Enhancing Food Compliance

with a Complete ERP Software Solution
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Introduction

Manufacturers and distributors of food products and nutraceuticals in North America face tremendous competitive, economic, and compliance pressures. While these pressures are always a priority for most organizations, the issue of food safety has continued to be the single pressing topic in food* today. Product recalls and related health consequences are easy and sensational headlines for television, print, and electronic media. Consequently, this has not only raised the national consciousness of the topic, it has also contributed to a higher lack of confidence in the food supply chain, increased vigilance on the part of retailers, and continuous public pressure for more regulatory oversight and action.

Polling of consumers clearly indicates that product quality and confidence in the organizations involved in food production and inspection are the top issues of concern. A 2018 survey conducted by the International Food Information Council Foundation indicated that nearly a third of Americans are not confident in the overall U.S. food supply, with foodborne illnesses from bacteria and carcinogens and chemicals in food being the most important food safety issues today.

With the formalization of the Food Safety Modernization Act (FSMA) starting in 2015, the FDA has been granted higher levels of authority to regulate the way in which food products are processed and handled. As a whole, the food industry has made great strides in adapting to the new regulations, with recent numbers indicating that the third quarter of 2018 experienced the lowest number of FDA recalls in more than two years. However, it bears noting that while the number of recalls may be decreasing, the quantity of units that are recalled remain high. It seems safe to say that, while more and more companies are putting policies and procedures in place to prevent recalls from occurring, those that do experience recalls are finding them to be far-reaching and involving a significant volume of products. This puts more pressure on individual organizations than ever before – with so many companies “getting it right,” the few that do not will suffer the consequences of reduced sales, product failure, and demands from customers. This places a great emphasis on the concept of “brand = quality” and the need to preserve brand image.

As a result, the concept of “compliance” takes on two aspects – regulatory and what we term the “blame chain.” Interestingly, regulatory compliance has historically not been a key driver in the area of quality management, although with the increased enforcement of FSMA provisions, this is becoming a greater quality management issue than a decade ago. Still, the highest pressure reported by the industry continues to be customers demanding improved product quality. We also find that the issue of product liability is a strong undercurrent in the product quality discussion – the fear of the courts is much greater than the fear of the USDA or FDA.

Compliance, regulatory and/or the blame chain, does not need to be difficult, complex, or expensive. Fundamentally, it is a function of good processes and procedures, oversight and review, consistency, and ease of access to information. However, in many of today’s production environments, the underlying information systems, business process control, and manufacturing execution systems are not capable of meeting the increasing demands of the marketplace. This white paper explores some of the ways bcFood, a vertical solution for the food industry built upon the Microsoft Dynamics 365 Business Central enterprise resource planning (ERP) application, can address these issues in an economical, scalable, and flexible solution, using the most current technologies and best practices.

* For purposes of this document, the term “food” is used for food & nutraceutical processing, manufacturing, and distribution, and may apply to retailers of food and nutraceuticals.
Overview – Compliance Foundations

THE CONCEPT IS SIMPLE
Regulation, law, and best practices all basically require that whatever comes into contact with a product, regardless of form, should be traceable. A corollary to this is that tracking the environmental conditions that may affect the product, such as storage temperature or potential contaminants in the production or storage environment, can be an especially important factor in the blame chain. We consider each of these situations to be a “touch point,” and each of them should afford an opportunity to record data.

Traceability is a documentation procedure that parallels the production, storage, distribution, and logistics processes related to a product in which touch points are recorded not only as unique data, but also as parts of a complete backward/forward audit trail. In actual practice, there is a wide divergence of compliance actions, even though there are very specific regulatory and legal definitions and examples for almost every product handling situation.

This white paper assumes that the concept of product lot assignment is known to the reader. It does not presume any specific lot identification procedure or methodology. Regulations vary by product and provide guidance in these areas, but lot definition ultimately remains the responsibility of the manufacturer.

THE EXECUTION CAN BE MORE DIFFICULT
When viewed end-to-end, even the simplest process can quickly become complex from a compliance perspective, due to the presence of many touch points. For purposes of illustration, consider a nut processing operation that receives whole nuts from growers, hulls/shells them, sorts/cleans them, and finally packages them for shipment to customers. While this example utilizes a primary or first stage food processor, the principles equally apply to secondary food processors, distributors, and nutraceuticals. These steps, as well as the main intermediate ones, are illustrated below.

![Flowchart of nut processing steps](image)

Even with this simple scenario, determining and documenting touch points can quickly become a daunting and time-consuming process if the proper procedures are not implemented. For example, while we could limit our traceability documentation requirements in Step 1 (Receiving) to nothing more than an initial lot identification, it is much more realistic to expect the inclusion of additional information such as grower, carrier, trailer number, grade, and quality in our traceability procedures. If interim storage takes place in a bulk unit such as a silo that holds multiple receipts, traceability immediately becomes more
complex, as we have co-mingled lots in an environment where cross-contamination can easily occur. The answers to how to best handle this situation vary by environment and product; solutions to tracking and recording this information are addressed in the following sections of this document.

Hulling/shelling creates another touch point (equipment), as does sorting. In many cases, these are not recorded, yet are an important aspect of documentation. The end result of this process is sorted product (i.e. different sizes/grades), which usually ends up in some form of container. Again, this is another touch point and a new trace identity needs to take place. In addition, the introduction of the container means that we now need to capture the source identity of the container along with the product within it. As noted previously, if the source is mixed, the establishment of a source identity becomes more complex.

Movement of the sorted product to storage does not change the identity, but location and environmental factors related to the storage may have an effect upon the product. Therefore, documentation of the location and any environmental factors can be important.

Packaging creates two new touch points – movement through the packaging line, and the product packaging, resulting in a new trace identity for the packaged product. If the packaged product is then cartonized, the outer pack identity needs to be linked to the inner pack identity, particularly if the outer pack is the storage unit and the inner pack is the use/sale unit. Once again, the usage of multiple sources (this time in the form of sorted product containers) to fulfill these packaging requirements will add complexity to defining a new source identity.

If product is palletized or aggregated into some form of material handling unit (MHU), the individual identities must be preserved within the data related to the MHU. The MHU then needs some form of unique identity for inventory (and possibly shipping) control. This type of information is not necessarily trace data, but can be, depending upon the operating and handling environment.

When shipped, the MHU and associated product data should be automatically related to the shipping documentation and invoicing information. The shipment activity constitutes another touch point and, like receiving, carrier and trailer information is typically recorded, as well as the use of materials for packing, blocking, or containment.

Thus, our ten step process has resulted in far more than ten data sources and components, due to the addition of new touch points and the establishment of new trace identities. When other information, such as testing and quality assurance (QA), is added, the data input requirements quickly multiply.

All of this information is required for complete traceability and risk management, as well as current good manufacturing practices (CGMP) and Hazard Analysis and Critical Control Point (HACCP) documentation. When this data is not collected on a consistent and easily-recorded basis against a common set of parameters, traceability and demonstration of compliance become very difficult.

Using our simple example, this white paper will step through each of these processes and illustrate solutions for data identity and collection through the use of bcFood and Microsoft Dynamics 365 Business Central. It will also explore the means by which you can simplify these processes, minimize costs and exposure, and help to assure compliance with regulatory and customer requirements in a modern, flexible, robust, and easy-to-afford enterprise system.
Receiving

While the receipt of product is the starting point of the compliance process, the foundations for good compliance may be set far in advance of receiving. Examples of this include purchase specifications, acceptable product quality ranges as determined by authoritative or regulatory bodies, contractual agreements, or other factors that set the level of expectation relative to the received product.

Receiving is where the first lot identity needs to be established, and, as it will impact every subsequent step of the compliance process, it is crucial that you practice sound lot assignment methods. In every case, the best practice is to assign your own unique identification; if you use the provider’s lot identification, there is no assurance that this will be unique. Furthermore, the introduction of multiple numbering schemes into your data will make tasks such as searching and identifying data more difficult. This does not mean that logging external identification numbers is unnecessary; to the contrary, you must record any provider’s lot identification relative to your lot identification. When a receipt is comprised of multiple provider lots, you should create unique internal lot numbers for them in order to provide a direct cross-reference. In addition, if a product receipt is based on a formal purchase or contract system, this information should be related to the receiving data, as it offers additional cross-referencing capabilities relative to the conditions of receipt. Utilizing bcFood, the receipt and assignment of lot identifiers, as well as relating this information to purchasing documents, is very straightforward.

The receipt function in bcFood enables the registering of information from a scale and associating the receipt record with a purchase or inbound transfer document.
Depending upon your receiving, inspection, and quality control (QC) procedures, additional data (such as Certificate of Analysis [COA], Country of Origin, and grade/test results) may be added to the lot information record either at or following the time of receipt. The ability to relate inspection and QC samples to a given lot is critical, so the lot identity must be linked to the sample. This is especially important if third parties are used for testing, QC, or analysis, as the results from those sources may lag the handling of the product. Whenever results become available, it must be possible to associate them to a specific lot record, regardless of the state of processing that may have occurred against that lot.
In certain segments of the food industry, additional complications may be present at the point of receipt. If you are a first stage food processor who processes food that has come directly from the farm, field, ranch, or other growing environment, assigning a simple country or region of origin to lot information records is not sufficient. The product you are receiving into your inventory has been harvested from one of many ranches, blocks, and/or fields in the grower’s possession, and it is necessary to record all this data with each lot information record you receive. In the event of a recall initiated by the grower, it is likely that will be notified of the specific ranch/block/field that is affected, and visibility to this information in your system will allow you to determine which lots of your inventory are compromised. If you receive these types of products, it is important that your software application provides you with the proper commodity receiving capabilities to record this information.

Processors of commodities can use bcFood’s Commodity Receipt page to record the grower’s ranch, block, and field, providing greater detail into a received product’s point of origin.
The hold features in bcFood make it possible to place lots on hold, preventing them from being used in various user-specified activities. Hold tags can be manually assigned or configured to be automatically generated and assigned as a response to certain actions (the receipt of a new lot into inventory, for instance).
Interim Storage

Depending upon the received item(s), interim storage or warehousing may be necessary. In a distribution-only environment, the product is usually warehoused. If the product is stored before processing or distribution, there is usually additional information that needs to be captured. This is especially true if the product is stored in bulk and co-mingled with like product, as the discrete lot identity then changes.

There are myriad approaches to addressing co-mingled product, identity, and traceability issues. Specific operational, business, and environmental factors usually determine the most practical procedure and, because of the breadth of variations, there is not a single “best way.” Regardless of the method used, it should be consistent and practical. Additionally, the logic associated with the process should be documented and incorporated as part of the traceability data.

By using automatically-created Put-Aways, Business Central can direct the movement of item lots to selected storage bins within a given location.

The issues associated with any type of interim storage mirror those of storage in general, but in many cases, interim storage is more fluid. Because of this, good product handling practices must be developed and enforced, but at the same time methods to accurately capture movement and other touch point information on a timely basis must be in place. These topics and solutions are covered in greater detail in the Storage section of this white paper.
Processing & Compliance

Any type of processing activity has the potential to add information to existing lot records, or create entirely new ones. Depending upon the processes, equipment, and data systems in place, the structure and logging practices of the required information can vary. This is often an area where missing and/or incomplete data has the potential to cause serious traceability consequences.

The realities of the production environment often create situations where a strict application of compliance is not possible, but any reality, including a lack of personnel, is quite frankly an indefensible reason for not collecting or recording data at appropriate data points. In these scenarios, recognizing the risk areas and implementing mitigation procedures is extremely important. Determining data points requires a good understanding of traceability requirements, CGMP, and HACCP, as well as the production environment and processes. The most practical approach to determining where data points exist is that every step in the process at which a discrete output is recorded (such as a full container, for example) presents an opportunity to establish a data point for compliance.

PROCESSING ISSUES

Using our example from the Overview section, the two steps that follow Interim Storage, Hulling/Shelling and Sorting, are a continuous process that result in products sorted by size. While the nuts go through two discrete processes (machine centers), a discrete identity cannot be established until the completion of sorting, which results in product in a bulk container. The combination of these discrete processes may be grouped together as a routing, which can simplify the recording of compliance data. By utilizing the machine centers within the context of the routing, other compliance data can easily be related directly to the machines. Thus, information such as HACCP data and machine metrics (including manual inputs or PLC device interfaces) can be captured as part of the production and lot data.

bcFood supports the use of machine centers (as well as work centers, which represent a group of like machine centers) in any user-defined configuration, as well as routings and tracking for products that are sent for outside processing.

ESTABLISHING NEW LOT IDENTITIES

As the sorted material is directed to its various containment units, a unique identity needs to be established for each configuration, as this process creates not only a new product, but also a touch point (the container) and an MHU that needs to be identified and tracked for inventory purposes. Whether or not each MHU is designated as an individual lot number will depend upon the processing environment.

This sorting scenario illustrates another common compliance issue. In any production environment where there are co-products that must be traced, the output (yield) is unlikely to be evenly split, resulting in one MHU filling faster than others. If multiple input lots are used, procedures and processes must be in place to assure a high degree of traceability to the product contained in the MHU. Often a combination of input lot data, date/time, shift, production order, run rate, and other data points all help to more accurately tie outputs to inputs for compliance.
An example of the establishment and recording of new production lots is shown below:

This example illustrates the output journal for a nut shelling process where the output includes the desired shelled product as well as the by-products: rejects and shells.

In many production environments, products that have reached an intermediate stage need to cool, dry, or rest, and may be covered or moved to another area of the production facility. This movement will oftentimes constitute another touch point, and the activity should be recorded as part of the production and/or inventory information.
Storage

Storage can create a number of compliance touch points that are often not apparent until a problem occurs. In addition to the issues described in the Interim Storage section, there are additional factors that may affect compliance.

The two primary factors in storage that have the greatest effect on compliance are inventory location control and environment. “Inventory location control” is visibility to where every lot of every product is at any point in time. “Environment” refers to both the location in which a product is stored and how that particular location might affect the product.

In a food environment, location control is critical to ensure proper handling and use of inventory. If you know what is available and where it can be found, and in real time, then picking, handling, counting, replenishment, and shipping all become much simpler and the accuracy of transactions greatly increases. The combination of compliance obligations, product life, customer requirements, and variability of product characteristics means you need to have systems in place that provide you with complete inventory transparency. This will allow you to easily specify the correct lots to fulfill sales and production orders according to your business rules and customer specifications, then validate the correct disposition of those lots.

Whether these activities are paper-based or electronic, the key to compliance is a single integrated system that controls all aspects of inventory, including sales, purchasing, production, warehousing, and logistics. Handling each of these activities in a vacuum results in ongoing accuracy, timeliness, and maintenance problems, with negative effects on customer service and satisfaction, as well as compliance.

The Lot/QA Questionnaire Overview page in bcFood makes it possible to search for lots and view availability based on categorization and filtering on lot attributes. In addition, predefined customer specifications (attribute filters) can be utilized.
The human element in the storage environment can be largely addressed through a combination of business software controls, technology, training, and oversight. While no application or technology will ever replace the need for personnel training and supervision, a well-designed system, when coupled with today’s technologies, can virtually eliminate inventory-related errors.

A situation we frequently see in production environments is the movement of product to an uncontrolled location or area. This typically occurs when there is a temporary capacity constraint and items in an intermediate form are moved outside of the usual processing environment. Examples of this type of situation are trays of product temporarily moved to the warehouse to cool due to production floor problems or moving items out of doors due to lack of warehouse space.

While these types of activity may not be viewed as a best practice, they are usually taken out of necessity so as to not compromise product integrity. If a system is in place that provides tracking of item movements at the lot identity level (and the ability to split a lot if only part of the original lot is subject to the conditions) as well as notation of the environmental changes, risk identification and mitigation is greatly enhanced.

The bcFood Item Availability Overview page allows users to easily locate items and pallets by warehouse location, storage bin, lot, etc.
The bcFood Lot No. Information Card allows for the specification of related receipt and production information. Examples include country of origin, crop year, and vendor lot no.

bcFood makes it possible to enter dynamic, rich text comments for a given lot, and its document management tools allow you to attach any type of document or note to a lot record with simple drag and drop functionality.
Document management functionality includes the ability to configure Microsoft Word’s mail merge to pull information directly from Business Central pages such as the Lot No. Information Card. In these samples, the screenshot above illustrates a mail merge definition, and the screenshot below presents the resulting Microsoft Word document.
Processing – Packaging, Cartonizing, and Palletizing

The placement of product into a use package (or “pack”), outer pack, and/or some manner of material handling unit poses a number of compliance and data issues for many organizations. A second obstacle for many systems is the inability to track and utilize an item according to multiple units of measure.

Many applications cannot provide either the controls or functionality needed to “see” product at a basic pack level, which can lead to compliance hurdles and customer service problems. Furthermore, an inappropriate application of traceability concepts can magnify these issues in the event of a product question. Visibility to all pack levels is key to compliance and customer service requirements.

Using the illustration below, we can easily see some of the issues at the heart of these requirements. While it looks very straightforward, there are significant visibility and operational issues under the surface.

Items are frequently cartonized for simplicity of handling, warehousing, maintaining product integrity, and sales. For the purposes of our discussion, “cartonized” can mean the placement of product(s) into another container that is used for sales, handling, or shipping. This could be an outer carton, a shipping carton containing other cartons, palletized cartons, bins, or any other material handling unit.

In situations where a single lot of product is used in cartonizing, compliance is quite straightforward, as the lot can pass through all levels of cartonizing. However, real world scenarios are generally quite different, with mixed lots of the same product being cartonized. Without appropriate processes and systems, this can create a number of risks.

If product is sold and/or received by the carton, special attention should be paid to carton labeling; beyond meeting your brand image and customer’s needs, carton labeling provides a built-in opportunity to enhance compliance. This is traditionally an area where the potential for a compliance disconnect exists due to an inability to easily relate contents to the outer pack.
With today’s software and technologies, however, this does not need to be a time-consuming, error-prone, and/or expensive process. bcFood features a native integration to Seagull Scientific’s BarTender labeling system. Consistently cited as a first-class application, BarTender streamlines the label design process. By integrating directly to your ERP software, BarTender can automatically and accurately obtain recorded information and print it on your different pack labels. Barcoding capabilities introduce further opportunities for efficiency as the labelled product is packed, moved, and shipped from your warehouse.

Integrating a labeling system such as BarTender to bcFood allows for the direct mapping of key identifying data to labels, making it easy to maintain visibility to container contents throughout multiple pack levels.

Regardless of the software in place, the solution remains the same: the data on the outer pack should include its relationship to the product data on the inner pack. This is true for any and all succeeding steps in which product is aggregated, whether it is for packaging or handling. It is extremely important to consider how the labeling at any level of cartonizing is used by your customer, and then implement procedures that minimize the possibility of a traceability compromise.
Consider the initial cartonizing component of the previous illustration. By using a production order model, the relationship between the inner and outer pack can be established.

When the processing environment creates situations where mixed lots are used to complete a cartonizing activity, you should carefully assess the degree of risk relative to how you identify cartonized product. If multiple lots are used in a production order, you may needlessly expose more product to recall risk because in addition to product lot numbers, you also need to provide an identifier for the outer pack. When smaller production runs are created, the window of risk is much smaller because you can more discretely identify the inner/outer pack relationship.

In actual practice, we find very few organizations utilizing any type of outer pack identification for compliance and traceability purposes. Even a cursory review of the FDA Enforcement Reports illustrates how much greater the degree of recall exposure becomes when manufacturers rely upon the carton’s UPC or other generic outer pack identifier. While organizations may have some production-related identifier on the outer pack, it is usually not directly related to the lot identity of the contents.

Creating the relationship between inner and outer pack is very simple with bcFood software, as the lot identities of the inner pack product (consumption) are automatically linked to the production outputs. The lot number needs to be applied to the cartons, which can usually be done through existing equipment and technologies such as labeling or by via ink jetting.

Another technology that should be taken into consideration is the implementation of a mobile warehouse and/or production solution. The barcode scanning capabilities found in handheld units designed specifically for processing warehouse activity will significantly increase efficiency and ensure inventory accuracy. Comprehensive solutions such as bcFood’s bcMobile module enhance compliance considerations by allowing warehouse personnel to record identifiers and other key traceability components in real-time.
Production orders can be created for both Make-to-Stock and Make-to-Order products. Because production orders are built upon a variable output quantity, inputs are automatically calculated by the system.

Using a mobile warehouse solution like bcMobile allows you to record pallets that are linked to a production order as they are outputted in real-time.
The information that is entered through the mobile device is automatically transferred to bcFood.

Pallet tags can be printed in advance or as part of finishing production.
Completed cartons are usually aggregated into a more convenient material handling unit, such as a pallet. In some cases, a product is sold solely in this aggregated unit (using the example of a pallet, we would sell our product to customer by the pallet). In other scenarios, multiple products may be aggregated onto a single pallet for warehouse material handling and/or shipping. Regardless of the unit used, the same data relationship between the outermost pack to the innermost product should be available.

The need for this type of information has accelerated greatly due to EDI becoming a common method for transferring data to trading partners, with some large customers such as Walmart and Costco requiring the usage of Advanced Shipment Notifications (ASN) containing details of each pallet’s contents, down to the inner pack information. This data must be available and accurate at the time the ASN is generated, because the penalties for inaccuracies are often very high.

To provide the highest level of visibility and compliance with your trading partners’ requirements, the ability to “build” a pallet on the fly and automatically capture content data is essential. Even though this need exists in food processing and distributing entities of all sizes, the ability to do so is generally available only on very large enterprise systems, costing hundreds of thousands of dollars. bcFood stands out as an exception, providing this critical capability as part of the product.

*bcFood’s various license plate journals make it possible to correct or adjust license plate records on the fly. For example, items such as slip sheets can be batch added to several pallets at the same time, and individual license plates can be broken if there is a need to return loose product to inventory.*
Load/Ship

Shipping constitutes another touch point, as this is when the custody of the product is transferred to another entity. To minimize exposure, as much information about the shipment as possible should be captured. Obvious examples of this include the shipper, trailer number(s), and bill of lading data, but information about the trailer’s condition, tare and gross weights, packing materials used (air pillows, blocking, etc.), photographs of the packing, and anything else that might mitigate product claims should be recorded.

A generated pick ticket can be defined to automatically select lots based on FEFO (First Expired, First Out) or FIFO (First In, First Out) rules. User-selected lots and pallets can also be pre-assigned to the pick as needed.

Full integration of all captured data can be especially important at this point for two reasons. The first is to ensure that what was supposed to ship to the customer is exactly what was shipped. In the event of a product problem, you have to be able to alert both the carrier and the customer. If the inner pack data is not related to the shipping information, timely notification may not be possible.
Loading and shipping in bcFood fully supports lot integrity, as well as allowing for the tracking of additional related information such as seal numbers.

The second argument for full integration is that, in the case of a customer using EDI, shipment information is consistent with the ASN. We have seen many situations where the penalty charges for errors related to these issues would go a long way toward paying for an entirely new bcFood solution.
Other Compliance Considerations

The model we have used for our compliance illustration maintained custody of the product within the confines of the production organization. However, many producers utilize outside parties for production, warehousing/logistics, or services (such as fumigation or toll processing) that may affect product integrity as well as compliance. Additionally, consigning inventory to a trading partner is an increasingly common occurrence. All of these scenarios create more complex data and tracking issues for you.

OUTSOURCED PRODUCTION & COMPLIANCE

Outsourcing part or all of a production process for which you have purchased the raw materials poses a number of challenging compliance issues. From a pure regulatory compliance perspective, the requirements for the outsourced processor are the same as they would be for you if you were handling the processing in-house. If the outside processor is not in regulatory compliance, this fact would be established in the event of a recall and perhaps serve to diminish the regulatory consequences to you. However, from the perspective of the blame chain, it is unlikely that your customers (or their legal counsel) will be as understanding. In any event, the consequences can be mitigated through a combination of contractual language and compliance actions within your own enterprise data system.

Ultimately, an outsourced process is the same as an in-house process. In a classic production model, the outsourced process is simply another step in the production routing in which materials are decremented and then returned to your inventory in some other form. What occurs during the outsourced processing may be known to you, but if the data associated with it is not transparent, you must take steps to mitigate the risk.

As described in preceding sections of this white paper, all data related to passing custody inspections should be available in your system and related to the movement of product. This is especially true when production is outsourced to a vendor. If there are multiple processes provided by the vendor, or the process requires a prolonged period of time, you may need data regarding the product status on a frequent and recurring basis in order to determine product availability and whether you are capable of meeting your promises to your trading partners. Once final production at the vendor’s location is completed and product is returned to your custody, you need to be able to attach compliance-related data to the receipt.

If your vendor uses a highly automated and integrated system, electronic transmission of data at all stages of processing is the most efficient way to handle these information needs. The integration of this kind of data with your software environment is usually very straightforward. While paper systems can also provide the necessary information, they generally provide you with the needed information available far after the fact and may make planning, compliance, and customer service more difficult. Regardless of the method, a careful review of the vendor’s product handling processes and procedures and data recording methodologies is necessary to ensure that traceability is not compromised. Furthermore, make sure that the data you receive is in an immediately useable form. The compliance obligations of the provider should be very clearly spelled out in contract documents. If necessary, there should be language in your contract with the vendor mandating lot identification procedures which support your internal processes and do not compromise your ability to recall product.
OUTSOURCED STORAGE ISSUES
When contract or third party logistics providers (3PLs) are used, there are a number of additional compliance and customer-related issues that can occur.

For example, we see many 3PLs assigning their own internal lot numbers to products provided by others; they then utilize those numbers for warehouse management, material handling, and shipping documentation. When it leaves the facility with their lot identity on the documentation, there is a good likelihood that the customer receiving product may record that number – not yours.

In addition, oftentimes a 3PL does not provide shipment lot information (including your lot numbers) to you on a timely basis, if at all, resulting in you having no idea of what lots were actually shipped. If these situations occur and there is a product issue, you cannot determine which customers might have received the product from the data you have available; you must work through your 3PL to get this information. If you do not have this information immediately available in an accurate form, it is likely that your recall will be excessively broad.

There are other product handling challenges that can occur in your own warehouse, but are magnified when working with a 3PL. A frequent issue occurs with picking product according to the customer’s specifications and your product life rules (FEFO, best before, etc.). Depending upon what information your system generates for order fulfillment, how that information (and in what form) is transmitted to the 3PL, and the manner in which the 3PL provider handles the information and subsequent order fulfillment (including the delivery of shipping information to you), what needs to be shipped and what is actually shipped are oftentimes not the same. Worse, the information that is captured and provided to you may not be correct.

This type of issue can be mitigated through careful consideration of your 3PL provider’s ability to receive, process, and provide turnaround data to you on an automated basis. EDI is often used as the vehicle for this data interaction, as it provides a standardized format and methodology.

Multi-Tenant SaaS Business Model

The SPS Commerce’s outsourced EDI for Microsoft Dynamics. bcFood’s EDI add-on integrates seamlessly with the SPS application, as well as other EDI providers. This approach provides your organization with the benefits of Software-as-a-Service (SaaS) EDI while tying directly into your company’s existing Microsoft Dynamics application.
Just as with an outsourced production vendor, a careful review of a 3PL’s product handling processes and procedures is necessary to ensure that your traceability is not compromised and that you receive inventory, shipping, and receiving data in an immediately usable form. The same contractual requirements noted for outsourced production vendors apply equally to 3PL providers.

CONSIGNMENT INVENTORY

Consignment inventories create some additional compliance challenges that vary based on consignment type. The two types of consignment commonly experienced in the food industry are vendor consignments and customer consignments. When a vendor consigns inventory to your custody, the responsibility for tracking and use of the product is in general no different than it would be if you owned it. Similarly, when you consign inventory to customers, they have these same obligations. However, whenever product is not in your custody, maintaining accurate data can be more difficult.

If you have systems, processes, and procedures in place that ensure your own product compliance, they can typically be applied to vendor-consigned inventory. Depending upon the arrangement with the vendor, you may have to provide specific reporting and tracking data relative to the use and tracking of product, as well as periodic inventory count information.

A common complication of vendor inventories relates to accounting and costing, as you neither want the inventory on the balance sheet nor costs to flow through until you use the product. Many systems cannot address this situation without complex inventory and accounting processes, but it is very straightforward with bcFood software. With bcFood, a purchase order is created for the consigned inventory, which is received in the same manner as any other traceable product. When consigned product is used, all that is necessary is the creation of a partial invoice that is posted against the usage activity. This allows the cost to flow through against the production (or sales) activity and establishes the liability to the vendor for normal payment procedures. It has the additional benefits of resulting in a zero value inventory (received, but not invoiced), complete traceability, and full inventory control functionality (including reporting, cycle counting, and location control).

Setting up a separate location for consignment inventory provides a clear level of segregation between these items and the rest of your inventory. bcFood tools such as the Item Availability Overview page allow users to quickly obtain a picture of inventory within the consignment location.
Customer-consigned inventories create an additional set of conditions that affect compliance and may have other financial impacts. Your ability to accurately track and manage these inventories is highly dependent upon the arrangement with your customer in terms of reporting and control responsibilities. While the inventory is in the customer’s custody and they have a de facto responsibility for proper handling and control, a clear contractual relationship will help ensure compliance.

Regardless of the arrangement, inventories at customer sites are subject to the same control problems that can occur in your own environment. The major difference is that typically you are not aware of discrepancies that occur offsite until well after the fact. Commonly observed problems include differences between the reported quantities on hand and what is physically present at the customer site, unexplained discrepancies at the lot level, and delays in the reporting of missing or damaged product.

If the customer is a manufacturer, lot discrepancies are generally not a concern, as it is the customer’s responsibility for the compliance aspect of product use. However, when the customer is a distributor, this type of discrepancy makes traceability suspect, as it demonstrates that the customer is not able to properly record data. This potentially creates a recall problem because it is evident that the customer is unable to properly record the use of an item lot, and therefore has erroneous data for recall.

Customer consignments are typically set up as a location and shipments to the customer are treated as a transfer between locations. When you receive notification from the customer that consigned product has been used, the transaction is processed as though a sale took place. When physical inventory data is received from a consignment customer, standard inventory adjustments, including lot-related data, are made. Because the transactions all occur at the consignment location, it is easy to use standard reports to evaluate the level of control demonstrated by each customer. The bcFood solution provides a number of additional ways to track this activity and simplify the transactional nature of the consignment inventory.
Full Traceability – Fast, Accurate, and Complete

All of the activities and data described in the preceding sections of this white paper form the basis for compliance and complete traceability, but without a fully integrated system with integral compliance capabilities, the necessary reporting can be a time-consuming and labor-intensive task.

With bcFood and Microsoft Dynamics 365 Business Central, tracing an item backward or forward through all levels of activity is simply a matter of entering the affected lot, selecting the desired trace method (Origin > Usage or Usage > Origin), and executing the trace function. All of the requested data will be immediately displayed and is available for export to a report, Excel, or Word.

Item Tracing allows for tracking finished good lots to the received raw materials through the complete production chain.
Conversely, a raw material can be tracked in the opposite direction in order to find all customers to whom products containing that material have been shipped.

The Item Tracing function provides full backward and forward traceability, making it possible to obtain the entire history of a lot regardless of whether it was sold, consumed as an ingredient, destroyed, disposed, repackaged, or used in any other activity. Additionally, there is instant access to related documents, entries, and lot-related information, including QC results, attached documents such as certificates of analysis, vendor lot information, on-hand information, and expiration data.

Determining where the affected lot is, who has it, where it was used, and its disposition is fast and easy with the bcFood solution and Business Central. Because the lot-related information is always automatically linked to the product transactions within the system, there is no opportunity for compromising data. Unlike many other systems, it is not necessary to implement complex processes or external reporting tools for complete access to compliance data.

When it is necessary to recall or alert customers to issues or concerns with a particular lot or group of lots, it is critical that you be able to perform this action in a prompt manner. A tool like bcFood’s withdrawal feature makes it possible to group together all customers to which a particular lot is shipped and manage the correspondence that is employed to alert them of issues. Combining withdrawals with item tracing ensures that every customer that is impacted at any point along the supply chain can be provided with the necessary information.
When it is necessary to recall or alert customers to issues or concerns with a particular lot or group of lots, it is critical that you be able to perform this action in a prompt manner. A tool like bcFood’s withdrawal feature makes it possible to group together all customers to which a particular lot is shipped and manage the correspondence that is employed to alert them of issues. Combining withdrawals with item tracing ensures that every customer that is impacted at any point along the supply chain can be provided with the necessary information.

bcFood’s withdrawal functionality allows you to manage all correspondence with external contacts that need to be informed of lot issues.
Conclusion

To remain competitive, food and nutraceutical organizations must overcome many challenges, including local and global competitors, increasing regulatory requirements, inventory and resource availability, allocation issues, and operational inefficiencies and constraints. bcFood and Microsoft Dynamics 365 Business Central provide powerful, flexible tools for these organizations to streamline their front and back office operations, maximize the return from their current customer bases, win new customers by becoming an effective and responsive competitor, and quickly react to market shifts.

bcFood is based on decades of expertise in the software and food industry and can be tailored easily with add-on functionality while still maintaining a low total cost of ownership, allowing you to adapt and upgrade with less risk and expense.

Food companies of every size, from small startups to multi-billion dollar organizations, use a bcFood solution every day, in every aspect of their business. The up-front cost of installing bcFood is low, and ongoing costs are minimal due to the stable Microsoft Dynamics platform and SQL Server backend. With virtually no downtime or ongoing maintenance required, IT resources can be directed to other tasks.

Beck Consulting believes that the key to helping businesses be more productive, efficient, and effective is to provide tools and expertise that enable you to focus on the highest-value tasks, maximize your resources and investments, and enjoy a competitive edge. With bcFood and Business Central, Beck Consulting can help food and nutraceutical organizations more effectively implement best practices, communicate within their supply chain and to customers, gain deeper insight into their businesses with real-time information, and more quickly take advantage of new business opportunities.
## Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>3PL</td>
<td>Abbreviation; see Third Party Logistics Provider.</td>
</tr>
<tr>
<td>Advanced Shipment Notification</td>
<td>This is an electronic notification of a shipment in EDI. It is commonly referred to as an 856 document. Typically, the data that is transmitted includes the products’ description and quantities, lot data, customer purchase reference information, carrier, and configuration of shipment. ASNs are frequently required by large trading partners such as Walmart, and inaccuracies in the transmitted data subject the vendor to fines and other charges.</td>
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<tr>
<td>ASN</td>
<td>Abbreviation; see Advanced Shipment Notification.</td>
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<tr>
<td>Batch</td>
<td>Batch is used in many different ways in food and nutraceuticals. Historically, the term “batch” referred to all components or products that are completed at a workstation before being moved to the next one. Mixing is a commonly understood batch determinant, as it involves the creation of a single “batch” from multiple product inputs (ingredients). Because the outputting of separate production batches presents a logical point for lot assignment, it has become increasingly common for the term “batch” to be synonymous with “lot,” implying a unique identifiable output. Depending upon the organization, the terms “batch” and “lot” may be interchangeable, mean different things depending upon context or use, or may always be defined differently.</td>
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<tr>
<td>Bill of Materials</td>
<td>Bill of materials is the term used to identify the various raw materials, intermediate products, components and packaging needed to manufacture an end item (finished good). All bills of materials represent a list of components in a hierarchical manner, with the finished product at the top. Manufacturing bills of materials are commonly used in food and nutraceuticals and may be referred to as “formulas,” “recipes,” or “ingredients lists,” and each may behave differently in terms of the production planning and execution process.</td>
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<tr>
<td>BOM</td>
<td>Abbreviation; see Bill of Materials.</td>
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<tr>
<td>Break Bulk</td>
<td>The process of breaking apart a container (such as a pallet) down into the individual units (such as cases, boxes, or bags) that were stored within it. Break bulk may be performed intentionally as part of a loading or unloading process. It may also be necessary to record unintended break bulk activities.</td>
</tr>
<tr>
<td>Certificate of Analysis</td>
<td>A document issued by a manufacturer, vendor, exporter, importer, or accredited firm or individual (such as an independent laboratory or testing organization) that certifies the quality, purity, and/or adherence to specifications of an accompanying product. It is sometimes known as a Certificate of Inspection in some organizations.</td>
</tr>
<tr>
<td>CGMP or cGMP</td>
<td>Abbreviation; see Current Good Manufacturing Practice.</td>
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<tr>
<td>COA or CofA</td>
<td>Abbreviation; see Certificate of Analysis.</td>
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<tr>
<td>Term</td>
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<tr>
<td>Containment Units</td>
<td>Any type of container that directly touches a food product for interim storage, processing, handling, transporting, or storage. Containment units are generally not, however, the units that are used for packaging. Examples include bins, barrels, trays, boxes, etc. As used in this document, a containment unit exists as a “touch point” for traceability purposes, but is usually not included as part of the final product.</td>
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<tr>
<td>COOL</td>
<td>Abbreviation; see Country of Origin Labeling.</td>
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<tr>
<td>Country of Origin</td>
<td>The originating country for a consumer food product. As regulated by the USDA, packers and processors that supply certain covered commodities to their retail customers must provide Country of Origin Labeling data to those retailers. This information can be supplied in a number of ways, such as including the information on invoices or other transaction documents, providing the labels to the retailer, or labeling the product directly.</td>
</tr>
<tr>
<td>Country of Origin Labeling</td>
<td>The labeling of consumer food products with the country of origin. Labeling can be either voluntary or mandatory, depending upon the item/commodity. See also Country of Origin for additional information.</td>
</tr>
<tr>
<td>Current Good Manufacturing Practice</td>
<td>This refers to the Current Good Manufacturing Practice regulations of the FDA, which require that manufacturers, processors, and packagers of various food and drug products take specific steps to ensure that their products are safe, pure, and effective. Regulations include record-keeping, personnel qualifications, sanitation and cleanliness practices, equipment, processing, and complaint validation.</td>
</tr>
<tr>
<td>Custody</td>
<td>The person, organization, or entity that has the food product under their direct physical control.</td>
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<tr>
<td>EDI</td>
<td>Abbreviation; see Electronic Data Interchange.</td>
</tr>
<tr>
<td>Electronic Data Interchange</td>
<td>The structured transmission of data between organizations by electronic means. Generally used to transmit specific electronic documents, such as a purchase order or invoice, between one trading partner and another. The goal of EDI is to eliminate the use of physical documents and the resultant need for re-entry of data or other data manipulation. As such, it requires a structured set of data in order for multiple systems to understand the information; in North America, the ANSI X.12 standard is used, while the UN/EDIFACT is the international standard.</td>
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<tr>
<td>FEFO</td>
<td>Abbreviation; see First Expired, First Out.</td>
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<tr>
<td>First Expired, First Out</td>
<td>A picking methodology in which product with an earlier expiration date is picked for inclusion on a shipment, as part of a production activity, or any other sort of usage ahead of identical products that expire at a later time. FEFO picking is common in environments that deal primarily with perishable products, such as food, as it ensures that items are used before they expire.</td>
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<tr>
<td>Term</td>
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<tr>
<td>Formula</td>
<td>A formula is a bill of materials that defines the relationship of each ingredient as a percentage of the BOM as a whole. Because key attributes of a given ingredient may vary on a lot-by-lot basis, a formula-based BOM system must have the ability to dynamically change an ingredient’s percentage based on user-defined rules.</td>
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<tr>
<td>HACCP</td>
<td>Abbreviation; see Hazard Analysis &amp; Critical Control Point.</td>
</tr>
<tr>
<td>Hazard Analysis &amp; Critical Control Point</td>
<td>A process established by the FDA/USDA for pharmaceutical and food processing in order to prevent foodborne illnesses. HACCP is used in the food industry to identify potential food safety hazards so that key actions, known as Critical Control Points (CCPs), can be taken to reduce or eliminate the risk of the hazard realization.</td>
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<tr>
<td>Hold</td>
<td>Any type of action that prevents a product or product lot from moving from one processing stage to the next. Common reasons for placing a product on hold include inspection, testing, re-processing, or quality failure.</td>
</tr>
<tr>
<td>Integrated System</td>
<td>An enterprise-wide information structure that includes all of the functional processes within the context of a single system. This may include multiple programs, but is characterized by the sharing of common data, no re-entry of information from one application to another, and consistent data in all modules of the application.</td>
</tr>
<tr>
<td>Lot</td>
<td>A lot is a set of product units that have been produced, processed, or packaged under similar circumstances. A lot may be measured as a single unit of product, but is oftentimes comprised of multiple units. The identification of a lot is established beforehand by organizations using a consistent and documented method of determining the lot numbering or coding system. A lot code refers to a unique series of letters, numbers, or a combination of both, by which any food or drug can be traced in manufacturing and identified in distribution.</td>
</tr>
<tr>
<td>Machine Center</td>
<td>Machine centers are the lowest level of a facility in the production hierarchy and represent a machine, a group of machines with identical characteristics, a person, or a group of people. The extent to which machine centers need to be defined can be determined by the user, but usually only those resources that need to be monitored, or tend to be bottlenecks, are designated as machine centers. When a production order is scheduled to a machine center, it consumes that machine center’s capacity, reducing availability. A machine center is measured only in terms of its own capacity, since there are no facilities beneath it in the production hierarchy. Multiple machine centers can comprise a work center (see Work Center). Overhead and other production-related costs can be applied through the machine center. Additionally, as used in bcFood, a machine center allows for the definition and recording of capacity, queues, setup, wait and move times, scrap amounts, min/max process times, and more advanced scheduling functions. A machine center is often a data collection point for traceability or HACCP purposes.</td>
</tr>
</tbody>
</table>
Material Handling Unit

In bcFood, a material handling unit represents product(s) aggregated in such a way as to facilitate physical handling and tracking. A typical aggregation is the palletizing of product, in which products are grouped together on a pallet. The contents of the pallet must be tracked within the four walls of the organization, but the pallet and its contents do not constitute a selling, production, or costing unit of measure. As a result, it necessary to utilize a material handling unit for the purpose of recording physical movements. Every material handling unit must be uniquely identified, as the contents of the unit may have individual product/lot identities. The material handling unit represents a convenient way to accurately track product without having to take extra steps.

MHU

Abbreviation; see Material Handling Unit.

PLC

Abbreviation; see Programmable Logic Controller.

Primary or First Stage Food Processor

As used in this document, a primary or first stage food processor is one who handles or processes food that has come directly from the farm, field, ranch, or other growing environment. The end product of this processing may be either a retail or end-user package or an intermediate package that is used in some other type of food processing by another entity (see Secondary or Second Stage Food Processor). Primary food processors often have more traceability issues due to seasonality, volume, and equipment factors.

Programmable Logic Controller

A form of computer used to automate electromechanical processes on machines in production environments. These typically connect to sensors or actuators which can provide electronic data to the production software, such as bcFood, for tracking values such as input, output, temperature, flow, and machine cycles. PLC vendors typically provide the software needed to interface their equipment with enterprise software. Third party vendors also provide interface software that can interact with multiple PLC devices.

QA

Abbreviation; see Quality Assurance.

Quality Assurance

Quality assurance is a systematic process designed to ensure that manufactured products meet or exceed customer and regulatory requirements. Depending upon the product(s), quality assurance may include testing, inspection, and statistical control. In an automated environment, quality assurance can be defined as a number of checkpoints in the production process that represent “pass/fail” points, based upon the inputted results of testing and inspection.

Recipe

A recipe is a bill of materials that is similar to a formula in how it is used in food processing. The formula concepts may or may not apply to a recipe. The typical difference between a formula-based and a recipe-based production process is that a formula lists the necessary ingredients and their quantities, while a recipe provides this ingredient information along with a set of preparation and processing instructions.
Routing

A routing specifies the sequence of operations needed to manufacture a product. Each operation can be performed at a work center or at a machine center (also referred to as capacities or facilities). Manufacturing companies use routings to manage the production process. Routings should always include any procedures performed by outside parties in which the custody of the product changes hands (such as sterilization or packaging), as these represent traceability control points, and the related data must be available for required documentation.

Secondary or Second Stage Food Processor

As used in this document, a secondary or second stage food processor is one that uses food products processed by others (i.e. ingredients), and produces another product that is typically packed for retail or end-user use. A food processor may be both a primary and a secondary processor.

Testing

As used in this document, this term refers to all types of testing, including measurement, sampling, chemical and biological testing (whether performed in-house or by third parties), data collection (either manual or through PLC interfaces), and destructive testing. The resulting data can be attached to the specific stage of the production process at which testing occurred and automatically related to the lot and traceability data.

Third Party Logistics Provider

An organization that provides outsourced supply chain services of various types. Typical services in the food and nutraceutical industries include warehousing, order fulfillment, and transportation.

Traceability

Traceability is the recording of product movements at every step of the production and distribution process, along with any data related to instances where an issue of contamination arises and a recall may be required. Good traceability capabilities make it possible to identify, by precise date and location, which goods must be recalled, and which are safe, potentially saving millions of dollars in the recall process. Traceability within the food processing industry is also utilized to identify key high production and quality areas of a business versus those of low return, as well as which points in the production process may be improved. Traceability both up and down the supply chain is required by law and regulation. The bcFood application provides users with an instantaneous 360° view of all levels of product.

Work Center

Work centers are specific locations in which work can be performed. Work centers might be set up for machines, groups of machines, or groups of people. Work centers are used in production routing and capacity planning. Production orders are scheduled to work centers through routings (described above). Work centers may also include machine centers on a discrete basis, or roll up the machine centers when determining availability. Typically, the machines or people within a work center perform similar tasks. A work center is often a data collection point for traceability and HAACP purposes. As used in bcFood, a work center can also be used to apply overhead, define capacity, apply a work calendar, and establish queue times.
Appendix – bcFood & Microsoft Dynamics 365 Business Central

A FLEXIBLE, SCALABLE PLATFORM
bcFood for Microsoft Dynamics 365 Business Central has built-in flexibility and scalability to help food and nutraceutical companies expand operations or extend their solutions. The layered solution architecture enables businesses to enhance one tier without affecting functionality on others, while providing a robust and integrated development environment that enables you to adjust your system as business needs change.

MAXIMIZING IT INVESTMENTS
With bcFood and Business Central, users can count on a familiar interface - one that not only looks and performs just like other common Microsoft applications, but is integrated with these very products, allowing users to utilize the capabilities Microsoft Office’s Excel, Word, and Outlook. Synchronization with external applications, such as web sites, and mobile connectivity is an inherent capability with the Microsoft Dynamics Server and External Connector functionality. Close integration with Microsoft SQL Server and its reporting services, Microsoft SharePoint, and other powerful Microsoft technologies can help you maximize existing IT outlays.

FASTER RETURN ON YOUR INVESTMENT
bcFood and Business Central provide a quick return on investment. Clients routinely report 100% payback in as little as 14 months, and most have achieved that level within two years of use. The most significant returns are in the area of responsiveness to customer requirements, general user productivity, better decision-making, and inventory control.
Comments & Feedback

The views, opinions, and conclusions contained in this document represent the experiences and observations of more than 200 years of combined experience with systems design, implementation, and project management in the food and nutraceutical industry.

Your comments and feedback will expand the scope of our knowledge, helping us to improve upon the information in subsequent versions of this document.

You can send comments to food@beckconsulting.com or contact us at 800-456-8474.

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