Expert Assistance with the Rule and Risk Assessment

The best scientific talent and data were assembled and used to structure the final Part 503 rule. Twelve experts (Table 4) with extensive experience in the field of evaluating the benefits and risks of using biosolids assisted in its formulation. These experts, who collectively had over 300 years of training and research experience, were from Universities, EPA, and other Federal

Table 4. Expert Cooperators in the Part 503 Risk Assessment

Dr. Rufus Chaney **USDA-ARS** **Beltsville, MD**	**Dr. Andrew Chang** **Dept. of Soil & Environmental Science** **University of California** **Riverside**
Dr. Willard Chappell **Center for Environmental Science** **University of Colorado** **Denver**	**Dr. Lawrence Gratt** **IWG Corporation** **San Diego, CA**
Dr. Robert Griffin **Dept. of Chemical Engineering** **University of Alabama** **Birmingham**	**Charles Henry** **College of Forestry Resources** **University of Washington** **Seattle**
Dr. Terry Logan **Dept. of Agronomy** **Ohio State University** **Columbus**	**Dr. George O'Connor** **Dept. of Soil Science** **University of Florida** **Gainesville**
Dr. Al Page **Dept. of Soil & Environmental Science** **University of California** **Riverside**	**Dr. Jim Ryan** **Risk Reduction Engineering Lab** **US EPA** **Cincinnati**
Dr. Robert Wagenett **College of Agriculture & Life Science** **Cornell University** **Ithaca**	**Dr. John Walker** **OWEC** **US EPA** **Washington, DC**

Agencies. The carefully reasoned science and policy decisions which occurred have provided the best rule ever developed for governing the use or disposal of biosolids. EPA believes that this Part 503 rule fully meets the Congressional mandate to be protective of public health and the environment and allows for the safe and effective recycling of biosolids -- indeed providing beneficial technology for a better environment.

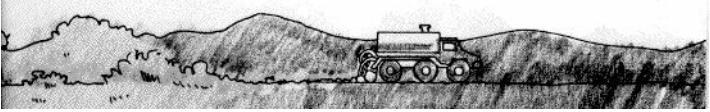
Features of the Risk Assessment Process

The following brief examples describe some of the valuable information that has come from extensive research by EPA and others on the safe and continuing use of biosolids. The examples show how this information was used in the scientific risk assessment that resulted in a comprehensive, sometimes less restrictive, and simplified final Part 503 rule.

Research has shown that the biosolids-organic-chemical matrix greatly impacts the plant uptake/bioavailability of pollutants, even after the biosolids have been mixed with soil. This means that certain pollutants cannot be drawn into the plant because they are bound in a form that is unavailable to the plant. Data from sites that are nearly 100 years old show that this binding effect does not change over time. Hence, only data from field experiments where biosolids had been applied were used, not data from chemical salts applied to soils.

Another area of intensive study and data review centered on the issue of potential cadmium toxicity. It was found that most crops grown in biosolids-amended soils do not take up high levels of cadmium. Those sensitive crops that do accumulate cadmium (generally vegetables) also accumulate calcium, iron and zinc, other elements that are contained in biosolids. Hence, persons eating "sensitive" accumulator crops will simultaneously ingest all those elements. Studies have shown that calcium, iron and zinc inhibit cadmium absorption in the intestine of individuals -- thus preventing levels of this metal from accumulating. Hence, the use of this information in the risk assessment process led to a Part 503 cadmium limit being less restrictive than when the rule was proposed.

Another example of how information was developed to formulate the final rule came from the National Sewage Sludge Survey (NSSS) conducted in 1988. In this survey, biosolids analytical data from about 200 statistically representative treatment plants across the United States were reviewed for the prevalence of more than 400 toxic organic pollutants. The scientific review of this data revealed that a



majority of the toxic organic pollutants were not present in biosolids at detectable levels and that risk assessment for the various toxic organic pollutants under consideration showed no anticipated adverse effects at the levels that were detected. This information, coupled with the fact that many of these toxic organic pollutants were no longer manufactured or in use, led to the decision not to include these pollutants in the final rule.

Part 503 Rule Has Conservative Elements

Even though research has shown that pollutant uptake by crops grown in biosolids-amended soils is less than linear (i.e., less than directly proportional to the amount of biosolids-contained pollutant that was added to the soil), the assumption used for the Part 503 risk assessment was that pollutant uptake by crops is linear (Figure 5). This means that the risk assessment assumes greater uptake of pollutants into plants and hence exposure to the humans and the environment than actually occurs.

EPA has also continued to use the conservatively established risk-reference-doses in the risk assessment for the final rule to estimate the lowest amount of pollutant that the highly exposed individual in each pathway can safely tolerate. The toxicological studies that were used to establish many of the risk-reference-doses often

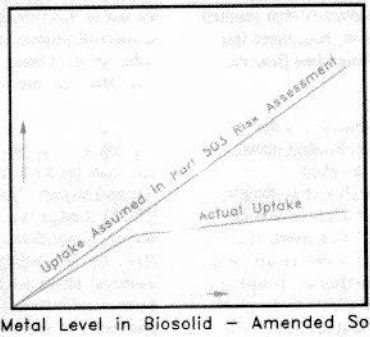


Figure 5. Conservative Assumption of Metal Bioavailability to Plants

were based on studies in which pure chemical doses of the pollutants were fed directly to the test animal without food or injected directly into the animal. These procedures overestimate risks because the actual bioavailability and toxicity of pollutants are much less when the pollutants are in a biosolids- or food-borne matrix than when the pure chemical form is placed directly in the stomach or injected directly into blood stream of the test animal.

High Quality Biosolids as a Product

A major simplification of the rule resulted because additional research and risk analyses showed that an exceptional quality (EQ) biosolids product with low levels of pollutants and highly reduced pathogen and vector attractiveness can be safely used by the general public in a manner similar to any other commercial fertilizer/soil conditioner product. Once the Part 503 requirements for EQ biosolids are met (this includes continued demonstration of EQ quality by periodic monitoring, record keeping, and reporting), there is no further regulation by the Part 503 rule. EQ biosolids are generally produced by composting, heat-drying, or stabilization with alkaline materials.

Equally Protective Regulatory Options

The Part 503 rule includes several options for regulating the uses of biosolids -- each with different levels of control. Each of the options is equally safe and protective of public health and the environment. The safety is ensured by the combination of pollutant limits and management practices imposed by each option.

The most simple option from a regulatory perspective is the EQ biosolids option just described. Here, safety is assured by imposition of stringent pollutant, pathogen and vector attraction reduction limits. Such EQ biosolids materials are marketed to, and used by, the general public without tracking. A more detailed, equally protective option is the one in which less stringent pollutant, pathogen and vector attraction reduction alternatives are coupled with site and crop controls and operational standards to ensure safe large-scale agricultural use.