



November 2009
Oregon Department of Agriculture
Pesticides Division
Fertilizer Program Policy

Issue: Some products that require registration under Oregon Revised Statutes (ORS) 633.311 to 633.479 contain microbiological ingredients, which, when used incorrectly or indiscriminately, may be harmful. ORS 633.366(3)(a) allows the Oregon Department of Agriculture (Department) to consider as adulterated any fertilizer, agricultural amendment, agricultural mineral, or lime product that "contains any deleterious or harmful ingredient in an amount that is injurious to humans, animals, water, aquatic life, soil or beneficial plant life when used in accordance with instructions for product use on the label." The sale or distribution of adulterated products is prohibited.

Policy: Any product requiring registration under ORS 633.311 to 633.479 that contains certain microbiological ingredient(s) identified by the Department, must carry an appropriate cautionary statement to avoid being considered "adulterated".

ORS 633.366(3)(a) describes a three step process to determine whether a product is "adulterated":

The first step is to determine whether a microbiological ingredient is potentially harmful. Information used to make this determination may include, but is not limited to, a review of published medical, microbiological, public health, and laboratory safety literature. The Department considers any microbiological organism described as a human pathogen to be potentially harmful.

Second, if an ingredient may cause harm, is the amount in the product sufficient to cause injury? Microbiological organisms included in any laboratory safety protocol as Risk Classification 2 or its equivalent, that also have a record of infection risk documented in medical, microbiological, or health literature, are considered to cause harm unless additional information is available to establish a "safe exposure."

Although the exact definition varies with the agency involved, a general characterization of Risk Classification 2 is a microbiological organism that has a moderate risk to someone handling the organism, but effective treatment and preventative measures are available, and there is a low risk to the community at large.

Lastly, when a microbiological ingredient has the potential to cause harm, and is present in an amount to have the potential to cause harm—or, it cannot be determined that the amount is safe—the remaining step is to determine whether the product label includes an appropriate cautionary statement for safe product handling and use. At a minimum, the cautionary statement should include basic good handling practices and any precautions recommended on the product's Material Safety Data Sheet (MSDS). The following is an example of a cautionary statement:

Avoid contact with eyes, mouth, and broken skin. Do not inhale product. Wear eye and skin protection when handling bacterial inoculants. Persons with a compromised immune system should consult their physician before handling bacterial products. Wash hands after using.

The requirement for a cautionary, or safe handling, statement may be reconsidered if the registrant can provide supporting data to show the individual product does not have the potential to cause harm, or that

the amount of pathogen in the product is not sufficient to cause injury. Supporting data must be from studies carried out by an independent person or organization, use generally accepted scientific techniques, and be performed with the product submitted for registration at application rates that are no less than those specified on the product label.

Pathogenic species of concern: As of this date, species requiring handling statements include:

Bacillus cereus

Burkholderia multivorans

Enterococcus faecium

Pseudomonas aeruginosa

Pseudomonas alcaligenes

As additional information becomes available, the Department reserves the right to add or remove additional microbiological species from the list of species requiring cautionary statements.

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