Successfully Importing Food Into the United States: Keeping the U.S. Food and Drug Administration Off Your Back

MELVIN N. KRAMER
President
Environmental Health Associates, Ltd.
Baltimore, Maryland 21209

ABSTRACT

The Food, Drug and Cosmetic Act regulates food in all phases of interstate commerce within the United States, as well as food entering the United States. Although there are numerous provisions of the Act, the areas most frequently violated by foreign processors are the inclusion of non-approved additives, preservatives, or coloring agents, the presence of Salmonella or filth, decomposition of the product due to improper processing, packaging, and/or transportation conditions, and improper labeling of the product. We shall explore these areas briefly, both in terms of what is required and how to achieve compliance.

The Food, Drug, and Cosmetic Act ("the Act") was passed by Congress of the United States over 50 years ago. The Act as it relates to food, has undergone numerous changes as general technology and specifically the art and science of processing and laboratory analysis has progressed. In this process, it has become more difficult to import food into the United States. Under the United States Constitution, American citizens, and also American-produced products are presumed to be innocent before the law, until proven otherwise in a judicial proceeding. However, under the provisions of the Act, products imported into the United States can be presumed to be "guilty" and detained without reason, meaning that FDA presumes that they are filthy, decomposed, unwholesome, and adulterated until FDA, by their laboratory testing, proves them "compliant." This is a purposeful reversal in our national philosophy.

This translates to mean that an American shrimp processor is innocent until proven guilty of violating the Act, either in an Administrative proceeding (which can be appealed to a judicial hearing), or Judicial (judge and jury) proceeding. Evidence must be gathered by the government under certain rules, with some evidence not permitted to be entered into the record of the court if it was obtained in a manner not "legal." For the foreign shrimp processor, FDA can stop the shipment at the port, detain it, sample it, and take up to forty-five days to analyze it in order to decide whether or not to allow the shipment entry into the United States. There is no presumption of "innocence," only "guilt," to be proven after the detention, not before, as it would have been for an American product. These are the basic rules by which every foreign processor must

play if they wish to import food into the United States. The challenge therefore for the foreign importer, is to be compliant and not develop a record with FDA that will eventually warrant them to check every lot of food entering the country. Whenever you are detained at the port by FDA, it costs you valuable time, money, and business opportunity. Let us discuss what FDA is looking for, and how you can, at the boat and plant levels, insure that you are complying with the Food, Drug and Cosmetic Act.

FDA's mission is to protect the health of the citizens of the United States within the scope of the jurisdiction of the Federal Government as defined by the United States Constitution. They are responsible for all food involved in interstate commerce. In keeping with this mission, one of the primary problems FDA looks for is the presence of the bacteria Salmonella in food. Salmonella are bacteria found in the intestinal tract of man and some animals. The bacteria cause a variety of disease states from severe typhoid fever, to a moderate infection lasting less than a week, to a mild upset stomach with vomiting and diarrhea. There are over 1,800 different types of Salmonella organisms, and the severity of illness is dependent on the type, and the individual's previous health prior to becoming infected with the organism. In a healthy individual, it usually takes up to 100,000 organisms per gram of food to cause illness.

It is interesting to note that Salmonella is totally destroyed by proper heat treatment of the product. However, FDA's attitude towards Salmonella does not change whether the food is raw, or ready to eat. There is no tolerance for Salmonella in food as far as FDA is concerned. It should be pointed out that the U.S. domestic poultry supply at the consumer level (supermarket) contains upwards of 40%+ Salmonella positive birds. Why is this tolerated? Simply, FDA does not have jurisdiction; the United States Department of Agriculture (USDA) does. FDA has almost exclusively banned frogs legs from being imported into the United States, the majority of which were being imported from India. Furthermore, eight (8) countries in the Near and Far East are on a "black" list related to importation of shrimp into the United States, mostly because of Salmonella. It is interesting to note that in the United States, over 99% of all shrimp are cooked prior to consumption, therefore killing the Salmonella. According to the U.S. Center for Disease Control, there has never been an outbreak of Salmonella reported or traced to the consumption of shrimp. Less than 1% of all shrimp are consumed raw, mostly at shusi bars. I find it incredible that FDA is not concerned about other parasites, including tapeworms from fish that can infest individuals eating raw seafood.

How do you insure that you are not going to have a Salmonella problem with your products? Marine biologists report that Salmonella is not part of the marine environment in areas where commercial fish and shellfish are caught, nor indigenous to fish or seafood in the wild. It is my opinion that the contamination can be from the flushing of toilets (heads) onboard

the boats during fishing. Picture the following scenario: a given percentage of people carry and excrete Salmonella in their stools (feces), even if they are not sick themselves. This is called a carrier state. It seems that in poor areas there are more carriers and more people that have chronic or intermittent Salmonella infections or diarrhea. If they are shedding the organisms and go to the toilet at the time the nets are being collected, some of the fecal material will be either on the nets or on/in the catch. Then the hold of the boat becomes contaminated. From there, the processing plant can become contaminated and Salmonella can be incorporated into your final product. Also, the individuals on the processing line can also be infected and contaminate the product. For this reason, frequent handwashing is recommended, always after going to the toilet. In my opinion, anyone who has vomited, had diarrhea, or a fever (38°C), must not handle food for twenty-four (24) hours AFTER symptoms have disappeared. They may be assigned to totally non-food areas, but for the sake of prevention of spread of these diseases, they should be excluded from the plant. Remember, a primary source of Salmonella and other organisms of concern is the human intestinal tract!

Another area of concern for the entry of Salmonella into a plant is via the water and ice used in processing the glazing. It is very important that ice be received, stored and utilized in a sanitary manner, not handled or contaminated with waste. All water and ice used in an operation should be from an approved source, complete with a chlorine residual of not less than 0.2 ppm of free residual or available chlorine. Without this level of chlorine, you may well be including Salmonella and other organisms into your product. If your plant has a laboratory, or if one is available to you in your area, it is adviseable to routinely have it analyzed for the presence of coliform organisms. These organisms are indicators of fecal contamination, and their presence indicates other harmful organisms, including Salmonella, may be present in your water system or ice.

Assuming that the organism does gain entry into the plant occasionally, it is important to eliminate it on a daily basis by sanitizing all processing equipment. There are specific methods, materials and frequency of germ-killing sanitization of food contact surfaces and equipment. This must be done consistently and on a routine basis which should be determined by production schedule and volume, accomplishing adequate clean-in-place washing, rinsing and sanitization of these food contact surfaces and equipment. Appropriate washing and sanitizing should be scheduled in concert with breaks in production for "time-off" breaks as well as meals. It is my opinion and recommendation that high pressure hoses connected to detergent sanitizers best and most easily accomplish this task. Water under high pressure is utilized in most food, meat, and poultry plants in the United States. With this system, which is available from several sources in the United States, the detergent-sanitizer is automatically mixed and dispensed in the correct concentrations through the system. Furthermore, the system can

flush it with plain potable water, therefore, the entire operation for clean-in-place washing and sanitizing can be accomplished with this one piece of equipment. This procedure should be accomplished at least twice a day. The first time should be performed during the mealtime break when production totally ceases. This has the effect that when production begins in the afternoon, you are beginning with a sanitized (no harmful microorganisms) environment. This should be repeated at the end of the day prior to leaving the premises. The beauty of this system is that the handle has a wand which will enable hard-to-reach areas of the equipment and especially the conveyer belts to be thoroughly, and under high pressure, cleaned and sanitized. The choice of sanitizers is a quartenary ammonium compound. This seems to best eliminate the present of Salmonella. Iodine and chlorine, which are other sanitizing agents, do not kill Salmonella as quickly, nor in the low concentrations recommended for food contact surfaces and equipment, as the quartenary ammonium agents.

Food that is found to contain Salmonella by FDA will not be able to be sold as such. It can be exported or reconditioned. Reconditioning is expensive, and always the reconditioned product is less valuable than the original product. For example, shell-on, headless shrimp with Salmonella can be reconditioned to a variety of cooked or processed products. However, the cost of the money for the product, the cost of storage (during the detention), the cost of the custom house brokers and other decision makers in the process all adds up rapidly. Therefore, it pays to prevent problems, rather than to pay for them when they occur.

Filth, like Salmonella, is incorporated into products at the plant level. Filth renders a product "adulterated" according to the Act. The most frequent filth is from insects and rodents. Rodent fecal pellets, hairs (a rat has 500,000 hairs and mouse almost as many, which are replaced twice per year, thus hair is almost always being shed by the rodent), insect excreta and fragments, in addition to extraneous material such as staples, nails, wood, glass, paint chips, grass, part of other species (a lobster antenna in shrimp) and the like all become incorporated into food. Although, there are "tolerances," called "action" or "defect" levels, it is always best not to have any extraneous material in your products. For these reasons, rodent and insect control, including fly control, is vitally important in your plant. The determination of what is and is not acceptable is often very subjective, and involved with the size, or statistical significance of the sample. FDA will not and cannot analyze all products, so the sample that they take is a statistical sample which is "representative" of the entire lot.

Decomposition is a subject that I feel needs little discussion. Product that is decomposed is usually the victim of one of two problems: Firstly, it was not pure when it was in processing. It was either "slightly" spoiled and decomposed when it was received at the plant, or not processed quickly enough. The second type is more difficult to control from the

processors perspective. Product that is "wholesome" when it leaves the plant, can spoil or otherwise decompose in transit. Temperature problems during storage and tranportation to the dock can develop, whereby the product can spoil. Refrigerated cargo ships can temporarily lose refrigeration for hours or days, thus the product may be "frozen" upon arrival, yet is decomposed in the package. It is for these reasons that you should be very careful in planning storage and transportation of products.

There are literally hundreds of additives, preservatives and colors that are acceptable under the provision of a list called GRAS - Generally Regarded As Safe. There are numerous additional chemicals which are not approved. The status of GRAS listed chemicals change on a frequent basis with additional research or finding that substances are or may be harmful. Of primary import to the fish and shellfish industry at this time is the subject of sodium bisulfite. This substance has been used as a preservative since the age of Greece and Rome, mainly to prevent secondary fermentation of alcoholic beverages, especially wine. It has been on the GRAS list since it's inception. However, recently, within the last year there has been a claim that people who suffer from asthma can have attacks initiated by food products with sulfiting agents in or on them. It is now popular in the United States to have salad bars in restaurants. Often the salad items are rinsed with sulfites to preserve the color and texture. There have even been deaths reported as being caused by severe reactions to the sulfites.

FDA's position in relation to the quantity in terms of parts per million of sodium bisulfite which is permissible is now set at 40 ppm. There is no scientific documentation suggesting a threshold limit value for sodium bisulfite and any disease status in humans, or for that matter, any test animal justifying the limit they are enforcing. The internationally accepted CODEX value for sodium bisulfite is 100 parts per million. The obvious problems with reducing the quantities of sodium bisulfite to the 40 ppm level is the increased risk of black spotting-melanosis. Shrimp which contain black spotting are less valuable in the marketplace, as well as run the risk of being misunderstood for decomposing or unwholesome shrimp by regulatory health officials and/or by the ultimate consumers.

We are presently in the process of trying to have the sulfite issue resolved in our favor. It is our contention and recommendation that FDA allow at least 100 parts per million of sodium bisulfite and/or sodium metabisulfite in shrimp and shrimp products. This is based on two main factors. Firstly, we have submitted a significant amount of data on the question of sodium bisulfite. One processor checks all shrimp from every ship for the quantity of sodium bisulfite. Furthermore, their laboratory has compiled data correlating the percentage of black spotting in the shrimp as a function of the quantity of sodium bisulfite in parts per million. Their data indicates that when less than 40 parts per million of sodium bisulfite is present, the percentage of black spots per pound is increased

to an unacceptable level. In no instance did the levels of sodium bisulfite exceed 70 parts per million, yet we feel that 100 ppm should be the level of regulatory tolerance.

Numerous importers of shrimp into the United States also do business with other countries, specifically Japan. Sodium bisulfite, like additional glazing, aids in preserving their products to withstand the long sea journey, and to have the products arrive in top quality. It is, therefore, an extreme burden to expect a plant to have several different standards to meet, especially when there is no scientific data to support a link of sodium bisulfite in the quantities discussed to human health.

FDA seized a significant quantity of shrimp from Spain due to an excess of 250 ppm of sodium bisulfite. We are in receipt of a copy of a letter to Mr. Mariano Garcia-Munoz, Embassy of Spain, Washington, D.C. dated January 30, 1984, from Mr. John M. Taylor, Director, Division of Regulatory Guidance where he states, "We consider that levels ranging from 20-40 ppm, but not greater than 100 ppm would result from the use of a sulfite dip of a 1%-1.25% solution for a period of one minute followed by draining of the shrimp." Yet, FDA will seize any shipment with quantities greater than 40 ppm, as not complying with what is termed "Good Manufacturing Practice." The present issue is what is Good Manufacturing Practice? The issue is not that 40 ppm of a sulfiting agent is "safe," and 100 ppm is "unsafe." The standard is based on the "quantity of a substance added to food (may) not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food." The purpose of the regulation is to prevent "unnecessary levels of additives" in food. What FDA is telling the industry, is that the 40 ppm level is the threshold to reasonably prevent melanosis, under Good Manufacturing Practice. Remember that the word is GOOD, not OPTIMAL or PERFECT, but GOOD. We strongly feel that with the time lag between catching the shrimp, processing, and shipping to the ultimate consumer, there is a need for the added protection that increased levels of sulfiting agents can render. This is especially true in light of no scientific conclusions that there is a cause and effect relationship in terms of adverse reactions in a statistically significant number of individuals. People will always react to chemicals in food, water, milk, drugs, and the like. The question is how frequently can we expect these adverse reactions to occur? People who are allergic to chocolate will not eat chocolate products, or products that they know or are likely to contain cocoa. This is a personal responsibility, not that of the government. All people must take responsibility for their personnel health and well being, public health agencies are responsible for the health of populations. Therefore, if the overwhelming majority of individuals are non-reactive to a substance, it is not, in my opinion, the government's responsibility to regulate the substance so others cannot derive the benefits, if any. I, and millions of others, for example am physically bothered by cigarette smoke; yet the government does nothing to protect me,

the non-smoker, from inhaling other people's smoke, no less prohibit them from having tobacco products available for purchase.

This sulfite issue is of vital importance to the entire fish industry, as it could spell economic disaster if not properly addressed. We shall be meeting later on this week with those interested parties who are directly affected by the sulfite issue, particularly in shrimp and other products, to discuss a strategic proposal to reverse the position taken by FDA.

The last issue I would briefly like to discuss is that of labeling. There are a variety of regulations that must be followed, yet, there are basically only three (3) that most frequently are violated which cause the most problems. Firstly, all products must be labeled with the ingredients listed, unless there is a standard of identity for that product. Products, ingredients, and/or additives which are not either on the GRAS list, or are prohibited from importation into the United States may not enter the United States, and are subjected to seizure (beetle nuts, pufferfish, red dye #2, etc). Secondly, ingredients must be listed in a descending order in terms of volume/content. For example a product contains salt, water, sugar, coconut flavoring, if there is more water than sugar, and more salt than coconut flavoring, the label must read: water, sugar, salt, coconut flavoring. The last area of confusion is that of the label itself. It must be in English and the weight must be in pounds and ounces. You may have metric, but the pounds and ounces must be the predominant marking. There are also size requirements for the type and numerals used on packaging. Of course, any false or misleading statements are considered to be misbranded and will not gain entry into the United States.

I hope that you can apply some of the information I have presented in order to prevent any of your products from being seized by FDA for non-compliance with the provisions of the Food, Drug, and Cosmetic Act.