# Hygienic Equipment Design

## By The Numbers

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May 2016

# *Agenda*

| | |
|---|---|
| **1** | Recalls & Outbreaks |
| **2** | Defining the Hygienic Level of Supply |
| **3** | Hygienic Risk Analysis |
| **4** | Cleaning and Hygienic Design |
| **5** | Costs of Hygienic Design |

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# *Recalls and Outbreaks*

In the USA, food recalls and foodborne illness have an annual costs of approximately $77 billion (including discarded product, revenue, health care costs, lost wages and litigation). The damage to a company's reputation, while difficult to measure, can be even more devastating.

The potential impact of food safety outbreaks on a food business or a company can be devastating. A single event can bring unimaginable economic losses.

# *Food Safety in the News*

Recall due to **Salmonella in Breakfast Cereals**

2009: breakfast cereal linked to Salmonella outbreak

**£20m salmonella** hit in chocolate

2007 UK

- Cost for recall 20 Mio £
- 1 Mio £ fine
- Caused by water leakage from a pipe

Recall due to **E. Coli in raw cookie dough**

2009: recalls of refrigerated cookie dough

2013: Precautionary recall involving 36,000 boxes of cereal due to possible presence of **glass fragments**

2014

Allergy warning

**Grain** mixture recalled due to **undeclared gluten**

2013: recall ice cream because **pain relief tablets were found**



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# Each year,

**1** in **6** Americans, or **48 million people,**
get sick from foodborne illnesses.

**128,000** are hospitalized,
and **3,000** **die.**




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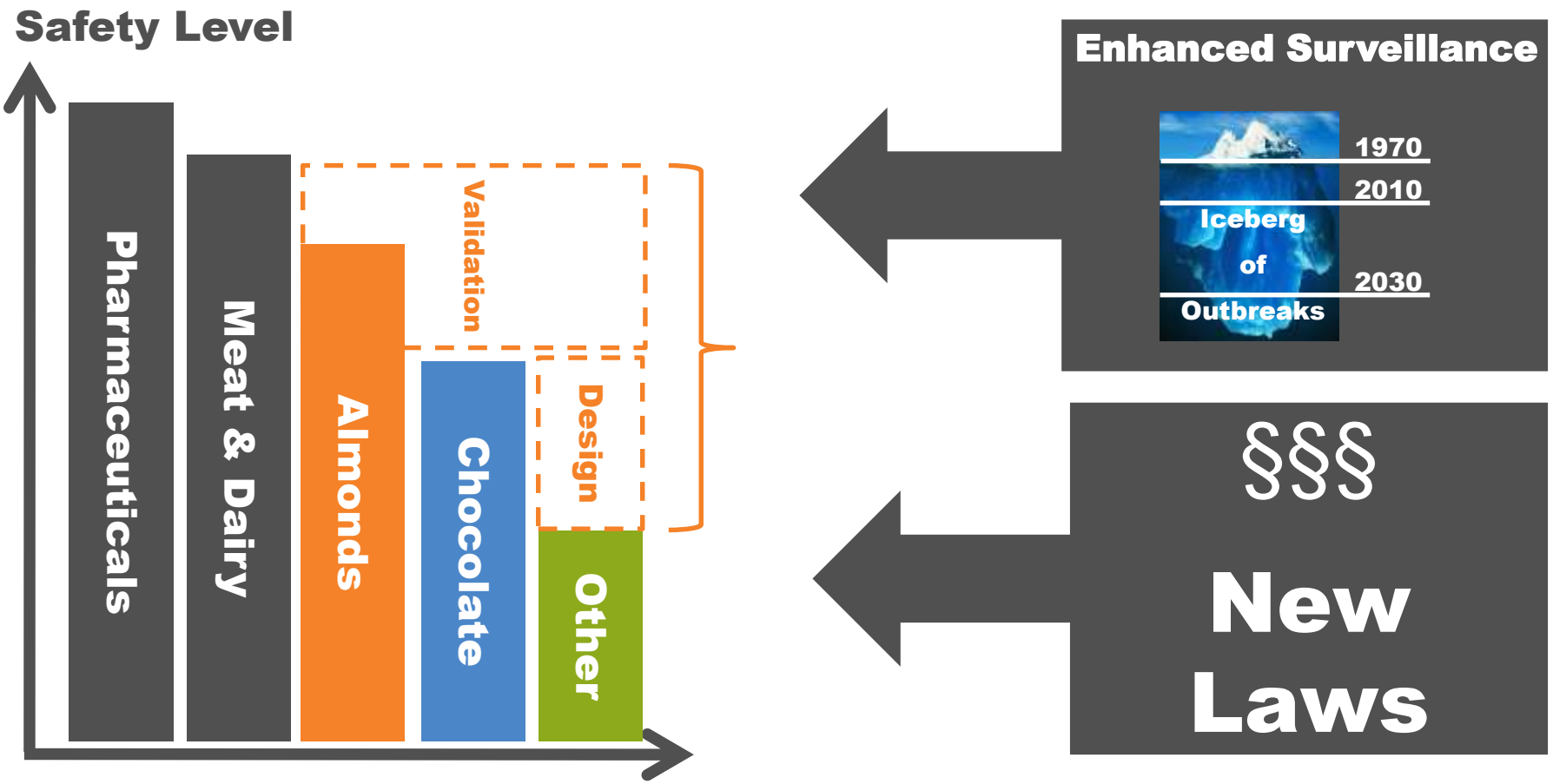
# ***Market Trend.***

*Required Food Safety Level Increases.*



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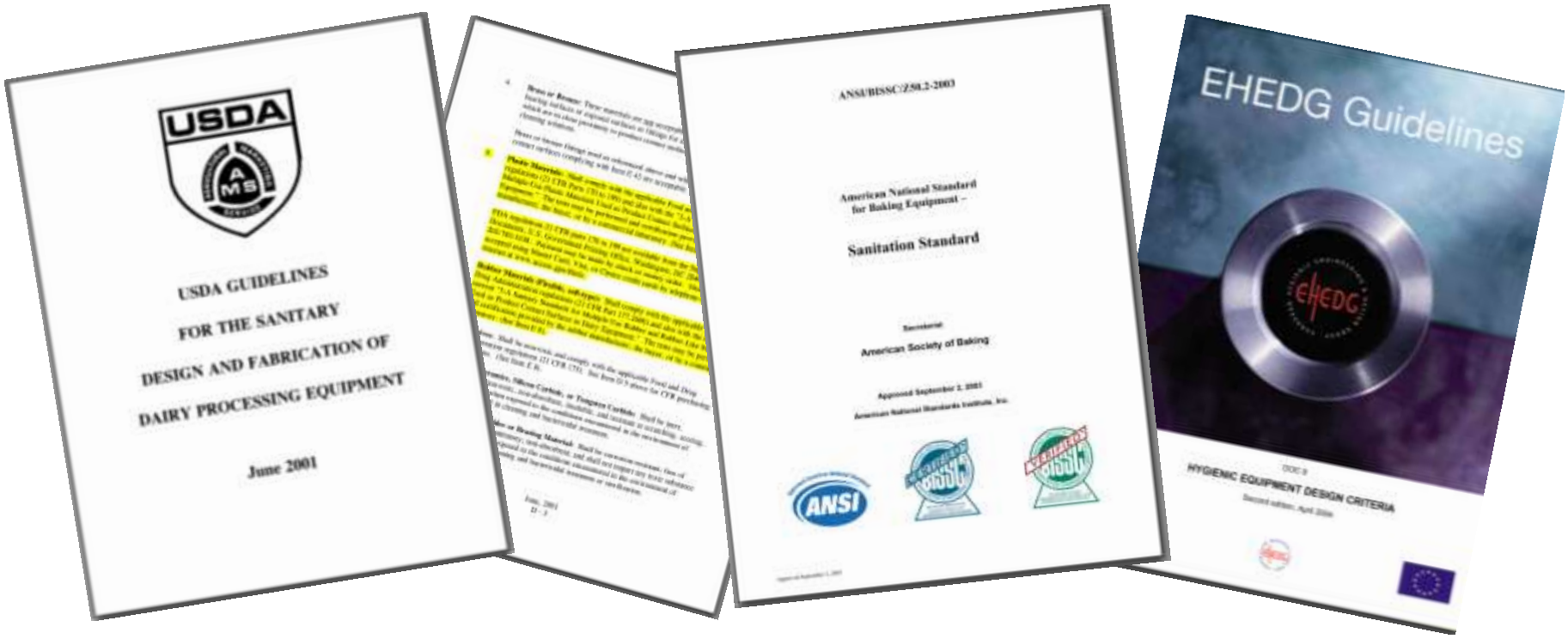
# *Request for Quote - Hygiene Specification*

- Specifications typically are a combination of several existing guidelines and segments are selected per application

- Within the same industry same piece of equipment can have different hygienic specification



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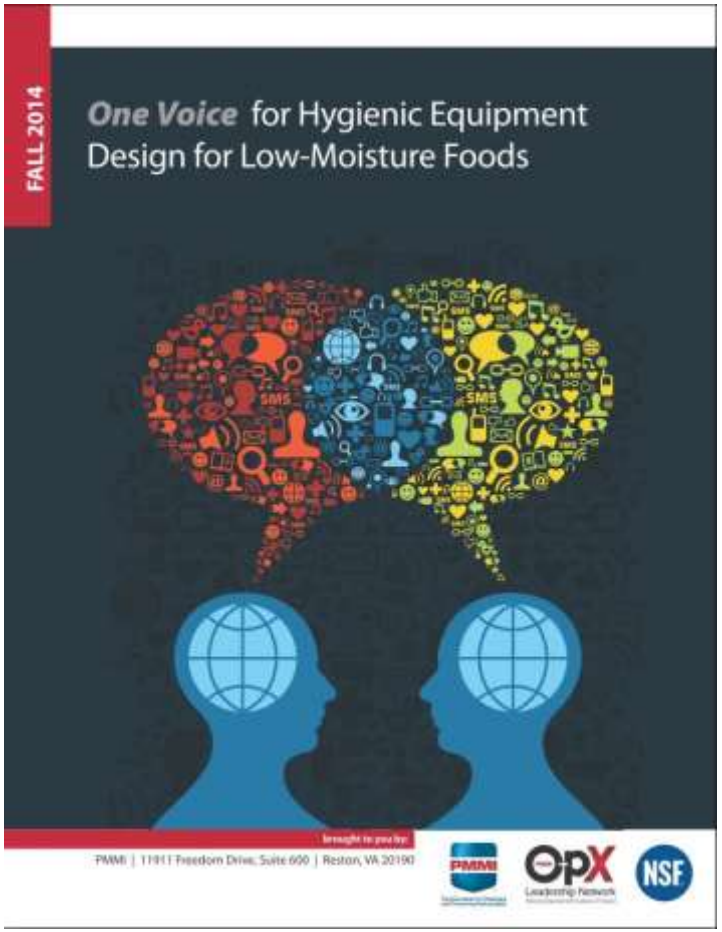
# *Define Hygienic Level of Supply*

- Food safety is not a competitive advantage
- Quickly identify basic hygienic requirements
- CPG's and OEM's understand each other
- Competitive bids – compare apples to apples
- Equipment is not over specified driving costs up

# *OpX – One Voice*

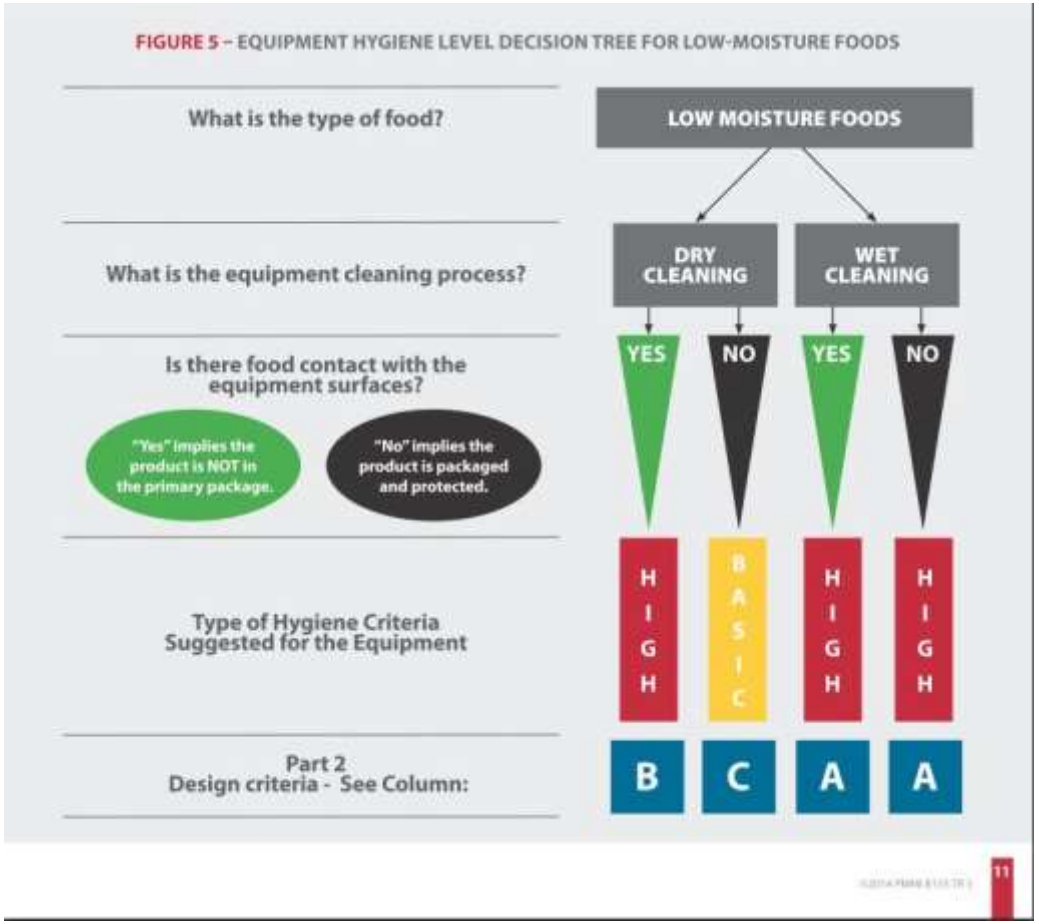
- Document utilizes existing industry standards
- Allows consumer packaged goods (CPGs) and original equipment manufacturers (OEMs) to reach consensus of design criteria for hygienic equipment for low-moisture food manufacturing.
- Developed through a collaboration of CPGs & OEMs resulting in ONE VOICE © for the industry.
- The document has two parts:
  - Part 1 describes the Joint Collaboration Process
  - Part 2 Criteria for the Design and Construction of Equipment used to Manufacturer Low-moisture Foods.
- Part 2 represents the design criteria and information from several industry resources that was coalesced into a “what is important and how to achieve the basic hygienic design needs” tool.



# *OpX – One Voice Part 1*

Hygienic requirements vary by product type, cleaning methods (wet or dry), and more. Consider the hygienic decision tree from OpX.

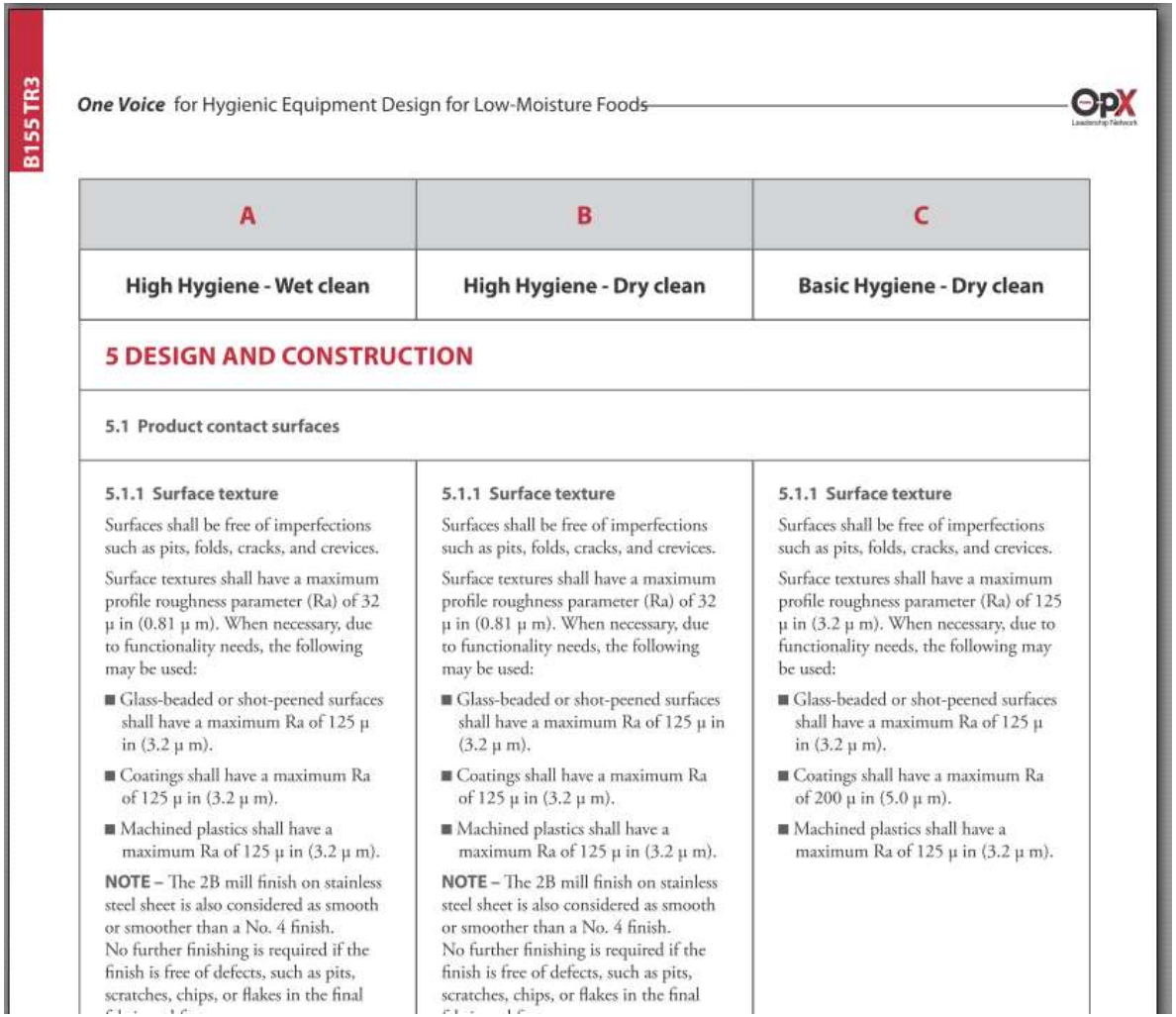
You can download the guideline at: http://opxleadershipnetwork.org



# *OpX – One Voice Part 2*

Columns A, B and C identified in Part 1

OEM's offer standard equipment vs customer specific equipment and take advantage of multiplication



B155 TR3

*One Voice* for Hygienic Equipment Design for Low-Moisture Foods

OpX

| A | B | C |
|---|---|---|
| **High Hygiene - Wet clean** | **High Hygiene - Dry clean** | **Basic Hygiene - Dry clean** |
| **5 DESIGN AND CONSTRUCTION** | | |
| **5.1 Product contact surfaces** | | |
| **5.1.1 Surface texture**<br>Surfaces shall be free of imperfections such as pits, folds, cracks, and crevices.<br>Surface textures shall have a maximum profile roughness parameter (Ra) of 32 µ in (0.81 µ m). When necessary, due to functionality needs, the following may be used:<br>■ Glass-beaded or shot-peened surfaces shall have a maximum Ra of 125 µ in (3.2 µ m).<br>■ Coatings shall have a maximum Ra of 125 µ in (3.2 µ m).<br>■ Machined plastics shall have a maximum Ra of 125 µ in (3.2 µ m).<br>**NOTE** – The 2B mill finish on stainless steel sheet is also considered as smooth or smoother than a No. 4 finish. No further finishing is required if the finish is free of defects, such as pits, scratches, chips, or flakes in the final | **5.1.1 Surface texture**<br>Surfaces shall be free of imperfections such as pits, folds, cracks, and crevices.<br>Surface textures shall have a maximum profile roughness parameter (Ra) of 32 µ in (0.81 µ m). When necessary, due to functionality needs, the following may be used:<br>■ Glass-beaded or shot-peened surfaces shall have a maximum Ra of 125 µ in (3.2 µ m).<br>■ Coatings shall have a maximum Ra of 125 µ in (3.2 µ m).<br>■ Machined plastics shall have a maximum Ra of 125 µ in (3.2 µ m).<br>**NOTE** – The 2B mill finish on stainless steel sheet is also considered as smooth or smoother than a No. 4 finish. No further finishing is required if the finish is free of defects, such as pits, scratches, chips, or flakes in the final | **5.1.1 Surface texture**<br>Surfaces shall be free of imperfections such as pits, folds, cracks, and crevices.<br>Surface textures shall have a maximum profile roughness parameter (Ra) of 125 µ in (3.2 µ m). When necessary, due to functionality needs, the following may be used:<br>■ Glass-beaded or shot-peened surfaces shall have a maximum Ra of 125 µ in (3.2 µ m).<br>■ Coatings shall have a maximum Ra of 200 µ in (5.0 µ m).<br>■ Machined plastics shall have a maximum Ra of 125 µ in (3.2 µ m). |



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**3** Hygienic Risk Analysis

4 Cleaning and Hygienic Design

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# *Hygienic Design Risk Assessment*

Hygienic risk assessment will help identify challenges within the supply.

GMA and AMI have great templates.

Customer input is always value added

Apply score to cost calculator

## Hygienic Design

**Summary:** This checklist is the Bühler Equipment Design Checklist for Low Moisture Foods to evaluate compliance with the Bühler Sanitary Design Principles for low moisture foods.

**Definition of Sanitary Design:** Sanitary Design is the application of design techniques which allow the timely and effective cleaning of the entire manufacturing asset.

**Purpose of sanitary design:** The purpose of a sanitary design is to improve cleanability, access for cleaning and inspection, and consistency of cleaning, thereby assuring effectiveness of the cleaning process.

**To complete this checklist, place an "X" in the appropriate box:**
**S = Satisfactory** (Design is acceptable and is easily cleanable to a microbiological level.)
**M = Marginal** (Design is marginally acceptable, and an enhanced design would improve the probability that the equipment can be routinely cleaned to a chemical, physical and microbiological level (HACCP).)
**U = Unsatisfactory** (Design is unacceptable and will need to be redesigned before a manufacturer should consider the purchase of this equipment.)

**The total score will automatically calculate and can be viewed on the summary page**

**Scoring System**
Satisfactory = Full pts
Marginal = 1/2 pts
Unsatisfactory = 0 pts

**Date:** 9/2/2014
**Completed By:** Steve Blackowiak
**Location:** BRAL
**Equipment:** Dryer - C1 120-85 RSC

Equipment and machinery must meet all federal, state and local personnel safety requirements during operation, cleaning and sanitizing. Any modifications must not affect compliance with these requirements.

| # | Description | S | M | U | NA | Pic | Comments | Pts Deducted | Pts Available |
|---|---|---|---|---|---|---|---|---|---|
| PRINCIPLE #1 - CLEANABLE | | | | | | | | | |
| 1.1 | Surfaces can be cleaned to a visually clean standard and meet pre-op inspection requirements. | x | | | | | Access for cleaning and inspection is provided thru doors, internal and external | - | 15 |
| 1.2 | Surfaces can be monitored prior to start up for a visually clean standard, and for allergen residues, ATP and microorganisms as needed. | | x | | | x | Piano hinges used in conveying system can be allergen risk with some products | 7.5 | 15 |
| 1.3 | Construction of equipment meets the GMP definition of "easily cleanable" (Machinery Directive 2006/42/EG ). | x | | | | | | - | 15 |
| 1.4 | A HACCP based product risk evaluation was completed during the product design/selection phase and the equipment is designed to address those risks. The choice of equipment has been validated as a proper choice for the product and operation. | | | | x | | Equipment is designed for multiple processes and products | - | 15 |
| 1.5 | Method of cleaning needed for the product risk was incorporated into the chosen design of the equipment, or in choosing the proper equipment. | x | | | | | Equipment is designed for high hygiene dry clean installation | - | 15 |
| 1.6 | Equipment design meets cleaning time targets established by the equipment user. | | | | x | | Cleaning times are product and customer resource dependent | - | 10 |
| 1.7 | Equipment has no apparent flaws that will fail over its life and make it uncleanable. | x | | | | | | - | 15 |
| 1.8 | If belting is used as product contact surfaces, it should be non-absorbent, fully encapsulated, cleanable and should be designed to be compatible with the cleaning methods employed at the location (wet or dry). | | | | x | | Belting material is not used in conveying system | - | 15 |
| TOTAL POINTS FOR THIS SECTION | | | | | | | | 107.5 | 115 |

http://www.gmaonline.org/resources/research-tools/technical-guidance-and-tools/

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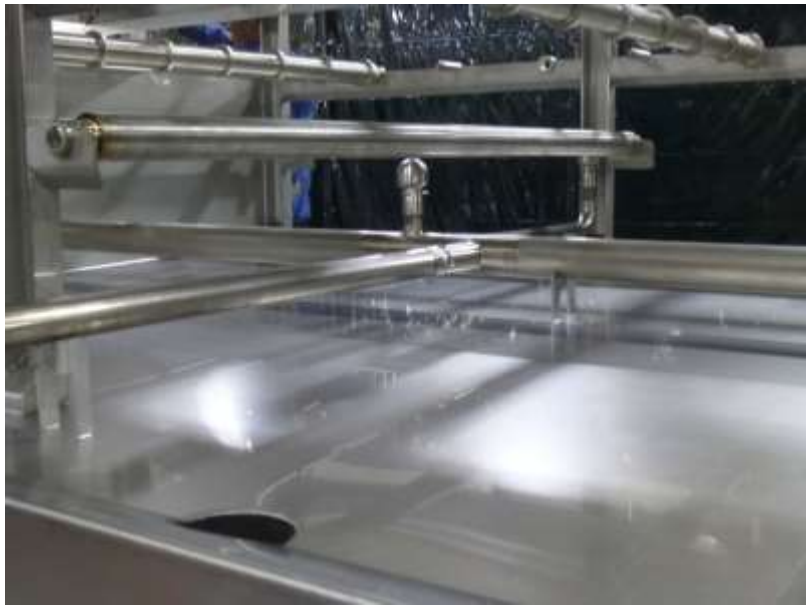
# *Cleaning*

- Cleaning method is a defining criteria which establishes the hygienic level
- Cleaning method must be understood at the onset of a development project
- Access for cleaning is paramount
- Reduced cleaning time reduces operating costs and improves uptime
- CIP solutions
- Build it and they will come…

*Manual Wash*



*CIP Conveyor Dryer*

# *Cleaning Study*

- Manual cleaning vs. automated cleaning
- We found a 50% reduction in time with automated cleaning

*Manual Cleaning*

*CIP Conveyor Dryer*

# *Recirculation Fan – Hygienic Challenge*

- Expanded metal
- Stitch welding
- Cracks & crevices
- Water collection /traps

# *Recirculation Fan – Hygienic Solution*

Direct drive recirculation fans eliminate belts, shafts, bearings, and guards for a clean installation. Aside from reducing maintenance requirements, these fans are quiet and consume less energy

# *Floor Panel – Hygienic Challenge*

Floor panel design on traditional supply is difficult to clean with areas that are not self draining

# *Floor Panel – Hygienic Solution*

Floor is a slab construction, pitched to one side with built in water management. Easy to clean with 2B mill finish.

# *Roof Panel – Hygienic Challenge*

Traditional drop in roof panel creates cracks and crevices which are difficult to clean. Seal material positioned over the food is a bacteria risk

# *Roof Panel – Hygienic Solution*

Pitched slab roof promotes water run off and easy to clean surface

# *Door Panels – Hygienic Challenge*

Traditional door skins are spot welded which can allow water to enter insulation creating a bacteria risk. Fasteners penetrate the skin also can allow moisture to enter.

# *Door Panels – Hygienic Solution*

Hinged exterior doors are continuously welded. There are no fasteners penetrating the door skin

Patent pending explosion relief door latch

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# *Hygienic Design Cost Calculator*

## HYGIENIC DESIGN COST SAVINGS CALCULATOR

| | | | | | |
|---|---|---|---|---|---|
| **Labor Rate** | $45 | **Product cost/kg** | $ 28.00 | **Chemical cost/L** | $ 0.65 |
| **Production (Process) Added Value Per Hour** | $100 | **Water cost/L** | $ 0.25 | | |

| **Calculate Production Savings:** | Old design | Hygienic design | Savings $ | |
|---|---|---|---|---|
| Downtime per week due to cleaning (hours) | 18 | 6 | | |
| Product wasted during cleaning (kg) | 60 | 25 | | |
| Yearly occurrences of cleaning event | 42 | 18 | | |
| **Estimated cost per year:** | **$146,160** | **$23,400** | $122,760 | |
| | | | | |
| **Calculate Cleaning resources Savings:** | | | | |
| Estimated time to clean machine (hours) | 8 | 2 | | |
| Estimated number of people | 5 | 3 | | |
| Yearly occurrences | 42 | 18 | | hours saved/year |
| **Estimated cost of cleaning per year:** | **$75,600** | **$4,860** | $70,740 | 1572.0 |
| | | | | |
| **Calculate Cleaning Supplies Savings:** | | | | |
| Water use per clean (L) | 300 | 515 | | |
| Chemical use per clean (L) | 5 | 60 | | |
| Yearly occurrences | 42 | 18 | | |
| **Estimated cost of cleaning per year:** | **$3,287** | **$3,020** | $267 | |
| | | | | |
| Other cost (if any): | $0 | $0 | | |
| **Estimated other costs per year:** | **$0** | **$0** | $0 | |

| | |
|---|---|
| **total savings per year** | **$193,767** |

*Edyta Margas*

# *Hygienic Design Cost Calculator*

## COST OF INCIDENT OF PATHOGEN POSITIVE ENVIRONMENTAL SAMPLE CALCULATOR

| | | | | | |
|---|---|---|---|---|---|
| **Labor Rate** | $45 | **Product cost/kg** | $ 28.00 | **Sample analysis** | $ 10.00 |
| **Line Production Value Per Hour** | $100 | **Where house cost/hour** | $ 20.00 | | |

| | Standard production | Positive | Savings $ |
|---|---|---|---|
| **Calculate Route cause analysis cost:** | | | |
| Downtime per incident due to positive (h) | 0 | 50 | |
| Product on hold - extra where house time (h) | 0 | 40 | |
| Investigation, sampling, communication - number of people | 0 | 1 | |
| Investigation, sampling communication - time spent per incident (h) | 0 | 70 | |
| **Estimated cost per incident:** | **$0** | **$8,950** | $8,950 |
| **Calculate Additional Sampling Cost:** | | | |
| Number of sample locations | 10 | 20 | |
| Sampling frequency/week | 1 | 7 | |
| Number of weeks when increased sampling | 4 | 4 | |
| Additional cost e.g. PCR, lab analysis | $ - | $ 2,000.00 | |
| **Estimated cost per incident:** | **$400** | **$7,600** | $7,200 |
| **Calculate Sanitation cost:** | | | |
| Number of people | 0 | 3 | |
| Time (h) | 0 | 20 | |
| Other cost | $ - | $ - | |
| **Estimated cost per incident:** | **$0** | **$2,700** | $2,700 |
| **Calculate improvements cost** | | | |
| New infrastructure/equipment | $ - | $10,000 | |
| New SOPs - number of people needed | 0 | 1 | |
| New SOPs - time spend/week (h) | 0 | 1 | |
| **Estimated costs per incident:** | **$0** | **$12,700** | $12,700 |
| Yearly occurrence | 0 | 1 | |
| **total savings per year** | | | **$31,550** |

*Edyta Margas*



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# *Hygienic Design Cost Calculator*

## RECALL SAVINGS CALCULATOR

| | | | |
|---|---|---|---|
| **Labor Rate** | $45 | **Product cost/kg** | $ 28.00 |
| **Line Production Value Per Hour** | $100 | **Total risk score for the equipment** | **4** |

| **Calculate Production Savings:** | Recall | Savings $ | Reference |
|---|---|---|---|
| Average recall cost | 10,000,000 | | GMA, 2011 |
| Occurrence - once in every (years): | 5 | | SwissRe, 2014 |
| Contamination due to cross-contamination post kill step | 50% | | Margas, 2016 |
| Recalls due to microbiology, allergens, foreign bodies (so possibly due to hygienic design) | 50% | | SwissRe, 2014 |
| **Estimated cost per year:** | **$500,000** | $500,000 | |
| **Risk reduction corresponding factor** | | 1 | |

| | |
|---|---|
| **total savings per year** | **$500,000** |

| | corresponding factor |
|---|---|
| 1-3 – low risk of product contamination from the equipment | 1 |
| 4-6 – medium risk of product contamination from the equipment | 1 |
| 8-9 – high risk of product contamination from the equipment | 0 |
| 12-16 – Extremely high risk of product contamination from the equipment | 0 |

*Edyta Margas*

# *Hygienic Design Cost Calculator*

## TOTAL SAVINGS CALCULATOR

| **Calculate Total Savings:** | Saving |
|---|---|
| Cleaning saving | $ 193,767.00 |
| Positive Environmental Sample saving | $ 31,550.00 |
| Recall cost saving | $ 500,000.00 |
| Other savings | $ - |
| **Estimated saving per year:** | **$725,317** |

**life cycle of the equipment (years)** **20**

| **Estimated total savings life of the equipment** | **$14,506,340** |
|---|---|

*Edyta Margas*

www.buhlergroup.com