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Item 4 of the provisional agenda

Concept note for the Workshop on “Traceability: a tool for managing risks”

Note by the secretariat¹

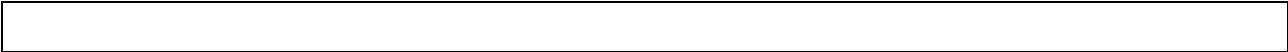
Summary

The Workshop "Traceability: a tool for managing risks" aims at improving the management of risks in regulatory systems by sharing best practice on how standardization, technical regulation, conformity assessment and market surveillance contribute to achieving traceability in supply chains. Experts will present their experience in developing and implementing traceability tools and the benefits and costs for various stakeholders.

The document:

- defines the term "traceability"
- provides an overview of how the concept of traceability is used in standards and existing legislation
- shows traceability as a tool for managing risks
- presents an outline of the event and a list of questions that the speakers will be invited to address during the Workshop.

¹ As discussed at the twentieth session of the Working Party and at the request of the WP.6 Bureau, a Workshop on “Traceability as a tool for managing risks” will be held, at the Palais des Nations, Geneva, on Monday, 31 October from 3 p.m. to 6 p.m. and on Tuesday, 1 November from 10 a.m. to 1 p.m.



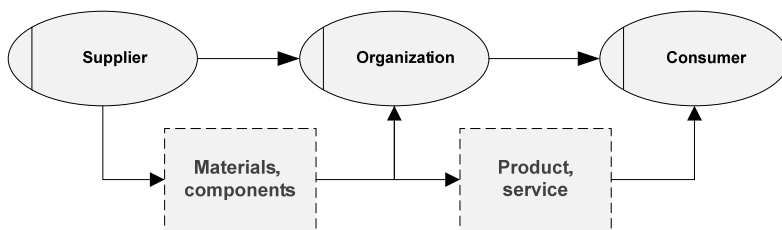
I. What is traceability?

1. 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 on the market could be traced back along all the steps of its production chain. It allows regulatory stakeholders to get information on processes, original materials and components used in the production.
2. 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 labelled 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.
3. As technological progress permits increasing specialization, supply chains are no longer under the supervision of individual craftsmen, who could, for example, produce cheese using their own grass lawns, cows, etc. In a global economy, supply chains are complex and intertwined, and often span continents. Tracing a product back to its components is now an important means of managing business and achieving regulatory goals.

II. Why is traceability important?

4. Regulatory stakeholders have a shared interest in ensuring traceability in supply chains. For example, consumers have always been concerned about the quality and safety of products, and the origin of the goods. Traceability allows companies to increase the stability and transparency of procurement and production processes. It helps regulators and market surveillance authorities take prompt and targeted action if a dangerous product is placed on the market, e.g. to perform efficient product withdrawals. Traceability is also an essential part of any system aimed at fighting counterfeited goods.
5. 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”.

Figure 1
‘Supplier-Organization-Consumer’ Supply Chain

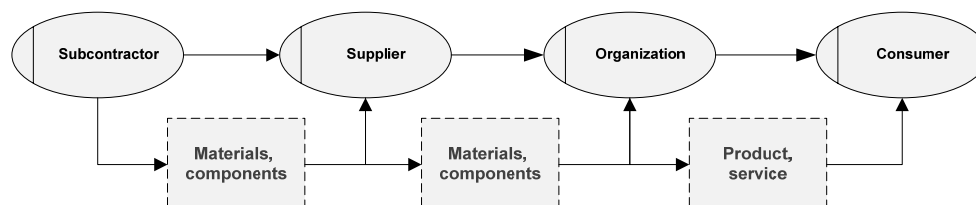


Source: UNECE secretariat

6. 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”:

Figure 2

‘Subcontractor-Supplier-Organization-Consumer’ Supply Chain



Source: UNECE secretariat

7. In the area of feed and food, ISO 22005:2007 “Traceability in the feed and food chain – General principles and basic requirements for system design and implementation” establishes the principles and requirements for designing and implementing a traceability system.

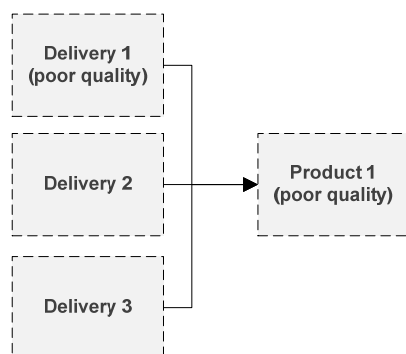
8. Traceability requirements in legislation are a key tenet of complex regulatory systems. For example, the Food Safety Regulation of the European Union contains provisions and introduces mechanisms to achieve transparency in the food and feed chain. Likewise, the Food Safety Modernization Act of 2010 (FSMA) also enhances food traceability in the United States 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.

III. Traceability as a tool for managing risks

9. 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, an organization needs to get full information on which components were used, where they came from, etc.

Figure 3

Product 1 is of poor quality because delivery 1 was of poor quality

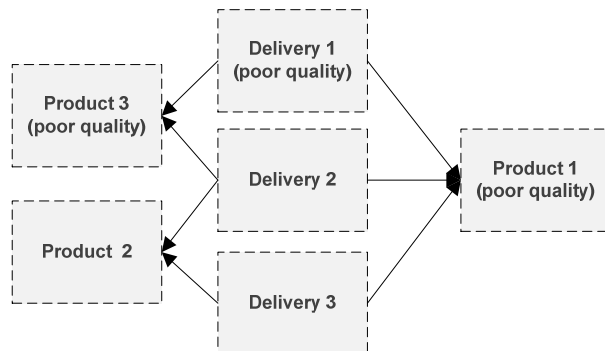


Source: UNECE secretariat

10. When, in turn, the cause of poor quality has been identified, the organization can identify and if necessary withdraw from the market only those items that are affected.

Figure 4

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



Source: UNECE secretariat

11. 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 necessary;
- (c) Achieving traceability within regulatory systems, which requires:
 - (i) Traceability of production processes of business companies;
 - (ii) Implementing traceability tools by the regulator.

IV. Preliminary outline of the event

A. Traceability and standardization

12. This session will discuss standards as tools that can be used to increase traceability of inputs used in production processes within supply chains at a reasonable cost.

13. Questions that will be discussed under this item include the following:

- (a) Which standards can regulatory stakeholders use as tools to increase traceability of inputs used in production processes?
- (b) Which standards can be used to increase traceability within the supply chain?
- (c) What can be considered as best practice in standards implementation?
- (d) What is the business experience of increasing traceability within production or service provision processes?

14. Speakers will be invited from:

- (a) Standardization bodies;
- (b) Businesses that have implemented standards to achieve traceability.

B. Traceability and regulatory practice

15. This session will discuss examples of how traceability has been used by regulators in different sectors and different countries to achieve their regulatory goals (consumer product safety, environmental protection, food safety).

16. Questions that will be addressed under this item include the following:

- (a) How has traceability been used by regulators in different sectors and different countries?
- (b) What are the costs and benefits associated with increasing traceability?
- (c) What are these costs and benefits for regulators, business companies, market surveillance authorities, and other stakeholders?
- (d) What are the positive and negative aspects of imposing traceability requirements?
- (e) Under which conditions do traceability requirements help to achieve regulatory goals?
- (f) What is the business experience in implementing regulatory requirements on traceability?

17. In particular, speakers will be invited from:

- (a) The EU Commission and/or from EU Member States;
- (b) Countries with economies in transition;
- (c) Other countries/regions.

D. Traceability in conformity assessment and market surveillance

18. This session will discuss how conformity assessment bodies and market surveillance authorities are using and could use different tools to increase traceability of inputs in implementing regulatory requirements and responding to business needs for traceability.

19. Questions that will be addressed under this item include the following:

- (a) How are conformity assessment bodies and market surveillance authorities using, and how could they use, different tools to increase traceability?
- (b) Which traceability requirements are essential for achieving effective market surveillance?
- (c) Which IT solutions can regulatory stakeholders use to increase traceability within regulatory systems?

20. In particular, speakers will be invited from:

- (a) Market surveillance authorities;
 - (b) Schemes of assessment of conformity to standards;
 - (c) Conformity assessment bodies;
 - (d) Accreditation bodies.
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