

How X-Ray Inspection Helps Food Manufacturers Improve Safety, Mitigate Risk, And Stay Compliant

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In early 2019, the United States Food and Drug Administration (FDA) updated several components of its food safety guidelines via the Food Safety Modernization Act (FSMA). A critical aspect of FSMA – one that is garnering significant attention from food manufacturers – is its stringent inspection and recall threshold. Manufacturers that receive more than two customer complaints are instructed to conduct robust, self-administered investigations and issue wide-scale recalls, as necessary.

In the past, investigations like these were “triggered” by the detection of large and/or problematic contaminants discovered during analysis, setting a clear and predictable standard for manufacturers. By describing applicable customer complaints and recommended remedial steps

in a general fashion, however, the new policy creates substantial uncertainty and risk for manufacturers. Unexpected inspections and recalls are very challenging and very expensive, capable of significantly hindering a food company’s resources and growth strategy.

Given these circumstances, ANRITSU is currently advising its food manufacturing clients to enhance and possibly replace their traditional metal detection-based inspection devices with devices based on newer X-ray technology. By widening the proverbial “lens” on detectable contaminants – including both contaminant types and particle sizes – X-ray inspection helps manufacturers proactively address compliance and safety concerns in the face of these new government policies.

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UPDATED GUIDELINES CREATE UNCERTAINTY AND RISK

The 2019 FSIS Guideline for Industry Response to Customer Complaints notes that "...when an establishment [i.e., food manufacturer] determines that a customer complaint represents adulterated or misbranded product that has entered commerce [,] the establishment should respond by performing an investigation, notifying FSIS, and taking corrective actions." ¹ These corrective actions, as detailed in the subsequent *Establishment Response Plan and Investigation* section, are described accordingly:

"The establishment should quickly identify any affected product (e.g., lot, date, line, etc.) and identify distribution of the affected product. Drafting and maintaining a written response plan is the recommended best practice. The response plan should include an investigation of the production that incorporates a review of relevant records generated during the production of the affected product and may include performing a visual inspection of any questionable product or labels available, observing ongoing operations/production of like product, and talking to employees who may have information pertinent to the investigation. Affected product that has not been shipped should be held and inspected prior to shipping to determine if there are additional instances of adulteration or misbranding. The establishment should use additional information to evaluate the design and implementation of the HACCP system including laboratory sampling results, the intended use of the product, supporting documentation, and expert analyses."¹

The phrasing of key provisions in this section establish that this updated policy is decidedly structured as a guideline instead of a mandate, incorporating terms like "should" and "may." While guidelines offer manufacturers more operational flexibility, they also create potential legal liability. Food manufacturers are faced with uncertainty regarding inspection and documentation best practices, as well as the concern that if they take "incorrect" measures to address customer complaints, the government may hold them liable after the fact.

Given the uncertainty and risk posed by these recent guideline updates, it is crucial to proactively mitigate risk by upgrading your detection capability to find the smallest size foreign contaminants as possible. This is where X-ray inspection offers manufacturers major technical advantages, making it a worthwhile investment – especially for large manufacturers producing at a national or global scale.

THE TECHNICAL ADVANTAGES OF X-RAY FOOD INSPECTION

Although X-ray technology is more expensive than traditional metal detector-based solutions, it is more reliable, robust, and capable in detecting contaminants compared to traditional metal detectors. Accordingly, X-ray delivers high operational value, improving a manufacturer's confidence in its HACCP program and ability to mitigate potential FM (foreign matter) from reaching its consumers.

Specifically, X-ray devices:

- 1. Detect a wider range of contaminants.** Metal detectors, as implied by name, are limited to the detection of ferrous and non-ferrous metals. With X-ray inspection, manufacturers can detect additional contaminants such as glass, stone, ceramic materials, and certain plastics. For companies that produce ground harvested products and are at greater risks for FM, including rocks and glass (from broken bottles), the expanded detection range proves especially valuable.
- 2. Detect smaller contaminant particles.** In addition to detecting more types of contaminants, X-ray devices can detect these contaminants at a much better level (smaller size) than metal detectors, to the degree of two to four ranks of scale (for instance, where a metal detector may require 4 mm of metal material to trigger an alarm, X-ray technology can detect and visualize metal material down to particle sizes of 1 mm). Newer, low power XR machines can detect SS as small as 0.5 mm to 0.6 mm.
- 3. Visualize detected contaminants.** When X-ray imaging devices detect a contaminant, they produce a grayscale image of the product with the contaminant clearly marked in the image. This helps quality assurance identify the contaminant's location, which can be valuable for identifying specific production or supply chain issues. Metal detectors, conversely, offer only a discrete "yes" or "no" when a contaminant is detected. X-ray inspection systems, including the ones we offer at Anritsu, allow inspectors to save image files tied to 2D matrix codes that can be printed and attached to individual food product inspection reports. If the

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manufacturer receives a customer complaint on that product, its food safety experts can rapidly access and reference the X-ray image associated with that specific food product.

4. Are stable across temperatures and humidity.

Products that are frozen, semi-frozen, or wet present serious challenges for metal detectors, dramatically affecting their accuracy and reliability. X-ray inspection devices, conversely, provide reliable detection regardless of product temperature or humidity and humidity differentials, making them an ideal choice for companies frequently moving product in and out of cold storage.

Today, large-scale food manufacturers are beginning to recognize the value in investing in X-ray technology. In early 2019 Tyson executed a massive recall of its poultry products, recalling over 11 million pounds of its chicken strips and chicken nuggets based on customer reports that its products contained visible pieces of metal. ² As part of its remedial measures to mitigate similar issues in the future, Tyson publicly announced that it would install X-ray inspection machinery to replace its plant's metal detectors. ³

IMPLEMENTING X-RAY ON A REGIONAL OR GLOBAL SCALE

Onboarding X-ray inspection technology at a regional or global level takes effort but offers worthwhile reward.

As an initial measure, all food manufacturers – irrespective of size and scale – should take time to familiarize themselves with the full scope of the FDA's new guidelines. Then, as suggested by FSIS, they should develop a robust response plan that incorporates the new technology and leverages

it to produce accurate and consistent visualization records that can be referenced and reported during adverse event response. This is an area on which we often consult with our clients during the early stages of product implementation.

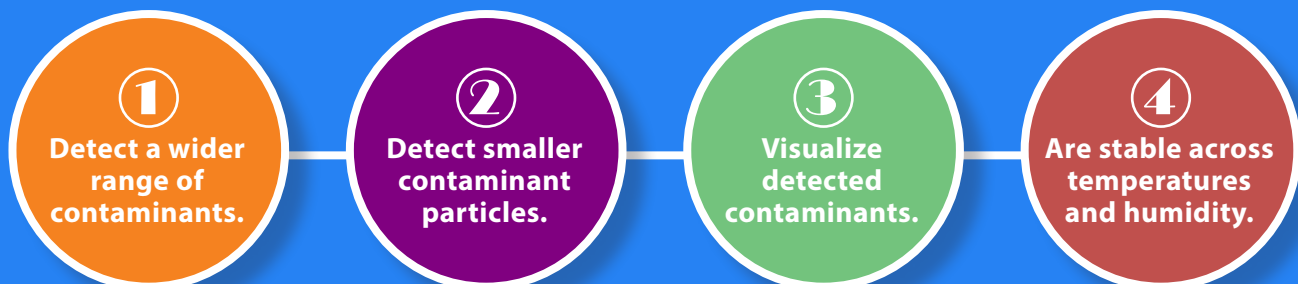
When we work with large clients – many of whom have an international presence – we typically receive requests wanting to integrate their **SCADA** (supervisory control and data acquisition) software package that automatically pulls in X-ray visualization data during factory production. This capability is offered on Anritsu XR machines and ensures every product is scanned and logged with minimal manual action required. Having this ability allows a large manufacturer's IT/Quality team to rapidly identify product reject rates in specific regions, operationalizing inspection and supply chain management at a global level.

CONSIDER THE BOTTOM LINE

Recent regulatory policy changes – when considered against the functional limitations of metal detection technologies – make transitioning from metal detection to X-ray inspection a top priority for food manufacturers. Waiting until a recall or customer complaint occurs, and then scrambling to address that event in line with new and often vague government guidelines, can significantly disrupt your day-to-day operations and negatively impact your bottom line. Instead, consider taking a proactive approach to your food safety policy and inspection best practices.

Work with the experts at ANRITSU INFIVIS to develop an inspection strategy and help provide the best possible detection of your products and minimize your risk for a product recall or consumer complaint.

The Technical Advantages of X-Ray Food Inspection



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About ANRITSU INFIVIS, Inc.

Anritsu is the #1 supplier of food XR systems globally with precision engineering inspection solutions for both the food and pharmaceutical industries. Formed in Japan, Anritsu has expanded its tradition of advancing quality control programs across the globe with innovative and reliable technology and solutions for over 50 years. As a global leader in food safety and product quality assurance, Anritsu has developed a growing presence in the North American market.

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