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Geneva, 25 – 27 October 2011

Item ? of the provisional agenda

Traceability: a tool for managing risks

To be held at the Palais des Nations, Geneva, on Tuesday, 25 October from 10 a.m. to

1 p.m.

I. Achieving traceability in regulatory systems: a concept note

a. What is traceability?

Traceability, a relatively new concept as it is applied within regulatory systems, has always been part of economic and social life. Figures of terracotta warriors created in ancient times were labeled with the names of craftsmen and can be traced back to their producers even today; the Royal Courts were always checking and carefully choosing their suppliers.

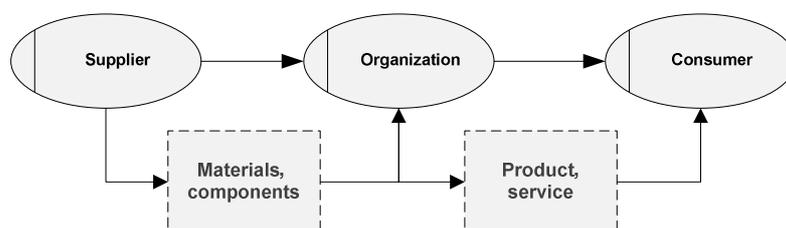
As technological progress allows for increasing specialization, supply chains are no longer under the supervision of individual craftsmen, who could produce cheese using their own grass lawns, cows, etc. By contrast, in a global economy, supply chains are complex and intertwined, and span across continents and beyond. Tracing a product back to its components is now an important means of managing business and achieving regulatory goals.

Traceability (which is defined in ISO 9000:2005 standard as “the ability to trace the history, application or location of that which is under consideration”) implies that any product present on the market could be traced back along all steps of its production chain. It allows regulatory stakeholders to get information on processes, original materials and components used in its production.

b. Why is traceability important?

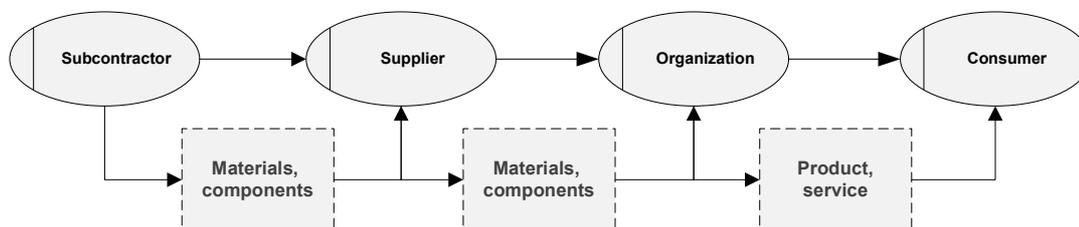
Regulatory stakeholders have a shared interest in ensuring traceability in supply chains. Consumers have always been concerned about the quality and safety of products. The origin of the goods has also become an important issue for the general public. Likewise, traceability allows companies to increase the stability and transparency of procurement and production processes. Traceability helps regulators and market surveillance authorities taking prompt and targeted action in case a dangerous product is placed on the market, e.g. to perform efficient product withdrawals.

Traceability requirements are present within regulatory systems at various levels. Management system standards and managerial best practices, such as ISO 9001:2008, the quality management system standards, contains a requirement for a firm to provide traceability of its production processes, within the chain ‘supplier – organization – consumer’:



Picture 1. ‘Supplier-Organization-Consumer’ Supply Chain

ISO 20000:2005 (international standard for Information Technology Service Management) takes the idea a step further and requires organization to be able to trace their products to the level of the ‘subcontractors of suppliers’:



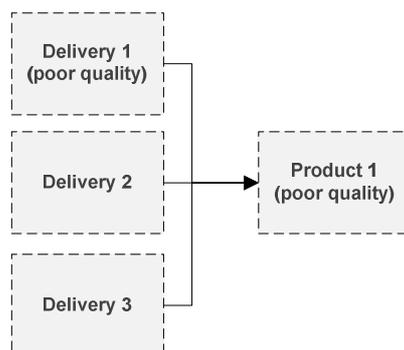
Picture 2. ‘Subcontractor-Supplier-Organization-Consumer’ Supply Chain

Traceability requirements in legislation are a key tenet of complex regulatory systems. For example: the Food Safety Regulation of the European Union contains provisions and introduces mechanisms to achieve transparency in the food and feed chain. Likewise, the the Food Safety Modernization Act of 2010 (FSMA) also enhances food traceability in the USA market. In other sectors, the registration of chemical substances under the REACH Regulation of the European Union is another tool for achieving traceability and transparency.

c. Traceability as a risk mitigation tool

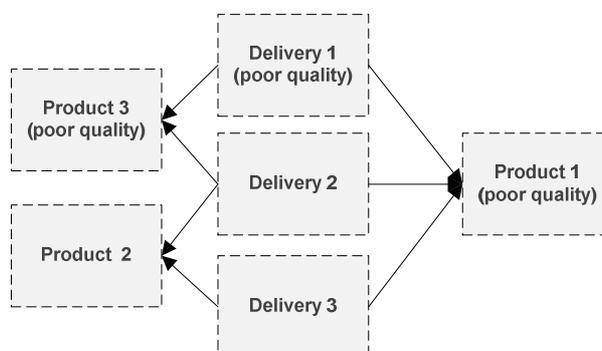
Traceability, in itself, is a risk mitigation tool. Within a business entity, traceability ensures a consistent level of quality in supplies, a prerequisite for a high-quality end product. Traceability also contributes to minimizing the costs of incidents. For example, if an end-

product is compromised or does not meet quality requirements, the organization needs to get full information on which components were used, where they came from, etc.:



Picture 3. Product 1 is of poor quality because delivery 1 was of poor quality

When, in turn, the cause of poor quality has been identified, organization can see (and, if poor quality products are already on the market – withdraw) only those items that were indeed affected:



Picture 4. Products 1 and 3 must be withdrawn because materials from delivery 1 (of poor quality) were used in their production

Within regulatory systems, traceability is a tool for:

- (a) Protecting consumers by minimizing risks related to proliferation of dangerous products on the market;
- (b) Accurate withdrawals of products from the market, when it may be necessary.
- (c) Achieving traceability within regulatory systems requires:
 - (i) Traceability of production processes of business companies,
 - (ii) Implementing traceability tools on the regulator's level.

II. The objectives of the panel session

The need for ensuring traceability throughout regulatory systems, and its role in mitigating risks of different kinds is widely recognized.

Traceability may however require the implementation of complex solutions, involve high costs and carry its own operational risks.

Within this context, the Panel Session will address the following questions:

- (i) How can traceability be achieved at a reasonable cost? Can a reference model for a regulatory system assist in achieving traceability within supply chains?
 - a. Proposed speaker: Regulators in food safety sector
 - b. Proposed speaker: Regulators, non food sector
- (ii) What are the operational risks that a regulator may face while imposing traceability requirements?
 - a. Proposed speaker: TBD
- (iii) Regional/international cooperation on traceability
- (iv) What standards, methods and IT systems could be used for implementing traceability systems?
 - a. Proposed speaker: IT service providers
 - b. Proposed speaker: Standardization bodies
- (v) What is the role of business companies in providing traceability within a system?
 - a. Proposed speaker: Business company
- (vi) How business companies achieve traceability of their production chains? Is there a best practice in achieving traceability?
 - a. Proposed speaker: Business company
 - b. Proposed speaker: Business company