

PERSPECTIVES ON  
ACHIEVING AND ASSURING  
HYGIENIC DESIGN

Regulatory Sanitarian  
Perspective

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# REGULATORY SANITARIAN PERSPECTIVE

The “A” Level Standard T00.00 ---  
Sanitarians view this as a “Safe Harbor”  
but recognize the probable need for fine  
tuning as it is put into effect.

B level standards are exceptions to the  
“Safe Harbor” .

These slides will present 4 General Principles  
Sanitarians use in evaluating both the “A”  
level safe harbor and the “B” level  
exceptions.

# REGULATORY SANITARIAN PERSPECTIVE

Understanding and accommodating the principles which guide the Sanitarians has a very real potential to ease, smooth, and speed the Sanitarian's ability to review something new, and to accept it or provide a clearer idea of what would be required for them to accept it.

# Regulatory Sanitarian Perspective

## 4 Guiding Principles

- ▣ 1. Public Health and Product Quality Concerns are primary in their evaluation process.
  - NOTE: In addition to public health issues, USDA and many State Regulatory Agencies must regulate product quality issues such as discoloration of products, smell, texture, scorched particles, and taste. Equipment design and construction play a big part in minimizing these deficiencies.

# Regulatory Sanitarian Perspective

## 4 Guiding Principles

- ▣ 1. Public Health and Product Quality Concerns are primary in their evaluation process.
  - Concerns that some material or manufacturing practice is cheaper or is commonly practiced or accepted elsewhere have not historically been persuasive in dealing with regulatory sanitarians.

# Regulatory Sanitarian Perspective

## 4 Guiding Principles

- ▣ **1. Public Health and Product Quality**  
Concerns are primary in their evaluation process.
- ▣ **2. Base technical decisions on the best available science.**
- ▣ Sanitarians will view that science conservatively when there is uncertainty or when the scope to what the science actually demonstrates is limited.

# Regulatory Sanitarian Perspective

## 4 Guiding Principles

- ▣ 1. Public Health and Product Quality Concerns are primary in their evaluation process.
- ▣ 2. Base technical decisions on the best available science.
- ▣ 3. Burden of proof --- Is on those proposing a change. (to demonstrate the public health safety of their proposed changes)
  - Example powdered/sintered metals)

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- ▣ 4. Support innovative and even precedent setting solutions that are supported as described above.

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