

Product Traceability in the Age of the Food Safety Modernization Act

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ABSTRACT

In the age of the Food Safety Modernization Act (FSMA), if hazard analysis identifies a hazard requiring a preventive control, the facility must have a written recall plan describing the procedures to perform a recall of the product. At the heart of this prerequisite lies the ability to perform product trace one up to customers one back to suppliers (one up/one back) which were lacking, resulted in the mountainous paper trail with convoluted records, and long mock recall sessions. With limited product trace, the scope of potential product implicated in mock recall sessions could cripple brand and business in real recall sessions. Of such, a real-time product trace approach was sought using purchase order numbers. While unique to each company, purchase order numbers once issued has quantity, description, date, and time tied to each issued number, a good candidate for such task for bulk handling process. Customer issued purchase order was paired with internal purchase orders issued to suppliers and vendors. Supplier/vendor-issued purchase order number was paired with internal issued numbers, resulted in one of four methods to retrieve full history using customized user interface: the customer purchase order number, the supplier/ vendor-issued purchase order number, internal purchase order number, or date range. Results produced in seconds compared to the former approach of hours and days. Significantly reduced the gap and scope of the potentially impacted product. The approach successfully demonstrated in regulatory, customer, internal, and voluntary audits such as Safe Quality Food Program (SQF) since implemented March 2019. If the employee failed to move raw material to the customer sales order by scanning, or manually if scanner inoperable, then product trace would be lost, and of such, controls implemented to ensure orders cannot be closed without accountability. Time saved now focuses on further improving the process, customer, and supplier relations.

Keywords: Product trace; Recall; Food Safety Modernization Act (FSMA); Safe Quality Food Institute (SQFI); Purchase Order Numbers (PO); Date range; Ease of use; Bulk handling

INTRODUCTION

The Food Safety Modernization Act (FSMA) mandates, "if the hazard analysis identifies a hazard requiring a preventive control, the facility must have a written recall plan that describes the procedures to perform a recall of the product" [1,2]. There have been many recalls affecting the food industry whether for potential pathogens, such as *Listeria* and *E. Coli*, to foreign material [3,4-6] and the list goes on. At the heart of this directive lies the ability to trace one up to customers, one back to suppliers (one up/one back). Having a product trace system or method that can accurately capture implicated product(s) to the source goes a far way in lessening the potentially crippling impact to brand and consumers while driving preventive control at the source. While overarching, the ability to perform product trace not limited to the Food Safety Modernization Act, and of such, the requirement consistently

demonstrated in annual regulatory audits such as United States Department of Agriculture (USDA) Organic; Animal and Plant Inspection Service (USDA APHIS); third party audits such as SQF [7,8-11], customer, and internal audits.

Purchase orders have been in existence for as long as there existed businesses, generated by the customer to authorize a purchase transaction. Defined as legally binding, it ensures invoices get processed as quickly as possible [12]. This number gets communicated for each purchase of raw material. To produce in the manufacturing setting, suppliers also issue a purchase order number. Both numbers while tend to be very different in sequence and format have the date, time, type of raw material or finish product, and quantity tied to each number. Both numbers also go through a full independent cycle.

When purchasing raw material, the purchase order gets issued to

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Chambers DA, et al.

the supplier/vendor. Suppliers are the main source, while vendors might source from another source and supply such as brokers. In the event a vendor would be involved, another purchase order tends to be involved, and of such, these two purchase orders are paired. Order gets filled on date and time, with the type and quantity of raw material needed for production. An invoice accompanies raw material being supplied, and the difference between quantity and quality received versus ordered gets ratified in paying vendor/ supplier, which would be one complete cycle. Quality was mentioned as in the event raw material not meeting the highest safety and agreed quality standards will be rejected. The same cycle exists with finish goods where customers issue purchase order number, order filled and shipped, and the difference between what was ordered and shipped gets ratified for the customer to make payment. What's missing, the communication between customer issued purchase order, internally issued purchase order, and supplier/vendor number once issued.

Being a bulk handling operation made it practical to pair these numbers in addressing product trace where only one number would be needed to retrieve full history one up to customers, one back to suppliers which have been working and so far used in several audits, regulatory, and voluntary. None of the listed objectives for this approach revolved finding a novel method, but it was very important to ensure business flow not impeded in any way while improving the overall process. As such, the system implemented further sought to considerably reduce training time by customizing an interface to Enterprise Resource Planning systems (ERP) [13] with functions specific to users at the point of use in operation capturing their required task, limiting data input, forcing as much as a possible selection from the dropdown list of what's available, thereby reducing errors; but most importantly, organize both raw material orders, and customer orders in First In First Out (FIFO) [14], to ensure raw materials are received and handled on time in best possible condition; whilst ensuring customers receive their orders Just in Time (JIT) [15,16], with highest possible safety and quality standards adopted through SQF, Organic, APHIS certifications adhering to customer specification.

MATERIALS AND METHODS

- 1. A custom user interface was designed merged on an existing ERP platform called PRIMS provided by Focus Works [17] with the process and user at the forefront
- 2. While the system can operate independently, it can also be merged with other ERP systems. To achieve this, an integrator was created
- a. Integrator allows the purchase order number, material, quantity, date, time, and price to remain the same from one

system to the next

b. Information flows one way from system to system when used integrator; therefore, finances can be kept on separate systems as desired

Product trace exercise

- 3. In the first test, a random customer-generated purchase order number was entered into a customized ERP System and generated full history in seconds of raw material used to produce customer order, date and time it was used
- 4. In the second test, a random supplier/vendor purchase order was entered in the system and generated results in seconds providing a full history of all customer orders that material from that supplier/vendor purchase order created
- 5. In the third test, date range was selected, and a huge report was generated in minutes with all raw material purchase order, and all customer sales order (the wider the date range, the more time required to generate results)
- a. Date range results were converted from PDF document to excel for sorting
- b. Once filtering was set for an excel file, the report was much easier to navigate
- 6. In the fourth test, purchase orders from another system were transposed to the customized system, both customer and supplier/vendor purchase orders in separate tests. These purchase order numbers were used to retrieve full history
- 7. Results generated from all approaches were compared to expectation by adding up totals and looking for gaps
- 8. When all bulk raw materials scanned to the customer purchase order, 100% product trace was achieved meeting the scope of the project

RESULTS AND DISCUSSION

The use of purchase order numbers for product trace presented several opportunities to have employees focus on numbers they are already using with significance. While lot numbers are active, reported, and may be used, they are not needed by the user to retrieved full history. In the event a supplier should call notifying of concern with material such as potential chemical contamination from the cleaning agent, once the supplier provides a purchase order number, the team can quickly isolate all customers where material from that purchase order was used to create. If suppliers only have a date range, again all potential customer orders that may have been impacted can be isolated. In either case, notify customers

Table 1: Product trace using a system-generated purchase order to the supplier.

Raw material for production								
Chose	en PO: 2920 P	O Date: 9/23/2	019					
Suppl	ier PO: DAC1	0918						
Lot	Date Time	Material Code	Material name	Trailer PO Num.	Customer Customer PO Num.	Pounds received	Pounds used	
1266	09/23/2019 15:32:00	6110	Organic Fresh Chicken Back	DAC1231TEST 2920	DAC1 DAC92319	300.00	300.00	
1266	10/22/2019 09:31:00	6110	Organic Fresh Chicken Back	DAC1231TEST 2920	DAC1 DAC92319	51.00	51.00	
Total						351.00	351.00	

Chambers DA, et al.

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to initiate a recall on applicable purchase order numbers if the product already at their locations. See an example of a product trace that started with the supplier purchase order (Table 1).

The date and time being reflected confirmed when the material was used to create a customer purchase order. The raw material name provided, transport that carried that raw material to the site; a system generated purchase order number which could have been used to retrieve the same report, the customer and the purchase order provided by the customer, pounds of raw material received and used being a bulk operation. Notice, yield loss of raw material not captured which would be areas for improvement; nonetheless, being a bulk handling operation, this report demonstrated that all raw materials received created specific customer orders.

Whether the supplier, vendor, or customer initiates a date recall, the report would be standard but arranged differently (Table 2).

Notice this report started with a date range. It provided the date and time raw material was used, the material name, trailer number transported raw material to the site, with system generated purchase order; next, it provided the supplier, the customer where the material was used, the pounds received and pounds used. Totals would be reflected but the report had to be edited to ensure only generic supplier and customer showed. Again, yield loss not captured.

Product recall initiated by the customer would again have a standard layout, arranged differently (Table 3).

Notice this report stated with customer purchase order number, date, and time raw material was used to create order, raw material name, trailer number, and system-generated purchase order number, supplier, pounds received and used to create the customer purchase order. Again, yield loss not captured.

Notice, at no point were either supplier or customer numbers altered in any way, they were simply paired allowing the ability to quickly tell what raw material was used to create what finish product and how much, being bulk handling with the continuous process and limited batching. This approach eliminated huge paper trail with convoluted records, not depended on handwritten data, missing date, and time of use. System designed with logs to know who did what thereby not depended on someone writing their names as each user must log in to process with their username and password. While the system does not prevent users from sharing passwords thereby logging on to the system, the management team can hold users accountable as necessary with log history.

The first limitation to tackle was to ensure all raw material purchase orders scanned or moved to customer orders. In the prior system, the scanner used for inventory management; when the scanner became inoperable, numerous concerns raised with gaps evident during audits depending on the huge paper trail with convoluted records. Consequently, a simple manual workaround was created with a customized system whereby should scanner failed, users could easily move raw material to customer order; and was demonstrated that once users scanned or move raw material to customer order, product trace guaranteed. It was further set up that to start taking customer orders out the system for shipment, at least one raw material order must first be scanned or moved to customer order; with dependence on line managers to ensure all raw material tickets got scanned or moved. The next limitation, while there existed no reason to not scan or move raw material to customer order, the team could miss tickets and of such, reconciliation for customer order required accounting for all raw material used. Additionally, controls built-in system for user accountability with a detailed log of key activities.

To further aid accountability and provide visibility on the raw material that may have been missed, not scanned, or moved to customer order, a bulk inventory monitoring report was introduced which complimented product trace report (Table 4).

This report shows exactly how much raw material was received on each purchase order if any was internally rejected for safety or quality concerns, totaled raw material used by scanning or moving, and if not used, the amount in inventory. The understanding shelf life of raw material, this report retrieved by date range and of such vital in ensuring raw material consumed within shelf-life; thereby aiding product trace.

The system was designed to flag expired raw material and organized all raw material and customer orders in First in First Out (FIFO).

Table 2: Product trace using a date range.

	Raw Material for Production From: 09/23/2019 To: 9/23/2020								
From:									
Lot	Date Time	Material Code	Material name	Trailer PO Num.	Supplier Supplier Customer PO Num. Customer PO Num.	Pounds received	Pounds used		
1266	09/23/2019 15:32:00	6110	Organic Fresh Chicken Back	DAC1231TEST 2920	DAC10918 DAC1 DAC92319	300.00	300.00		

Table 3: Product trace using customer issued purchase order number.

	Raw material for production								
Chosen Customer PO: DAC92319 Date: 9/23/2019 Customer: DAC1									
Lot	Date Time	Material Code	Material name	Trailer PO Num.	Supplier Supplier PO Num.	Pounds received	Pounds used		
1266	09/23/2019 15:32:00	6110	Organic Fresh Chicken Back	DAC1231TEST 2920	DAC10918	300.00	300.00		
1266	10/22/2019 09:31:00	6110	Organic Fresh Chicken Back	DAC1231TEST 2920	DAC10918	51.00	51.00		
Total						351.00	351.00		

Table 4: Visibility of raw material consumption to enhance product trace audits and inventory monitoring.

Raw material for production									
From: 08/23/2019 To: 9/23/2020									
PO Number	Supplier PO (Optional)	Supplier	Raw Material	Received (lbs)	Rejected (lbs)	Used (lbs)	Inventory Not scanned to load on Production Floor		
2920		DAC10918	Organic Chicken Back	300.00	0.00	300.00	0.00		
670		DAC10918	Fresh Chicken Frames, Fresh Chicken Backs	426.00	0.00	426.00	1.00		

Having spent over three years developing this program, performed hundreds of tests per-implementation, and continuously after implementation, the results could be considered accurate once all operators do their part as the weights were constantly checked for gaps comparing total pounds received versus total pounds used. No matter how effective a system may be, that buy-in from everyday users cannot be taken for granted. Each layer of control implemented has been met with understandable pushbacks and of such, each round of controls implemented had been methodologically applied, getting continued team support at each level, and adjusting where necessary.

CONCLUSION

The purchase order approach to product trace in the age of the Food Safety Modernization Act proved a winning approach for intended operation as successfully demonstrated in regulatory and voluntary audits. With reduced recall time, better visibility, and ease of use of overall system ratified by operators of the system, controls implemented continue to produce expected results.

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