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Quality Assurance and Control of Food Products Containing Soya Protein Ingredients

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In organizing this session, my cochairman and I sought a paper to review the prudent steps a conscientious U.S. processor would take to ensure that food products containing soya proteins comply with existing regulations, and reach the home in the desired quality.

Several food companies and consulting laboratories declined to provide speakers on this topic. This was surprising, especially in view of the many articles, symposia and short courses held in recent years on quality assurance and food safety. This reluctance to speak on what is everyday practice in the food industry is probably indicative of: (a) finding, through experience, that some of the quality assurance programs proposed recently were too grandiose and expensive to sustain; and (b) a "gray" area, on the part of industry, in interpreting existing laws and awaiting the vegetable protein regulations that have been under consideration for several years.

Nevertheless, people from many nations and entrepreneurs anticipating entry into the food products business in the U.S. and elsewhere would like to hear the technical aspects for ensuring product quality. This paper is offered as a summary of the major principles that might be considered in establishing corporate quality assurance policies, and quality control programs for food products. The specific legal requirements, of course, vary with respective domestic laws.

In this presentation, "quality assurance" is defined as the program of establishing corporate policies and procedures to ensure compliance with existing regulations, and ascertaining that the day-to-day quality control program is functioning as intended. "Quality control" is the means for ensuring that the product is being made as intended (in composition and process), and that it reaches the consumer's household in the condition desired.

What are the major considerations in Quality Assurance and Control? In both programs, it is important to: (a) know and understand the applicable existing regulations; (b) use objective (numerical) standards and appropriate procedures in quantitating product characteristics and processes; (c) have personnel knowledgeable in making compositional and other determinations, and in interpreting their relation to product standards, quality and compliance; (d) have adequate commmunications within corporations (not only between the quality assurance and control personnel who

often report to different supervisors, but also between corporate management, marketing, production, purchasing and distribution personnel); and (e) have adequate communication between the individual firm, its trade association and the respective regulators.

Where does one get information about existing regulations and their interpretation?

The basic source is the Code of Federal Regulations (CFR) Title 21: Food and Drugs, and Title 9: Animals and Animal Products, for foods that come under jurisdication of the USDA. New sets of CFR volumes are printed yearly. However, new regulations become applicable as they are published in the *Federal Register.* An alert trade association will call its issue immediately to the attention of its members, but it may also be worthwhile to subscribe directly to the *Federal Register,* or to one of the several private updating and interpretation services available. All formal FDA regulations are contained in CFR Title 21. Some major interpretations of USDA regulations are only in inspector's handbooks, although efforts are in progress to include them in CFR: Title 9.

Several parts of CFR Title 21 may be applicable to a new food ingredient or product. Topics may include definitions of specific protein and other food ingredients; definitions of foods that may contain vegetable protein ingredients (Title 9 for meat products); listing of generally recognized as safe (GRAS) ingredients that may be used without limitation; listings of food additives with specific applications and levels permitted; determination and format of nutritional labeling; definitions of foods for specific purposes (such as infant and dietetic foods); acceptable methods of product analysis (usually Association of Official Analytical Chemists or AOCS methods); food packaging materials permitted to come in contact with foods and procedures for determining migration of packaging components into food products; listing of permitted sanitizing agents, insecticides, fumigants and food machinery greases; procedures for operating retorts and evaluating can seamer performance, and certification of operators; and good manufacturing practices (GMPs) for ensuring noncontamination and safety of foods and maintaining required quality control records. Regarding GMPs, it should be noted that the current trend is not to specify GMPs for individual products, but to establish general, industry-wide GMPs for processing and handling foods.

Today's food processor also has to be concerned with many other regulations besides CFR Titles 9 and 21, including those of agricultural products marketing, the Federal Trade Commission, the Environmental Protection Agency, the Occupational Safety and Hazards Act, and respective state and local restrictions.

Large food processors typically have a corporate staff of "regulation watchers" who are knowledgeable about pertinent requirements and restrictions. Small firms may need to obtain information from suppliers, supplier trade associations (e.g., the Food Protein Council, Washington, D.C., for vegetable protein products), an industry trade association (such as the Grocery Manufacturer's Association [GMA] in Washington D.C.), or the specific association for their respective product line (breads, cookies and crackers, confections, snack foods, processed meats, etc.) Also, small processors may choose to use services of consulting laboratories and private consultants, and add to their internal technical staff as their business grows.

Many food manufacturers wrestle with the question of when to approach the FDA or USDA for direct interpretations. In recent years, the federal government has come under considerable criticism for excessive bureaucratic burdens on small businessmen. These criticisms have been acknowledged, and most federal agencies are particularly responsive to the inquiries of small businessmen. Food processor with resident USDA inspecors are well aware that new product labels must be approved before they can be used, and that layouts of new facilities must be approved before construction or remodeling can begin. The FDA does not require label or process review before new products are marketed. However, the food processor just entering the business must remember that the FDA has taken the basic position that all new food materials (even genetically improved varieties of currently consumed plants, ingredients extracted by new processes, or conventional types of foods preserved by new techniques) come under the food additives law and are subject to review for safety. Every processor hopes that sales of his new product will grow boundlessly. Even though the FDA may not immediately notice or act on a new ingredient or food, chances are that it will become aware of it in time, or have it brought to their attention by other industry members. Thus, a manufacturer should be reasonably certain that he could convincingly substantiate his position that his new product complies with existing regulations before investing heavily in equipment, market development and filling the distribution pipeline.

In the process of developing regulations, all interested parties are invited to comment on proposed regulations before they are finalized. Whereas the merits of presenting evidence against a proposed regulation that would adversely affect a processor are obvious, good reasons exist for presenting comments supporting desired proposed regulations. FDA personnel have said on several occasions that they can only consider whatever information is available at the time of development, and that revision of regulations is difficult after they have been issued.

There are many major considerations to keep in mind when establishing a corporate quality assurance program for a new food product or ingredient. These are discussed below. For instance, what will the new vegetable protein ingredient be called? The user needs to satisfy himself that the new ingredient actually qualifies under an existing definition. This determination is often entrusted to the ingredient supplier. But what if you are dealing with a new and possibly inexperienced supplier? Or what if the food processor buys commodities and he himself converts them into ingredients or intermediate products?

Another consideration is how much of the food protein ingredient can be used in the product? The first point to consider is whether the ingredient is GRAS (which most soya protein ingredients are), or whether it can be used only up to maximum levels for specific purposes permitted by food additives regulations. Specific quantities are permitted in processed meats and canned meat products by USDA. Other considerations include the amounts required to achieve desired functional properties and (depending on protein quantity and quality) to support specific nutritional claims.

What can the product be called? Specific USDA and FDA regulations may apply when the protein ingredient is added to a conventional food. When larger amounts are used, such as in the preparation of animal product analogs (like imitation meats and milk), regulations may require that the product be nutritionally equivalent to the one it will substitute. This area of labeling should be watched closely as the new vegetable protein and imitation and extended dairy product regulations now under consideration, are released.

Labeling must also be considered. Depending upon the product and container size, the relative sizes of print for the brand name, product name and nutritional labeling may

be specified. Labels are typically required to show the appropriate product name, name and address of the producer or distributor, weight of contents, and listing of ingredients in order of diminishing preponderance. Nutritional labeling requires specific formats for presenting the size of serving, the number of servings per container, the amounts of calories, and grams of protein, carbohydrates and fat per serving; specific formats are also required for claiming percentages of U.S. Recommended Daily Allowances (RDAs) of protein and specific vitamins and minerals provided per serving. (Interestingly, claims for RDAs can be made only in specific increments [2 or 5%] depending upon the relative extent of dietary needs furnished.) If additional voluntary claims are made for degree of fat saturation or cholesterol levels, other specific formats come into effect. Special labeling regulations exist for foods intended for specific segments of the population, including infant foods and dietary foods. Also, the label must be approved and contain the USDA inspection seal if made under their inspection program. Specific labeling and tagging requirements also exist for bulk ingredients and foods shipped in large sacks, boxes and drums, and in large volumes such as palletized containers, hopper cars and tanks.

Still another point to consider is other types of claims. Any information offered by a producer about the product is a claim and a form of extended labeling. For example, most food companies make additional information about a product's nutritional properties and uses available to professional dieticians and the general public in response to letter requests. The literal meaning of claims made in advertising should be documentable. Some magazines, newspapers, radio and television media have occasionally requested evidence before accepting advertisements that the food processor stands ready to document claims if challenged.

In their eagerness to expand product sales, advertising staffs have occasionally become overzealous in making claims which could not be substantiated technically. It is most important that a company's management ensure adequate communications between its product promotion and technical staffs to avoid embarrassment if advertising claims are challenged.

The quality assurance program is obliged to document the original basis for new product claims, and to ensure that quality control records are kept of day-to-day compliance with established claims.

Food processors must also consider manufacturing processes. Formal GMPs have been established to ensure that wholesome products reach the public. However, a food processor usually needs to establish other process standards that define the desired characteristics of the product, such as appearance, color, shape, texture, flavor, odor, permissible breakage, particle size, functionality, and so on. These characteristics are not related to product safety, but their uniformity is required to connote high and consistent quality in the marketplace. The quality control program should be designed to ensure compliance with internal corporate standards as well as legal regulations.

The quality assurance function also establishes specifications and acceptance-rejection criteria for ingredients, packaging materials, processes, intermediate and final products, and ingredient and product storage conditions (including moisture, temperature, and warehouse and store shelf-life of product). Audit procedures should be established and followed to ensure that products are made and handled according to corporate standards as well.

Establishing purchase specifications is still another important consideration. Crops are usually purchased on the basis of USDA grades, commodities on the basis of industry trading standards, and ingredients and packaging materials on the basis of purchase specifications developed by the supplier and/or buyer. Writing a meaningful purchase specification without unnecessary criteria is a talent in itself. A typical ingredient purchase specification developed by a buyer often contains the name of the product; a description of its manufacture; composition requirements and granulation, when appropriate; a listing of maximum tolerances of undesirable components (e.g., heavy metals or other toxic substances, as given by a recognized reference such as Food Chemicals Codex); a statement of functional properties or criteria if defineable; specifications for protective packaging if required; and an umbrella statement that the ingredient is not to be mislabeled or adulterated as interpreted by FDA requirements (to ensure against pesticides, herbicides and other unanticipated incidental contaminants).

Food technologists often get to see only several lots of proposed ingredients when developing new products and processes, and recommending initial purchase specifications. They may encounter a broader variability in ingredients than they expected when the product goes into production. This is especially likely to occur if the ingredient supplier also shifts production from pilot plant or batch scale to continuous processing lines to meet his increased sales. It may then be found that the purchase specification did not adequately describe the most desired properties of the ingredient (especially in functionality or flavor characteristics) and additional specifications are necessary. To avoid the problems of inadequately defined purchase specifications, companies often require that the performance of samples from new suppliers or processes be checked in the product at the research laboratory, to ensure that unexpected usage difficulties not occur.

There are also many major considerations to remember when organizing and supervising a corporate quality control program. One such consideration is analytical procedures. It is desirable to require numerically quantifiable assays procedures to avoid variations between individuals in subjective judgements. Where objective (numerical) standards are not possible, go-no-go samples or product models (depicting the upper and lower acceptable levels of color, shape and other attributes) are desirable.

Most official analytical methods are complex and too slow for adjustment of the process, and are used mainly for after-the-fact documentation of performance. The food processing industry is currently undergoing a revolution in rapid analysis systems for near-line analysis, and nondestructive on-line monitors (some of which can be integrated into automatic process-adjusting feedback loops). These rapid analysis systems, are typically not as sensitive or as reliable as the official methods identified in regulations. When rapid analysis systems are used, the quality control programs must ensure that their results correlate well with the official methods, and that sensors do not malfunction without corrective action being taken.

Another consideration is ingredient checking. A small amount of undetected substandard ingredient could balloon into a large inventory of unsaleable merchandise. Although the processor can sometimes obtain reimbursement through legal action for quantifiable losses, other significant losses, such as not being able to fill product orders on time, may occur. Multiproduct plants, using ingredients that are similar in appearance, also run the risk of misdirecting bulk shipments into the wrong holding tanks. It behooves the processor to establish necessary dockside procedures to ensure the correct identity of ingredients and recognition of readily detectable substandard color, flavor, off-odor, or contamination problems at the receiving dock.

The processor must consider product analysis procedures. Numerous chemical and microbiological assays exist. Various

techniques such as statistical quality control charts can be used to record results and to alert the quality control manager when product or process may be beyond acceptable control limits. However, before the quality control supervisor becomes mesmerized with these various techniques, it is essential to ensure that the analytical methods chosen are appropriate to the product being analyzed, and that representative samples are being taken for analysis. Even the "official" AOAC methods have limitations in their applicability. For example, acid hydrolysis methods typically recover more fat than ether extract methods, and are better suited for fat-containing products that have undergone high heat treatment during processing; similarly, the type of catalyst used may affect results of the common Kjeldahl method when analyzing certain high-protein content ingredients. Obviously, the analyst only assays the specific sample brought to the laboratory, and must rely on a representative sample having been delivered.

It is important to identify the specific points in the process at which intermediate products should be checked. Principles of the Hazard Analysis Critical Control Point Program (HACCP), which has been developed to identify and monitor potential trouble spots that could affect the safety of products for consumers, are also applicable for identifying monitor points for other product characteristics.

Obviously, the food processor needs to conduct and keep records of assays that document compliance with label claims. However, many freshly compounded foods have characteristics quite different from the product after it has equilibrated during aging—this is even true for dry mixes where interactions of ingredients might not normally be expected to occur! Therefore, processors may have to devise unique tests for fresh products, which differ in functional performance from aged products, and to conduct storage tests.

The quality control function is also usually responsible for ensuring that ingredients and finished products are properly stored (i.e., so that temperature, humidity and duration are correct; and ingredients are protected from insect infestation, rodents and other contamination, etc.) while in the plant, or in the distribution network under the processor's control. This may include inspection of box cars and trailer trucks for insect infestation and potentially contaminating materials and odors.

It is essential that the food processor adequately code his product by reasonably short processing periods, and keep records of where specific batches of ingredients were used Coding is often necessary to ensure timely removal of typical products with limited shelf-lives from store shelves. However, in the event that accelerated storage tests show that specific ingredients or product lots are predisposed to faster aging than usual, the processor may need to take special action to hasten turnover of product in warehouses or withdrawal from store shelves.

Processors must also consider product recall. Unavoidably, quality assurance personnel live with the concern that some unknown problem may have occurred in ingredient contamination, product formulation, processing, or post-processing, which may require a recall. At times like this, the value of a well-kept set of records, documenting conscientious and consistent quality control practices in ingredient acceptance, processing and distribution, becomes evident.

Every ingredient and food processor should have a recall procedure with clearly designated responsibilities and authority in readiness. The FDA requires notification even if the company decides to voluntarily recall nonhazardous products for quality control reasons. If public health is threatened, the FDA may require that the recall be conducted according to prescribed procedures, depending upon the apparent degree of hazard. Regardless of the degree of hazard, it is necessary to ensure that all suspect products be withdrawn from the market. If records do not permit narrowing the suspect products to specific production lots or distribution areas, the only recourse may be to withdraw large quantities—possibly all of a company's stock in warehouses and store shelves! Regardless of where the ultimate fault may lie, a massive withdrawal can be financially devastating to the processor in recall and examination expenses, and in loss of sales.

With the exceptions of identifying proper names of products containing vegetable protein ingredients, and the nutritional requirements of imitation foods intended to substitute for foods widely used currently, quality assurance and control criteria are no more severe for foods containing soya protein than for other processed foods. The measures I have mentioned are followed daily by food processors—sometimes far more elaborately than I have described. In this presentation, I have tried to emphasize to prospective processors of soya protein foods the need to ensure that they have knowledgeable and competent quality assurance and control personnel who are following the practices required by law, and who have become prudent in the food processing industry.