HERBICIDE LABELING'

Ken McNabb[2]

ABSTRACT- Knowledge of pesticide law and regulation is necessary for the proper use of crop protection chemicals and to remain vigilant against the potential loss of useful compounds.The principle legal framework for pesticide use is the Federal Insecticide, Fungicide, and Rodenticide Act. There are a number of ways this legislation directly impacts the labelling and use of herbicides and other pesticides in forest tree nurseries.The legislation was modified by the Food Quality Protection Act of 1996. This new law may have serious negative effects on the availability of crop protection chemicals in all areas of agriculture, including nurseries. It is expected this legislation will make pesticides more expensive and less available. Examples are provided of strategies and activities aimed at securing crop protection chemical labels for use in forest tree nurseries.

INTRODUCTION

The use of pesticides is an integral and necessary component in the production of quality seedlings for afforestation. Without crop protection chemicals production costs would increase and seedling quality would decrease. The use of herbicides in particular has had a tremendous impact on seedling cost by reducing the necessity for hand weeding and the improvement of seedling quality through competition control. The availability of herbicides and other crop protection chemicals is controlled by federal and state legislation. Not only is understanding the basics of pesticide law necessary to properly and legally use pesticides, nursery managers also need to follow and keep abreast of trends or changes in the law. Since forest tree nurseries are a very minor use in terms of acreage, they are not given a high priority by pesticide manufacturers or regulatory agencies. Looking out for our own best interest requires a basic knowledge of the legal framework of pesticide registration and regulation.

THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

FIFRA is the principle legislation controlling the manufacture, registration, distribution, sale, and application of pesticides in the United States. This law requires pesticides to be registered (i.e. "labelled") before they can be manufactured and distributed in the U.S. FIFRA also sets up the concept of "restricted use" pesticides whereby the purchase or use of these compounds require training and certification. This law also establishes fines and penalties for using a pesticide in "a manner inconsistent with its labelling". FIFRA is enforced by the Environmental Protection Agency in collaboration with state pesticide regulatory authorities. Originally passed in 1949, the law has been amended several times, most recently by the Food Quality Protection Act of 1996.

There are two sections of FIFRA that most directly pertain to the labelling of herbicides and other pesticides. The main labelling provision of FIFRA falls within Section 3 which is considered the full national EPA approved pesticide label. In order for pesticides to be sold or used in the U.S., the product is required to obtain a Section 3 label. To issue a Section 3 label the EPA must conclude:

1. The composition of the product is such as to warrant the proposed claims for it.
2. Its labelling and other material required to be submitted comply with the requirements of FIFRA.
3. It will perform its intended function without unreasonable *adverse effects on the environment (parentheses* added).
4. When used in accordance with widespread and commonly recognized practice it ***will*** *not generally cause unreasonable adverse effects on the environment (parentheses* added).

To meet these requirements a pesticide manufacturer must submit to the EPA a series of toxicology, environmental fate, and chemical characteristics tests.

The second section of FIFRA which is most directly applicable to the labelling of nursery herbicides is Section 24, or the "special local needs" label. In this case, FIFRA allows that an individual state may provide registration for additional uses of federally registered pesticides. Although the specific requirements for Section 24 labelling will vary between states, there are requirements common to all state procedures: the product must already have a Section 3 national label, the Section 3 registrant must support the special local needs request, a need must be established for the product, crop safety data must be provided, as well as data indicating effective control of the specific pest. All state issued Section 24 labels require EPA approval.

One of the provisions of FIFRA is that the pesticide label is a legally binding document and can be viewed as a contract between the product manufacturer and the user. It is a specific point of the law that a pesticide cannot be used in "a manner which is inconsistent with its labelling". There are six important exceptions to this statement. First, FIFRA

[1]McNabb, K. 1999. Herbicide labeling. In: Landis, T.D.; Barnett, J.P., tech. coords. National proceedings: forest and conservation nursery associations-1999. Gen. Tech. Rep. SRS-25. Asheville, NC: U.S. Department of Agriculture, Forest Service, Southern Research Station: 65-67.
[2] Associate Professor, Auburn University, School of Forestry, Auburn University, Auburn, AL 36649; TEL: 334/844-1044.

provides that a pesticide can be used at a lower dosage than what is specifically mentioned on the label. Second, users can apply a chemical to a specific pest that is not mentioned on the label if the application is made to the site approved by the label. While pest control warranties of the manufacturer may be invalid in this case, it is legal to use the product if it is labelled for the site. Third, users may apply the pesticide using methods not included on the label as long as the application method is not specifically prohibited on the label. Fourth, it is legal to mix a pesticide with a fertilizer unless specifically prohibited on the label. Fifth, the law allows for additional use of the product through "experimental use permits" (Section 5), Section 24 labels, and emergency use (Section 18). Emergency use must be declared by state and/or EPA administrators. Finally, EPA reserves the right to approve off-label product usage when it deems necessary.

FIFRA clearly indicates that while the EPA has overall responsibility for administering FIFRA, the states are responsible for enforcing the provisions of the law. Each state has its own legal structure to meet this requirement. Certification of applicators for the use of restricted use pesticides and inspection of applicators to ensure their compliance with FIFRA are regulated by these individual state organizations. Importantly, states can impose further restrictions on pesticide use including the addition of products to the list of restricted use chemicals. For example, the EPA has stated that products labelled for horticultural nurseries are also labelled for forest tree nurseries, in other words, they are considered the same "site". This interpretation can be nullified by the states, however, and nursery managers should check with state authorities before assuming that horticulturally labelled products are legal for use in their nurseries.

THE FOOD QUALITY PROTECTION ACT

The FQPA passed congress unanimously in August 1998. The law was intended to resolve serious conflicts between FIFRA and the Federal Food, Drug and Cosmetic Act (FFDC). The FFDC authorized the EPA to set pesticide tolerances on foods. The Food and Drug Administration is responsible for enforcement of the FFDC through periodic inspections of foods. Unfortunately, a section of the FFDC stated that absolutely no level of any carcinogen could be present in any food. Because analytical capabilities as well as our knowledge about how chemicals produce carcinogenic reactions in the body have improved significantly since this law was passed, the law was often in conflict with EPA and manufacturer data indicating the safe use of many products. The FQPA attempted to resolve this conflict as well as others between these two important laws. Although the FQPA relates primarily to food tolerances, it nevertheless has an important and indirect effect on labelling of nursery pesticides.

One of the fundamental changes the FQPA introduces to FIFRA is that the EPA must use a different standard to determine the safety of pesticide residues on foods. Whereas before, the standard required that a pesticide have no "unreasonable adverse effects", the new FQPA language requires "reasonable certainty of no harm". This effectively sets a higher health safety standard for food tolerances. A second significant change requires the EPA to use a "common mode of toxicity" to assess the danger of individual products. To assess the potential threat to human health regarding Goal® use on Broccoli, for example, the EPA would not just determine the effect of oxyfluorfen (the active ingredient in Goal"), but all the diphenyl-ether compounds currently on the market. Third, the FQPA requires the EPA to assess dietary and non-dietary exposures. This means the use of Goal@ in forest tree and horticultural nurseries becomes a part of the equation whereby the EPA tries to assess a reasonable certainty of no harm for Goal® applications to broccoli. Finally, there is an additional safety hurdle imposed by the FQPA whereby there must be special consideration given to children when setting tolerance limits. Any pesticide exposure to children requires an additional 10 fold safety factor when setting tolerances.

To meet the requirements of the FQPA, the EPA uses the "risk cup" concept. The risk cup represents the total allowable theoretical exposure which presents "unreasonable certainty of no harm" to any individual. The size of the risk cup is called the "reference dose". To satisfy the FQPA safety standard, all the pesticides with a common mode of action must fit into the risk cup. The risk cup cannot overflow. Therefore, when adding all the uses of a pesticide, plus all the pesticides with a common mode of action, plus the 10-fold safety factor for children, the result has been that the labelling of entire classes of compounds has been put in jeopardy. A good example is the recent debate regarding the use of all organophosphates (which includes guthion and diazinon). The EPA has determined that based on the FQPA standards, the current use of organophosphate pesticides exceeds the reference dose and overflows the risk cup for this class of compound. The EPA therefore decided that all OPs would be discontinued. Only the complaints of the entire agricultural community and pesticide manufacturers were able to reverse this decision. The issue has not yet been resolved, however.

There are several other changes required by the FQPA. The law mandated all pesticides be reregistered within 10 years of its passage. In addition, endocrine disruptor assessments are to be part of the reregistration process. (This is a test to verify that compounds do not interfere with the human endocrine systems.) Moreover, the FQPA requires reregistration on a 15 year cycle. And finally, the law allows EPA to cover the cost of additional data review through the assessment of fees. In summary, the FQPA results in stricter safety standards, several new tests, and increased costs for pesticide registration. The end result will most likely be the reduced availability and increased price of agricultural chemicals including herbicides.

The impact of these new regulations on nursery herbicide availability is very difficult to predict at this time. The EPA has not yet made it clear how the new endocrine disruptor test is to be conducted or evaluated. Nor have they provided consistent guidelines for the determination of "reasonable certainty of no harm", how "aggregate exposure" is to be calculated, and when will the 10 fold safety factor for children be imposed. The situation is even more complicated given the fact that several companies may

manufacture and distribute different compounds within a class of chemicals. Each company will have their own strategy when evaluating the possibility of dropping a label so as not to overflow the risk cup.

LIABILITY AND COST

The principle hurdles to maintaining current labels and getting new ones for forest tree nursery herbicides will most likely continue to be the same we have faced during the past 20 years. While the new modifications of FIFRA through the FQPA will make things more complicated, it is expected that the two issues of liability and the cost of obtaining field data for a minor use crop will continue to be the most important issues for nursery managers. The economic motivation for manufacturers to label a compound for nurseries is marginal at best. Nurseries represent a small acreage crop of high value. In this situation companies are asked to assume crop damage liability risk for an exceptionally small market. Assuming this risk and paying the costs of obtaining field data and pursuing a Section 3 or Section 24 label is all to often not economically justifiable to manufacturers.

One of the strategies recently developed to overcome the liability and data cost issues for minor crops has been initiated by the Florida Fruit and Vegetable Association. The FFVA formed a separate legal entity called "Third Party Registrations Incorporation" for the express purpose of obtaining Section 24 labels for the fruit and vegetable growers of Florida by becoming the registrant themselves instead of the manufacturer. They require (1) a binding agreement between the manufacturer and TPR Inc. to absolve the manufacturer of liability regarding crop damage, (2) a limitation and waiver of liability between the individual grower and TPR to protect TPR from crop damage lawsuits, and (3) a non-transferable label is issued to an individual grower carefully specifying where and how much product can be used. A fee is assessed to the grower to help defray the costs of obtaining the crop safety and other data that might be necessary to obtain the label.

The Auburn University Southern Forest Nursery Management Cooperative is exploring the possibility of this and other legal arrangements that might facilitate herbicide labelling for forest tree nurseries. The organization of such a Coop is in itself an effective strategy for producing crop safety data that manufacturers might not be interested in paying for. Currently the Coop is obtaining field data for Stinger@ (clopyralid) for sicklepod control, Goal® (oxyfluorfen) for use on large seeded hardwoods, and Manage® (halosulfuron-methyl) for nutsedge control. In each of these cases we will pursue a Section 24 label in states where member nurseries request it. Although we are a long way from obtaining a structured methodology such as that of the Florida program, the Coop is also investigating the possibility of removing crop damage liability as an issue through formal agreements with Coop members in collaboration with pesticide manufactures.

THE FUTURE

Certainly the future of herbicide labelling is complicated and difficult to predict at this point in time. There are numerous uncertainties resulting from the FQPA. Perhaps minor use crops will actually receive a boost as this new legislation specifically addresses the difficulties of minor use registrations in some positive ways. On the other hand, the opposite is just as likely as minor use labels may be lost when manufacturers seek to maintain larger markets for their products by eliminating the smaller ones in order to not overflow the "risk cup". In all probability it will be important that minor users maintain a line of communication with manufacturers so their particular label is not lost. University Cooperatives and user associations will be critical in this regard as manufacturers look for partners to assist them work on high value crops with small markets.