since the 1988 FIFRA amendments, the exemption is no longer limited to data on *safety* of purchased products, and the regulations should be updated in that respect. OPP’s preamble states (70 FR at 12283) that §158.50 is to be relocated to §152.85. However, the proposed relocation does not appear in the actual proposed regulatory text, although other modifications to Part 152 do appear (70 FR at 12328). The provisions of §158.50 should be moved at the time the final rule is issued, and a short cross-reference to §152.85 should be added to Part 158.

Current 40 CFR §158.60(a) sets forth several statements of EPA policy regarding data requirements for minor uses of pesticides. These provisions are not based on statutory provisions and relate directly to the question of what data will be required and when data will be required. The proposal states (70 FR at 12283, Table 2) that these provisions are being “Deleted as unnecessary. Definitions and minor use policies are largely governed by statutory mandates and priorities, not regulatory policies.”

It is true that a definition of “minor use” and several provisions regarding data requirements for minor uses were added to FIFRA in 1988. However, most of those provisions, aside from FIFRA §3(c)(2)(E) regarding data waivers and some provisions regarding exclusive use status of data, concern only the conduct of the reregistration process that will end in 2008 and thus shortly will be obsolete. While PRIA has a significant effect on certain advantages that otherwise would be accorded to minor use applications, that portion of FIFRA (§33) has a sunset provision and might be outlived by minor use policies in part 158. We believe that a reference to FIFRA §3(c)(2)(E) and to the definition in FIFRA of “minor use” should be added to the new rule’s section on data waivers. We also believe that paragraphs (1) through (4) make sense, have ongoing utility, have not been replaced by statutory provisions, and should be retained in the new regulations. FIFRA §31, added in 1996, directs EPA to establish policies regarding minor uses. If EPA intends to abandon the policies set forth in current Part 158, a discussion of its rationale for doing so would be useful to stakeholders.

It is entirely appropriate to continue to include an updated minor use policy with respect to data requirements in Part 158, even if it largely repeats statements of law, in order to remind the regulated community of its rights, and the more than 800 employees of OPP (with varying levels of experience and expertise) of their obligations in handling applications for minor uses.

Grouping of Related Sections

We suggest that the more concise versions of §§158.30 and 158.50 that we have proposed should be relocated so that they appear directly after proposed §158.5, “Applicability,” in order to make clear to readers the relationship between what data are required, who need not submit certain data, and when data must be submitted.

We also think that the readability of Subpart A would be improved if other related provisions were grouped together or combined. In particular, proposed §158.30 (on flexibility), §158.45 (on data waivers), and §158.75 (on requirements for additional data) deal with closely related matters (how many studies are needed) but they are separated by unrelated material. The three sections easily could be combined and, by removing redundant material, made shorter. We see no particular advantage in attempting to preserve some of the section numbering from the current Part 158.

Format of Data Submissions

Proposed §158.32 is similar to the current provision having the same numbering. We do not object to the proposed revisions. We are troubled, however, by the fact that although both the current and proposed versions appear to be a detailed and comprehensive list of formatting requirements, compliance with the regulatory language is insufficient to ensure that data will not be rejected for formatting reasons. EPA staff follow PR Notice 86-5, which contains requirements in addition to those in §158.32. We strongly urge the Agency to integrate the formatting requirements from the two documents and either include them all in the regulations or include them only in a PR Notice which is cross-referenced in a much-shortened §158.32.

SUBPART B—HOW TO USE THE DATA TABLES

Insufficient guidance about decisionmaking on whether studies are required

We have already discussed the need to return to the final rule some of the language in Subpart A that deals with the question of *when* required studies must be submitted, i.e., in connection with what Agency proceeding. The purpose of Subpart B is to explain how registrants determine *whether* various studies are required, and according to Subpart B and the preamble's explanation of it, this is to be done, for each study, by looking at the use pattern of the product, the code designation (Required, Conditionally Required, or Not Required), and the footnote(s) that apply to each study.

What Subpart B does not address is *who* determines whether studies are required and the related question of *when* those determinations are made. The question of whether a conditional requirement applies can be answered by an applicant if the prerequisite information exists and the criteria for deciding are clearly stated. If the criteria are clear, and applying them to the information on hand indicates a need to perform and submit the study, an applicant knows that unless a data waiver is obtained, the study must be performed. For example, Footnote 6 in the §158.400 table specifies that the avian dietary toxicity study for aquatic nonfood residential outdoor uses must be performed if the LD₅₀ result from another required study is lower than a specified value.

In many other cases, however, the criteria furnished by OPP give an applicant very little to work with. Footnote 7 in that same table states that “[Wild animal] Tests are required based on the results of lower-tier toxicology studies, such as the acute and subacute testing,

intended use pattern, and environmental fate characteristics that indicate potential exposure.” A great many of the footnotes to several of the tables in various Subparts are equally unspecific. In such cases the rule should state that these decisions are not meant to be made by the applicant, but rather by OPP. Whenever possible the rule also should specify what information OPP will need to make the decisions. Finally, the rule should describe how a prospective applicant can obtain a decision by OPP in a manner that does not cause undue delay if the decision ultimately is to require the study. To avoid delay, OPP must be willing to either (a) conduct a pre-application review upon request and make the decision promptly, so that the applicant can conduct the study before the application is filed, or (b) grant the registration without the study and impose the data requirement as a post-registration condition.

Use patterns

In the preamble (70 FR at 12287), OPP says that it is creating 15 major use patterns to replace the current 9. One of them is aquatic nonfood outdoor use; another is residential outdoor use; another is residential indoor use. However, the proposed rule itself seems to use different major use patterns. For instance, in the table of requirements in Subpart E we find a use pattern called “Aquatic Nonfood Residential,” which does not seem to belong to any of the 15 patterns. It would be useful for the rule to actually follow the use patterns listed in the preamble, or for the preamble to explain that there are additional use patterns.

The preamble also states that OPP will publish as a non-regulatory document a revised detailed list of specific use patterns to replace current Part 158’s Appendix A. To the extent that OPP will expect applicants to look at that list of specific use patterns, determine whether they belong in particular general use patterns, and thereby determine the applicable data requirements, which current Part 158.100(b) now directs applicants to do, it is our understanding that the list must either be codified as part of the regulation or incorporated by reference and kept on file at the Office of the Federal Register. If that is not what OPP now expects of applicants, OPP needs to clarify what the purpose of the list of specific use patterns would be and should consider adding considerable detail to its description of the various general use patterns. OPP also needs to state its schedule for revising and republishing the material now in Appendix A, which has not been revised since it originally was issued in 1984.

SUBPART D—PRODUCT CHEMISTRY

OPP proposes to add a requirement for determining an active ingredient’s ability to absorb UV and visible light. According to the preamble, this study is required in order to determine whether the “photodegradation in water” study (§158.1100) is needed. No other reason for the light absorption study is presented. However, the photodegradation study is only required for some use patterns (outdoor nonresidential); it would seem that the UV absorption study should similarly be limited to the outdoor nonresidential uses. It also might be more logical to move the UV absorption study to §158.1100 and designate it as a first-tier study.

A second new requirement is for measurement of particle size distribution. The test substance is to be the technical grade active ingredient or pure active ingredient. The requirement applies only to substances that are extremely insoluble in water. According to Guideline 830.7520, the study can only be applied to powders, although this limitation is not mentioned in the proposed rule. The guideline also makes it clear that there are several test methods (but does not bother to discuss any of them) and a host of standards with regard to the expression of results, which are not known to be consistent. According to the preamble to the proposed rule (70 FR at 12288), the data “are needed in the environmental fate assessment to estimate potential chemical drift to nontarget areas,” although the test guideline says it is “designed to provide information on the transportation and sedimentation of insoluble particles in water and air.” The TGAI is used only in enclosed manufacturing facilities for formulating end-use products. It is never applied in the field for pest control. It makes no sense to require data on particle size distribution for such products.

SUBPART E—ECOLOGICAL EFFECTS
SUBPART N—ENVIRONMENTAL FATE

Status Of Guidelines For Series 835 And 850

In the preamble to the proposed rule, OPP mentions that the guidelines for environmental fate are currently being updated and that the current guideline numbers are being used in the document and will be revised in the final rule if the new guidelines are issued prior to promulgation. However, the only guidelines EPA includes in the old guideline series are those concerning nontarget insects (Subdivision L, Series 140). EPA still has not finalized the guidelines for environmental laboratory and field testing (Subdivision N, Series 160), ecotoxicology (Subdivision E, Series 70), or nontarget plants (Subdivision J, Series 120), yet this proposed rule purports to codify the new guideline references and data requirements as though they were now in effect.

The guidelines in the 850 series (Ecological Effects), which, when finalized, will encompass the guidelines in the old Subdivisions E, J, and L, were drafted in 1998 but were never issued in final form.

The only guidelines in final form for the new 835 series (Fate, Transport, and Transformation) are specific to OPPT (the toxic substances guidelines formerly found at 40 CFR Part 792). The OPP-specific guidelines do not exist even in draft form, insofar as we can determine.

The proposed guidelines that EPA is attempting to codify in this proposed rule and their corresponding name and numbering changes from the existing guidelines are more than just clerical exercises. They contain requirements that are new and/or changed compared to the old guidelines. Particularly in view of OPP’s claim that the “enhanced clarity and transparency of the information presented in Part 158 should enhance the ability of industry to avoid wasted time and effort,” 70 FR at 12281, Part 158 must not contain references to testing guidelines that as of yet do not exist. While we recognize that the testing guidelines

are guidance documents, the content of which are not, in and of themselves, formally codified in 40 CFR, they must actually exist in final written form, having proceeded through an appropriate review and vetting process, and be available to data submitters for review, before EPA says that applicants must or should or may follow them. Until EPA finalizes guidelines under the 835 and 850 series, Part 158 should refer to the guidelines currently in place, utilizing the current scheme for when individual guidelines are required. To do otherwise places an unfair burden on applicants and denies them access to the substance of the data requirements. It also has the potential to massively confuse the data compensation process.

See also our comments on this issue with regard to Subparts K and U.

Endangered Species Act Data Requirements

OPP has not included any data requirements regarding the Endangered Species Act evaluations it needs to make, but has discussed the issue in the preamble. The agency has over the last several years been requiring, on a case-by-case basis for certain pesticides, data demonstrating specific geographic location(s) of threatened and endangered species (listed species), which can be compared with areas of potential pesticide use. These special data are currently not required by Part 158, and have only been requested on a few occasions. However, OPP anticipates that they may be requested in the future in connection with other registration and reregistration actions. These comments are in response to the Agency's request for comments on utility and appropriateness of this data requirement.

First, the Agency needs to clarify the triggers for when these endangered species data are required to support regulatory decisions. This is necessary in order to provide transparency and consistency to the Agency's requests for data requirements consistent with how EPA has approached other "Conditionally Required" studies in part 158.

Second, this requirement for endangered species data should only be necessary for outdoor uses of pesticides where EPA must conduct a refined species-specific assessment and should not be requested for indoor uses or where ecological risk assessments show no concerns for endangered species.

Third, the Agency should provide guidance on what information needs to be provided to fully satisfy the data requirement for endangered species. It is important that affected stakeholders understand exactly what type of information is being required and also the standards of quality that the data must meet in order to be acceptable. This approach would be consistent with the transparency associated with other data requirements within part 158.

Fourth, an industry FIFRA Endangered Species Task Force (FESTF) was formed to develop these data in response to data call-in notices on several pesticides. It is clear from the extent of membership of this task force (which has been in existence for over a decade) that there have been a substantial number of pesticide specific data call-ins for information on the location of endangered species and the proximity of these areas to pesticide use sites. With the Agency's efforts to implement requirements under the new ESA/FIFRA

Counterpart Regulations, it could be anticipated that EPA's needs for such endangered species information could substantially increase. Therefore it is unclear why the agency is treating this requirement as a "special study." The task force deliverables described in the PR Notice 2000-2 will improve the consistency, quality, availability and use of existing information on listed species for assessing pesticide use. However greater clarity is necessary to determine how the task force work products should be used to satisfy pesticide specific data requirements, or what other ways of satisfying the information requirements might be possible.

In summary, EPA's current practice of treating endangered species as "special studies," only required on a case-by-case basis, ignores several items of great importance to affected stakeholders. These include clear triggers for the requirement, guidance on the content of the actual deliverables, and quality standards that would govern acceptance of the submitted data.

SUBPART K—POST-APPLICATION EXPOSURE

SUBPART U—APPLICATOR EXPOSURE

OPP proposes to increase dramatically the number of use scenarios with regard to which exposure data must be gathered. Our discussion will focus on Subpart K, but it largely applies also to Subpart U.

The current regulatory provision, 40 CFR §158.390, is oriented toward providing data to set reentry intervals for commercial agricultural uses of products with high acute toxicity, or, as OPPTS Guideline 875.200 puts it,

If neurotoxic, teratogenic, or oncogenic effects ... or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from entry of persons into treated sites, taking into account the pattern and frequency of pesticide use and the results of a risk analysis based on margins of safety or derived from mathematical models ...

The current OPPTS Guidelines also indicate that waivers of exposure testing provisions will be granted if it appears that substantial exposure is unlikely.

To the extent that OPP were to propose that Subpart K post-application exposure studies are warranted for nonagricultural uses when there are toxicity data and use pattern information to suggest a potential that toxic effects could be caused by post-application exposure, we would have no objections. Instead, however, under proposed §158.810(a), studies are to be required for *all* products and *all* uses, without regard to severity of toxicity or likelihood that exposure levels may present unacceptable risk of toxic effects. The new toxicity "criterion" would call for testing of any compound showing any toxic effect at any dose level: "Evidence of potentially significant adverse health effects have been observed in any applicable toxicity studies." The proposed exposure criterion calls for testing if "post-

applicator exposure could occur,” at any level, without regard for toxic significance. These proposals should be modified in the final rule to drop this brute-force approach and address potential for actual risk. (The same problem occurs in Subpart U and the same changes are needed there.)

The preamble discussion of Subpart K presents a distorted and damaging picture of OPP’s current evaluation process. The preamble asserts that

The post-application data requirements are being revised because the existing data requirements no longer meet the needs of the Agency to protect human health from unreasonable adverse risks in all post-application settings. Data to determine post-application exposure are essential to assess the risk to people resulting from exposure to pesticides after they have been applied. ... FFDCFA now mandates that EPA perform additional scientific analyses which have not been a routine part of the Agency’s risk assessment process, such as the assessment of aggregate exposures. The new data that would be collected under the approach outlined in this proposal would allow the Agency to conduct improved exposure assessments for residential and occupational sites. In addition, such post-application studies would allow the Agency to assess aggregated and cumulative risks to consumers, with special emphasis on children.

This statement (70 FR at 12299) ignores the tremendous effort by EPA and stakeholders to establish policies under FQPA for assessment of residential exposure, provide the necessary data, and actually conduct the risk assessments. It directly contradicts statements by the Agency in policy papers developed in that process. Taken at face value, the statement would appear to invalidate much of the tolerance reassessment work (requiring aggregate risk assessment of dietary, drinking water, and non-occupational residential exposures) conducted to meet the FQPA deadline of August 2006.

OPP’s November 2001 science policy paper entitled “General Principles For Performing Aggregate Exposure And Risk Assessments” is completely at odds with the preamble language regarding Subpart K. In discussing how EPA actually conducts FQPA aggregate exposure analyses, it states:

Currently, OPP uses the draft “Standard Operating Procedures (SOPs) for Residential Exposure Assessments” (commonly known as the Draft Residential SOP’s) (USEPA, 1997a) as guidance for conducting estimates of residential exposure. These SOP’s identify common (approximately 13) pesticide use patterns/use sites (e.g., treatment of residential lawns, garden plants, etc.) that result in residential exposures. Each of these residential activities/use sites is further divided into

handler and post-application categories. (“Handler” exposures may occur when individuals mix, load, or apply a pesticide; individuals could incur “post-application” exposure either as bystanders affected by the application of a pesticide or when they enter a treated site.) These are further divided by age group (e.g., adult, toddler, etc.), route (oral, inhalation, dermal), and specific activity (e.g., incidental ingestion of soil, incidental ingestion from hand-to-mouth transfer)...These SOP’s produce a point estimate of exposure for each assessed scenario.

Useful data for residential assessments are available from several sources. Data addressing nondietary exposure have traditionally been required (under the Series 875 Occupational and Residential Exposure Test Guidelines Group A–Applicator Exposure Monitoring Test Guidelines and draft Group B–Post Application Exposure Guidelines) (USEPA, 1998a; USEPA, 1987) when certain toxicity and exposure criteria are met. Acutely toxic compounds in Acute Dermal Toxicity Category I and Acute Toxicity Category II, are triggers for applicator exposure and post-application exposure monitoring data requirements, respectively. Other adverse effects such as developmental or neurotoxicity are also considered, if results of those studies show adverse effects.

Other sources include proprietary data submitted to the Agency to support residential uses of pesticides, and in a few cases published studies. However, for most nondietary exposure assessments, surrogate data and screening-level (Tier I) assessments presented in the Draft Residential SOP’s (USEPA, 1997a) will be used...[I]f food and residential exposures are above the level of concern for a pesticide, a risk management decision may include a requirement for additional data...

The Part 158 preamble asserts, contrary to the November 2001 document, that OPP does not allow the use of surrogate data for residue testing. Although the preamble says that OPP does accept surrogate data to satisfy requirements for other kinds of post-application studies, the preamble does not indicate that there exists a suitable surrogate database on indoor exposure. In fact, such issues are being or have been addressed to some extent by the Non-Dietary Exposure Task Force (see PR Notice 2000-7) and the Residential Exposure Joint Venture, as well as the SOPs.

In short, it often is possible to use screening tools and/or surrogate data to show that a pesticide’s use is approvable without much of the data that the proposed Subpart K would require. It would be helpful to inform the reader of this possibility instead of stating flatly that data are required. The final rule’s preamble also should retract the broad statements about the need for comprehensive new data in order to perform adequate assessments. This

should be done both to be accurate and to avoid providing helpful ammunition to those who are challenging the adequacy of EPA's reviews in litigation. The current preamble's discussion of other new requirements should be reviewed for the same purposes. Both the Preamble and the proposed rule itself should be carefully reviewed by the Agency to bring them into agreement with policies established during the implementation of FQPA.

Finally, for several of the studies, the cited OPPTS guidelines (875.2300, 875.2700, and 875.3000) do not exist in final or published form. The current final Guidelines that do exist clearly are oriented only toward exposure under agricultural conditions, and in several respects are outdated or obsolete (see comments by CropLife America). While there are newer drafts of some of the guidelines, their current status and availability are not stated. Some of these draft guidelines were reviewed by the SAP in 1998 and found to need more work and additional review by the SAP. They have not gone back to the SAP since and we are not aware that revisions have been made. OPP says that

Test guidelines are not the subject of the [Part 158] proposal, which is directed solely to the types of data needed to conduct EPA's risk assessments. Comments on the Agency guidelines would not be relevant to the proposed data requirements since test guidelines are developed through a separate public process.

Docket item OPP-2004-0387-0060. In the case of the 875 Series Guidelines, however, the "public process" seems to have either gone private or evaporated. We do not think that such an extensive set of new data requirements should be required routinely until OPP has found it possible to issue final testing guidelines.