Clean Break for Dry Food Processing Environments
FDA “Swab-a-Thons”

FDA investigators are visiting and inspecting every food facility, executing microbiological swab-a-thons where they’ll collect up to 100s of samples, testing them for pathogens such as Listeria and Salmonella. Any positive samples would be compared to the PulseNet database, where a match found could lead to recall.
The PulseNet database has been receiving isolates for 20 years. Most illnesses stem from “unknown sources” that haven’t been traced back to any source.

At this point, there are over 1,000,000 unsolved illnesses which can still be matched to food manufacturing sites in the future if positive environmental swabs are found during inspections.
If the FDA finds a positive sample during an inspection, they will compare it against the PulseNet database. A match could provide evidence of a longstanding contamination coming out of your facility depending on when the isolate was input into PulseNet.

*PulseNet implicated Blue Bell to 9 illnesses spread out over 5 years.*
Recurring Pathogens

If your facility comes up positive for the same strain of a pathogen that was previously found, logic will point to the problem having never gone away.
A clean break is a defined production break that involves a documented, verified, and validated cleaning and sanitation process of all food contact surfaces.

Clean breaks are used to establish lots to trace their products and limit the quantity or product recalled in case of a contamination.
Clean Breaks

Similar to a firebreak in a forest
Validated Clean Breaks

If your clean break cannot be defended during a recall, your recall will grow.

October 2018, McCain Foods recalled 63 different products that were shipped all the way back to January 1, 2016.

34 Months worth of production!
How do you defend your sanitation?

The only way to fully prove that your environment and product are 100% safe is to swab every surface and sample every bit of finished product.
EASY AS PIE?

FALSE. PIE IS A COMPLICATED PROCEDURE THAT REQUIRES EXACT MEASUREMENTS.
Sanitation is also a complicated procedure that requires exact measurements.
YOU'RE WELCOME
How do you defend your sanitation?

In order to defend your sanitation, you must understand sanitation.
In order for any sanitation method to be effective, the method must:

- Be able to kill the organism in question
- Achieve good and complete distribution
- Achieve thorough and total penetration
- Achieve sufficient contact time at the correct concentration
Growth Niches
Potential Growth Niches
Traditional Dry Cleaning Methods

- Manual cleaning with hand tools
- Vacuum
- Compressed Air
- Product Flushes
- Sanitizer wipe downs
- Sanitizer applications (w/minimal water)
- Steam Cleaning
- Dry Ice Cleaning
- Specialized Cleaning Tools (brushes, scrapers, etc)
Chlorine Dioxide Gas

Chlorine dioxide gas is a dry gas decontamination method.

Benefits:

- True gas at room temperature
- US EPA registered sterilant
- Offers superior process control
Chlorine Dioxide Gas Process

- **Pre-Conditioning**
  Raise relative humidity to 65-75%

- **Conditioning**
  Hold that humidity level for a short period of time

- **Charge**
  Inject CD Gas to a concentration of about 1 mg/L (360 ppm)

- **Exposure**
  Hold time at that CD Gas concentration

- **Aeration**
  Remove CD Gas
Raising Humidity?

You can’t raise humidity in a dry environment…
that defeats the purpose of keeping it dry…
right?
If your sanitation method will kill all the pathogens in the environment that are promoted by the moisture then it really doesn’t matter.
Spores are considered the hardest organism to eliminate, compared to live viruses and bacteria which are considerably easier.

### Antimicrobial Efficacy

<table>
<thead>
<tr>
<th>Target Organism</th>
<th>Dosage Required using CD Gas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td>~100 ppm-hrs for 6-log kill</td>
</tr>
<tr>
<td>Listeria</td>
<td>~300 ppm-hrs for a 5-log kill</td>
</tr>
<tr>
<td>Spores</td>
<td>~600 ppm-hrs for 6-log kill</td>
</tr>
<tr>
<td><strong>ClorDiSys Decon Cycle</strong></td>
<td>720 ppm-hrs</td>
</tr>
</tbody>
</table>
Humidity’s Role Towards Efficacy

Chlorine dioxide has been validated to be effective at lower relative humidity, but requires a higher dosage

<table>
<thead>
<tr>
<th>RH</th>
<th>Dosage Required for 6-log Spore Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>65%</td>
<td>~600 ppm-hrs</td>
</tr>
<tr>
<td>55%</td>
<td>~1000 ppm-hrs</td>
</tr>
<tr>
<td>45%</td>
<td>~1550 ppm-hrs</td>
</tr>
</tbody>
</table>
A study was performed to demonstrate the effect of chlorine dioxide gas on *Salmonella typhimurium* (ATCC# 14028) at 25% RH

<table>
<thead>
<tr>
<th>Sample</th>
<th>Treatment</th>
<th>CFU Recovered</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test 1</strong> (5 glass slides)</td>
<td>720 ppm-hr</td>
<td>&lt;10</td>
</tr>
<tr>
<td><strong>Test 2</strong> (5 glass slides)</td>
<td>720 ppm-hr</td>
<td>&lt;10</td>
</tr>
<tr>
<td><strong>Test 3</strong> (5 glass slides)</td>
<td>720 ppm-hr</td>
<td>&lt;10</td>
</tr>
<tr>
<td><strong>Positive Control</strong> (5 glass slides)</td>
<td>N/A</td>
<td>3.2 x 10⁷</td>
</tr>
</tbody>
</table>

Study performed at EMSL Analytical, Inc
Cinnaminson, NJ 9/12/2017
Validating Chlorine Dioxide Gas

Work with your food safety team, including your QA Microbiologists, and your outside laboratory if you use one.

Include your legal counsel too.

You’d want everyone in agreement that you can support your clean break.
## Science

<table>
<thead>
<tr>
<th>Principles of Decontamination</th>
<th>Chlorine Dioxide Gas</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Be able to kill the organism in question</strong></td>
<td>There are chlorine dioxide gas products that are US EPA registered as sterilants proven capable of eliminating all microbial life</td>
</tr>
<tr>
<td><strong>Contact all pathogens</strong></td>
<td>As a true gas, it will evenly and completely fill the space its introduced into, including niches and crevices.</td>
</tr>
<tr>
<td><strong>Achieve sufficient contact time at the correct concentration</strong></td>
<td>Chlorine dioxide gas can be measured very accurately in real-time using a photometric device.</td>
</tr>
</tbody>
</table>
BI's contain over 1 million *geobacillus stearothermophilus* spores, providing the ability to show a 6-log (99.9999%) sporicidal reduction.

### Data

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Concentration Monitoring Data</strong></td>
<td>Chlorine dioxide gas can be measured at multiple points within the environment to guarantee the right dosage was achieved at all sample locations</td>
</tr>
<tr>
<td><strong>Biological Indicators</strong></td>
<td>Biological Indicators (spore strips) can be placed in challenging locations to illustrate antimicrobial kill at that location</td>
</tr>
<tr>
<td><strong>Environmental Monitoring Results</strong></td>
<td>Swab results can provide further verification</td>
</tr>
</tbody>
</table>
Chlorine Dioxide Gas is able to decontaminate HVAC units as the gas can travel through the bends, blowers, and filters that correspond to the ductwork.
Ductwork

Chlorine Dioxide Gas is able to decontaminate ductwork as it can travel through the bends, blowers, and filters that correspond to the ductwork.
This powder filling line was connected to processing vessels across multiple rooms. The entire line was sterilized at the same time after a contamination was found.
What is a Clean Break Worth?

Preventive measures are always hard to value.

Like insurance, its hoped to be a sunk cost that has no ROI.

But if its used, its value is tremendous.
There are a few reasons as to why material compatibility continues to be our most frequent question about chlorine dioxide gas:

- You’re filling up a space with a chemical, and it’s always nice to double check that you won’t ruin everything inside.
- The first word in the product is “Chlorine” and everyone knows how nasty that chemical is.
- You’ve used liquid chlorine dioxide products and those have been corrosive.
- You’ve read documents from various sources that chlorine dioxide is corrosive.
Chlorine vs. Chlorine Dioxide

Just like carbon is very different from carbon dioxide, chlorine is not the same as chlorine dioxide!

Similar Names, but very different chemicals

- Chlorine kills through chlorination, while CD kills through oxidation
  - As CD does not chlorinate organic material, it eliminates the formation of trihalomethanes (THMs), haloacetic acids (HAAs) and other chlorinated organic compounds that chlorine produces when used for water treatment

- Chlorine reacts with water to form hydrochloric acid, CD does not
  - Chlorine dioxide does not react with water at all and stays as chlorine dioxide in the water, decontaminating the water itself and the surface beneath.

- Chlorine is far more aggressive on materials such as stainless steel than chlorine dioxide
Better Ingredients, Better Chlorine Dioxide

Chlorine dioxide does not last long enough to be bottled and shipped, so it must be generated on demand. Depending on the method in which chlorine dioxide is generated, the end product can vary greatly.

ClorDiSys generates pure chlorine dioxide for decontamination

(4% Chlorine Dioxide – 96% Nitrogen)

Other methods of generating chlorine dioxide (liquid or gas) generate acidic byproducts along with the chlorine dioxide

Base + Water + Activator → Acidified Sodium Chlorite + Chlorous Acid + Chlorine Dioxide
Liquid CD Residues

Liquid CD products can leave corrosive residues due to their byproducts

**SOP on liquid CD use:** Wipe covered surfaces, such as stainless steel counters, shelves, sinks, etc., with cold tap water, Sporicidin, or isopropyl alcohol to remove salt residue and limit corrosion

**ClorDiSys CD Gas has no residues**

One of the first commercial uses for ClorDiSys’ (Then J&J’s) chlorine dioxide gas was to sterilize implantable contact lenses. It was proven to the FDA that this sterilization method left no measurable residuals.

We are starting to receive FDA approvals for treating food products with our chlorine dioxide gas as well. Each approval requires residual testing to prove that the food is safe to eat.
Oxidation potential is a chemical property that measures the chemical’s tendency to oxidize. This can also be thought of as the corrosion potential. The higher the value, the greater stronger the chemical’s oxidizing (or corrosion) power.
## Oxidation Potential

<table>
<thead>
<tr>
<th>Biocidal Agent</th>
<th>Oxidation Potential (volts)</th>
<th>Oxidation Capacity (electrons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ozone</td>
<td>2.07</td>
<td>2e-</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>1.81</td>
<td>2e-</td>
</tr>
<tr>
<td>Hydrogen Peroxide</td>
<td>1.78</td>
<td>2e-</td>
</tr>
<tr>
<td>Bleach</td>
<td>1.49</td>
<td>2e-</td>
</tr>
<tr>
<td>Chlorine Dioxide</td>
<td>0.95</td>
<td>5e-</td>
</tr>
</tbody>
</table>

Chlorine Dioxide is scientifically gentler on materials than these other sterilant methods.
Material Compatibility

CD gas is safe on:

- Stainless steel
- Galvanized metals
- Anodized aluminum
- Painted / coated metals
- Plastics
- Epoxy Paints / Coatings
- Electronics

CD can affect:

- Unpainted ferrous metals
- Urethane Foam
- Some Natural Rubbers
Preventive Contamination Control Products
Portable CD Gas Generators

Minidox-M

Megadox-P

- Real-time Concentration Monitor
- Easy to Validate
- Portable
# Equipment Comparison

<table>
<thead>
<tr>
<th></th>
<th>Minidox-M</th>
<th>Megadox-P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Capacity</strong></td>
<td>Up to 25,000 ft³</td>
<td>Up to 100,000 ft³</td>
</tr>
<tr>
<td><strong>Concentration</strong></td>
<td>One location</td>
<td>Up to 5 locations</td>
</tr>
<tr>
<td><strong>Monitoring</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Portability</strong></td>
<td>On Wheels</td>
<td>Palletized</td>
</tr>
</tbody>
</table>
Thank you

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