INACTIVATION OF FOODBORNE PATHOGENS BY PREMIXES AND IMPACT ON FLOUR SAFETY

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Viobin U.S.A. founded in Monticello, IL

1936

Research Products Compnay Founded in Kansas City, MO

1946

1978

Formed holding company, McShares

1978

Acquired Brandywine Ingredient Technology

2015

Began REPCO Nutritional Solutions for nutritional premixes

AUG 2016-2017

JAN

JAN

1959

1959

1996

2016

AUG

SEP

OCT

2018

DEC

Moved to Salina, KS

Viobin Acquired by McShares Inc.

Changed name to REPCO

Viobin sold to PHM

For Goodness' Sake

REPCO MILLING SOLUTIONS

Millers need quality vitamin ingredient blends, consistent accurate dosing, & a reliable supplier with milling expertise.

REPCO provides the ingredients, equipment, & service, so millers can focus on operations.

REPCO BAKERY SOLUTIONS

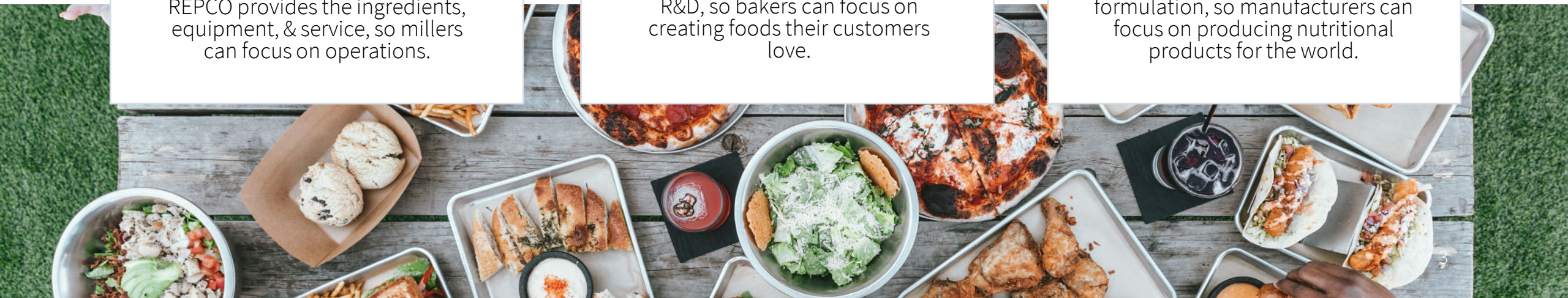
Bakeries need clean-label solutions formulated to improve baking performance.

REPCO provides the blend and the R&D, so bakers can focus on creating foods their customers love.

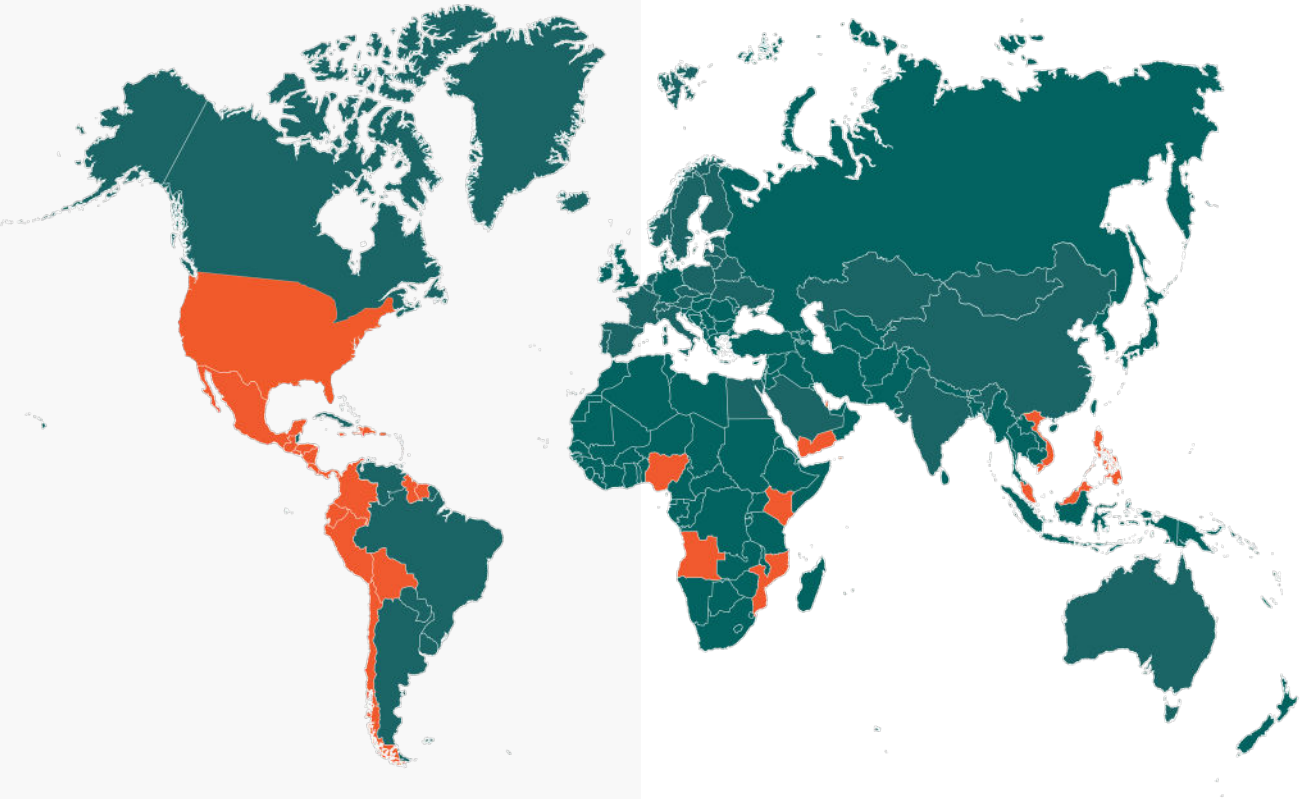
REPCO NUTRITIONAL SOLUTIONS

Food & Beverage Manufacturers need nutritional blends that fit their formula.

REPCO provides the blend and formulation, so manufacturers can focus on producing nutritional products for the world.




engrain™
Feed the World with Peace of Mind™



Global Operations

- Formed in 2008
- Headquartered in Manhattan, KS USA

  Serving more than 70 customers world-wide
- Sales and distribution through Latin America, America, Africa, and Southeast Asia

Flour Recalls

- In the United States, the flour milling industry has had numerous recalls in the last 20 years
- Some of the recalled product has caused human illnesses
- Millions of dollars have been spent on recalls
- Millions of additional dollars have been spent on remediation and prevention efforts
- Flour product recalls are conducted of adulterated product (e.g., testing positive for pathogens) even if no illnesses are reported

Microbiological risk

Microbial populations are inherent in wheat…right?

- Studies in the marketplace have shown that wheat is a contributor of microbial load in wheat flour – but do we know if that is the only source?
- Wheat and flour can have microbial loads reduced with various types of inactivation technologies

Well, enrichment has low water activity so should be good…right?

- So does flour. Therefore, this is wrong. It does lessen potential for growth, but some microbes can survive. Enrichments generally have a_w of ~0.40 but not lethal for sure.

Enrichment has low pH so that should make it unable to have microbial activity…right?

- Enrichments generally have a pH of 3-6 depending on the blend so maybe. Again, it lessens the probability, but pH and generalizations alone do not give enrichment something to stand behind. Some microorganisms thrive at lower pH.

No one eats raw flour and therefore, no one eats raw enrichment?

- Common sense and rationale are no longer true with some people pushing the limits on food "challenges" or foreseeable unintended use. Even if people did everything correct, the FDA has changed this playing field and logic.

Microbiological risk

So… “What if”?

- Many different operations designs are present in the industry. Some add enrichment after applying validated 5-log microbial reduction steps.
- Could all the time and money spent on eliminating the threat be wasted if microbial loads were increased by something introduced late in the process?
- Worse yet, what if microorganisms were directly added late in the process?

We were asked from some of our customers what our microbial loads are

- We checked samples periodically per requests but in general were not testing finished enrichments
- There were no recalls or concerns with enrichments’ microbial safety that we had seen in the marketplace
- However, this kept us up at night wondering!

We considered the need for a validated kill step or to sell a sterilized product similar to heat treated flour

- We researched numerous technologies such as ozonation, heat, ultra high pressure, microwave, infrared, and others
- Each had limitations and considerations including reducing levels of vitamins that the enrichments were intended to deliver
- And the biggest question, what microbes were we killing? At what level? In what product?

Microbial environmental monitoring

Wouldn't we be "safe" enough with just testing the environment?

- REPCO conducted significant proactive environmental monitoring including Zones 2 and 3, but we kept getting negative results

- So we got a bit crazier and started testing inside garbage can covers, dusty areas (we work with powders, so this does not take much time to get dust, even with good cleaning), we even tested forklift tires…all came back negative for results

- We started questioning our kits, methods, and ability to get good results, so we tested things we knew would give results like a puddle outside after a rain that a bird had defecated in and got findings

- So how can we not get results inside? Auditors and customer audits asked about this, and we did not have a definitive answer on why, but the results appeared correct.

Pushing the limits to see if we can break it

Then how can we know if that material had microbes, and what would happen if it did?

- We partnered with an external lab to have 4 sample kinds run with replicates and inoculated with ~10^6 CFU/g of:
  - Listeria monocytogenes
  - Salmonella Typhimurium
  - E. coli O157:H7
- Inoculum levels were verified with APC counts
- Time zero and time 24 hours
  - Most microbes were not detected at 24 hours, except for one sample that while showing significant reduction, did have 10-80 CFU of Listeria monocytogenes at the end of 24 hours
  - So we checked at 72 hours and all results were zero CFU/g
- We felt pretty good about this but wanted another party's input to see if we were missing something

That was too easy. What if we push it even further?

Ok, so what if the material had microbes at even intentional addition type levels AND what would happen if you gave them "resuscitation" type optimal conditions?

- We now partnered with The Acheson Group (TAG) and an external lab to have 5 sample kinds of our products run with replicates and inoculated with several strains each at ~$10^{9\text{-}10}$ CFU/g of:
  - Listeria monocytogenes
  - Salmonella Typhimurium
  - E. coli O157:H7
- Inoculum levels were verified with APC counts
- Time zero and time 72 hours with optimal growth media and growth temp of 35°C to allow recovery of potential sub-lethally injured microbes
  - A considerable reduction (>6 log CFU/g) in viable pathogens was seen within one hour of inoculation for all REPCO vitamin mixes
  - No microbes were recovered at 72 hours
- aw and pH had little variation throughout this process
- But we also decided this was not enough of a stop and conclude point

Now, what if we put it in flour?

We thought the enrichment had killed all microbes, but a question remained as to if we put contaminated enrichment in flour, could that then create conditions that would revive whatever microorganisms under "resuscitation" type optimal conditions?

- We had flour sterilized and dosed enrichment per our normal instruction rates for each product
- Samples were tested throughout a 72-hour window with optimal growth media and temperature of 35°C to aid in resuscitation
- No microbes were recovered at any time during the study and testing was concluded at 72 hours after enrichment addition

Conclusions and Next Steps

Conclusions

- Even when intentionally inoculated with pathogens, REPCO enrichments are not able to sustain microbial life despite of optimal resuscitation conditions that consider sub-lethally injured microbes
- Flour enriched with contaminated REPCO product does not exhibit microbial growth in a 72-hour window even when using ideal growth media and optimal growth temperature to promote resuscitation

Next Steps

- We welcome input as REPCO is evaluating some next steps looking at the viability of making a product that would be allowed by regulators but would inhibit or eliminate pathogens in flour, while still remaining at safe levels of vitamins and minerals for human consumption

Thank You

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