

Since the early 1900s, scientists have been investigating uses of viruses that infect bacteria. A century later, the FDA has approved spraying six different bacteriophage viruses on ready to eat meats and poultry in order to fight food born infection by listeria bacteria.

The FDA has approved application of these viruses only on meats, such as hot dogs and cold cuts, that will not be cooked prior to consumption. Products treated by this method will be required to have a label such as “bacteriophage preparation” or a less specific listing in the ingredient label such as, “beef steak treated with an antimicrobial solution to reduce microorganisms.”

They listeria bacteria these viruses are intended to kill can grow even at refrigeration temperatures. Estimates from 1993 show that there were approximately 1795 mild cases and 1860 severe cases that year. Around 60% of those infected recover completely. Approximately 16% suffer from chronic complications. Up to 24% of cases are fatal. In 1993, the number of fatal cases was 431.

Several theoretical concerns about bacteriophage treatment have emerged.

The first concern is that there have been cases of bacteriophages absorbing toxins from bacteria they have infected and then passing those toxins on to mammals. One example is shiga toxin being passed to sheep by a bacteriophage. The FDA says that this is unlikely because they will require “that the additive must test negative for *L. monocytogenes*, and the *L. monocytogenes* toxin, listeriolysin O, must not be present at detectable levels.” Low-level chronic exposure to low levels of listeriolysin O were not explored.

Another concern is the possibility of excess immune system stimulation by increasing the body's viral load. The FDA responded to these concerns by citing the use of bacteriophages in other countries to treat infection although they are not approved for this use in the United States. Bacteriophages have been used on crops in the United States.

Disruption of normal bowel flora by antibiotics can induce bacterial infections such as clostridium difficile or fungal infections such as candida. Because bacteriophages are typically infectious to one type of bacteria, it is not known if chronic exposure to high dose bacteriophages will disrupt bowel flora.

The human genome project recently showed that our genetic structure can be affected by the input it gets from microorganisms that live in us. We have 223 genes that appear to have been adapted from environmental bacteria. With either DNA or m-RNA, it is not known whether genetic material left over from viruses can create genetic change in humans.

None of these safety issues have been explored in the United States in live humans. They have been studied in other animals and in test tube models. Previous attempts at preventing food borne infections with antibiotics may have been responsible for development of resistance to quinolone antibiotics such as ciprofloxacin. Bacteria may become resistant to bacteriophage viruses. In order to reduce, but not eliminate, that use, a blend of six different bacteriophage viruses will be used.

The FDA has not yet required clinical testing in humans on effects of long term or cumulative exposure to higher than natural levels of bacteriophage viruses.

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