

Guidance for Selecting an Outside Laboratory

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Most food, beverage, and ingredient processors, even multi-national operations, will utilize an outside or third-party laboratory on occasion. There are some operations that utilize third-party laboratories for almost all quality, safety, and verification activities because they either do not have the resources to do such work in-house or they have decided they do not want to do so. Work that may be done by outside laboratories includes microbiology, chemistry, microanalysis, product and process development, and much more. Cereal grain processors and handlers may require special types of testing, so finding and developing a working relationship with a laboratory may present additional challenges.

One of the elements that make up the U.S. Food Safety Modernization Act (FSMA) of 2010 is supplier verification. In fact, one of the regulations enacted to ensure proper enforcement of the act is the Foreign Supplier Verification Program. In addition, the Preventive Controls Regulation (21 CFR, Part 117, Subpart G) specifically addresses supply chain programs (3). The expectation is that food, beverage, and ingredient processors should develop, document, implement, and maintain programs to identify, select, and maintain working relationships with food, ingredient, and packaging material suppliers. One of the primary elements of this program is conducting risk assessments on all purchased materials, which includes assessing risks associated with the country of origin and the supplier itself—the assessment should be much more than an assessment of the purchased material. As an example, the melamine issues associated with dairy ingredients originating from China a few years ago made purchasers leery about buying these ingredients from China. The risk is now deemed to be higher than if one sources such products from, for example, New Zealand or the United States.

In fact, consideration should be given to applying the same rigid program required for establishing a supply chain program to the selection process for a third-party laboratory. Like a food, raw materials ingredient, or packaging supplier, contract laboratories are partners for progress and for ensuring the safety, quality, and wholesomeness of what a company manufactures. Therefore, selecting a contract laboratory from the Internet, phone book, or out of a hat is not a good idea. A program should be developed that documents precisely how a laboratory should be selected and how that operation will be evaluated on a regular basis. It is surprising how few companies have such programs, and even those that have established selection criteria often don't include an evaluation process in the equation.

Evaluating and Approving Laboratories

So, what might a laboratory approval program look like? As noted earlier, such a program should be properly documented, which includes assigning responsibility for managing the program. A generic version of what such a program might look like is provided in Figure 1.

Although generic, the form does provide the general structure for what a company might do when selecting and evaluating a potential laboratory partner. One extremely important element is noted under the Procedures: "Visit the contract laboratories and prepare a summary report." Get out and visit prospective laboratories. Doing an audit of a potential laboratory partner is absolutely essential for any processor, and it should not be a huge burden to the company. Processors may utilize hundreds or even thousands of vendors when it comes to ingredients, raw materials, and packaging. With these operations, relying on third-party audits is part of doing business. How many laboratories will a processor utilize—one, two, three, maybe more? There is no excuse for not getting out to see and learn about specific laboratory operations. If your company is small and lacks the necessary technical expertise, a consultant or technical advisor can be engaged to accompany you on laboratory visits. The laboratory will want to add you as a client, and a technical advisor can help you to better understand what a laboratory is offering and whether it would be a good fit.

Criteria for Selecting a Laboratory

There is one thing a processor must determine before they visit a potential contract laboratory—what criteria are important to the company when it comes to laboratory support. The following is a list of potential criteria a processor might use to select and evaluate a laboratory partner (2). There may be more or fewer criteria depending on the processor and what is needed.

- 1) The laboratory has the ability to do the work needed using official and recognized methods.
- 2) The laboratory is ISO/IEC 17025 certified (1).
- 3) The work can be started as soon as the samples arrive, and results will be available as the testing protocol dictates.
- 4) The laboratory can provide references with whom the company can speak.
- 5) The laboratory will pick up samples.
- 6) The laboratory allows audits.
- 7) The company has trained employees who participate in check sample programs.
- 8) The laboratory has experience with the company's product matrix or matrices that are very similar.
- 9) The laboratory will not only provide results but will interpret results if needed.
- 10) The laboratory demonstrates a sense of urgency with testing the company's samples.
- 11) The laboratory has the ability to suggest tests that are possibly more appropriate, in addition to or in place of the testing the company is requesting.
- 12) Cost of services.

What Are the Laboratory's Capabilities? The processor must determine what kind of testing they want done by the contract laboratory before they begin their search for a partner. Do they want to do water testing only? If so, the goal will be to find a

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certified water testing facility. Are they going to ask the laboratory to develop certificates of analysis that can be shared with their clients? If so, the goal is to not only find a facility that has some familiarity with their products or ones that are similar, but a facility that can develop the necessary documentation. Is the processor manufacturing a ready-to-eat (RTE) pasta product and needs to develop and implement an environmental monitoring program per the requirements of the Preventive Controls Regulation (21 CFR Part 117) (3)? If this is the case, they should look for a microbiological laboratory that can help build the program, which may include training staff to collect and ship samples for testing. This would be a major undertaking and is a topic that requires an article all by itself.

Another FSMA requirement is that processors must validate their processes to ensure they are adequate to eliminate food pathogens. If this is a concern in the operation, the goal would be to find a facility that understands how to properly conduct process validation trials that will not only demonstrate that the

products are safe but will stand up to scrutiny by regulators and customers. As an example, a supplier of specialty flours or seeds may want to offer their customers the option of purchasing heat-treated products. As part of installing such a system, it would be imperative that validation studies be conducted on the processing equipment.

The needs of a processor may be much less complex, however. They may only require only a few simple tests to be done. Before any search for a laboratory partner is initiated, it is imperative that the operator define what is needed.

Verify ISO/IEC 17025 Certification. ISO/IEC 17025 certification (1) is becoming more and more prevalent throughout the food industry. One of the driving forces is the expectation in the Global Food Safety Initiative (GFSI) food safety audit schemes that if a food processor is using any kind of laboratory support services, they will select an ISO-certified laboratory. What does this mean? The laboratory must have established, documented procedures for managing all aspects of laboratory operations,

SUBJECT: Selection and approval of contract laboratories
OBJECTIVE: To ensure that any contract laboratory needed by the company meets criteria established by the company for service, quality, and potential performance
<p>PROCEDURE:</p> <ul style="list-style-type: none"> • Establish what the company needs from outside laboratories. Support services may include, but need not be limited to, <ol style="list-style-type: none"> a) Microbiology b) Chemistry c) Product development d) Nutritional analyses e) Environmental monitoring • Conduct a search to select potential contract laboratories. • Submit a contract laboratory approval form to the laboratories that have been selected for evaluation. Information on the form may include, but need not be limited to, <ol style="list-style-type: none"> a) Contact information b) Capabilities c) Certifications – ISO 17025, water testing, etc. d) Response times e) References f) Pick-up program g) Audits/visits by customers h) Check sample program i) Data interpretation j) Experience with the company's products or type of products k) Ability to offer other options l) Pricing • Review the contract laboratory approval forms. • Visit the contract laboratories and prepare a summary report. • Determine which laboratory or laboratories with which to work.
<p>RECORDS (Append All Forms to Procedure):</p> <ul style="list-style-type: none"> • Contract laboratory approval form • Results of laboratory visit or audit • Contracts with laboratory
RESPONSIBILITY(IES): Purchasing manager
<p>VERIFICATION ACTIVITIES:</p> <ul style="list-style-type: none"> • All laboratories providing analytical services must participate in a check sample program and share results with the company. • Once a year, laboratory performance will be reviewed with the laboratory and company management.

Fig. 1. Generic laboratory approval program.

from receipt of samples to testing to reporting. For many, if a laboratory has achieved an ISO/IEC 17025 certification that is more than enough to approve the operation. However, is that really adequate to meet the needs of a food or ingredient processor? This is one reason why it is imperative to develop guidelines for selecting and approving a contract laboratory, especially for smaller processors. Smaller processors often rely on contract laboratories for technical expertise, so the requirement that the laboratory understand and have experience with their products, or similar ones, should be a prime selection criteria. This topic will be addressed later.

According to Jay McBurney, a consultant who works with both processors and laboratory operations and conducts audits for both the GFSI food safety audit schemes and ISO/IEC 17025 certification (1), there are several areas that present challenges when it comes to obtaining and maintaining certification. These areas are proficiency testing, traceability, and proper documentation of these and other areas. When selecting a laboratory, treat the laboratory as one would an ingredient supplier—ask for the audit to see if there were any issues noted. Remember, ISO certification does not mean that all the tests being conducted in the laboratory have been certified. Have the laboratory define the scope of the testing procedures that have been ISO certified. At a minimum, pathogen analysis should be included in the ISO/IEC 17025 (1) scope for the laboratory's certification. Routine tests may or may not be included in the scope of certification. Laboratories may exclude routine tests, such as total counts, yeast, and mold, from the scope of testing due to the requirement and cost for including those tests in the required third-party check sample program.

Work Is Started Promptly. When selecting a laboratory, find out how long it will take them to complete the different analyses that the company will need them to conduct. As part of this question, ask about samples collected at the end of a week. Will they be cultured immediately or will they sit in the refrigerator over the weekend? Allowing samples to sit may be okay for some analyses, but it would certainly be a mistake, for example, to allow an edible oil sample submitted for peroxide analysis to sit. Ideally the list of tests performed by the laboratory would also provide information on turnover times. Along these lines, require that the laboratory provide information on any tests that are not done in-house and are contracted out to another laboratory, because this will affect turnover time. In addition, if samples are contracted out, there is a high probability that the laboratory does not have the knowledge to interpret results.

Finally, if the laboratory does conduct rapid tests, verify that they are using tests that have been validated against an official method. One client with whom I have worked sent seed samples to a new laboratory. They had never been out-of-specification for aerobic plate count until they began working with the new operation. In an effort to figure out what happened, they sent duplicate samples to the new laboratory plus three other testing laboratories. The sample submitted to the new facility was again out-of-specification, while those submitted to the other laboratories were all within established specifications. It turned out that the new operation was using a rapid test that should not have been used for seeds.

Laboratory Will Provide References. Before selecting a laboratory, make sure the potential contractor will provide references, preferably from operations that produce similar products and are similar in size to your operation. References should include not only names of companies, but potential contacts and

contact information as well. This may be even more important if the company is small. What difference does this make? Every client should be treated the same, whether their operation is small or large. Ask references whether smaller companies feel they may have been ignored in favor of larger companies.

Laboratory Will Pick Up Samples. Many laboratories provide pickup services, i.e., they will make arrangements to pick up samples at client facilities. The contract laboratory will coordinate with their customers to arrange schedules for regular pickup of samples. As part of this service, the laboratory will provide information on how to collect, label, and package samples. Of course, sample collection, labeling, and packaging should be included in the documented quality procedures for every processor. This is a service and a convenience, however, not a requirement.

Pickup services are something that processors should consider carefully. If samples are not picked up, it is up to the processor to pack and ship samples. Shipping entails ensuring that the sample remains in good condition (e.g., using blue ice, insulated shipping containers, etc.). Shipping adds costs and takes work to do properly. Weigh the pros and cons as part of the selection process.

Laboratory Will Allow Audits. The importance of visiting the contract laboratory as part of the selection process was alluded to earlier. As a food or ingredient processor, treat the laboratory as you would an ingredient or packaging supplier. Although food processors, especially large operations, may have hundreds of vendors that provide ingredients or packaging, most only utilize a handful of laboratories. So, visit each potential contract laboratory. Meet the account managers, the technical personnel, and make an effort to understand the operation. The laboratory should become your partner in assuring the safety and quality of your products, so make sure you are not only comfortable with the operation but feel that they can become a viable partner. This is also a great time to determine whether the laboratory has experience with your products and the type of processes that you employ.

Laboratory Has Trained Employees and Participates in a Check Sample Program. One of the basic elements for ensuring competence for most laboratories is a check sample program. As part of the evaluation of a facility, ask whether they participate in such a program. These are designed to evaluate the technicians who do the work using samples prepared by a third party. Third parties may include associations such as AACC International, allied industry groups, or other laboratories. Participation in a third-party check sample program is also a requirement for being ISO certified. In addition, many global food processors run their own check sample programs, both with the laboratories with which they work and also with their suppliers.

Laboratory Knows Your Products and Processes and Will Interpret Results. These two points go hand-in-hand. Interpretation of results is something that was alluded to earlier. Large companies often have the expertise in-house to look at results from a contract laboratory and make sense of a report. This is not always the case for small- to medium-sized processors. In fact, many small processors rely on their contract laboratory to let them know if results indicate there is a problem or issue.

Data interpretation has been an issue in recent years. Some laboratories do not provide interpretation because they deem it to be consulting, whereas others feel that if they provide an interpretation of results they are at risk if there are problems. In

other words, they would be liable if there was a legal issue. There are also some who believe that under the ISO/IEC 17025 standard, they cannot interpret data. This is not entirely true, however, according to McBurney. Under ISO/IEC 17025, clause 5.10, laboratories can offer opinion and interpretation if they are qualified to do so (1). Referring back to capabilities, be sure that your laboratory selection criteria includes an understanding of your products and processes. If the laboratory knows your products, then they may be qualified and comfortable enough to evaluate and interpret data.

Laboratory Has a Sense of Urgency. Be sure that the contract laboratory has a sense of urgency concerning testing your samples. It has already been mentioned that it is not a good idea to pick up samples on a Friday and leave them sitting over the weekend. Good laboratories will assign staff, especially people in their microbiology group, to work weekends and keep samples moving through the laboratory. There may be an extra charge for weekend work, especially if the laboratory is working on a special project.

Laboratory Has Capability to Suggest Other Tests. A processor's relationship with its contract laboratory should be a partnership that benefits both parties. A good laboratory will work with its customers to not only perform the requested work, but will offer advice when it comes to testing. In addition, the contract laboratory should provide guidance on other tests that could be performed. This kind of support is especially valuable for small companies or those without in-house technical expertise.

One of the hottest issues today, thanks to FSMA, is environmental monitoring. Food processors, especially those manufacturing RTE products, need to evaluate what they are doing and set up such a program. Many laboratories will assist with the development of an environmental monitoring program, which would include determining sampling sites and collection and analysis of samples. An environmental monitoring program should focus on what is needed to meet both the letter and the spirit of the regulation.

Cost of Services. There is an old adage, "You get what you pay for." This applies across many industries, especially the food industry. Selection of a contract laboratory should never be based solely on price. When evaluating laboratories, keep track of how each operator prices goods and services, but make your selection based on your established criteria.

Are There Things to Worry About?

When looking at contract laboratories, there are several issues that could potentially create problems. Some have been alluded to earlier. The laboratory that you ultimately select should ideally do all the work in-house. Verify this up-front, because testing that is subcontracted may still be reported on the company's letterhead. If your main contractor cannot do the testing, ask for recommendations as to who can do the testing and contact the source directly.

The use of the wrong test method has also been mentioned. The test methods a contract laboratory utilizes should be of-

ficial methods approved by groups such as the AOAC International, AACC International, the American Oil Chemists Society (AOCS), the International Union of Pure and Applied Chemistry (IUPAC), or others. Microbiological testing methods should be drawn from the *Bacteriological Analytical Manual* (BAM). If the laboratory does use rapid methods, ask them whether these methods have been validated against official methods.

This is not to say that there is anything wrong with a rapid method or quick test, but you do need to be sure they are accurate. The best example that I have heard of was a situation in the Southern Hemisphere a few years ago. A pet food manufacturer was involved in a situation where their products were making pets ill. Tests of the products revealed that they had high levels of aflatoxin. The company used a rapid test to screen every lot of corn they received prior to use. Unfortunately, the rapid test did not work with corn. The test produced false negatives, and it turned out that the test itself had never been validated against the official method.

Summary

The bottom line is that selecting a contract laboratory should be an organized process. Any company that utilizes, or is considering utilizing, a third-party laboratory should develop, document, and implement procedures to do this (Fig. 1). Third-party audits are a fact of life in modern food processing. The expectation is that food processors, both large and small, will be able to pass a third-party audit; for most, this would be a GFSI, Safe Quality Foods (SQF), British Retail Consortium (BRC), Food Safety Systems Certification 22000 (FSSC 22000), or International Featured Standard (IFS) food safety audit scheme. Selection of vendors, including laboratories, is included in these audit schemes. Very small companies might maintain, "The Food Safety Modernization Act of 2010 (FSMA) excludes my company." However, if your customers want food safety programs that are FSMA equivalent or a GFSI audit scheme, you will need to develop and maintain such a program or risk losing customers. Laboratory selection is part of this equation.

Acknowledgments

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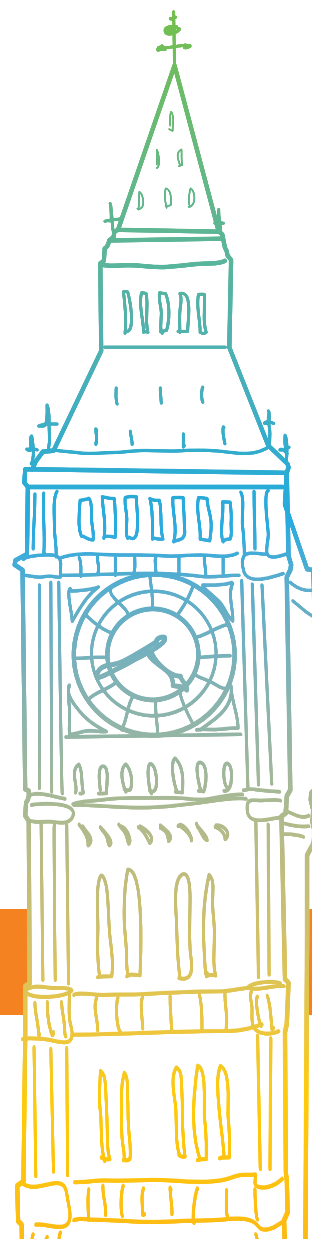
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