Quality Assurance: National and International

THOMAS W. HOLZINGER

Corporate Quality Assurance and Compliance, Dairy & International (Food), Borden, Inc., 990 Kingsmill Parkway, Columbus, Ohio 43229

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Abstract

In this age of instant communication, product quality complaints or adverse publicity originating from any point on the globe can have potentially world-wide repercussions and devastating effects on any firm operating on an international basis. For this reason, effective Quality Assurance must ensure that all products made by a firm throughout the world are safe, wholesome and in compliance with company quality standards and all applicable regulatory requirements. Borden, which operates food and dairy plants in more than 22 countries and markets its products in over 100 countries, is committed to establish in all non-U.S. food and dairy plants the same standards of product safety and quality required of domestic plants. To achieve adherence to this company policy on a world-wide basis, Corporate Quality Assurance put into effect a comprehensive program entailing a formula approval procedure, quality and process control procedures, a process deviation reporting and evaluating system, plant sanitation inspections, product compliance audits and an effective communication system.

Need for Quality Assurance

The need for strong quality assurance involvement is far greater today than ever before. There are more governmental regulations affecting our products and plants. Some countries which never had specific food regulations before, have been concerned about becoming the dumping place of products rejected elsewhere, suddenly promulgating stringent regulations, the implications of which often have not been thought out. The enforcement of existing regulations is often far stricter today than before. Consumers are more active and the media coverage of an issue can be very damaging to a company.

In this age of instant communications, a product quality complaint or adverse publicity originating from any point on the globe can have potentially worldwide repercussions and devastating effects on any firm operating on an international basis. You may recall how promotion of an infant formula in Africa resulted in the organization of a worldwide boycott of this firm's products. The incidence of product liability suits and the size of the settlements, have been steadily increasing. Such suits can put a company out of business.

Quality Assurance Program

To assure that our customers receive products of consistent quality, and to minimize the risk of regulatory action, adverse publicity or the resulting financial losses, the Quality Assurance Department has set up a number of programs and procedures I would like to outline briefly. Let me start with the organization and reporting relationship of Quality Assurance at Borden. Borden has four operating divisions - Dairy & Services, Foods, Chemical, and International. Quality Assurance is working with all these Divisions but does not report to Division Management. Quality Assurance reports to the Corporate Vice President for Product Safety and Quality, who in turn reports to the Office of the Chairman. Scattered in various parts of the world are five Area Managers who perform the quality functions in the countries assigned to them. There are two individuals in Europe, one in Denmark to cover the Northern operations, one in Spain for the Southern region, one Area Manager covers Latin and South America, one is located in South Africa, and one in Australia for the Far
East. The Canadian operations are covered from our home base in Columbus, Ohio.

Quality Assurance in Columbus must review and approve a product, its formula and specifications before it can go into production anywhere in the world. The documentation needed to obtain such approval includes the following: ingredient specifications, manufacturing procedures, packaging specifications, finished product specifications, shelf-life studies, quality control programs including sampling and testing frequency, and label claim verifications. This material need not come to us in English. We do not burden the operations with having to translate any of this material. We at Quality Assurance have the capabilities to understand the various languages of the countries in which Borden operates plants. If we find that we cannot approve a specific request, we try to assist the operation which submitted the request to overcome or correct the condition so that approval can be granted. Label approval is given by Quality Assurance only for products to be sold in the U.S. With the multitude of different language and regulatory requirements encountered outside the U.S., we rely on the Area Managers to secure regulatory approvals for the labels of products to be marketed in their territories. However, we do review these labels. This tight control over product formulations is not intended to discourage the implementation of changes. It is needed to carry out the mandate assigned to Quality Assurance. We are receptive to changes, provided of course their implementation will not create any quality, safety or regulatory problems. The review and approval procedure is quite speedy. This procedure is intended to make sure that all concerned, including marketing and profit center management, are aware of and concur with these changes. It is to prevent any location from making any formula or process changes on their own without evaluation of the possible implications on consumer acceptance, legality, shelflife, etc.

Formulas are not necessarily the same for a product from country to country. This is most often due to different regulatory requirements and product standards, as well as local preferences that cannot be ignored.

INSPECTING AND RATING PLANTS

In the dairy and food industries, clean facilities and adherence to Good Manufacturing Practices are the major pre-requisite for assuring the wholesomeness of the products. With this in mind, Quality Assurance has established a program of inspecting and rating all its plants at least twice a year. The compliance requirements are spelled out in a manual provided and explained to all operations. It follows closely F.D.A.'s Good Manufacturing Practices but is somewhat more detailed and explicit. It also includes some portions of the Pasteurized Milk Ordinance (PMO), pertaining to process controls. We expect adherence to the same sanitary standards on a worldwide basis, regardless of location.

We have on our staff five individuals whose function it is to perform these unannounced plant inspections and ratings in the same manner as an F.D.A. inspector would perform an inspection. The key difference is, that our staff members have access to laboratory data and production records not readily available to F.D.A. Also our representatives, whose title is that of "Compliance Counselor", will assist the operations in solving problems pertaining to their area of expertise and concern. The Plant Manager is encouraged to accompany the Compliance Counselor during the audit. All violations are recorded as observed. The Plant Manager or his representative is given an opportunity to challenge findings at the time of the inspection and at a conference held after the completion of the inspection at which time all findings are discussed with all concerned. The plant is given 10 days to reply as to what action has been taken, or is contemplated for each item listed. Some of the Plant Manager's incentive program is partly based upon the Quality Assurance plant rating score. This plant inspection program has been in use for many years and found to be very effective. The numerical score enables us to measure progress, and convey a simple meaningful report to top management. All suppliers of critical ingredients such as milk powder or egg noodles must get inspected by Quality Assurance and approved before their products can be used. Likewise all co-packers of Borden or affiliated products are inspected to make sure they comply with the same sanitary practices and Good Manufacturing Practices expected of our own plants. No co-packers can be used unless approved by Quality Assurance. All public warehouses used by Borden are also inspected by these Compliance Counselors. They are not given numerical ratings. Either a satisfactory status, conditional approval, or unsatisfactory status is assigned to them.

Finished products are audited for compliance to specifications in two ways. One is to purchase products at store level and have them sent in to our Central Laboratory for analysis and evaluation. The other means of assuring compliance to specifications is through an audit of the plant laboratory records and procedures. Plant laboratories are requested periodically to split samples with the Central Quality Assurance Laboratories to ensure the reliability of the results. Plant laboratory personnel are often given training either on location by Columbus-based personnel, or an individual comes to our Central Laboratory for indoctrination.

Sampling and testing programs are custom-tailored for each operation, and reviewed periodically to make sure all key tests are performed, that proper action is taken based upon the laboratory findings and that no time is wasted on meaningless analyses or tests. The lack of worldwide acceptance of the same testing methods often causes problems. While Borden uses the same methods throughout its laboratories, different methods have to be used occasionally to conform to local requirements or to challenge suppliers.

LABORATORY TESTS

The Central Laboratories in Columbus will do tests for
the plants that require sophisticated equipment not available at the plant level. Examples of such are pesticide analyses, tests for toxins, or heavy metals, to name but a few. The Central Laboratories also do Salmonella tests for many plants since we do not allow any food plant to do such tests on location. If a live pathogenic organism were to present in a sample tested, the required enrichment and incubation steps could yield high counts of such organisms, and through a laboratory accident could expose the plant and its products to potential contamination. We will not let any processing plant take such a risk. Effective communications with our operations and Area Managers are vital to any effective Quality Assurance program. Whenever a major process deviation takes place in any of our plants, the nature of the deviation is communicated to us either by phone or telex. The product is placed on hold until the deviation and its potential effect are evaluated and disposition instructions are issued by Quality Assurance. With operations in so many different time zones, the telex is a most valuable tool. This is particularly so in dealing with Australia and the Far East since their working hours do not overlap with ours.

**COMMUNICATION**

Another aspect of our communication system is what we call “Operation Alert.” Operation Alert is a corporate wide emergency warning system for the immediate reporting of emergency situations involving any Borden product or operation. By a single telephone call to a certain number any hour of the day or night, any Borden employee can report an emergency and set in motion an alert to all the corporate and divisional departments potentially affected. There are 17 types of emergencies which must be reported through Operation Alert. The reporting procedure and these 17 categories are spelled out on a card which fits into almost any wallet, and is distributed to all operations.

The situations which must be reported are as follows:
1. Reports of acute or serious illness, alleged or substantiated, due to the consumption or use of any Borden product, whether sold by the Company or distributed under private label.
2. Any alleged or substantiated customer complaint in the area of health, injury, accident, death or any potential hazard attributed to a Borden product, its container or packaging components.
3. Reports of alleged or substantiated illness involving humans or animals, attributable to Borden plant emissions.
4. Inspections by FDA, USDA, DOD, state, county, municipal counterparts in which a Form 483 or similar list of observations made by inspector is issued.
5. Environmental incidents, such as major spills or air emissions.
6. Reports of alleged or substantiated illness of Borden employees attributable to in-plant environment.
7. Death, injury or illness alleged or substantiated of non-employee on company premises.
8. Any major injury or any serious illness of employee.
9. Alleged or substantiated contagious illness of an employee which may be transmitted through food or dairy products or may pose a serious threat to the health of fellow employees.
10. Transportation accidents involving Borden personnel or Borden products which result in admission to hospital, death or any major property damage estimated in excess of $2,000.
11. Transportation incidents resulting in exposure of Borden employees or non-employees to Borden chemical products.
12. Property damage or business interruption due to explosions, fires, or similar causes involving Borden products, their processing and warehouse facilities. (In cases of damage due to these causes, only occurrences in excess of $10,000 need to be reported).
13. Strikes (whether authorized or not), work stoppages, boycotts or the threat of such action.
14. Violence or threat of violence, including serious crimes, such as murder, arson, rape, aggravated assault, armed robbery and any sizable loss resulting from burglary, theft or fraud. Also any bomb threats or explosions at or near Company property.
15. Any seizure, embargo, restrictive orders or threats thereof, affecting products manufactured, distributed or sold by Borden.
16. Visits by personnel of Consumer Product Safety Commission (CPSC), OSHA, EPA, DOT or similar state or municipal regulatory agencies.

This system has been in effect for 6 years, and has been found to be of benefit not only to Quality Assurance but also to other Corporate Staff Departments such as Law, Public Affairs, Insurance and Personnel.

**IN CONCLUSION**

Any quality assurance program, be it local, national, or world-wide to succeed requires a clear commitment to the cause by top management. Such a commitment must be sincere and must provide tangible evidence to all levels of management. Getting top management commitment for effective quality assurance should not be a difficult task. Strictly in terms of dollars, quality assurance can and must reduce the cost of quality failures which are quite often very significant. Nothing will sell a program to top management as rapidly as a projected increase in profits. This too applies on a national basis as well as on an international basis regardless of whether savings are in dollars, marks, pounds, francs or pesos. All our efforts in Quality Assurance are in vain unless top management can be sold on the merits of the programs and makes its endorsement known to all concerned.