RAW MATERIALS: Selection, Specifications, and Certificate of Analysis

by Robin Amsbary

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Raw materials (ingredients, processing aids, and packaging materials) are the foundation of finished food products. As such, they must meet regulatory requirements (safe and legal for your intended use) and your specifications (contribute to the functionality and quality of your process and product).

Historically, research and development worked alone when selecting a new raw material. But now a broad team of expertise is needed, due to increased access to unique and complex materials, global sourcing, handling methods, customer locations, and regulations. The team assesses if the material has limitations or may be too costly to handle, and determines if additional measures are necessary to prevent potential safety issues for the employees and product.

TRADITIONAL ROLES

A description of team responsibilities helps in the understanding of the diverse expertise needed to identify key raw material characteristics.

- **Research and Development (R&D)** – Invents the finished product to meet the customer's expectations.

- **Quality** – Ensures that the programs and practices will result in finished product that is safe, is legal, and meets the company standards as well as specifications outlined by R&D.
- **Production (from receiving to shipping)** – Handles the raw materials and in-process and finished product in an appropriate manner (including equipment capability) to ensure the finished product is safe, is legal, and meets R&D's specifications.
- **Sales** – Works with R&D and the customer to define and negotiate an acceptable product with an affiliated price point.

Each area's expertise is necessary to determine the desired specifications for each raw material.

RAW MATERIAL SELECTION

R&D selects the appropriate raw materials based on functionality. Functionality can encompass multiple areas, such as providing identified characteristics of the finished product (binders, thickeners, type of resin for plastic packaging, etc.), organoleptic characteristics (flavor, color, aroma, texture), product safety characteristics (to lower the pH or water activity), and preservatives (extension of shelf life, color, or flavor retention, etc.).

CONSIDERATIONS IN SELECTION

Is there a raw material already in use that has the same or similar characteristics?

If so: Don't add unnecessary complexity.

Resource: List of existing approved materials and their specifications.

Is this a raw agricultural item, commodity item, or one that has a standard of identity?

If so: Develop a general specification that can be used between multiple potential suppliers.

Resources: Supplier technical information, the standard of identity, food action defect level from regulations, comparison of different suppliers' specifications from the Internet.

What are the limitations on the use of the raw material?

- No limits or qualifications, such as the Generally Recognized as Safe (GRAS) listing in the United States.
- Use has been limited to specific products.
- Limitations or ban on the use, such as genetically modified materials for organic products.

Resources: Supplier technical information, regulations for the country of sale, e.g., U.S. Code of Federal Regulations (CFR), Canadian Food Inspection Agency, European Commission, etc.

Are there legal, maximum levels for use, both in the country of manufacture and the country of sale/use?

Resources: Same as previous.

Does the raw material meet existing company or customer standards (e.g., kosher, halal, organic, gluten-free)?

Resources: Company standards, customer requirements, supplier technical information, supplier-provided certificates.

HISTORICALLY, RESEARCH AND DEVELOPMENT WORKED ALONE WHEN SELECTING A NEW RAW MATERIAL, BUT NOW A BROAD TEAM OF EXPERTISE IS NEEDED.

PLANT DISCUSSIONS AND TRIALS

Trials require close collaboration between R&D and the manufacturing team. These examples of questions to be answered and the method for initiating discussions before, during, and after the trials will help facilitate the trial process.

OSHA Considerations

- Does the new material present a potential safety or handling concern to the employees or the facility (such as a flammable material or an irritating powder that needs venting)?
- Are there additional reporting requirements?

Food Defense Considerations

- Are there potential toxic levels of the raw material? If so, how is potential purposeful abuse handled?

Product Safety Considerations

- Find historic information about the material via search engines (e.g., "pathogen + name of the material"; "recall + name of the material"; "foodborne illness + name of the materials")
- The food safety team assesses the potential biological, chemical, and physical hazards affiliated with the raw material (HACCP/HARPC review) as well as affiliated prerequisite programs and downstream prevention/elimination/reduction steps for identified hazards.
- Determine if existing product safety measures are circumnavigated (e.g., the particle size is too large for the existing sifters or metalized packaging passing through a downstream metal detector).
- Are additional processing steps necessary (e.g., an invert and clean if glass containers are the new material being used)?
- Do new programs or procedures need to be developed (e.g., an allergen program and/or validation that the existing changeover procedures are effective in removing a different allergen)?

Facility and Equipment Capabilities

- Can the plant appropriately handle the material (e.g., is sufficient storage capacity and special equipment or preparation available)?
- Is the existing equipment capable of handling the material (e.g.,granulation is too large for the dispenser)?

Material and Production Costs

- Are there additional costs associated with the material, such as holding for COA review and/or in-house testing, additional labor, decreased line flexibility, increased time for changeovers, increased lead time prior to use (such as thawing, hydration and mixing, etc.)?
- Will additional rotation controls be necessary for short shelf-life materials and will there be additional costs affiliated with more frequent delivery?

POST-TRIAL DISCUSSIONS

AFTER THE TEAM HAS AGREED ON THE KEY CHARACTERISTICS FOR THE RAW MATERIAL, THE NEXT STEP IS TO DOCUMENT THESE EXPECTATIONS.

Flexibility in sourcing and cost

- Is the material a commodity-type item that can be purchased from multiple sources? If so, compare existing specifications from multiple suppliers; allow comparison bidding/purchasing.
- Can the tolerances for characteristics be expanded to be able to purchase from more than one source or a wider range of possible, existing materials (such as granulation size for materials that are going to be dissolved or melted)?
- Can purchasing find a similar functionality material that has costs less or has fewer concerns?

Size and type of packaging based on forecast use

Typically, the larger the container purchased, the cheaper the cost-per-pound. However, if the forecast is for use of 100 pounds in a year, what is the appropriate-sized container to purchase? It would not make sense to purchase in 50 pound bags (multiple handlings of the package with resulting potential of damage or contamination) or in a Super-Sak (with destruction of, or potential use of, expired materials).

RAW MATERIAL SPECIFICATIONS

After the team has discussed and agreed upon the key characteristics for the raw material, the next step is to document these expectations. This can be as simple using as the dated Technical Data Sheet from the supplier. A purchase order should list the supplier's specific name and item number for the material. A recommendation is to include the revision date of the Technical Data Sheet (with associated specifications).

As a company grows, or your requirements become more complex, the supplier's information is expanded upon within your own specifications. At a minimum, the information should include technical and food safety information, including:

- The name of the product and the supplier's item number.
- Components or composition of the material.
- The presence of regulated or customer-recognized food allergens.
- Organoleptic information (appearance, flavor, and aroma).
- Pertinent physical, chemical, and microbiological information.
- Shipping and storage information.
- Shelf life.
- Handling directions.

PRODUCT NAME

General name

Material identification can be general for commodity-type products or those with a standard of identity, such as salt, granulated sugar, FD&C Yellow #5, and so forth. General names or descriptors ease use and sharing specifications, especially when soliciting and comparing prices between multiple suppliers.

Material-specific name

A product-specific name or number may be assigned by the supplier when the item is a unique or proprietary material (such as with most flavors).

Item number

This is the number you assign to the purchased item in order to track materials within your system.

COMPONENTS

The ingredient/material composition is listed in decreasing order of presence or as outlined in labeling regulations. For packaging materials, the specific composition of the packaging material would be specified, such as glass, polyethylene (PET), polypropylene (PPE), and so forth.

FOOD ALLERGENS

It is not unusual for a supplier's Technical Data Sheet to state that the material does not contain an allergen; however, most U.S.-based suppliers are only considering U.S.-regulated allergens. If you are controlling more than these, ensure you receive written confirmation of the presence/absence of the allergens you are managing.

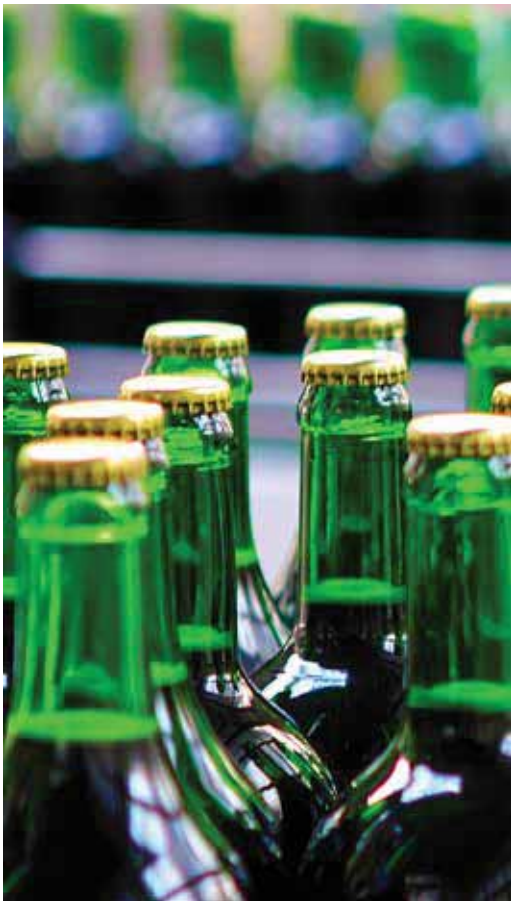
ORGANOLEPTIC INFORMATION

Organoleptic characteristics are tested with your senses, including visual appearance, aroma, and flavor. This brief description is typically used during the receipt or pre-use at the plant to confirm that basic expectations are met or identify issues that can be readily checked by appearance (puree rather than whole fruit), aroma (off odors such as musty or chemical), or flavor (caramelization with high fructose corn syrup or rancidity with oils).

ANALYTICAL INFORMATION

Analytical characteristics typically require testing with instruments rather than your senses. For example, an organoleptic description of a product could be "red liquid" and the analytical information would be the colorimeter reading.

Characteristics to be outlined include those affiliated with functionality, quality, and food safety. You do not necessarily need a Certificate of Analysis or in-house testing



for all of the listed characteristics, rather, these characteristics are outlined as an agreement about what you are purchasing and as a basis for discussion if concerns are identified.

As described earlier, determining the key biological, chemical, and physical parameters requires R&D and plant management to review historic information about the material, regulatory requirements, and the supplier history, as well as how the material will be handled in-house.

Food safety parameters or tolerances could include biological, chemical, or physical characteristics.

- Biological – Microbiological limits for pathogens, such as *Salmonella* and *Listeria monocytogenes*.
- Chemical – Fortification levels, sulfite levels, heavy metal content, etc.
- Physical – Size and foreign material (rocks, glass, metal, bones, etc.)

Functionality or quality parameters would include characteristics that can impact the functionality of the material or adversely impact your product.

- Biological – Microbiological limits for spoilage organisms or indicators of poor sanitation, including total plate count, yeast, mold, and coliform.
- Chemical – Characteristics such as concentration levels or purity.
- Physical – Characteristics such as viscosity, color, granulation size, insect parts, crush strength, physical measurements, etc.

Outline the appropriate conditions for shipping and storing the material. Include any special storage or handling directions, such as "do not freeze" or "store in a flame-resistant cabinet."

Following the supplier's storage recommendations, describe the product's shelf-life (the supplier's safety and quality guarantee for the product).

Determine if there are special directions for handling the material, such as if employees need to wear a face mask or other personal protective equipment (PPE) or if the material needs to be shaken before use.

Additional information about a new or revised material may be vital to your company and customer. You may wish to stipulate these requirements in the raw material specification, such as:

- Packaging size and composition (such as a 25-pound, multi-layered paper bag; poly-lined corrugated box; Super Sak; bulk tanker).
- Religious dietary requirements such as halal or kosher as well as clarification if dairy or pareve.
- Where the material has been approved within regulations. This information can be found in the Code of Federal Regulations (CFR) for the U.S. This information can be received from the supplier or you can conduct a web search for "CFR + name of the raw material."
- Colors – Is it a "certified color" (i.e., Yellow #5, Red #40) or "exempt from certification"?
- Flavors – Is the flavor artificial and/or natural?
- Organic – Does it meet the National

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Organic Program (NOP) specifications, as regulated by the USDA (7 CFR 205)?

- Restrictions or limits – If there are defined maximum levels, what are they?
- California Proposition 65 – Does the product or components within the product meet the declaration requirements as outlined in California Proposition 65 (carcinogens)?
- Heavy metal composition or warrantee – Heavy metals, specifically lead, mercury, cadmium, and hexavalent chromium are not purposefully added to material. For packaging materials, this warranty typically stipulates that the material contains less than a combined total of 100 ppm of heavy metals, regardless of how introduced.

CERTIFICATE OF ANALYSIS (COA)

A certificate of analysis (COA) is the supplier's test results on the specific lot being provided to you. Before requiring a COA, determining the key characteristics that can fluctuate, past concerns, and compliance to specifications is essential to your product or process.

You may find that many of your raw materials, such as packaging materials and refined oils, may not need a COA, however, ensure that you are following any requirements outlined in customer or audit standards (such as GFSI audits).

There may be upfront or hidden costs with requiring a COA. Ask suppliers what tests they routinely conduct or for a specified analysis if you are asking for this. There also may be costs for your receipt or review, for potentially holding the material while waiting for a result, and for an action plan if the results identify that the material does not meet your specifications.

VALIDATION AND DOCUMENTATION

The standards for validation and documentation are: *Prove it, scientifically* (validation) and *If it is not documented, it was not done* (documentation). These encompass the research information, meetings, and the team's conclusions. For web searches, document dates, the name of the person who did the search, key words used, and the findings. Meeting documentation should capture dates, participants, the scope of the discussion, conclusions, and potential action plans.

A clear understanding of the materials being purchased is vital for suppliers and customers. Materials that do not meet your expectations can significantly reduce productivity, increase costs due to additional testing, rework, or destruction; and can place your product, company, customers, and consumers at risk for hazardous issues.

On the other hand, understanding the material and appropriate handling practices, as well as obtaining those that meet your expectations, increases productivity, decreases potential food safety risks, and is a key building block toward making a consistent, high-quality finished product. **AIB**

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