Combinatorial Effects in Supply Chain Processes

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Abstract. With the technology evolving every day and with the increase in global competition, industries are always under the pressure to be the best. They need to provide good quality products at competitive prices, when and how the customer wants them. They need to do all this within a very restricted evolving regulatory rules and guidelines.

Since industries are living in such a dynamic environment that is constantly evolving and changing, they have to make sure that their products and/or processes are flexible and evolvable as well.

The goal of this paper is to give some examples on why the business processes in a supply chain may undergo changes, what are the drivers behind those changes, how those changes impact other processes in the chain and how it may have a combinatorial effect on more areas of the business.

This paper will not prove that those changes also impact the software and databases that controls those processes, although they do to a great extent.

1 Introduction

In this paper we will focus on Business Processes of a manufacturing industry; specifically Supply Chain Management (SCM) processes.

"A business process or business method is a collection of related, structured activities or tasks that produce a specific service or product (serve a particular goal) for a particular customer or customers. It may often be visualized as a flowchart of a sequence of activities with interleaving decision points or as a process matrix of a sequence of activities with relevance rules based on data in the process." [2]

We can represent an organization with a set of flowcharts that describes the activities of different areas of the company in blocks linked and interconnected together.

Those processes are mapped into a software information system "..those information systems capture, store, process and distribute information regarding an increasing range of aspects of organizations on the operational, tactical and strategic levels." [1]

Hence in this paper we are giving examples to show how processes in a supply chain evolve and undergo changes continuously, driven by requirements to improve the product and/or to be compliant with governmental regulations. Also we want to demonstrate on how those changes impact other processes in the chain and how it may have a combinatorial effect on more areas of the business.

1.1 Definitions

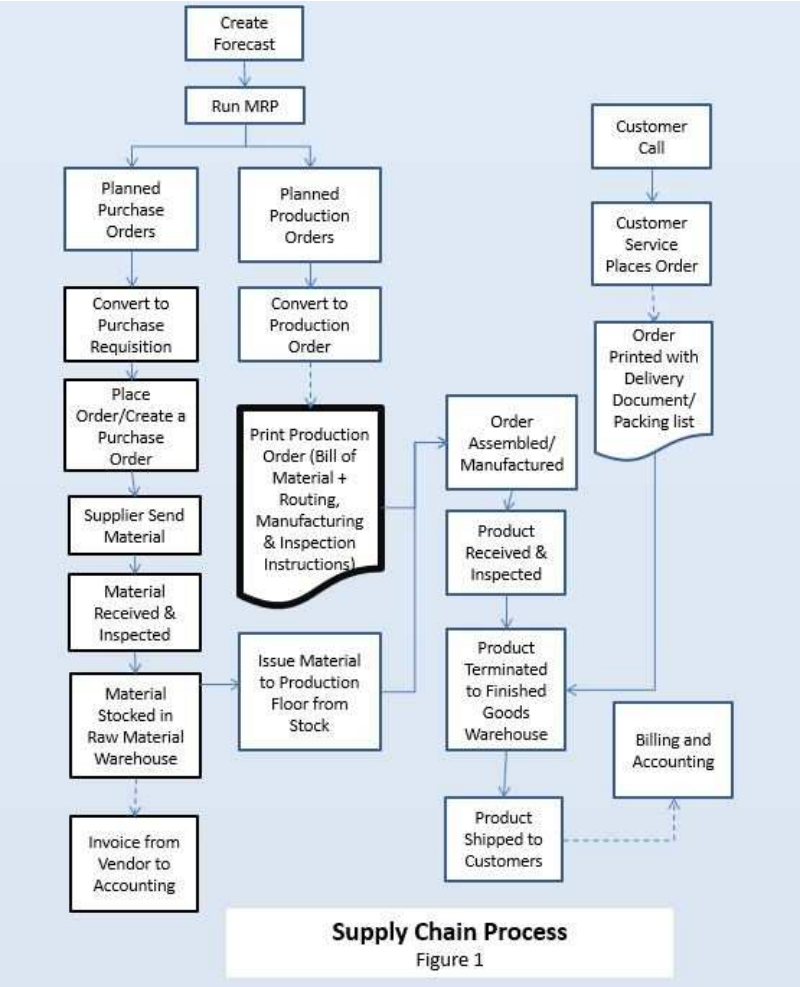
Evolvability: "..evolvability at the business process level; the capability of a modular business process design to adapt to identified change drivers, which requires the absence of so-called combinatorial effects at the business process level." [5]

Combinatorial effect: "..is caused when a change that is imposed on a system has an impact that is not only proportional to the nature of the change, but also proportional to the size of the system on which it is imposed." [6]

1.2 Supply Chain Management

The following models are based on the personal professional experience of the first author and he is ready to validate them with other experts of the industries.

As can be seen in figure 1, a supply chain process starts with a forecast which triggers a requirement to purchase and/or to produce.



Supply Chain Process
Figure 1

For the purchasing flow, a planned purchase order is created which is converted to a purchase requisition and then to a purchase order. The purchase order is placed/sent to vendors who prepare products/materials and ship them to the organization.

The materials then are received, inspected and then stocked in raw material warehouse. The organization then processes payments through its accounting department.

As for the production flow, the planned production orders are converted to production orders. Then released/printed into a production order packet, as represented within the bold frame in figure 1 and as will be discussed later in detail in figure 2. After the materials are issued to the manufacturing floor and the finished products are assembled/manufactured, following the production order packets instructions, they get inspected and terminated to the finished goods (FG) warehouse. Products in the FG warehouse are packed and shipped to customers when a customer sales order is received. Finally, accounting will invoice the customers and collect payments.

1.3 Drivers Behind Evolving Processes in a Supply Chain

Listed below are some examples why companies change their business processes:

1.3.1 Improvements Manufacturing firms change their processes to improve their gross margins, by reducing the cost of their products or to better the quality of their products for competitive reasons.

Manufacturers try to improve their tooling, automate the manufacturing processes and minimize scrap by using more precise equipment or adding online Statistical Process Control (SPC) machines to monitor the consistency of production and captures inconsistencies as early as possible.

Sometimes manufacturers modify their products to introduce a better new version because of either a market requirement to stay competitive and/or due to customers' feedback.

1.3.2 Regulatory requirement: A good example will be the Food and Drug Administration (FDA) or European Food Safety Authority (EFSA). Those organizations monitor most products in USA and Europe and accordingly come up with rules that may force manufacturing companies to change their processes, for example:

- New rules: New regulations can be added when a loop hole in the system is found
- Tighter processes and inspection: For instance, when there is a failure in a product or a label issue that caused damage or life loss, organizations need to demonstrate that they took the right measurements to forbid this from happening again. An example of those measurements can be a recall of the faulty products from the market and/or changing the processes for the issue never to happen again.

We will use the above examples to demonstrate how some of the SCM processes evolve because of those drivers.

2 Case Study

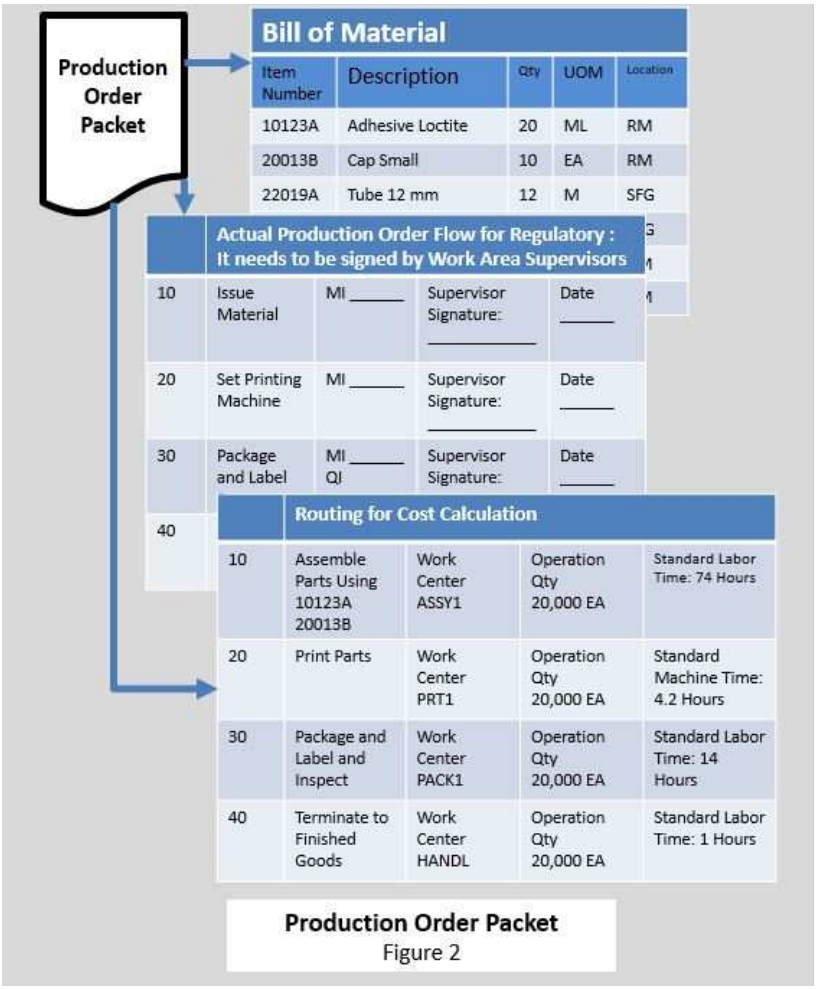
We chose two cases/examples below to demonstrate that the processes in a supply chain system are always evolving due to the two drivers: improvements and regulatory requirements.

2.1 Case 1: Changes to the Production Order Packets:

This case will be describing a production order packet which is a part of the SCM as shown in the bold block in figure 1. It consists of a bill of material a routing and a production order flow sign off sheet.

After looking at the order packet we can notice that any changes on the product, the process or instructions will have a combinatorial effect on many processes and master data.

2.1.1 A Production Order Packet consists of a bill of material (BOM), a production order flow sign-off sheet, to be approved by production supervisors, and a routing as shown in figure 2 below. This is the bold frame section of figure 1.



Production Order Packet
Figure 2

2.1.2 Bill of Material As per example in Figure 3, we have a bill of material A, which consists of two sub assemblies B and D and another material C. The bill of material of B also consists of two materials E and F while D consists of material G only.
When the bill of material becomes a part of a production order packet, then it contains a list of all

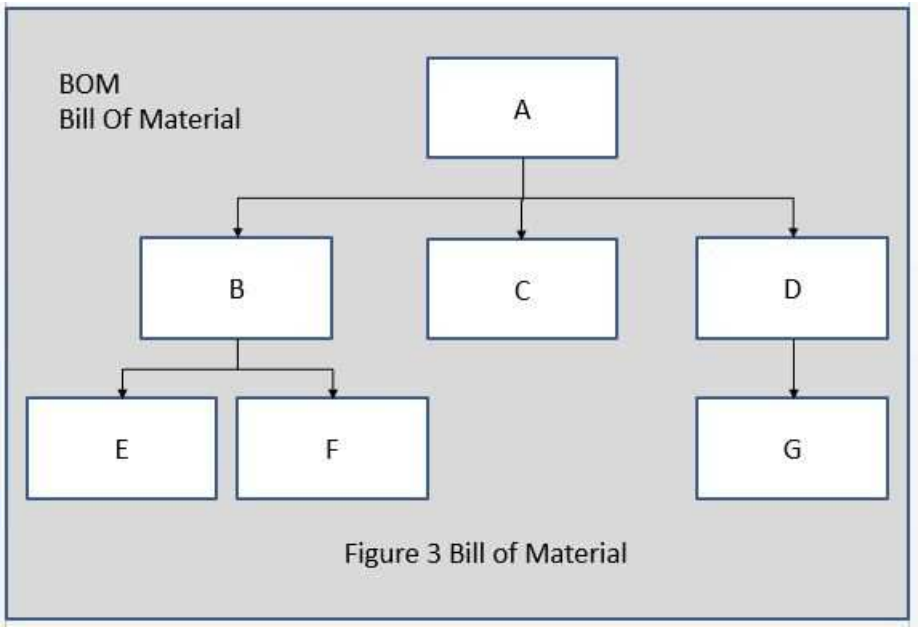


Figure 3 Bill of Material

the materials that make the product with their respective material numbers, description of materials, quantities needed to build and assemble the products per the quantity of the production order, location in which the material is stored and other fields not mentioned here. Please refer to figure 4 below.

Bill of Material

Item Number	Description	Qty	UOM	Location
10123A	Adhesive Loctite	20	ML	RM
20013B	Cap Small	10	EA	RM
22019A	Tube 12 mm	12	M	SFG
23654C	Container	12	EA	SFG
22245C	Wire 15 mm	12	M	RM
23651F	Label	1	EA	RM

Figure 4 Bill of Material

2.1.3 Routing Contains the operations with their respective work-centers, to build a product, and their corresponding standard (labor and machine) hours. This is used for cost calculations. Those numbers are compared to actuals by the system and hence the variances are calculated. Also it captures the overhead of a work-center. Please refer to figure 5 below.

	Routing for Cost Calculation			
10	Assemble Parts Using 10123A 20013B	Work Center ASSY1	Operation Qty 20,000 EA	Standard Labor Time: 74 Hours
20	Print Parts	Work Center PRT1	Operation Qty 20,000 EA	Standard Machine Time: 4.2 Hours
30	Package and Label and Inspect	Work Center PACK1	Operation Qty 20,000 EA	Standard Labor Time: 14 Hours
40	Terminate to Finished Goods	Work Center HANDL	Operation Qty 20,000 EA	Standard Labor Time: 1 Hours

Figure 5 Routing

2.1.4 Sign-Off sheet This defines the production order logistics and actual flow of the product as it has been manufactured. It is a regulatory requirement. It includes the manufacturing instructions (MIs) and quality instructions (QIs) used. Supervisors sign their operations/work-centers indicating that the operation was completed with the right quantities as per figure 6 below.

	Actual Production Order Flow for Regulatory : It needs to be signed by Work Area Supervisors			
10	Issue Material	MI _____	Supervisor Signature: _____	Date _____
20	Set Printing Machine	MI _____	Supervisor Signature: _____	Date _____
30	Package and Label Box	MI _____ QI _____	Supervisor Signature: _____	Date _____
40	Terminate to Stock	MI _____	Supervisor Signature: _____	Date _____

Figure 6 Signed Production Order Flow

The processes in a supply chain system keep on evolving constantly due to improvements. For example as seen in figure 7, if a manufacturing process changes because a new machine is bought to print and pack products at the same time, instead of two steps. A new work-center is created PRPACK to replace the two work-centers PRT1 and PACK1, where PRT1 was used to print labels and PACK1 was used to package products.

Hence the routing needs to change by replacing the two operations 20 and 30 by one operation as shown in figure 7. This work-centers change will also trigger the manufacturing instruction and the quality inspection to change. This may affect thousands of routings to be changed for the different values of the new machine for similar products.

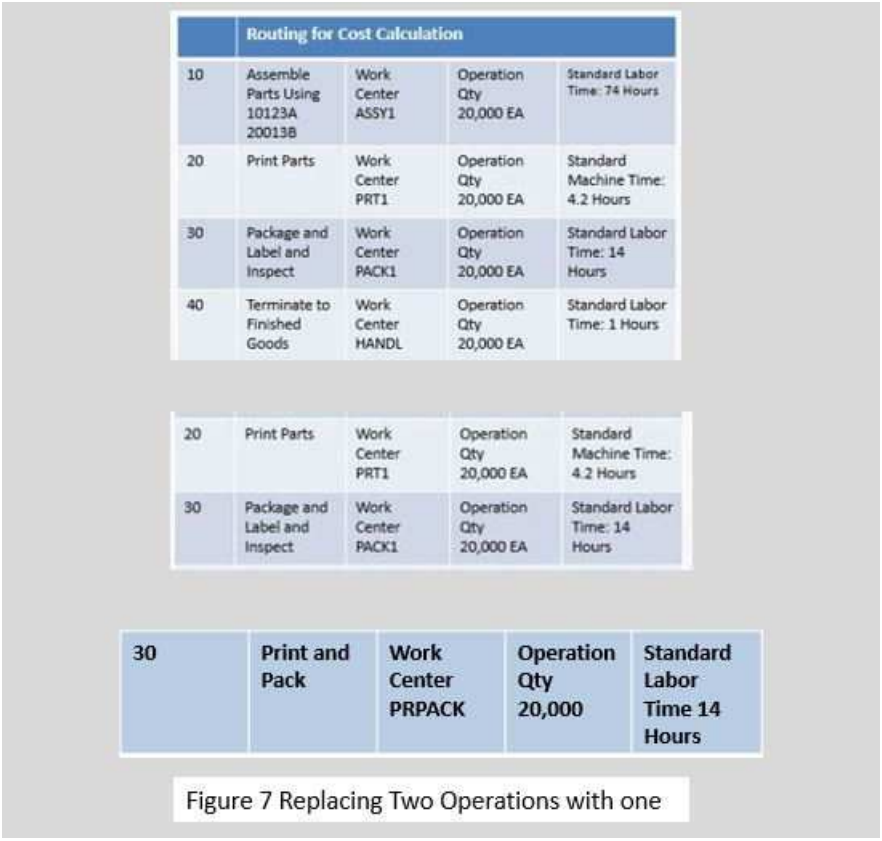


Figure 7 Replacing Two Operations with one

Such a change represents a tremendous effect on the supply chain information system and data bases and a combinatorial effect on other processes too.

2.2 Case 2: Changes to the FDA Regulations

Case 2 involves a warning from the FDA about some allergic effect of latex material on some humans. We will start presenting the case with some definitions about the product that got impacted by some FDA regulations.

2.2.1 Catheters are: "..medical devices that can be inserted in the body to treat diseases or perform a surgical procedure. By modifying the material or adjusting the way catheters are manufactured, it is possible to tailor catheters for cardiovascular, urological, gastrointestinal, neurovascular, and ophthalmic applications." [2]

2.2.2 Catheter Embolectomy procedure is typically done: "..by inserting a catheter with an inflatable balloon attached to its tip into an artery, passing the catheter tip beyond the clot, inflating the balloon, and removing the clot by withdrawing the catheter. The catheter is called Fogarty, named after its inventor Thomas J. Fogarty." [2]

2.2.3 FDA issuing Latex related warnings Some of the catheters were made of a material called Latex, until the FDA started issuing warnings related to Latex. "Latex Allergy: Issue: Cases of sudden

death associated with the use of barium enema kits were reported to the FDA in 1989 and 1990. In some instances, the reported incidents occurred prior to the introduction of the barium solution."[3]

This was an alert to industries dealing with Latex products, like catheters, gloves, condoms etc. Some industries started proactively searching for alternative material to latex because they realized that a can of warms just had been opened. A race had just started. This will not stop here, especially when the market knows about it, so the sooner dealing with that issue the better.

2.2.4 What does searching for an alternative mean? Searching for an alternative in a manufacturing firm means a new project will be created and given to the Research and Development (R and D) department and the engineering team will start searching for a new material to replace latex that has the same characteristics and specifications of latex. Then they will test and qualify the new material.

After the new replacement material is qualified, products are built with the new material, which for some companies can be tens of products that contained latex before. The products with the replaced material are registered; then clinical and field testing starts. Those testing involves sterilization testing, aging testing and actual surgery testing.

When all the tests pass, then new processes to manufacture the material and products with the new material are established. As an example a new sterilization method, new manufacturing instructions (MIs), new quality instructions (QIs), routings, bill of material (BOMs) and Standard Operating Procedures (SOPs.) Those modifications will create a combinatorial effect since a product is made of sub-manufactured products that may change too. So changes will not stop at one level, they will ripple to lower levels of the products as per figure 3.

With the above modifications of the BOMs, MIs, QIs, routings and processes the information systems attached to those modules get impacted too. They get impacted in a combinatorial effect, but as mentioned before that this paper will not discuss those changes here.

As a part of changing the products with a new material that replaced the latex and from a marketing perspective, some companies modified the Labeling of the products by adding, Latex Free to the labels. After getting all the approvals, including the FDA and/or International approvals like the EFSA, the product is released to production with the new material. Just as a note here that the above changes takes years of hard work between all departments of an organization to implement.

2.2.5 What happened next? In March 2015 FDA issued a Consumer Health Information (CHI) stating that: "If youre allergic to natural rubber latex, FDA has good news for you: in the future, you are less likely to be misinformed about the absence of this allergen in such products as medical devices. To avoid false assurances about this hazard to your health, FDA is recommending to manufacturers to stop using the labels "latex-free" or "does not contain latex"." [4]

"..At this time, there are no regulations requiring a company to make any labeling statements when natural rubber latex is not used as a material in the manufacturing of a medical product. However, some manufacturers have included such labeling statements as "latex free" or "does not contain latex" in their labeling. FDA believes that these labeling statements are not sufficiently specific, not necessarily scientifically accurate and may be misunderstood or applied too widely. Therefore, it is inappropriate to include such statements in medical product labeling. Statements such as "latex free" are not specific about the type of latex involved and can cause confusion. Not all types of latex are from natural rubber and contain the proteins responsible for natural rubber latex allergy. For example, products containing nitrile and polyvinyl chloride are made of synthetic latex that does not

contain those proteins and will not cause a latex allergy. Further, these statements do not account for the potential for accidental contamination of the medical product with natural rubber latex allergens during manufacturing or packaging."[4]

The above new issued Consumer Health Information again triggered another labeling project. That involved the following changes mentioned in section 3.1, regarding the changes related to the shop order packets, another huge combinatorial effect took place:

- New Labels/Products had to be designed with a new drawing and a new material number/description
- Bill of Material/Product had to be changed for all products that had a Latex Free material number assigned to them
- Possibility of MIs and/or QIs had to be changed

3 Conclusion

We like to start the conclusion by citing the following from the book: Normalized Systems Theory by Herwig Mannaert Jan Verelst Peter De Bruyn. "..as software changes over time, its structure tends to become more and more complex. This increasing complexity is harmful, in the sense that it is a symptom that reflects structure deterioration or degradation. Software therefore becomes less evolvable."[1, p. 127]

The above applies to processes also. If the processes are not designed initially to be modular, flexible and evolvable, then when we are forced to make changes, the tendency will be to patch solutions since a change cannot be simply implemented. Hence the structure becomes more complex and rigid.

In this paper we showed a couple of examples on how a supply chain processes go under continuous changes. Some are for improvement in order to reduce cost and/or to be competitive in an evolving market, and some are to be in compliance with a continuously changing regulatory rules. These changes may drive the system with time to be more complex and rigid that only a major costly overhaul implementation can rescue the business.

4 References

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