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## Supply chain design under quality disruptions and tainted materials delivery

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### ABSTRACT

Events such as the 2008 Heparin tragedy, in which patients lost their lives due to tainted pharmaceuticals, highlight the necessity for supply chain designers and planners to consider the risk of even low probability incidents in supply chains. The goal of this research is to design a single-period, single-product supply chain model with capacitated facilities to hedge against the possibility of sending tainted materials to consumers. Given that our mixed-integer stochastic model is NP-hard, we develop efficient heuristic and metaheuristic algorithms to obtain acceptable solutions. Computational experience is presented and discussed.

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## 1. Introduction

Some supply disruptions are not only costly, but may have catastrophic consequences in spite of their low probability of occurrence. Consider a supplier that begins sending tainted or contaminated products without awareness and the product reaches the final consumers. This may cause late delivery or product shortage and in some supply chains, such as healthcare, this disruption may put final consumers i.e., patients' lives in danger. As an example, the disruption of a flu vaccine manufacturer in Bristol, UK in 2004 resulted in disastrous consequences. The UK government stopped production when U.S. regulators inspected a manufacturing plant and found evidence of bacterial contamination problems. This reduced the US's supply of the vaccine by nearly 50% during the 2004–2005 flu season (Everett and Baker, 2004). A healthcare supply chain is also very susceptible to disruptions caused by contamination. Heparin, a widely-used blood-thinning medicine that is made from pig intestines, was contaminated by an undetected outbreak of blue ear pig disease in China in 2008. This led to 81 patient deaths as well as hundreds of allergic reactions in the United States (Usdin, 2009). The investigation engaged several government agencies, university researchers and a biotech company with a generic heparin under FDA review. Although no one at the time knew what was causing the reactions, members of Congress concluded that the issue was the result of “regulatory failure” (Usdin, 2009). In another supply chain disruption, a baby food producer who purchased vitamin supplements from a Chinese supplier found out that the supplements were contaminated by cement (Lyles et al.,

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2008). This incident involved 22 Chinese and 10 global manufacturers and led to kidney problems and kidney stones in Chinese babies, illustrating the result of poor or failed inspections by FDA or production facilities (Schoder, 2010).

A 2008 US Government Accountability Office (GAO) report indicated that in 2007, the FDA inspected approximately 8% of foreign facilities and declared that, at that rate, it would take 13 years to inspect all such facilities (Benson, 2012). On the other hand, inspection of raw materials is usually a significant portion of manufacturing costs whereas manufacturing facilities are searching for cost-reduction opportunities (Green and Brown, 2009). As a result, while consumers may assume all materials are inspected, some are either not inspected or are inadequately inspected.

These types of incidents indicate not all materials entering the supply chain can be inspected by regulatory agencies and accentuate the need to consider risk of receiving contaminated materials in the design and planning stages. It is also vital to contemplate risk of supply disruptions when designing a supply chain so that it can be responsive and resilient in the case of an unplanned incident. However, managers, deceived by the small likelihood of these types of incidents, often tend to underestimate the impact of such mishaps.

The goal of this research is to design a single-period, single-product supply chain model with capacitated facilities to hedge against the risk of supply quality disruptions and sending tainted materials to consumers. Inspired by the aforementioned incidents, we reduce (but do not completely eliminate) tainted materials by introducing producer-implemented inspections. We also consider the loss of all or a significant fraction of the expected supply quantity due to contamination or discarding tainted materials after implementation of inspection. In all cases, we assume some tainted materials are also shipped to consumers. We, therefore, model the risk of shipping tainted materials with a penalty cost. In cases where reducing tainted materials is of the first priority, using a high penalty cost will cause the model to avoid it as much as possible. When we inspect, we also incur costs related to inspection and the disposal of discovered tainted materials.

Typically, the decision making process dealing with supply chain disruptions involves both strategic and tactical considerations (Drezner and Hamacher, 2004). Strategic decisions comprise decisions such as choosing which markets to serve, from which suppliers to source, the location of facilities/suppliers, and how many suppliers to use. Tactical decisions include decisions such as inventory management production planning (Drezner and Hamacher, 2004; Chopra and Sodhi, 2004).

Our model examines the strategic decision of facility selection and the tactical decision of capacity allocation among facilities. Additionally, we consider the implementation of inspection at a facility as a tactical decision. This aspect of the work was inspired by tragedies such as the heparin. If the risk of shipping tainted materials can be minimized prior to such tragedies, producers can decrease liability and improve consumer safety. Insights into how our model should be configured to reduce the risk of tainted materials reaching consumers are of interest to several types of supply chains such as healthcare, pharmaceutical, cosmetic and beauty, and food or dairy industries.

The objective of the model is to minimize the expected overall cost which is composed of the cost of selecting the facility, shipping untainted materials, shipping tainted materials, inspecting the facility, and discarding tainted materials. We formulate this problem using a two-stage stochastic mixed-integer problem. A number of researchers address various solutions of two-stage stochastic problems in the literature such as Bender's Decomposition (MirHassani et al., 2000), Lagrangian relaxation (Daskin et al., 2002), or L-shaped methods (Laporte et al., 1994). However, while this approach may allow for exact solutions in some situations, it can be very challenging to draw concrete analytical insights from such models and to obtain good solutions for large instances within a limited time frame (see Santoso et al., 2005) since the problem is a special case of the two-stage stochastic capacitated facility location problem which is NP-hard (Doerner et al., 2007; Shapiro, 2008). Based on our experience in solving various size problems using commercial software in this paper, we show that the number of facilities used have a significant impact on the solution time. As a result, we develop several heuristics and a metaheuristic approach i.e., simulated annealing, to efficiently solve and handle large size problems.

The paper is organized as follows. In Section 2, the problem description and the mathematical formulation are discussed. In Sections 3 and 4, the solution procedure and data generation method are presented, respectively. Computational results are discussed in Section 5. Finally, Section 6 presents conclusions and future extensions.

## 2. Problem description and mathematical formulation

### 2.1. Description

The earliest work in supply chain design was developed by Geoffrion and Graves (1974). They introduced a multi-commodity logistics network design model for optimizing finished product flows from plants to distribution centers to final consumers. Based on this work, a large number of optimization-based approaches have been proposed for the design of supply chain networks. These works have resulted in significant improvements in the modeling of these problems as well as in algorithmic and computational efficiency but they all have assumed that the design parameters for the supply chain are deterministic (Drezner and Hamacher, 2004; Vidal and Goetschalckx, 1997; Demirtas and Üstün, 2008; Brandeau and Chiu, 1989; Caserta and Rico, 2008; Hinojosa et al., 2008). Unfortunately, critical parameters such as consumer demand, supply capacity are generally uncertain. Therefore, traditional deterministic optimization is not suitable for capturing the behavior of the real-world problem.

The significance of uncertainty has encouraged a number of researchers to address stochastic parameters in their research. Most of the stochastic approaches for supply chain design only consider tactical level decisions usually related

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