Approaching Compliance from an Operational Point of View
The cost of adjusting current food safety, sanitation, and food defense programs to meet new requirements in the Food Safety Modernization Act (FSMA) will cost hundreds of millions of dollars. Once in compliance, the key challenge for food manufacturers is to maintain that status as efficiently as possible. Let’s explore how to approach food safety, sanitation, and quality compliance from an operational/financial point of view in order to achieve and maintain legal compliance and minimize the cost of doing so.

Compliance to official requirements is determined through inspections and audits to ascertain whether the right sanitary and food safety conditions are present (inspection) and whether the records reflect the true manufacturing conditions under which the product is being manufactured (audit). Any non-compliance issue needs to be addressed and corrected to protect the product to avoid future recurrence.

Specific operational inspections take place numerous times on a daily basis. Less frequent inspections, for instance on a weekly or monthly basis, look more broadly into the compliance status of operational and preventive support programs to assure compliance with regulatory requirements and industry best practices.

Audits are generally done on an annual basis to review records and evaluate the robustness and degree of compliance of the food sanitation (GMPs), safety (HACCP/HARPC), and quality programs.

A “YES OR NO” APPROACH
The legal compliance approach to sanitation and food safety is a “yes or no” situation. A given observation, activity, or result can only be in compliance, or not. There is no halfway or 80% compliance. Another way of looking at this is determining whether a given activity or program is effective (i.e., achieves expected results). If so, it would be in compliance.

While absolutely necessary, this “yes or no” approach to compliance has a major drawback in that it doesn’t determine how much compliance efforts

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cost. By not looking into the financial effects, the legal-only approach to food sanitation, safety, and quality deprives itself of the capacity to measure the opportunity costs of not doing it right the first time. Every time a non-compliance issue is identified, a corresponding non-budgeted cost is associated with its correction. These additional costs can be small or large, depending on the non-compliance issue.

Looked at from an investment point of view, the first time any planned activity of an operational or non-operational support program is carried out, it is considered a needed investment. However, every time a given task has to be redone because it was not carried out correctly the first time, it leads to additional unplanned costs, which increase the costs of goods sold and erodes the gross margin. At the end of the day, the activity or program achieves compliance, because it has to; however, it is at a higher cost of doing business.

**EVALUATION AND MEASUREMENT**

This combined approach to evaluate and measure the cost of achieving compliance of food sanitation, safety and quality, is visually presented in Figure 1 (above).

**E1** = Effectiveness
- to be or not to be in regulatory compliance. If 1, then the result is in compliance; if 0, the result is not in compliance.

**E2** = Efficiency
- the unplanned costs of not doing it right the first time. If 1, then it is being done right the first time; it can be less than 1, say 0.75, because it was not done right the first time and the task has to be repeated in order to achieve compliance.

It could be worse, the task needs to be done twice or more in order to get it right, or it may fail several times during the year and it has to be repeated, say 10 times at 10 separate occasions to get it right. The more “first time right” failures occur, the lower the efficiency with which compliance is achieved, and consequently the higher the total cost of compliance.

**E3** = Efficacy
- measures how optimally compliance is being achieved. By aggregating the number and costs of planned tasks being executed right the first time during a given period of time, with the number of tasks and costs having to be redone to get them right, a total number of activities and associated compliance costs are estimated, which includes the good part (compliance at first try) and the bad part (compliance at second or more repeats).

**FINANCIAL IMPACT**

As shown in the lower right portion of Figure 1 (above), the financial impact of not achieving compliance the first time a given activity is carried out is observed in the productivity index (PI) and the corresponding changes in Cost of Goods Sold (COGS) and Gross Margins (GM).

This is detailed as follows:
- As PI decreases (more re-dos), COGS increases and GM decreases.
- As PI increase (fewer re-dos), COGS decreases and GM increases.

**E3**, or the Total Compliance Cost function, can be expressed as follows:

\[ TCC = \sum [(I_{FTR}) + (I_{V}) + (C_{C} + C_{OP})] \]

\[ TCC = \text{Total Compliance Cost.} \]
INVESTMENTS IN TASKS AND ACTIVITIES

The $I_{FTR}$ and $I_V$ components of the Total Compliance Cost function are the good ones; they represent the investment in tasks and activities designed to bring about compliance. The $C_C$ and $C_{OP}$ components are the bad ones, that is those additional unbudgeted costs incurred due to failing to do it right the first time.

The more that re-dos occur, the more the initial investment in $I_{FTR}$ and $I_V$ is degraded.

A few practical examples will demonstrate the advantages of combining the legal approach to compliance with the operational/financial approach.

- **Basic preventive programs**
  - **Sanitation program**
    - How many scheduled cleaning tasks are being redone due to non-compliance or non-effectiveness of the first attempt during a given time period, say a month or last 12 months?
    - How many of these failures incur only the additional costs to achieve compliance ($C_C$)?
    - How many of these failures incur both the additional costs to achieve compliance as well as the opportunity costs of lost production time ($C_{OP}$)?
    - How many of these failures are detected after line startup? In such cases, product loss would be an additional opportunity cost incurred. The additional opportunity cost incurred is expressed through $C_{OP}$. Compliance to official requirements is determined through inspections and audits to ascertain if the right sanitary and food safety conditions are present (inspection) and if the records reflect the true manufacturing conditions under which the product is being manufactured (audit).
Plant Management

“When the legal approach to compliance is accompanied by an operational and financial assessment component, the food manufacturing and distribution facility will not only achieve and maintain compliance, it will do so more efficiently.”

as the productive time lost while a line, a piece of equipment, or some utensils are re-cleaned to compliance requirements.

• How many cleaning tasks are being successfully conducted the first time, but do not get done in the allotted amount of time? While successful, there could be huge opportunity costs associated with the extra time it takes to finish the cleaning tasks.

○ Sanitary design and maintenance program
  • How many scheduled maintenance tasks are being redone before the next scheduled maintenance service? How many of these incurred only the \( C_C \) and how many both the \( C_C \) and the \( C_{COP} \)? If maintenance cannot guarantee a specific period of time for a given piece of equipment to operate within expected operational limits, then the frequency of the preventive maintenance schedule needs to be addressed.
  • How many unscheduled repair activities take place during a given time period resulting in both the additional \( C_C \) and the \( C_{COP} \) costs? How many incur product loss as well? While the repair brings equipment back into compliance, the true cost of such unplanned activity can and does carry a huge opportunity cost.

• Operational programs
  ○ Receiving
    • How many kinds and types of incoming raw materials have been rejected during the past 12 months? The receiving program worked as designed. It was effective in preventing out-of-spec materials from entering the facility, however it implies that either the supplier or transport service failed.

• What is the cost of resolving such failures and reordering?
• Was production affected? If so, what does this opportunity cost amount to?

○ Allergen control
  • How many allergen-related issues are discovered on incoming labels and packaging materials? When are these issues identified? At receiving, during storage, at packaging, during storage and shipping of finished product, after shipping the finished product?
  • All these different failure identification scenarios have different \( C_C \) and \( C_{COP} \) cost levels, from the lowest at receiving to the highest when the failure is discovered after product has been shipped and a recall has to be undertaken.

○ Foreign matter control
  • How many non-conforming failures due to foreign matter issues in raw materials, in process, and finished product have been documented and corrected in the last 12 months?
  • Was the adulteration a sanitation, safety, or quality issue?
  • Where in the process was it identified and how was it corrected?
  • Each one will have different \( C_C \) and \( C_{COP} \) costs. A quality issue may be corrected internally, say by reprocessing the product, while a food safety issue may be resolved in the same way, by disposing of the product, or by a recall.

THE COMPLIANCE MANAGEMENT PROGRAM

The legal/operational compliance and financial information obtained from queries like those previously described—which are also applicable to all other preventive, operational, HACCP, HARPC, and quality programs—provide the necessary inputs to develop a highly successful compliance management program.

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By combining the legal approach to compliance with the financial impacts of first-time-failures, management is in a position to:

- Develop a “SMART” goal or objective for each operational and non-operational program.
- Develop sets of key performance indicators (KPIs) for each program and its main activities.
- Establish the TCC function for each program and main activities.
- Introduce a risk assessment component to evaluate the impact of sanitation, safety, and quality failures.
- Combine the TCC function and the risk assessment results to prioritize and manage a continuous improvement project cycle.
- Verify effectiveness of corrective actions and measure returns on investment.
- Provide a feedback loop to upper management.

**SUMMARY**

Compliance is often perceived as an imposition that must be obeyed in order to avoid legal issues and penalties. This perception can lead to a lack of understanding of the true intent and scope of regulations (albeit good ones) and therefore to a reluctance to fully develop and implement effective “first-time-right” programs and activities to proactively prevent re-dos associated with food sanitation, safety, and quality issues.

When the legal approach to compliance is accompanied by an operational and financial assessment component, guiding management in terms of risk-based economic return resource allocation, the food manufacturing and distribution facility will not only achieve and maintain compliance, it will do so more efficiently.

Such facilities do exist in the industry—and these facilities are always among the most productive and competitive installations.

Changing the attitude from “I have to do it, it is the law” to wanting to do it right the first time will not be easy, but estimating and sharing the costs and the competitive disadvantage of not wanting to do it right the first time can work as a great stimulator for behavioral change. **AIB**

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