Appendix C: A Discussion to Address Your Concerns: Will Herbicides Hurt Me or My Lake?

Bernalyn D. McGaughey: Compliance Services International; bmcgaughey@complianceservices.com

1. Our lake is pristine and we don't want to put dangerous chemicals in it. Why should we use herbicides now?

A pristine lake is balanced, stable… and very rare, especially when lakes are surrounded by homes or used for recreation. The lakes we live near and play in are often inundated by excess nutrients and foreign and invasive species. Most water bodies that require herbicide treatment have experienced explosive growth of invasive aquatic plants. While your lake may seem natural and pristine, there are sufficient nutrients in the water to allow exotic weeds – which don't belong in the lake – to dominate the system. Control of these weeds will enhance plant diversity and water quality (both of which are degraded by dense weed growth) and will help restore the overall health of the lake.

Your lake association or responsible public agency has evaluated all the options for aquatic plant management and has decided that the most effective means of controlling weeds at this point is to use herbicides. The herbicides that will be used are biodegradable and will not affect the pristine nature of the lake in the long term. When used by professionals according to label directions, herbicides are not "dangerous chemicals" but instead are curative products that have been extensively tested and can effectively control nuisance and invasive aquatic weeds.

2. How dangerous are these chemicals? How do we know they're safe?

Interestingly, aquatic herbicides are one of the smallest niches of specialty weed control products (Chapter 11), yet they are also among the most extensively tested. Because these products are added directly to water, the EPA requires extensive data to assess the safety of a herbicide before it can be registered for use in aquatic systems (Appendix A). Many years of testing and use have shown that registered aquatic weed control products can be used safely in all areas of the US. In addition, many years of safety and monitoring tests in the laboratory and in the field have been conducted to determine exactly how a given product should be used in a particular situation. It is also important to remember that the treatment level (or concentration in water) of a herbicide is typically much lower (100- to 1000-fold more dilute) than the concentration that might be harmful to you, your pets or nontarget organisms that live in the lake.

The data required by the EPA for registration of an aquatic herbicide are generated in studies that are conducted according to stringent protocols of conduct, design and evaluation. For example, a single study is conducted using a testing guideline that describes the number of organisms that must be tested, how they are housed and even the temperature and daylength under which the organisms must be maintained. The test is also governed by a series of "Standard Operating Procedures" that have additional parameters for testing and documentation. The guidelines for the test are further supported by a "Standard Evaluation Procedure", which outlines the criteria that must be met in order for the study to be defined as "acceptable." The EPA toxicologist produces a "data evaluation record" for the study and ultimately classifies the study as acceptable or unacceptable for incorporation into the risk assessment process. In a parallel requirement, the Standard Operating Procedures mentioned above must be conducted following formal "Good Laboratory Practice" requirements as outlined by the EPA. Good Laboratory Practice Standards are validated through both internal and external audits. Once a study has conformed to all of the requirements for study acceptance, data generated by the study are combined with data from all other acceptable studies of the herbicide and a risk assessment profile is developed.

The risk assessment process is complex and requires identifying which studies should be integrated into the hazard and exposure evaluation process. The 84 to 124 different studies required for registration of an aquatic herbicide take from 6 to 10 years to complete and are integrated in a robust scientific assessment that is evaluated by the EPA in a process that can take an additional one to three years before labels are approved.

3. Do these herbicides break down in the environment? I realize the herbicides themselves have been evaluated by regulatory agencies but what about their breakdown products?

Identification and evaluation of the components into which a herbicide breaks down is a critical and required part of the data that must be submitted as part of a product's registration process. Degradation and metabolism pathways must be studied and the molecules that are produced along those pathways must be identified. If any molecules are believed to be "of toxicological concern" (and there is a definition for that), then those molecules must be tested as well, both alone and in combination with the original or "parent" molecule.

Testing of breakdown products is not limited simply to toxicity; breakdown products must also be evaluated for their persistence in the environment. In addition, the mechanism (light, heat, microbial action) that produces them and acts to further break them down must also be understood. The final fate of the parent and breakdown products must be completely identified, reported and understood by chemists and toxicologists. Additionally, there are flagging criteria that are used to put "stop lights" on certain uses or environmental introductions of herbicides. These "stop lights" can be associated with direct toxicity, persistence, bioaccumulation or other important environmental and toxicological properties of the pesticide. If a product is flagged by one of these "stop lights" during testing, the company developing the product (especially one that will be used in water) may reconsider whether to proceed with the high cost of registration if there is a good chance the product will not successfully make it through the registration process.

4. If the chemical companies do the research and submit their data to the EPA, isn't this like the fox guarding the henhouse? Their data may be falsified!

With the current regulatory standards and rigor of EPA review, it is virtually impossible to falsify the data supporting a product. Companies submitting studies must certify that they are conducted in accordance with EPA regulations for good laboratory practices and usually hire independent quality assurance scientists to conduct audits as the studies are performed. In addition, the EPA has established a random laboratory and study audit program. This program has the authority to audit laboratories that conduct studies in support of pesticide registration and companies that sponsor them and can randomly select submitted studies for auditing. It must be possible during this audit process to confidently recreate the entire study from the "raw data" (laboratories are legally required to maintain all data for any submitted study on which registration relies). If a problem is found or the results cannot be reconstructed, not only is the study rejected for regulatory use, but the facility conducting it or the company sponsoring it is likely to undergo a more complete audit of all studies conducted during the same period, at the same facility or on the same product. Penalties for falsifying studies can be severe and include fines and/or imprisonment.

5. If herbicides make up only part of the chemicals that are applied, how do we know whether any other part of the product or its inert ingredients are dangerous?

First of all, let's understand a little bit about herbicide formulations. The chemical that controls the weed, in its pure form, is called the "active ingredient." The technical grade of the active ingredient is used in testing, and that technical grade must contain all those components that are found in the typical manufactured product that makes up the active ingredient. Technical grade chemicals are usually very pure (98%+), but may include additional compounds that are formed as the active ingredient is made. Components in the technical grade product, other than the pure active ingredient, are usually remnants of the manufacturing process, molecules that are impossible to separate from the parent compound, or other unintentionally added ingredients. All such impurities must be identified even if they are present in extremely low quantities. If any are of toxicological concern, they must be removed from the technical product or reduced to levels considered acceptable by the EPA.

Testing with the technical grade of the herbicide will identify toxic and environmental effects that might be caused by the active ingredient itself or any chemical components formed by the active ingredient. The technical grade form of herbicides are too concentrated and are rarely useable as herbicides without some modification to allow proper measurement (dilution by water, clay granules or other solvents or carriers), tank mixing (conditioners, such as emulsifiers, anti-foaming agents or wetting agents), and stability and distribution to the target site (by use of surfactants, drift control agents, dyes or other similar agents) (Chapter 12). The proper addition of these materials to the technical grade product produces an end use formulation, which is what is then purchased and used in weed control. This end use formulation must also be tested, but in a limited way unless the initial tests show that there is a measurable difference in toxicity between the technical product and its end use formulation. If there is a difference, the typical remedy is to change the components of the formulation so that they do not affect the toxicity or environmental characteristics of the end-use formulation.

Collectively, the formulation products discussed above are often referred to as "inert ingredients" because they do not contribute to the activity of the active ingredient. Formulations are considered trade secrets because their components may provide a competitive advantage and will be associated with a brand trademark. As such, the "secrecy" surrounding inert ingredients is one of competition, not toxicological properties. Additionally, not just any compound can be used in a formulation. The EPA requires that all inert ingredients in pesticide products be cleared prior to use and maintains a list of products from which the formulation chemist can choose. If the formulation chemist chooses a product that is not on the cleared list of inert ingredients, then supporting data must also be submitted for that "inert" ingredient. A separate and thorough review process will determine whether the inert ingredient can be added to the EPA's cleared list and safely used in the subject formulation. Incidentally, these inert ingredients are not "secret" from the EPA. Each technical and end use product must be supported by a complete "confidential statement of formula" so that the EPA can evaluate the acceptability of the full product and its additives. The confidential statement of formula is also used by the EPA when random or purposeful samples of the product are pulled from chemical plant distributors or applicators and analyzed for their compliance to the stated formula.

Inert ingredients in products to be used on food (and most aquatic uses are considered food uses due to the subsequent exposure to fish and shellfish, which in turn could be food items for people) or potable water must also have tolerances (allowable dietary levels of the product and any breakdown products of concern) set under the Federal Food, Drug and Cosmetic Act, which is administered by the Food and Drug Administration. Scrutiny of products that are used in, or may reach drinking water sources, is especially intense because the underlying assumption is that exposure could occur over a lifetime, from any and every drinking water source. In the case of aquatic herbicides, this assessment process greatly overstates exposure and thus results in a very conservative risk assessment.

6. When will it be safe for my kids to swim in the water again?

Each herbicide has a specific label statement regarding water use and swimming after weed treatment. Label statements are based on the results of various studies and the risk assessment process described above. Swimming restrictions listed on the label are most often related to the dissipation of the herbicide in water and added "safety factors" that build in at least a 100- to 1000-fold margin between what is observed in studies as a "no effect level" and the potential exposure level when a lake is treated. Therefore, the restriction interval (if any) is related to all studies conducted on the degradation and dissipation of the product and its dermal, oral and dietary toxicity, as well as any potential to irritate the skin or eyes or penetrate the skin. Herbicides that lack swimming restrictions may dissipate very quickly and/or the toxicity of the product at treatment levels is far below the "no effect level" in studies supporting product registration.

7. Will herbicide treatments kill the fish in our lake?

Aquatic herbicides are extensively tested for their effects on fish and other nontarget aquatic organisms. For the most part, these products are relatively non-toxic to fish because their mode of action (the way they affect the target weed) is based on photosynthesis or other plant processes that differ from animal biochemistry. A few types of aquatic herbicides (usually algicides) are toxic to fish at or near treatment levels, but application techniques that provide fish with the opportunity to escape from treated waters can reduce or prevent the loss of fish populations. This information is on the herbicide label; applicators are required to read and follow all label directions and precautions.

The applicator must consider the amount of plant cover and the manner in which it will be treated in his professional assessment of the needs of the lake. Decomposing vegetation can deplete oxygen levels in water, which can cause fish mortality if application precautions are not taken. Extreme infestations of weeds may require treatment of the lake in stages instead of using a single whole-lake treatment. Partial treatment will allow fish to escape to untreated, oxygenated waters as target plants in the treated area decompose.

8. The herbicide label says that the product is "toxic to fish and wildlife." Does this mean the herbicide treatment will kill our fish? If not, why do these chemicals kill plants without harming people or fish?

The statement referenced here historically has been required on a label when a pesticide intended for outdoor use contains an active ingredient with a fish LC50 (acute toxicity level) of less than 1 ppm [equal to one part (or molecule) herbicide per one million parts (or molecules) of water]. "LC50" is an abbreviation for "lethal concentration 50%" and represents the calculated concentration of the substance that is expected to kill 50% of the organisms studied. The standard label statement required in this case is, "This pesticide is toxic to [fish] [fish and aquatic invertebrates] [oysters/shrimp] or [fish, aquatic invertebrates, oysters and shrimp]." Likewise, if the product "triggers" a toxicity level preset for birds or mammals, a similar statement is required. When a pesticide intended for outdoor use contains an active ingredient which has a mammalian acute oral toxicity of less than 100 mg material/kg bodyweight, an avian acute oral toxicity of less than 100 mg/kg, or a subacute dietary toxicity of less than 500 ppm (500 parts of material per 1,000,000 parts diet, by weight), the label must state "This pesticide is toxic to [birds] [mammals] or [birds and mammals]." It is important to note that pesticides with lower LC50 values are more toxic than those with higher values. For example, a product with a toxicity of 100 mg/kg is more toxic than one with a toxicity of 250 mg/kg.

There are several circumstances that can make toxicity to organisms in the field less severe than suggested by the label statement when herbicides are used for weed treatment. Some of these are:
Effective control levels: most aquatic herbicides are applied at rates well below those that would cause fish or wildlife toxicity. This is either because the target weed is particularly sensitive to the herbicide or because the herbicide interrupts a biochemical pathway that animals do not possess.
Application techniques: your professional applicator or supervising state agency knows what precautions to take for products that have a treatment rate close to a wildlife effect level. These precautions can include partial lake treatments; optimal treatment timing at the lowest rate possible; the use of drift control agents; and other informed choices made by the professional applicator.
Dissipation rate: Some aquatic herbicides essentially break down immediately or are rapidly absorbed by plants and vegetative matter. Studies to determine fish toxicity are conducted in pure-water systems (without plants) over a period of several days. Such studies provide comparable standards for judging toxicity and regulating products, but they are not necessarily equal to fish exposure and product toxicity in a natural, living system when a herbicide is used according to label directions.
Sediment binding: Some aquatic herbicides ultimately bind to organic matter, algae and soil particles and partially end up in lake sediments, where they may be metabolized by microbes or made unavailable through the physical process of mineralization. A product that is bound in the soil this way rarely presents a toxicity concern.

9. Is it safe to eat fish from the lake after herbicides have been applied?

No aquatic herbicides currently registered by the EPA have fish consumption restrictions. There are no restrictions because herbicides have established "tolerances" that are set by the EPA and the FDA. Tolerances are boundaries for acceptable levels of pesticide residues in food and are established after review of submitted data and in accordance with the Federal Food, Drug and Cosmetic Act. If an aquatic herbicide has tolerances set for fish, then the label will instruct whether the fish can be consumed immediately after treatment or if there is a waiting period. Where there is no established tolerance (either because the registrant has not sought it or due to the properties of the product), the label will prohibit the consumption of fish from a treated lake until enough time has passed for no residues of the product to be found in fish tissues. Professional applicators are well aware of the restrictions necessary for fishing and fish consumption, as these restrictions are clearly specified on the herbicide label. Applicators are required to post signs or otherwise clearly inform lake users of any water use restrictions.

10. How long does it take for herbicides to break down? Do the chemicals become concentrated in the fish or the sediment of the lake?

There are some specialized terms that will help you understand the metabolic processes that are at the root of this question. They are adsorption, depuration, bioaccumulation and bioconcentration. Adsorption is the manner and rate at which an organism assimilates a chemical into its system, whereas depuration is the manner and rate at which the organism rids itself of a chemical. Bioaccumulation occurs when the rate of adsorption (taking up the chemical) exceeds the rate of depuration (ridding of the chemical) during the period of exposure. When exposure is stopped, depuration continues and the organism will gradually clear itself of the chemical. Some scientists debate whether there is a difference between bioaccumulation and bioconcentration. However, bioconcentration is slightly different than bioaccumulation because the levels of a chemical that bioconcentrates build up and become more concentrated over time. This occurs because depuration is non-existent or very slow, so the organism never clears the chemical from its system and may build up higher and higher concentrations upon every exposure to that chemical. Bioconcentration does not occur in any currently registered aquatic herbicide. A herbicide may have a short bioaccumulation period in edible organisms like fish and in such a circumstance would be labeled with restrictions to prevent consumption until the depuration process has cleared the chemical from the organism's system.

Some aquatic herbicides may accumulate in sediments, but as discussed above, this is typically also associated with sediment binding that limits the biological availability of the product. The EPA takes into account potential accumulation of pesticides in fish and sediment prior to registering any product for use in water. In fact, pesticide accumulation in living systems or the environment is one of the "stop lights" discussed in Question 3 above. It is unlikely that any chemical that bioconcentrates would be registered for outdoor use in today's regulatory environment. It is possible that a product that bioaccumulates might be registered, because in most instances this property can be managed by restricting application rates, treatment intervals and consumption of treated organisms. If risks to man or the environment are unacceptable or unmanageable, then the product simply will not be registered.

11. Are aquatic herbicides carcinogens? Will they give me cancer?

There are currently no registered aquatic chemicals that are classified as carcinogens. The treatment of water systems with herbicides is considered a widespread use with high potential for human and nontarget organism exposure. Consequently, products registered for use in water must present a very low risk profile, even when – in the case of aquatic herbicides – potential exposure to humans is neither pervasive nor long term. Any legitimate evidence of carcinogenicity would immediately put the registration and use of an aquatic herbicide in jeopardy.

This brings up an area that confuses many people – how to interpret different kinds of studies with respect to their validity for use in the "risk equation." A number of factors contribute to the validity of a study, such as the purity and reliability of the test system (contaminants not found in the product or nature, or the use of unusual species or strains of test animals that could create false results), the statistical power of the experiment itself (inadequate numbers of test organisms or improper statistical analysis of results could yield false conclusions), or the route of exposure (an exposure route impossible in nature, such as intravenous injection of high concentrations of chemical). For these reasons, some studies are not used in the risk assessment process, provided there is a body of reliable information that contradicts their findings. In the event a new finding is of concern, the EPA has the means to restrict use, cancel use or put other protective measures in place until additional data are generated or assessed.

12. Plants that have been treated with herbicides rot and sink to the bottom of the lake and cause a buildup of muck. We don't want muck buildup so we shouldn't use herbicides, right?

The best time to treat with herbicides is usually in the spring when plants are very actively growing but still small. This practice results in very insignificant organic matter additions to the lake. Furthermore, research has shown that when the growth of plants is restricted or controlled with herbicides or other means, much less organic matter is produced than if plants are left untreated. Plants that are not managed in some way grow until they reach their full annual biomass and then naturally die back each winter; as a result, all the material produced by a plant over the course of the year is added to the lake annually. By reducing plant growth, herbicide use can actually reduce organic matter production and accumulation. Another factor contributing to "muck" is sedimentation. Dense stands of weeds tend to trap particles suspended in the water column and increase sedimentation or "muck" buildup.

13. I've watched herbicide applications in other lakes and the applicators always wear "moon suits" and all sorts of protective gear even though the label says we can swim and fish immediately after application of the herbicide. This makes no sense – what gives?

Pesticide labels are developed to take into consideration both the exposure to workers (handlers and applicators) and the exposure to the environment. Workers repeatedly handle concentrated herbicides before they are diluted for application. Therefore, applicators are required to wear personal protective equipment to minimize their exposure to high doses of chemical if the chemical properties of the concentrated herbicide pose a risk to them. Herbicides are diluted literally millions of times when they are applied to water and they are usually applied once per season. As a result, the same precautions are simply not necessary for any lake water users who are not repeatedly exposed to high concentrations of herbicides. For comparison, a tablespoon of salt in a batch of yeast dough contributes to the flavor and perfection of the final loaves of bread – but a tablespoon of salt taken alone could be dangerous for you.

14. People used to say that DDT, chlordane and all those other pesticides were safe and now they're banned. Will this happen with more modern herbicides too?

DDT was first registered as a pesticide in the 1940s; chlordane was first registered in 1948. Both of these compounds were insecticides and are in no way related to any currently registered aquatic herbicides. There is absolutely no comparison to the testing standards and regulatory requirements in place today with the meager parameters that were in place in the first half of the last century. Needless to say, our understanding of science, toxicology and the environment has increased tremendously in the last 50 years.

The oldest registered aquatic herbicide appeared first in the late 1950s. Any products surviving since then have been subjected to additional reviews and many additional data requirements, culminating in updated and more rigorous risk assessments, including reregistration. It is a testimony to their safety that, as testing and registration requirements increase, older aquatic herbicides are still in use today. In fact, with the additional testing, many restrictions have actually been removed from older products. Products developed over the course of the last 30 years, during our cycle of increased understanding and advanced science, are designed to have a minimal impact on the environment and are simply not comparable to the "first generation" pesticides like DDT and chlordane. Today's products are developed with the knowledge of their toxicity and impact and would not be registered or commercially developed if they carried a high "risk burden."

15. I agree that we have to use herbicides to get our weed problem under control, but how can we as residents reduce the risks associated with the use of these chemicals?

First of all, by taking the time to read and understand this manual, you have already invested in reducing your own risks, because you now understand the importance of following label directions and the instructions provided to you by your professional applicator.

Second, plan carefully and completely for a herbicide application in the early stages of an aquatic weed infestation so that your lake can be treated at the optimum time of the year with the lowest effective treatment rates, which can reduce the need for multiple treatments. This action will likely provide more effective weed control, reduce costs and lower the total amount of chemical that may be required for adequate weed control.

Additionally, many states have regulatory agencies that conduct additional risk assessments to refine their understanding of product properties as specifically as possible for the conditions in their state. In some cases, specific permits or precautions are required on a treatment-by-treatment basis, thereby further ensuring that lake residents and users understand the restrictions, if any, on the use of the lake or its resources. For example, New York takes an additional precautionary step and adds another layer of protection by restricting swimming in any treated lake for 24 hours after any pesticide application to its waters – even though scientific data, the label and product properties do not call for this additional precaution.

The risk-reducing protections necessary for safe use of a registered product are already in place once the product is registered. All you have to do is follow the label, the instructions of the applicator and any additional local regulations.

16. What exactly is risk? I don't want any risk!

We cannot live in a risk-free environment. Living near a lake is in itself a "risk." Risk, as related to the science of risk assessment, is poorly understood by anyone other than risk-assessment scientists. Most people equate "risk" with "being exposed to a risk", but these are not the same thing. Risk assessors deal with the likelihood (or probability) of an event happening at all, while being at risk is the likelihood of being affected by an event that is known to happen. Thus, the risk assessor will come to a conclusion (for example) that a given dose of a chemical has a one in a million chance of causing cancer, while the statistician following causes of death will report that an individual has approximately a one in four chance of dying from cancer. Two very different endpoints.

When we put actual quantifiable risks in perspective, the risk of harm from an aquatic herbicide (or any pesticide, for that matter) is negligible. The National Safety Council (2005) reports the following:

- The leading causes of death in the US are heart disease, cancer, stroke, respiratory disease and unintentional accidents, in that order.
- Of unintentional accidents, the fourth ranked cause of death is drowning. The odds of drowning in natural water (as opposed to a swimming pool) are 1 in 2,378.

No risk estimate for the effects that might result from exposure to a pesticide even begins to approach this number.

In risk assessment, the end point sought is that the probability of a risk is so low that it is expected to not occur. In risk assessment, "risk" is defined as the relationship between hazard and the likelihood of exposure. When aquatic herbicides are used in a lake, most residents and lake users will have little or no exposure to the product used for weed treatment, based on the application methods, precautions taken and infrequency of treatment. Your risk of suffering from an event related to herbicide use and exposure is miniscule.

17. Does the EPA guarantee that these herbicides are safe?

The regulatory language of FIFRA (Appendix A) actually prohibits descriptive language that would imply any registered pesticide is "safe." In part, this is because "safe" is a relative term that could easily be misleading. No agent, natural or man-made, is completely "safe." Even water, which is essential for life, can be dangerous if too much is consumed because in excess it can disrupt the balance of electrolytes in a living system. Electrolyte imbalance can lead to shock and eventual death if not corrected.

As discussed above, EPA registration requirements and the risk assessment process supporting a pesticide registration are intense and thorough. The directions for use that are listed on the product label take into account risk management measures that are necessary to reduce the risk of exposure to the point where there is no reasonable expectation of environmental or human health effects.

Furthermore, there is now a revolving and formal Registration Review process, assuring that new scientific procedures and risk assessment methods are applied through a revolving process to all EPA registered products over the life of their registration.

18. Who else studies these chemicals besides the EPA?

Chemical use and its effects on the environment are closely scrutinized by many groups, including independent university scientists, state regulatory agencies, environmental groups and even the chemical companies themselves. Additionally, as the world economic and regulatory systems become more global, there is a closer coordination between countries in their requirements for and review of data on chemicals.

There are also protections written into FIFRA with respect to the discovery of previously unobserved effects. If a legitimate finding is made known to the company holding the registration for the chemical, that company must, within 15 days, report that finding and its significance to the EPA. If the EPA deems that the event is critical, it can immediately stop the sale or otherwise limit the use of the product. If the significance of the event is not major, but requires further understanding, the EPA may issue additional data requirements so that the initial finding can be studied and causes for it can be determined. Failure to follow these reporting requirements carries heavy penalties.

19. Big corporations are only interested in making money – they don't care whether their product is safe!

The development, registration and marketing of a pesticide take place in a highly visible segment of business in which relatively few companies compete. Add to that the extra burden of registering products for use in water systems and the general business risk couldn't get much higher. This is a mature industry with extremely high standards, a heavy regulatory obligation and a tremendous amount of exposure. Corporations employ scientists to conduct the research required for pesticide regulation, and these scientists eat the same food and use the same resources that we all enjoy. No company in such an environment would survive negligence, data falsification or poor business ethics. The mistakes of the early years that occurred in an emerging regulatory system and a budding scientific understanding of the environment that surrounds us are simply not inherent to the business today. They are of the past. Today's aquatic herbicide registrants are heavily invested in the safe and beneficial use of their products, environmental stewardship and sustainable practices. They have to be, or they wouldn't be here tomorrow. And being here tomorrow is how they survive, not simply by making money with no future in sight.