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A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

REVIEW OF EPA'S DRAFT TERMITE BAIT PRODUCT PERFORMANCE TESTING GUIDELINE

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Date: October 15, 2002

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NOTICE

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The FIFRA SAP was established under the provisions of FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, to provide advice, information, and recommendations to the Agency Administrator on pesticides and pesticide-related issues regarding the impact of regulatory actions on health and the environment. The Panel serves as the primary scientific peer review mechanism of the EPA, Office of Pesticide Programs (OPP) and is structured to provide balanced expert assessment of pesticide and pesticide-related matters facing the Agency. Food Quality Protection Act Science Review Board members serve the FIFRA SAP on an ad-hoc basis to assist in reviews conducted by the FIFRA SAP. Further information about FIFRA SAP meeting minutes and activities can be obtained form its website at http://www.epa.gov/scipoly/sap/ or the OPP Docket at (703) 305-5805. Interested persons are invited to contact Larry Dorsey, SAP Executive Secretary, via e-mail at dorsey.larry@epa.gov.

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Federal Insecticide, Fungicide and Rodenticide Act
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REVIEW OF EPA'S DRAFT TERMITE BAIT PRODUCT PERFORMANCE TESTING GUIDELINE

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP) has completed its review of EPA's Draft Termite Bait Product Performance Testing Guideline – OPPTS 810.3800. Advance notice of the meeting was published in the *Federal Register* on July 5, 2002. The review was conducted in an open Panel meeting held in Arlington, Virginia on July 30-31, 2002. Steven M. Roberts, Ph.D., chaired the meeting. Ms. Olga Odiott and Ms. Myrta Christian served as Designated Federal Officials.

The FIFRA SAP was asked to review the design and scientific soundness of the Draft Termite Bait Product Performance Testing Guideline. The guideline outlines testing methodologies and performance standards for efficacy data submitted to the Agency to support the registration of termite bait products.

CHARGE

Question 1 The draft guideline is organized around three types of tests: Laboratory Tests, Small-Scale Field Tests, and Field Tests Using Existing Structures and Buildings. For each type of test, methods and criteria are presented for evaluating the performance of bait products as preventive or remedial treatments. Please discuss:

(a) whether the laboratory tests described in the draft guideline produce sufficient data to determine whether a termite bait kills termites feeding directly on the bait ("direct kill") and kills other termites in the same population that have not fed on the bait ("secondary kill").

(b) whether data from the laboratory tests showing that a termite bait product causes both direct and secondary kill reasonably support an inference that the termite bait product should be efficacious under conditions of small-scale field testing.

Question 2 The draft guideline presents two differing approaches for small-scale field tests to evaluate the termite bait for structural protection/zero tolerance for structural infestation vs. termite population management. The former approach is based on the concrete block or concrete slab tests presented in the guideline that are similar to testing conducted for soil-applied termiticides. The performance standard is 100% protection (0% infested with termites) for preventive treatments while infestations must be eliminated within 12 months in remedial treatments. The latter approach uses termite baits to "manage" or control termites at the population level with product evaluation emphasizing the ability of the bait product to suppress termite populations on an area-wide basis with a performance standard of 80% (4 of 5 treated colonies suppressed or exterminated). Please discuss:

(a) the feasibility and scientific soundness of each approach.

(b) whether the small-scale tests provide sufficient data to show whether or not a termite bait product works.

(c) to what extent the proposed small-scale field tests mirror actual use conditions.

(d) which is the best method for testing termite baits.

(e) what modifications or additional tests could be recommended to improve small-scale field testing.

In answering these questions, please address the following aspects of each method: the criteria used to select testing sites, the number of replicate observations at each site, the placement of the termite baits in the test system, and

the applicability of the methods for the different species of termites.

Question 3 The draft guideline presents a method for field tests using existing structures and buildings. The evaluation criteria presented in the draft guideline are based on the presumption that termites must not infest a structure for a structure to be protected. The evaluation criteria presented in the draft guideline are based on visual inspection of structures for termite infestations, use of monitoring devices (acoustical emission devices, microwave devices, bait stations and bucket traps), and measurement of wood consumption before and after termite bait treatment at bucket traps or other non-bait product monitoring stations (independent monitors). The performance standards for remedial and preventive treatments at existing structures are presented below.

The product performance standard for remedial treatments should include elimination of an existing termite infestation in 12 months or less in 100% of the structures treated and the treated structure must remain termite free for 12 months following treatment. If termites are not detected from structures but remained active in the monitoring station or independent monitor (IM), then structural inspections every month are needed during the 12-month period. After baiting eliminates the infestation in the structure based on a structural inspection but the activity resumes during the 12-month post-baiting observation period at the monitoring station, additional bait application has to eliminate termite activity within 12 months at the station and IM following the re-application of baits without causing >10% of the maximum wood consumption as recorded in the IMs during the pre-baiting period. After the re-application of baits, termites should remain absent for another 12 months in the structure and IMs.
Preventive treatment tests must prevent structural infestation by termites in 100% of the structures for the duration of the field test, for a minimum of five years, as measured by 60 months of termite activity at the monitoring stations/bucket traps/wood stakes. Alate swarms, mud tubing, and presence of worker or soldier termites in or on the structure are indications of a termite infestation and can indicate the failure of a bait product to protect a structure. Please discuss:

(a) the criteria used in the selection of a structure for testing, the number of structures that should be included in each test, the bait placement intervals around the structure, and the applicability of the method for the different species of termites.

(b) whether the evaluation methods and criteria for detecting termites in and around existing structures are consistent with the state of the science for assessing termite activity. Would another measure be more informative and useful for the guidelines?

(c) whether the product performance standards are appropriate to show if termite bait products work successfully when applied at existing structures?

(d) Termite bait technology is based on a sophisticated knowledge and understanding of termite biology and foraging behavior. Many regulatory Agencies at the State and Federal level are concerned about homeowner use because of structural damage that could occur if an application is not done correctly. Should the guidelines recommend field tests designed to evaluate the performance of termite bait products following homeowner applications? In answering this question, please provide a supporting discussion that addresses what is known about homeowner applied baits and why it may or may not be important to test product performance under this application scenario. If the answer to this question is yes, please discuss the design of such field tests including: the criteria used to select sites, the criteria used to select study participants, and the number of replicate observations at each site.

Question 4 Please provide comments on the clarity, accuracy and completeness of the draft Termite Bait Testing Guideline. In your comments, please provide a supporting discussion that highlights any areas of the draft guideline that may need to be clarified and relevant topics that may be missing. Include references to any published literature that could help improve the completeness and clarity of the draft guideline.

GENERAL PANEL COMMENTS AND RECOMMENDATIONS

Laboratory studies

Laboratory experiments are controlled studies that can provide information that often cannot be observed directly in the field. For example, laboratory studies can provide information on how much active ingredient must be consumed by a colony to kill it. For example, dosing studies may be performed to determine the number of workers that must access the bait to affect colony survival significantly. Dosing a variety of sizes of groups of workers, e.g. from 100 individuals to 100,000 individuals, can be performed. Such laboratory results help develop an expectation of what amount of bait can realistically be harvested and consumed from a given bait station. In another example, laboratory studies could be used to describe how colonies and bait will respond under different climate conditions.

The objectives of the laboratory test should include evaluation of both the efficacy of the active ingredient and the palatability of the matrix material separately and in combination. The discussion was based on the following premises.

- The active agent will have a biological effect which may be a direct effect such as mortality or a secondary effect such as modifications to the reproduction cycle.
- The active agent should not prevent feeding so the laboratory test should provide evidence that the organism will forage on the bait (active agent and supporting matrix) and transport and eventually consume it. This will require demonstration in both non-choice and choice trials.
- Biological effects may take some time to manifest.

Minimal laboratory data.

- If the expectation is for direct mortality of some life-stage (caste), then laboratory results should demonstrate direct mortality. Most current baits have some direct lethality, hence the focus on mortality in the draft guideline.
- If the biological effect hypothesized is a secondary effect, the laboratory study data should demonstrate that the bait will reach the appropriate life stage (caste) and act as expected.
- If colony level effects are hypothesized, it may be necessary to establish full colonies for testing. This concept is discussed in more detail below.
- The laboratory study should also provide some initial information that the proposed delivery system (the bait in a specific container) will work as expected. There are examples where the delivery system was not tested before going to full-scale studies with resulting failure of the system. Requiring proof of effectiveness of delivery format may be required.

The guideline should allow flexibility in development of the needed information. This includes the flexibility to demonstrate not just mortality but appropriate secondary effects. Detailed protocols should be included as examples of what kinds of studies are appropriate to generate needed data for certain situations. These protocols are not to be considered as mandated or the final word.

The laboratory tests discussed in the guideline represent one dimensional views of termite behavior in that it only measures worker consumption without examining worker foraging behavior or worker interactions with other life stages in the colony. The Panel discussed the feasibility of establishing arenas to support a small colony laboratory. Such arenas could allow simulation of worker foraging and transport behavior by having the colony in one location and allow dosing to occur in a connected but distant second location. At best, colonies in the laboratory will be two dimensional simulations of the full three dimensional wild colony in the field. In addition, any transport structures created in the laboratory will be limited to a couple of prescribed pathways compared to the many that would be expected in the field. The space limitations on a laboratory colony may be such that the population dynamics of the colony will be changed in such a way that the colony is no longer a perfect model (or replica) of what would be found in a wild colony. The benefit of laboratory colonies is that these studies come closer to having a natural composition of life stages and that the actions of foraging workers are more realistic. Despite its limitations, the laboratory setting will be the best location for demonstrating detailed mechanisms for such things as secondary action. Finally, an example was given of a class of products (early juvenile hormone analogues) that promised to be effective bait toxins based on laboratory data. However, they failed entirely when offered to wild colonies. In the laboratory, when experimental groups were provided with more natural settings (type of food, caste composition) it could be demonstrated that the efficacy of the compounds was far less than in applications to groups of only workers fed treated filter paper. This example highlights that the more natural the experimental settings are the more likely it is that results will reflect the field situation. Small-scale studies of the type identified in the guideline may provide a much more optimistic result than would be found using laboratory colonies. It was also pointed out that maintaining laboratory colonies of *Coptotermes* would be probably quite difficult.

There was concern that there should not be a disconnect between the data needed to request an Experimental Use Permit (EUP) and data needed for subsequent registration of the bait system. Any laboratory data provided should be able to serve both purposes, and the guideline should be specific enough to facilitate this. Data used in the development of the bait may not be totally adequate for requesting an EUP. The Panel discussed how much of the total information needed for an EUP can come from the laboratory. For example, demonstrating that workers will consume the bait, that the bait is no less palatable than monitoring stakes, that workers will feed the bait to appropriate life stages in the colony and these life stages will consume it and pass it on to other life stages may represent 90% of needed information. The other 10%, unfortunately, can be critical to the effectiveness of the bait system. Again, reference was made to the example where simple and larger laboratory studies indicated that the bait would work only to find that the system did not work in the field. In one case mentioned the failure was traced to engineering problems with the size and number of openings of the plastic container in which the active bait was placed. Some of the Panel members felt that laboratory studies may only be able to provide at most 40% of needed information since other factors that cannot be controlled in the laboratory, such as interactions with soil nematodes and unexplained movement of the whole colony, may account for a large fraction as well.

Some Panel members felt that laboratory data can be somewhat predictive of termite and colony behavior and, in particular, response to bait. What changes as experimentation moves to the field

is the social behavior of the insects. Behavior in the laboratory may be different in the field. Many of the behaviors in the colony are chemically based and baiting may change these chemical signals. The action of the colony will depend on the mode of action of the active ingredients in the bait. A number of baits that initially looked promising in laboratory studies have failed in the field. Understanding of how one chemical from a class of similar chemicals (for example hormone regulators) works for larger laboratory populations (colony–sized) in a laboratory setting, provides information that can be inferred to the whole class of chemicals.

Bait by colony size interactions may be impossible to demonstrate in the laboratory. A number of Panel members felt that size of colony might be a factor in bait failures. As size increases, the effect of the bait may be diluted. For example, in a small colony a loss of 10,000 workers may be catastrophic, whereas in a large colony the same loss may have little effect. Larger colonies may have greater redundancy in functionality that should result in increased survivability.

The Panel discussed the necessity of demonstrating the bait secondary effects. To claim colony elimination or elimination of a significant fraction of a colony, the bait needs to affect more than the worker foragers. The bait has to reach the core of the colony that can be up to 100m distant from the bait site. Bait must be transported back to the colony. There is evidence that workers of some termite species develop or utilize site-specific foraging patterns. If this is the case, only a small proportion of workers will come in contact with any one bait station, and only those workers that forage at that station and the life stages fed by these workers will be directly affected. If there is task-switching among foragers, the dose to individual foragers will be further reduced which should further slow transfer rates for the active ingredient. This is another process that could be examined only in the controlled environment of a laboratory colony.

The impact of other important factors, such as the presence of multiple breeders and/or multiple nesting sites in one colony may be impossible to demonstrate in either the laboratory or the field.

Small-scale field studies

A number of Panel members were of the opinion that it may not be possible to "prove" that a bait can eliminate a colony. Direct kills in the field are typically not observed. Studies have demonstrated the success of baits in eliminating foraging in an area, and the severe impacts on a population as a result of bait feeding.

The terms "population management" or "population suppression" was preferred to the term "colony kill". Small-scale field test can be designed and implemented to demonstrate population suppression. If population suppression can be demonstrated in a small-scale study, then this should be taken as evidence that the bait has a reasonable chance of performing successfully in an EUP test. Claims of "colony kill" (colony elimination) by bait systems often refer to the situation where "termite activity in a structure and around the structure has been eliminated for a given period of time". If the EPA accepts this definition it would have to set the threshold for what constitutes significant termite activity and how long is an acceptable no-activity period.

The Panel noted the following desirable characteristics of a small-scale field experiment. The small-scale field experiment should demonstrate:

1. That the bait system has the ability to eliminate any existing termite activity in and in close proximity to the area supposedly protected by the bait station.
2. The rate at which an existing termite population can be eliminated from an area. This rate may be dependent on the size of the colony and the mode of action of the active chemical in the bait and the number and geographical locations of the bait stations.
3. How long an area initially baited will remain termite-free once the bait has been removed.
4. That the bait system has the ability to kill other life stages of an active colony and the rate at which this occurs.
5. That the baits are acceptable to all termite foragers that come in contact with it.
6. That the proposed delivery system (e.g. the bait and the "plastic box") can allow foraging termites to return sufficient bait to the colony.
7. That the results of the individual baiting experiments are repeatable. By running the tests over a 3-5 year period, one can estimate the number of cycles of infestation/removal that will be expected in a year. This should help determine the level of monitoring of the area and management of the bait system that would be needed to keep a treated spot relatively termite free over a period of time.

Some Panel members felt that simply demonstrating that the bait can eliminate termites from an area repeatedly is not enough information to predict the degree of protection the baiting system will afford to a human-built structure. The small-scale experiments simply a second phase of the laboratory experiments. The two sets of information are complementary and together inform the decision for a EUP. The two together do not eliminate the need to demonstrate the bait system's effectiveness in large-scale sites.

Finally, there was discussion on whether the costs of small-scale experimentation could be reduced if a method could be developed that could create/form/encourage a uniform sized and compact colony in a specified location. Apparently efforts to do this have been initiated by a number of researchers. If successful, this would present researchers with a means of replicating colonies, reduce unwanted variability and as a result reduce sample sizes and resulting costs.

Large-scale studies

As part of a EUP, the study protocol is defined by the proposed bait product label. It is assumed that all EUP units will follow this same protocol. It is possible that changes to the proposed label may be requested as the study proceeds to reflect bait system changes suggested by the experience of the early implementers.

EPA requested that the Panel revisit the discussion of the method to facilitate a finding of efficacy for "remediation" versus efficacy for "prevention". Earlier discussions had suggested that the prevention level of efficacy was being proposed for structures being newly constructed but without any chemical barrier. The absence of any chemical barrier protection allows termites to approach the structure from any direction, including directly under the structure. A site with an effective chemical barrier will force termites to approach from only limited directions.

For sites identified for remediation with the bait system under the EUP, the amount of residual termiticide at the site is a confounding factor to determining bait system effectiveness. If the site

already has a high level of residual termiticide, the task left for the bait system may be relatively easy and result in easy success. With unprotected new construction, it will be much more difficult for the bait system to demonstrate success. To help reduce the numbers of structures that require testing, the amount of residual termiticide could be determined for structures that are not currently infested with termites and those with levels considered below minimal protection levels could be considered for preventive baiting. In general the Panel felt that if bait systems are being proposed for stand-alone protection on newly constructed structures it must be tested on newly constructed structures.

While the Panel was not fully supportive of using Good Laboratory Practice (GLP) standards for large-scale tests, some modification of GLP (a GLP-lite for example) should be part of the guideline. There was disagreement among Panel members as to how much modification of GLP standards to suggest. Issues such as documentation for sample preparation, chain of custody forms for transferring test substances, having written protocols for training and keeping records of the qualifications of the individuals doing measurements are some that are important and might be included in a GLP-lite. A number of Panel members were very clear that the more subjective the measurements are, the clearer the practice guidelines and associated written protocols need to be.

The issue of how many structures are needed for a study was not directly resolved. The Panel felt that the appropriate answer probably represents a compromise between setting a target for the precision of the estimator (i.e. how confident do regulators need to be in the effectiveness of the bait treatment) and the costs per unit tested. Numbers such as 100 to 150 were mentioned as values many Panel members would be comfortable with. There was discussion about focusing EUP studies on just the two major termite pest species as one way of managing sample size and costs.

At least one Panel member expressed concern that EPA not depend too much on data that comes from published literature. These data may be biased for the simple reason that data that demonstrate a negative result rarely get published. The EPA representative assured the Panel that published data are typically only considered supportive of an application but that original data developed for the specific application must be present.

Finally, the Panel recommended that EPA continue termite bait research supported by the Office of Research and Development (ORD).

MINUTES OF PANEL DELIBERATIONS

Question 1 **The draft guideline is organized around three types of tests: Laboratory Tests, Small-Scale Field Tests, and Field Tests Using Existing Structures and Buildings. For each type of test, methods and criteria are presented for evaluating the performance of bait products as preventive or remedial treatments. Please discuss:**

(a) whether the laboratory tests described in the draft guideline produce sufficient data to determine whether a termite bait kills termites feeding directly on the bait ("direct kill") and kills other termites in the same population that have not fed on the bait ("secondary kill").

The Panel agreed that the laboratory tests outlined in the draft guideline would produce limited data to show that a termite bait will kill termites feeding directly on the bait, but would not produce any data on secondary kill (as this was not tested in the outlined experiments). The Panel members agreed that the demonstration of secondary kill was an important component of the laboratory testing.

The Panel noted that the potential registrants would conduct laboratory testing similar to that described in the draft guideline during the development of a potential toxicant, so therefore it was likely that they would have little additional work in the laboratory with respect to registration.

(b) whether data from the laboratory tests showing that a termite bait product causes both direct and secondary kill reasonably support an inference that the termite bait product should be efficacious under conditions of small-scale field testing?

The purpose of the choice test was to show that the bait was palatable compared with wood. If the choice tests demonstrate this, then the Panel members agreed that it would appear reasonable to anticipate that the bait may be eaten and kill directly in the field (but see comments below). However, as only a small proportion of the colony will feed directly on the baits in the field, it is important to demonstrate secondary kill to infer that the bait product should be efficacious in this situation. As stated above, the tests in the draft guideline do not address secondary kill.

The Panel members agreed that once suitable laboratory tests that demonstrate secondary kill are performed, these laboratory tests plus the direct kill laboratory tests will give some indication of possible effects in small-scale field testing. As suitable tests for secondary kill were lacking, most Panel members felt that it was impossible to comment further.

Laboratory tests are important for several reasons, not the least being that it is only here that kill due to the toxicant can be demonstrated explicitly (typically, field observations are limited to the presence or absence of termites in baits, with absence having several plausible explanations). Several Panel members were not convinced that the laboratory tests in the draft guideline would produce data suggesting that a bait product would be efficacious in the field because groups of 100 workers (plus one or five soldiers, depending on the species) in a small jar is not at all similar to natural termite colonies found in the field. Some Panel members felt that supplying these data to the EPA was unnecessary due to its poor predictive power.

Placing 100 termites of one worker instar into a very small jar with only one food source does not adequately address likely outcomes in field programs because:

1. They are unrepresentative of total diversity in the termite colony – there is a problem with determining which caste/instar actually eats the food once it has been collected and returned to the nest.
2. The number of foragers used in the laboratory trials, as suggested in the draft guideline, is at least 2 and usually 3 and occasionally 4 orders of magnitude smaller than a field colony. Scaling up the results from these laboratory trials to that level is problematic.
3. The physical scale is unlike field experiments. Termites forage over many tens of metres (up to 100m), which is 3 orders of magnitude greater than the diameter of the glass jar used in the laboratory trial. Walking raises the metabolic rate and it is difficult to compare how active termites react compared with sedentary ones.
4. There is no alternative food.
5. There is no escape from the presence of the active ingredient, and not all active ingredients are designed to kill by ingestion, so the method of death is indeterminate.

Some Panel members felt that larger scale laboratory experiments would be useful for better prediction of bait product effect in small-scale field testing. One example was to use infested logs that contain tens of thousands of termites (and perhaps reproductive and young), and another was to use aquaria containing thousands of termites. Placement of the bait at some distance from the termites was also suggested.

Specific Comments

Background

The level of importance of each of these points depends on what information is desired by the Agency. The agency describes two categories under which a bait product might be reviewed: Category 1, with data to support structural protection claims, and Category 2, without such data. Obviously, data from laboratory tests are unable to address Category 1 claims; therefore this answer (to Question 1) will address only Category 2 bait products. Category 2 bait products "are required to show that termites find the bait palatable and that termites are killed when they feed on the bait under actual use conditions" (as described in the 'Presentation Brief, FIFRA SAP Termite Baits', draft dated 1 July 2002).

Clearly, the laboratory tests are unable to test the bait product under "actual use conditions". However, it is important to remember that demonstrating termite death is difficult in the field, as

most bait products use toxicants with delayed action, and therefore cadavers are not readily observed (typically field observations are limited to presence or absence of termites in baits, which can be explained in several ways). It is only in the laboratory that the direct action of the toxicant can be observed; therefore these tests are critical to support the 'kills termites' claims.

Responses to each paragraph

(1) **Species**. The Panel agreed that the draft guideline listed the economically important species of termite in the USA, and these should be used in the laboratory tests. However, the manufacturer of a bait product ought to be able to test only those species for which claims of efficacy are made – and these species ought to be listed on the label. The collection method of Su and Scheffrahn (1986) is 12 years old and improvements have been made since then. Furthermore, this collection method was designed for urban areas, and previously existing, faster methods ought to be allowed in forested areas.

The draft guideline asks for three colonies per species tested. The majority of the Panel felt that this was insufficient to measure variability of response. This number of colonies was copied from Su and Scheffrahn (1989) and it was an arbitrary number in this study. Obviously colony replication is used to measure the variation in response to a bait product, and reduced replication usually results in reduced variability, and therefore reduced statistical confidence in the result. Since the expectation is that all colonies are susceptible to the active ingredient in the bait (at the rates to be used in the commercial product), the sample size issue for colonies becomes one of specifying an upper 95% confidence limit on the projected fraction of colonies that will fail when exposed to the bait. The computation of this upper 95% confidence limit is straightforward once the acceptable limit is set.

One area of variability is completely overlooked in the draft guideline laboratory studies: geographical variation. A range of geographic regions is listed in the draft guideline field tests. However it is important to note that geographic variability is simpler, faster and cheaper to measure in the laboratory than in the field. Therefore, colony replication ought to be increased, if only to include regions. The number of regions required in the laboratory tests should match that elsewhere in the guideline: at least three regions (the draft guideline requires a minimum of three regions for the small scale field tests and six regions in the large scale field tests). However, the number of regions may differ for each species dependent on distribution: more for *Reticulitermes*, fewer for *Coptotermes* and only one region for *Heterotermes* (if these species are listed on the label claim).

(2) **Stage, caste, and ag**e. The draft guideline stipulates the caste and stage of the termites to be tested. This is unnecessary and inappropriate as active ingredients may have different modes of action, and these may have different effects in each caste. This is especially true for CSI and JHA as these have a greater impact on younger workers (or larvae). Therefore, the guideline ought to incorporate a stipulation that caste and stage composition of the termites used in the laboratory tests ought to be appropriate for the mode of action of the active ingredient. The Panel agreed that 90 days was the maximum period of time that termites can be maintained in the laboratory before use in tests. The word 'cultured' ought to be changed to 'maintained' as

'cultured' suggests growth and development, which is the opposite of what happens to groups of termites kept in the laboratory.

(3) **Rearing techniques**. Termites are rarely 'reared'; instead they are collected from the field and maintained in the laboratory (as indicated above). A description of how the termites were maintained in the laboratory, including how long they have been there, ought to accompany the laboratory test data.

(4) **Bioassay design.** The laboratory test methods follow those of Su and Scheffrahn (1989) (ref. 58). These were criticized widely. In general, the lead discussants and the rest of the Panel felt that rather than one detailed method, a general outline of a protocol ought to be given, with clear instructions about the data that should be produced and analysed from the tests. This would allow for flexibility in choosing the method, but stringent requirements in the data that are produced (see comments on 95% confidence limit above).

The type of data that ought to be collected could be expanded. Currently, the only data collected will be mortality data at three time points. Other data that might be collected include: mortality rate (too fast and the workers die too quickly to affect the colony, too slow and the effect is too diluted to affect the colony or to produce effective control), non-mortality outcomes such as rate of conversion to soldier (pre-soldier) life stages (for hormone-based baits), consumption rates at different formulations of toxin and matrix, etc.

The sampling method of Su and Scheffrahn (1989) is destructive and therefore requires three times the replication (i.e. one for each time point). Using a repeated measures design would be appropriate and require fewer replicates. Flexibility in experimental design will allow for such changes.

The use of wooden blocks was widely criticised by the Panel (and also by Su and Scheffrahn themselves, due to the poor distribution of active ingredient through the wood). Furthermore, no existing bait product uses wood as a matrix, which raises questions about why it is required. It was felt that the matrix used in the commercial product was the most appropriate material to use.

Holding the termites in a small jar with the bait is not at all similar to the field situation; termites walk to their feeding sites to collect food and carry it back to their nests. Therefore the set up is not at all natural, and mortality may be enhanced due to these factors.

(5) **Feeding preferences and palatability testing.** The laboratory test methods follow those of Oi et al. (1996) (ref. 45). These were criticized, though less than those of Su and Scheffrahn (1989). As for (4) above, the Panel felt that a general outline of a protocol ought to be given, with clear instructions about the data that should be produced and analysed from the tests. This would allow flexibility in choosing the method, but stringent requirements in the data that are produced.

Some of the Panel members stressed that bait 'consumption' is a misnomer. Termites do not eat food at a foraging site; instead they have an organized collection system at foraging sites: some workers gnaw the wood (or other food) and make balls of fibres that are collected by other

workers that transport them back to the nest. The food balls are eaten or stored in the nest. Therefore termites may collect bait they do not necessarily eat. Duncan et al. (1990) [Bull. Entomol. Res. 80, 277-287] showed that although baits were collected by forager termites (*Hodotermes* in South Africa), they were not consumed in the colony.

(6) **Test arenas and testing condition**s. See comments above for (4) and (5).

(7) **Data reporting**. The Panel agreed that GLP requirements are suitable and acceptable for laboratory scale testing.

(8) **Data evaluation and analyse**s. See comments above for (4).

Only one Panel member felt that the tests were adequate as described in the draft guideline, but agreed that secondary kill was not tested.

Question 2 **The draft guideline presents two differing approaches for small-scale field tests to evaluate the termite bait for structural protection/zero tolerance for structural infestation vs. termite population management. The former approach is based on the concrete block or concrete slab tests presented in the guideline that are similar to testing conducted for soil applied termiticides. The performance standard is 100% protection (0% infested with termites) for preventive treatments while infestations must be eliminated within 12 months in remedial treatments. The latter approach uses termite baits to "manage" or control termites at the population level with product evaluation emphasizing the ability of the bait product to suppress termite populations on an area-wide basis with a performance standard of 80% (4 of 5 treated colonies suppressed or exterminated). Please discuss:**

(a) the feasibility and scientific soundness of each approach.

The draft guideline as written presents two approaches (with three alternative methods) that attempt to determine structural protection (Methods 1 and 2: Concrete Block Method and Concrete Slab Method, respectively) or termite population suppression (Method 3: Population Management Method). There was general consensus from the Panel that Methods 1 and 2 are methods in search of a question with respect to bait product performance. These methods test the concept of protection based on a "barrier" of some type, which baits are not and have not been designed to provide. The majority of the Panel agreed that applying this "barrier concept" to bait products was unreasonable and therefore the concrete block and concrete slab tests should be excluded from the guideline.

It is important to remember that baits themselves do not perform in the same manner as a baiting system. Grace and Su, (2000) Evidence Supporting the Use of Termite Baiting Systems for Long-Term Structural Protection (Isoptera), IRG/WP 00-10377) state "baits are not a barrier to termites and protect against continued infestation and damage, not against simple encounter

between termites and the structure;" and "probability dictates that termites may locate the wooden block first or simultaneously in some cases. There is question that this should be treated as a failure of the baiting system." To ask more of the bait system than that it kill the colony it was originally targeted at may be asking too much. This is especially true if you expect as the current draft guideline suggests, that not just death of the target colony but no additional area re-colonization occur. Re-colonization is very likely to occur in a location where a previous colony was established because the location was previously favorable to colony establishment and the infrastructure built by the previous colony, such as foraging tunnels and galleries, enhances the site even more. Since the bait is not expected to leave residual chemical then residual treatment should not be expected as well.

Furthermore, the Concrete Block Method (Method 1) does not simulate building construction, and for that reason is overly artificial. Nor are baits typically applied in crawlspaces. The test is feasible but expensive, but more importantly the scientific soundness of the approach is questionable. The objective of the test is a comparison of outcomes at baited and unbaited control units (sites). Despite the requirement that units be placed no closer than 23m from each other, there is still the potential for baited sites to overlap and therefore impact colonies whose feeding is linked to nearby control sites making it very difficult to accurately assess bait performance. The Panel addressed the difficulty and expense of using marking techniques to link units to colonies. As written, the only purpose of the marking techniques is to link feeding at the bait stations with feeding on the pine sandwich. It is assumed that each unit has its own colony but there is no provision in the guideline to assess the truth of this assumption.

The requirement of no recurrence of feeding on the pine sandwich in treated units represents an unsupportable target given the mechanism of action of baiting systems. While the bait system may initially kill the colony associated with it, the remaining galleries could provide an easily exploited pathway for neighboring or newly established colonies. Even with the toxic bait in place, termites from the new colony may choose to utilize first those galleries that lead directly to the pine sandwich but that bypass the baits. In this case the unit will be judged a failure because the termites did not choose to utilize the baits first. Even if the termites choose to start feeding at the bait stations, the long time frame for the bait mechanism of action to have effect may allow other workers from the colony to find the pine sandwich and begin feeding on it. More importantly, the structural protection tests as written are designed to test the effectiveness of a (usually) chemical barrier to prevent termites from reaching a target block of wood. Baits and bait systems are not designed to act as barriers, but rather are means of achieving structural protection by suppressing termite populations in a particular area. Using these methods to test for activities which baits are not designed to perform is not sound science. Thus the proposed structural protection tests are not suited for assessing the effectiveness of baits.

Methods 1 and 2 are unproven and rely on major assumptions that will likely double the quantity of work (and cost) already proposed by each method. There are problems with logistics, feasibility, and scientific soundness of both approaches. For instance, a single trial wherein one bait would be tested remedially would require 3.5 acres of undisturbed land. Moreover, extreme expense in terms of material and manpower make using these approaches unfeasible.

The success of Methods 1 and 2 hinges upon termites eating dyed filter paper from the six-board sandwiches. Termites are not likely to eat the dyed paper in the six-board sandwich, creating major operational difficulties for both methods. If the termites don't eat the dyed filter paper in the six-board sandwich, then the methodology gets more labor intensive. The methodology (section (e)(3)(iv), Other Marking Techniques) calls for collecting and feeding a dye to 1,000 or more termites collected from bait stations containing wood monitoring devices. It is doubtful that 1,000 or more termites can be collected from a registrant's bait station. These numbers of termites are generally collected from bucket traps containing six-board sandwiches, but not from a commercial bait station.

The consensus of the Panel is that Population Management (Method 3) is the superior method for small-scale field testing.

Field sites are available for each of the *Reticulitermes* species listed in the guideline and are therefore feasible from that standpoint. Field sites for *Coptotermes formosanus* having the requisite population structure, levels of infestation, and probability of remaining undisturbed over a significant length of time may exist, but have not yet been delineated. A site must be identified for *Coptotermes formosanus* small-scale field trials prior to the requirement for such testing in the guideline. A possibility is to test the bait concept using only *Reticulitermes* species and include *Coptotermes* in large-scale tests. One possibility for population management testing for *Coptotermes* is to utilize individually infested trees, possibly in metropolitan New Orleans, to assess the acceptance and population reduction by individual bait products, with the caveat that many of the trees in New Orleans have been treated using liquid chemical foam treatments and therefore pristine trees may not be in sufficient supply to provide such a testing location.

The Panel agreed that existing literature suggest that the Population Management approach using a well defined grid of termite foraging activity provides a reasonable measure of population effects by bait treatments and suggests that the approach is scientifically sound. However, there was substantial discussion with respect to the determination of population effect and the use of mark-recapture studies and/or DNA methodology to determine if colonies feeding on the baits and independent monitoring stations were from the same "colony" or population. One Panel member indicated that marking termites with fat-soluble dyes could act synergistically with the test bait and therefore affect the outcome of the procedure. Another Panel member suggested that a grid of pine logs (pine logs quartered and then tied together, as used and referenced by the USDA Forest Service) could be placed at suitable sites. *Reticulitermes* tends to establish breeding colonies within such logs. Such a relatively well defined population could then be baited and assessed using a system of pine stakes surrounding the logs. Several Panel members argued that the guideline should require the use of at least 5-6 bait stations within a defined population to account for the large number of termites that could be present within the baited population. Defining a larger number of bait stations within the area should ensure that sufficient bait active ingredient is delivered to the colony to produce the expected population level effects. Several Panel members commented on the need to have more precisely worded guidelines on what the metric should be to assess "population management" effects. The guideline provides no specification of number of baits with regard to the size of population or foraging area, neither is there any indication for a minimum or maximum colony size nor a balance of colony sizes between baited and control treatments. There was also general Panel

consensus on the need to differentiate between effective population reduction of the original baited colony and the subsequent appearance of termites within the monitoring stations which could represent reinvasion of the vacated territory by another unrelated and untreated population of nearby termites. Careful marking and collection and preservation of termites for use in developing DNA tests represent the most promising way to ensure that reinvading termites do not represent the original population, which indicates that population was suppressed.

One proposed method to evaluate the effectiveness of a bait product is to collect termites (at least 25 soldiers and 100 workers in 100% ethanol) from Nile Blue dye-connected bait stations or six-board sandwiches (1) the day bait is first introduced into a bait station, and (2) each time termites are found in a monitor (bucket trap/six board sandwich or registrant's bait station) during the period that all stations are required to remain free and clear of termites. This process would protect the registrant from false positive results of a termite return (different colony) and it would bolster the Agency's claim that baited termites did or did not return during the specified time period.

The guideline should also specify how many colonies will be assigned to baited and control treatments when using this approach. The guideline implies that current marking techniques are adequate for associating termites feeding at bait stations with those occupying the monitoring stations. Current marking techniques may not be adequate for this purpose.

(b) whether the small-scale tests provide sufficient data to show whether or not a termite bait product works

The Panel generally agreed that Method 3 (Population Management) tests would provide information regarding whether baits have the ability to provide colony level reduction. There was some confusion as to whether this constituted an answer as to "does a bait product work?" One Panel member questioned if the small-scale tests would provide sufficient data to assess how a bait product works when used in an overall termite management system (with monitoring, inspection and re-baiting as needed) in a larger arena.

The small-scale field trial is basically designed to assess whether a bait product will kill a termite colony. There may be other small-scale systems that could provide this information.

It was suggested that because there are 38 different pieces of data listed in the guideline for Method 3, it is important to prioritize the data needed and include key references that would provide the necessary guidelines for what data to collect to help evaluate whether a bait works.

The Panel agreed that evaluating whether a bait works should exclude from consideration termites which had not been exposed to the bait treatment. The remedial evaluation criteria for success of small-scale field test Method 3 states that "The bait should eliminate a termite infestation from the wood in the monitoring devices within 12 months of bait station application with the pesticidal active ingredient using the methods described in this guideline in 80% (4 of the 5 colonies of each species in the field plots). In addition, each replicate should be termite-free for 12 months following cessation of termite activity."

The situation described in the preceding paragraph presents a potential confounding situation because the guideline does not specifically exclude the infestation of the six-board sandwich/station, etc. by termites from an unrelated colony of the same species or from a colony of a different species. This is important because fat-soluble dyes are not likely to remain in a termite fat body for more than a few months after feeding. In the southeastern U.S., for example, it is common to have three *Reticulitermes* species present in the same area. Small *Reticulitermes* colonies throughout the southeast are common, and researchers have shown that different colonies of the same species, and even different species, will visit and use the same food resource (wood block). Termites showing up in a bucket trap within the 1-year period would cause that particular replicate to "fail" to meet the guidelines' criteria, even if the termites were unrelated to the group that was originally baited. The guideline should only address what happens to individually-baited groups of related termites.

(c) to what extent do the proposed small-scale field tests mirror actual use conditions.

The Panel consensus is that Method 3 does not mirror actual use conditions. The Panel generally agreed that the fact that they don't mirror actual conditions may not be a bad thing and does not prevent small-scale field tests from assessing population effects of proposed bait products. The intent of Method 3 should be to answer the simple question, "Does the candidate bait eliminate a single, baited colony?" Answering the question of colony elimination should be the goal of the small-scale field test. Mirroring actual use conditions is what the large-scale field tests are designed to do.

The small-scale field tests mirror actual use conditions in only insomuch as they can be expected to sample termite population reductions over a defined area. The tests as outlined in the guideline suffer from the fact that structures within the area do not exist and the effects of such structures on the foraging dynamics of the population would not be imposed in the small scale field tests as stipulated. Further, the geometry of bait installations in actual use situations is reduced by the footprint of the existing structure, resulting in "gaps" in the application of baits within a possible foraging territory.

Concrete Block/Slab Experiment – Provides a simple model of the residential frame on slab construction. Active and adaptive management of bait systems are not mirrored at all.

Population Management Experiment – No model of residential structure is used. Makes no linkage to interaction between construction and termite access and hence does not mirror actual use conditions.

The Panel discussions raised very strong doubts as to whether any small-scale field test can mirror actual use conditions. The task seems much easier with barrier systems because the object that is treated is the structure. The structure is relatively permanent and hence can be repeatedly examined, and failure of the barrier can be directly observed. With bait systems, the object that is treated is the colony. Once the bait affects one colony, the probability that a second colony will move into the area is high. With a new colony we have a new experimental unit. In actual use conditions, a new colony would be detected and the bait redeployed. The failure modes of bait

systems involve not just the potential failure of the bait but the potential failure to re-deploy.

(d) which is the best method for testing termite baits.

The Panel concluded that the best method of the three posed for the small-scale field tests is the Population Management (Method 3). Unlike the Concrete Block and Concrete Slab methods, the Population Management Method is a proven method, and is currently the state of the art for determining colony-wide impacts, including elimination, on subterranean termites.

One Panel member noted that the question here is "Which is the best method for testing which characteristics of termite baits?" If the answer is "testing termite baits for their ability to reduce or eliminate colonies" then the answer is to use method 3, the Population Management Experiment. If the answer is "testing termite baits for their ability to remove and keep termites out of pseudo houses" then the answer is the concrete block/slab experiment, but these would have to be modified to employ the monitoring and redeployment strategies of actual bait use and account for incursion of termites that have not been subjected to bait treatment. The two methods have two different objectives and are best for these objectives. Both methods are expensive and to a certain extent unfeasible.

It was suggested that the directed creation of colonies using pine logs or alternatively large buckets filled with boards would enable identification of a well-defined colony. Tree sites for *Coptotermes* could be used as small-scale model. These tests would not be a perfect model for house infestation but they do provide a well defined target and could be used to test the population suppression ability of a bait.

It is, however, unclear what the guidelines should be for the population suppression test. (Suppression could be low at 100% of the stations, or 100% suppression of activity of only 75% of the stations) A consensus on what levels of suppression constitute population effects should be considered and defined within the guideline. The Panel did not come to any conclusion as to what the number should be. However, there appeared to be some support of total suppression of the activity by a baited colony at 80% of the sites of a baited colony over the period of one year.

(e) what modifications or additional tests could be recommended to improve small-scale field testing.

The Panel agreed that it was important to put some distance (20 feet or more) between the bait and the independent monitoring device. There is a need to define an appropriate metric for performance of a population test as suggested above, perhaps along the lines of: Elimination within a year, no return from the same colony in a year, 80% success. One of the key problems with the small scale field test is with eventual loss of dyes and low percentage of populations dyed. Re-invasion of bait stations fairly quickly could be from undyed individuals of the "baited" colony or represent members of another colony. There is expectation of high failure rates unless one can differentiate between the colonies and all methods of delineating colonies should be available to differentiate between the two situations. All field tests measure activity, not mortality. Therefore the standard metric must involve some level of reduction in termite activity. Some Panelists felt that the bottom line is the cessation of all activity at the target sites. The

Panel also discussed the need for control sites to account for possible seasonal/environmental cessation of activity but did not come to consensus on what the controls should consist of. One Panelist suggested an assessment of times to new feeding activity on the stake in an area that had been vacated because of baiting. There was general agreement that control areas should be of sufficient distance from the treated area to ensure that there was no effect by the treatments. Mark-recapture trials have been done before the pesticide is applied, but they mark only a relatively small proportion of a total colony. DNA technology is in its infancy but if it could be successfully applied to termites it will help to accurately identify colony membership.

It was suggested that laboratory tests with whole colonies could be used to determine the colony level effects of baits. However, there was general agreement that laboratory colonies were not very representative of field colonies. Moreover, laboratory colonies of *C. formosanus* are slow to grow from primary reproductives and do not readily form secondary reproductive individuals in laboratory settings, making the use of defined laboratory colonies very difficult for this species.

There was also a recommendation to use techniques to encourage colony formations of uniform size in prespecified locations by using split logs buried in the field.

A related question that was not asked is "Do either of these tests provide the best information and the most appropriate information needed to inform the decision on an Experimental Use Permit". It seems clear that the combination of laboratory experiment and small-scale experiment data represent the bulk of information used to inform the decision to allow an Experimental Use Permit. The laboratory data informs us that the matrix in which the toxin is placed is palatable and possibly preferred by foraging termites of the target species, and that the active bait ingredient when placed in the matrix material at some appropriate concentration will be collected/consumed by the foraging workers. With modifications of the laboratory tests one can show that the foraging workers can transmit the bait material to the target life stages and that these target life stages will respond as expected. The small-scale field study should inform us that the bait material when properly placed will be collected/consumed by the foraging workers and transmitted to the target life stage individuals in the colony and that sufficient material will be transmitted in this way to adversely affect the whole colony, eventually destroying some significant part of the colony or the whole colony. Both laboratory and small-scale experiments must be replicated enough times to provide acceptable confidence that the effects noted are not random but the result of the bait treatment. With additional information in efficacy of any associated barrier treatments to be used in conjunction with the baits, one has enough information to decide on an Experimental Use Permit.

One Panel member suggested that each colony be considered as the experimental unit, with each successful elimination of a colony by the bait considered as a successful simple experiment. Once these simple experiments yield enough information the overall experiment can be stopped. It was noted that if the experiment is performed during drought conditions, it may be difficult to get colonies to feed on the bait or to find colonies at all.

It was suggested that EPA consider testing guidelines from other countries as models, in particular Australia, although the Australian termite situation is quite different from that in the United States.

There was considerable confusion among Panelists as to whether the proposed guideline as written is truly a tiered program. Will laboratory information be submitted for a pass/fail before moving to small-scale studies that will then be pass/fail? This issue should be defined in the guideline. The Panel noted that most registrants would have already conducted sufficient laboratory scale data before embarking on the path to small-scale field testing.

The Panel agreed on the need to differentiate between failures in small-scale field tests due to recolonization by the baited colony and invasion of territory by a previously unbaited population. Until definitive methods are available to differentiate among colonies infesting the bait/monitoring station, it is recommended that some population of individuals be collected and preserved in alcohol for later testing using more refined DNA testing.

Since dyes will disappear from termites after just a few months, the only reliable method of separating colonies will be to collect termites and to catalog them. If problems (i.e., > 20% failure rate) arise thereafter, then the registrant should be given the opportunity to utilize all techniques available in an attempt to resolve discrepancies.

The geometry of placement of baits within the "polygon" delineated in the population management test is unclear and should be defined. Results of the baiting in such a test will be related to the number of active stations and consequent bait consumption. Several Panel members felt the guideline should state a minimum and/or maximum number of stations per active monitoring site (area) and should relate to an actual number of bait stations per unit area.

One discussant stated that these small-scale field tests are to determine if a bait can kill a colony and thus the tests should be designed with this stated goal in mind. The control and treatment plots must clearly be of sufficient distance apart that there is no linkage between colonies. One Panelist suggested the use of a checkerboard type design, with baited areas lying between adjacent unbaited territories. One could then look at the rate of reinfestation. However, the logistics of such an approach would be more suitable and feasible with respect to testing for *Reticulitermes* vs. *Coptotermes* . There was no significant discussion about the dimensions of the layout nor about what metric should be met with respect to achieving success using the time to reinfestation type approach.

If EPA does select to utilize the concrete block/slab system, the units should be sited in such a way that each unit is associated with its own unique colony and provision should be made to supply sufficient bait material to the individual colony to achieve rapid colony mortality.

Question 3 The draft guideline presents a method for field tests using existing structures and buildings. The evaluation criteria presented in the draft guideline are based on the presumption that termites must not infest a structure for a structure to be protected. The evaluation criteria presented in the draft

guideline is based on visual inspection of structures for termite infestations, use of monitoring devices (acoustical emission devices, microwave devices, bait stations and bucket traps), and measurement of wood consumption before and after termite bait treatment at bucket traps or other non-bait product monitoring stations (independent monitors). The performance standards for remedial and preventive treatments at existing structures are presented below.

The product performance standard for remedial treatments should include elimination of an existing termite infestation in 12 months or less in 100% of the structures treated and the treated structure must remain termite free for 12 months following treatment. If termites are not detected from structures but remained active in the monitoring station or independent monitor (IM), then structural inspections every month are needed during the 12 month period. After baiting eliminates the infestation in the structure based on a structural inspection but the activity resumes during the 12-month post-baiting observation period at the monitoring station, additional bait application has to eliminate termite activity within 12 months at the station and IM following the re-application of baits without causing >10% of the maximum wood consumption as recorded in the IMs during the pre-baiting period. After the re-application of baits, termites should remain absent for another 12 months in the structure and IMs.
Preventive treatment tests must prevent structural infestation by termites in 100% of the structures for the duration of the field test, for a minimum of five years, as measured by 60 months of termite activity at the monitoring stations/bucket traps/wood stakes. Alate swarms, mud tubing, and presence of worker or soldier termites in or on the structure are indications of a termite infestation and can indicate the failure of a bait product to protect a structure. Please discuss:

(a) the criteria used in the selection of a structure for testing, the number of structures that should be included in each test, the bait placement intervals around the structure, and the applicability of the method for the different species of termites.

Criteria for selection of a structure

Remedial - Termiticide history

Houses selected for remedial treatment should have a known history of termiticide application. Structures without any past termiticide treatment would clearly be the preferred ones. Cases of past applications of organochlorines should be excluded. Through consultation with USDA Forest Service and other relevant bodies, it should be ascertained whether 5 years after application of a repellent insecticide (synthetic pyrethroids) the residual repellency of the insecticide has fallen to a level that no longer affects termite behaviour and hence the success of the baiting program. Otherwise, the period before such houses can be included in the program may have to be extended, at least in some parts of the US (assuming climate has an impact on the

length of the efficacy period). Houses treated in recent years with non-repellent insecticides (such as imidacloprid, fipronil or chlorphenapyr) or other termiticides (excluding fumigants) should also be excluded from the trial. Data from USDA Forest Service and other sources will have to be used to determine the length of the exclusion period for any of these products.

Analysis of soil samples from the perimeter and below the structure may have to be used to determine whether inclusion of a structure with past termiticide treatment can be justified. This is especially pertinent for organochlorine treatments.

The Panel noted that termites may enter a building through a limited breach in or bridging of a termiticide barrier. Targeted bait placement may eliminate the infestation. However, such cases would be unsuitable to use subsequently for longer-term preventive bait system evaluation [see Note under F (1), p. 17 of draft guideline] since the otherwise intact termiticide barrier will affect termite behaviour and may be the dominant factor over the bait system in protecting the structure.

Remedial – Termite presence

The Panel agreed that an infested structure should be defined as one with one or more of the following present: live termites in structural and other wood (sills, beams, door frames, skirting boards etc.), mud tubes with live termites inside (active tubes) and/or presence of and/or a report of a recent (past year) swarm.

Preventive

The option of converting a successful remedial bait treatment into a longer-term preventive one was discussed and found acceptable by most Panel members as the most appropriate way to evaluate the efficacy of all features of a bait system. If new constructions (the label may specify "for the prevention of termite damage to new constructions") were taken in areas with termites present in the surroundings, there is no guarantee that such a structure would ever be attacked by termites. Data from other parts of the world indicate that the likelihood of termite attack in a structure increases with the age of the building. An assessment period of five years may not bring the structure within that increased risk age; hence the fact that a structure remained termite-free for that period may not be attributable at all to the monitoring and bait system.

The Panel noted that termiticide history and other factors may restrict the number of houses that could be included in the trial. Soil cores may need to be taken to determine residual levels of insecticide if the structure has a past history of treatments.

Geographical distribution of EPA structures

The Panel recommended the inclusion of northern inland sites where termite activity has greater seasonal limits than at the recommended southern and more coastal test regions. Determination of bait treatment success may take longer and be more difficult to achieve at the former sites [refer also to Public Presentations by S. Jones (Ohio State University) and R. Rosenberg and L. Alonso (National Pest Management Association)]. It is also noted that the criteria for success of bait system applications may vary to some extent with geography (climate).

While it may be true that the main market for termite management products is in southern and coastal regions, hence a greater emphasis on those parts of the US for bait system evaluation, the needs of consumers in other regions of the US with termite problems will also have to be addressed adequately by this guideline.

Number of structures that should be included in each test

The number of 500 structures each for remedial and preventive is considered very excessive. There are too many practical constraints which would be difficult to meet: finding so many suitable houses (the number of houses to look at initially would be well in excess of 500, but many would not qualify); cost (only a limited number of larger companies would be able to afford such an evaluation); huge demand on research and pest control operator time (preventive treatment evaluations will have to run for 5 years). Such an excessive requirement may seriously stifle the process of bringing innovation in termite management to the market place.

Depending on label specifications, a breakdown of the number of structures has to consider:

- Geographical region: has to include not only currently listed EPA preferred test regions but also sites in central and northern US.
- Termite target species: if a general claim of efficacy against "subterranean termites" is made, then all target species as detailed in the guideline will have to be adequately represented; otherwise only sites with the species listed and within their respective distribution range.
- Main construction types.

One Panel member suggested general sample sizes of 100 to 200 structures each for remedial and preventive treatments (assuming a label claim against subterranean termites in general). If the position is accepted that remedial bait application has to precede preventive ones, only one set of buildings will have to be included.

The Panel consensus was that the issue will have to be re-visited by the EPA (in close consultation with biometricians), taking into account considerations of minimum sample sizes required to produce statistically significant outcomes and the practicalities of EPA house assessments.

The Panel noted that depending on label claims, in some scenarios the sample size may be relatively small, i.e. for a product that has a geographic restriction or targets only a certain species of termites.

Bait placement intervals around the structure

Bait placement should follow label instructions, which as a rule may ask for regular intervals but may also include the placement of additional bait stations at targeted positions (i.e. placement of extra stations at points where termites enter/have entered or are likely to enter a structure etc.). The latter can significantly increase the efficacy of a bait system as studies and practice by pest control operators indicate.

Comparisons of regular, or regular + targeted, or targeted placement of stations may prove invaluable in developing and improving a bait system and its label specifications. However, at least the independent monitors should be placed not only at regular intervals but at targeted positions to increase the likelihood that remnant or re-occurring termite activity is detected.

Some Panel members commented on the importance of having research staff and industry (producers and practitioners) working together in evaluating a given bait system around houses. Evaluations around houses should not just follow label specifications but they are also the opportunity to develop further, improve, and fine tune the bait system and the relevant specifications. If EPA's evaluation of a bait system would be the first opportunity after the laboratory and small-scale field trial for a bait system to be assessed in "real life", then one cannot necessarily expect that the label specifications are correct, and therefore, house evaluations are the opportunity for fine-tuning the specifications. Hence there has to be room for some flexibility. The guideline may be too restrictive in its current form. Local circumstances, individual work practice and experience of the pest control operator, and input from the producer and others should be allowed, as long as all activities and circumstances are properly documented.

Applicability of the method for different species of termites

The procedures as described in the guideline were developed by researchers for species of *Reticulitermes* and *Coptotermes formosanus*. The EPA will have to consult with researchers working with *Heterotermes aureus* in order to find out to what extent the methods are suitable for this species.

(b) whether the evaluation methods and criteria for detecting termites in and around existing structures are consistent with the state of the science for assessing termite activity. Would another measure be more informative and useful for the guideline.

Methods for detecting termites in structures

Detecting termite activity inside a structure is a difficult task. The guideline lists many of the tools of the trade. Because none of the methods is completely reliable, all of the currently available methods (i.e., infrared technology) should be listed as options for the detection of termites within the structure. A combination of as many methods as possible should be used. However, there is no substitute for getting dirty and crawling every last inch to find termites. A record of termite activity inside the structure should include any one of the following: presence/absence of live termites, presence/absence of newly-built mud tubes, and report of swarms inside the structure. A report of a termite swarm must be accompanied by a sample of swarmers (alates), as most homeowners cannot differentiate between ant and termite alates.

Methods for monitoring termite activity

It was recommended that, on the day the first quantity of treated bait is provided to the termites, the structure should be inspected, and all visible evidence of live termites removed (i.e., remove

all visible mud tubes, so that if tubes show up later, during the 12-month period when they should be eliminated from the structure, they should be considered as new and the termites in the structure as active). Another option is to record the location and extent of building activity (i.e. take a photographic record) and leave such sites undisturbed except for confirming, by gently probing, whether such constructions have termites present or not. Intense disturbances may result in termites shying away and re-directing their activity to other parts of the construction/surroundings. The less termites are disturbed, the better.

For mark/release/ recapture studies the dye Sudan Red is unsuitable. It does not persist, is mildly toxic, and is difficult to see in red clay soils found in many states.

The marking program is very prescriptive and also very intrusive, resulting in significant disturbance of termite activity ["Termites may be removed from bait stations containing active ingredient…" (p. 21 of guideline)], thus impairing the baiting process. Bait stations with the active ingredient should be the least disturbed components of the monitoring/baiting program. They ought to be used as self-marking stations, and presence of dyed termites should only be monitored at the independent monitors (for establishment of the territory occupied by the target colony). Commercial bait stations (which are to be used) often contain inadequate amounts of food. Hence, bait stations may not necessarily present a "valuable" resource termites want to adhere to and return to after disturbance.

In general, for any monitoring and marking programs, allow for <u>flexibility</u> of placement of independent monitors and bucket traps to suit local circumstances, staff resources etc.

The Panel expressed concern that the marking/recapture process is too involved and will add considerably to the overall effort and cost. Taking and analyzing DNA samples is the most reliable and least intrusive way of establishing colony identity and complexity of the population of termites inside the structure, at bait stations and independent monitors at any given time. DNA sampling should become a key method in the monitoring process. It may make the mark/recapture process redundant.

Another matter for concern was that placing independent monitors and bucket traps for mark/recapture as part of the evaluation process would alter the environment around the buildings. These measures may increase overall termite activity at a building, and thus increase the rate at which termites will find the monitors and the active bait stations, as prescribed by the label for the bait system, compared to standard applications of a bait system where the extra monitors and bucket traps (extra food sources) will be absent. In other words, the outcome of applying a bait system in the monitoring program might be more positive than it would be in reality. In order to address this concern, a site could be monitored very carefully before the baiting program starts, as follows: remove monitors that are extra to the ones prescribed by the bait system; allow the treatment to take its course; and, after a given interval, inspect and monitor very carefully. In a given region compare the success rate of such homes with those that have the full monitoring program as per EPA guidelines.

For the evaluation of remedial installations [p. 22 (v)] note that in some bait systems, matrix with the active ingredient is incorporated into the bait stations only after termites are present in the bait station.

The value of measuring wood consumption was questioned. It is highly variable and can be influenced by a number of factors (i.e., effects of climate – drought versus wet years – on the level of foraging activity at a given time) and may not necessarily reflect changes in feeding activity due to baiting. ASTM ratings and/or photographic records may suffice for comparison of activity prior and post baiting. These data will have to be considered only in conjunction with other measures of changes in termite activity (see above).

(c) whether the product performance standards are appropriate to show if termite bait products work successfully when applied at existing structures.

General considerations

Several public presentations and Panel member comments stressed that after successful elimination of an infestation from a structure through baiting termites can readily re-appear at and in such structures, depending on circumstances, even within a few months. The re-invaders can either be remnants of the original colony or originate from a new colony that has expanded its territory into the area that became vacant after elimination of its original occupants, or belong to a different species of termite. Termite foraging and population biology are very dynamic. A baiting program can reduce and even eliminate termite numbers around a structure at a given point of time, but it cannot prevent termites from re-entering at a later date.

A good analogy is found with drywood termites. Fumigation will eliminate the infestation, but will provide no protection beyond the time of fumigation. The structure can readily be re-colonized by drywood termites. Likewise, aerial infestations by the subterranean termite *Coptotermes formosanus* in high-rise buildings can be eliminated through fumigation. Again, this treatment is not a preventive measure, re-infestation is readily possible.

The other important point to keep in mind is that termites can bypass bait stations (currently the guideline appears to assume that any re-invading termites may appear first, or even only at, the bait stations). However, the structure itself may be the most attractive target for the termites. But even if termites appear first at bait stations or simultaneously at baits and in the structure, it can take some time before the termites are affected by the active ingredient and the re-invaders are eliminated. In that period of time some damage to the structure or consumption of wood at monitors will have to be expected.

The success or failure of a bait system, assuming an efficacious active ingredient, will largely be a function of how well the bait stations intercept termite activity (importance of targeted placement!), how much active is removed and actually enters the termite population within what time period, and the frequency and intensity of the inspections, of both the monitors, bait stations, and the structure.

In light of these considerations, the Panel agreed that the proposed performance standards appear to be set too high.

Remedial treatments

Length of evaluation

It is recommended that termite activity be followed for three years, not five as currently proposed in the guideline. This appears to be a holdover from the 5-year residual activity thinking based upon liquid treatments. Published literature attests to the fact that the evaluation of bait efficacy for eliminating an infestation inside a structure can be fully answered in a 3-year study.

Different periods for determination of success of bait program may be required depending on the geographic location of the structure. For example, houses in the northern inland US, with a shorter season of termite activity, may require lengthier monitoring before success can be claimed compared for example to sites in the southern US. Again, some flexibility in the guideline is required to take account of local circumstances.

Success rate

Performance standards as written in the draft guideline are currently 100%. No product can achieve 100% success and therefore no bait system could be registered based upon this rigid standard. The performance requirements should be somewhere between 80 and 100% protection, for example 80% in the first year, 90% in the second year. The Panel generally agreed to a 90% standard for remedial treatments.

Preventive treatments

There was substantial discussion among the Panel concerning the requirement for preventive treatment but no final position was reached. As previously indicated, use of bait systems as a preventive measure appears to be a holdover from the liquid barrier treatment concept which should not govern the approach to assessing bait systems. The view emerged that if remedial treatments could eliminate termite populations from around a structure then the preventive treatments could also do the same thing. First one could consider the time taken to become pest-free, then the time taken to remain pest-free. Once reappearance of termites at baits or reappearance in the structure has occurred, it is largely a maintenance issue.

The process of elimination and reoccurrence could potentially be expected to repeat itself several times within the 5-year evaluation period. If remedial treatment proved successful with a given bait system within the requirements of the guideline, the pattern of reoccurrence of termites during the 'preventive phase' of the evaluation may not necessarily be taken as an indication of failure, but rather as a guide to modifying aspects of the label specifications to achieve earlier detection of re-infestation and more efficient elimination of re-infestation. For example, inspection schedules, targeted placement of baits, provision of active matrix right from the start or after termite contact in the bait stations, could be revised based on the data.

Note in this context also the point from the biometricians on the Panel that the "period for which a structure remained termite free" could be taken into account, rather than considering such cases as failures if they do not meet the 5-year target.

Preventive bait treatments over time really consist only of monitoring and dealing with repetitive cycles of infestation and elimination of infestation in the structure and reducing the termite population around a structure, thus reducing the risk of re-infestation. However, bait systems cannot protect a structure in the same sense that a chemical or physical barrier can. The EPA will have to re-assess its approach to claims of 'preventive bait systems'.

One Panel member, who supported the complete removal of preventive bait evaluations from the guideline, stated that the most important component of this guideline should be to determine the impact of a registrant's candidate bait on groups of related termites only after they find and eat the bait.

(d) Termite bait technology is based on a sophisticated knowledge and understanding of termite biology and foraging behavior. Many regulatory Agencies at the State and Federal level are concerned about homeowner use because of structural damage that could occur if an application is not done correctly. Should the guideline recommend field tests designed to evaluate the performance of termite bait products following homeowner applications?

The guideline as written seems to indicate that it was designed to test the products and not the quality of the applicators (homeowners in this case). These products should be evaluated with the same methods and be subject to the same assessment criteria as other bait systems. The Panel agreed that bait applicator should not be the variable under evaluation. Better education and labeling should be included, but should not be part of the product efficacy testing.

Question 4 **Please provide comments on the clarity, accuracy and completeness of the draft Termite Bait Testing Guideline. In your comments, please provide a supporting discussion that highlights any areas of the draft guideline that may need to be clarified and relevant topics that may be missing. Include references to any published literature that could help improve the completeness and clarity of the draft guideline.**

There was apparent consensus that the document lacked clarity and, generally, that specific protocols were not necessary although at least one member of the Panel thought that specific detailed protocols should be contained in the document, especially for the laboratory tests.

There was Panel consensus on the following:

a) **General format was difficult to follow**.
An example of an alternative format (Outline) of the document was given:

1.
    1.1
    1.2
2.
    2.1
    2.1.1
    2.1.2
etc.

b) **There was also consensus that the intent and purpose of various items and issues in the document were not always clear.**
The issue of "remedial treatments" vs. "protective treatments" is an example. The only difference in the protocols for the two was the presence (remedial) or absence (protective) of termites in the structure at the start of the test. One member suggested that properties enrolled in "remedial treatment" tests (termites in structure) could also serve as demonstration of "protective treatment" (termites not in structures but nearby) once the infestation was eliminated from the structure. This point led to the issue of "Pre-treatments". "Pre-Treatments" were not mentioned in the document, and were presented only after discussion on the issue of "remedial" vs. "protective" treatments was debated at length. Some members of the Panel did not recommend baits for pretreatments. The Panel seemed in full agreement that baits could be tested and eventually used both remedially and protectively in post-treatment of structures. Again it was presented by at least one member that protocols for both were essentially the same. Demonstration that termites are removed from the structure in 12 months or less (remedial) and that the structures remain free (protective) from inhabitation by the same colony of termites for at least another 12 months would prove the remedial and protective claims of the bait product. If during the test termites reappeared in the structure and evidence was provided that they were from the original colony, then it would be concluded that the remedial test failed. If the re-infestation was by a different colony, it is necessary to demonstrate its elimination (protective) from the structure, which should remain free for an additional 12 months. The Panel agreed that baits do not inherently "protect" a structure from an invasion by termites, as might be expected of a fully active protective barrier (liquid treatment). The effectiveness and efficiency of bait technology are determined by the potential of the bait to kill all members of the colony; those directly feeding on bait stations as well as nest mates. It is this characteristic "to kill" that renders bait technology suitable for remedial as well as protective treatment of structures.

c) **Laboratory, Small-scale field tests, and Large-scale field test**.
Other examples of the confusion within the document were the protocols and descriptive titles given to the three levels of testing for baits in the document. Most members agreed that detailed protocols were not necessary in the document, especially for the laboratory

tests. Generally, the Panel suggested that the document should contain clear descriptions of the expected performance of the bait, with less emphasis on specific protocols at the various levels of testing. The guideline should clearly identify and differentiate performance criteria for the testing levels. The Panel agreed that 100% over five years was an unrealistic expectation of the performance of a bait product. Ninety percent for three years was generally what was suggested.

Laboratory testing should demonstrate: 1) efficacy (toxicity, mode of action ((biochemical, developmental and behavioral)), 2) lethal rates and time, amount consumed, 3) palatability, 4) acceptance of the bait as a competitive foraging site, and 5) primary (those feeding directly) and secondary kill (nest mates not feeding on the bait product). It was noted that no one test (especially the one in the draft document) has been designed to provide complex data set needed to address all of these questions.

One member suggested that "small-scale field testing" was not appropriate terminology. The protocols for concrete blocks were considered flawed and possibly misleading with regard to expected performance of potential bait. The concrete block tests were for testing residual activity of soil termiticides. Baits do not provide residual activity. They provide protection because they kill and thereby eliminate colonies. Perhaps an alternative terminology for "small-scale field tests" might simply be "Field tests". The purpose of these tests should mostly be to test the ability of the bait product in question to suppress/eliminate a colony or colonies. The protocol could specify infested structures in an urban setting or it may specify a field, savanna or forest with no structures where there is an identifiable area of termite foraging activity. The test protocol should specify techniques for trapping, marking (dye) and identifying (molecular, not cuticular hydrocarbons) specific colonies and their foraging territories. Voucher specimens should be collected and preserved. The parameters (specific activity) i.e. amount of bait consumed, number of foragers present, etc. should be specified. Since various forms of activity (not mortality) are ultimately being recorded, and since termite activity in the field is seasonally dependent, the protocol should require at least two complete cycles of foraging activity.

Alternative terminology for "Large–scale field test" might simply be "Experimental Use Permits". All of these tests should require infested structures and may also have specifications for the presence (not required) of termite activity (colonies) surrounding the test structure but not infesting it. Techniques for trapping, marking (dye) and identifying (molecular, not cuticular hydrocarbons) specific colonies and their foraging territories should be described. Voucher specimens should be collected and preserved. The Panel agreed that 500 structures were too many and suggested 150 to 200 structures were sufficient to demonstrate product performance. Again the requirement for 5-year duration was considered too long. A period of time (two to three years) that included two to three periods (seasonal) of activity was suggested. The Panel cautioned that strict adherence to requirements for EPA regions for location of tests were not reasonable. More appropriately the requirements should be for representative regions (various climates) that included the distribution of the species of termite in question.

In Summary:

- The guideline lacked clarity and was too verbose.
- The guideline need not specify protocols; only the specific data required to support claims. Several members recommended that the guideline allow flexibility with the choice and development of study protocols.
- Some members suggested that a three-tier testing system (Laboratory, Small-scale field tests, Large-scale field test) might not be necessary. Some believed that the laboratory and large-scale field test (EUP's) were the most critical for registration. It was suggested that laboratory studies were more in the domain of discovery by the manufacturer and specific laboratory protocols should not be in the guideline.
- The requirements for 100% performance for 5 years were excessive.

General Recommendations:

- Amend the guideline and allow for another period of public comment.
- Eliminate block/slab protocols from the guideline.
- Clarify and be specific about intent and purpose of each testing level in the guideline. Allow flexibility in choosing appropriate treatment protocols. Certain techniques should be described, but methodologies should not be limited to those contained in the guideline.
- Be specific about the nature of data required to support claims intended for the label. If for example "colony elimination" is claimed, the registrant should be required to demonstrate with a statistically valid sample size complete cessation of termite activity for at least two consecutive active periods in a pre-described foraging territory.

APPENDIX

One Panel member (Dr. Dan Suiter) provided the following detailed comments to be presented to the Agency for their future consideration:

I. On Preventive Treatments: Justification for Their Removal from Guidelines

Based on what scientists have learned in the past few years about termite biology, it is probably not possible to create a permanent termite-free zone around structures with the use of termite baits, or any technology for that matter. But it is clear that we can reduce termite populations around structures with the use of baits. It should be noted that before the introduction of termite baits into the marketplace that there did not exist a single technology that provided for significant reductions in termite forager populations in soil around structures. At any rate, strong evidence is emerging, both here and abroad, suggesting that when termite colonies are eliminated or suppressed significantly with a bait treatment that the foraging dynamic of local colonies (i.e., other colonies of the same species and other colonies from different species) is altered. It seems that unbaited, and thus unrelated, colonies may take advantage of foraging resources and territories left unexploited by the now extinct group of termites. Indeed, the foraging dynamic of subterranean termites is very plastic.

The underlying assumption throughout the guideline that the populations of termites that surround a structure are somehow destined to infest that structure is not scientifically sound. A structure's susceptibility to attack is dependent on a number of variables, some we are aware of and have researched and some we have undoubtedly not yet discovered. For instance, a building's construction type is one variable that certainly impinges upon a structure's susceptibility to attack by subterranean termites. The "preventive", or "risk reductive", nature of termite baits is that they reduce, by population management, that structure's risk to termite attack by reducing the source of the risk—that is, the termites. This is the essence of preventive termite control. To assume that every structure will eventually be infested is not good science.

The guideline penalizes a bait product that remains active after installation in a preventive manner, even when no termites have been found in the structure. I maintain that the presence of feeding termites in bait stations on the outside of a structure is a good thing, not a bad thing. It reduces risk.

The most important component of the guideline should be <u>to determine the impact of a registrant's candidate bait on groups of related termites only after they find and eat the bait.</u> If, for example, in small-scale field tests it was determined that bait XYZ eliminated/suppressed colonies of termites when they ate enough of it, then it is not unreasonable to expect a similar fate from a colony that consumes the bait in a preventive scenario around a structure. Furthermore, a structure with fewer termites around it today compared to last week is better off in light of termite infestation. But, to maintain that the structure is unprotected even when no live termites can be found inside the structure (the ultimate and only determination of a failure) is not reasonable.

Finally, based on the argument put forth above I strongly urge the Agency to remove from these guidelines experiments where the preventive nature of termite baits are being evaluated. Again, the focus of these guidelines should be the determination of the impact of a registrant's candidate bait on groups of related termites only after they find and eat the bait.

II. On Determining the Relatedness of Termites in Monitors after Elimination in Small-Scale Field Test Method #3

The remedial evaluation criteria for success of small-scale field test method #3 states that "The bait should eliminate a termite infestation from the wood in the monitoring devices within twelve months of bait station application with the pesticidal active ingredient using the methods described in this guideline in 80% (4 of the 5 colonies of each species in the field plots). In addition, each replicate should be termite-free for 12 months following cessation of termite activity" This situation presents a potential confounding situation because the guideline does not specifically exclude the infestation of the six-board sandwich in bucket traps by termites from an unrelated colony of the same species or from a colony of a different species. This is important because fat-soluble dyes are not likely to remain in a termite fat body for more than a few months after feeding. In the southeastern U.S., for example, it is common to have three *Reticulitermes* species present in the same area. Small *Reticulitermes* colonies throughout the southeast are common, and researchers have shown that different colonies of the same species, and even different species, will visit and use the same food resource (wood block). With the requirement that no termites return to a previously-connected bucket trap/six-board sandwich for a 12 month period, baits will be unfairly penalized for events (i.e., visit to a wood monitor by termites that did not eat the bait) that cannot be controlled. Termites showing up in a bucket trap within the 1-year period would cause that particular replicate to "fail" to meet the guidelines' criteria, even if the termites were unrelated to the group that was originally baited. The guideline should only address what happens to individually-baited groups of related termites, and should be focused on whether or not consumption of the candidate bait eliminates the colony or not.

To remedy the above situation, I propose that termites be collected (at least 15 soldiers and 50 workers in 100% ethanol) from a Nile Blue dye-connected bait station or six-board sandwich (1) the day bait is first introduced into a bait station, and (2) each time termites are found in a monitor (bucket trap/six board sandwich) during the period that all stations are required to remain free and clear of termites; this process would be required for the small-scale field test. This process would do a couple things. It would protect the registrant from false positive results of a termite return and it would bolster the Agency's claim that baited termites did or did not return during the specified time period.

A Comment on Colony Differentiation Techniques: Determining whether termites are from the same foraging group is not a straightforward undertaking. In the context of the above scenario, researchers would need to be able to differentiate not only between species (a difficult, but manageable task) of termites, but also between colonies of the same species (a more difficult challenge). Generally, cuticular hydrocarbons can be used to differentiate species only, but not colonies of the same species since cuticular hydrocarbons are generally thought to be species-specific, not colony specific. The same can be said of morphological keys—they, of course, can

separate species (based mainly on soldier and or alate morphology), but cannot separate colonies. The use of termite-termite agonism (in the current context, the contention that termites from different colonies always show aggression towards one another) is not foolproof, and has been challenged in recent years as being somewhat unreliable. Ultimately, being able to sort out the relatedness of groups of termites will best be achieved with the use of molecular tools supported by data from the tools described above. As we learn more about the social structure and mating habits of subterranean termites we may one day be able to differentiate between related and unrelated termites with a higher degree of certainty than we currently enjoy.

III. On Large-Scale Field Tests: Sample Size and Performance Standards

I suspect the answer to the question "Does a candidate bait remedy a structural infestation of termites?" can be answered with much fewer homes than 500. The methods described herein to evaluate the remedial nature of baits around structures are very labor intensive and require a meticulous attention to detail. The requirement of 500 structures would tax the termite research community beyond what they're capable of providing. There are operational difficulties in working with so many homes. For instance, for each home in the study, I would guess that three would need to be inspected before one was found that qualified for the test (i.e., an existing infestation [active mud tubes, recent swarms]). Additionally, many homeowners, for a myriad of reasons, drop out of studies that are long-term. Finally, the cost (time and money) required to collect data from 500 structures will do more to hurt consumers than help them. With so many structures required for field evaluation, it is possible that we might not ever see any new termite baits enter the marketplace, or at least none that had been field-tested.

Might I suggest these numbers: 100-125 structures tested remedially against the most widespread termite in the U.S., *Reticulitermes flavipes* (20-25 from each of the following five EPA regions: Region III [DE, DC, MD, PA, VA, WV]; Region IV [AL, FL, GA, KY, MS, NC, SC, TN]; Region V [IL, IN, MI, MN, OH, WI]; Region VI [AR, LA, NM, OK and TX], Region VII (IA, KS, MO, NE); and 50 structures against *C. formosanus*.

According to the guidelines, the evaluation of a remedial bait treatment at structures is based on the reduction through time of three response variables:

(1) the proportion of active independent monitoring devices (i.e., any combination of at least two of the following: wood stakes driven into the ground, modified wood stakes that fit into the registrants bait station, and blank bait matrix placed in the registrants station) placed every 6 feet or less around the structure's perimeter and within 1 meter of the wall;
(2) quantity of wood consumed by termites at several established bucket traps (in addition, the quantity of wood consumed from modified wood stakes that fit into the registrants bait station and/or quantity of blank bait matrix consumed may also be reported); and
(3) termite activity inside the structure (i.e., presence/absence of live termites in walls, presence/absence of newly-built mud tubes, and report of swarms inside the structure [must be accompanied by a sample of swarmers, as most homeowners can't differentiate between ant and termite swarmers]).

I recommend that the day the first quantity of bait is provided to the termites that the researcher inspect the structure and remove all visible evidence of live termites (i.e., remove all visible mud tubes, so that if tubes show up later, during the 12 month period when they should be eliminated from the structure, they should be considered as new and the termites in the structure as active).

Since the methodology (in the paragraphs above) involved herein is generally beyond the scope of termite technicians employed by the pest control industry, I recommend that all large-scale field trials be conducted in cooperation with University-based research and extension programs, or their professional equivalent (consultants, technical directors, government scientists, etc.).

I propose that activity be followed for 3 years, not 5 as is currently in the guideline. Published literature attests to the fact that the evaluation of a bait's activity can be fully answered in a 3-year study.

I suggest that some baseline of activity be established before baiting is initiated. For instance, the structure would have to have been inspected at least once (for qualification) and at least two inspections would need to have been executed to determine a baseline for wood consumption rates in bucket traps (and similar devices) and the proportion of independent monitoring devices "hit" by termites.

Product Performance Standards for Large-Scale Field Tests. Instead of the criteria "...remedial treatments should eliminate an existing termite infestation in 12 months or less in 100% of the structures treated and the treated structure must remain termite free for 12 months following treatment", I suggest changing this to "....remedial treatments should eliminate an existing termite infestation in 12 months or less in 90% of the structures treated and the treated structure must remain termite free for 12 months following treatment". Remedial treatments with liquid termiticides rarely provide 100% termite control. Why should baits?