

Complementary Translation

June 23, 1998

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~~The Honorable Donna Shalala
Secretary U.S. Department of Health
and Human Services
Washington, D.C.~~

Re: Docket No. 97N-0451

Dear Secretary Shalala:

In my capacity as Under Secretary for Agriculture and Livestock for the United Mexican States, and on behalf of the Secretariat of Agriculture, Livestock and Rural Development, I am pleased to provide the enclosed comments on the U.S. Government's *Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, which was published for public comment on April 13, 1998.

Like the United States, Mexico is committed to a plentiful, safe and nutritious food supply and to food safety standards and procedures consistent with sound science and applicable international trade principles. Consistent with the Joint Statement on food safety recently signed by you, Secretary of Agriculture Dan Glickman, Secretary of Agriculture, Livestock and Rural Development, Romárico Arroyo Marroquín, and Secretary of Health, Juan Ramon de la Fuente, the Government of Mexico looks forward to working in close partnership with the United States to protect the safety of the international food supply.

Thank you and best regards.

Sincerely,



~~Francisco Gurria Treviño
Under Secretary for Agriculture and Livestock~~

Enclosure

Cc: Ing. Romárico Arroyo Marroquín. Secretario del Ramo.- Present.
Cc: Dr. Juan Ramón de la Fuente. Secretario de Salud.- Present.
Cc: The Honorable Dan Glickman, Secretary of Agriculture.- Present.
Cc: Dockets Management Branch, Food and Drug Administration.- Present ✓

97N-0451

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Subsecretaría de Agricultura y Ganadería

Oficio No. 300. 98/ 001568

SECRETARIA DE AGRICULTURA,
GANADERIA Y DESARROLLO RURAL

México, D.F., a 23 de junio de 1998

**The Honorable Donna Shalala
Secretary U.S. Department of Health
and Human Services
Washington, D.C.**

En representación de la Secretaría de Agricultura Ganadería y Desarrollo Rural y en mi calidad de Subsecretario de la misma, me es grato enviar a usted los comentarios anexos a la propuesta realizada por el gobierno de los Estados Unidos de América referente a la "Guía para reducir los riesgos microbiológicos que coadyuvan a la Inocuidad Alimentaria de las frutas y hortalizas frescas", documento que fue publicado el pasado 13 de abril del presente año.

Al igual que el gobierno estadounidense, el gobierno de México esta comprometido a asegurar que sus productos agroalimentarios, sean sanos, inocuos y nutritivos y a respetar que los estándares y procedimientos sobre Inocuidad Alimentaria se basen en evidencia científica y en los principios de comercio internacional vigentes. En concordancia con la Declaración Conjunta sobre Inocuidad Alimentaria recientemente firmada por usted, el Secretario de Agricultura Dan Glickman, el Secretario de Agricultura, Ganadería y Desarrollo Rural, Romárico Arroyo Marroquín, y el Secretario de Salud, Juan Ramón de la Fuente, le reitero una vez más el compromiso de nuestro gobierno de trabajar conjuntamente con los Estados Unidos en mecanismos que permitan proteger la Inocuidad Alimentaria de los productos agroalimentarios.

En espera de contar con su valiosa asistencia, aprovecho la ocasión para reiterarle la seguridad de mi consideración distinguida.

**Atentamente
Sufragio Efectivo. No Reelección
El Subsecretario**

Francisco J. Gurría Treviño

- C.c.p. Ing. Romárico Arroyo Marroquín. Secretario del Ramo.- Presente.
- C.c.p. Dr. Juan Ramón de la Fuente. Secretario de Salud.- Presente
- C.c.p. The Honorable Dan Glickman, Secretary of Agriculture. Presente
- C.c.p. Dockets Management Branch, Food and Drug Administration. Presente. ✓

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Secretaría de Agricultura Ganadería y Desarrollo Rural

**Comments of the Secretariat of Agriculture, Livestock and
Rural Development (SAGAR) in Response to April 13, 1998,
Draft Guidance for Industry: Guide to Minimize Microbial
Foods Safety Hazards for Fresh Fruits and Vegetables**

Docket 97N-0451

June, 1998

General Comments

Mexico has watched with interest the development of President Clinton's Food Safety Initiative and, in particular, the development of the Guide: Guidance to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Like the United States, Mexico is committed to ensuring a safe and sanitary food supply, based on scientific principles, and not maintained without sufficient scientific evidence. It is important that the Guidance be applied consistently and equivalently to both U.S. and non-U.S. operators, that the Guidance not be a vehicle for competitors to restrict trade, and that the United States recognize non-U.S. producers' use of equivalent standards and systems, laws and regulations in force in their countries.

Consistent with the previous concepts, on June 10, 1998, the U.S. Department of Agriculture ("USDA"), the U.S. Department of Health and Human Services ("HHS"), the Secretariat of Agriculture, Livestock and Rural Development (SAGAR) and the Secretariat of Health (SS) of the United Mexican States signed a Joint Statement pledging to work together to:

- Reduce the incidence of food-borne illness and to enhance the safety of all foods, both domestically produced and imported;
- Identify appropriate fora under NAFTA and bilateral agreements for discussions on food safety issues; and
- Share information and experiences in the scientific area with regard to food safety, especially the microbiological safety area.

Consistent with this Joint Statement, it is important that the Guidance be developed and its underlying principles adopted consistent with the international trade principles contained in the provisions of NAFTA, bilateral agreements, and the Marrakesh Agreement establishing the World Trade Organization ("WTO"). Such international trade principles include transparency, national treatment, equivalency, harmonization, and the specific provisions, obligations and requirements of these Sanitary and Phytosanitary ("SPS") Agreements, among others. These SPS Agreements obligate each party to ensure that any SPS measure applied:

- (1) Is based on scientific principles and appropriate risk assessment;
- (2) Is applied only to the degree necessary to provide a country's chosen level of protection and is not maintained when there is no longer a scientific basis; and
- (3) Does not arbitrarily or unjustifiably discriminate between goods or act as a disguised restriction on trade.

Consistent with the Joint Statement of June 10, the Government of Mexico (i.e. SAGAR and SS) would like to work with the U.S. government (i.e., FDA and USDA) to develop and share in the

development of mutually acceptable research, technical assistance, training, inspection and verification, education and outreach goals, including the application of new technologies.

Further, the President's Food Safety Initiative states that food safety principles will be promoted among all economic agents involved from "farm to table." This means that minimizing microbial risk factors on produce has to be a responsibility of all agents along the food chain. Regarding the definition of the word "operator" within this Guidance, however, it appears that the U.S. Government places an overwhelming share of the responsibility for minimizing microbial risks on the grower, and some (but far less) responsibility on processors and packers. Conversely, virtually no responsibility is placed upon, or guidance provided to, those who receive, handle and consume the product further down the food chain. Therefore, the activities of all of the actors in the food chain, from growers to packers, processors, transporters, distributors, retailers, consumers and others, from "farm to table," should be subject to the Guidance. The Grower can control the product only as long as it is in his/her hands. Consistent with the Fight Bac education campaign, which is targeted primarily at consumer product safety in the food sector, the Guidance should be expanded to address potential contamination of products at stages in the food chain subsequent to production and should give explicit responsibilities to every agent along the chain. In addition, the Guidance's outreach and education should be directed to the producer, the packer, the processor and all other relevant actors throughout the food chain.

Before this Guidance is finalized in October, there are important concepts that need additional emphasis and/or clarification by the U.S. Government. While several of these concepts are addressed in the Addendum to the document, the following points need additional clarification or emphasis:

- ☛ The Guidance is voluntary and "is not a regulation, and therefore, does not have the force and effect of law. The proposed Guide will not bind FDA, USDA, or the public, nor will it create or confer any rights, privileges or benefits for or on, any person."
- ☛ The Guidance refers throughout to U.S. laws and regulations and federal, state and local government, quasi-governmental and other entities. These references do not appear consistent with use of the Guidance by international operators. The document should be modified, consistent with relevant international principles of harmonization and equivalence, and should explicitly anticipate and accommodate the use of comparable laws, regulations and other standards of other nations;
- ☛ The Guidance lacks adequate science and risk assessment methods to support many of the concepts and risk factors included in the Guidance;
- ☛ The burden for minimizing microbial risk should be shared by actors throughout the food chain (see above);
- ☛ Microbial risk factors can be reduced but not eliminated;
- ☛ The Guidance is a living document and will be changed as technology and science are developed on those risk factors;
- ☛ There are certain levels of pathogens that may be safe; and
- ☛ Each element of the Guidance does not apply to every product.

In addition, there are internal inconsistencies between defined terms and the usage of these terms throughout the Guidance. A prominent and important example is the definition of "operator,"

which in many places effectively appears to refer only to the “grower.” Throughout the Guidance, there are broad statements of policy, status of research, or goals, which are neither useful nor intended to “guide.” These statements should be eliminated or transferred to a policy and goal statement accompanying the Guidance.

The documents referenced in the Guidance are cumbersome and difficult to obtain and understand. It will be important to provide easy-to-understand summaries of the concepts included in these documents. In addition, foreign operators are not bound by and will not have access to U.S. laws and regulations. In the meantime, the U.S. Government should recognize that non-U.S. operators will be bound by the equivalent laws and regulations of their own countries.

Given the previous, the SAGAR encourages the FDA and USDA to take this opportunity to develop and use

“harmonized sanitary and phytosanitary measures on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health.”¹

In addition to the previous, the SAGAR recommends to the FDA and USDA that the two nations work jointly to design and implement clear and transparent third-party verification and certification procedures. An important part of the verification and certification program will be working with the private sectors of both nations to implement total food safety quality assurance programs for agrifood products. In this context, it will be important for both governments to promote the celebration of mutual recognition agreements among government agencies and third-party conformity assessment entities or to use the provisions set under article 908.2 of NAFTA.

¹ World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures.

Specific Comments

PREFACE

Comment: *FDA should emphasize that the Guide is based in large part, at this stage, on common sense and general concepts of hygiene, sanitation and cleanliness and that the document will likely be revised and expanded as science and technology are developed. To say that it is based in or focused on science appears inconsistent with several statements throughout that acknowledge substantial scientific gaps in dealing with the different risk factors of this initiative.*

INTRODUCTION

Page 3: "Several recent outbreaks of illness associated with produce. . . have raised concerns regarding the safety of fruits and vegetables.

Comment: *The Guidance mentions two outbreaks associated with mesclun mixed lettuce and raspberries from Guatemala. Are those the only cases? How many others? It is important for the Guidance to distinguish between public concern and real problems. Does the FDA have a plan for addressing consumer hysteria in the wake of such outbreaks? It may be important here to acknowledge that consumer activities such as handling and preparation can play a role in the increased incidences of outbreaks. It may also be important to acknowledge that increased consumption, which is applauded by the U.S. Government, may result in increased incidences, but not in proportional increases.*

Page 3: "Growers and packers, in order to ensure the marketability of their products, need to assess their individual operations and implement steps to reduce the risk of microbial contamination of raw produce."

Comment: *The FDA should carefully consider this statement, which could be read to suggest that only compliance with this Guidance will guarantee access to U.S. and other markets. The statement also provides an important example of the need to spread the burden of minimizing microbial risk throughout the food chain. This statement suggests that the entire burden rests upon the grower and packer.*

USE OF THIS GUIDE

Page 4: The Guide indicates it will identify the broad microbial hazards, the scientific basis, and good practices to address the hazards.

Comment: *The scientific basis for many of the microbial risk factors cited in this Guide are not identified. Consideration should be given to deleting or modifying the reference to scientific basis.*

Page 5:“(2) The guide provides broad, scientifically based principles”

Comment: *It is important to be clear that the Guide does not include broad scientific principles for minimizing microbial risks for fresh fruits and vegetables. Broad scientific principles would include identification of the risk factors, the scientific basis, the risk evaluation technique and the methods for ameliorating the risk.*

We are pleased to see that producers are encouraged to assess the climatic, geographical, cultural, and economic conditions that apply to their own operations in their use of the Guidance. This concept needs additional public emphasis. In addition, principles of national treatment require that, if these factors are utilized by U.S. producers and packers, these concepts must be equally available to non-U.S. producers and packers, as well.

(3) As new information is developed. . . [the agencies will take steps] to update the recommendations and information contained in this Guide.

Comment: *Consistent with the June 10 Joint Statement, Mexico believes the ongoing development of the Guide provides an opportunity for partnership in the development of the new recommendations and information in the Guide, particularly in the development of the science and technology.*

4) The Guide focuses on microbial hazards for fresh produce [and not other types of risks to the food supply or the environment, but growers and packers should] strive to establish practices that do not increase other risks to the food supply or the environment.

Comment: *It appears that the Guide, by including this statement, is in fact imposing another requirement on the grower. This Guidance is by its nature limited to microbial hazards and should not be a vehicle, through incidental statements, to expand its reach to broader environmental or other concepts. We suggest the comment be eliminated.*

BASIC PRINCIPLES

Principle #2 “To minimize microbial food safety hazards in fresh produce, growers or packer should use good agricultural practices in those areas over which they have some degree of control.”

Comment: *In the Spanish version of the Guidance, the language different. The Spanish version also includes the phrase “while not increasing other risks to the food supply or the environment.” This phrase is important.*

Principle #3 “Anything that comes in contact with fresh produce has the potential of contaminating it.”

Comment: *This statement is inflammatory, alarming and should be reworded. The*

production of fruits and vegetables requires intensive handling and contact. We suggest this be changed to read, "Care needs to be taken to ensure that contact with fresh produce is done to minimize contamination."

Principle #7: It is important to follow local, state and federal requirements.

Comment: *This principle does not appear to take into account the use of the Guidance by non-U.S. producers going to comply? Non-U.S. producers should be able to develop and follow their own appropriate food safety laws and standards, consistent with international principles of equivalence and harmonization.*

Principle #8: "Establish a system for accountability at all levels of your agricultural environment . . . [including provisions for effective monitoring and maintenance to ensure the standards are being followed.] "

Comment: *When Mexico exports avocado and mango to the United States or when the United States exports apples and peaches to Mexico, the U.S. Government and the Government of Mexico have to develop comprehensive working plans for exporting such products. The Government of Mexico believes it is crucial that the Guidance be consistent with and recognize the existing systems, such as these work plans, in place to ensure the safety and sanitation of exports. Creating new "qualified personnel and effective monitoring and maintenance" may create additional unnecessary costs and procedures, elevating costs to consumers and, possibly creating trade tensions.*

I. Definitions

Operator

Comment: *The definition of the term "operator" includes production, harvesting, distribution or processing, but throughout the document, even when reference is made to "operators," it seems that it is referring only to growers. This results in the Guide placing the burden of minimizing microbial contamination primarily on the grower. The document needs to be expanded to provide guidance to address other hazards throughout the food chain.*

Adequate

Comment: *In the Spanish version of the Guidance, the word "appropriate" is used. This word has very specific meaning within the WTO. It is a term of art in international trade law and FDA should be careful that the word is used appropriately. In Spanish, "adecuado" means adequate and may be a better choice.*

Fresh fruits and vegetables

Comment: *What does raw mean? Is there a more complete definition? The produce*

(strawberries, raspberries and strawberries) that are mentioned as being harvested “intact” are subject to substantial human contact in their growing and processing processes. What does intact mean?

Food safety control operation

Comment: *With regard to “planned and systematic procedure for taking all action necessary to prevent food from becoming unsafe for the consumer,” it appears that this scope is broader than microbial contamination, although the Guidance is limited to microbial contamination.*

Throughout the document, the FDA refers to U.S. laws published in the United States Code, regulations, published in the Code of Federal Regulations, and other government and scientific publications that are difficult for operators (U.S. or non-U.S.) to obtain, and even more difficult for them to understand. Further, U.S. laws and regulations may provide guidance to non-U.S. operators, but they are not binding upon them. As such, the Guidance should acknowledge that FDA anticipates foreign governments to use equivalent standards and procedures.

Sanitize

Comment: *When reading the definition, it appears that if you use chemicals to sanitize, you will destroy the micro-organisms, but later in the water discussion (Section II), the Guidance states that chemicals will not eliminate the microbial risk. This appears to be an inconsistency because the Guidance encourages the use of products that it later states are not effective. This may need to be reworded.*

I Water

Page 10: “Water has the potential to be a direct source of contamination and a vehicle for spreading localized contamination. . . . Wherever water comes in contact with fresh produce, its source and quality dictate the potential for pathogen contamination.”

Comment: *This language is, again, inflammatory and provides no guide for the operator. We suggest adding that water is a “potential” source of direct contamination, but, because it is also a necessary part of the production process, this language is too strong.*

In addition, it is unclear what methodology the FDA suggests to determine when water is contaminated? What are the parameters for determining that there is a microbial risk? What is the risk assessment threshold?

A. Microbial Hazard

“Water can be a carrier of certain microorganisms Even small amounts can result in food-borne illnesses.”

Comment: *Given the broad scope of the previous statement, the following questions must be answered. What are the parameters for detecting these microorganisms? Is there science to support the statements that small amounts cause food-borne illnesses? What are the risk assessment factors?*

“It is not known what portion of produce may become contaminated by water used in agricultural or packing house operations. However, growers and packers are urged to take a proactive role in minimizing those microbial hazards over which they have some control”

Comment: *Although the Guide acknowledges that there is not science to support how much or when produce is contaminated by water, the growers and packers appear to bear the sole burden for minimizing the risk. That seems unfair. First, consistent with other comments, the burden for minimizing contamination should follow the product, and water is used at almost every link in the food chain. Second, it is difficult to minimize a risk you cannot define.*

B. Control of Potential Hazards

page 11: “In general, the quality of water in direct contact with produce may need to be of better quality compared to uses where there is minimal water-to-produce contact.”

Comment: *If only a minimal amount of contaminated water is used, the product can be contaminated. As such, it appears that there is no scientific evidence to support this statement, and it appears inconsistent with later statements, which indicate that clean water is more important later in the production and processing chain than in the initial washing of the product, for example.*

Page 11: “Some sectors of the produce industry use water containing sanitizers to minimize potential surface contamination.”

Comment: *The definition of sanitize indicates that, for food contact surfaces, it is the reduction of microorganisms by 5 log or 99.99%. Does “minimize” suggest a different level of reduction of microorganisms? Minimize should be defined.*

1.0 *Agricultural Water*

This section discusses both surface water and ground water and the measurement of microbial contamination. The Guidance acknowledges that microbial contamination and overall quality of surface water will vary.

Comment: *How is the quality of surface water measured, given the Guidance’s acknowledgment that the quality may change rapidly. How will producers assess quality and contamination in the ground water?*

In the Spanish version, the Guidance substitutes the word “appropriate” for

“adequate” in English. “Appropriate” is a term of art in international trade law and is used in Representative Anna Eshoo’s proposed legislation. The Government of Mexico prefers that the Spanish version use “adecuado,” consistent with the English version.

1.1 General considerations

“It is generally assumed that ground water is less likely to be contaminated”

Comment: Please provide any citation or scientific basis for this statement.

*“The Extension Service Farm*A*Syst program available from County Extension Offices may help [producers to examine the quality of wells, which may impact ground water quality].”*

Comment: County Extension Offices and the relevant documents are not available to non-U.S. operators. We suggest adding that U.S. trading partners may be able to provide harmonized or equivalent guidance for detecting ground water contamination.

“Agricultural water can become contaminated . . . by improperly managed human and animal waste.”

Comment: FDA needs to consider how much of agricultural water is contaminated and what are the thresholds/parameters for assessing risk from such waste.

Consider the “historical use of land”

Comment: The burden of assessing the factors that impact the watershed must be shared. Growers simply cannot assess all the industrial, natural and other factors that impact the watershed. This is beyond the scope of the documents.

Consider testing water quality:

Comment: Based on the significant scientific gaps acknowledged by the document the FDA states that microbial testing may not be useful for some growers. But in footnote 3, the Guidance also states that the FDA is not aware of existing microbial standards for agricultural water. What testing can be done without standards? Which growers can do so? Is the FDA suggesting that producers refer to the EPA standard for recreational standards. That raises important questions of equivalency, as mentioned throughout. If not, what is the acceptable level of bacterial density. What tests or systems would be considered adequate to have a system or procedure that is in compliance with the Guidance? Are there systems or procedures for detecting the other pathogens mentioned here (e.g., vibrocholera, salmonella, etc.)?

“Growers may elect to test their water supply for microbial contamination on a periodic

basis. . .which may be performed by private, state or local government authorities. Consult local water quality experts.”

Comment: *The Guidance should explicitly recognize non-U.S. water quality standards and expertise. What kind of labs are going to be authorized/certified to perform these tests and analysis abroad? Will the U.S. and Mexico agree to send water to a central place or to third-party entities? How quickly must results be delivered? Some may take overnight, for example. We suggest these tests, systems and procedures should be governed by a rule of reason. If not all of these suggestions/recommendations for water quality management are required, which are?*

1.2 Irrigation Water:

“Irrigation practices that expose the edible portion of the food to contaminated water increase microbial food safety hazards” The Guidance recommends the use of drip systems as opposed to spray irrigation systems.

Comment: *What is the scientific basis for this? Isn't this statement based more on common sense than scientific fact? What are the specific problems with spray? If this is read in the context of previous comments that there is no way to determine certain water is safe and other is not, then how can you determine one method of irrigation is preferable?*

Be Aware of Risk Factors

“. . . as water-to-produce contact increases, microbial water quality needs to be better, especially close to harvest.”

Comment: *What is the scientific basis for this statement?*

☛ Non-irrigation water uses.

“. . . should be considered in the same manner as agricultural, irrigation and non-irrigation water.”

Comment: *In general, we agree that growers should consider practices to protect the quality of water. But what is the standard for irrigation water? The Guidance is using a term that is not defined. The same is true for irrigation, agriculture and non-irrigation water. Quality is not defined. How is quality determined?*

“The potential for contamination depends on the crop, the amount of water contacting crops. . .”

Comment: *What is the scientific evidence to support that use of water may be good or bad depending on the physical characteristics of the crop?*

3.00 Processing Water

“Water used during processing . . . usually involves intimate water-to-produce contact. Although water is a useful tool for reducing potential contamination, it may also serve as a source of contamination or cross-contamination.”

Comment: *Reference to the CFR is not useful for non-U.S. operators. At least its basic applicable provisions should be summarized. The Guidance must explicitly take into consideration use of relevant non-U.S. laws and regulations. What are the parameters for measuring the quality of processing water. It would be helpful to provide easy-to-understand summaries of the relevant standards and for comparisons with relevant non-U.S. standards, procedures, laws and regulations.*

“Follow good management practices to minimize microbial contamination. . .Water that meets the microbial standards for drinking water is considered safe and sanitary.”

Comment: *Drinking water standards appear to be excessively high for processing water.*

In the Spanish version, there is a typographical error on p. 14. It should read “del agua”

“Consider practices that will ensure and maintain water quality”

Comment: *There is a typographical error in the Spanish version: mantiengan should be mantengan.*

We would suggest replacing the word “ensure” with “reduce or minimize risk.” It is difficult to ensure water quality.

“The quality of water, including recycled water, should be appropriate for its intended use.”

Comment: *What is the “quality” being sought? In using the word “appropriate,” does the FDA intend to utilize the WTO term of art? In the Spanish version, here, the FDA uses “adecuado”. This mis-usage is confusing.*

“Periodic water sampling and testing.”

Comment: *What is the appropriate sample and testing procedures? How often, what size of sample at what time of the day? What other relevant aspects should be considered?*

“Monitoring ph and sanitizer levels.”

Comment: *What are the ph and sanitizer levels needed for processing waters? For drinking waters? If the appropriate levels depend upon the stage of processing, then what are the standards for the relevant stages?*

Changing water as necessary to maintain sanitary conditions.

Comment: *The Guidance recognizes that water quality differs in different stages, but the Guidance also recommends sampling and testing. Again, the parameters for the different stages should be clarified.*

“Water contact surfaces should be kept clean and sanitary.”

Comment: *Define clean and sanitary. Is this defined to as meeting the drinking water standards?*

2.2 Wash Water

Comment: *The document should outline parameters for measuring wash water quality.*

“Use appropriate wash methods – use hot water or water containing surfactant.”

Comment: *It is not always appropriate for growers to use hot water, which may affect quality, on produce. Perhaps this comment should be changed to say, consider the use of hot water as long with its effect on the quality of the product.*

“As water -to-produce contact increases. . . the potential for contamination also increases. Spray wash treatments may be less likely to disseminate microbial risks than submerged wash treatments.”

Comment: *What is the basis for this? Spraying contaminated water may spread contamination.*

“Consider the use of sanitizers or antimicrobials in wash water.”

Comment: *The Guidance refers in footnote 5 to CFR. This information is not readily accessible to non-U.S. growers. Non-U.S. producers should be able to use comparable national standards.*

“Maintain the efficacy of wash treatments.”

Comment: *See comment on the definition of sanitizing, which is said by be a means to treat produce by a process that is effective in destroying or substantially reducing. . . for food contact surfaces by 5 log or 99.99%. Yet this comment acknowledges that wash water, even with microbial chemicals, (10-100-fold) will not necessarily eliminate contamination. This section is inconsistent with the definition of sanitization.*

“Consider the wash water temperature for certain produce. There is some evidence to suggest that submerging warm tomatoes in cold waters may create a pressure differential causing pathogens that may be present on the surface of tomatoes to be internalized or pulled into the tomatoes. The recommendation is that wash water be hyper-chlorinated

and ten degrees [Fahrenheit] warmer than the tomatoes.”

Comment: *In the Spanish version of the Guidance, the grades (Fahrenheit or Celsius) are not specified. By way of example, when growers in Culiacan, Sinaloa, harvest tomatoes, the temperature of the tomato in the field is approximately 30-35 degrees Celsius, and the water used to wash is approximately 25-30 degrees Celsius. This document suggests that the tomato has to be washed at a temperature ten degrees higher than the field temperature, or at approximately 40-45 degrees Celsius. For the tomatoes in Sinaloa, then, the quality of the product could be damaged. What is the scientific basis for stating that tomatoes should be washed at that temperature? These factors should depend upon region, time of day and other aspects. We encourage the FDA to establish parameters depending on region, time of day and other relevant aspects.*

“Several alternative disinfectants are under study.”

Comment: *This is not Guidance. That is a statement and will be helpful only when the results of the study are available.*

2.3 Cooling Operations

Comment: *What are the parameters for assessing the quality of water used in cooling operations? In the Spanish version of the Guidance, page 18, 2nd paragraph, third line, there is a typographical error. Rather than el it is la. In addition, in to the penultimate line of that same paragraph, insert pudo after lechuga.*

“Maintain temperatures that promote . . . optimum produce quality. . . . There is general agreement that good quality intact produce is most resistant to microbial contamination and growth.”

Comment: *What is the scientific basis for this statement? Is the Guidance suggesting by use of the word intact that there should be no handling, which increases temperature, of the produce? The concern is expressed, but no guidance is provided for maintaining temperature.*

“Water and ice used in cooling operations can be potential source of contamination. . . .”

Comment: *What is the scientific basis for that and what are the parameters for water and ice quality?*

“Keep water and ice clean and sanitary.”

Comment: *See comment above.*

“Water and ice in hydrocoolers should be changed as needed to maintain quality.”

Comment: *What does that mean? Quality is not defined.*

III. Manure and Municipal Bio-solids

“Properly treated manure and bio-solids can be an effective and safe fertilizer. Untreated or improperly treated manure or biosolids used as a fertilizer, used to improve soil structure, or that enters surface or ground waters through run off, may contain pathogens of human health significance that can contaminate produce.”

Comment: *What are the definitions for treated, improperly treated, and un-treated. How safe? How effective? What is the difference between use of that or improperly treated manure that “may contain” pathogens. If you want to have an effective and safe fertilizer, what are the practices that will give you properly treated manure? What techniques for proper treatment? What is the scientific basis for saying that properly treated manure is safe or that improperly treated has pathogens?*

A Control of potential hazards.

The document refers to EPA’s notice outlining U.S. Environmental Protection Agency published a notice outlining U.S. policy statements about the beneficial use of biosolids on Federal land, including its use on federal lands.

Comment: *Again, non-U.S. operators have limited access to and understanding of EPA documents.*

“Growers using bio-solids must first meet the requirements of Title 40 of the U.S. Code of Federal Regulations, part 503, as well as comply with any additional state requirements. . . growers may want to consider some of the principles behind the Part 503 requirements and consider the appropriateness of adopting some of these principles to the land application of manure.”

Comment: *The Guidance should be modified to restrict the application of 503 only to those parts relating to microbial standards. In addition, non-U.S. operators will have difficulty obtaining and understanding these regulations. These laws and regulations do not apply to non-U.S. operations. This may provide an opportunity for the U.S. Government and the Government of Mexico to develop harmonized standards and systems in this area.*

“Growers may obtain guidance on proper agronomic methods for the use of biosolids from USDA’s Natural Resource Conservation Service. . . and Cooperative State Research, Education and Extension Service. . . [as well as consult] the resources at the end of this section.”

Comment: *Again, non-U.S. operators will have difficulty obtaining and understanding the documents referenced in this statement and have non access to the services referenced therein. In addition, these agencies and services and the laws and*

regulations they implement are not binding on non-U.S. operators. This kind of activity may present an opportunity for the Government of Mexico and the Government of the United States to develop harmonized standards for appropriate handling of biosolids.

2.0 Good Agricultural Practices for Manure Management

Comment: *The Government of Mexico proposes that the Guidance provide more practical advice for operators' handling of manure.*

2.1 Composting

“Composting is a common treatment to reduce the microbial hazards of raw manure. . . [and composting c]an kill most pathogens in a number of days. Much of the research on the composting of manure and application of manure to field crops has focused on the effects of different practices on soil fertility and crop quality. Research on pathogen survival in untreated manure, research to reduce pathogen levels in manure and assessing the risk of cross-contamination of food crops from manure under varying conditions is largely just beginning.”

Comment: *Consistent with our earlier comments, the Guidance is not providing any assistance to operators in suggesting, outlining or otherwise guiding composting methods to eliminate or minimize the presence of pathogens.*

“. . . the agencies do not have sufficient data to make specific time and temperature recommendations.”

Comment: *The Guidance is stating that composting may work, but is providing no guidance for how to compost to reduce pathogens.*

2.2 Handling and Application.

“Equipment, such as tractors, that comes into contact with untreated or partially treated manure and is then used in produce fields can be a source of contamination.”

Comment: *What is the scientific basis for assessing the risk of contamination by this method?*

2.2.1 Untreated manure

“Use of untreated (raw) manure on food crops carries a greater risk of contamination, compared to the use of manure that has been treated to reduce pathogens.”

Comment: *Manure is called both an effective and safe fertilizer and a potential source of pathogens, but the Guidance is not providing concrete steps for reducing pathogens.*

“Growers may reduce the risk of contamination by maximizing the time between application of manure to a field and harvest. The National Organic Standards Board,

formed under the Organic Food Production Act of 1990, following the guidance of the act, recommended that raw (untreated) manure should not be applied within 60 days of harvest of organic crops intended for human consumption.”

Comment: *The U.S. law referenced above is not binding on non-U.S. operators. This may be an important opportunity for harmonizing guidelines and recommendations for the application of manure.*

Footnote 13: “There are two studies that have found that *E. coli* 0157:H7 may survive in dairy cattle for at least 70 days, depending on temperature, and, perhaps, moisture conditions.”

Comment: *This is a good subject for additional research on the lifespan of E. coli 0157:H7 and other pathogens in manure. In addition, the references included in the Guidance for manure handling may not be available to non-U.S. operators.*

2.2.2 Treatments to Reduce Microbial Contaminants in Manure

“Composting and other treatments may reduce but might not eliminate pathogens in manure.”

Comment: *Earlier, the Guidance suggests that properly treated manure can be effective and safe. This appears inconsistent. In addition, it is important to stress that, below a certain level, the presence of certain pathogens may not be harmful to human health.*

“. . . to the extent feasible, growers using treated manure may want to consider some of the recommendations made for untreated manure. . . .”

Comment: *If the Guidance is going to recommend identical steps for treated and untreated manure, maybe some of the information can be eliminated or consolidated.*

3.0 Animal Feces

“Domestic animals such as cows or sheep should be excluded from fresh produce fields.”

Comment: *All of the burden is on the fresh fruit and/or vegetable producer and not on the producer of livestock, who is in an important role to control the movement of his cattle or sheep. Wild animals, by their very nature, are not subject to controls. This suggestion, while an important goal, may not be economically feasible.*

“In addition, Federal, state and local animal protection requirements must be considered.”

Comment: *Again, these federal, state and local requirements are not binding upon and are not readily available or understandable to non-U.S. operators. The Guidance should explicitly acknowledge the use of comparable non-U.S. laws and regulations.*

Helpful Resources

Comment: *The resources provided at the end of this section are solely U.S. resources that are not readily available or understandable to non-U.S. operators. In addition, of course, the rules and regulations discussed in these resources are not binding upon non-U.S. operators.*

IV. Sanitation and Hygiene

“At every phase of the food chain, from the field to the table, good sanitation and hygiene practices are essential for reducing microbial hazards in fresh fruits and vegetables.”

Comments: *Whose responsibility is the adoption of good sanitation and hygiene management from the field to the table? The grower and packer cannot be responsible from field to table.*

A Worker

“The U.S. Code of Federal Regulations Title 21, Section 110.10 (21 CFR 110.10) prescribes worker health and hygienic practices for food production, packing and handling.”

Comment: *As mentioned in previous comments, the Guidance should explicitly acknowledge the use of comparable or equivalent non-U.S. laws and regulations governing hygiene in food production and packing. The reference to these documents, without summaries of the specific, relevant provisions, does not “guide” non-U.S. operators who, will have difficulty obtaining and understanding U.S. regulations, which are not binding upon them.*

“Operators should be aware of all applicable OSHA standards.”

Comment: *See above.*

1 Microbial Hazard

“Past outbreaks of food-borne illness associated with fresh fruits and vegetables are usually the result of produce becoming contaminated with fecal materials.”

Comment: *This is a broad statement, the basis for which should be provided. Earlier, the Guidance stated that contamination may occur in the field, in the processing plant in the packing facility. If the risk is predominantly from fecal material, then perhaps the Guidance can be consolidated to address that specific risk.*

“Therefore, operators should place a high priority on ensuring the use of agricultural practices that minimize the potential for direct or indirect contact between fecal materials and fresh fruits and vegetables.”

Comment: *The previous statement appears to be unnecessary, since every operator wants to minimize direct and indirect contact between his/her product and fecal material.*

2.1 Control of Potential Hazards.

Comment: *Throughout this section, the Guidance references to "established principles of hygiene." If the Guidance has particular practices in mind, it would be helpful to outline them here.*

The section also refers to U.S. laws and regulations. These source materials can be difficult for non-U.S. operators to obtain and understand. Principles of equivalence suggest that the Guidance should summarize these requirements for foreign producers, packers and processors and should explicitly provide for the use of comparable non-U.S. laws, regulations and rules. Of course, U.S. laws and regulations are not binding on non-U.S. operators.

"Become familiar with typical signs and symptoms of infectious diseases."

Comment: *This is an unrealistic burden for the grower, who is not trained in medicine. An alternative approach would be for growers to encourage their workers to report illness.*

In addition, this section references the FDA food code, which is not binding upon non-U.S. operators. Principles of equivalence suggest that the Guidance explicitly recognize non-U.S. operators' reliance on comparable non-U.S. laws, regulations and/or guidelines.

2.2 *Training*

“When providing training for employees, OSHA standards should be considered.”

Comment: *As mentioned above, OSHA and its implementing regulations are not binding on foreign operators. Principles of equivalence suggest that the Guidance explicitly recognize non-U.S. operators’ reliance on comparable non-U.S. laws and regulations.*

“The importance of good hygiene. All people should understand the impact of poor personal cleanliness.”

Comment: *How should growers, packers and processors assess whether all people understand this? In addition, the responsibility for good hygiene and cleanliness should be shared by all actors from “farm to table.” In addition, the Guidance should acknowledge that personal hygiene standards differ regionally within the United States and abroad.*

“The importance of using toilet facilities.”

Comment: *We suggest rewording this section to state, “owners should be encouraged to provide toilet facilities.” How is the worker to know whether the facilities are connected to sewage facilities?*

B. Sanitary Facilities

2.0 Control of Potential Hazards

“Operators should become familiar with laws and regulations that describe appropriate field and facility sanitation practices.”

Comment: *This and subsequent sections reference OSHA. As stated previously, this law and its implementing regulations do not apply to non-U.S. operators. Principles of equivalence suggest that the Guidance explicitly recognize comparable non-U.S. laws and regulations on these points. In addition, the documents referenced herein may be difficult for non-U.S. growers to obtain and understand. If necessary, the Guidance should include summaries of the relevant provisions.*

2.1 Toilet facilities and hand-washing stations

Comment: *This series of comments implies a basic lack of respect for the worker as a human being. The Government of Mexico encourages its operators to treat agrifood workers with respect and to provide basic toilet and hand-washing facilities. This series of comments may be too specific.*

2.2 Sewage disposal.

“Operators should follow EPA regulations for use or disposal. . .”

Comment: *EPA regulations are not readily accessible or understandable to non-U.S. operators. These regulations, as mentioned previously, are also not binding upon non-U.S. operators. Consistent with principles of equivalence, the Guidance should explicitly recognize that non-U.S. operators may follow relevant and comparable laws and regulations promulgated in their countries. This issue may provide an opportunity for harmonization.*

C. Field Sanitation

1.1 Microbial Hazards.

“Contamination or cross-contamination may result from contact with water, soil, workers”

Comment: *This is an extremely broad comment that provides little or no guidance to the operator.*

2.1 General Harvest Considerations

“Clean harvest facilities prior to use.”

Comment: *Is the grower or the packer responsible for cleaning these facilities?*

2.2 Equipment Maintenance

“Field equipment. . . can easily spread germs to fresh produce. [Growers and operators should be aware of the use of their equipment and ensure it is being operated appropriately.]”

Comment: *There is no scientific basis provided for this very broad statement. Of course, it is in the interest of operators to ensure their equipment is used and maintained correctly.*

D Packing Facilities

Comment: *In some copies of the Guidance, this is noted as C.*

1 Microbial Hazards.

“Operations with poor sanitation in the packing house environment can significantly increase the risk of contaminating fresh produce and water.”

Comment: *This statement is too broad and provides no guidance to the packer for ameliorating this risk. In addition, the definition of sanitizing has a very specific meaning in this document. It is unclear whether the Guidance intends for the parameters included in that definition to apply here.*

2.2 General considerations for Facility Maintenance.

“The equipment used in packing fresh fruit and vegetables should be of such material and workmanship as to be cleanable. The design, construction, use and general cleanliness of equipment can help reduce the risk of cross-contamination of produce.”

Comment: *What is the scientific basis for this statement?*

2.3 Pest Control.

“All animals, including mammals, birds, reptiles, and insects, are potential sources of contamination in produce environments because they harbor, or could be a vector for, a variety of pathogenic agents, such as *Salmonella*. Pest problems can be minimized [in the following ways.]”

Comment: *This is a very broad statement. It is important throughout this document, as here, to discuss minimizing as opposed to eliminating risk. We recommend this statement be amended to recommend establishing an appropriate system of pest and animal control, especially since it is impossible to ensure the absence of insects, animals in the fields.*

“Monitor or maintain facilities regularly.”

Comment: *How regularly?*

1 Customer Pick Operations and Road Side Stands.

Comment: *Growers appear to bear the entire burden of ensuring that the humans that interact with the product do not contaminate the produce. The customers and those who choose to enter the fields should share the burden for ensuring that they employ good sanitation and hygiene.*

“Provide convenient, properly equipped handwashing stations in the field.”

Comment: *The Guidance should provide additional information about what is considered a “properly equipped” handwashing station.*

Helpful Resources

Comment: *The USDA Resource referenced herein is not readily available to or understandable by non-U.S. operators.*

F Transportation

“Operators are encouraged to pay particular attention to the product as it is transported between the field and the cooler, packinghouse, processing facility, distribution and retail centers. The proper transport of fresh fruits and vegetables will help reduce the potential for microbial contamination.”

Comment: *This section places too much responsibility on the grower/operator for a function that is frequently out of his control. For example, if the grower sells his product to a packer, he may never see the product again and can have no control over whether the product is properly transported.*

2.2 General Transport Considerations.

“Operators should strive to assure that sanitation requirements for trucks or other carriers are met before loading produce to help reduce the likelihood for microbial contamination.”

Comment: *The burden of ensuring that sanitation requirements are met for trucks and other carriers does not properly rest with the grower. The Guidance should state explicitly that the burden does not rest solely with the grower or packer. Brokers, exporters, importers, retailers, wholesalers and others must share this responsibility.*

☛ “Keep transportation vehicles clean to help reduce the risk of microbial contamination or cross-contamination of fresh produce.”

Comment: *In the Spanish version of the Guidance, line 4 “no ser” should replace “no se”*

V. Traceback

Comment: *There is a general concern that the traceback initiative will be used as a pre-text for mandating country-of-origin labeling, which is viewed by many in both countries as a non-tariff trade barrier designed to restrict competition. In addition, FDA has acknowledged that there is inadequate science to support a trace-back program at this time. Perhaps the traceback portion of the Guidance should be implemented only when the scientific capability is developed.*

Overview of traceback inspection process; challenges facing the produce industry; advantages of an effective traceback system.

Comment: *These general statements about the state of research and development of traceback systems, the state of the produce industry and the advantages of traceback provide no guidance for the operator and should be eliminated from the Guidance.*

Instituting effective trace-back systems.

Comment: *The Guidance should provide more detail on these proposals and additional opportunity for affected operators to comment.*

“Many farmers, especially those from small farms, have little control over what happens to produce after it leaves their property.”

Comment: This point should receive additional emphasis throughout the document. It is inconsistent with some previous statements, particularly on transportation and underscores the need for actors throughout the food chain -- not just growers and packers -- to share the responsibility for minimizing microbial hazards.

VI. Conclusions

“This guidance document provides some basic principles and recommended practices for operators to consider that will help minimize microbial food safety hazards in the production of fresh fruits and vegetables. While research is ongoing and will continue to provide new information and improved technologies, the industry is urged to take a proactive role to minimize those microbial hazards over which they have some control. Operators are encouraged to utilize this guide to evaluate their own operations and assess site-specific risks so they can develop and implement reasonable and cost effective alternative management practices.”

Comment: *The points included in this statement are important and should receive additional emphasis throughout the document. The Guide substantially deviates from these concepts in significant ways in the specific recommendations offered throughout..*