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Potentials of Traceability Systems - a Cross-Industry Perspective

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Abstract

Recently, traceability systems have become more common, but their prevalence and design vary significantly depending on the industry. Different law and customer-based requirements for traceability systems have led to diverse standards. This contribution offers a framework to compare the state of traceability systems in different industries. A comparison of industry characteristics, motivations for traceability system implementation, common data management, and identification systems are offered. Upon that analysis, the potential of cross-industry traceability systems and approaches is identified. This extended usage of traceability systems supports the quality assurance, process management and counterfeit protection and thus expands customer value.

1. Introduction

Traceability is the ability to capture and describe the processes related to a specific product [1]. This contribution points out internal traceability, meaning tracking and tracing products and processes at one stakeholder's site, as well as inter-supply chain traceability. Traceability is an enabler technology, facilitating a wide range of applications. For example, it allows more precise quality-related recalls [2], serves as a platform for supply chain control [3], limits product piracy [4], and improve the efficiency of sorting processes in circular production systems [5]. Though these benefits have been discussed, this research shows, that the implementation's state of traceability systems in the manufacturing industry is still very heterogeneous. Also, the motives for using traceability differ significantly from one industry to the next.

This contribution presents a comparative analysis of traceability use in three selected industries: Automotive, Food, and Pharmaceutical. It then identifies best practices and emphasizes improvement potentials. The contribution is structured as follows: A discussion of current research work in this area is followed by the chosen methodologies. Section 4 shows the research results that include a characterization of the examined industries, a distinction of application types and motives for traceability-use, and traceability solutions in all three industries. Section 5 discusses future potentials.

2. State of the Art

In the existing literature, various definitions of traceability are used. The DIN EN ISO 9001:2015 defines traceability as the "ability to identify the history, application and location of an object." Organizations need to ensure that product tracking conforms with requirements both regarding documentation and storage of information [6]. The ZVEI guide adds that traceability enables product and material tracking along the whole value chain [7]. Bosona and Gebresenbret distinguish forward traceability or tracking, describing the current state of an object, and backward traceability called tracing revealing an object's past [8]. Core elements of traceability systems are identification, data collection and data recording. The link between information flow and the physical flow of goods is crucial for the traceability system's functionality. Luft states that traceability is a "multi-party challenge"

that involves all stakeholders along the supply chain. [9] The ZVEI guide classifies available commercial solutions and lists applications fields in several industries [7]. Kern shows the benefits of traceability, discusses challenges and proposes a concept of integrating traceability in small and medium sized enterprises [6]. Others focus on the granularity of traceability systems [10] or specific traceability technologies [11]. A technical review of industrial traceability practices is provided by Schuitemarker et al., identifying the inconsistency and variability of existing traceability systems [12].

Another crucial aspect of traceability systems is data management and transfer. While management is typically handled by dedicated IT-tools, data transfer can be facilitated using a variety of strategies. These strategies differ in terms of the storage location, standardization, and synchronization. Colledani et al. for example, showcase the qualitative advantages of in-line product traceability[13]. To show transfer potentials to other industries the industries as well as the prevailing technologies in each are analyzed, and reasons for their use are identified.

3. Methodology

This contribution combines the review of scientific literature and commercially available solutions with expert interviews to provide a comparative overview of the application and maturity of traceability in three industries. First the three selected industries were characterized and typical fields of application of traceability were identified in a scientific and technical documentation study. Then, common, and new traceability technologies were recognized and categorized. according to a previously developed framework for traceability systems [14]. This framework was further developed and crosschecked in open interviews and four workshops with experts from multiple companies and industrial backgrounds.

These workshops focused on specific industrial applications, covering a range of scenarios. In these workshops, the motives behind the use of traceability in different practical scenarios were mapped out using the matrix shown in Fig. 2. The expert opinions were supplemented with findings from the literature review. Additionally, the state of traceability use in the examined companies was captured. Finally different options for the technical solution of the industrial applications were developed and discussed, considering their advantages and disadvantages. This discussing was based on the prior review and categorization of traceability solutions.

The results from the literature, from solutions review, from the workshops and the interviews were mapped to the here focused industries to provide an overview of traceability use.

4. Research Results

To better understand the results the tree examined industries are first characterized. Subsequently, typical fields for application and motives are analyzed in all three industries. Lastly, technical implementations are examined. Fig. 1 shows an overview of the supply chains of all three industries.

4.1. Industry Characteristics

The three examined industries: Automotive, Food and Pharmaceutical, differ significantly in their production organization and structure, their product characteristics, and the degree to which different legal requirements apply. In this section, the respective production processes, product and component characteristics, the supply chain with relevant stakeholders, IT-infrastructure, and standards are described.

Fig. 1. Supply chains in the automotive, food, and pharma industry

Automotive Industry - The most important process technologies in the automotive sector are metal forming and assembly technologies. These production processes are designed for high volumes and rely on economies of scale. The typical manufacturing form is discrete one-piece flow production. Automotive products and components feature high complexity and specificity towards their application. Even though, the automotive industry's components are typically shared across various products, indicating a significant degree of modularity. The automotive supply chain features a tiered hierarchical structure, which has led to the high specialization of companies and cost-efficiency. Typically car sales involve a dealer network, both for consumers and businesses, though direct to consumer models are becoming increasingly common. Automotive companies employ a portfolio of IT tools, including ERP, MES, computer aided quality (CAQ), and product lifecycle management (PLM) and product data management (PDM) systems. The suppliers usually have less digital maturity compared to the OEM's. [15] Standards and regulations exist concerning quality management in the form of the ISO 9001:2015 that focuses on the traceability of products and the EN 10204 and the ISO/TS 16949 that describes in particular quality agreements with suppliers like the required batch traceability.

Food Industry - The food industry is split into an agricultural side and a processing side. The production processes are characterized by high variability and uncertainty and long predetermined growth phases on the agricultural side. On the food processing side, the production is typically organized in continuous process steps that include thermal, mechanical, or biochemical processing, as well as discrete packaging processes. In addition to those two sides, the supply chain comprises retailers, restaurants, and individual consumers. Food products typically pass through many stations and stakeholders before arriving at the customer. Products in the food industry are consumables and, on average inexpensive and simple. They consist of packaging and the alimentary that can

comprise many ingredients from a biological, biotechnological or chemical origin, depending on the degree of processing. Whereas processing companies have dedicated IT systems for their production, agricultural facilities are more heterogeneous in terms of data acquisition and usage, as some large providers utilize a comprehensive modern technology suit while others still rely on analog documentation systems. Food safety or quality assurance is a relevant topic for standardization. Therefore many regulations and standards exist like the HACCP-System (Hazard Analysis Critical Control Points). Challenging processes are defined as critical control points for even more intensive controls [16].

Pharmaceutical Industry - Processes of a typical pharmaceutical production begin with the active ingredient manufacturing, followed by secondary steps, including drug formulation and packaging. The manufacturing proceeds either batch-wise or continuously. Pharma products and processes are costly and time-consuming in development. Comprehensive patents typically protect pharmaceutical products incentivizing companies to develop new products even though only a few developments result in marketable products. There are two categories of products, traditional 'small molecules' which are based on chemical compounds and 'biopharmaceuticals' which are synthesized of specific biological molecules in microorganisms or cells. Both product categories exist in various formulations, for example, as solida, liquida or sprays. The pharmaceutical industry is quality-driven as any deviations may affect patients' security. Pharma's value chains are highly integrated, as one company often oversees most value creation processes. Multiple suppliers provide necessary chemicals, biologics, and materials for manufacturing. Distribution after production occurs either directly to the pharmacy or hospital or via a wholesaler to the pharmacy before arriving at the patient [17]. Manufacturers have distinct data infrastructure systems, as the high number of accruing quality-based data have to be stored over 20 years. Processes are supervised, Process Analytical Technology is used to derive critical process parameters and critical quality attributes for each manufacturing step. A central part of the data infrastructure is often still paper-based, although digitalization is in realization. Commonly used IT systems are ERP, MES, and CAQ. 'Good Manufacturing Practices' and other regulations dictate how the production requiring Standard Operating Procedures and regular audits.

4.2. Fields of application for traceability systems

While several other applications exist, this contribution focuses on four distinct fields of application for traceability systems and examines their occurrence in all three industries. These fields are counterfeit protection, production and logistics control, quality management and recalls, and sustainable practices and circular economy.

Automotive Industry - Product piracy primarily affects the automotive aftermarket and the used-car market, as defect compounds are exchanged, and counterfeit compounds may be installed. This damage can be restricted with appropriate identification technologies and traceability. Better protection against counterfeits may improve customer safety as these products are often lower quality.

Process and logistics control is an essential application of traceability in the automotive industry. The automotive industry heavily utilizes the just-in-time principle and logistically integrates its suppliers to minimize the bound capital. This integration increases dependency and raises the importance of disturbance management, minimizing effects by proactively reacting to any issues in upstream processes.

For safety-relevant components such as brakes, airbags and steering columns, traceability plays a particular role in quality control. A component's supplier must guarantee functionality before and after assembly in the car. Quality related recalls may harm companies in multiple ways, as brand reputation may suffer, and exchange and compensation costs are relatively high. More than 50 % of the recalled components in Germany in 2014 were safety relevant. Fast identification of faulty components through traceability can save lives and reduces monetary and brand damage for the producers.

Recycling and remanufacturing as part of sustainable practices, are becoming increasingly important in the age of electromobility. Battery cells contain valuable material that is only obtainable limited quantities. Traceability could facilitate effective resource reuse by improving sorting and used product routing. Within this context the ISO standard 22628 presents a calculation method for the recoverability and recyclability of vehicles.

Food Industry - In the food industry protection against fraudulent activities is paramount. The high price discrepancies between products of different quality standards and the difficulty to assess the quality on the consumer side make product piracy a lucrative business. Due to the difficulty of placing fraud-proof identification tags on food items, companies have created specific identification technologies integrated into the product as chemical markers.

Like the automotive industry, the food industry is heavily logistics integrated due to its limited storage life. Therefore, tracking product volumes throughout the supply chain is crucial. Additionally, many agricultural processes carry large uncertainties regarding the quality of the product and total crop shortfalls. Therefore, it is essential for stakeholders in the food supply chain to closely monitor developing products at their suppliers and communicate with them.

Quality management is crucial for consumer food safety. Traceability is used to quickly identify the affected batches and disseminate information about harmful products or to recall them counteracting unrecognized food risks. Reaching the customer quickly can prevent serious damage.

Traceability systems that deliver information regarding increasingly sustainable packaging materials on the product can support more efficient recycling [18]. More accurate storage life control, facilitated by monitoring food storage conditions, improves sustainability by reducing waste.

Pharmaceutical Industry - Counterfeit protection especially matters when multiple traders are involved. The ID technologies typically used in the pharmaceutical industry are holograms, barcodes, and serial numbers. Those are prescribed by law and provide some protection, but products can

be repacked nevertheless. In the worst case, placebo or fraud can be replaced with the original, representing a danger for the patient and high costs for manufacturers. Product-integrated identification methods help to track originality [19].

Since development costs are dominant in pharmaceutical products and the value creation concentration is high, process optimization for costs and real-time process control are less attractive. However, various ID and sensor technologies regularly supervise the product throughout processing. Temperature and humidity control is essential during the drugs' transport and storage, ensuring stability and efficacy.

The product's quality is permanently checked during production due to the high degree of process control. Recalls are very rare. Before market entry, efficacy and dose are well defined by clinical trials. Side effects are recorded even after market-entry for the pharmaceutical's long-term supervision.

4.3. Motives for traceability system implementation

There are several reasons for the use of traceability technologies in each industry. Fig. 2 shows a matrix that classifies the reasons into three main motives for three different levels of data activity in traceability systems. The main motives are legal requirements, customer-driven requirements, and self-initiated motives. The first level of data activity is data acquisition. Data are acquired and stored, enabling, for example, access to product or process relevant data in a callback event. Data analysis represents the second level. Data is correlated and evaluated for better understanding and to optimize processes and products. The third level is data-based control. Data is used automatically in processes and enables targeted control. With this last level, the full potential of captured data can be exploited.

Fig. 2. Matrix for the classification of motives for traceability systems

Automotive Industry - Compared with the other two industries, legal requirements for traceability are less important in the automotive industry. Besides the mentioned ISO and EN norms in section 1, describing required batch traceability as an agreement between OEM and suppliers, the VDA 5005 recommends and defines automotive supply chain processes.

The industries' traceability systems are driven by customers, which are typically Tier 1's. They are designed to help OEMs identify risks and disruptions in their supply chain. In this context, automobile manufacturers have established various systems to gain visibility of risks down to Tier 3 suppliers [20]. OEMs require components' ID to be issued according to DIN ISO standard. The customer-driven motivation also extends to recalls. One exemplary event from the past is the software defect that caused uncontrollable acceleration

and has led to recalls at Toyota [21]. These use-cases belong to the first and second level of the matrix.

A self-motivated reason on the third level is disruption control. It requires a production or assembly with a distinct degree of digitalization and automation. Industry 4.0 is a key driver for the development of traceability systems [22].

Food Industry - Regulatory compliance demands, requiring the documentation of processes, are a primary motive for traceability in the food industry. Several national and international regulations specify which information about food must be accessible. These norms include the DIN EN ISO 22005, which describes the principles and requirements for implementing traceability in the feed and food supply chain and the basic food regulation VO EU 178/2002. The RASFF (Rapid Alert System for Food and Feed) system intends to standardize traceability integration. Food law specifies that identification information from supplier and customer and product type and date, must be available to inspection by authorities. When a risk is identified, any product information one step forward and backward in the food chain must be analyzed. State authorities ensure that production, processing, and distribution are monitored in traceability system. In addition to general requirements, there are detailed animal product regulations ensuring origin transparency.

Food manufacturers increase customer satisfaction and confidence by providing transparency about their products. Traceability systems control food hazards, provide reliable product information, and guarantee product authenticity as they make said data available to customers. [23].

Traceability is part of risk management, or rather an implemented measure and thus a self-initiated motive. It prevents loss of sales and minimizes cost increases in the event of a claim due to recalls, disposal of food or new marketing strategies [24]. In the matrix, this is represented on the third level. Also, the agriculture processes have traceability-systems for self-motivated reasons. The optimal yield can only be achieved when feeding and watering conditions are optimally adapted to the current circumstances.

Pharmaceutical Industry - A 2015 EU directive on counterfeit medicines requires companies to track medicines and verify codes on packaging. Many EU-wide directives exist to ensure the safety of pharmaceutical products. Companies face the challenge of providing the necessary mechanisms paying particular attention to the serialization of pharmaceutical products. Besides, various documents (Aide-Memoire) help companies meet the requirements of the FMD (Falsified Medicines Directive, Directive 2011/62/EC). The DIN EN ISO 13485 lists criteria to ensure a sufficient quality management for traceability systems that enclose authorities' regulations and customer needs. Legal requirements prescribe the need and use of traceability on the third level of the matrix. The other two motives are subordinated.

4.4. Traceability solutions

A traceability system consists of data acquisition systems, subdivided into identification (ID) technologies and secondary data acquisition systems, and data management systems.

Table 1 gives an overview of typical ID technologies that find application in the examined industries.

Table 1. Extract of identification and anti-counterfeit technologies

Technology	Originality	Identification	Additional Information	Automatable	Human-readable	Tag-required
Holograms	x				x	x
Punch motifs	x			x	x	
Watermarks	x				x	x
Digital watermarks	x			x		x
DNA fingerprint	x			x		
(Electro-) magnetic properties	x			x		
IR / UV pigments	x			x		
Optical fingerprint and spectroscopy (NMR, MRI, EPR)	x			x		
Alphanumeric coding		x	x	x	x	
Barcodes		x	x	x		
Near Field Communication (NFC)	x	x	x	x		x
Radio Frequency Identification (RFID)	x	x	x	x		x

Secondary data acquisition technologies are sensors used to describe a products environment, the relevant processes, the product quality, and its usage.

Data management systems require data and system integration and appropriate exchange strategies. Data format and security are key variables. System design and exchange strategies depend on the stakeholders' infrastructure and willingness to share data with others.

Automotive Industry - The most commonly used ID technologies are barcodes and RFID. In Asia, RFID is utilized to a larger degree than in the EU. The barcode technology is established, and lock-in effects hinder a change to RFID. In applications with low automation, like service relevant parts, alphanumerical codes are also commonly used. Anti-counterfeit technologies are not very common in the automotive industry. The use of standardized ID via GUID or GS1 (see below) are rare, instead companies rely on proprietary numbering schemes to save costs in the absence of specific regulations. The automotive industry exchanges data using standardized messages with the EDI standard. Non standardized messages are also quite common.

Food Industry - Beside RFID and barcode, biological identification technologies, such as DNA fingerprinting, tracer molecules and biological fingerprinting are in use. In the food industry product fraud is a major issue, thus, anti-counterfeit technologies both based on packaging and in the product are commonly used. Standards play a ubiquitous role (compare Table 2). The use of Traceable Resource Units (TRU), consisting of a batch unit, a trade unit, and a logistic unit, is standardized by international marking systems such as GZVEIS1, GLN, and GTIN. An ISO compliant standard (ISO 11784) is the Electronic Product Code (EPC) to store and retrieve data. "Traceability can only be achieved if it is built upon global standards that enable interoperability between traceability systems across the whole supply chain." [25] Global Standard 1 (GS1) is a global traceability standard describing processes, independent of the used technology, and meets legislative and business needs. Physical Markup

Language (PML/XML) is used in the food industry for the inter-supply chain exchange of information. Web-based systems are recommended for data processing, storage and transfer for flexibility and good usability [26].

Table 2: Extract of common standard technologies.

Aspect	Usage	Standard Technology
Data format	Data storage	EPC (Electronic Product Code), TRU (Traceable Resource Unit)
Inter supply chain standards	ID standardized coding	GS1 (Global Standard 1)
	ID standardized coding for RFID	EPC Global Network (ISO 11784)
	Data sharing - inter supply chain level	EDI (Electronic Data Interchange), PML/XML (Physical Markup Language)
Process description		GMP (Good Manufacturing Practice), SOP (Standard Operating Procedure)
Network communication and interfaces	Network Models	RAMI Model (Reference Architecture Model I4.0)
		OSI Model (Open System Interconnection): application layer (HTTP), transport layer (TCP/UDP), network layer (IP)
	Network communication	Ethernet, Fieldbus, Industrial Ethernet
	Integration of sensor interfaces	IO-link, Omlox
	Protocols	Pub/Sub, Request/Response Protocols: MQTT, CoAP
	Data sharing - IT level	OPC-UA
	ID standardized technology	Barcode Standard, RFID Standard

Pharmaceutical Industry - 1D and 2D barcodes, optical reader recognition and RFID are commonly used. The combination of a serial number and an originality marker increases the security against counterfeiting. Also, some drugs are marked with biological identification technologies. GS1 is primarily used due to legal requirements.

5. Future potentials

Automotive Industry - The multitude of individual existing traceability systems, including the degree of implementation and different used data formats within a supply chain, complicates and slows down tracing. Especially in the automotive industry where production processes are divided among multiple stakeholders the linking of ID systems is of major importance. Further potential lies therefore in standardized traceability solutions, as is the case in the food and pharma industry. Company-wide standards facilitate data exchange to accelerate the recall processes.

In the future, reuse, remanufacturing, and recycling processes will likely reshape the production landscape due to resource scarcity. The current high level of data-based control and process automation in the automotive industry offers great potential. Recorded data on product condition and history could be accessed fast by automated identification and enable disassembly and sorting processes.

The use of marker particles to trace bulk material, similar to the food or pharma application, could be an option especially for resources from doubtful origin. Further potential lies in tracking not just safety-relevant components to optimize own production processes.

Food Industry - Further potential is seen in customer satisfaction. Traceability systems could return user-information about satisfaction to a product, as side-effects are reported in the pharma industry. So far, user satisfaction is interpreted quantitatively out of demand for a specific product or qualitatively by user stories or personalized advertisement in online trade. Some manufacturers offer detailed product information via a QR code. This can be coupled with a survey to query product wishes or satisfaction, automatically analyzed and evaluated, and initiates new product development.

Product authenticity is a critical customer requirement with additional potential. Safer ID technologies could enhance legally prescribed labels of the product's origin and the individual product manufacturing history. Information that lies primarily in the manufacturing company's data management system could be passed on to the consumer maximizing transparency and trust.

Pharmaceutical Industry - Customer-driven and self-initiated motives lack behind legal requirements. Potential is seen in the complete digitalization of the required documentation to enable real-time data-based process control and faster disturbance management. Data integrity is important when digitalization takes place.

The pharma industry might be primarily quality-driven, but also costs and time will play a major role in the future. If digital data management and Industry 4.0 approaches are introduced in the development stage, it could be sped up significantly. Research and development of new drugs have the most significant effect on final product costs. Correlating multiple data and evaluating them automatically might significantly affect time-to-market and final product costs.

Further customer-driven potential is seen concerning product authenticity monitoring available for the patient with to new product-integrated identification solutions. These should be inseparable from the product and originality enable verification by the customer using a smartphone.

Traceability can also make price transparency and fair negotiations possible. The cost share borne by patients varies, leading to high prices and difficult access to medicines[27].

Another future potential concerns circular economy. For example, active pharmaceutical ingredients entering wastewater cannot be wholly purified and thus affect the groundwater and ecosystems. Since purification can only occur if the substance in wastewater is known, traceability could offer application potential.

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