Impact of Drug Supply Chain Security Act on US Pharmaceutical Industry Under Decentralized Information Flow

Meng Ying Chang, Raghavendran Mohan

Agenda

- Drug Supply Chain Security Act (DSCSA)
- Implementation Solution Design
  - Physical Flow
  - Information Flow
- Supply Chain Impact Evaluation
  - Scenarios
  - Operations Cost
  - IT Investment
  - CAPEX
  - Overall Impact
- Conclusion & Future Research

Fighting Counterfeit Drug

10% of the US pharmaceutical products

$75B business worldwide

50% are sold through websites

60% don't have active ingredients

17% have inaccurate dosages

16% have incorrect ingredients

* 2011 data source

Drug Supply Chain Security Act (DSCSA)

Serialize Product

- All prescription drugs should have a unique serial# at the unit level

TS/TI/TH

- Records need to be maintained at serial# level when there is a transfer of ownership

FDA Tracing Request

- All requests for records regarding a serial# needs to be addressed within 48 hours

Overview of U.S. Drug Supply Chain

Manufacturer

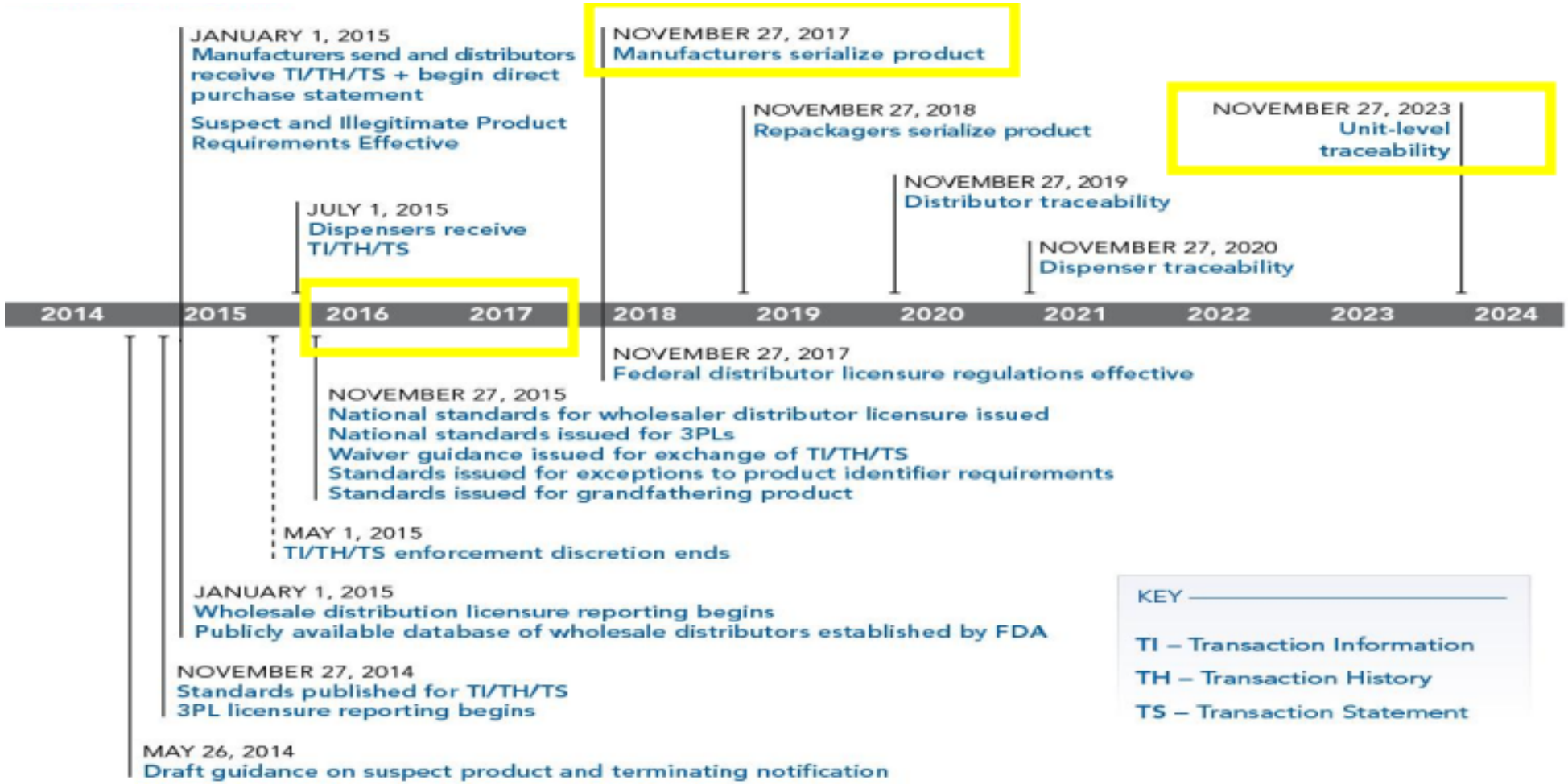
Distributor

Dispenser

Repackager

Patient

DSCSA Implementation Timeline

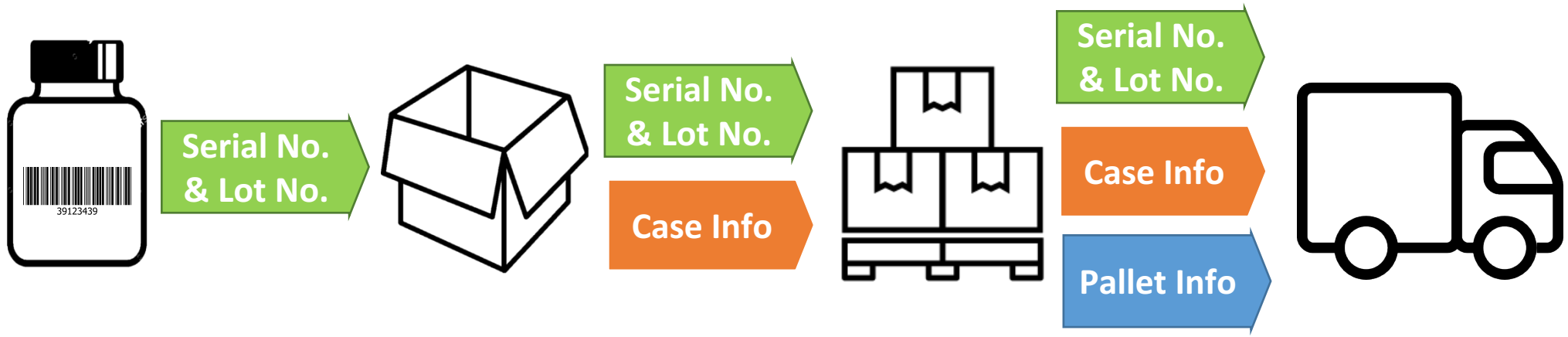


Implementation Solution Design

Physical Flow

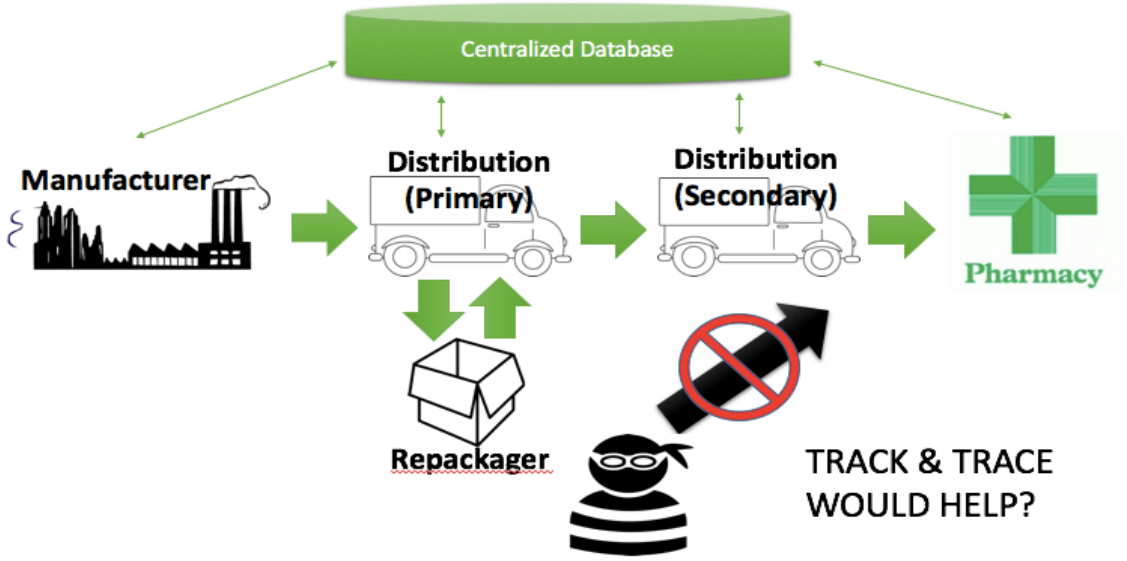
- Unit Level Model
  - All drugs are serialized but there is no mapping to higher UOMs

- Matryoshka Model

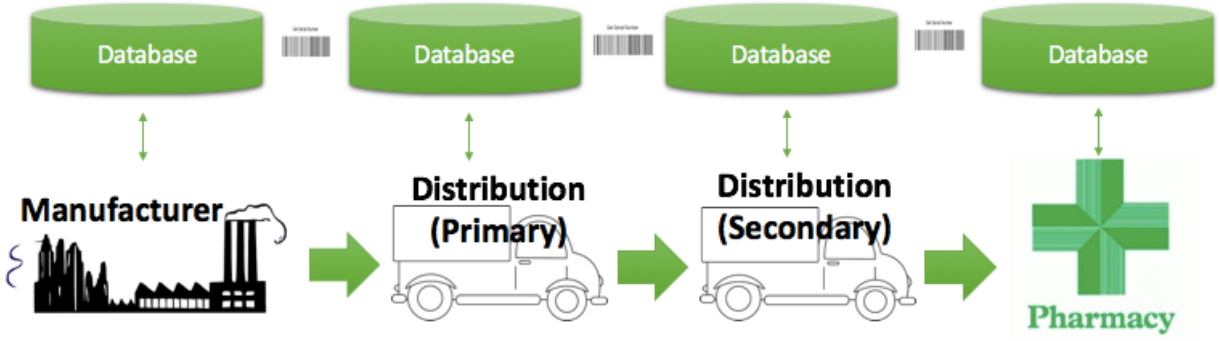


Information Flow

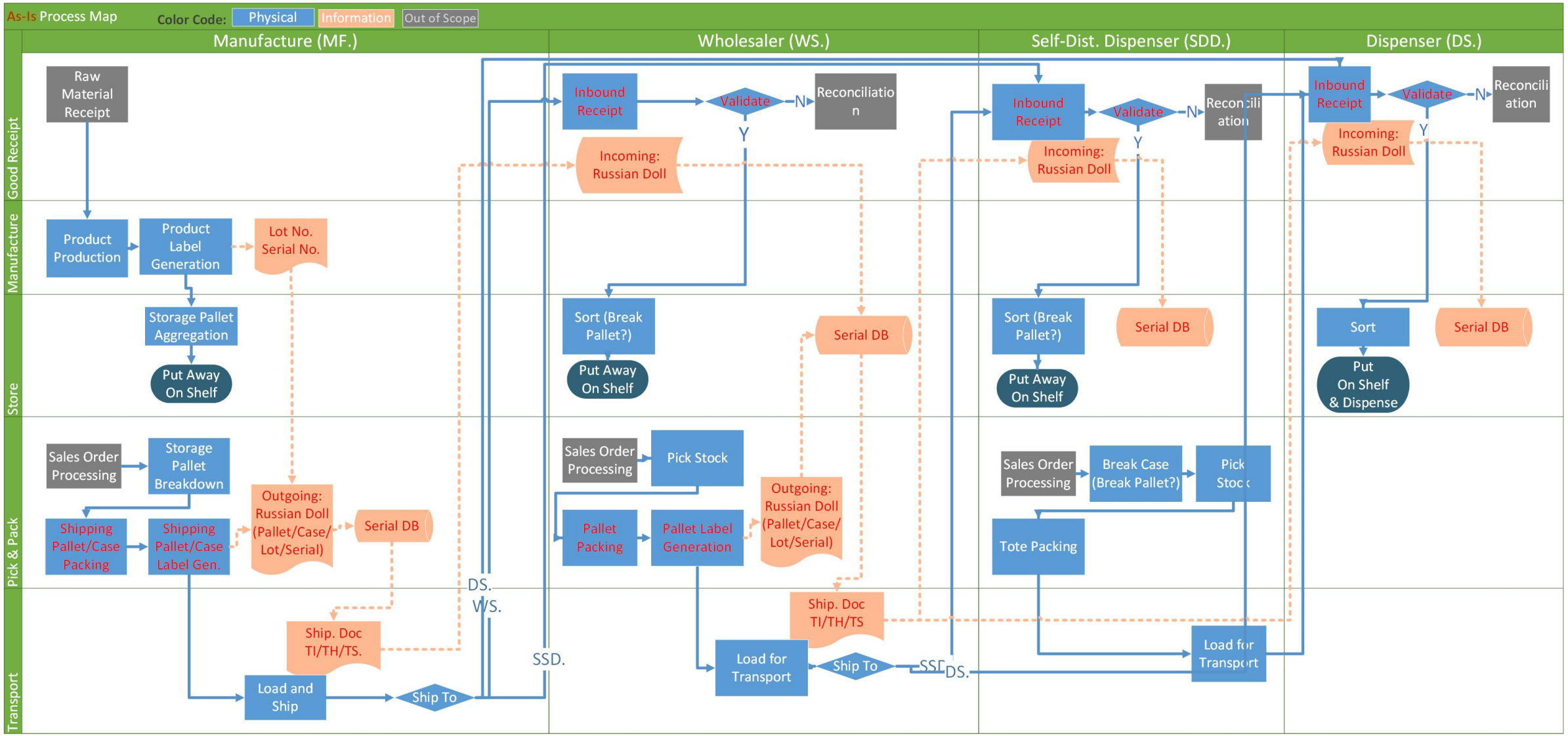
Centralized Model



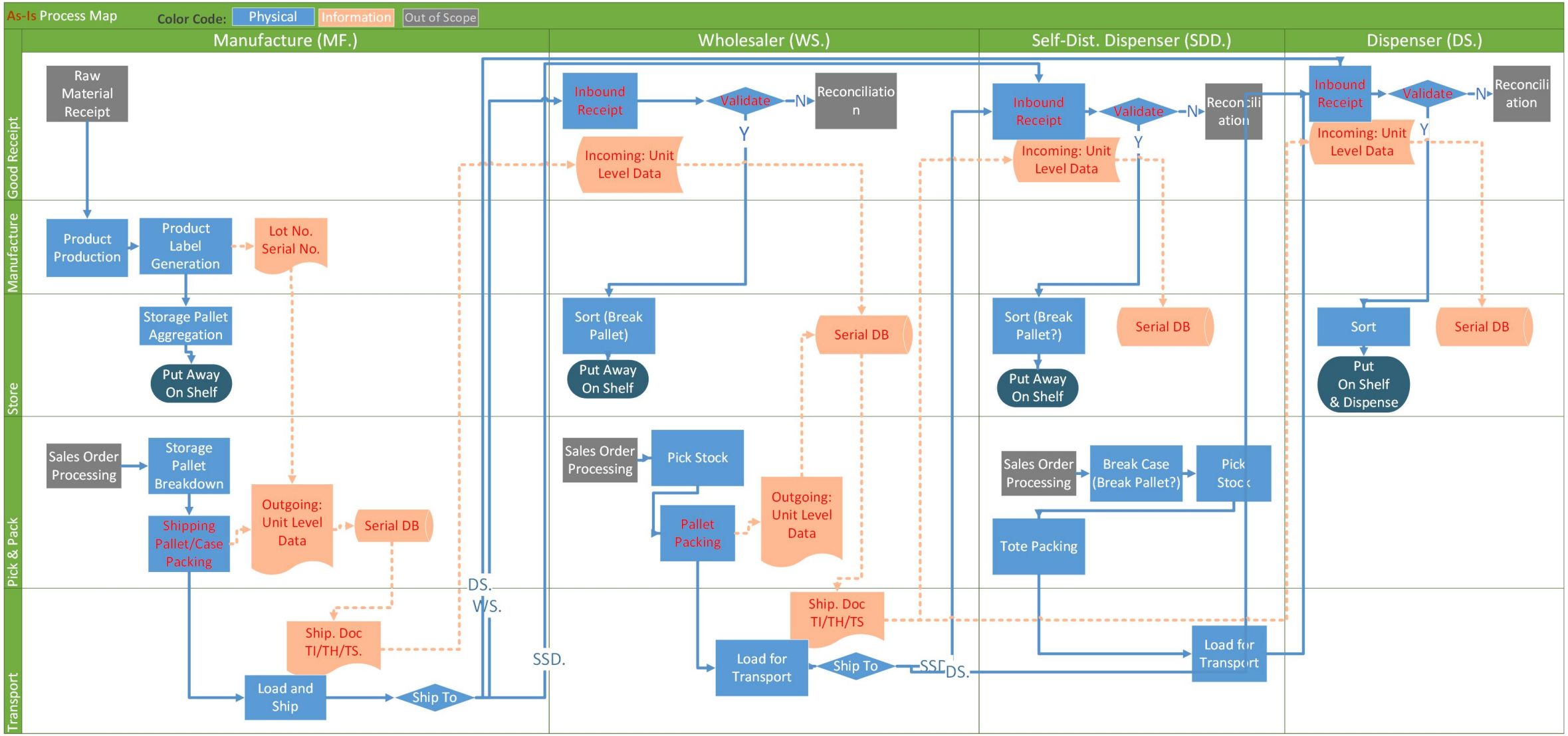
Decentralized Model



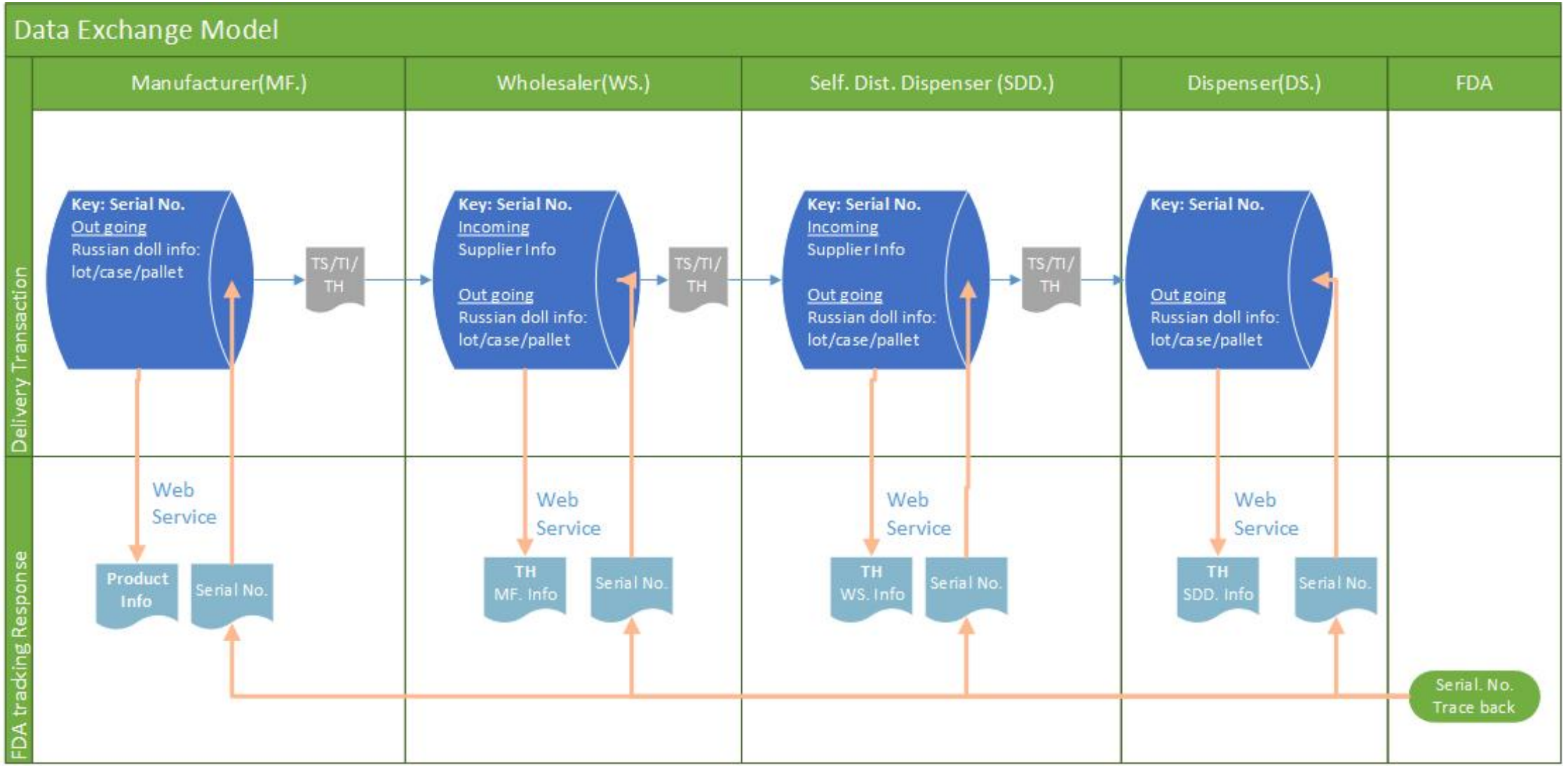
To-Be Process Map - Matryoshka Model



To-Be Process Map – Unit Level Model

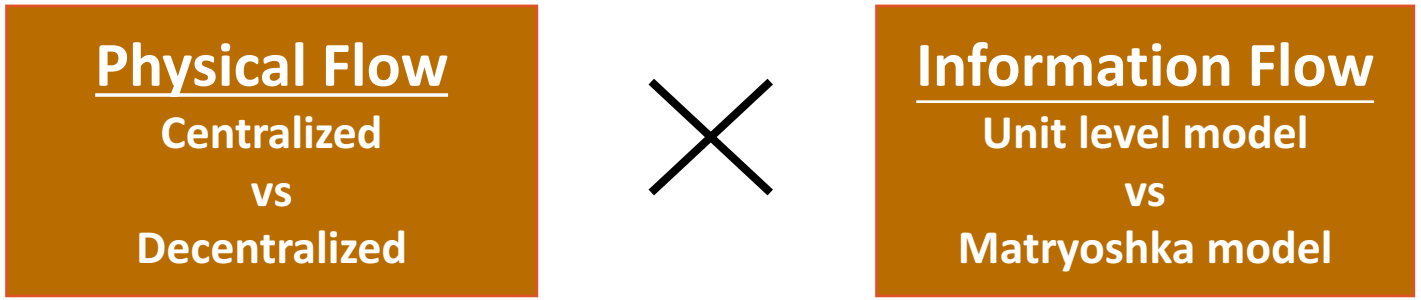


To-Be Decentralize Data Exchange Model



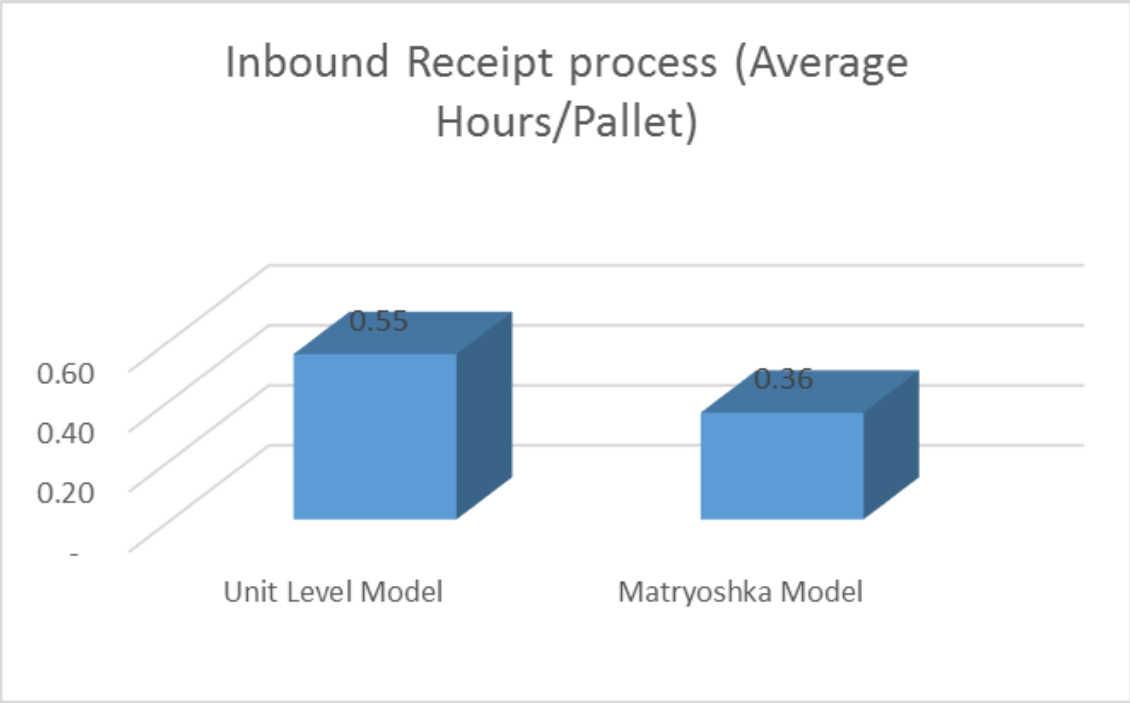
Supply Chain Impact Evaluation

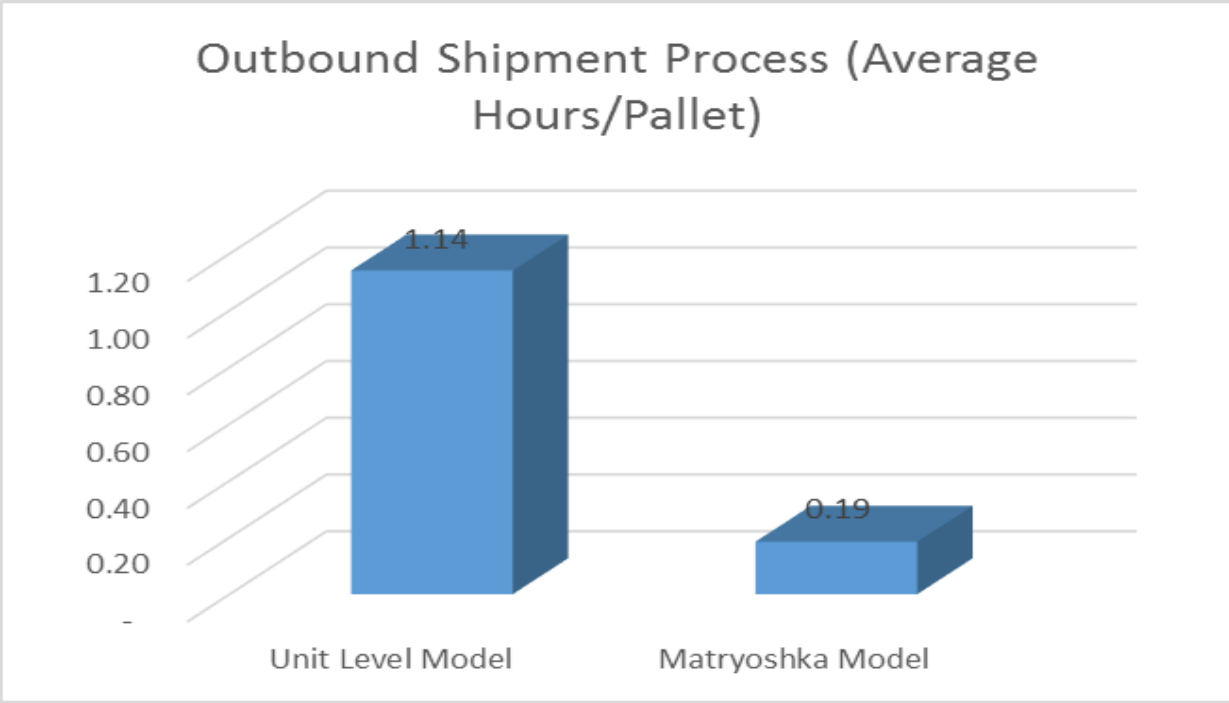
Evaluation Scenarios



- Centralized information flow with “Matryoshka” nesting of data
- Decentralized information flow with “Matryoshka” nesting of data
- Centralized information flow with unit level data, no nesting
- Decentralized information flow with unit level data, no nesting

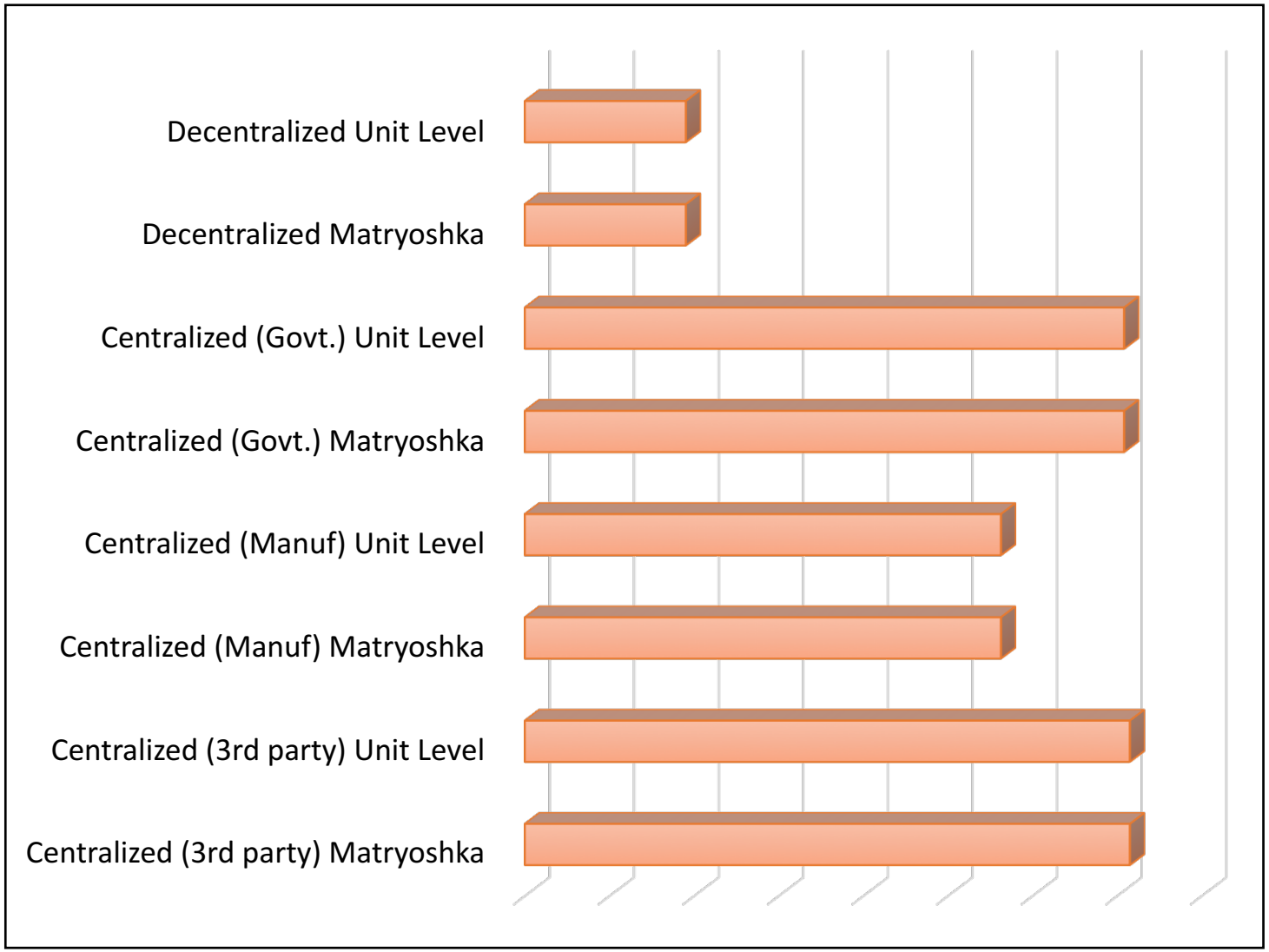
Operations Impact - Turnaround time





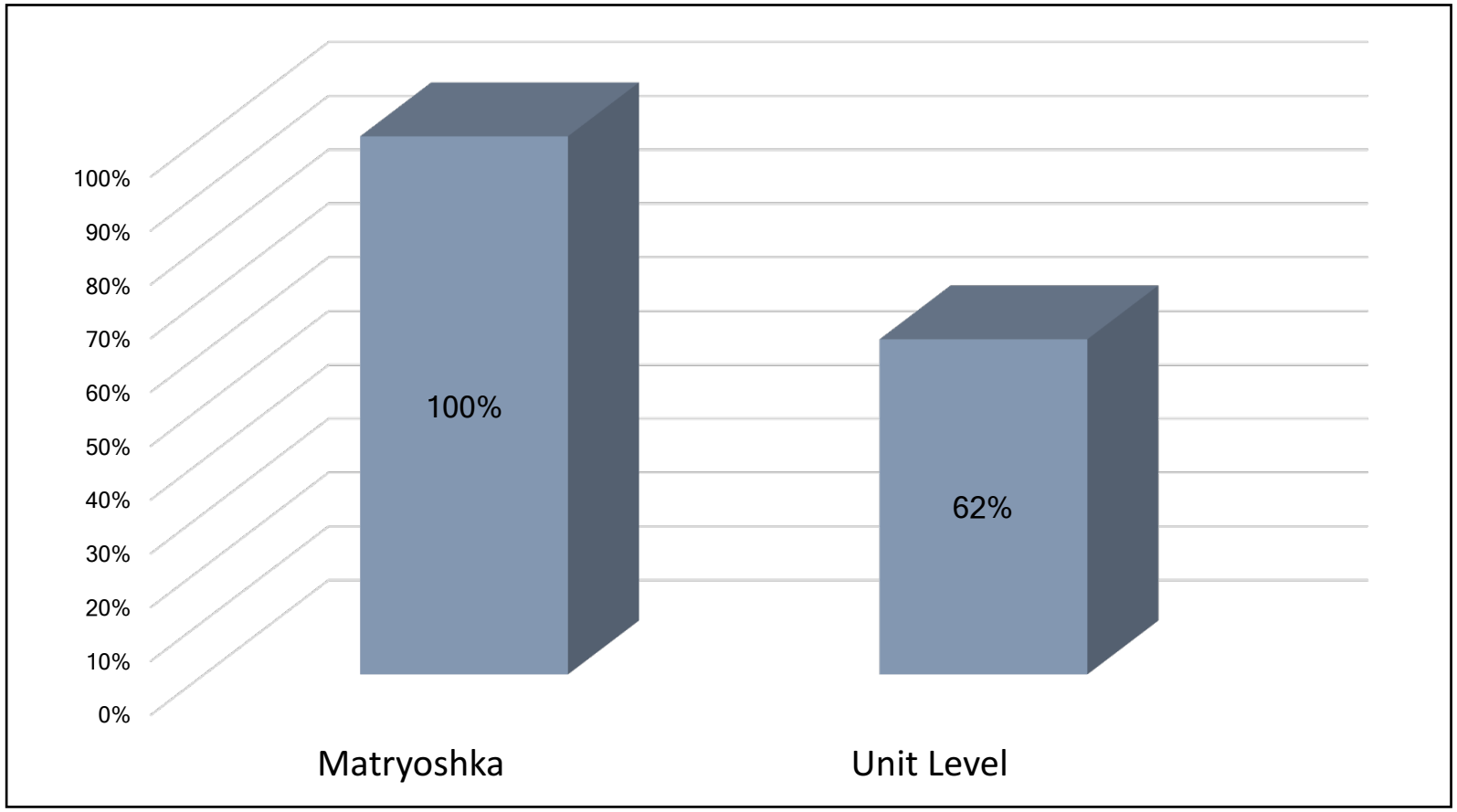
- Impact on Inbound process is lower as the DSCSA only mandates verification on a sample (10% volume)
- Outbound shipment impact can be reduced by effective inventory management, which is not in scope for this thesis

IT Impact – Initial Investment & Recurring Cost



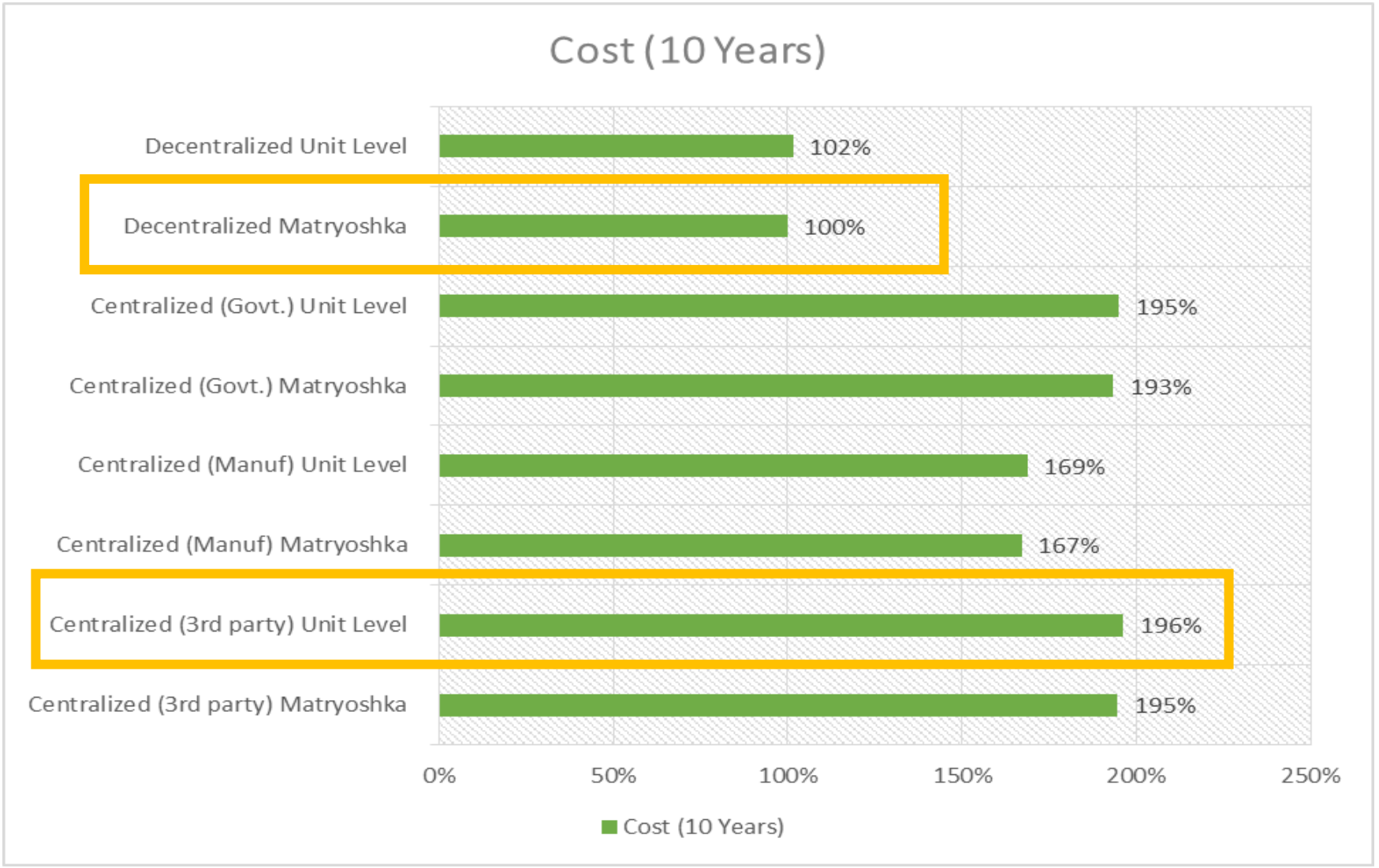
- **Decentralised models** require least investment and recurring cost as they will be built on existing data interfaces
- **Centralised models** require most investment as new data exchanges have to built from scratch

Financial Impact - CAPEX



- **Matryoshka model** require more CAPEX in labelling equipment
- **Unit level model** require less CAPEX from manufacturers and wholesalers

Overall Comparison



Conclusion & Future Research

Conclusion

Advantages of Decentralized Model

- Information flow solution can be built on existing IT infrastructure
- Ensures business privacy and data security for individual players

Least Impact Scenario

- Matryoshka + Decentralized model has least financial impact
- Lower operations cost & IT recurring cost

The Hybrid Reality

- Difficult to standardize implementation across the whole supply chain
- Hybrid model would increase complexity of execution

Future Research

Complexity for Repackager

- Number of units increase significantly.
- Difficulty in mapping inbound serial numbers with outbound serial numbers

New Technology Application

- Implement Cloud service for decentralized data storage
- Apply RFID in product palletization
- Leverage Block Chain to verify incoming data

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