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The Federal Insecticide, Fungicide and Rodenticide Act and Its Impact on the Development of Wood Preservatives

Registration Requirements

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An overview of FIFRA and its recent amendments and their impact on the registration requirements for wood preservatives. New amendments and statues have been passed in response to societal concerns and technological advances that have impacted on how EPA reviews pesticide products. This paper will discuss some of these amendments/statutes and their impacts on the registration of wood preservative products.

The Environmental Protection Agency (EPA) regulates the use of pesticides under the authority of two federal statutes: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). These statutes are the basis of the Agency's regulatory authority as it applies to pesticides. The authority to establish tolerance or exemption from

tolerance originates from the FFDCA. And the authority to regulatory pesticides is given to the Agency by FIFRA. In carrying out its responsibility, the Agency has promulgated rules that define its process and the responsibilities of the Agency as well as those of the regulated community. In these regulations, the requirements for issuing a registration, for restricting a registration, and for canceling as registration are defined. The regulations are further clarified by the use of Pesticide Registration Notices. These statues have been amended through the years to reflect the concerns of society regarding the use of pesticide and the exposure to pesticide residues from registered uses.

The Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes EPA to set maximum residue levels or tolerance (the legal amount of residue contamination in or on foods and feeds as a result of a pesticide use) for each pesticide and its toxicologically significant residues which may be in or on foods or animal feeds as a result of the registered uses. The Federal Food, Drug, and Cosmetic Act also allows EPA to exempt pesticides from the requirement of a tolerance. Exemptions are allowed with those pesticidal chemicals or formulation chemicals that demonstrate little or no risk (reasonable certainty of no harm) from the residue levels associated with the pesticidal use. [(1)]This Act defines the rule-making process required in set tolerances or exemptions from tolerance. Compared with FIFRA, FFDCA normally does not take into consideration the benefits received from the use of the pesticide. However, it can in limited extreme circumstances. In order to establish a tolerance, or to exempt from a tolerance, for a pesticidal chemical the FFDCA requires the Agency to reach a finding that there is reasonable certainty that the tolerance or exemption from tolerance will result in "no harm". In reaching its decision, extra consideration must be given to protect infants and children. The FFDCA requires that a tolerance or exemption from tolerance be established prior to registration.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provides EPA the authority for regulation, sale, distribution and use of pesticides in the U.S. The Act authorizes EPA to require the appropriate data necessity to reach its regulatory decision on a use-by-use basis. The Federal Insecticide, Fungicide and Rodenticide Act requires that all pesticide products must be registered before they can be manufactured, distributed for sale or sold. In registering pesticides, the Environmental Protection Agency (EPA) is required to take into consideration the risks posed by the pesticide to society and the environment compared to the societal benefits achieved from its use. That is, any risk to society and the environment as a result of exposure from the use of a registered pesticidal chemical and/or its residues or metabolites must be out-weighed by the benefits achieved from the use of the pesticidal chemical. In order to minimize risk from a pesticide, the Agency can regulate the pesticide product through use restrictions, labeling, packaging, composition and disposal. The Act also allows the EPA to ask for additional data (i.e., Call-in) in order to better

understand the risks and/or exposure associated with a pesticidal chemical's use.*(1)*

Over the years, FIFRA has been amended in order to address new scientific technology or societal issues. "Passage of the 1972 amendments to FIFRA enacted through the Federal Environmental Pesticide Control Act*(2)* (FEPCA) was part of a wave of environmental legislation which completely overhauled Federal environmental regulatory authority."*(3)* "The Endangered Species Act (ESA) of 1973 prohibits any action that can adversely affect an endangered or threatened species or its habitat. In compliance with this law, EPA must ensure that use of the pesticides it registers will not harm these species."*(4)* "The Food Quality Protection Act (FQPA) of 1996 amended FIFRA and FFDCA. These amendments fundamentally changed the way EPA regulated pesticides whose uses may result in residue of the pesticide chemical or its toxicologically significant metabolites in or on food or feed. The requirements included a new safety standard of "reasonable certainty of no harm" that must be applied to all pesticides used on foods.*(5)* "The Pesticide Registration Improvement Act (PRIA) establishes pesticide registration service fees for registration actions carried out in the three pesticide program divisions: Antimicrobials, Biopesticides and Pollution Prevention, and the Registration Divisions."*(6)*

These amendments have had varying impacts on the registration process and data requirements. The Endangered Species Act mainly altered the way the supporting fish and wildlife toxicity data submitted to support registration of a technical chemical is used. The Food Quality Protection Act significantly altered the Agency's tolerance setting process with its impact on the data requirements in order to make a finding of "reasonable certainty of no harm" prior to establishing a tolerance or an exemption from tolerance. Also, the FQPA amendments require EPA to make expedited decisions on antimicrobial pesticides. The Federal Environmental Pesticide Control Act (FEPCA) and The Pesticide Registration Improvement Act (PRIA) had substantial impact on the data requirements and costs association with registration of a pesticidal chemical. These two amendments are worth discussing in depth because they have significant impact on the cost of registration.

The Pesticide Registration Improvement Act changed the relationship between EPA and the regulated community. This legislation authorized EPA to recoup the cost of its review process from the applicants requesting registration. The amount of fee is determined by the nature of the registration activity being requested. Basically, costs increase with the more complex applications (i.e., more supporting data and use of more Agency scientific resources). Associated with the legislation is the fee associated with every category of registration action and the corresponding decision time period allotted to the Agency to reach a regulatory decision on the action. The goal is to create a more predictable evaluation process for affected pesticide decisions. The legislation also promotes shorter decision review periods for reduced risk applications.

*(7)*Reduced risk initiative was required by the FQPA amendments to FIFRA. This initiative mandates expedited reviews for applications for registration and amendments to registration for pesticides that may reasonably be expected to reduce risks from pesticides to human health or nontarget organisms, to reduce potential contamination of groundwater, surface water or other value environmental resources, or to broaden or make available integrated pest management strategies.

To initiate the process, the applicant must demonstrate how the use of the proposed registration or amendment of their current product registration may reasonably be expected to meet the above criteria. The information demonstrating how a product meets the above criteria is called the Reduced-Risk Rationale.

The Agency has defined all the factors that must be addressed in the reduced risk rationale package. If all these factors are not addressed, the request for reduced risk review is considered by the Agency to be incomplete. The documentation must discuss the inherent properties of the new product that leads to the reduced-risk, as well as a comparison of those properties to commonly used alternatives if appropriate. The complexities in drafting a reduced-risk rationale often are best left to those with extensive experience and knowledge of the registration process. The applicant is notified no later than 30 days after receipt if the submission is complete.

The Pesticide Registration Improvement Act was a joint effort that involved the regulated community, concerned citizen groups, and the Agency. In anticipation of PRIA, the regulatory service fees were determined based on the amount of Agency resources utilized for a given type of action. The list of actions and the related fees are published and available from the Office of Pesticide Program's web site for fees. These fees range from $1,000.00 for a product that is identical in all respects to one already registered to $525,000.00 for a new active ingredient requesting experimental use permits and temporary tolerances. For wood preservation products, fees can vary depending if the product is used for control of microbes or for control of insects. The Federal Insecticide, Fungicide and Rodenticide Act contains language that permits those chemical wood preservatives used against microorganisms to be considered as an antimicrobial product reviewed in the Antimicrobial Division of the Office of Pesticide Programs (OPP). Conversely all other chemical wood preservatives would be considered conventional chemicals reviewed in the Registration Division of OPP. From the fee structure in place, a new wood preservation active ingredient for use out doors reviewed in the Registration Division would require a fee of $330,000.00. Whereas a new wood preservation active ingredient for use out doors reviewed by the Antimicrobial Division would only require a fee of $150,000.00. It will not always be easy to discern exactly what registration fee is attached to wood preservation chemicals. The Agency has

recognized this problem, telling applicants not to send money until the Agency determines the appropriate category of action and invoices or bills the applicant.

The Pesticide Registration Improvement Act also recognizes that for a small company the registration fee may be so prohibitive as to put the company out of business. In certain cases, the Agency will waive or reduce the fee for service. The Federal Insecticide, Fungicide and Rodenticide Act, Section 4 (i)(5)(E)(ii), defines small business as a legal entity with 500 or fewer employees and 3-year average annual gross global sales from pesticides are $60,000,000.00 or less. Gloss global sales are the total sales of the applicant and all affiliates. The Agency will waive 50% of the required fee for those entities the meet the above criteria. It will waive 100% of the required fee if the 3-year annual average of gross global sales from pesticides is $10,000,000.00 or less. A request for waiver from the fee for service must be appropriately documented.

The Federal Environmental Pesticide Control Act of 1972 drastically changed the way pesticides were being evaluated in the registration process. With the passage of FEPCA, FIFRA was changed to an Act not only concerned with the efficacy and safe use of a pesticidal product by the consumer but also concerned about societal and environmental health and risks. For the Agency to approve a pesticide product registration not only did the product require proper labeling for efficacy and consumer safety, it had to demonstrate that it would not pose an environmental or health related risk greater than the societal benefit achieve by the use of the product. FEPCA required the Agency to define by regulation how it would do business: It required the Agency to delineate its data requirements and the registration, reregistration, and classification procedures among out processes. The expansion of the data requirements and reregistration had substantial impact on the regulated community. "Before pesticides can be marketed and used in the United States, EPA evaluates them thoroughly to ensure that they will meet federal safety standards to protect human health and the environment. The process of registering a pesticide is a scientific, legal, and administrative procedure through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and the appropriate storage and disposal practices. Pesticides that meet the requirements are granted a license or "registration" that permits their distribution, sale, and use according to specific use directions and requirements identified on the label.

In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. The producer of the pesticide must provide data from tests done according to EPA guidelines and carried out according to the EPA standards of Good Laboratory Practices."*(7)* As required by the FIFRA, the Agency has published the list of data needed to support registration of a pesticide chemical or product according to major categories of use (i.e., in-door non-food, in-door food, terrestrial non-food, etc.). These lists are given published in 40 Code of

Federal Regulations (CFR) Part 158. Data lists are given for the conventional chemical pesticide, for the biochemical pesticide and for the microbial pesticide. The data lists indicate whether the data in required or conditionally required. Within each type of pesticide, the list is further differentiated by scientific areas such mammalian toxicity, fish and wild-life toxicity, plant protection (non-target plants), non-target insects, residue chemistry, environmental fate and transport, spray drift, exposure and product performance. Each scientific area requires data that will allow the Agency to estimate the hazards associated with the pesticide chemical and its uses and the exposure to the hazards from the various uses. The end-result is an Agency calculation of the estimated over-all risks associated with a given pesticide for a given use. Theoretically, the data lists in 40 CFR Part 158 are to assist and enlighten the regulated industry as to the data that would be required to support the registration of a new pesticide chemical or of a pesticidal product. However, this is not the case.

Inherent in developing the database to support the registration of a pesticide is the risk of what the data may or may not demonstrate. Toxicity studies, such as teratogenic, reproduction, chronic feeding, or carcinogenic studies, require several years and many thousands of dollars to run. The results of which may demonstrate a hazard that, because of the exposure, will result in unacceptable levels of risks or margins of safety. Or toxicity to fish, other wildlife, and non-target insects and plants could results in limiting the extent of one's planned uses. These studies could demonstrate effects that are totally unacceptable to EPA. Even though, a chemical may not demonstrate any toxicological significant risk, the product efficacy field testing may not demonstrate the same degree of effectiveness as was demonstrated under laboratory conditions. It is very important to have a research regimen and in place that allows for critical go or no go decisions early in the development process.

Because of the inherent investment risks and costs involved with the development of new pesticidal chemicals, most companies are not equipped financially, physically or technologically to undertake chemical development. Companies most apt to develop new pesticide chemicals are aligned with the agricultural industry and therefore only remotely connected to silvaculture. New pesticide chemicals are developed for the major agricultural markets (i.e., field crops and orchard crops). They are not interested in small specialty markets. Therefore most companies selling to specialty market hope to piggyback on the already registered chemicals.

Even this approach is not without its risks and difficulties. Generally new pesticide chemicals are protected by patents or by the exclusivity provision of FIFRA. The primary producer must want to work with another company to share their data and knowledge about the pesticide. Often, this is not the case. Unless there is a desire to transfer new technology into the smaller market, it is unlikely the small market will receive it until patent and exclusivity rights of the chemical producer have expired. Even then, the company wishing to piggyback

must develop the additional data to support the proposed uses. The inherent investment risks in developing new data also becomes an issue as mentioned above

As stated above 40 CFR Part 158 lays out the data needs for several different broad use scenarios. The list indicates whether the data is required, conditionally required or required for an experimental use permit (EUP). In the list of studies in 40 CFR Part 158 there is an indication what the test substance must be. Some studies are carried out on a technical grade of the active ingredient, the pure active ingredient, the end-use product or a typical end-use product. The studies lists are footnoted to clarified when a conditional study must be carried out. Because the variety of chemical pesticides and uses, 40 CFR Part 158 does not covered every use scenario and is difficult to interpret, with many studies, if a study is really required. The advise of a consultant is often useful in determining a basic test regimen of testing. Discussions with EPA personnel regarding the testing regiment may be warranted. Notwithstanding all the safe guards to ensure the all the correct data are available at time of the submission of the application, EPA may require additional data after reviewing the original application.

In registering a new pesticide chemical, it is necessary to have answers to several preliminary questions. The questions relate to formulation, the application technique, claimed protection and use of the treated wood. First, what formulation or formulations you want to register? Second, are you planning to apply the pesticide chemical by spray, brush, or soaking, by pressure treatment or any other technique? Third, what claims will you be making for the treated wood? And fourth, is the treated wood to be used indoors, outdoors, for food or feed contact surfaces, for soil contact or buried in the soil? These questions determine what kind and how much data are required.

If I as a chemical producer wished to register a pesticide chemical for pressure treatment to protect wood used for bulkhead structures from the attack of marine organisms, I can look in Appendix A of 40 CFR 158, *DATA REQUIREMENTS FOR REGISTRATION: USE PATTERN INDEX,* to determine what general use pattern indicates under item 8, Wood or Wood Structure Protection Treatments fall within the general use pattern a Domestic outdoor or indoor. However, Appendix A also indicates that boat bottoms and other submerged structures fall into the general use pattern of Aquatic Noncrop. Without past experience or input from a knowledgeable person, it is not clear what data are needed based on the general use pattern. Because of the impact on the aquatic environment, EPA would consider this an aquatic use.

If the producer, after searching the Appendix A, sees item 8, makes a determination that the proposed use fall in the general use category as a outdoor noncrop use. Then, using 40 CFR Part 158, the database that EPA expects to be submitted with an application for registration can theoretically be determined. The required data can be divided into those data developed on the pesticide

chemical, per se, and those data developed on the formulated product as sold. The difficulty encountered using 40 CFR Part 158 is it was developed with agricultural pesticides as the model and not with wood preservatives. Hence interpretation is not easy and often requires professional guidance from consultants and EPA.

The chemistry data requirements are discussed first in 40 CFR Part 158. The EPA requires information on the product composition, a description of materials used to product, a description of the production process and the formulation process, a discussion of formation of any impurities, a preliminary analysis of the pesticide chemical. Certified limits of the ingredients in the pesticide product and an enforcement method for determining the active ingredient in the product. The EPA also requires a number of physical and chemical properties of the pesticidal chemical and of the formulated product. Many of the required studies, such as preliminary analyses, storage stability, and chemical stability, are required to be carried out under EPA's standard of good laboratory practice regulation. With a new pesticide ingredient, EPA requires the submission of a chemical standard.

The data requirements listed under the residue chemistry section of 40 CFR 158 are very confusing to the uninitiated, especially to a person not in the mainstream agriculture chemical business. The data lists indicate that the chemical identity, direction for use, residues in potable water and residue in fish are required. The chemical identity applies to the technical grade of the active ingredient and direction for use covers the end use product. The information discussed in the above paragraph is being requested again with labeling. The other two studies are not required if the pesticide is not directly applied to way. That is fairly straightforward. But would the study be required if the treated lumber was used in a fish farm? The answer to this question is it depends on the nature of pesticide chemical. It is not always clear if a study is or is not needed. EPA might require this data or additional information on the nature of the residues in the wood; their capability to leach into the water; or the concentration of residues immediately around the submersed lumber.

In the environment fate data requirements, the difference in data requirements between the use category domestic outdoor and aquatic non-food is significant and more costly to carry out. Both use patterns require a hydrolysis study and a leaching and adsorption/desorption study. However, the domestic door use only requires an aerobic soil metabolism study and a field dissipation study. Whereas the aquatic non-food requires a photodegradation in water study, an aerobic aquatic metabolism study, an aquatic soil (sediment) dissipation study. Should the wrong decision be made concerning the use pattern, studies might be carried out that are not required. Or the use of the treated lumber might require data to support both the domestic outdoor or aquatic non-food.

The data requirements for toxicity studies are generally straightforward regarding a technical product or end use product. The database for these products is generally known as the "six pack." Six toxicological studies needed to support primarily the labeling of the product formulated for distribution and sale. They are the acute oral LD_{50}, the acute dermal LD_{50}, the inhalation LC_{50}, the primary eye irritation, the primary dermal irritation, and skin sensitization. The inhalation study is not required for product that does not produce a respirable vapor or is not sprayed. For products that have a pH less than 2 or greater than 10, the pH may be used as the basis for requesting a waiver of the primary skin and eye irritation studies. Products on the extremes of the pH scale are known to be very corrosive. The skin sensitization does not need to be run if the product is not formulated with any known sensitizers. These studies are also used in the over all risk assessment performed by EPA. The remainder of the toxicity studies listed in 40 CFR Part 158 relate to the active ingredient, per se, and normally the responsibility of the primary producer of the chemical. For a new pesticide chemical used in wood preservation for submerged structures – this would be a chemical never before seen by EPA – the data requirement are extensive and not as straightforward. Normally EPA would expect the six-pack of acute studies a battery of mutagenicity studies (gene mutation, structural chromosomal aberration & other genotoxic effects). And, if the chemical is neurotoxic, EPA requires a delayed neurotoxicity study. The remaining toxicity studies may be required depending on exposure or toxicity findings. Only with expert advice and consultation with EPA is one reasonably certain that a study is not needed.

The exposure issue associated with the treatment and use of treated lumber is critical in determining what conditional studies will also be required to support this use. If wood treaters might be women of child bearing age or the treated lumber might be used in a manner the women of child bearing age could be exposed or used around residences or public facilities, EPA would likely want to see a dermal exposure study, a teratogenicity study in one species and a 12-month chronic feeding study. Depending on the results, other toxicological studies or exposure studies may be needed.

In use exposure studies, per se, are not a direct requirement of FIFRA. These exposure studies are requested or carried out if there is a toxicological end-point for which the margin of exposure (MOE) is approaching the target of 100 or unacceptable to EPA. EPA normally uses a computer model (PHED Version 1.1) for assessing human exposures during pesticide handling activities in the absence of exposure data.*(9)* An applicant with approval from EPA may design a study that reflects actual exposures occurring during various uses of the treated material.

Studies required by FIFRA to enable EPA to evaluate potential effects to fish and non-target organisms (Plants, birds, mammals, etc.) are develop in a three tier progression. Tier one contains the basic data requirements. These

data are the same for domestic outdoor and for aquatic non-food. They are an avian acute oral LD_{50} study, two avian dietary LC_{50} studies, two fresh water fish LC_{50} studies, and a freshwater water invertebrate LC_{50}. However, in our example the treated wood will be used in a marine environment, therefore EPA may require data in species other than those given in 40 CFR part 158 or EPA may require additional studies be carried out using marine organisms. Clearly, early outside consultations are important, if the goal is to have a cohesive and complete database to support the application for registration.

And, lastly, with a new pesticidal active ingredient, EPA requires product performance data. The nature of the performance data required must address the manner in which the chemical is applied (i.e., dip, brush-on, sprays or pressure treatment). Modifications of the Stake method, Ground board method, and the modified ground board method are acceptable. There are no recommended protocols to study the effectiveness of wood treatment of infested lumber or wood treatment for above ground uses. Protocols for these studies should be pre-approved by EPA prior to initiating the study. The data must be obtained from 3 geographically located sites where there is year round pest pressure. The data must show complete resistance to termite attack for at least 5 years. If acceptable data shows effective for at least 2 year but less than 5 years, the product may be registered based on a labeling statement that require annual inspection.*(9)*

It is becomes quite obvious that the time, costs and risks active ingredient are very high in bringing a new pesticide chemical to the market place. Strategic planning for the regimen of data is critical. There must be in-place criteria guiding a decision to stop the development or to continue with additional studies. The cost of developing a database to support registration of a new pesticide chemical continues to rise well into the 10's of millions of dollars. To save costs, a decision to stop the development project needs to occur as early as possible. And it needs to be made based on the results from either preliminary investigations or on the results obtained in ongoing studies. Because of the high financial risks involved, this approach is not viable for small market products.

A less timely, costly or risky approach to registering a new pesticide chemical for wood preservation is expanding the use patterns of an already registered pesticide. If a currently registered pesticidal chemical is identified as having those properties necessary for use by the wood preservation industry, working with the manufacturer or registrant of the chemical, a smaller database would have to be developed. Given the extensive database already developed, a much clearer picture of the additional data needs can be derived. Also, the impact of the additional exposure on the chemical's MOE's from the proposed expanded new wood preservation uses can be determined using the available database. This calculation allows the developer to know whether EPA would accept the propose uses or if a safe use issue might arise.

Most companies in the wood preservation field are not prime manufacturers of the pesticidal active ingredient. They desire only to obtain registration for an end use product that they can distribute and sell in their normal channels of distribution. Although this is less daunting than registering a new active ingredient, it can be extremely frustrating for the neophyte. The application has to meet EPA criteria for acceptability. Many times, just getting in the proverbial door can be a challenge. After months of receiving rejection after rejection, the registrant will turn to a consultant to assist in the paper work alone. So let's review a typical end use product registration requirements.

An application for registration must have all the appropriate forms. There are six forms that must be required:

The application form gives EPA pertinent information about the product (such child resistant packaging, the various sizes of packages, the similarity to currently registered products, etc.). The application form also must give the service fee classification and the fee for the purposed registration.

The confidential statement of formulation that gives EPA information about some physical characteristics and identifies each of the ingredients in the product along with the percent by weight for each. The percent by weight is given for the nominal concentration and certifies the upper and lower limits for each ingredient.

The formulator's exemption statement form that states the applicant is purchasing and using a registered manufacturing use product. The purchased product is identified by name and EPA Registration Number.

The certification as to the citation of data form tells EPA how the applicant is supporting the registration. The FIFRA requires that each pesticide product registered by EPA be supported by its own database. There are several ways this can be accomplished. There is the cite-all method of support, the selective method of support, and the selective method with cite-all for some of the data. These methods of support will be discussed more in-depth later in this paper.

The Data Matrix form delineates the data identified in 40 CFR Part 158 as being required to support the registration of the pesticide product. The form requires the applicant to identify who submitted the data and the status of the data. The data may be from the public domain (i.e., scientific journals, government publications, etc.) or old data (data submitted to EPA 15 or more years ago) or exclusive use data (data submitted to support a new active ingredient can only be used with the expressed written consent of the owner for 10 –13 years following the date it was first registered). There is also a form that is releasable to the public with most of the above information blacked out.

The last form is the certification of the physical chemical properties. The applicant indicates to EPA that there exist test reports for each of the end-points given. These report are available and can be sent to EPA for review if required. This form is must be included in the Report B – Chemical/Physical Properties Report.

Let us back up some and discuss the actual database needed to support an end-use product. Based on 40 CFR Part 158, the database that may needed to support registration of an end-use product is shown Table I:

Table I Registration Data Requirements for an end-use product

OPPTS GUIDELINE NO.	*STUDY TITLE*	*OPPTS GUIDELINE NO.*	*STUDY TITLE*
REPORT A: IDENTITY, COMPOSITION AND ANALYSIS		*GROUP B – PHYSICAL CHEMICAL PROPERTIES (CONT.)*	
830.1550	**PRODUCT IDENTITY AND COMPOSITION**	830.7100	**VISCOSITY**
830.1600	**DESCRIPTION OF MATERIALS USED TO PRODUCE THE PRODUCT**	830.6319	**MISCIBILITY**
830.1650	**DESCRIPTION OF THE FORMULATION PROCESS**	830.6320	**CORROSION CHARACTERISTIC**
830.1670	**DISCUSSION OF FORMATION OF IMPURITIES**	830.6321	**DIELECTRIC BREAKDOWN CONSTANT**
830.1700	**PRELIMINARY ANALYSIS***	*TOXICITY STUDIES*	
830.1750	**CERTIFIED LIMITS**	871.1100	**ACUTE ORAL TOXICITY – RAT***
830.1800	**ENFORCEMENT ANALYTICAL METHOD**	871.1200	**ACUTE DERMAL TOXICITY***
GROUP B – PHYSICAL CHEMICAL PROPERTIES		871.1300	**ACUTE INHALATION TOXICITY – RAT***
830.6302	**COLOR**	871.2400	**PRIMARY EYE IRRITATION – RABBIT***
830.6303	**PHYSICAL STATE**	871.2500	**PRIMARY SKIN IRRITATION***
830.6304	**ODOR**	871.2600	**DERMAL SENSITIZATION***
830.7200	**MELTING POINT**	*PRODUCT PERFORMANCE*	
830.7220	**BOILING POINT**	810.3600	**STRUCTURAL TREATMENTS**
830.7300	**DENSITY, BULK DENSITY, OR SPECIFIC GRAVITY**		
830.7840	**SOLUBILITY***		
830.7950	**VAPOR PRESSURE***		
830.7370	**DISSOCIATION CONSTANT**		

*Study must be carried out in accordance with Good Laboratory Practices (40 CFR Part 160)

In developing the application package, each one of the data points should be address. If the data are not needed, the application should give the reasons why. The footnotes in 40 CFR Part 158 gives the conditions requiring the data. Some data may be waived. In these cases, the basis for requesting a waiver from the data requirement must be presented.

As stated above, there are two ways FIFRA recognizes as acceptable means to meet these requirements: the Selective Method and the Cite-All Method. One can also use a combination of the Selective and Cite-all Method to support an application for registration. Each of the support methods needs to be discussed.

The Selective Method of Support tells EPA what studies you want the Agency to use in support of your product. An applicant can carry out each study on the proposed pesticide product and submit the results to EPA. This is the cleanest way of supporting the registration of a pesticide product. However, there are costs associated with this approach. There are the costs of the studies themselves and the cost associated with the time to obtain the final reports and for EPA to review the results. The second way, an applicant can meet some or all of the requirements, is identifying a study EPA has in its files for each requirement. These must be studies carried out on a product that is substantially similar to your product or a plausible explanation must be given to EPA why the identified can be used to support your product. Also, understand that data submitted to EPA is compensable for 15 years from the date the data were submitted. Consultants familiar with the EPA and its workings can be an enormous assistance to someone not fully versed in FIFRA and pesticide registration. And finally, an applicant can develop some of the data, identify available data and use Cite-All for the remainder.

The Cite-All Method tells EPA to use whatever data it has in its files to support the application. This method is often seen as a blank check approach. As discussed in 40 CFR §152.86, the user of Cite-All must certify that he has make an offer to pay to each and every person on the Data Submitters List regarding the chemical of question. He must indicate a willingness to enter into negotiations over the cost of the data. And the user of the Cite-All Method also acknowledges that the application relies on all data submitted with the application and any previously submitted data. Previously submitted data must be concerned with properties or effects of the applicant's product, or an identical or substantially similar product or on any of the active ingredients in question. This method of support is extremely useful in shortening the time to obtain a registration provided there are identical or substantially similar products already registered. The down side to the Cite-All is the mandated negotiation with a possibility of binding arbitration concerning the cost of using someone's data.

In summary, the data requirements for any pesticide product can be determined from 40 CFR Part 158.

EPA's pesticide laws include provisions to ensure the protection of fish and wildlife. EPA requires and evaluates extensive ecological effects test data before

registering a new pesticide or reregistering an existing pesticide. Therefore, EPA already performs much of the scientific analysis that the Services perform in the consultation process.

Under the ESA, and in consultation with FWS and NOAA Fisheries, EPA must ensure that its regulatory actions are not likely to jeopardize threatened and endangered species or destroy or adversely modify their critical habitats. EPA's pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of nontarget species. Because endangered species need specific protection, EPA has developed risk assessment procedures to determine whether individuals of an endangered species have the potential to be harmed by a pesticide, and if so, what specific protections may be appropriate.

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