ADMINISTRATIVE RULE DEVELOPMENT TO DECLARE LIMITS OF CERTAIN METALS IN FERTILIZER, AGRICULTURAL AMENDMENT, AGRICULTURAL MINERAL AND LIME PRODUCTS DISTRIBUTED IN OREGON

Background

On August 3, 2001, Governor John Kitzhaber signed into law House Bill 3815, the first comprehensive revision to Oregon's fertilizer law in nearly 50 years. The amended Oregon Revised Statutes (ORS) Chapter 633 stipulates that all fertilizer, agricultural amendment, agricultural mineral and lime products sold or distributed in Oregon must be registered with the Oregon Department of Agriculture (ODA) and contain a product label that identifies the sources of all guaranteed nutrients and/or non-plant food ingredients. In addition, any product derived, in whole or in part, from a designated waste must be identified in the registration as "waste derived". Specific product information, including levels of certain metals, must also be made available to the public through a website identified on the product label. Under the legislation, ODA must embark on administrative rulemaking to set numerical limits for certain metals in fertilizer, agricultural amendment, agricultural mineral and lime products. The rule declaring the maximum level of arsenic, cadmium, lead, mercury and nickel allowed in such products is to become operative no later than January 1, 2003.

Introduction

The Oregon Department of Agriculture is proposing the attached rules for adoption into Oregon Administrative Rules (OAR) Chapter 603 to address a statutory requirement to set maximum levels of arsenic, cadmium, lead, mercury and nickel in fertilizer, agricultural amendment, agricultural mineral and lime products. Several options were considered in addressing this issue including soil loading, human health risk assessments, ecological impacts, and other mechanisms not necessarily based on scientific data. To most accurately assess the risk that metals in fertilizer products may pose, it is imperative to set metal levels based on science when at all possible. After evaluation, ODA has concluded that using a human health risk assessment would provide the most protective and defensible means to regulate metals in fertilizer products. It is also recognized that any risk assessment evaluation may be influenced by the input factors chosen. However, risk assessment models are designed to ensure the outcome is overprotective of human health. The assumptions that must be made will nearly always overpredict potential health risks resulting in a more conservative end point. Ecological risk data with regards to metals from fertilizer products is still in its infancy. ODA recognizes these weaknesses in the fertilizer risk assessments that were available for review. However, it was necessary to go forward and set limits based on data that was available which focused on human health effects. The lack of ecological data to accurately reflect Oregon conditions highlights potential topics of future research needed to improve the basis of knowledge and any necessity to adjust these metal levels in the future.

Work Group

Working toward this goal of setting metal levels, ODA facilitated a working group composed of a wide variety of interested parties to discuss and work toward the development of several administrative rules including setting metal levels in fertilizer, agricultural amendment, agricultural mineral and lime products sold or distributed in Oregon. Workgroup participants included persons with interests in agriculture, by-product recycling, home & garden consumers, the environment, the fertilizer industry, and the multi-faceted regulations over-arching most of these interests. In addition to

input from the workgroup members, input was provided by a representative from the U.S. Environmental Protection Agency (EPA), an independent scientific research consultant and the involvement of the Association of American Plant Food Control Officials (AAPFCO). AAPFCO is a national group of representatives of the fertilizer regulatory programs of the majority of states. In addition, ODA contracted the scientific review services of Drs. Larry Curtis and Brian Smith from the Oregon State University Department of Molecular and Environmental Toxicology. It is the goal of ODA to assure the public that fertilizer, agricultural amendment, agricultural mineral and lime products registered in Oregon do not pose a risk to applicators, users, farm families or the general public.

Process

The Oregon Department of Agriculture was charged with the task of developing administrative rules setting the maximum metal levels to be allowed in fertilizer, agricultural amendment, agricultural mineral and lime products sold or distributed in Oregon. It is required in statute that these rules be operative no later than January 1, 2003. With this time constraint, it was necessary for ODA to rely on research that had already been concluded and to review processes in other states that have already implemented similar limitations on metals in fertilizers. To conduct an Oregon risk assessment on fertilizer metals interaction with the environment and/or on human health was not economically feasible or practical within the period of time available to implement these rules.

The different mechanisms established to address metals in a variety of situations were reviewed. Levels set to limit metals in application of human biosolid wastes, soil contamination clean-up sites, land disposal restriction standards for recycling hazardous wastes, Washington State and Canada's soil loading process, California's phase-in reduction approach, the EPA technology based numbers for zinc, and others were taken into consideration. It was evident that every effort taken to address metals levels is dependent on a wide variety of parameters. The scientific research data available on human health effects of metals and the background levels of metals in Oregon soils was generally available. However, the research data available for assessing ecological impacts of metals was significantly deficient. Parameters such as metals degradation in soil, plant uptake capability, leachability, bioaccumulation, atmospheric deposition, and metal speciation left many questions unanswered.

The process which took the widest variety of factors into consideration was the risk assessment process. Other means of setting metal levels appeared to be on a "best guess" basis where compliance with metal levels was accomplished through adjustments in application rates on a product label with the assumption that users would voluntarily comply with the label. Admittedly, risk assessments are not a perfect science and some assumptions must be made to allow the assessment process to function. Given this inherent weakness, ODA chose to adopt the risk assessment process to provide a credible foundation to setting metal levels dependent on real scientific data when at all possible. *Risk assessment* is defined as "the systematic scientific characterization of potential adverse health effects resulting from human exposures to hazardous agents or situations." Risk management involves the development of regulatory options based on the outcome of the risk assessment. This may explain how regulatory agencies derive different metal limits with the limited amount of scientific data available to influence risk assessment outcomes.

For Oregon, ODA looked at the compromise approach between two risk assessments where addressing the most influential factors in different ways generated significantly different results. The Association of American Plant Food Control Officials (AAPFCO) also used this compromise approach in proposing a national uniform standard for adoption by state regulatory programs to address levels of metals in phosphate and micronutrient products. This AAPFCO Statement of Uniform Interpretation and Policy (referred to as SUIP 25), is based on the 90th percentile level of confidence. This 90th percentile covers 90 percent of the possible exposure scenarios given the variability in the input parameters. A risk based concentration (RBC) value is then established based on the level of confidence chosen (in this case, the 90th percentile) and represents the acceptable upper limit of a specific metal in a fertilizer. The resulting RBC value is designed to be health protective in 90 percent of cases where a specific metal is present in a fertilizer. ODA accepted this process as a sound basis for regulation. However, ODA chose to reduce the level of uncertainty even further by increasing the level of confidence, and the resulting RBC values, to the 95th percentile. This significantly increases the protection level provided to Oregonians.

Other state programs currently regulating metals in fertilizer products address only products containing phosphate and/or micronutrients. In Oregon, ODA took a more restrictive approach by requiring metal standards applicable to <u>all</u> fertilizer, agricultural amendment, agricultural mineral and lime products. Although the concern of metals is greatest in products containing phosphates and/or micronutrients, ODA chose to include all products and eliminate the possibility of any product regulated by ODA Fertilizer Program to exceed specified metal levels.

Future Plans

The Oregon Department of Agriculture has accepted this scientific risk assessment approach as a responsible and reasonable first step in regulating metals in fertilizer, agricultural amendment, agricultural mineral and lime products. ODA is also the first to recognize the need for additional research to improve the science available to better understand the interaction of metals and the environment. In addition, the statute regulating fertilizer, agricultural amendment, agricultural mineral and lime products (ORS 633.362(11)) requires ODA to reevaluate any established levels of non-nutritive constituents every five years. Toward this goal, ODA plans to facilitate specific research projects in the near future to address some of the assumptions that had to be made in the risk assessment process. The mechanism to initiate this research is already established through inspection fees (tonnage taxes) paid to ODA by the fertilizer industry. A fertilizer research fund is managed by ODA and will be utilized as a source of funding to design and conduct research on the interactions between metals in fertilizer, agricultural amendment, agricultural mineral and lime products and surface water and/or groundwater. With sound scientific data pertinent to Oregon conditions available to replace some of the assumptions contained within the risk assessments, ODA will have the basis to address metals in fertilizers more accurately and adjust allowable metal levels accordingly if necessary.