Food safety and legislation today:

How to address its critical implications

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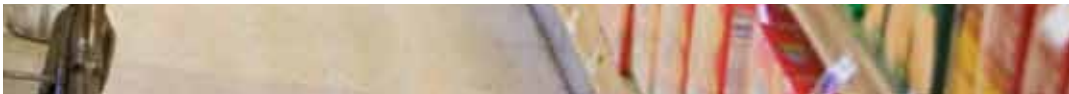
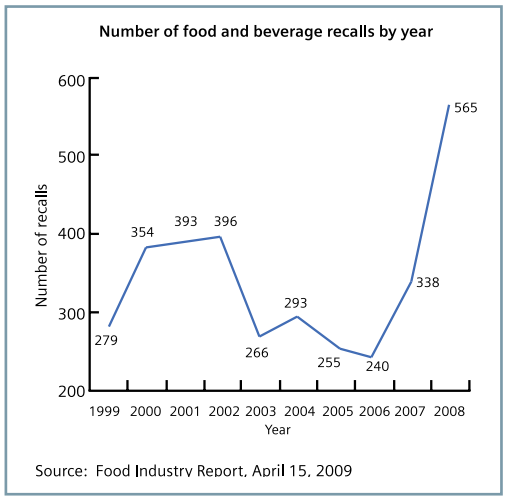


Wary consumers, concerned legislators, uncertain producers

The call, text or email could come any time of day or night, weekends or holidays too: “We’ve got a problem.” For food and beverage producers, among the worst possible news would be that products, already in stores, are contaminated serious enough to have caused consumers illness, hospitalization or, most terrible of all, death.

According to the U.S. Centers for Disease Controls, each year approximately 76 million Americans – about 25 percent of the total population – get sick from contaminated food or drinks, resulting in some 300,000 hospitalizations and 5,000 deaths. As the chart to the right shows, the trend in food and beverage recalls is not encouraging: From 2006 to 2008, the number has more than doubled.[1]



Hard facts like these are why consumers have more concerns with food and beverage safety, concerns that are fanned by national recalls that seem to be increasing. Not surprisingly, these recalls are undermining consumer trust – a key brand attribute for food and beverages – and now, at a time when more than ever, that trust is built on food safety.

[1] *Food Industry Report, August 2009*

Short and long-term business impacts. Financial concerns about food and beverage safety haunt producers, too. On average, recalls cost $10 million – monies that come straight from the bottom line. That's just the average; some recalls have hit producers much harder, up to $100 million or more. Adding to those huge sums are hidden post-recall costs for such things as:

- Lost brand equity
- Investigations
- Inventory losses
- Product removal
- Product destruction
- Legal fees
- Product replacement
- Loss of sales
- Brand "re-marketing"

When a recall does occur, time is critical as each passing day can lead to more illness among consumers, while devastating a company's market capitalization and ruining its brand image.

For example, one day after a recall announcement, producers experience an average 2.3 percent drop in share price compared to their sector index. Worse, if a recall is handled poorly, a producer's share price drops on average 22 percent compared to its sector index just two weeks after a recall announcement.[2]

Brand loyalty and even a product category preference can evaporate just as quickly. The 2010 spinach recall stopped consumers from not just buying the brands being recalled but all spinach – with five percent of consumers surveyed saying they would never buy spinach again.[3] Many reported that they stopped buying bagged salad items altogether, despite the convenience bagging can provide.[4]

A walk down the food and beverage aisles in today's supermarket is a walk through long-term treasure trove of brand investments in advertising, shelf-placements, couponing, and the like worth hundreds of millions, if not billions, of dollars. Should a recall strike any one of those products, not only will it be pulled from its shelves (and possibly replaced with a competitor) but all its brand investment is also at risk, if not completely ruined depending on how serious the recall. Worse, if the product is part of a larger brand portfolio, its recall can also taint consumer trust in other members of the brand family.

Today more than ever, product success is built not just on brand quality but food safety, too.

The uncertain path forward. Given the growing number of recalls, it's a small wonder that the polls have shown nearly 90 percent of voters support stricter food safety regulation. And state and federal legislators are responding. Most notable are two bipartisan pieces of landmark federal legislation – H.R.2749, the Food Safety Enhancement Act, and S.510, the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act. While these seem certain to become law, it's uncertain when and, until then, they have cast tremendous uncertainty over the food and beverage industry about how to proceed with investments in product safety.

To be sure, food and beverage producers share the public's concern for a healthy food supply. Industry associations have long recognized a shared responsibility for the healthy hygiene of the farm-to-fork supply chain, working with regulators to ensure the safety of its throughput. After all, they and their families are ultimately food consumers, too.

A core challenge, however, is the growing complexities of that supply chain. Some drivers of those complexities include the globalization of the food supply, exploding numbers of in-store SKUs, error-prone (and unscalable) human processes, and counterfeiters and malcontents intent on compromising the safety of food and beverages for the sake of profit and notoriety, respectively.

Practical, proactive risk management. Of course, to protect consumers as well as their own brands and businesses, food and beverage producers can never be too vigilant about the quality and provenance of their ingredients, the cleanliness of their operations or the sanitation of their distribution channels.

What's more, whenever they change any part of their production process – adding a new ingredient supplier, opening a new process line, rearranging a cooler or any other changes – they need to reassess their food safety risk profile. Obviously changes can introduce new hazards and those hazards need to be identified and addressed. Food safety is not static; it's a matter of continuous improvement.

But all that is a lot to track. And playing the odds of not breaking a critical control point (CCP) sometime or somewhere along the supply chain are odds best left in Las Vegas.

The most practical, proactive approach to managing this risk is the systemic use of real-time and historical data to derive informational insights and avert trouble before it happens. Then, should a problem occur, even a recall, response times can be much faster, helping to contain the harm to customers, the business and the brand. Better yet, producers can use this data to help them build their brands through greater value, superiority, consistency and, as mentioned, safety.

With new federal legislation likely, food and beverage producers may face uncertainties about its implementation and timing. However, out of all the key legislation components, they can take steps today to meet four certain implications of the draft legislation: Food Defense; HACCP; Record-Keeping & Reporting; and Traceability & Genealogy.

[2] *Collaborative Approaches to Improving Consumer Safety and Confidence, 2010*
[3] *DailyFinance.com, August 2010*
[4] *Food Institute Policy Report, 2007*

Food Defense

Food and beverage producers can do a lot to ensure food safety by addressing the sources of accidental contamination by biological, chemical and physical hazards. However, their efforts cannot stop there. They also must take action to prevent intentional contamination by people intent on doing harm. These people can be intruders or insiders, such as disgruntled current or former employees who may know facility security controls and how to bypass them.

In short, preventing the intentional harm of food by others is called "food defense." Such measures not only can protect ingredients, work-in-progress and inventories of finished goods but they can also help to improve the safety of other employees and other plant assets. Ultimately, like food safety vigilance and systems, food defense can help protect the well-being of a food or beverage producer's business.

Prudence and good business practices suggest writing a Food Defense Plan. The plan will identify all the gaps in facility and food security that might exist both inside and outside a plant, including storage and shipping and receiving – general points of vulnerability.

A straightforward and effective approach to developing a Food Defense Plan takes three steps:

1. **Perform a Food Defense Assessment:** An individual or team should be put in charge of this assessment, which takes a critical look at security around the property perimeter – gates, locks, access control, lighting, human or video surveillance and the like -- then similarly evaluates the exterior and interiors of all buildings on the property. It also considers who has authorized access to what parts of the plant and if existing restrictions are sufficient protection.

2. **Build a Food Defense Plan:** After performing an assessment, any security vulnerabilities should be identified. A clear set of measures to address those risks should be drawn up, with a budget and timeline for their implementation. For example, if food storage areas are open to all, some form of access control should be put in place. It could be as simple as a lock-and-key system, with a paper log of who checked out the keys and when, or it could be a more sophisticated electronic access control system with badge entry that automatically logs who is coming and going from food storage areas.

3. **Implement the Food Defense Plan:** Based on the budget and timeline of the Food Defense Plan, the necessary steps to close the gaps need to be taken with oversight by the person or team in charge of the plan. In case of a crisis, the plan should be enhanced with contingent operational specifics such as internal and external contact lists, an issue escalation protocol and staff training in the plan itself and any new procedures required. It should include dates for periodic reviews of the plan (at least annually) and any needed revisions to reflect plant changes or newly discovered vulnerabilities. Also suggested is a "tabletop" exercise of the key personnel who would be involved in a Food Defense crisis, based on a prescribed scenario with the team responding according to the protocol(s) outlined in the plan. This is valuable before a crisis because it helps familiarize the key players with those protocols and it tests the steps in those protocols against the scenario.

With a Food Defense Plan implemented and complemented by a comprehensive food safety program, producers can be confident that they have done all they can to protect their end-use customers, their channel partners and their own brands and businesses from harm – or, if somehow these protections are violated, they know that they will be able to contain the harm as much as possible.

Hazard Analysis Critical Control Point (HACCP)

Before the widespread adoption of HACCP by the food and beverage industry, food safety relied on spot-checks of production environments and random samplings of final products. The drawback of this approach, however, was it being inherently reactive instead of proactive.

HACCP, in contrast, is a systematic, preventive approach to food and beverage safety. It originated in the 1960s to help the U.S. National Aeronautics and Space Administration (NASA) develop safe foods for space flights. In the following decades, HACCP was increasingly recognized worldwide as the basis of a logical, science-based food safety system.

Today, the U.S. government mandates its use by the meat, seafood and juice producers, and other food and beverage producers are using it voluntarily. The International Organization for Standardization (ISO) also incorporated HACCP's principles into its comprehensive food safety standard ISO 22000.

A CCP is any step in a food and beverage production process where a control can be applied to prevent, eliminate or reduce food safety hazards to acceptable levels.

While CCPs can be applied and monitored manually, large-scale production plants make it impractical to do so because there may be hundreds of CCPs and the effort and potential for human error is huge. This has driven the development of advanced applications of information technology such as Totally Integrated Automation (TIA) and Manufacturing Execution Systems (MES) that can provide an electronic HACCP system – or "e-HACCP" if you will.

TIA is a comprehensive process control system (PCS) that includes both the necessary process line controller (PLC) and the human machine interface (HMI). It can help optimize the overall performance of food and beverage production facilities while helping to address health threats by monitoring CCPs in their processes.

An MES can complement TIA's "watch" on production by linking food and beverage plant processes with Enterprise Resource Planning (ERP) systems like SAP, Oracle and others. An MES can capture hundreds of CCP data points every minute and display key indicators in full-color graphs, charts and dashboards.

In its role as an interface between real-world automation systems and upper level planning and financial systems, the MES layer provides production monitoring and modeling. It can also provide a view into Overall Equipment Effectiveness (OEE) as well as downtime monitoring and inventory control.

With an electronic-based HACCP system in place, food and beverage plant operators can gain tremendous production precision, flexibility and efficiencies. In addition, and critical to ensuring food safety, they can also realize greater operating transparency across their production lines, less time in discovering deviations and taking corrective actions, and greater confidence in the safety of their products. All of this can help to dramatically reduce compliance costs, too.

HACCP's seven principles

1. Conduct a hazard analysis. Determine all possible food safety hazards and identify what can prevent these hazards. A food safety hazard is anything that may cause a food to be unsafe for human consumption.
2. Identify critical control points (CCPs). Identify those steps in food and beverage production where controls can apply and help prevent, eliminate or reduce hazards to acceptable levels.
3. Establish critical limits for each critical control point. Critical limits set maximum or minimum values to which food safety hazard must be controlled at a CCP.
4. Establish critical control point monitoring requirements. Monitoring helps ensure a process is under control at each CCP.
5. Establish corrective actions. When monitoring indicates deviations from established critical limits, corrective actions bring the CCP back within those limits and that no output enters the food chain because of the deviation.
6. Establish record-keeping procedures. These document a plant's monitoring of critical control points, critical limits, verification activities and how deviations are handled.
7. Validate that the HACCP system works as planned. This ensures that plants operate as designed to ensure safe products.

Recordkeeping & Reporting

The data produced by manually monitoring a food or beverage plant's quality from just periodic spot-checks can create a nightmare of paperwork, not to mention the potential for errors and omissions. Even with automation, the flood of real-time data from 24x7 monitoring can pose challenges of data storage, backup, mining, reporting and analysis. Simply put, having a lot of data isn't useful if it's not accessible.

Data accessibility is critically important to optimize production processes for maximum efficiency and output. Food and beverage production managers face issues enough each day having to constantly tame a wide range of variables associated with source inputs and the production environment (e.g., temperature, humidity, production timing, channel and market demands among them). They should at least be able to be assured that their CCPs are operating within set parameters and, if not, that they'll be alerted so they can take fast corrective actions.

Faster access, faster response.
For example, via CCP sensors specified by the quality control design of a process, a TIA system coupled with an MES can gather and log production data in real-time. Collecting data this way eliminates the labor, latency and mistakes of doing so manually. Real-time CCP data also can trigger alarms as soon as a parameter is violated, initiating automatic responses based on preset rules. If human intervention is needed, the system can alert the right person.

Of course, the sooner a CCP violation is known, the sooner it can be corrected and the less production is wasted, not to mention the vastly reduced chances of any contaminated output making its way into the food supply. Even better, to avoid CCP violations altogether, statistical process control (SPC) can issue advisory alarms when a process starts to destabilize but before it exceeds a CCP limit.

TIA and MES systems can also tie into a laboratory information management system (LIMS) module, seamlessly integrating automatic sample testing with the plant's production and quality management systems. A LIMS can be used to sample raw material, work-in-progress or final products, ensuring their specification conformance. If not, plant management can be alerted before production runs are expensively compromised or final products enter the food chain.

Better quality control and compliance reporting.
Another reason for rapid data accessibility is to improve quality management and compliance reporting. Although more and more food and beverage producers are making regulatory compliance a normal business practice, they face a delicate balancing act: Reconciling quality and regulatory compliance requirements with their needs for efficiency, productivity and flexibility to meet profitability and market demands.

TIA coupled with an MES can help producers strike the right balance in a much more precise and data-driven way. Together these systems can help producers tie their process control into their business systems while synchronizing their operations along the entire production life cycle. This can offer them a detailed and more nuanced view of their entire manufacturing and supply chain, both in real-time for optimizing operations and quality and historically for trend analysis.

Data associated with alarms, for example, can be logged for corrective action to document a plant's response to process failures and help drive continuous improvement efforts. When CCP limits destabilize or breach limits, analytics can help derive operational and process insights to quickly identify and eliminate the problem's root causes. Paper-based systems can require days or weeks – and offer nothing close to the analytical power of an automated approach that may take mere minutes or hours.

To meet regulatory, customer and internal audit requirements, TIA and MES systems can generate needed HACCP reports almost instantly from the plant database. This eliminates the cost and trouble of storing paper records not to mention the time required to get the records and rebuild a production history from them.

Traceability & Genealogy

Food traceability and genealogy capabilities are vital to the public's health as well as that of the food industry. Typically when a large-scale, food- or beverage-borne illness breaks out in the public arena, regulators and producers rush to find the cause to prevent additional cases from occurring. But days can pass and confusion can mount about the source or sources of contamination, given our food supply chain's enormous complexities.

In that time, despite a regional or nationwide recall, people can keep falling ill. An entire food category can suffer, sometimes unjustifiably so, like the salmonella breakout in 2008 that was initially blamed on tomatoes. Although jalapeno peppers eventually were at fault, average tomato prices dropped about 50 percent with a total industry cost estimated at $100 million.

Product traceability within the food and beverage supply chain documents where intermediate and final products are, where they are going and where they came from. An important capability of a traceability system is handling recalls quickly and efficiently, to limit the spread of illness and damage to customers' confidence and trust to a producer's brand.

At the same time, producers need to respond to increasing market demands for more products, for shorter time-to-market and for multi-site production, all of which requires them to create strict production protocols that always ensure high quality output.

It's important to note that traceability is a plant issue and not a business one. That's because it's only at the plant level that you can achieve the right visibility of the individual product lots and their process CCPs. Plant IT infrastructure must support continuous integration of production operations and shop-floor activities to effectively monitor where and when ingredients and intermediate products are moved and transformed or where and when final products are stored or shipped.

Process genealogy supports traceability by providing two key functions: One is called "genealogy execution," which builds a record of the myriad production steps taken inside a plant; the other is called "genealogy analysis," which provides the means to display upstream or downstream information from any point within the plant or, given extended interoperability with the systems of suppliers and channel customers, within the supply chain. If a recall is needed, every ingredient can be traced for every product. If done soon enough, product lots can be recalled before their goods reach a store, saving customers from possible illness and saving producers expense and brand damage.

TIA and an MES can build comprehensive product genealogies by recording data on any inbound ingredient such as ID number, incoming date and time, its supplier's delivery information and so forth. The systems then can record every step of those ingredients' processing along the entire manufacturing lifecycle. This includes their transformation into intermediate materials and where they flow through the plant. In case of contamination, finding out where and when products were processed, moved and stored during production becomes quick and easy, thanks to a complete genealogical history of a product.

[5] *Fresh Tomato Industry Shaken by FDA Salmonella Link, Seeks Answers," by Cary Blake, Western Farm Press, Aug. 21, 2008*

Making the business case for addressing these issues now

Given the critical importance of food safety and food defense to producers, both need to be viewed not as expenses but as an important capital investment in the future of their businesses while providing risk management. The same return on investment (ROI) criteria should be used, just as if a new production line or packaging machine are being considered.

Take, for example, the fact that an average recall costs $10 million, not counting hidden contingent costs. For a producer with $100 million in annual sales and 10 percent net margins, a recall's cost of that size would wipe out bottom line profit for the year. If a high-quality food safety and defense program, with the former based on TIA coupled with an MES, would require up to a million dollars in startup capital investment, amortized over 10 years, that's $100,000 a year.

Add to that a 15 percent operating cost of $150,000 a year, the total annual investment in comprehensive food safety and defense protections would be $250,000 or about 0.25 percent of annual revenue, which would seem a reasonable investment in protecting annual profits and brand equity, which in quantified terms, would be the sum to-date of all investments in promotion and distribution during the life of the product.

Notably, this investment calculation only takes into consideration the cost avoidance of a recall and does not include other quantifiable benefits from a TIA/MES combination such as greater operating precision, production line flexibility and product throughput, while realizing labor savings through automation.

Conclusion

Many food and beverage producers have already embarked on the path to TIA and MES in their production facilities, taking steps to integrate these systems into their quality and process architectures. They also realize that actionable information can be used to both build and protect brand value. However, many "homegrown" legacy systems may still be in place, either manual, paper-based systems, proprietary, closed-ended electronic systems or some combination of the two.

With stricter federal and state food safety legislation almost certain, it's understandable if not ironic that this certainty has produced extreme uncertainty in what kinds of investments will be needed when. The resulting "wait-and-see" approach could be inaction. However, inaction can have hazards all its own, especially complacency.

While food and beverage producers are watching legislative developments very closely, they should also take the time before any legislation becomes law to fully evaluate their current food safety and defense infrastructure and programs. They should do this not only in light of new regulatory implications but also in the context of how TIA and MES can help them improve their overall business efficiency and performance, while reducing their recall risk profile and protect the value of their brand.

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- **SIMATIC PCS7** provides food and beverage producers with **Totally Integrated Automation (TIA)**. It enables full integration of all plant automation systems including process, batch, discrete and safety and all field devices. More than 6,000 installations worldwide make it a proven TIA platform.

  It also integrates instrumentation, analytics, motors, drives and safety devices, with tools for engineering, visualization and facility-wide asset and maintenance management. It can provide for automatic scheduling, coordinating and controlling food and beverage product flows as well as cleaning-in-place (CIP) operations across an entire plant, small or large.

  SIMATIC PCS7 is more than just a process line controller (PLC) and human machine interface (HMI). It offers a comprehensive library of pre-built and pre-configured generic and food and beverage-specific functions in discrete software modules based on best-practices from around the world, across automated industries and from within the food and beverage industries.

- **SIMATIC IT Manufacturing Execution System (MES)** connects existing automation "islands" across a plant as well as enables manual processes to be automated and incorporated into a plant-wide MES. Like the SIMATIC PCS7, this MES offers a library of pre-built and pre-configured generic and industry-specific functions. Based on a modular, object-oriented, open and scalable architecture, the SIMATIC IT MES offers both horizontal integration and vertical integration of plant floor control layers into higher-level systems such as the plant's ERP system. It uses the ISA-95 standard as its architectural blueprint.

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- **Contact:** Walter Staehle
  VP Food & Beverage
  Director VMM
  +1 (215) 646 7400 x2522
  walter.staehle@siemens.com

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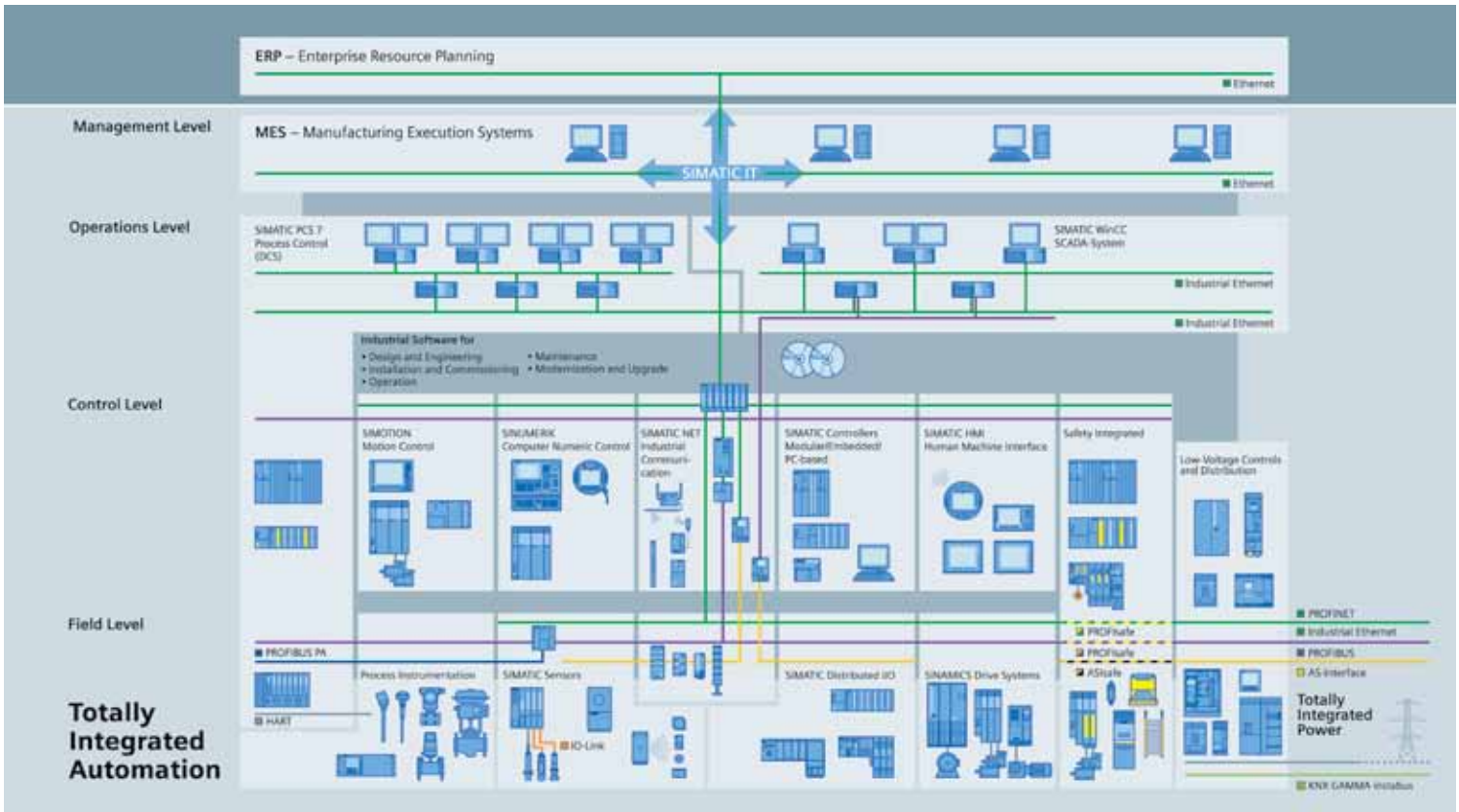

Siemens Industry, Inc.
Industry Automation
3333 Old Milton Parkway
Alpharetta, GA 30005

1-800-241-4453
info.us@siemens.com

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