United States Department of Agriculture

Foreign Agricultural Service

Office of Agricultural Affairs

American Embassy
Dag Hammarskjölds Alle 24
DK-2100 Copenhagen O

July 2, 1998



Dockets Management Branch, (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm 1-23
MD 20856
USA

Enclosed are the comments we have received from The Danish Ministry of Food, Agriculture and Fisheries to the draft guidance on general principles to be followed to reduce the risk of microbial contamination on domestic and imported produce.

Sincerely

Hasse Kristensen
Agricultural Specialist

24 JUNI 1998

**Ministry of Food, Agriculture and Fisheries**

American Embassy
Dag Hammarskjölds Alle 24
2100 København Ø

Den 22 JUNI 1998
J.nr.: 1997-4830-0001
Ref.:

Att.: Steven D. Yoder
Agricultural Counselor

./. Referring to your letter of May 5, 1998 please find enclosed copy of the comments of the Danish Veterinary and Food Administration on "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables".

Additional comments are available from Lene Rasmussen, Danish Veterinary and Food Administration, telephone number 33 95 61 99.

Sincerely,

Søren Abildgaard

Holbergsgade 2 Tel: +45 33 92 33 01 Telex: 27 157 minag dk X.400: C=DK;A=DK400;P=FVM;S=FVM

*General comments:*

The guide has very fine intentions and a good description of risks. It is fine to give priority to prevention of contamination over treatment.

There is no proposal on the use of antimicrobials. It should be highlighted that the use of sanitizers or microbials in most cases would be regarded as a food additive uses which must be in complience with the general requirements in the food additives legislation.

The guide does not mention pumping of water into certain fruits (melons) as a very unhygienic practice.

*Specific comments*

*I. Definitions and II. Water*
The text mentions that "water need to be of better quality", i.e. Paragraph II, B. The text should define water of better quality. Also, a clarification on the use of water of drinking water quality would improve the text.

It is mentioned that the use of sanitizers and antimicrobials should be restricted. Sanitizers and antimicrobials would in most cases be used with such intentions that their use would be a food additive use, covered by the definition on food additives. This would require an approval in accordance with the legislation on food additives, e.g. the substances used should either be accepted in the EU's directives of food additives, or should be evaluated specificly, based on toxicological data. The substances mentioned e.g. chlorine is not approved as food additives and futhermore, documention on the safety aspects of especially the reaction products seams not to exist.

The text only looks into microbial contaminations, however, use of sanitizers and antimicrobial products can cause a health risk with respect to their use as food

additives or if residues from other used are found in the food as chemical contamination.

The aspect of food safety hazards should include chemical contaminations from water, especially water reuse and the use of sanitizers and antimicrobials.

In paragraph I, definitions: The definition of "agricultural water" should include water sources, as mentioned under paragraph 1.1: "typical sources of agriculture water include flowing surface waters from rivers, streams, irrigation ditches, and open canals, impoundments such as ponds, reservoirs, and lakes; and ground water from wells and municipal supplies".

Paragraph II, B, 1.1: Older wells with cracked casings **should be avoided**.

Paragraph II, B, 1.1: Growers with older wells (...) or who have other reasons for concern about possible contamination, **should** have their well examined by a water quality expert.

Paragraph II, B, 2.0: Reusing processing water may not only result in built up of microbial loads, but also on chemical contaminations.

Paragraph II, B, 2.1: "Water that meets the microbial standards for drinking water is considered safe and sanitary". However, the required use of water of drinking water quality should be specified.

Paragraph II, B, 2.1: Chlorine dip is in Denmark considered as a food additive, as the chlorine dip is carried out to prevent microbial growth in the final product. The use of chlorine dip should be evaluated with respect to safety aspects.

Paragraph II, B, 2.2, First dot: Washing in hot water can result in a chemical contamination, as the hot water contains higher concentrations of metals migrated from the water pipe system.

Paragraph II, B, 2.2, Second dot: The use of chlorine and other antimicrobials should be restricted due to health concern. Where chlorine and antimicrobials are allowed,

limits of residual concentrations should be set with respect to health concern.

Paragraph II, B, 2.2, Third dot: The use of sanitizing dip and rinse in direct food contact should be avoided.

*III. Manure*

There is no specific demands on the use of animal manure and human fecal matter.

Paragraph III, B, 2.1: Treatments to reduce patogen levels does not go into detail (passive/active treatments).

*IV. Sanitation and hygiene*

The guide does not mention auto-control and the HACCP-principle.

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