Food Safety Modernization Act

Helping You Achieve Compliance

METTLER TOLEDO

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This interactive PDF is optimized for Acrobat Reader.

What is the Food Safety and Modernization Act? (FSMA)

Food Safety and Modernization Act (FSMA)
Passed in 2010

FSMA amends the Food, Drug and Cosmetic Act (FDCA) and gives FDA the authority to mandate preventive-based controls across the food supply chain.

The FSMA contains five elements:

1. Preventive Controls – gives FDA legislative control to set preventative risk requirements in place

2. Inspection and Compliance – provides for enhanced inspection approaches

3. Imported Food Safety – tools to safeguard that imported foods meet U.S. standards

4. Response - mandatory recall authority for all food products

5. Enhanced Partnership – strengthening collaboration among all food safety agencies

Food Safety and Modernization Act (FSMA)
Introduced in 2019

The New Era of Smarter Food Safety represents a new approach to food safety, leveraging technology and other tools to create a safer and more digital, traceable food system.

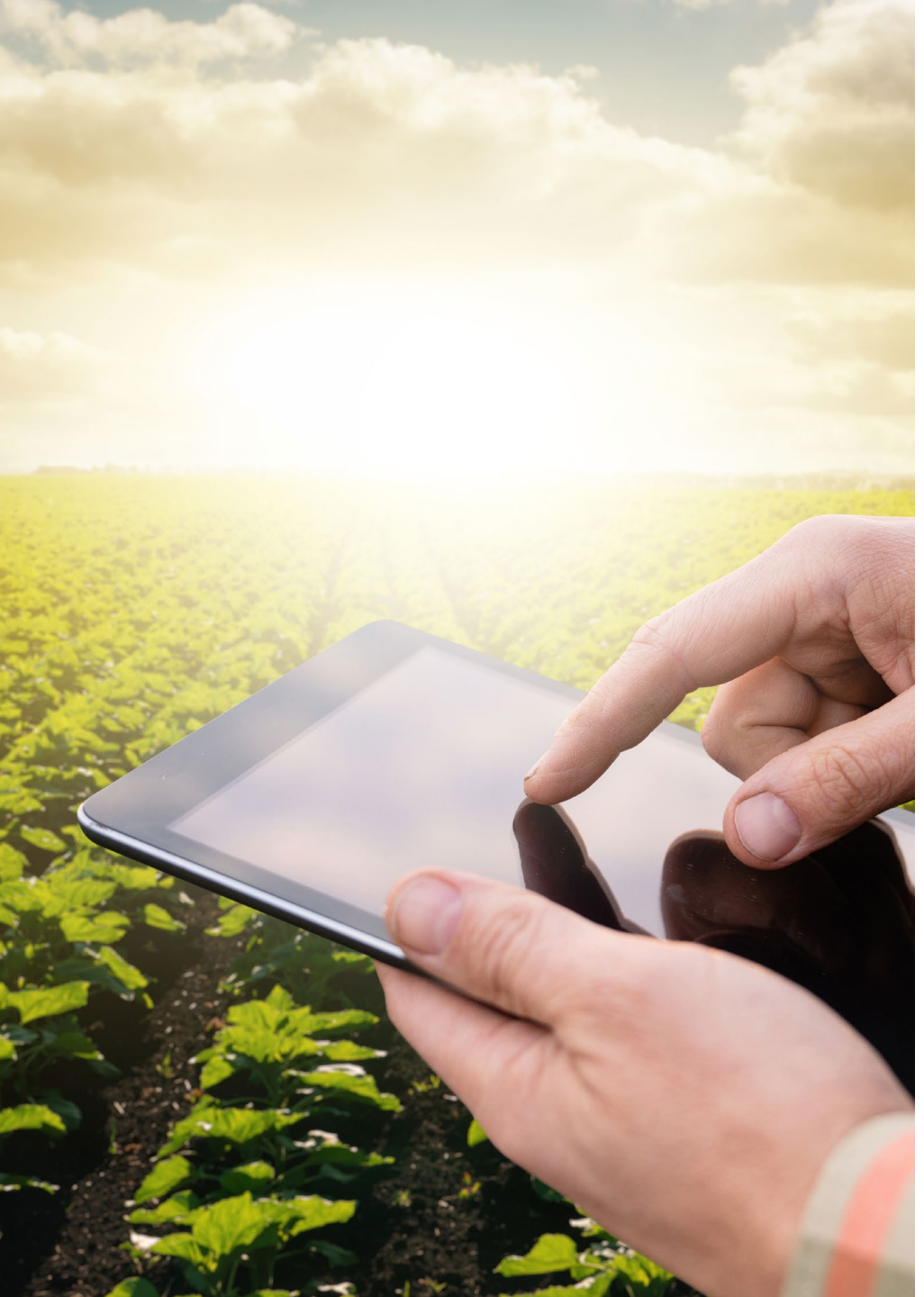
- Tech-enabled Traceability: The records involved in moving food through the supply chain are still largely paper-based.

- Smarter Tools and Approaches for Prevention and Outbreak Response: With better traceback, our ability to conduct root-cause analyses will be greater, and findings from this work can be used to better inform the prevention-based framework that FSMA established.

- New Business Models and Retail Modernization: How to adapt oversight to help ensure the safety of novel ingredients, new foods, and new food production methods.

- Food Safety Culture: Influence and change human behavior, addressing how everyone – employees and consumers - think about food safety.

New Aspects of the FSMA: Data Traceability



New Aspects of the FSMA
Data Traceability

Food Traceability Final Rule

- Establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL)
- Requires that food producers maintain records containing Key Data Elements (KDEs) associated with specific Critical Tracking Events (CTEs).
- The data that must be captured and maintained can differ, depending on the type of activities a food producer performs with respect to an FTL food.
- Most central to the new requirement is the assignment, recording, and sharing of traceability lot codes (TLCs) for FTL foods, which links them to other information identifying the foods as they move through the supply chain.
- Covers domestic and foreign firms producing food for U.S. consumption, along the entire food supply chain

Deadline for compliance is July 20, 2028

Complying with Data Traceability Rules

What Do I Need to Track? How Can I Capture It? How Long Do I Need to Keep It?

You must be able to produce and maintain records that contain the following:

- The commodity and, if applicable, variety of the food received.
- The date you received the food or that it was harvested.
- The quantity and unit of measure of the food received.
- The location where the food came from.
- Identifier for exact location where product was harvested or culled.
- The date of harvesting or cooling if applicable.
- The location description for where the food was cooled or stored.
- The traceability lot code you assigned.
- The product description of the packed food.
- The location description for where you initially packed the food (traceability lot code source), and traceability lot code source reference.
- The date of initial packing.
- The reference document type and reference document number.

You must keep records as original paper or electronic records or true copies (other accurate reproductions of the original records). All records must be legible and stored to prevent deterioration or loss.

You must update your traceability plan as needed to ensure that it reflects your current practices and that you meet the requirements of the rule. You must keep your previous traceability plan for 2 years after you update it.

Data must be made accessible within 24 hours of an FDA Request. You must maintain records containing the required information for 2 years from the date you created or obtained the records.

Data Integrity in Manufacturing

Data Integrity in Manufacturing

Principles of Data Integrity

Data Integrity refers to the ability for data gathered as part of the manufacturing process to be relied upon. This reliability requires completeness, accuracy, and consistency of data.

The Integrity of production data is judged according to industry standards which state it must be:

- **Accurate:** correct and unedited data
- **Legible:** readable data
- **Original:** original data present in master record
- **Contemporaneous:** include the precise time of data collection
- **Attributable:** represent the entity responsible for acquiring or using data
- **Complete:** include all data generated
- **Consistent:** identical regardless of which platform data is accessed
- **Enduring:** stored long after collection
- **Available:** able to be retrieved when needed

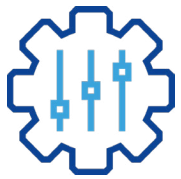
Data Integrity in Manufacturing

Data Governance Framework

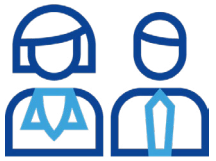
Data integrity must be implemented as part of an overall data governance framework. The data governance framework is designed to assemble people, processes, and technology to ensure reliable data.

What are the responsibilities of manufacturers?

- Utilize equipment and software that provide technical controls to minimize risk
- Implement procedural controls and operator training which minimize risks
- Ensure systems are built-for-purpose for high-quality data
- Implement processes and systems to ensure data is secure, traceable, and adheres to standards of data integrity are maintained



Technical Controls



Procedural Controls

Data Integrity

Data Security

Data Quality

Data Traceability

Data Integrity in Manufacturing

Threats to the Integrity of Production Data

Human Error

Data Entered by Human Intervention

Manual entry of data can create issues in legibility, consistency, and accuracy.

Data Transfer Error

Transfer of Data Between Production Systems

Faulty data transfer mechanisms can cause incomplete records.

Hardware/Device Error

Incorrect Devices Collecting Data

Devices which are not fit for the purpose they are intended can cause faulty data to be created.

Bugs/Hacks/Cyber Threats

System Vulnerability or Lack of Security

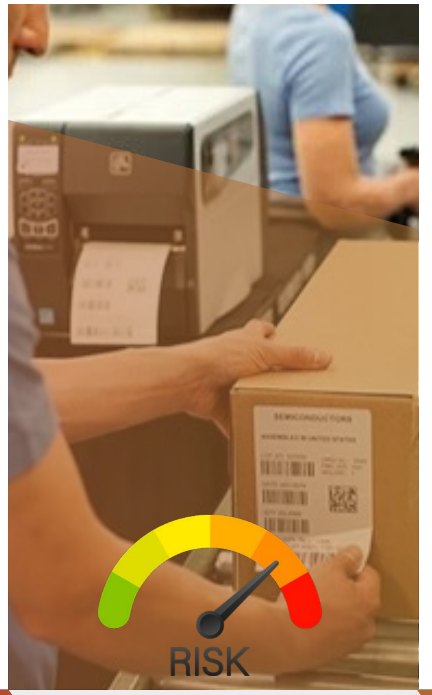
Lack of appropriate security can erase or alter original data.

Electronic data captured digitally on fully networked devices, which feed that data to compatible and secure process systems creates production records which exhibits the highest integrity.

Data Integrity in Manufacturing

The Journey to Preserve Data Integrity

Paper Documentation



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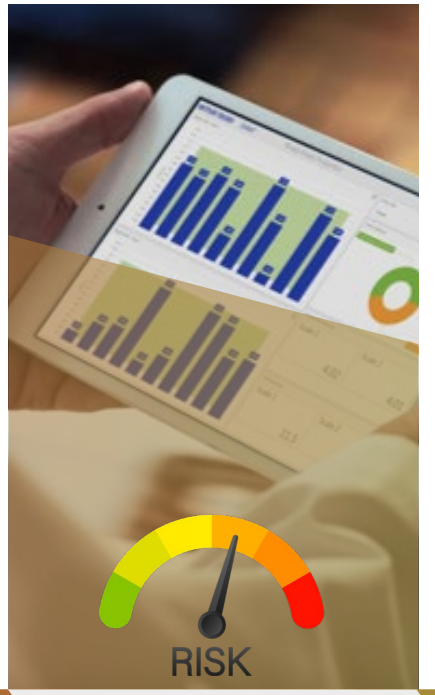
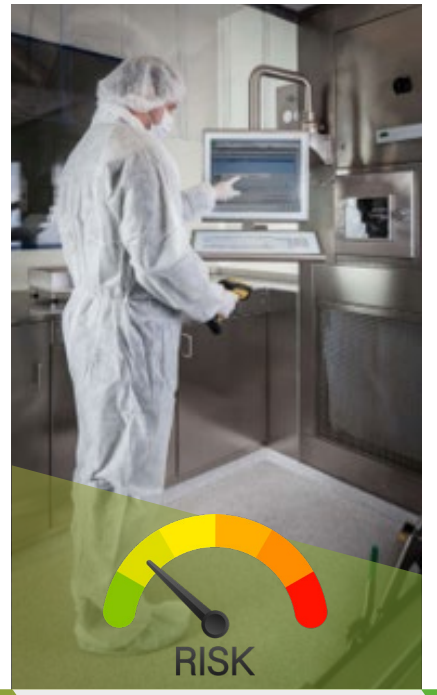


Electronic Data Capture

Secure Data Storage



Electronic SOP Workflows

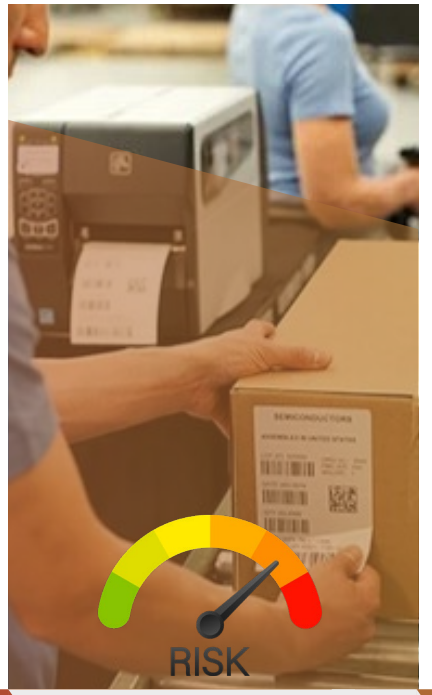
Business Systems Integration

Digitization: converting or capturing production data records to a digital format.
Increased digitization decreases risk associated with data integrity as manual and human based methods for capturing data are eliminated.

Data Integrity in Manufacturing

Solutions Across the Data Integrity Journey

Paper Documentation



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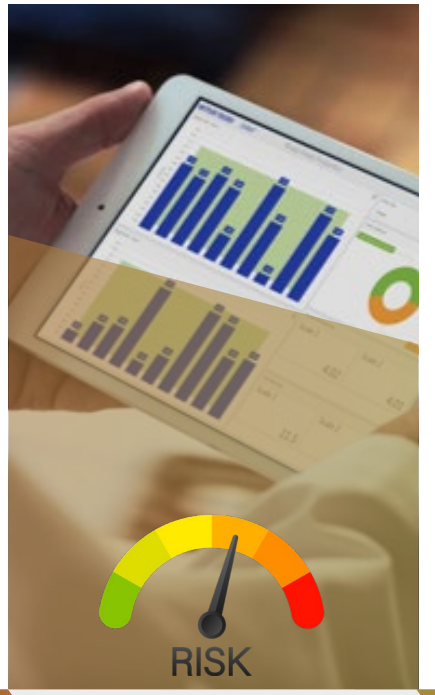

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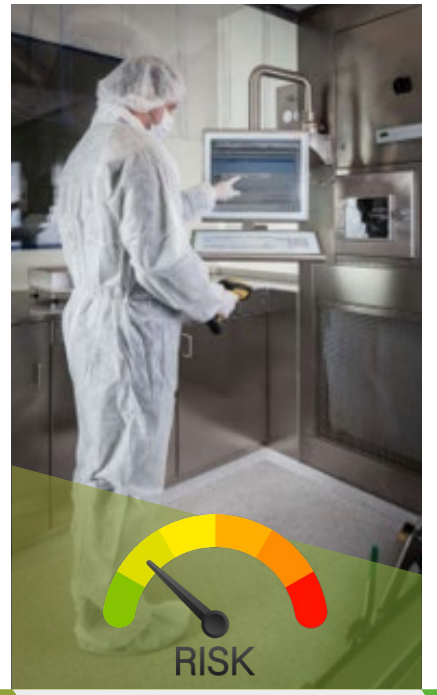

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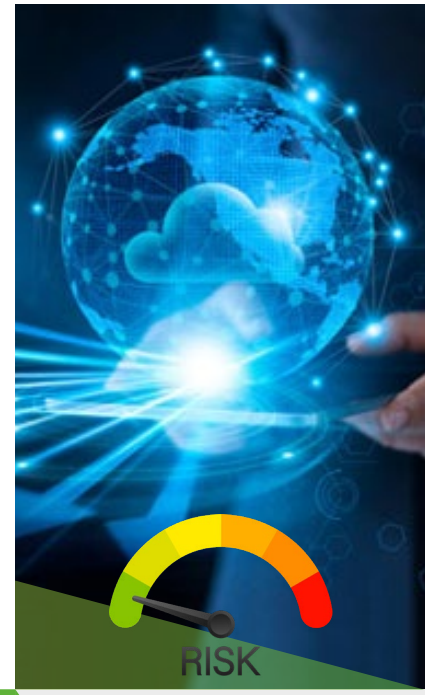


Business Systems Integration

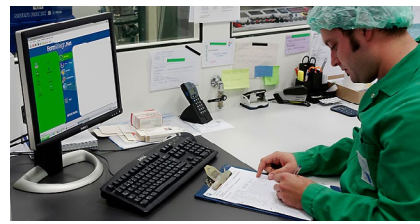
APR530 Printer

Verified Process Data

Collect+

Central Database

FormWeigh.Net & FreeWeigh.Net



ERP Integration Services

Data Traceability Does More than Just Help Your Organization Achieve Compliance

By leveraging digital transformation and implementing an internal digital technology system, you can:

- Gain better insights into your production yields with data that can be easily retrieved and analyzed
- Identify gaps in your process which may be causing you to waste labor, raw materials, or space in your production facility
- Ensure consistent quality outcomes for your product

FSMA and Contamination Risks

FSMA and Contamination Risk

Ensuring Operation and Equipment Compliance

FSMA moves from a system that responds to outbreaks to one that works to prevent them, controlling contamination by evaluating hazards in operations and developing effective measures to prevent food contamination.

Required to adhere by 2016

- Create and maintain a written food safety plan which includes analysis of hazards
- Perform hazard analysis
- Establish preventative controls for hazards that are reasonably likely to occur
- Monitor controls performance through verification activities
- Take corrective actions

Equipment that fails to prevent contamination is a hazard risk

FSMA and Contamination Risk

Hygienic Design Standards are Found Across Multiple Regulatory Bodies

GMP/CGMP Cleaning Validation

The FDA and GFSI, through the GMP/CGMP regulations, underline the need for effective cleaning processes.

GMP guidelines on cleaning validation, specify criteria for equipment cleaning assessment.

Hygienic Design Guidelines

The European Hygienic Engineering & Design Group (EHEDG) and the National Sanitation Foundation (NSF International) are experts in the area of good design practices for sanitary equipment.

EHEDG is engaged in 40+ countries.

Cleaning Tools/Equipment

Cleaning equipment shall be: hygienically designed and fit for purpose; cleaned and stored in a hygienic manner to prevent contamination.

Guidelines on cleaning conditions, aids, processes and post-cleaning inspections.

Hygienic Design and Mitigating Contamination

Hygienic Design and Mitigating Contamination

Principles of Hygienic Design

- **Cleanable to a microbiological level:** Food equipment must be constructed to ensure effective and efficient cleaning of the equipment over its lifespan. The equipment should be designed as to prevent bacterial ingress, survival, growth and reproduction on both produce and non-product contact surfaces of the equipment.
- **Made of compatible materials:** Construction materials used for equipment must be completely compatible with the product, environment, cleaning and sanitizing chemicals and the methods of cleaning and sanitation.
- **Accessible for inspection, maintenance, cleaning and sanitation:** All parts of the equipment shall be readily accessible for inspection, maintenance, cleaning and sanitation without the use of tools.
- **No product or liquid collection:** Equipment should be self-draining to assure that liquid, which can harbor and promote the growth of bacteria, does not accumulate, pool or condense on the equipment.
- **Hollow areas should be hermetically sealed:** Hollow areas of equipment such as frames and rollers must be eliminated whenever possible or permanently sealed. Bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps, sleeves and other such items should be continuously welded to the surface, not attached via drilled and tapped holes.
- **No niches:** Equipment parts should be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets and dead ends.
- **Hygienic compatibility with other plant systems:** Equipment design should ensure hygienic compatibility with other equipment and systems, such as electrical, hydraulics, steam, air and water.

Hygienically Designed Equipment Prevents Contamination and Ensures Compliance

Hygienic risk
Hygienic design

Construction Materials

- Corrosion resistant
- Non-toxic/non-absorbent
- Surface roughness < .81µm

Hygienic risk
Hygienic design

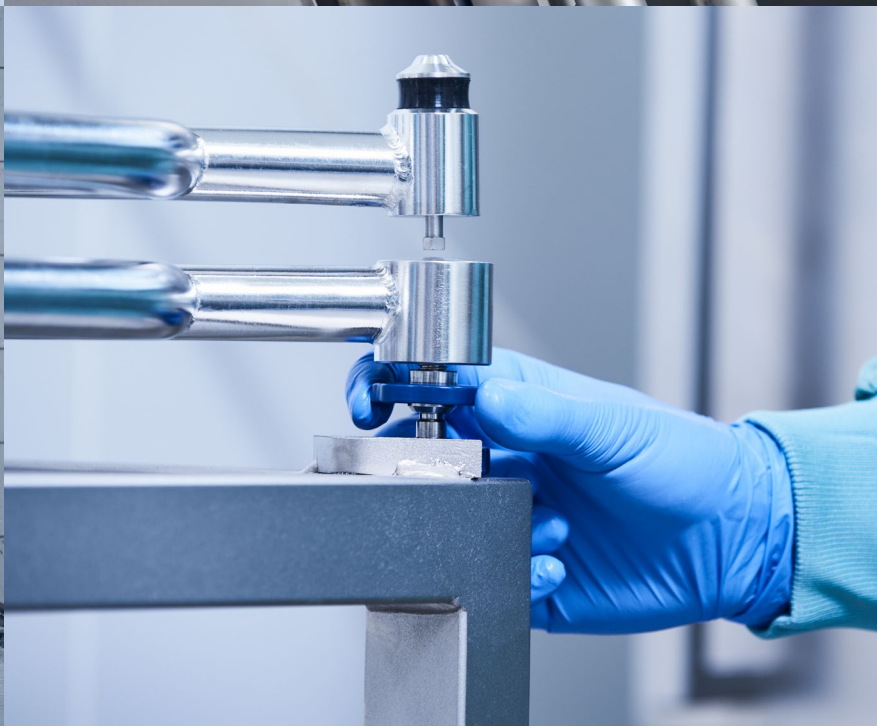
Open Construction

- Open and easily accessible
- Rounded horizontal elements
- Avoid dead spaces/hollows

Hygienic risk
Hygienic design

No Crevices or Niches

- Rounded corners/angles
- Smooth, continuous welds
- Avoid open threads/fasteners



Hygienic Design and Mitigating Contamination

IP Rating vs. Hygienic Design

Ingress protection (IP) ratings

- Grade the resistance of an enclosure against the intrusion of dust or liquids.
- Voluntary, not verified by any governing body.
- IP68/69k: defined as dust tight and liquid resistant from high pressure and high temperature water jets. This rating provides the highest level of case, enclosure and seal testing.

Hygienic Design

- The utilization of design principles/techniques that optimize efficient sanitation in an effective and time saving manner.
- Equipment which is designed to eliminate the risk factors associated with contamination in production.

Hygienic Design and Mitigating Contamination

Solutions Designed for Hygienic Environments

Bench Scales: PBA639/PBD659/PBK989


Indicator protection

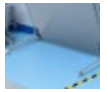

Open design


Hygienic foot design


Smooth surface

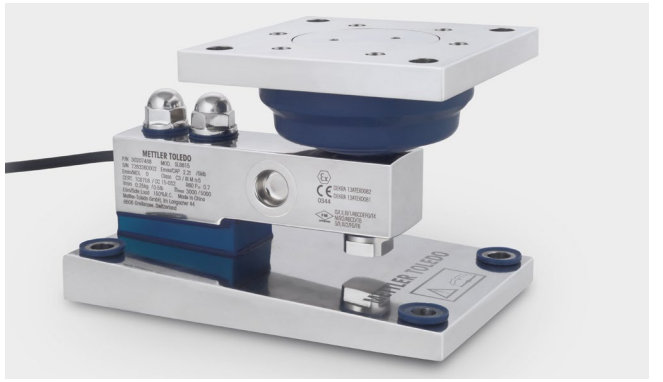
Floor Scales: PHD779


Easy cleaning access


Open design


Protected structure


Smooth surface



Tank Weighing: SWB805 Hygienic


Patented gasket design


Angled base plate


Sealed interfaces


Hygienic cable and load cell design

Conclusions – Fit for Purpose and the Whole Picture

Fit for Purpose and the Whole Picture

Ensure Proper Specification

Good Weighing Practice™ (GWP®) uses a scientific approach to ensure proper specification.

The three stages of GWP:

1. **Selection: Definition of purpose**
   Collect customer process information and regulatory requirements to support the selection of the right scale.

2. **Confirmation: Fit for purpose**
   Confirm the scale meets your process requirements and is therefore accurate enough for your needs.

3. **Routine Operation: Fit for purpose over time**
   Confirm the scale continues to meet your process requirements throughout its lifetime with a calibration and routine testing plan.

Optimize Your Equipment and Processes

Understand Your Risks
FSMA has different impact depending on your place in food supply chain and processes.

Data Traceability
Establish your Data Traceability Plan, leveraging technology where possible to optimize data integrity.

Fit-for-Purpose
Ensure your equipment meets the unique needs of your facility and processes.

Hygienic Design
Understand how the design of your manufacturing equipment can impact your contamination risk.

Review these criteria on a regular basis to ensure you are always meeting your business and compliance needs.

Additional Resources

Ready to start your journey towards FSMA Compliance? Learn more about some of our products that can help.

Digitalization

IND400 Weighing Terminal

APR530 Label Printer

Collect+ Software

FormWeigh.Net

FreeWeigh.Net

Hygienic Solutions

PBA639/PBD659 (Bench Scale)

PBK989 (Bench Scale)

PHD779 (Floor Scale)

SWB805 Hygienic (Tank Weighing)

If you are interested in learning more about how METTLER TOLEDO can help you to achieve compliance with the FSMA and achieve your food safety goals, visit us at www.mt.com/fsma to learn more and be connected with one of our representatives.

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