Environmental Protection Agency

§ 158.2204 Public health and nonpublic health claims.

(a) Public health claim. An antimicrobial pesticide is considered to make a public health claim if the pesticide product bears a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to man in any area of the inanimate environment. A product makes a public health claim if one or more of the following apply:

(1) A claim is made for control of specific microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include, but are not limited to: *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *Escherichia coli* (*E. coli*), *human immunodeficiency virus* (HIV), *Streptococcus*, and *Staphylococcus aureus*. Claims for control of microorganisms infectious or pathogenic only to animals (such as canine distemper virus or hog cholera virus) are not considered public health claims.

(2) A claim is made for the pesticide product as a sterilant, disinfectant, virucide, sanitizer, or tuberculocide against microorganisms that are infectious or pathogenic to man.

(3) A claim is made for the pesticide product as a microbiological water purifier or microbial purification system.

(b) Nonpublic health claim. An antimicrobial pesticide is considered to make a nonpublic health claim if the pesticide product bears a claim to control microorganisms of economic or aesthetic significance, where the presence of the microorganism would not normally lead to infection or disease in humans. Examples of nonpublic health
§ 158.2210 Product chemistry.

The product chemistry data requirements of subpart D of this part apply to antimicrobial products covered by this subpart.

§ 158.2220 Product performance.

(a) General—(1) Product performance requirement for all antimicrobial pesticides. Each applicant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(2) Product performance data for each product that bears a public health claim. Each product that bears a public health claim, as described in § 158.2204(a), must be supported by product performance data, as listed in the table in paragraph (c) of this section. Product performance data must be submitted with any application for registration or amended registration.

(3) Product performance data for each product that bears a nonpublic health claim. Each product that bears a non-public health claim, as described in § 158.2204(b), must be supported by product performance data. Each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(4) Determination of data requirements. Subpart B of this part and § 158.2201 describe how to use the table in paragraph (c) of this section to determine the product performance data requirements for antimicrobial pesticide products.

(b) Key. R = Required; EP = End-use product.

(c) Antimicrobial product performance data requirements table. The following table shows the data requirements for antimicrobial product performance.

<table>
<thead>
<tr>
<th>Guideline No.</th>
<th>Data requirement</th>
<th>All use patterns</th>
<th>Test substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>810.2100</td>
<td>Sterilants—Efficacy Data Recommendations</td>
<td>R ..................</td>
<td>EP</td>
</tr>
<tr>
<td>810.2200</td>
<td>Disinfectants for Use on Hard Surfaces—Efficacy Data Recommendations</td>
<td>R ..................</td>
<td>EP</td>
</tr>
<tr>
<td>810.2300</td>
<td>Sanitizers for Use on Hard Surfaces—Efficacy Data Recommendations</td>
<td>R ..................</td>
<td>EP</td>
</tr>
<tr>
<td>810.2400</td>
<td>Disinfectants and Sanitizers for Use on Fabrics and Textiles—Efficacy Data Recommendations</td>
<td>R ..................</td>
<td>EP</td>
</tr>
<tr>
<td>810.2500</td>
<td>Air Sanitizers—Efficacy Data Recommendations</td>
<td>R ..................</td>
<td>EP</td>
</tr>
<tr>
<td>810.2600</td>
<td>Disinfectants for Use in Water—Efficacy Data Recommendations</td>
<td>R ..................</td>
<td>EP</td>
</tr>
</tbody>
</table>

§ 158.2230 Toxicology.

(a) General. Subpart B of this part and § 158.2201 describe how to use the table in paragraph (g) of this section to determine the toxicology data requirements for an antimicrobial pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions are listed in paragraph (h) of this section.

(b) Uses. The applicant for registration must first determine whether the use is likely to result in pesticide residues in food or water and therefore consult the “Food Use” columns of the table in paragraph (g) of this section. Generally, if the residues of the antimicrobial result from an application to a surface or if incorporated into a material that may come into contact with food or feed, and residues may be expected to transfer to such food or feed, then the “Indirect Food Uses” columns is to be consulted.