

November 13, 2002

This letter provides guidance regarding the use of graphics depicting fruit on antimicrobial labels.

Ms. Brigid D. Klein
Consumer Specialty Products Association
900 17th Street, NW
Washington, DC 20006

Dear Ms. Klein:

This is in response to your letter of April 18, 2002 regarding the use of graphics depicting fruit on antimicrobial labels. In your letter you state that the California Department of Pesticide Regulation (CA DPR) will no longer register antimicrobial products bearing graphics depicting fruit, even if the product contains the fruit fragrance as part of its formula. You further stated that the CA DPR decision is based on a May 25, 1999 letter to CSPA from Frank Sanders, Director of the Antimicrobials Division (AD) which described new policies and procedures being implemented by AD. That letter, which contained a statement "Graphic symbols such as lemons (for lemon scent) are unacceptable", does not fully communicate the complexity of this issue. This letter will provide guidance regarding the use of graphics depicting fruit on antimicrobial labels.

As you are aware, the Agency has historically been concerned with the use of food or food-like fragrances in pesticide formulations due to the potential attractiveness to children of such product formulations containing such fragrances. At one time, pesticide products containing food or food-like fragrances were considered as not acceptable for registration, although that policy was rescinded in 1993 for most pesticide products except for insect repellants products. Insect repellent products are addressed in PR Notice 2001-3. The result is that food or food-like fragrances are reviewed on a case-by-case basis in products other than insect repellants.

Over the years, AD has registered a number of antimicrobial products with formulations that contain food or food-like fragrances. However, until very recently AD was not aware that the graphics depicting the fruit upon which such fragrance is based were being placed on antimicrobial labels. The draft labeling we receive, review, and, if found acceptable, approve is typically a word processing copy and does not contain any of the actual graphic images that actually may be intended to appear on antimicrobial products as they are to be sold or distributed in the marketplace.

Given the importance of this issue to the Agency, the public, and the industry, we believe we need to receive and review the actual graphics that are intended to appear on the product as it would be sold or distributed.

In determining whether to propose placing graphics depicting fruit on a label you should take into account the following:

Does the product contain the fragrance depicted by the graphic? If a product does contain a fruit fragrance, then the product may be eligible for graphics to be added using the notification process described below. If the product does not contain a fruit fragrance, then graphics depicting fruit likely would not be appropriate to be placed on a label because doing so could misrepresent the product. Graphic images cannot be false or misleading.

What is the acute toxicity profile of the product? Is the product assigned Toxicity Category 1 by the oral, dermal or inhalation route of exposure? If the product is assigned Toxicity Category 1 on the basis of oral, dermal or inhalation toxicity, then the label must contain the word "Poison" in red as well as the skull and crossbones as indicators of the high acute toxicity of the product (40 CFR 156.10(h)(i)). We believe it would be inappropriate to place certain graphics such as those depicting fruit on the label due to the high acute toxicity of the product, the possible adverse effects that could occur if children gained access to such a product, and the potential that such graphics could distract from other important labeling.

Will the product be packaged in child resistant packaging (CRP)? Since we are concerned about the potential attractiveness of product formulations containing fruit fragrances and any associated graphics depicting fruit, a product packaged in child resistant packaging should help prevent children from gaining access to the product. A product not in CRP is more accessible to children .

What type of fruit graphic will appear on the label? Although the past policy prohibiting food or food-like fragrances in pesticides formulations has been rescinded, except for insect repellent products as discussed earlier, the Agency is still concerned about the use of certain food or food-like fragrances in antimicrobial products. We believe there are certain fruits that generally should not appear on pesticide labels, i.e., fruits that are frequently eaten by children in the form depicted such as cherries, grapes,, watermelon slices. We believe that such fruits and thus any graphics representing them may be inherently more attractive to children. On the other hand, citrus fragrances and certain citrus fruit images are more frequently associated with cleaning products. As we stated earlier in this letter, food and food-

like fragrances in products other than insect repellants will continue to be reviewed on a case-by-case basis. Insect repellent products are addressed in PR Notice 2001-3.

Are the graphics on the label presented in such a way as to make the product more attractive to children, i.e., cartoon-like images, smiley faces, and the like? If so, then the Agency would have concern that the product attractiveness to children and thus that the potential for accidental ingestion or other exposure could increase due to heightened product attractiveness to children.

Please note that FIFRA Section 3(c)(9)(A) allows an antimicrobial label to be modified "...to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity." However, such modifications cannot be false or misleading, or conflict with or detract from any statement required by law or the Administrator as a condition of registration. We believe that the addition of fruit graphics to a registered antimicrobial product label is subject to this provision of FIFRA. Therefore, in accordance with this provision you must notify the Agency in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling including, but not limited to, the addition of any graphic depicting fruit. A copy of the proposed modification of the label bearing the actual proposed graphic must be submitted with the notification. The Agency will follow section 3(c)(9)(A) - (C) in reviewing the proposed label modification.

Additionally, any new registration application which seeks registration of a product intended to contain a food or food-like fragrance, (and is not an insect repellent), needs to include a draft label that presents all of the actual proposed graphics (if developed) intended to appear on the label as the product would be sold or distributed rather than only a word processing copy which does not include the actual intended graphics. If graphics have not been developed at the time of submission of the registration package, you must then use the notification process described above to notify the Agency prior to distribution or sale of a product bearing the modified labeling.

For existing products already in the marketplace bearing graphics depicting fruit, companies should review their graphics using the guidance presented in this letter. As previously stated in this letter, we believe we need to receive and review the actual graphics that are intended to appear on the product as it would be sold or distributed. We suggest that companies marketing such products take appropriate steps to provide the Agency with a copy of the label bearing the graphic material. A product could be considered misbranded if its labeling bears any statement, design, or graphic

representation which is false or misleading or which conflict with or detract from required labeling.

In summary, we recognize that graphics/images may, in some cases, convey useful information to the consumer/user which is consistent with the requirements of

FIFRA. The guidance provided in this letter should help assure that the practice of using graphics including certain depictions of fruit can continue under appropriate circumstances in a way that is consistent with the purposes and requirements of FIFRA and its regulations.

Sincerely,

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Frank T. Sanders, Director
Antimicrobials Division (7510C)

cc: Barry Cortez, CA DPR