conclusion on the safety of food use of acetic acid, FDA believes that use of acetic acid as proposed in this rule will result in residual levels on product "as served" below the most restricted use levels specified in § 184.1005 for acetic acid (FDA November 29, 1982), 0.15 percent for "all other food categories."

¹ Lactic acid is approved as GRAS at 21 CFR 184.1061 with no limitations other than good manufacturing practice. In addition, lactic acid is listed for use as an antimicrobial agent in foods, also at a level not to exceed good manufacturing practice.

Citric acid is listed for multiple purpose use in 21 CFR 182.1033, when used in accordance with good manufacturing practices.

In addition, sections 318.7(c)(4) and 381.147(f)(4) of the regulations (9 CFR 318.7(c)(4) and 381.147(f)(4)) currently allow the use of acetic, lactic, and citric acids as acceptable ingredients in various meat and poultry products when used as acidifiers or as esterifiers in margarine. Citric acid may also be used as an anticoagulant, a flavoring agent, and a synergist at various levels in various meat and poultry food products. Citric acid is acceptable as a curing accelerator to speed up color fixing or preserve color during storage of cured pork and beef cuts and cured comminuted meat food products.

In 1990, FSIS determined that lactic, acetic and citric acids can be safely and effectively used as antimicrobial treatments on meat and poultry carcasses and by-products during slaughter and dressing procedures. That determination was based on an extensive review of the scientific literature on methods of reduction of bacteria on meat surfaces.

During the past twenty years the use of organic acid rinses to reduce spoilage and pathogenic microorganisms on foods has been studied extensively. Numerous researchers have demonstrated that organic acid rinses can produce a significant reduction in bacterial levels on the surfaces of meat and poultry. Although most of these studies have been conducted under laboratory conditions, there have been some studies that have specifically assessed the efficacy of these antimicrobial systems under production conditions. Also, some of the laboratory research has been conducted under simulated in-plant conditions.

The results achieved in the various research trials have not been unequivocal, in part because the effectiveness of the compounds is dependent on their interactions with a number of other factors. Some of the factors that have been identified include

(1) pre- versus post-rigor tissue, (2) prewashing prior to treatment, (3) tissue type, (4) method for acid delivery, (5) droplet size, (6) flow rate/pressure, (7) temperature, (8) pH, (9) contact time, (10) bacterial species, (11) type of acid, (12) buffering capacity, and (13) moisture content. Differences in study design, especially factors such as methods used to collect tissue samples and analyze for bacterial species or the preadaptation of bacterial cells to an acid environment, affect results. Interpretation of research results can also be confounded by difficulty in obtaining valid microbiological data because of large carcass to carcass variations, as well as differences in microflora associated with different slaughter facilities, carcasses, and sample sites on individual carcasses.

The literature suggests it is important to lower the pH of the meat surface if bacteria are to be controlled effectively by using an organic acid. Most organic acids are effective only at low pH values of pH 5.5. Apparently the anion exerts some effect on bacteria at pH values of pH 5.5. The pH affects the extent of dissociation. Undissociated weak acids are more effective than the dissociated form and dissociate to produce acidification of the cell interior.

Overall, the available scientific data indicate that washing of carcasses with organic rinses or sprays can achieve a 90–99.9 percent reduction in levels of spoilage bacteria (e.g., Pseudomonas fluorescens) though in some cases the reductions were not statistically significant and in others no improvement was noted. In addition, acid sprays and dips have also been shown to decrease the levels of specific pathogens, as well as the incidence of carcasses that are positive for specific pathogens. This includes activity against Salmonella spp., Staphylococcus aureus, Campylobacter jejeuni, Yersina enterocolitica, and Listeria monocytogenes. However, these techniques do not and cannot be expected to completely inactivate or eliminate pathogens.

One of the bacterial species that appears to be among the more resistant to the effects of organic acids is *E. coli* O157:H7. A number of investigators have found that O157:H7 has a relatively high acid tolerance. Again, the extent of inactivation achieved with *E. coli* O157:H7 has varied among the various studies. For example, one researcher found that *E. coli* O157:H7 reductions were similar to those observed for *Salmonella* spp. and *Listeria monocytogenes*, with up to a 99.9 percent reduction in the levels of all three bacteria from inoculated tissues

and concluded that an acetic acid carcass sanitizer could be used as an effective method to control these bacterial pathogens. Conversely, another reported that up to 1.5 percent acid treatments did not appreciably reduce E. coli O157:H7, whether at 20° or 55°C and "was of little value in disinfecting beef of E. coli O157." It has been reported that there are differences among E. coli O157:H7 isolates in relation to their acid tolerances. These investigators also found that inactivation was dependent on acid concentration (5 percent gave greatest reductions), and tissue type (reductions greater on adipose tissue than lean). Some investigators have suggested that lactic acid is more effective than acetic or citric acid against *E. coli*. It has been suggested that the primary determinants of effectiveness were the pH achieved at the surface of the carcass and the corresponding period of exposure.

Organic acids apparently are more effective when applied as soon after slaughter as feasible, and when they are at elevated temperatures (53°–55°C). The bacteria found on a carcass soon after slaughter are believed to be present in a water-film on the surface and, therefore, are relatively easy to remove, contrasted with bacteria that have become attached to the carcass surface itself by the time chilling is complete and are therefore more difficult to remove.

Overall, organic acid rinses appear to be a generally effective antimicrobial intervention that have several distinct advantages. Specifically, the advantages include: (1) the technique can achieve up to a 99.9 percent (3 log) decrease in the levels of specific pathogenic and non-pathogenic bacteria; (2) the effectiveness of the application can be readily monitored; (3) the technology can be implemented through a relatively straightforward modification of existing equipment; and (4) this is a process for which there are no apparent "tradeoffs" in relation to other risks or negative attributes (e.g., the presence of residues or the need to eliminate environmentally sensitive byproducts). The primary disadvantage is that the effectiveness of acetic acid rinses against E. coli O157:H7 is not as great as against other pathogens, and at least some studies indicate that these rinses may not achieve the results desired.

In 1992, FSIS issued a directive (FSIS Directive 6340.1, 11/24/92) that provided guidance to FSIS employees on conditions of use, and how to evaluate and respond to livestock establishments' requests for approval of pre-evisceration carcass spray systems using an acid spray to reduce the