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The Wave of the Future

Macrowave™ Radio Frequency Pasteurization

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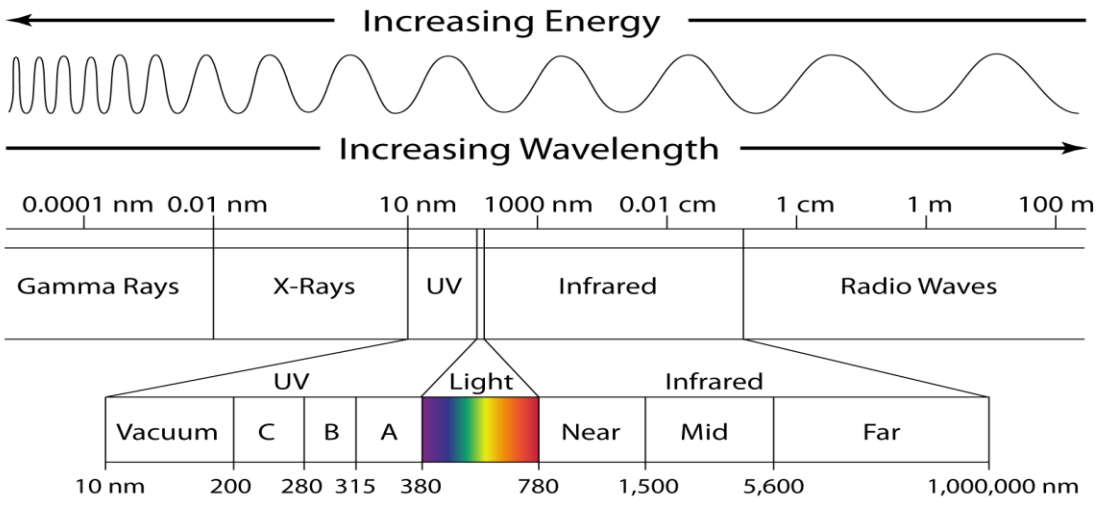

Macrowave™ RF Technology is a clean, efficient Pasteurization process for a wide-range of food products and can achieve up to a 5Log reduction in pathogens. The systems provide the food manufacturer with a validated “kill-step” to comply with the current FSMA regulations.

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1 - Introduction

In the United States FSMA regulations, effective this year, address the concerns of food safety in our supply chain. The requirements apply to both Human and Animal Food. The RF treatment process does not require special labeling and doesn't involve irradiation, noxious gases or the use of chemical additives. RF pasteurization equipment can be utilized for continuous or batch processing and often products can be treated in their final packaging, thereby eliminating further possible contamination. The following statistics are evidence of the existing problems modern food and pet food manufacturers need to address.

2 - Background

> *"About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable."*[1]

> *The US Federal Government's present philosophy is to regulate pet food in a manner consistent with human food. Under the new Food Safety Modernization Act (FSMA), the same standards that govern human food will also apply to pet foods, this includes aspects related to safety, sanitation, and labeling, which can ultimately impact the health and well-being of animals as well as the health of humans. People with companion animals often eat pet food, either intentionally or accidently, and also may come into contact with an animal's mouth and/or fecal material. This contact can lead to potential zoonotic transmission of Salmonella from animals to humans.*[2]

There are already numerous 2016 recalls of Human food, many for pathogen contamination. To date, May 2016, there are eight (8) 2016 Pet Food recalls listed on the FDA's website, three (3) were for Salmonella/Listeria contamination. All three notices contain warnings not only for symptoms of illness exhibited by animals, but also for humans who handled the products. A few of the major elements that food and pet food manufacturers' need to consider for their implementations for complying with FSMA are: Preventative Controls, Inspection & Compliance, Foreign Supplier Validation and Recalls.

RF Pasteurization systems are a Preventative Control and are another tool food and pet food manufacturers can utilize in establishing a validated process. Challenge studies, using samples inoculated with surrogates and pathogens, have validated the efficacy of the process with up to a 5Log reduction in pathogens, confirmed.

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[1] Frequently Asked Questions on FSMA, Section - General, G.1; http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#General.

[2] B.A.Stawick, MS, CCFS, Microbac Laboratories, Inc. & J.L.Kornacki, PhD, Kornacki Microbiology Solutions from *The Microbiological Safety of Low Water Activity Foods and Spices*, Springer Science+Business Media New York 2014, Pages 315-316.

3 – What is it?

Radio Frequency is a long-wave length, non-ionizing form of electrical energy. Similarly, and for a simple frame of reference, microwaves are a short-wave length non-ionizing form of energy. However, RF's long-wavelength energy – which will be referred to as Macrowaves™ – have a superior depth of penetration allowing for a rapid, uniform and volumetric heating of a product, simultaneously throughout the entire thickness. There are no cool or hot spots from uneven heating such as with microwaves. And, there are no prolonged exposure times for the heat to penetrate from the surface to the interior like conventional heating. For a pasteurization process, this rapid and volumetric heating throughout the bed depth or product thickness, prevents heat acclimation on the part of the pathogens thereby preventing them from surviving the heating process.

In a recent paper published in Science Progress, Dr. A. D. Russell reviews the lethal effects of heat on bacterial physiology and structure1. Of particular interest is the discussion of how Salmonella will attempt to protect itself when the microbe senses impending stress, such as elevated temperatures, and how elevation of heat resistance relates to temperature rate of rise. Dr. Russell points out that the heat resistance of Salmonella at 55°C increases progressively as the cells are heated up at linearly rising temperatures; the slower the temperature rise, the greater the Salmonella's increase in heat resistance.[3]

4 - How Does it Work:

In an RF System, the RF generator creates an alternating electric field between two electrodes. The material to be treated is conveyed between the electrodes where alternating electrical energy causes the polar water molecules in the material to continuously reorient themselves to face the opposite poles, much like the way bar magnets behave in an alternating magnetic field. The friction resulting from the molecular movement causes the material to rapidly heat throughout its entire mass. In the illustration below, the figures in the material represent polar water molecules. Note how the polar water molecules will want to face the oppositely charged electrode when the electric field reverses as the RF generator oscillates, as shown by the wave form on the right in Figure 1 below:

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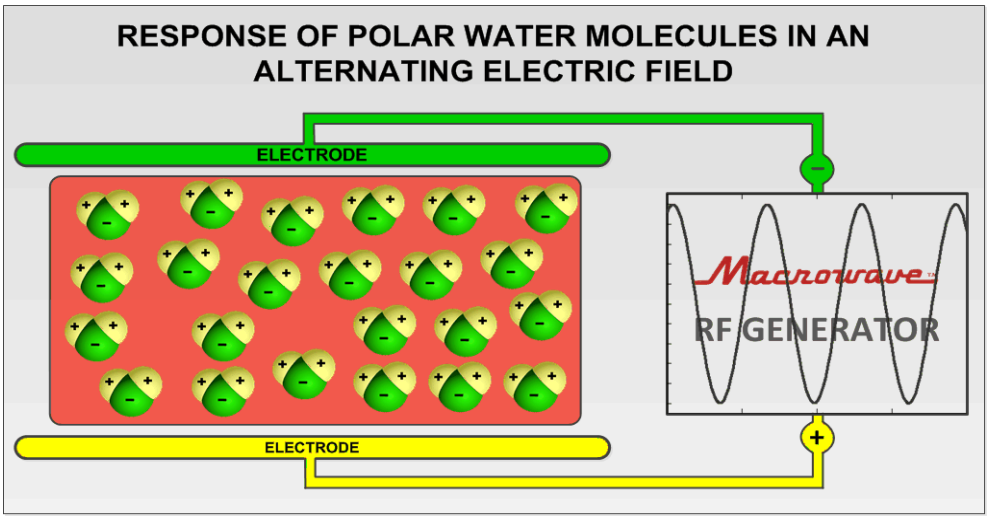
[3] A.D. Russell, *Lethal Effects of Heat on Bacterial Physiology and Structure*, Science Progress 86:115-137 [c]2003 Science Reviews.



Macrowave™ systems operate within the approved 40.68 MHz radio frequency band width, which is an ISM (Industrial-Scientific-Medical) band width allowed for this type of equipment, as well as for medical devices commonly used for muscular diathermy. RF systems are appropriately shielded to meet with FCC regulations and the CE normative EN-55011. All units also comply with all OSHA regulations for safety.

5 – Reduction in Water Activity (w_a)

For many years, researchers tried to equate bacterial growth potential with water content. They found that the values were not universal, but specific to each food product. W. J. Scott first established that bacterial growth correlated with water activity, not water content, in 1953. It is firmly established that growth of bacteria is inhibited at specific water activity values. U.S. Food and Drug Administration (FDA) regulations for intermediate moisture foods are based on these values.

Water activity is used in many cases as a critical control point for Hazard Analysis and Critical Control Points (HACCP) programs. Samples of the food product are periodically taken from the production area and tested to ensure water activity values are within a specified range for food quality and safety. Measurements can be made in as little as five minutes, and are made regularly in most major food production facilities.

Food designers use water activity to formulate shelf-stable food. If a product is kept below a certain water activity, then mold growth is inhibited. This results in a longer shelf life.

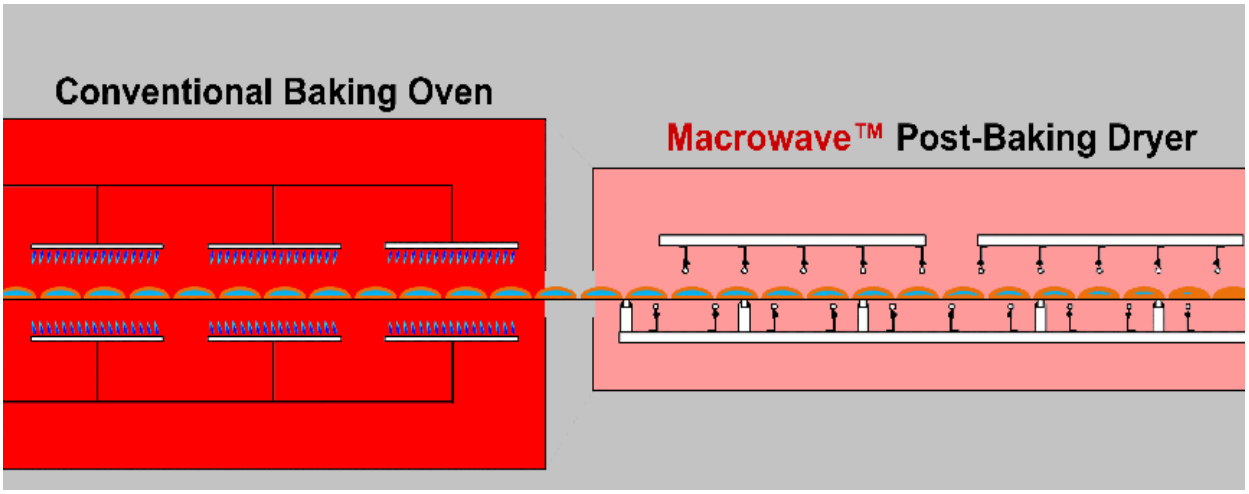
Water activity values can also help limit moisture migration within a food product made with different ingredients. If raisins of a higher water activity are packaged with bran flakes of a lower water activity, the water from the raisins migrates to the bran flakes over time, making the raisins

hard and the bran flakes soggy. Food formulators use water activity to predict how much moisture migration affects their product.[4]

Radio Frequency heating has the unique capability to heat a product where the moisture content is the highest, as it is the polar water molecules that are the most receptive in many food products. Where the water is equally dispersed in a homogeneous material, the heating will be simultaneous and uniform throughout the products thickness. However, if the moisture content is predominantly located in a certain area, or areas, those areas will preferentially heat and dry first, until the moisture has equilibrated throughout the mass.

In a conventional tunnel oven used for baking biscuits, crackers or pet treats, the oven heat is applied externally to the surface of the dough. Gradually during the baking process, the oven heat penetrates into the product thickness; however, it is common to have a moisture gradient from the exterior to the interior. In certain product formulations, this center "bone" of moisture can be problematic in terms of water activity (a_w).

Adding a radio frequency post-baking dryer, is a proven and accepted solution to this type of (a_w) problem. In the figure below, product is exiting the conventional oven with higher interior moisture content. As that product then enters the Macrowave™ (RF) Post-Baking Dryer, the higher interior moisture content is preferentially heated and dried quickly and efficiently. This also enables the oven to run at faster band speeds as prolonged residence times for interior dryness are no longer required.



6 – The Wave of the Future

Macrowave™ RF pasteurization technology has lately been referred to as the "*The Wave of the Future*," as a means to effectively satisfy new FSMA requirements. However, that isn't entirely accurate. RF heating and drying equipment has been utilized by major food manufacturers for decades. As RF post-baking dryers, this technology has increased the traditional conveyorized oven efficiency and throughput capacity by as much as 30%, improving shelf-life, eliminating checking and over-coloring, and also minimizing water activity both in human as well as pet

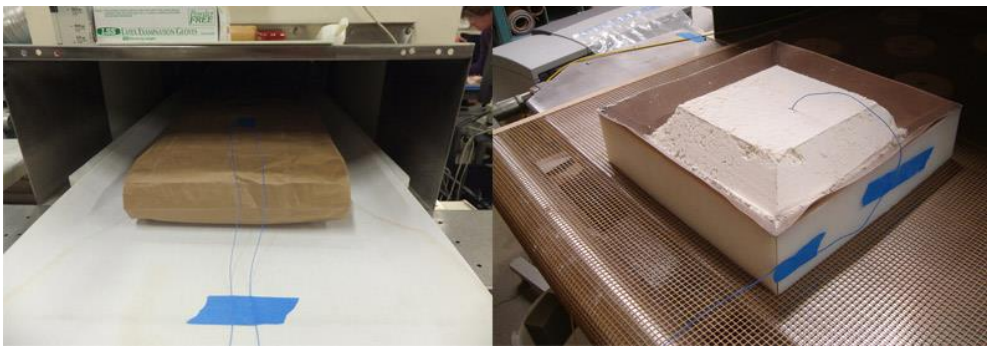
[4] https://en.wikipedia.org/wiki/Water_activity

treats. It's Pasteurization and Disinfestation capabilities have also been tested and utilized since the 1960s. However, the new 2016 FSMA requirement has created a "*new wave*" of interest in the pasteurization and disinfestation applications of this mature technology with food and pet food manufacturers evaluating the safety of their supply chain and manufacturing processes.

Like conventional forms of heat treatment, RF systems provide a safe pasteurization and/or disinfestation method that do not require any special labeling of the product, which also can still be labeled as organic. Macrowave™ energy is also a highly efficient, "direct" form of heating such that no energy is wasted heating large volumes of air or preheating the system itself. The technology is "instant-on, instant-off" using energy only during the treatment process.

The most prevalent and exciting application for RF pasteurization technology is in the treatment of dry ingredients. In a dry state, perhaps between 5% and 15% average moisture content, microbes are considered "dormant" and are in the most difficult state to kill. RF has proven to be very effective with dry ingredients like flour (pictured below), cereal grains, protein supplements, spices, seeds and pet foods – to name a few. Historically, low-water activity foods were not considered an issue for the support of pathogens like Salmonella. But this has been proved false.

Bagged flour and "bulk" flour tested in carriers



"Low-water activity foods, which were once thought to be microbiologically safe, have in recent years, been shown to be contaminated with foodborne pathogens, most notably and frequently Salmonella, leading to numerous food product recalls and foodborne illness outbreaks"[5]

As shown above, fiber-optic temperature probes are inserted into the products during testing and can be monitored using a Fiso model UMI-4 fiber optic temperature monitoring unit. Temperature profiles are monitored and recorded using compatible software.

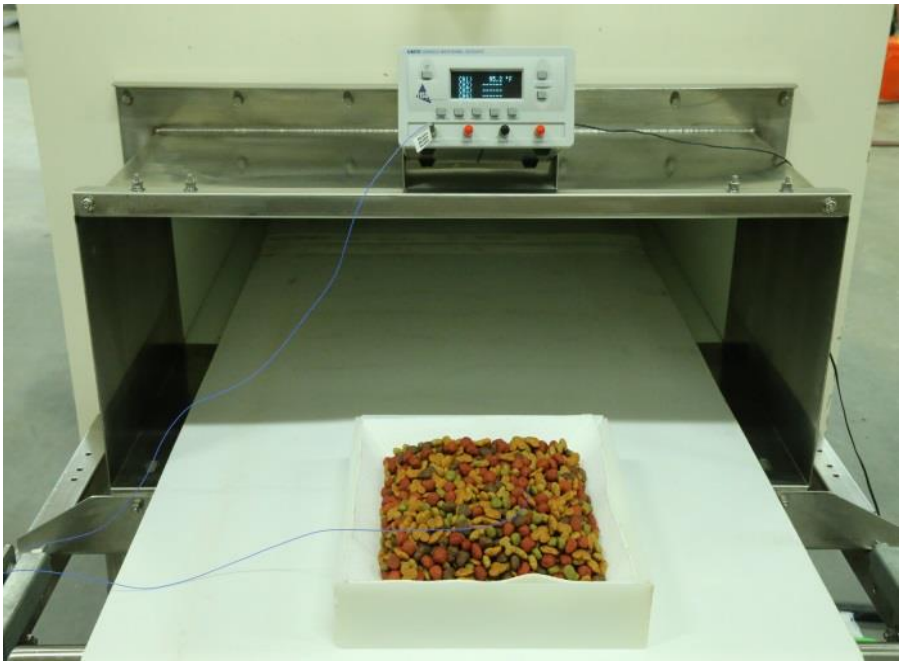
[5] J.B. Gurgler, USDA Research Scientist, M.P.Doyle, University of GA, Center for Food Safety, and J.L. Kornacki, Kornacki Microbiology Solution – Editors *The Microbiological Safety of Spices and Low-Water Activity Foods and Spices*, Springer Science+Business Media New York 2014

Currently, other food product types of concern are RTE (ready-to-eat) foods where the cooking, or “kill-step”, is provided by the consumer. Items that will be consumed “raw”, like flours, meals, or seeds and toppings that are added to foods after the cooking “kill-step.” Also cookie-dough inclusions in ice cream and products like health bars that are cold-pressed are all good examples of products that need an alternative method for pasteurization prior to reaching the customer or consumer to prevent any outbreak of illness caused by pathogen contamination.

7 – Product Testing

Preliminary functionality testing is always advisable before proceeding to the more costly challenge study phase. Below, Figure 5, is an example of a dog kibble mix being prepared for functionality testing in an RF system. In the initial functionality test, the product is treated in accordance with a likely protocol or protocols that are expected to yield the log reductions required. During the trials, process parameters such as temperature and dwell time are recorded for later production system scale-up consideration. After the trials, the product is returned to the manufacturer so that they can make the necessary functionality tests of protein quality, color, texture, and other organoleptic and nutritional qualities.

Figure 5: Example of dry pet meal



Successful functionality testing will show that the RF treatment process has had no discernable effect on any of the measured properties of the food item. At that time, moving into an inoculated challenge study is the next step in validating the process for that particular material.

Third party accredited laboratories are recommended for this testing as an essential part of the validation process. One such national laboratory that has conducted many Macrowave™

challenge studies is Lapuck Laboratories of Canton, MA, led by Dr. Khalil S. Zadeh. Dr. Zadeh has validated up to a 5Log reduction using ***Salmonella polurum, e-coli and listeria*** inoculants with the Macrowave™ treatment process. Other uses of this technology have utilized their own in-house experts to self-validate the treatment process.

8 - Treatment Options:

The RADURA Label for Irradiated Products

There are a number of pasteurization options available today. Fumigation involves noxious gases which are increasingly undesirable both internationally and domestically. Chemical additives that increase the acidity of the food to prevent microbial growth are also increasingly less desirable as consumers are more aware of ingredient labels and are looking for more natural, organic ingredients only. High pressure processing (HPP) is a method of preserving and sterilizing food, in which a product is processed under very high pressure, leading to the inactivation of certain microorganisms. However, this process can only be done in batches and is very expensive, but possibly a good choice for certain applications. In the US, irradiation is only permitted after approval by the FDA.[6] Also irradiated products require the "Radura" label (pictured above) which often carries a negative consumer perception. Other methods, like Ozone or UV treatments, are surface treatments and a better match for products like fresh produce, but not a good match where depth of penetration for the treatment is required. Manufacturers' will need to match a pasteurization process to their own product's FSMA requirements and to the nature of their product that preserves all the product's functionality and organoleptic properties.

9 – RF System Design

RF systems can be designed to accommodate bagged or bulk product depending on the manufacturer's process requirements. In many cases, food products can also be processed in their final consumer packaging. Obviously when product can be processed through the RF system, post-packaging, it eliminates any further opportunity for contamination of the product

[6] Food Facts for the US Food and Drug Administration, November 2014, Pages 1-2
http://www.fda.gov/downloads/food/resourcesforyou/consumers/ucm262295.pdf

prior to shipping. This flexibility of design offers manufacturer's more process options than most other pasteurization methods. However, there are limitations to packaging materials and packaging designs that can be reviewed with the manufacturer and product testing is always advised.

In terms of capacity, RF remains a very versatile option. Batch and conveyorized systems are available for processes as low as 25 pounds per hour and range through systems capable of processing 50,000 pounds per hour. Because of this range, a manufacture can select a system where the capital costs for the machinery are in synch with the quantity of material to be processed. The system pictured below is a 30kW Macrowave™ Pasteurization System designed for bulk product processing and has a throughput capacity of approximately 2,000 pounds per hour.

10 – Hazard Analysis and Critical Control Points HACCP

> "Hazard analysis and critical control points or HACCP is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe, and designs measurements to reduce these risks to a safe level. In this manner, HACCP is referred as the prevention of hazards rather than finished product inspection. The HACCP system can be used at all stages of a food chain, from food production and preparation processes including packaging, distribution, etc."[7]

[7] https://en.wikipedia.org/wiki/Hazard_analysis_and_critical_control_points

Radio Frequency (RF) Pasteurization Systems are available with all of the critical monitoring, control, corrective action, and data logging functionality required for a modern and verifiable HACCP system.

In an RF pasteurization system, as with any thermal pasteurization system, time and temperature are the most important factors in achieving the desired log reductions. Accordingly, temperatures are continuously monitored throughout the process to confirm the appropriate temperatures are achieved and maintained throughout the given treatment process.

RF pasteurization systems are inherently versatile for the processing of multiple products. In most cases, each product will likely have its own treatment protocol. Accordingly, both the treatment process parameters, as well as the critical control points, are recipe selectable from the Human/Machine Interface (HMI).

All controllable set-points, such as belt speed, power level, applicator cabinet temperature and product temperature are monitored, recorded, and programmed to alarm and/or divert the product stream in the event of a critical fault.

RF Pasteurization System for 25,000 Pounds Per Hour Configured for HACCP

Complete and verifiable hazard analyses will most likely cover production processes both up and downstream from the RF Pasteurization System. However, with Ethernet connectivity the RF Pasteurization System can provide data acquisition to the "*supervisory"* plant control system, as well as the system's local control functionality. Therefore, the integration of the RF pasteurization system, and maintaining a verifiable HACCP system, are a good fit and operational commercially throughout the industry

11 – Conclusion

Regardless of the new 2016 FSMA regulations, food manufacturers have always been cognizant of the problems establishing and maintaining the safety of their food supply chain. There is always the increasingly challenging aspect of foreign suppliers and the quality of the products purchased from countries with fewer modern resources, or being able to change ingrained traditional practices, that pose a threat to food safety. There is always the concern of resilient strains of pathogens that have proved resistant to certain heat or other pasteurization processes. There is always the opportunity for any number of contaminants: pathogens, insects, particles (metal, glass, plastic etc.) and other "pollutants" to enter the food chain from either an external or internal source.

RF Macrowave™ Pasteurization and Disinfestation systems offers a cost effective and energy efficient method for reduction of pathogens, such as Salmonella, as well as the elimination of insects, from a manufacturer's food processing chain either as an in-house process where the product is heat-treated prior or post packaging – or by requiring the process be used by the manufacturer's supplier so incoming product doesn't bring any contamination into the manufacturer's plant. FSMA notwithstanding, no food manufacturer wants to face the cost of a recall (financial and/or reputation) or the responsibility and liability of a food-borne illness being traced back to a product they supplied.

The new FSMA requirements extend to the Pet Food and Feed industry as well, and are no less of a challenge for their manufacturing process than for the Human food side of the requirements.

For exploring the possibility that RF Macrowave technology will be a positive for you or your suppliers' product, Radio Frequency Co., Inc. Millis, MA can offer RF testing at its fully equipped lab facility and validation services through a third party or the manufacturer's own microbiologists.