



Research support for an informal expert group on product traceability

Final Report

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DISCLAIMER

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TABLE OF CONTENTS

Acknowledgments.....	2
Disclaimer.....	2
Executive Summary.....	5
1. Introduction	7
1.1. Objective of the document	7
1.2. Methodology	7
1.3. Scope and traceability definition	8
1.4. How to read this document.....	8
1.5. Terminology	9
2. Setting the scene.....	10
2.1. Regulatory background	10
2.2. Functioning of the RAPEX system	11
2.3. Traceability best practices	13
2.4. Overall issue	15
3. Raising awareness on traceability benefits	17
3.1. Benefits for economic operators.....	17
3.2. Benefits for market surveillance authorities.....	19
3.3. Benefits for consumers	20
4. Capacity building of economic operators	20
4.1. Towards a common understanding of traceability	20
4.2. Application of best practices and automation of traceability systems	28
4.3. Guidance and education of economic operators.....	39
5. Capacity building of market surveillance authorities	40
5.1. Towards a common understanding of traceability	41
5.2. Better use of all existing sources of information.....	41
5.3. Best practices in market surveillance authorities	44
5.4. Review RAPEX templates	46

6.	A collective effort to fight against irresponsibility.....	48
6.1.	Legal framework and enforcement.....	48
6.2.	Addressing online channels and freight forwarders	49
6.3.	Consumer awareness and involvement	49
7.	The key role of customs.....	50
7.1.	Leveraging the collaboration between market surveillance authorities and customs to collect and access product information	50
7.2.	More Authorised Economic Operators : a potential common interest	52
8.	Trends and thoughts for the future	52
8.1.	The digital consumer in demand for product information.....	52
8.2.	Traceability networks and new technologies.....	54
8.3.	Triggering international momentum to improve traceability in supply chains	55
9.	References	56
	ANNEXES	58
	Annex 1 : Self-assessment checklist for economic operators	59
	Annex 2 : Self-assessment checklist for market surveillance authorities	59
	Annex 3 : Four models to manage traceability information across the chain.....	60
	Annex 4 : Case studies	63
	Annex 5 : GS1 standards and corresponding ISO or other standards.....	66

EXECUTIVE SUMMARY

This report is aimed at presenting the findings of an informal expert group on product traceability set up by the European Commission's Directorate General Health and Consumers (DG SANCO).

Traceability is key to consumer safety. It makes recalls and withdrawals more efficient. It is an integral part of economic operators' quality and safety management systems. It facilitates market surveillance authorities' tasks of determining if an unsafe product is on their market, tracing economic operators involved and proceeding with effective corrective measures. It ensures proper information about unsafe products can be given to consumers in case of recall.

As supply chains, from raw materials and components to points of sales, often span the globe, ensuring traceability throughout the whole supply chain has become more challenging. Market surveillance authorities encounter significant difficulties collecting information about economic operators involved in the supply chain of unsafe products. The specific issue the Product Traceability Expert Group (Group) has addressed is to ensure that Member State authorities creating RAPEX notifications have as complete and accurate information as possible concerning product identification, traceability and can find which actor made available the product on the market in order to proceed efficiently with corrective measures.

To that purpose, the Group has analysed the problem and reviewed best practices, international standards, systems, tools and on-going international developments in the area of traceability for non-food consumer products, or similar areas, both in terms of best practices to comply with legal requirements as well as measures that go beyond those requirements to ensure consumer safety.

The Group concluded with seven key recommendations :

1. Economic operators should label their consumer products at least with a product identification code and contact details of the responsible economic operator.
2. Economic operators should automate their traceability system by using data capture, data recording and data exchange technologies with applicable global standards.
3. Economic operators should get trained on traceability in order to be aware of traceability benefits, understand best practices and get the knowledge to choose and implement the most relevant tools to automate traceability within their organisation.
4. Traceability assessment exercises should be conducted across the chain with the cooperation of market surveillance authorities and trade associations.
5. Information about how to use barcodes / product codes to get additional information should be included in RAPEX trainings for market surveillance authorities.
6. Best practices for market surveillance authorities should be developed for best use of available information when products are crossing borders within the EU, including real case studies.
7. Consumer associations should raise awareness on the importance of product identification and inform consumers on possibilities to alert authorities on suspicious products.

These recommendations are based on the analysis of the potential reasons for missing information on product identification and economic operators in RAPEX notifications :

- No product identification or unclear or not sufficient.
- Information on economic operators is not available or insufficient because of lack of documentation and records by economic operators.
- Economic operator is out of the jurisdiction of the market surveillance authorities submitting the RAPEX notification.
- Fraud and deceptive business practices (e.g. counterfeited products, unofficial trade, false information).
- Information on economic operators is available but the operators cannot be reached (e.g. temporary actor, bankrupt, no fixed premises).

The recommendations were also based on observations on the interest, the capacity and the willingness or unwillingness of the different economics operators to implement traceability.

Overall, the key to success is to set a level playing field for traceability across the chain and globally. Economic operators, market surveillance authorities, customs and consumers all have a role to play. A common understanding of traceability and of its benefits for and by all actors should be the foundation. Capacity building of economic operators, capacity building of market surveillance authorities and combatting deceptive practices are the right direction while legal requirements and economic operators' needs - in supply chain efficiencies for example - will drive the path for implementation.

Looking forward, the growing importance of online sales and new consumer behaviours bring new challenges that shall be specifically addressed. New technologies and traceability networks may help and should be considered. In any case, global, regional and national efforts to strengthen public and private cooperation will be a cornerstone to ensure traceability and more importantly, consumer safety.

1. INTRODUCTION

1.1. OBJECTIVE OF THE DOCUMENT

In June 2011, the European Commission's Directorate General Health and Consumers (DG SANCO) established an Informal Product Traceability Expert Group (the Group) whose purpose was to :

- Provide information to the European Commission about best practices, international standards, systems, tools, problems, constraints, etc. in the area of traceability for non-food consumer products both in terms of measures to comply with legal requirements as well as measures that go beyond those requirements to ensure consumer safety
- Comment on ongoing international developments in this area
- Inform the European Commission of gaps and weaknesses in the existing EU practices and, potentially, the legal framework for ensuring traceability for non-food consumer product safety
- Recommend actions to the different actors involved to improve the current situation

Further to the call for tender SANCO/2011/B3/002, GS1 (hereinafter "the Contractor") was selected to provide research support for the Group.

This document wraps up the findings of the Group.

1.2. METHODOLOGY

A balanced expert group consisting of fifteen experts from market surveillance authorities, manufacturing, retail, industry associations and advisory organisations were appointed to the Informal Product Traceability Expert Group. DG SANCO chaired the Group. The Contractor was tasked with overall program management, meetings facilitation, discussion papers and report writing.

The Group held six physical meetings. The Contractor delivered four intermediary non-binding discussion papers on :

1. Voluntary Product Traceability schemes
2. Pushchair Traceability
3. Actors Mapping
4. Authorities' Processes for RAPEX Notifications.

These papers were a way to trigger the discussions on the current situation and to document the research in specific areas. Desk research, interviews, questionnaires and field visits completed the learning and validation process. This final report consolidates the information resulting from all these activities. A difficulty encountered during the research support was that the literature review revealed the limited amount of existing literature specifically addressing global traceability of non-food consumer products.

Cautionary note : This document is the result of a collective effort between the Group and many other stakeholders directly or indirectly involved. A consensus was sought from the Group whenever possible, however, the content of this document does not reflect the endorsement of DG SANCO, any other European Commission service, GS1 or any particular member of the Group.

1.3. SCOPE AND TRACEABILITY DEFINITION

This document focuses on best practices for products traceability.

Traceability is defined in International Standards Organisation (ISO) standard 9000: 2005 as the “ability to trace the history, application or location of that which is under consideration. When considering product, traceability can relate to :

- the origin of materials and parts
- the processing history, and
- the distribution and location of the product after delivery”

The scope in terms of product categories is non-food consumer products that would come within the scope of application of the General Product Safety Directive (GPSD) hence excluding food, feed, medical devices and pharmaceuticals. The harmonised products sectors may find value in the document but all recommendations and best practices highlighted in this report cannot overrule any existing legislative requirement. As a consequence some recommendations and best practices - such as for example the first recommendation - do not apply to harmonised products for which a legal requirement already exists.

The Group was created in parallel to the GPSD revision process. Rather than commenting on existing or potential future legislations, the aim of the Group and of this final report was to bring a complementary view on non-regulatory aspects of traceability such as existing best practices, standards and systems, tools and opportunities to improve the current situation beyond regulatory matters.

In the context of consumer safety, traceability serves to identify both economic operators and physical products in the entire supply chain. With this information, corrective measures, such as product recalls or withdrawals, can be effectively put in place. In this report, traceability is looked at as part of quality and safety management systems.

1.4. HOW TO READ THIS DOCUMENT

This report highlights the conclusions and recommendations of the Group. It does not aim to present an exhaustive overview of all the detailed learning and knowledge available. Readers interested in getting more details can use documents listed in references.

The contents of this report are as follows :

- Chapter 2 provides background information and defines the issue.
- Chapter 3 highlights the benefits of traceability for all stakeholders.
- Chapter 4 provides a summary of the learning and makes recommendations related to Economic Operators.
- Chapter 5 provides a summary of the learning and makes recommendations related to market surveillance authorities.
- Chapter 6 addresses actors beyond the scope of capacity building.
- Chapter 7 focuses on the collaboration with customs.
- Chapter 8 pinpoints a few considerations for the future.

1.5. TERMINOLOGY

The vocabulary used in this document is aligned with definitions from the EU New Legislative Framework¹:

making available on the market

any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge

placing on the market

the first making available of a product on the Community market

manufacturer

any natural or legal person established within the Community who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark

authorised representative

any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks

importer

any natural or legal person established within the Community who places a product from a third country on the Community market

distributor

any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market

economic operator

the manufacturer, the authorised representative, the importer and the distributor

technical specification

a document that prescribes technical requirements to be fulfilled by a product, process or service

recall

any measure aimed at achieving the return of a product that has already been made available to the end user

withdrawal

any measure aimed at preventing a product in the supply chain from being made available on the market

Additional vocabulary may be used when relevant and is then explained if necessary.

The term “product label” for example is used to designate the information available on the product in the state it is sold to end consumers. It can be on the packaging or on the product.

¹ DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

2. SETTING THE SCENE

2.1. REGULATORY BACKGROUND

This chapter intends to provide some background information on how existing regulations relate to traceability. It does not aim at providing a complete and detailed analysis of traceability requirements across all existing regulations.

GENERAL PRODUCT SAFETY DIRECTIVE (GPSD)

The GPSD contains references to elements of traceability such as in Article 5)1)a) “Other obligations of producers and obligations of Distributors”. The measures referred to in the third subparagraph shall include, for example:

- a) an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified and [...]

Nevertheless, it is up to the Member States to adopt concrete measures to implement such obligations.

The GPSD is currently under review and will be replaced by a package of regulations on Product Safety and Market Surveillance. The legislative proposals that the Commission adopted on February 13, 2013, includes clearer traceability requirements. The final text is yet to be voted at the time of the completion of this report.

NEW LEGISLATIVE FRAMEWORK

The Decision 768/2008/EC sets up the definition of economic operators’ roles and states the importance of traceability for market surveillance :

- (28) Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant products available on the market.

Moreover, articles R2, R4, R5 and R7 provide model articles addressing traceability for new sectorial legislation. New specific regulations applicable to cosmetics and toys for example already include clear identification and traceability requirements that can be inspiring for other sectors.

COSMETICS

In addition to records of suppliers and customers in Article 7, the regulation (EC) No 1223/2009 on cosmetic products, sets out in article 19 detailed rules for the labelling of cosmetic products². The responsible person must make sure that all products under his responsibility meet the following requirements:

- (i) Name and address of the Responsible Person (Article 19(1)(a))
- (ii) The country of origin for products imported into the EU
- (iii) Content (Article 19(1)(b))

² *Compliance with regulation 1223/2009 on cosmetics products, roles and responsibilities along the supply chain, a practical guide*, Cosmetics Europe

- (iv) A date of minimum durability or a Period after opening (PaO) where appropriate (Article 19(1)(c))
- (v) Precautions of use (Article 19(1)d))
- (vi) The function of the product (Article 19(1)(f))
- (vii) The list of ingredients (Article 19(1)(g))
- (viii) Small products (Article 19(3))
- (ix) Unpackaged products (Article 19(4))

TOYS SAFETY DIRECTIVE (TSD)

The Toys Safety Directive as adopted in 2009 includes clear elements of traceability following the model of the New Legislative Framework³ in article 4, 5, 6, 7, 9, 21 and articles on notification and links with the RAPEX system. Article 4 “Obligations of manufacturers” says for example :

3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market.
[...]
5. Manufacturers shall ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy.
6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy. The address shall indicate a single point at which the manufacturer can be contacted.

Article 7 is about Obligations of Distributors who shall verify for example that the manufacturer and the importer have complied with the requirements set out in Article 4(5) and (6) and Article 6(3), such as the availability of the address of the manufacturer and/or the importer. Article 9 is about the Identification of Economic Operators who are obliged to be able to identify, upon request from the authorities and for a period of ten years, any operator who has supplied them with a toy, and any operator to whom they have supplied a toy. Article 21 is about the Technical Documentation detailed in Annex IV including the detailed description of the design and manufacture with a list of components and materials used in the toy as well as the safety data sheets on chemicals used and the addresses of the places of manufacture and storage.

Cosmetics and Toys regulations are just examples of harmonised products with legal traceability requirements.

2.2. FUNCTIONING OF THE RAPEX SYSTEM

The RAPEX system ensures that information about unsafe non-food consumer and professional products posing a serious risk found in one country Member of the RAPEX network (28 Member States of the European Union and 3 countries from EFTA/EEA) is rapidly sent to the European Commission and circulated among all the other national authorities for follow-up.

³ See also TIE Factsheet on “*Traceability in the 2009 Toy Safety Directive*”

This system has been in place since several years and successfully prevents dangerous products from reaching consumers and professional users every day.

A NETWORK OF NATIONAL CONTACT POINTS

Each Member State has a contact point for information sharing with the EU Commission, ensuring a link with market surveillance authorities and overcoming the challenges of local specificities. The contact points from a community with a common knowledge and culture around RAPEX including processes to investigate on products traceability.

RAPEX NOTIFICATIONS AND TRACEABILITY

When a dangerous product is discovered in a Member State, national authorities collect information – from economic operators, consumers, customs or other sources of information – and the RAPEX contact point of this Member State submits a RAPEX notification to the European Commission. Information about dangerous products is circulated among national authorities using this RAPEX notification.

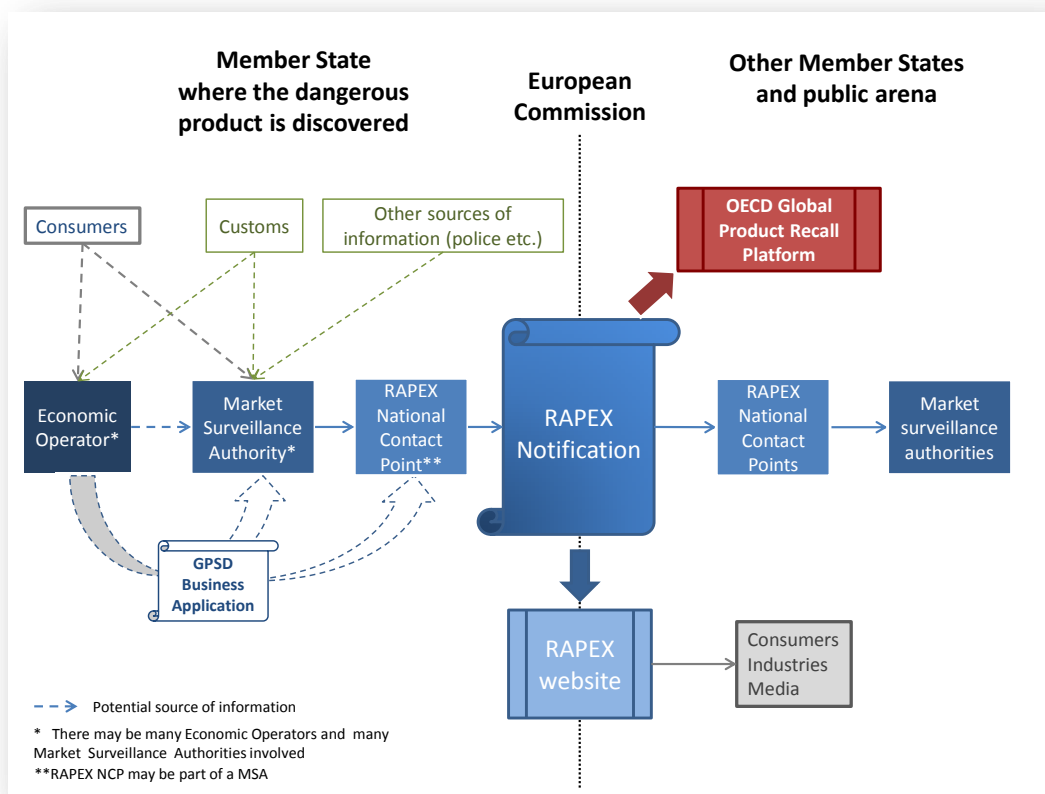


Figure 1 : Overview of actors linked to the process of collecting and using the information of a RAPEX notification

RAPEX notifications shall include all the information necessary for helping authorities to effectively take corrective measures. The notification form⁴ includes fields concerning “Product identification” and “Traceability” with details of economic operators involved⁵. Information in these fields enables authorities when relevant to most effectively :

- determine if the products are on their national market
- reach economic operators that may have these products
- remove the products from the market and communicate with consumers who may already have them.

As a consequence, effective traceability in supply chains is critical for RAPEX to deliver as much useful information as possible to authorities and ultimately to consumers.

2.3. TRACEABILITY BEST PRACTICES

PROVIDING THE “HOW-TO” FOR THE “WHAT”

Historically, traceability best practices have been developed and implemented in various sectors driven by the industry need for improved efficiency or driven by regulatory requirements⁶. While regulations and many international standards generally define WHAT should be done in a non-prescriptive manner, best practices and industry developed global standards provide the critical HOW-TO in prescriptive language in order to meet these requirements.

For example, regulatory requirements (the What) include the definition of what shall be traceable – which products and with which precision, which information should be accessible, how long etc., and responsibilities. Best practices (the How-To) include specific and prescriptive ways to identify products, data format for automatic processing and agreements on enabling technologies such as the type of barcodes and data that can be shared in an interoperable system across many trading partners.

ENABLING INTEROPERABILITY FOR FULL CHAIN TRACEABILITY

Global best practices focus on ensuring interoperability between traceability systems of operators successively involved in the chain. They provide a way to overcome jurisdictional, geographical and languages limits.

The choice of internal tools and procedures remains a choice for every actor or industry sector preference. Interoperability is ensured by the integration of these practices in internal systems. For example, global standards for product data structure and format are independent from the choices of enterprise software and can be integrated by competent organisations. Standard specifications for physical symbologies that are machine readable, such as barcodes are freely available and highly recommended. This allows for supply chain efficiencies by automating key processes and data capture from manufacturing through distribution and retail. Each economic operator remains free to decide on their preference for barcode printers and scanners.

⁴ Commission Decision 2010/15/EU

⁵ Economic Operators can use the GPSD Business Application form (Commission Decision 2004/905/EC) in order to notify authorities of dangerous products. The format differs from the RAPEX notification form but it includes similar information.

⁶ *Discussion Paper on Voluntary Product Traceability Schemes*, EU Informal Expert Group on Product Traceability, September 2011

SUPPORTING A WIDE CHOICE OF TOOLS

A collateral benefit of standards and best practices in general is to enable the availability on the market of multiple solutions that enable vital interoperability across the many actors in the supply chain. Solutions providers of all sizes can compete with different added value and services. Economic operators are ensured their internal traceability system will be compatible with those of their trading partners as long as it embeds the standard specifications to be interoperable.

EXISTING REFERENCES FOR TRACEABILITY BEST PRACTICES

Best practices are typically defined by economic operators through standards and industry association guidelines⁷. Traceability management systems must be based on commonly agreed standards which are cross industry and universal such as ISO and GS1.

ISO (International Organization for Standardization) is the well-known and world's largest developer of voluntary International Standards. Created in 1947, ISO is an independent, non-governmental organization made up of members from the national standards bodies of 163 countries. GS1 is a global, neutral and not-for-profit, supply chain standards organisation driven by its users. With over one million member companies in 150 countries, the GS1 system of standards is the most widely used supply chain standards system in the world. These standards are recommended as best practices by the group but each operator is free to decide on how to implement his internal traceability system as long as he is able to receive, process and communicate the necessary information to its business partners.

Other global standards⁸ may play a role in specific parts of the traceability processes or on their technological aspects such as the World Wide Web Consortium (W3C) for the Web or the International Telecommunication Union (ITU) for information and communication technologies. Regional standard bodies such as the European Committee for Standardization (CEN) must also be taken into consideration even if not global. In addition to available global standards, ECR (Efficient Consumer Response) Europe, the association gathering value chain partners in Consumer Goods and working on best practices published in 2004 guidelines for "Using Traceability in the Supply Chain to meet Consumer Safety Expectations".

Apart from non-food consumer products, the food⁹ and healthcare¹⁰ industries have interesting traceability schemes addressing the full traceability process. The principles of these schemes are comparable in terms of best practices regarding enabling technologies, possibilities offered by the one-up one-down principle and other models, applicable standards etc... Differences are directly driven by specific needs such as combatting counterfeiting or specific regulations such as for beef¹¹, fisheries¹² or in healthcare for the Unique Identification of Devices (UDI¹³).

⁷ See documents about best practices listed in References

⁸ See overview of other global standard bodies in chapter 4.2, best practice 5

⁹ See for example *Implementing Traceability in the Food Supply Chain*, CIES-The Food Business Forum, 2004; *Traceability of honey, specification of the information to be recorded in honey distribution chains*, Nofima, 2008; Produce Traceability Initiative at <http://www.producetraceability.org/>; *Food Traceability, International Union of Food Science and Technology (IUFoST) Scientific Information Bulletin (SIB)*, March 2012

¹⁰ See for example *Healthcare Supply Chain Traceability White Paper*, GS1; *Global Traceability Standard for Healthcare*, issue 1.0.0, GS1, 2009;

¹¹ Regulation (EC) No 1760/2000

¹² Regulation (EC) No 1224/2009

¹³ Commission Recommendation of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union 2013/172/EU

2.4. OVERALL ISSUE

Traceability has grown steadily in relevance and importance due to the need for integration and collaboration and the need to “speak the same language” when sourcing products globally. As the journey from the factory floor to the store shelf often spans the globe, ensuring traceability throughout the whole supply chain has become more challenging. The issue the Group has addressed is to ensure that Member State authorities creating RAPEX notification have as complete and accurate information as possible concerning product identification, traceability and know which actor placed the product on the market. This will increase the chances that other Member States receiving the notification can find and take actions against the dangerous products.

LACK OF PRODUCT IDENTIFICATION AND TRACEABILITY INFORMATION IN RAPEX NOTIFICATIONS

The number of notifications through the RAPEX system of consumer product safety alerts in which the product is untraceable has decreased. Yet it remains exceptional for competent authorities to be able to fill all the fields concerning product identification and traceability¹⁴.

For example, products that pose a serious risk where the brand/clear product identification is missing still accounted for 18% of all notifications in 2012. In recent consultations of Member States by DG SANCO :

- 93% of authorities stated they had at least sometimes problems with identifying the manufacturer of the dangerous product (17% of them had this problem often)
- 78% of the authorities had the same problem with respect to importers (15% of them had this problem often)

CONSUMER HEALTH AT STAKE

The lack of product identification and of information on economic operators such as manufacturer and importer are an important obstacle to proper enforcement of product safety.

From an authority point of view, missing information has two levels of consequences¹⁵:

- For the effective follow-up of the notification, incomplete information makes it difficult and time consuming for market surveillance authorities to check if the product is sold on their markets.
- For consumer safety, there is a risk of not being able to withdraw from the market or recall from the consumer large quantities of products that have been identified as dangerous. There is a risk of not submitting a RAPEX notification and consequently not being able to alert the other Members States about the dangerous products that could be possibly found on their market.

Similarly and from a business standpoint, it is time consuming for economic operators to have to verify if they are selling the product and to find additional information :

¹⁴ Moreover RAPEX notifications submitted by National Contact Points are accepted only if they contain sufficient information. Statistics do not take into account RAPEX notifications that may have been distributed only for information without obligation for the national authorities to do a follow-up because of too much missing information. Market surveillance authorities might also not submit notifications that are very likely not to be distributed.

¹⁵ The statistics under the RAPEX - China system, which facilitates joint EU - China action to address safety issues with products originating in China, have also made it clear that there are problems with traceability. Not being able to trace the manufacturer of the product is a major reason why the Chinese authorities cannot take corrective actions or stop dangerous goods at source. The activity reports received from the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) indicate that, in almost half of the cases investigated, the lack of corrective measures taken was due to the fact that they could not identify and locate the Chinese companies responsible for manufacturing or exporting the notified dangerous products to the EU, whether from lack of information or false identification data.

- Identifying the source of the problem may take days, weeks or be unsuccessful.
- Products may not be uniquely identified and cause confusion with safe products at risk of being removed from the market unnecessarily.
- The image of the economic operators or even of the whole category of products may suffer resulting in more economic damages than if the recall had been under control.

For the consumer, it means products recognized as dangerous may still be available on the market. No product identification makes it more difficult to verify if a product already purchased is unsafe and recalled.

Finally, the lack of consistency in implementing effective traceability and recall processes as well as consistent information sharing is a global issue. The Organisation for Economic Co-operation and Development (OECD) Global Product Recall platform¹⁶ launched in October 2012 aims at informing member jurisdictions of dangerous products. The information available in the OECD platform is based on the information provided by the jurisdiction where the dangerous product has been discovered. As RAPEX will feed information into the OECD recall portal, missing information in RAPEX will have a negative knock-on effect in the OECD global Product Recall Platform as well.

WILLINGNESS AND CAPACITY OF OPERATORS

In order to help determine which actions are the most appropriate to improve traceability, the Group considered the following categories of economic operators :

- Category 1 : Operators who care about the rules and are in a position to implement them
They usually see an interest in traceability for themselves or are ready to follow the rules and can get benefits of it owing to their proactive approach. They can help define best practices based on their experience and spreading them at least with their direct trading partners.
- Category 2 : Operators who care about the rules but face difficulties to implement them
They need guidance and support to implement traceability. Sometimes economic operators don't have an intentional bad practice but have little knowledge of regulatory requirements or basic business practices.
- Category 3 : Operators who choose to ignore regulations and law
They are beyond the scope of good practices. They are in the scope of law enforcement. Best practices for other actors can sometimes help limit their impact in the chain.

¹⁶ <http://globalrecalls.oecd.org/>

3. RAISING AWARENESS ON TRACEABILITY BENEFITS

Effective traceability across the supply chain benefits economic operators, authorities and consumers. A fundamental problem is the lack of awareness and understanding among all stakeholders of why traceability is important for themselves and for others. In some sectors such as food, traceability is becoming a critical element for market access¹⁷.

In non-harmonised products, traceability has not yet been a regulatory topic. Operators would normally have elements of traceability in place as part of their usual business activities but some operators may have never looked at their traceability system in a methodological way and at how it is interoperable, or not, with their trading partners.

Economic operators may not be fully aware of why market surveillance authorities need traceability in case of dangerous products found on the market or of the practical information and documents that will be needed. Some operators are de facto accustomed to dealing with withdrawals or recalls on a regular basis (on average once per day in big hypermarkets including minor withdrawals) but others may never have faced any withdrawals or recalls and are unprepared.

3.1. BENEFITS FOR ECONOMIC OPERATORS

QUALITY MANAGEMENT AND MORE EFFICIENT RECALLS

Rather than considering traceability as an additional cost, traceability is an integral part of quality and safety management systems. It relates directly to a company's risk management strategy and on the desired level of quality/safety assurance. It is often tied to product recall and corporate risk insurance policies because part of traceability is to prevent problems and another part is to effectively manage quality problems when they occur.

Traceability enables economic operators to¹⁸:

- Ensure compliance with regulatory requirements concerning traceability, recall, product identification and the maintenance of records
- Determine the source of quality incidents and appropriate corrective measures
- In case of recall, demonstrate control, increase efficiency and reduce the cost of the product recall notably by sharing precise recall information between trading partners and with authorities
- Demonstrate compliance with product specifications and statements¹⁹
- Contribute to establish product authentication and anti-counterfeit policies

¹⁷ See for example the new FDA Food Safety Modernization Act in the US and *Commission recommendation of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union*

¹⁸ Adapted from ISO 10377:2013(E)

¹⁹ Notably for product with specific statements such as ethical trade

BETTER LOGISTICS PERFORMANCES

Beyond product and consumer safety, traceability systems contribute to have a better visibility and supply chain efficiency throughout the chain²⁰. They accurately answer the “what, when, where & why” of a specific product’s movement. Traceability is recognized as an indicator of logistics performance²¹. When companies and their logistics service providers have a better access to knowledge about the flow of products and transactions in their supply chains, sometimes real-time, they can make decisions that drive business value for transport and logistics processes :

- More accurate planning, forecasting and replenishment
- Optimised fleet management
- Easier collaboration using common identification and information sharing mechanism
- Reduced, and in some cases even entirely eliminated, paperwork
- More secure import controls
- Reduced CO2 emissions (fewer “empty” miles and optimized cargo management)

Supply chain management best practices may go beyond needs strictly related to product safety in terms of following the movement of goods. Current global activities in the apparel sector²² are a good example of these benefits for the industry.

L'ORÉAL CASE STUDY : HOW THE INDUSTRY REALIZES BENEFITS

L'Oréal France, a global cosmetic company, already works with EDI (Electronic Data Interchange) for most of its global brands in 130 countries. L'Oréal benefited from reduced out-of-stock rates in storage areas and shops, improved anticipation of merchandise flow (production, logistics) and optimized truck loads. With use of EDI “order-to-cash” messages in mind, L'Oréal started the exchange of product master data synchronised via the Global Data Synchronisation Network (GDSN). The synchronised database management system enables a standardised and security-rich process for data distribution, which aims at “data alignment”. This process has increased the capacity of commercial units to distribute more reliable, quality product information and has considerably accelerated the information flow, allowing L'Oréal in France to react faster.

Source : IBM Global Business Services 2012

MOVING FROM COMPLIANCE TRACEABILITY TO VALUE TRACEABILITY

Organisations can extract significant value from implementation traceability and extend from a “must-do” to comply with regulatory requirements to a “must-have” to differentiate their products in the market place. Depending on the degree of implementation and the infrastructure selected by a company, product traceability processes may require significant investment. The benefits and savings are not obvious at first glance and the expenditure should be considered as a long-term strategic

²⁰ *Using Traceability in the Supply Chain to meet Consumer Safety Expectations*, ECR 2004

²¹ The World Bank’s Logistics Performance Index (LPI) analyses countries in six components including “The ability to track and trace consignments.” Source : *Connecting to Compete 2012, Trade Logistics in the Global Economy, The Logistics Performance Index and Its Indicators*, The World Bank, 2012

²² Apparel workshop, GS1 Standards and industry events, Dallas, 2013

investment because it is linked to consumers' perception, the image of the company and the trust consumers display when buying a product²³.

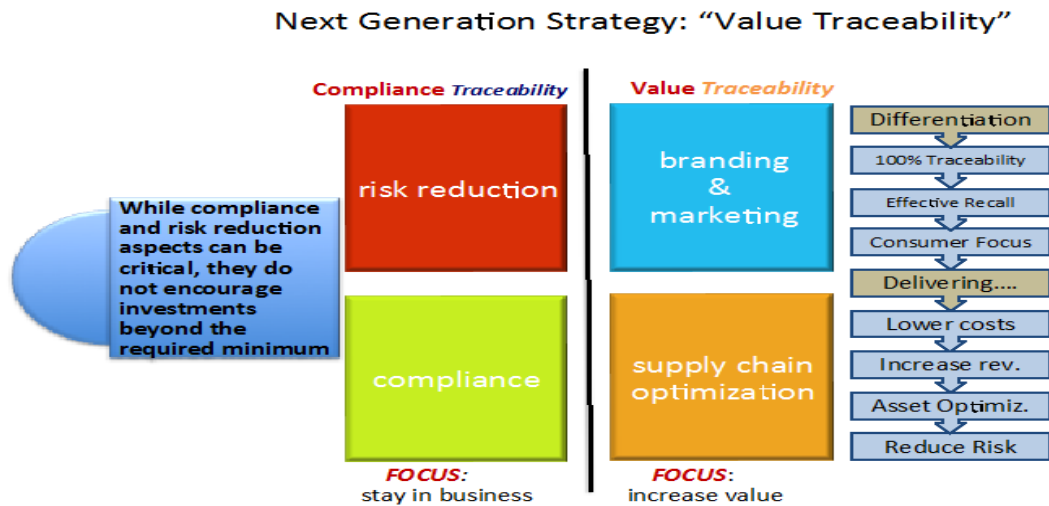


Figure 2: From "Compliance Traceability" to "Value Traceability", source GS1

By including traceability in the agenda of their conference, seminars, workshops or work group meetings, trade associations can greatly help increase the awareness on traceability benefits.

3.2. BENEFITS FOR MARKET SURVEILLANCE AUTHORITIES

Traceability helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' tasks of :

- determining if a dangerous product is on their market
- tracing economic operators who made non-compliant products available on the market²⁴
- checking compliance with applicable regulations
- verifying the presence or absence of product attributes (e.g. child safe)
- accessing the technical specifications of the product and retracing the actual history of the product as necessary to protect consumers health
- proceeding with effective risk assessment and corrective measures based on reliable and complete information, ensuring consumer safety while avoiding irrelevant costs for economic operators when removing products from the market
- proceeding with enforcement actions with all relevant stakeholders

²³ Using Traceability in the Supply Chain to meet Consumer Safety Expectations, ECR 2004

²⁴ EC No 768/2008, (28)

3.3. BENEFITS FOR CONSUMERS

Traceability added value for consumers may not always be visible at first sight yet it plays an essential role in consumer safety and in the reliability of consumer information. Traceability helps ensure that :

- Products have been manufactured and placed on the market with labels and identification that facilitate increased trust in the brand.
- If a safety issue occurs, all dangerous products are properly identified and removed from the market rapidly.
- Proper information about dangerous products is given to consumers in case of recall (product identification, distribution channel...).
- Product information and statements on labels are accurate and verifiable.

4. CAPACITY BUILDING OF ECONOMIC OPERATORS

The lack of knowledge about traceability has been identified as a key problem among economic operators. Many stakeholders are involved along the chain and the absence of a common understanding of traceability is a first barrier to efficient tracking and tracing. Best practices and enabling technologies are available and increasingly implemented but there is opportunity for further improvements.

4.1. TOWARDS A COMMON UNDERSTANDING OF TRACEABILITY

THE LACK OF A COMMON APPROACH

Economic operators have different views concerning traceability as well as authorities. As there is no common recognized and updated reference document in non-food consumer goods, these different views are directly influenced by professional backgrounds, sectorial environment and culture.

Managing product and traceability information involves multiple internal sources of information:

- logistics data about the flow of goods and customers
- upstream sourcing and suppliers
- quality management
- production process and history
- third parties documentation such as from laboratories or certification bodies
- etc.

They are typically owned by different departments and each having their own view on traceability.

The evolution of Information and Communication Technologies (ICTs) has brought many possibilities in terms of choice of tools and information sharing models. Fifteen years ago, good practices for traceability were straight forward : linear barcodes²⁵ on all products and EDI²⁶ to exchange all data. Since then, RFID tagging, traceability networks, data pools, smartphones and 2D barcodes²⁷ have become part of the landscape. Standards have been developed for all of them to enable the best use of these new technologies. Yet this choice turned out to potentially slower implementation and investments from economic operators who are not sure about what is the right direction for the future or facing different requirements from their customers.

UNDERSTANDING GLOBAL SUPPLY CHAINS

In order to understand how to achieve traceability today, it is fundamental to first understand global supply chains. They tend to involve multiple actors and distribution channels (physical and digital) so that traceability management requires more awareness and collective effort than ever before.

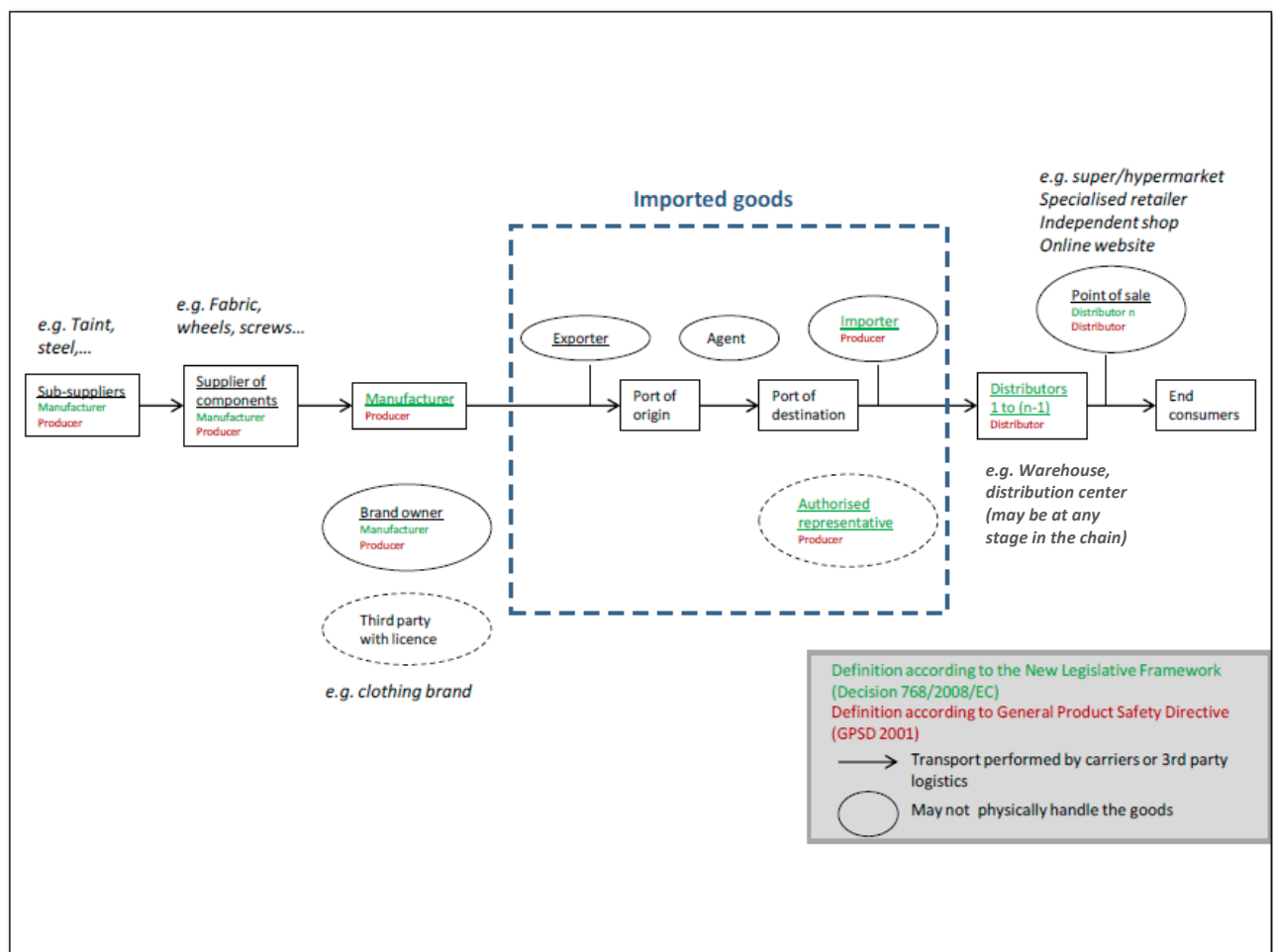


Figure 3 : Supply chain actors overview

²⁵ Read by laser scanners such as EAN/UP and GS1 128

²⁶ Electronic Data Interchange

²⁷ Read by imaging scanners such as QR code and Data Matrix

Multiple economic operators are involved. By the time a consumer product is purchased, consumed or used, it may have gone through a number of supply chain events and physical transformations²⁸. Each event or transformation may have involved a number of actors :

- manufacturers
- distributors
- exporters and importers
- authorised representatives

In addition to the direct actors mentioned above, there can be various **logistics service providers** involved such as :

- 3rd party transport service providers
- carriers
- freight forwarders
- warehouse service providers
- customs brokers

They are bound to their contractual agreement with their customers with regards to traceability information recording and access.

Multiple solution providers - such as providers of electronic data interchange (EDI) services, traceability networks or online services and data pools - may handle traceability data but the scope, use and access to these data are limited by contractual relationships with their customers.

Products often consist of multiple **components** manufactured in different countries as illustrated in the iPhone case. A pushchair for example is mainly made of plastic, metal (aluminium, steel...) and fabric and has three key parts : a chassis, wheels and a seat / carry-cot. Yet pushchairs can contain up to 400 components : multiple bars, tubes, axles, reinforcements, protections, buttons, covers, screws, springs, joints, boards, clicks, harness, strips... Tracing back to manufacturers of each of these components may be useful in case a problem comes from upstream and may impact other products with different brands or even in different categories of products.

There are multiple **distribution channels**, such as :

- Large organised retailers (generalist, super/hypermarkets)
- Specialised retailers (focusing on certain categories of products such as do-it-yourself, childcare or toys, cosmetics...)
- Independent retailers (shops that are not part of a larger organisation)
- Market and vending
- Online / Internet
- Second-hand (including charities)/ gifts / loans

Various scenarios can happen in a supply chain. The same product could be distributed and placed on the same or different markets under different brand names and in different packaging by several authorised economic operators. Consumer products can be designed by a brand owner and then manufactured specifically for this brand owner or can be bought already manufactured by a distributor. Components can be produced specifically for a manufacturer or “off the shelf”, i.e. standard

²⁸ See functions in a supply chain in ISO 10377:2013(E)

components can be used by different manufacturers and brands without them knowing about it. The colouring of a final fabric for example (supplier of the supplier of components), could be done in different factories from batch to batch without any control from the manufacturer’s side. Unlike in other sectors such as food, a batch of products may be manufactured in one row and be sufficient for all the season (e.g. a T-shirt). Deliveries may be scheduled (e.g. childcare, cosmetics), seasonal (e.g. outdoor games, swimming pools, Christmas decoration) or occasional (e.g. on-line sales). These are just examples.

UNDERSTANDING TRACEABILITY CHALLENGES

OWNERS AND HANDLERS

The complexity to achieve traceability is increased by the fact that stakeholders involved in the physical flow actually handling the products (handlers) may be different from those who own the products and have responsibility for it. For example, a brand owner may never “touch” the product although he owns the product specifications and is considered as a “manufacturer” from a legal perspective.

This is increasingly true with the development of online sales. The online retailer can delegate the physical distribution of the products to contracted parties such as freight forwarders. If the online retailer is based out of the EU, there is currently no clear responsible party within the EU although the products are distributed on the EU market²⁹.

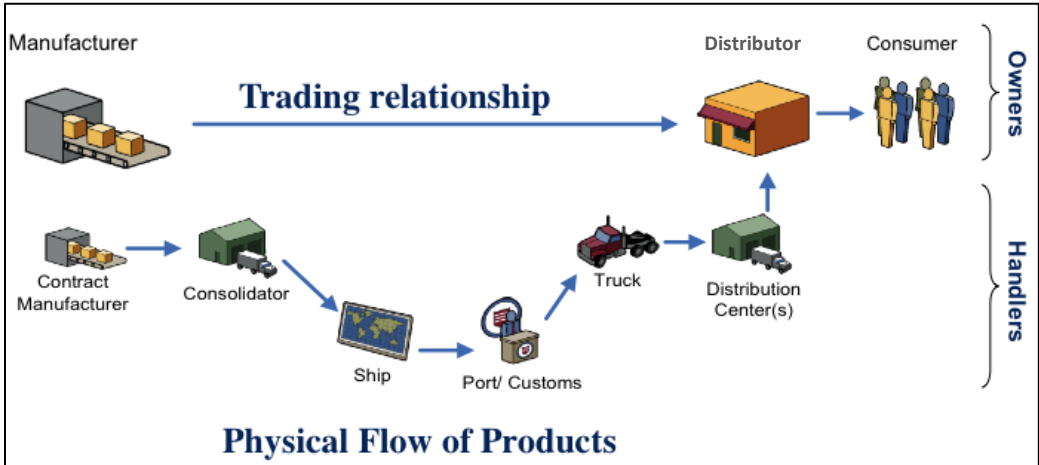


Figure 4 : owners and handlers, source GS1

INTELLECTUAL PROPERTY RIGHTS (IPR)

Constraints in sharing traceability information with third parties includes considerations for privacy laws with restrictions for sharing personally identifiable information (PII) and confidentiality of business critical information such as pricing, cost information, key suppliers and customers, distribution channels in general as well as product specifications including ingredients, raw materials, quality inspection results and other process or production methods. The risk of intellectual property rights infringements increases in global multi-party supply chains.

²⁹ See Chapter 6.2.

PRIVATE DATA

The level of product detail exposed or shared by a brand owner with their trading partners including 3rd parties can increase competitive, legal and financial risk. It might lead to a whole chain traceability constraint with limited or restricted product data shared. Traceability data linked to the movement of goods has been increasingly shared between trading partners in the past years in order to enable logistics practices such as Vendor Managed Inventory (VMI) or Collaborative Planning Forecasting and Replenishment (CPFR). Yet documents linked to the design, manufacturing, quality or safety of products such as technical specifications and results from laboratories are often confidential in nature. They are considered as “private” data³⁰.

IMPORTANCE TO TRACE BACK TO THE MANUFACTURER

The access to these data by market surveillance authorities can be justified when consumer’s health is at stake but these data will often have to be shared directly by the owner of the information with the authorities without intermediaries. Moreover, the owner of this information is often the manufacturer so that tracing back to the manufacturer remains an ideal target in many cases. If the manufacturer is not located within the EU, the importer has information concerning the product but may not always have all the specific data necessary to solve an investigation.

CONSIDERATIONS CONCERNING PRODUCT PACKAGING

Information on the packaging may be lost when/if the packaging is thrown away by the consumer or does not accompany the product until the final user of the product. Gifts and second hand products are challenging from a traceability point of view. If there is no packaging and no information on the product itself, the consumer will not know where the product was initially bought from to inform the authorities.

Small products without packaging are another example of challenge in that domain as they may miss space to feature all information ideally expected by all the audiences in a readable format.

The table below lists a few supply chain characteristics that typically increase risks in terms of traceability.

Supply chain characteristic	Consequence	Possible solution
Multiple actors involved	<ul style="list-style-type: none">• Higher risk for traceability to be lost by one of the actors (traceability is as strong as the weakest link in the chain)• Higher risk for counterfeit’s or products with poor traceability practices to enter the chain	<ul style="list-style-type: none">• Clear legal responsibilities• Actors awareness and capacity building
Multiple countries and jurisdictions involved	<ul style="list-style-type: none">• Risks for traceability to be lost because of different languages and practices• Higher risk for authorities to face difficulties when investigating about all economic operators involved• Easier for operators with fraudulent practices to “hide” behind poor, false or inexistent product	<ul style="list-style-type: none">• Legal framework and collaboration between authorities• Global best practices

³⁰ See “public” and “private” data in the next section

	identification.	
Transformation with mixing products and large size batches	<ul style="list-style-type: none"> Loss of precision 	<ul style="list-style-type: none"> Precision of traceability depending on risk management
Manual traceability systems	<ul style="list-style-type: none"> Limits in collecting and recording information Problem of speed to capture and access to data Problem of reliability and data quality 	<ul style="list-style-type: none"> Automation Best practices
Proprietary systems and identification codes	<ul style="list-style-type: none"> Risk of loss of traceability when changing of trading partner More time needed for authorities when tracing back and forward to other economic operators 	<ul style="list-style-type: none"> Standards for traceability and product identification
Online sales	<ul style="list-style-type: none"> Freight forwarders with no clear legal responsibilities³¹ 	<ul style="list-style-type: none"> Legal framework

Table 1 : sources of traceability weaknesses

UNDERSTANDING TRACEABILITY KEY PRINCIPLES AND CONCEPTS

A few key principles and concepts are the basis for a common understanding of traceability. Their summary in the table below can be used as guidance when building curriculums for traceability trainings.

Key principle or concept	Main idea or related topics
Full Chain traceability	<p>To achieve full chain traceability, all actors must not only achieve internal traceability but also collaborate with their trading partners to ensure their traceability systems are interoperable (external traceability).</p>

³¹ See chapter 6.2 on this matter

One step up, one step down principle	Traceability does not mean that each supplier on its own needs to be able to provide the full traceability information across the supply chain. Instead, each member of the supply chain should be able to trace back to the direct supplier of traceable items and identify the direct recipient of traceable items.
Tracing back and forward	Traceability includes the ability to trace back (upstream) the chain to find the source and history of a product and to trace / track forward (downstream) the distribution chain to find its location or applications.
Traceability system	A traceability system can be described in terms of : <ul style="list-style-type: none"> • <i>breadth</i> : the amount of information collected in the traceability system records • <i>depth</i> : how far upstream or downstream / back or forward in the supply chain the system tracks • <i>precision</i> : the degree of assurance with which the system can pinpoint a particular product’s movement or characteristics • <i>reliability</i> : how accurate is the information that will be found and what is the quality of the data.
Designing efficient traceability systems	<ul style="list-style-type: none"> • Automation • Procedures and processes • Collaboration within and between economic operators • Use of best practices and global standards • Assessment of systems in place
Sub-processes	<ul style="list-style-type: none"> • Identification of products and actors • Labeling and data capture • Data recording • Data exchange
Product labeling	The label must at minimum include a clear, non-ambiguous identification of the product that will serve as the “key” to record and access traceability data and to enable authorities to contact at least one key actor in the chain (e.g. manufacturer, brand owner, importer).
Data carried VS data carrier	It is important to understand the difference between : <ul style="list-style-type: none"> • The data carried : a set of data which is encoded in a data carrier and usually includes identifiers • The data carrier : the technology and media that can hold data and allows automatic data capture (e.g. barcodes and RFID ³² tags)
Identification code	An identification code is a numeric or alphanumeric code that enables the recognition of one entity versus another. In the context of product traceability, it is a sufficient key to access data available about the item that is identified.
Product identification components and granularity	The most usual product identification components found on product labels are : <ul style="list-style-type: none"> • Category of product (e.g. pushchair) • Product name • Product brand • Product type or number of model • Product identification code that identifies the class or reference of the product (typically the number under the barcode used at the point of sale) • Batch number or a serial number linked to the history of product <p>The level of granularity to identify a product should be based on the objectives of the traceability system and the risks associated with the product.</p>

³² Radio Frequency Identification

Traceable item levels	<p>In order to ensure the traceability of a consumer product, the successive stakeholders along the chain track and trace various levels of items, depending on what they handle. Traceable items³³ can be :</p> <ul style="list-style-type: none"> • a shipment (e.g. truckload, vessel) • a logistic unit (e.g. pallet of products) • a grouping of trade items (e.g. carton of products) • the sales unit itself <p>So that traceability of consumer products for many actors is a result of logistics best practices.</p>						
Traceability data	<p>Traceability data can be :</p> <ul style="list-style-type: none"> • “public” (at least for trading partners) or “private” (confidential) • “master data” (permanent/lasting nature such as everything on a product label at retail) or “dynamic data” i.e. created during the physical flow of the goods (including information about transactions such as actual deliveries and invoices and about physical events) <p>The nature of each data determines the corresponding best practices and possible tools to record and access to it.</p> <div data-bbox="365 724 1429 1344" style="text-align: center;"> <p style="text-align: center;">Depends on product type</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">Master Data</td> <td style="width: 50%; text-align: center;">Dynamic Data</td> </tr> <tr> <td style="vertical-align: top;"> <p>Parties & Location Information (GLN, Address, Contact...)</p> <p>Trade Item Information (GTIN, product name, classification, dimensions, weight...)</p> </td> <td style="vertical-align: top;"> <p>Shipment Information (Despatch Advice Number, date of despatch/receipt, ship from/to, transporter identification...)</p> <p>Logistic Unit Information (SSCC, content description...)</p> <p>Batch/Lot or serialised trade item Information (Batch/lot or serial number, quantity, best before date...)</p> </td> </tr> <tr> <td style="vertical-align: top;"> <p>Product details as planned, for example :</p> <ul style="list-style-type: none"> - Product specifications - Process of production - Components - Origin of raw materials, - ... </td> <td style="vertical-align: top;"> <p>Actual product details, for example :</p> <ul style="list-style-type: none"> - Quality records, - Results of analysis - Batch/lot number of raw materials - Identification of interchangeable components that have been used - ... </td> </tr> </table> <p style="text-align: right;">Public Information</p> <p style="text-align: right;">Depends on contractual relationship</p> <p style="text-align: right;">Private Information</p> </div> <p style="text-align: right;">Source GS1</p>	Master Data	Dynamic Data	<p>Parties & Location Information (GLN, Address, Contact...)</p> <p>Trade Item Information (GTIN, product name, classification, dimensions, weight...)</p>	<p>Shipment Information (Despatch Advice Number, date of despatch/receipt, ship from/to, transporter identification...)</p> <p>Logistic Unit Information (SSCC, content description...)</p> <p>Batch/Lot or serialised trade item Information (Batch/lot or serial number, quantity, best before date...)</p>	<p>Product details as planned, for example :</p> <ul style="list-style-type: none"> - Product specifications - Process of production - Components - Origin of raw materials, - ... 	<p>Actual product details, for example :</p> <ul style="list-style-type: none"> - Quality records, - Results of analysis - Batch/lot number of raw materials - Identification of interchangeable components that have been used - ...
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Managing information	<p>There are four models to manage traceability information across the chain³⁴:</p> <ul style="list-style-type: none"> • One-up, one-down (most feasible basis of traceability for all) • Traceability network (emerging, can overcome the limits of breaks in the chain of custody, pilots recommended) • Centralised database (for a limited community, important feasibility challenges) • Cumulative tracking (outdated) 						

³³ GS1 Standards Document, Business Process and System Requirements for Full Supply Chain Traceability, GS1 Global Traceability Standard, Issue 1.3.0, November 2012

³⁴ See also “Four models to manage traceability information across the chain” in annex

Accessible information	<p>A key characteristic of traceability systems is the capacity to find more information than the information directly available on the product or owned by one actor. Traceability data may be available :</p> <ul style="list-style-type: none"> • directly on the product label • by requesting the information to an online service if available • by contacting the owner of the information directly (if identified) or a distributor of the product in case the information has been exchanged between trading partners • by contacting any of the economic operators involved in the chain that will enable to reach the owner of the information or a distributor of the product in case the information has been exchanged between trading partners <p>To that aim, the traceability system must enable market surveillance authorities to identify economic operators who can provide the information they need in addition to the identification of the product.</p>
Recall and withdrawal ³⁵ use cases	<p>Traceability enables to have effective recalls and withdrawals.</p> <p>Recall and withdrawal process goes from the notification to reverse logistics.³⁶</p>

Table 2 : Key principles and concepts of traceability

A MULTI-SECTORIAL FRAMEWORK

There are no strict barriers between industry sectors. The same raw materials can be used in various sectors. Generalist distributors sell harmonised and non-harmonised products : food, toys, electric appliances, cosmetics, apparels, jewelry, hygiene products etc... Each difference in the traceability approach among regulations adds complexity to economic operators. A common approach should provide a common global and multi-sectorial basis as much as possible and then move to sector specific views when necessary.

4.2. APPLICATION OF BEST PRACTICES AND AUTOMATION OF TRACEABILITY SYSTEMS

Considering the current shortcomings in traceability across the chain, best practices contribute to :

- Set up a level playing field by providing a way to ensure at least a minimum of traceability along the chain
- Ensure interoperability between systems of economic operators and an easy flow of information
- Reduce costs to all stakeholders
- Advance global trade and market access to international and local companies
- Make possible a wide choice of compatible tools on the market for economic operators

³⁵ For an authority point of view in the food sector, see also *FAO/WHO guide for developing and improving national food recall systems*, 2012

³⁶ See also *Product Recall in Multiple Recall Jurisdictions, Implementation Guideline*, Issue 1.0.0, GS1, 2012

BEST PRACTICE 1 : WRITTEN PROCEDURES ADDRESSING THE FULL TRACEABILITY PROCESS

The Group considers that fully addressing all the traceability process requires to properly design a system. This system shall be part of the quality and safety management system of the operator. Procedures should include a description of how to :

- a) identify products
- b) label and/or capture data on products
- c) record all relevant traceability information
- d) share any relevant information with other trading partners

The way to implement such a traceability system in an organisation depends on :

- the cost/benefits of applying such a system (i.e. depending on applicable regulations, trading partner's expectations, internal needs and risks related to the product)
- technical limits inherent to the organization and products (i.e. nature of the raw materials, size of the batches, collection and transport procedures, processing and packaging methods)
- the outlook of the management of the organisation

Detailed responsibilities vary per stakeholders depending on their role and functions in the chain :

- The manufacturer must assign the product identification and apply it at source.
- Actors who physically handle the products must capture product identification information from the product label. This applies to manufacturers, distributors, exporters and importers-directly involved in the physical flow but also to providers that may operate on their behalf.

In all cases, a fundamental best practice is that economic operators shall design a traceability system and have written procedures for traceability.³⁷

BEST PRACTICE 2 : MINIMUM LABELLING INFORMATION

A lot of products on the market are correctly identified and labelled. Yet RAPEX statistics and investigations on the field show a significant number of products with no or unclear identification. 51% of the products were missing a product reference or product code (such as GTIN or "barcode") among RAPEX notifications in 2010. 18% of the products were missing either the brand or the type/model number in 2012. In 25 cases (2%) neither the brand nor the type/model number were known.

Categories with most problems in product identification appear to be in 2012: clothing, textiles and fashion items, toys, electrical appliances (including small electrical products in these statistics), cosmetics and chemical products.

This lack of product identification is a barrier for market surveillance authorities to reach responsible economic operators and to efficiently communicate in case of recall.

³⁷ This principle is clearly established in ISO 22005 for traceability of food and feed but is actually relevant to all sectors.

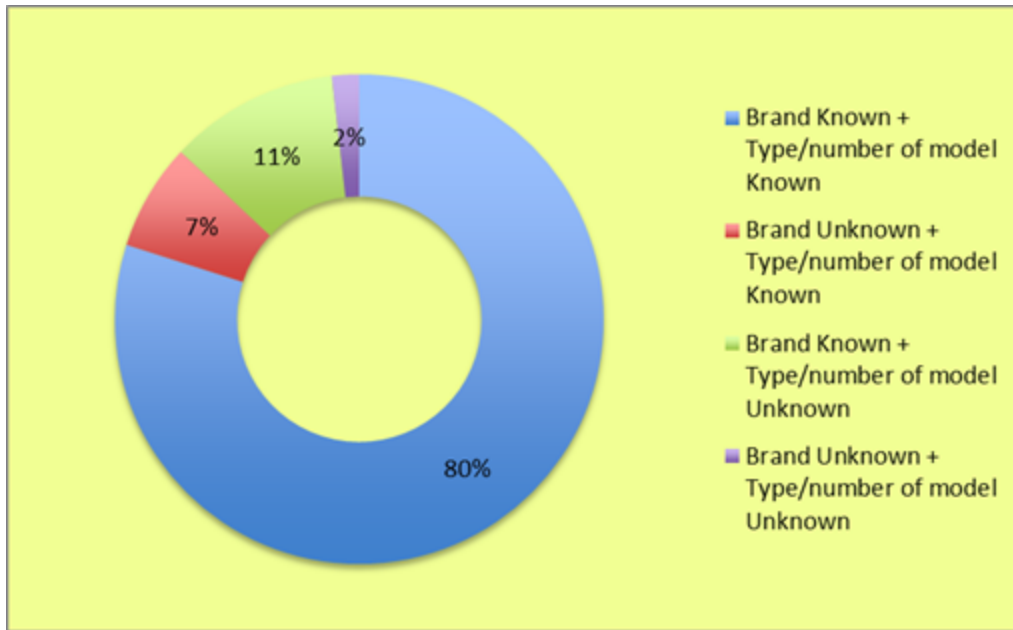


Figure 5 : Notifications in which brand and model numbers are known/unknown (%), source RAPEX

Key recommendation 1 :

Economic operators should label their consumer products at least with a product identification code and contact details of the responsible economic operator.

A fundamental best practice for traceability is that information on consumer products should enable to identify the product and to contact the responsible economic operator. The General Product Safety Directive does not include a clear requirement for that. To that purpose, the informal Product Traceability Expert Group recommends that product should be labelled with, at minimum :

- a product identification code(s) identifying the product reference and/or the batch or serialised item
- the name and address of the organisation responsible for placing the product on the EU market for the first time

This recommendation does not apply to harmonised products for which this is already a legal requirement.

Marking the batch or serial number is a best practice but the level of identification of the product remains a risk based decision of the manufacturer or importer. Batch numbering is helpful in recalls and helps to save economic operators from the cost of unnecessary recall of all products from multiple batches that may be unaffected and safe. Some products may be considered very low risk for example shoe laces. Others may present a significantly higher risk if they are unsafe. The importer or manufacturer must decide if they need to apply batch marking to products based on regulatory and customer requirements in markets where they place their products, as well as based on the number of products sold, the risk the product may present and all the other relevant factors. In respect of operators producing low volumes of products or products with low risk, a product identification code may be sufficient.

The information may be on the physical product or if not possible, on the packaging.

The product identification code should preferably follow global standards. The issued code will allow the manufacturer or importer to unambiguously identify the product and provide information about the brand owner³⁸. Automatic processing of the information for efficient logistics and in case of product recall and interoperability is enabled only by following globally accepted standards as information systems and tools generally follow established standards.

A product name and a brand name are nice to have. If the product brand name is a globally unique registered trademark and provided the product name is meaningful and unique for the owner of this brand, this combination may also help identify the source. It may help expedite the traceability of the product but may not be reliable and practical enough to be recommended as a systematic option.

Additional minimum requirements may be agreed and added for specific categories of products considered as high risk or because of specific constraints.

In case of regulatory requirements, every Member State should adopt the same requirements for product labelling in order to ensure the proper functioning of traceability and not to prohibit the free movement of products through the EU market.

BEST PRACTICE 3 : MINIMUM DATA TO RECORD

One of the reasons given for missing information on economic operators in RAPEX is the lack of documentation and records by economic operators. There may be no expedient way to identify the source of the product beyond the retailer where the consumer bought the product or where the unsafe product has been discovered. This makes it more difficult for market surveillance authorities to proceed with corrective measures.

As a consequence, the Group recommends that, where this is not yet a legal requirement, all economic operators involved in the supply chain of a consumer product should record the following information in order to achieve at least “one step up, one step down” traceability :

IN A MANUFACTURING ENVIRONMENT

- a) Direct supplier and direct customer (name, address, global identifier if available)
- b) Product code identifying the reference of the product components received and consumer products dispatched
- c) Batch number if available and relevant
- d) Consumer product description (product brand, product name, category and/or short description)
- e) Quantity of product components received and consumer products dispatched
- f) Receipt and dispatch dates
- g) Any other relevant information or document concerning the history, application or location of the product that may be relevant for consumer safety purposes and that is owned by the operator (e.g. bill of material, technical specifications, quality reports linked to the product or batch)

³⁸ www.gepir.org

IN A DISTRIBUTION ENVIRONMENT

- a) Direct supplier and direct customer (name, address, global identifier if available) if the customer is an economic operator involved in the supply chain of the product
- b) Product code identifying the reference of the consumer product received and dispatched
- c) Batch number if available and relevant
- d) Consumer product description as available (e.g. product brand, product name, category and/or short description)
- e) Quantity of products received and dispatched if the customer is an economic operator involved in the supply chain of the product
- f) Receipt and dispatch dates if the customer is an economic operator involved in the supply chain of the product
- g) Any other relevant information or document concerning the history, application or location of the product that may be relevant for consumer safety purposes and that is owned by the operator (e.g. technical and safety instructions)

Most of this information is typically used as part of logistics and commercial operations between economic operators. Additional minimum requirements may be agreed and added for specific categories of products considered as high risk or because of specific constraints.

Note on Economic Operators that cannot be reached

Traceability information is sometimes missing in RAPEX notification because the contact details for the economic operator were available and accurate but the economic operator cannot be reached.

Typical cases of this situation are when the economic operator :

- went bankrupt and no longer exists (products with a long life time such as televisions and furniture are de facto more exposed)
- was a temporary distributor or importer
- is vending in the street, with no fixed premises (legal registered trader but that cannot be contacted or physically checked as moving)

These situations are mostly unavoidable and it is not currently possible to obtain figures or statistics concerning the impact of the above. Temporary actors seem to be an important factor for product traceability failures in some countries or categories of product.

Key recommendation 2 :

Economic Operators should automate their traceability system by using data capture, data recording and data exchange technologies with applicable global standards.

This key recommendation is explained by the following best practices 4 and 5.

BEST PRACTICE 4 : AUTOMATION OF TRACEABILITY SYSTEMS

Managing traceability is synonymous with capturing data, storing that and translating that into usable information. The amount of data to record increases with the number of consumer products and the volume of the physical flow. These records may be paper-based and manual, however, this introduces various levels of risk for record retention, reliability, accuracy and accessibility, especially in an urgent safety crisis. Additionally, investments for manual procedures may appear low at first sight but the operational cost may become unbearable for large volume of products.

As a consequence, computerised systems and automatic data capture and processing are recommended as best practices. This can be achieved for example by using well established automatic identification and data capture (AIDC) methods, electronic data interchange (EDI) or other Internet-based systems. One key advantage of computer based data management is the potential for higher speed of reaction when looking up relevant information.

Many types of tools may be applicable to automate product traceability. Technologies range from a simple printer of barcode to a complex enterprise management system.

The data storing, visualization, and analysis is usually embedded in the quality, production or supply chain management tools of the company such as WMS systems (Warehouse Management Systems) or an ERP (Enterprise, Resource Planning tools that provide an integrated suite of software modules supporting all the basic functions and business processes of a company).

Yet the traceability data management may be performed by specialised traceability solutions. Web-based traceability tools have increased on the market in the past ten years. Some focus for example on downstream traceability (managing information linked to deliveries and sending a dispatch advice including traceability information to customers). They are typically designed for small companies with little existing infrastructure for data management, enable a first level of automation but do not support the full traceability process of the company. Some focus on recording the links between all operators of a product supply chain. They are typically designed for limited communities of economic operators that have a common interest and agreement to get a fast access to all the history of a product and to use the same tool. Some other tools focus on providing a network of databases recording only critical tracking events data to be able to get the chain of custody of the product owing to search engines. Some other tools focus on data management for traceability of private brand products (products for which the brand is owned by the retailer) for which the product specifications should be accessible both by the operator physically manufacturing the good and by the brand owner. The use of mobile devices to collect the data on the field and to provide access to information to consumers has more recently emerged and is rapidly increasing.³⁹

Concerning product labeling and data capture tools, there are a number of solutions offered by vendors on the market. The minimum package of tools would include a printer, a scanner, a computer and software.

The cost of automating a traceability system greatly depends on each company, its environment and the desired breadth, depth, precision and reliability of the traceability system. Little literature exists on the cost of traceability tools and how spread they are. Existing material is usually more qualitative.

³⁹ See also Annex 3 for traceability data managements models

The costs of implementing an automated traceability system can be split into two categories :

- Investment costs : fixed costs for the design of the system (external consulting for example), the initial purchase of new equipment (software, printers, scanners...) or for equipment improvements, the installation costs and trainings for people operating the system
- Operational costs : variable costs such as additional labor costs, labels etc.

The costs may vary from 75 euros per year plus 35 centimes per message for a downstream traceability Web EDI service⁴⁰ (the economic operator types traceability data on a web platform that stores and translates the data into an EDI message) to one million euro of investment in a manufacturing plant with large production volumes. Yet the level of automation, depth, reliability and benefits of the traceability system are not equivalent.

In Argentina⁴¹, the average cost for a small manufacturer to implement a simple automated system for downstream traceability is estimated to be around 15, 000 Euros (20, 000 Dollars). That includes two scanners, a computer, software and a printer.

In the food sector, Chryssochoidis and others (2009) and IFT (2012) report the case of a bottled water company with 30 employees in a South European Country that moved from paper records to an electronic (computerised) records system. The company was able to make the transition without any additional computer. Its custom software development costs were 600 Euros per day and the license cost was 150 Euros. The costs associated with trainings were the equivalent of two people over half a day each. The cost of the initial data conversion was 1, 100 Euros and the ongoing license cost was 105 Euros per month.

According to IFT (2012), barcode printers cost range from less than 700 Euros (1,000 Dollars) to 15,000 Euros (20,000 Dollars). Scanner costs range from 300 Euros (400 Dollars) for hand held scanners to 55,000 Euros (75,000 dollars) for scanner hardware costs estimated by pilot participants. The cost of a label itself would be less than ½ cent of Euro (½ cent of Dollar).

The application of technologies and tools will vary depending on each product and on each stakeholder environment. For example, traceability practices that are feasible for high cost products may be more difficult for low cost products. The cost of labeling for example must remain acceptable with regards to the cost of the product itself. However, manufacturers gain trust from their customers and consumers when products are clearly labelled and identified to enable warranty, recall, returns, etc.

Each operator is free to decide on how to implement his internal traceability system as long as he is able to receive, process and communicate the necessary information and data to his upstream and downstream trading partners in an accurate and timely manner.

⁴⁰ Example of a Web EDI traceability tool certified by GS1 France

⁴¹ Source GS1 Argentina

BEST PRACTICE 5 : USE OF GLOBAL STANDARDS TO ENSURE INTEROPERABILITY

Economic operators may have excellent internal traceability systems but if interoperability is not ensured at the interface with their trading partners, traceability may stop at their walls and will have a higher collective cost.

For example, a product identification code assigned by the manufacturer and which is not globally unique and unambiguous cannot be used by all economic operators along the chain. This may cause a downstream actor to re-label the product with their own internal numbering scheme, this can break traceability if effective cross-references systems are not created and well maintained. Labelling products with proprietary formats of barcodes will also cause next actors to re-label the product with barcodes they can effectively read in commonly deployed AIDC technologies such as scanners and point-of-sale cash registers.

Global standards enable interoperability.

Many standard bodies may play a direct or indirect role in specific traceability sub-processes, technologies, regions or product categories. The table below summarises a few key standard bodies and their scope of competencies. This is not an exhaustive list.

Standard body	Scope of competencies
CEN	European organisation for the planning, drafting and adoption of European Standards in all areas of economic activity with the exception of electrotechnology and telecommunication.
CENELEC	European organisation for the planning, drafting and adoption of European Standards in the field of electrotechnology.
ECMA International	Ecma International is an industry association dedicated to the standardisation of Information and Communication Technology (ICT) and Consumer Electronics (CE).
ETSI	European organisation for the planning, drafting and adoption of European Standards in the field of telecommunication.
GSI	GSI is a global organisation that develops and maintains supply chain standards for the identification of products, locations and actors, for automatic data capture and data sharing.
IEC	IEC (International Electrotechnical Commission) is the world's leading organisation for the preparation and publication of International Standards for all electrical, electronic and related technologies
IEEE	IEEE (Institute of Electrical and Electronics Engineers) is the world's largest professional association dedicated to advancing technological innovation and excellence for the benefit of humanity.
IETF	The goal of the IETF (The Internet Engineering Task Force) is to make the Internet work better by producing high quality, relevant technical documents that influence the way people design, use, and manage the Internet.
ISO	ISO (International Organisation for Standardisation) is the world's largest developer of voluntary International Standards for products, services and good practice, helping to make industry more efficient and effective.
ITU	ITU (International Telecommunication Union) is the United Nations specialised agency for information and communication technologies. It develop the technical standards that ensure

	networks and technologies seamlessly interconnect.
OASIS	OASIS (Organization for the Advancement of Structured Information Standards) is a non-profit consortium that drives the development, convergence and adoption of open standards for the global information society.
OMA	OMA (Open Mobile Alliance) delivers open specifications for creating interoperable services that work across all geographical boundaries, on any bearer network. OMA's specifications support the billions of new and existing fixed and mobile terminals across a variety of mobile networks, including traditional cellular operator networks and emerging networks supporting machine-to-machine device communication.
UN/CEFACT	Within the United Nations framework of the Economic and Social Council, the United Nations Economic Commission for Europe (UNECE) serves as the focal point for trade facilitation recommendations and electronic business standards, covering both commercial and government business processes that can foster growth in international trade and related services. In this context, the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) was established, as a subsidiary, intergovernmental body of the UNECE Committee on Trade, mandated to develop a programme of work of global relevance to achieve improved worldwide coordination and cooperation in these areas.
W3C	The World Wide Web Consortium (W3C) is an international community that develops open standards to ensure the long-term growth of the Web.

Table 3 : Overview of key standard bodies and their scope of competencies

This research focused on global standard bodies addressing the full traceability process : ISO and GS1.

ISO recently published standards for product safety (ISO 10377:2013(E)) and for product recall (ISO 10393:2013) including traceability definitions. This should contribute to increase the awareness about the necessity to have good traceability practices in place. ISO 22005 is a traceability standard but specific for food and feed.

GS1 published in 2006 a specific application standard for full chain traceability⁴². GS1 is an official Issuing Agency recognised by the ISO/IEC 15459 standard for identifiers starting with a numeric digit. All identifiers assigned according to GS1 standards rules -such as the GTIN for trade items identification– ensure a global, unique and unambiguous identification.

GS1 Company Prefix >												< Item Reference	Check Digit
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	

Figure 6 : GTIN 13 structure

⁴² GS1 Standards Document, Business Process and System Requirements for Full Supply Chain Traceability, GS1 Global Traceability Standard, Issue 1.3.0, November 2012

All data carrier following GS1 standard specifications ensure the barcode or RFID tag is readable not only by the company applying it but also by its customers and following stakeholders in the chain. The figure below summarises the type of barcodes per application.

Barcode				
Name	EAN/UPC	GS1 128	GS1 Data Matrix	GS1 QR Code
Content	GTIN	Alphanumeric such as : SSCC ⁴³ , GTIN, batch, serial number, dates, country of origin...	Alphanumeric such as : GTIN, batch, serial number...	Alphanumeric such as : GTIN, batch, serial number...
Application	Items scanned at point of sale	Logistics units and grouping of trade items	Small items and direct part marking	Capture with mobile devices

Table 4 : Type of GS1 barcode standard per application

Many of the GS1 standards are actually based on ISO standards or other standards such as the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) standards. They are put together in a consistent system and adapted for the consumer goods sector or other industry sectors.

The table below presents a highlight of key traceability sub-processes, corresponding rules in best practices, enabling technologies and applicable ISO and GS1 standards.

Part of the traceability process	Key rule in best practices	Key enabling technologies	Main applicable ISO and GS1 technical standards ⁴⁴
Identify products	The level of precision of product identification depends on risk management.	Identification systems	ISO/IEC 15459-6, GS1 Global Trade Item Number (GTIN) ISO/IEC 15459-1, GS1 Serial Shipping Container Code (SSCC)
Label products and capture data	The label should enable at minimum to identify the product and a responsible economic operator in the EU. The label should be applied at source and stay on the product during all its life cycle.	Data carrier / Automatic Identification and Data Capture (AIDC) such as barcodes and RFID ⁴⁵ tags	ISO/IEC 15420, GS1 EAN/UPC barcode ISO/IEC 15417, GS1-128 barcode ISO/IEC 18000-63, 18000-3, mode 3, ISO/IEC 15962, ISO/IEC 24791-2, ISO/IEC 24791-3, ISO/IEC 24791-5, GS1 standards linked to EPC RFID tags

⁴³ Serial Shipping Container Code

⁴⁴ This is not an exhaustive list. Applicable ISO and GS1 standards will depend on the choice of technologies and cases. See annex 5 for a more detailed list of GS1 standards with corresponding ISO and other standards.

⁴⁵ Radio Frequency Identification

Record data	Data recorded must enable at least one-up one down traceability	Electronic data processing	Not applicable (apart from parts of GS1 Global Traceability Standard)
Share data	Data shared must at least enable the next economic operator to ensure its upstream traceability.	Information and Communication Technologies (ICT) such as Internet and Electronic Data interchange (EDI)	GS1 Global Data Synchronisation Network (GDSN) ISO 9735, GS1 EANCOM for EDI Despatch Advice GS1 EPCIS for event data
Traceability complete process	Have written procedures Perform self-assessment	All the information system	ISO 10377:2013(E) ISO 10393:2013 GS1 Global Traceability Standard GS1 GTC Control Points and Compliance Criteria

Table 5 : Overview of traceability sub-processes, rules in best practices, enabling technologies and GS1 and ISO standards

According to The Consumer Goods Forum and IBM Global Scorecards⁴⁶ :

- 90,8% of consumer units are allocated a GTIN in manufacturers, 96,8% for retailers
- 64,7 of pallets/unit loads are labeled with SSCC in manufacturers, 75,2 % in retailers
- 41,4 % of shipments have a despatch advice transmitted via EDI, 63,3 % in retailers.

BEST PRACTICE 6 : SELF-ASSESSMENT OF TRACEABILITY SYSTEMS

Traceability systems efficiency are impacted by numerous factors including the quality of the initial assessment of the needs, the level of automation, the application of best practices and global standards and the effectiveness of procedures in place.

A traceability system for product safety should not be built in isolation from existing information systems and other needs requiring visibility across the chain. An important added value of an effective traceability system is to link the various sources of information already in place within and between economic operators. Performing self-assessments of traceability systems and (bi)annual mock recalls are best practices. It is a pro-active approach that allows operators to get the most of their systems and to make the best use of existing sources of information.

Performing traceability assessments based on global best practices enable companies to :

- improve their traceability and start by analysing gaps to get guidance for the implementation or
- benchmark the traceability system in place with best practices.

Because of the complexity of traceability, they may be performed by trained auditors. A first level of simple assessment can be performed using the self-assessment grids in annex 1.

⁴⁶ *Global Compliance Survey 2011*, The Consumer Goods Forum, IBM

4.3. GUIDANCE AND EDUCATION OF ECONOMIC OPERATORS

The lack of knowledge among economic operators is one of the barriers for efficient traceability across supply chains. Best practices for economic operators are available and tools integrating these are available on the market. Educating and providing guidance to economic operators thus is a cornerstone for traceability.

To reach the targeted audience, various channels for capacity building of economic operators can be used such as :

- Initial academic education
- Organisations providing continuing education to professionals
- Consultants supporting economic operators
- Conferences and exhibitions
- Industry associations
- Media
- ...

Trade associations (industry sectors, retail, standard bodies...) can collaborate with each other and develop guidelines for Economic Operators on how to implement traceability with best practices. For example the cosmetics sector in France⁴⁷ developed a Logistics Best Practices Guide for commercial shipments to warehouses. Interesting initiatives in other sectors are showing the benefits of a collective approach in the industry⁴⁸.

Key recommendation 3 :

Economic Operators should get trained on traceability in order to be aware of traceability benefits, understand best practices and get the knowledge to choose and implement the most relevant tools to automate traceability within their organisation.

Implementing traceability can be ensured by training all actors involved. This can take the format of seminars, workshops or formal trainings in which the concerned stakeholders learn how to affix identification, what records to establish and in general best practices for traceability. Member States authorities may be trained together with economic operators in order to facilitate a common understanding. If no training is available for economic operators, trade associations may get involved to ensure operators do have opportunities to be trained in their country or sector.

⁴⁷ Fédération Française de la Parfumerie Sélective, Fédération des Entreprises de la Beauté together with ECR France and GS1 France

⁴⁸ For example Produce Traceability Initiative Action Plan : <http://www.producetraceability.org/>

Key recommendation 4 :

Traceability assessment exercises should be conducted across the chain with the cooperation of market surveillance authorities and trade associations.

Traceability tests can be performed across the chain with the purpose of concretely experiencing full chain traceability (or the need for it). Some operators already perform traceability tests or recall exercises. Yet internal tests do not allow them to experience traceability at the interface with trading partners. Some operators do experience real withdrawals and recalls on a regular basis. The highest added value of such exercises will be with economic operators not used to dealing with such situations.

For example, market surveillance authorities (or customs) may take note of the arrival of a shipment of products at customs that is likely to be split and distributed in multiple distribution channels : independent and specialized distributors, vending, online, etc. They would record the identification of the product and quantities. A few months later, they would contact economic operators from upstream to downstream and try to track forward the products until their points of sales. By being asked for traceability information, economic operators could learn about the use of traceability systems. They could be better prepared in case they happen to be involved in the distribution of a dangerous product and review their traceability system if necessary. It is important these exercises to be performed with an educational spirit and to be organised collaboratively between market surveillance authorities and trade associations.

5. CAPACITY BUILDING OF MARKET SURVEILLANCE AUTHORITIES

Market surveillance authorities themselves have a key role to play in ensuring RAPEX notifications are as complete as possible with regards to product identification and traceability fields.

RAPEX statistics show that market surveillance authorities encounter difficulties collecting information about economic operators involved in the supply chain of dangerous products⁴⁹. For pushchairs for example in 2010⁵⁰ :

- The supplier was missing in 43% of the notifications (16 out of 37 cases notified).
- The distributor was missing in 19% of the notifications.
- The manufacturer was missing in 22% of the notifications.
- The importer was missing in 43% of the notifications.
- The exporter was missing in 81% of the notifications.
- The countries of destinations were unknown in 59% of the cases.

The information is sometimes unavailable and impossible to find but capacity building with best practices can also help making a better use of all existing sources of information.

⁴⁹ See also case studies in annex 4

⁵⁰ Source : RAPEX statistics for the *Discussion Paper on Pushchair Traceability*, EU Informal Expert Group on Product Traceability, January 2012

5.1. TOWARDS A COMMON UNDERSTANDING OF TRACEABILITY

Capacity building activities in each Member State should ensure better alignment between the major stakeholders across government agencies and out to the economic actors. Having a common understanding of traceability is a fundamental step. This common “big picture” should be similar to the one for economic operators in order to better bridge the gap between the WHAT and the HOW-TO and in order to support inquiries for traceability information. See Chapter 4.1. for more information on this topic.

5.2. BETTER USE OF ALL EXISTING SOURCES OF INFORMATION

Efficient searches for information combine sources of information such as the product packaging, documents available in contacted economic operators, Internet, market surveillance registers or customs databases. This chapter gives indication of possible sources but may not be exhaustive.

TO COLLECT INFORMATION ABOUT PRODUCT IDENTIFICATION

Information on Product Identification (product name, brand, model, barcodes, batch number...) are usually collected by :

- The visual inspection of the product itself
- The packaging of the product (if available) : the product code (GTIN) can usually be read directly under the barcode.

Other ways include :

- supporting documents such as invoices and packaging lists if available
- technical information related to the product for manufacturers
- Internet to check for brand, product codes and names.

Depending on the product categories, economic operators have specific reference number (e.g. white appliances...).

Note on product image

Despite current and any future legal requirements and all attempts to find information on product identification, market surveillance authorities may face dangerous products on the market with no identification element. Submitting a recall alert with only a product picture to identify a product is not a good practice. The lack of a brand identification and product identification marks make it very difficult to look for a product with reasonable resources and can make it impossible to find any distributor, importer or manufacturer. Yet it may still be worthwhile communicating the product picture in RAPEX notifications and to economic operators as it may be sufficient for retailers to find out if they distribute the product and to trace back to the supplier, notably if the buyer of the product is still working there.

TO COLLECT INFORMATION ABOUT ECONOMIC OPERATORS

USEFUL DOCUMENTS AND WEBSITES

Authorities can ask for the following documents or consult the following websites when looking for economic operators :

- a) Invoice : used to confirm the supplier address and the entity responsible to put the products on the market
- b) Bill of Lading (if stopped at the port of entry)
- c) Information on boxes, cartons, pallets...
- d) Certificate of conformity and quality, testing protocols or compliance documents
- e) Customs related documents
- f) Contracts : with information regarding how to deal with nonconformity (corrective actions, responsibility...)
- g) The new OECD Global Product Recall platform (<http://globalrecalls.oecd.org/>)
- h) Website to check product codes and brand owner (www.gepir.org)

The way for each economic operator to find the information may vary :

- Manufacturers have all the information and can immediately inform the supplier and any other business unit in Europe who sells these products in order for them to recall the products too.
- Business-to-Business retailers use membership cards or loyalty cards.
- Distributors ask their commercial partners or find information via the invoice.

Where the information is, is not important, what matters is that the information is recorded somewhere and available when necessary. The Internet is more and more useful to complete the information that is physically available. Checking the product code, brand name and brand owner by inquiring on the Internet can often reveal the factory address⁵¹.

USEFUL CONTACTS

Useful contacts for market surveillance authorities include :

- a) the consumer who initiated the inquiry (e.g. to know the place of purchase)
- b) all economic operators involved in the supply chain of the product (each one shall know its immediate previous supplier)
- c) trade associations (e.g. owner of a product brand)
- d) market surveillance authorities themselves (they sometimes have information registered in their own database)
- e) customs authorities (they may provide a customs code and information about who imports the goods)
- f) certification bodies if the product label contains any specific claim that requires certification

⁵¹ See case studies in annex

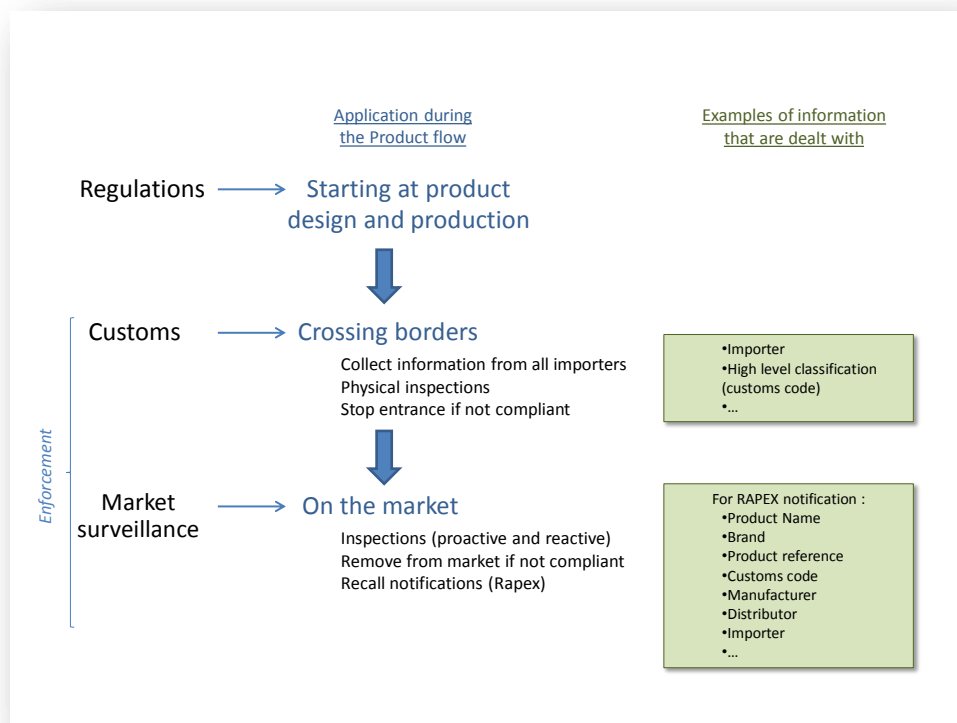


Figure 7 : Three “filters” for unsafe products and current examples of information that are dealt with

Beyond legal obligations for recall, the industry – economic operators and industry associations - can greatly help authorities when looking for traceability information on products and actors in a supply chain. Economic operators can obtain information from different actors such as the product’s buyer internally and from their commercial partners. They can contact their supplier and importer directly by phone or email in order to obtain details regarding deliveries (quantities and warehouses).

Retailers are not always in direct contact with the factory (when there is an importer or a commercial agency in the EU) but they have direct contact with commercial and quality teams of their direct supplier. Retailers can usually trace back to the manufacturer and/or importer with a piece of information on the product and a date, be it for harmonised or non-harmonised goods :

- If the product is their own brand, the retailer has direct access to all the necessary information in their files.
- If the product is a national brand, providing the product reference (and if possible the batch number) and showing the product picture to the retailer will usually allow finding the invoice that will include the name of the supplier. If the supplier is not the manufacturer or the importer, the supplier could then contact its own supplier.

Key recommendation 5 :

Information about how to use barcodes / product codes to get additional information should be included in trainings for market surveillance authorities.

Training and educating market surveillance authorities can help market surveillance authorities collect information they need. The trainings could take the format of a seminar or workshop and could take place in the context of RAPEX trainings. The content could include how to make the best use of all information sources, introduction to product identification components, how to look up barcodes using the Internet and what information you can get, what documents to verify, etc.

5.3. BEST PRACTICES IN MARKET SURVEILLANCE AUTHORITIES

The investigation phase shall aim at submitting complete RAPEX notifications, including all information related to the product identification and to economic operators and getting the appropriate corrective measures carried out.

LOOKING FOR ALL SUCCESSIVE ACTORS

Collecting information on economic operators is performed by looking for information in the supply chain and for all successive actors in the reverse direction from the supply, i.e. from far down the chain (e.g. the shop, the retailer) to upstream (e.g. the wholesaler, the importer, the manufacturer...).

It is important for national market surveillance authorities to trace back to the manufacturer, to the importer or to the first distributor in their Member State : the first distributor enables market surveillance authorities to know to whom the product has been distributed in their market. After tracing back to the origin, information found will be used to track forward and locate all the products in order to ensure that the appropriate measures will be applied to all of them. In the case of goods imported into the EU, tracing back to the EU importer(s) is important as it enables authorities to know to which Member States and to which distributors the product has been sold or shipped to.

MORE EFFECTIVE COLLABORATIONS FOR PRODUCTS CROSSING BORDERS

Authorities typically face more problems collecting traceability information about and from economic operators when products move across countries within the EU or have been imported in the EU⁵². While Europe is a free market for products⁵³, authorities are bound to the limits of their jurisdiction.

Market surveillance authorities are competent authorities only within their national borders. Economic operators located in other Member States (or outside the EU) are not responsible for supplying the information (whereas the national economical operators are according to the legislation). Moreover if coercive administrative measures are needed, market surveillance authorities can enforce those only within their competence.

⁵² It can also be challenging or impossible to find information about products that remain within the EU country where they have been produced.

⁵³ This is why information in RAPEX notifications about the countries of destination cannot be guaranteed as exhaustive.

Therefore the primary concern of market surveillance authorities is to deal with the case at hand within that Member State and they are not required to directly contact economic operators in other Member States. Their priority is to find economic operators in their Member State and, in the case of imported goods or of goods coming from another EU State, to trace back as close as possible to the first operator in their Member State. That enables them to make sure all dangerous goods are removed from the Member State. This is also a way for market surveillance authorities to allocate resources efficiently.

Moreover sometimes if the supplier is in another EU Member State, retailers are expected by market surveillance authorities to complete the GPSD Business Application instead of involving upstream suppliers. All the information about a product cannot be collected by asking just one party to complete the business application form. For example, only the manufacturer has access to all the technical information about the product and information about who else may have been supplied with the same product. The consequence is that this information is then missed.

Key recommendation 6 :

Best practices for market surveillance authorities to follow should be developed for best use of available information when products are crossing borders within the EU, including real case studies.

Collecting information about economic operators when they are in different Member States is certainly more challenging than if a product is produced and distributed in the same country. There may be practical (e.g. language) barriers to investigating across borders within Europe. Jurisdictions are limited to national territories. Yet depending on the cases, the following practices can be considered :

- The RAPEX National Contact Point in the country initially investigating a potentially dangerous good can directly contact his/her colleague in another Member State. Each market surveillance authority yet decides its priorities and resource allocation.
- It may be relevant for market surveillance authorities to contact the economic operator in the other country. It may be the most efficient way to gather information. In these cases, the good practice is to inform the market surveillance authorities in the country where this economic operator is located.
- The Information and Communication System on Market Surveillance (ICSMS) platform can be used to exchange information especially on product identification.
- Moreover a good practice is for the authorities and business operators to collaborate and help circulate the information to other countries : for example, the retailer A informs the supplier B, who may be in another country, and the supplier B informs the market surveillance authorities in its own country. Alternatively the distributor informs the head office in another country in Europe who transfers the information to all contractors wherever they may be.

After a few cases of effective collaboration have been identified, the learning may be collected and more detailed guidance could be provided to market surveillance authorities on how to proceed when economic operators are in different Member States.

COMPETENT AUTHORITY TO COLLECT THE INFORMATION

A practice that works well is for inspectors from the relevant market surveillance authority to collect the information, inquire and draft the RAPEX notification. Some market surveillance authorities have developed forms to be completed by economic operators and this proved to be an efficient practice. Inspectors will always inquire if any information is not complete on the RAPEX notification form and aim at gathering the details concerning the full chain, e.g. Retailer-Wholesaler-Importer-Agent-Manufacturer. The RAPEX National Contact Point does not directly contact economic operators unless he/she is part of the competent authority.

EASY ACCESS TO THE RELEVANT CONTACT POINT IN AUTHORITIES

Member States sometimes have numerous market surveillance authorities dealing with safety (and potentially other things as well). Retailers often know whom to contact in market surveillance authorities per category of product, locally or nationally. Yet smaller companies – and consumers – would not always know whom to contact.

Simplifying who the contact for each economic operator is can help maximize efficient communication for both businesses and authorities : sparing the time of looking for the right contact and aligning information levels, product and company history established and known in one place. In the UK for example, the home authority or primary authority principle was developed so that there is a single market surveillance contact point for large businesses and in some cases smaller businesses.

RELATIONSHIP WITH CONSUMERS

Making sure there is a clear way for consumers to check if a product is recalled and to alert authorities if they have suspicion is a good practice for market surveillance authorities.

5.4. REVIEW RAPEX TEMPLATES

ENHANCE GPSD BUSINESS APPLICATION

The GPSD Business Application could be improved by allowing for the addition of information or documents, integrating new functionalities and having a more structured format with specific fields, allowing less room for interpretation. Guidance to fill in the information may also result in better outcomes even if the most important remains for the information to be supplied to authorities, whatever the tool.

CLARIFY PRODUCT IDENTIFICATION COMPONENTS IN RAPEX NOTIFICATION TEMPLATE

The current notification fields could be clarified and aligned with the new OECD global recall platform in order to simplify its use and interconnections. The current template presents one field for “batch number / barcode”. Yet the barcode is only a data carrier and does not have a meaning in itself. This could be reworded as “product identification codes” or split into two fields for more accuracy :

- a) one field for batch number / serial number
- b) one field for any product code identifying the class or reference of product (typically the code under the barcode scanned at point-of-sale or GTIN)

ADD THE DISTRIBUTION CHANNEL IN RAPEX NOTIFICATION TEMPLATE

By sharing experience, traceability problems do not seem to occur equally in all types of distribution channels⁵⁴. Yet no study, no statistic could be found to support facts based statements.

If there is a clear direction in safety authorities to fight against bad traceability practices, the efficiency of surveillance authorities’ resources during investigations could be increased by focusing on channels presenting most of the problems. In order to do that, more figures and statistics should be collected.

A field about the “type of distribution channel” could be added in the RAPEX notification template. In order to allow statistics, possible responses should be pre-determined and could be :

- Large organised retailers (generalist, super/hypermarkets)
- Specialised retailers (focusing on certain categories of products such as do-it-yourself, childcare or toys, cosmetics...)
- Independent retailers (shops that are not part of a larger organisation)
- Market and vending
- Online / Internet
- Second-hand (including charities)/ gifts / loans
- Others

Combining this information with missing product identification or economic operators in RAPEX notifications would enable reporting of statistics to better direct investigations related to traceability problems.

⁵⁴ Statistics are available per category of products

6. A COLLECTIVE EFFORT TO FIGHT AGAINST IRRESPONSIBILITY

One of the reasons for missing information on economic operators is fraud and deceptive business practices (e.g. counterfeited products, unofficial trade, and false information). The fraudulent or deceptive practice can be at different levels :

- The product itself is counterfeited
- Information on the product label is false, e.g. the label says it is “made in Germany” and it is in fact “made in Pakistan”
- An economic operator is an illegal actor, which is unofficial trade

In such cases, the information available or part of it may not be reliable. Moreover economic operators sometimes refuse to reply to correspondence or use a false address and disappear if they know inquiries are being made. Some sellers hide their true identity with selling methods such as fulfillment houses.

Other sources of information might still help⁵⁵. This chapter highlights a few possible ways forward yet keeping in mind that irresponsible practices cannot be solved by best practices but are in the scope of enforcement.

6.1. LEGAL FRAMEWORK AND ENFORCEMENT

There is currently no legal base for traceability of all products. A product today can have no product identification or identification label and be legal. For example, a pen or children's clothing may have no brand, no product reference, no batch number, no contact details, etc., and be fully compliant with current regulations. There are traceability requirements for specific categories of products with specific applicable regulations (“harmonised products”) such as toys and cosmetics but not for non-harmonised products.

In this context, low priced, high volume products (possibly unbranded) are more likely to have less elements of identification. Product safety is not directly related to a low price or poor identification yet products with no brand for example de facto face less brand damages in the case of recall and may not invest as much as other products in the product compliance.

Moreover a regulatory basis⁵⁶ is important to enable enforcement. Market surveillance authorities today have the General Product Safety Directive to refer to when asking for traceability information from economic operators for non-harmonised products but it is not sufficiently clear. In the case of RAPEX, that could help market surveillance authorities request traceability information from economic operators that are not being fully cooperative and not implementing good practices by themselves.

With or without legal basis, the awareness of the “willing” economic operators can always help. Economic operators can for example avoid buying products with unclear or no identification and inform their suppliers on product identification good practices.

⁵⁵ see case studies in annex 4

⁵⁶ In terms of legal requirements, regulations tend to offer a better basis to avoid national interpretations than directives

6.2. ADDRESSING ONLINE CHANNELS AND FREIGHT FORWARDERS

Online channels have brought new distribution models and new traceability challenges. When consumers buy from the global Internet market place, freight forwarders or “fulfillment houses” can be involved to store and post the product. The issue is that when the goods are bought via online platforms based outside of the EU, there is no clear EU-based responsible party for placing the goods on the market⁵⁷; actors are difficult to trace and products difficult to recall.

At no time do freight forwarders actually own the product. The goods come in large shipments direct to the EU. They are transported by a logistics operator to the freight forwarder. They are delivered there already packed for postage as this was done in the country of origin. Freight forwarders may use the local postal system for delivery. They store products in warehouses or sometimes lock up stores where market surveillance authorities would not know a business is operating. All that needs to be done is for the customer to order and the seller in the third country will tell the freight forwarder the address and unit number they put on the packet for it to be posted to the customer.

The problem is that many products in this context have no product code, no brand name and often happen to be unsafe. The customer cannot trace the seller of the product in the third country. This causes major problems for recalls and stopping the product from entering the market place. Even the freight forwarder cannot often identify the items in their warehouses.

A legal clarification is needed regarding the responsibility of these actors and the different Internet sales models being used as a result of the Internet becoming the main business platform. This is essential to allow traceability through these actors and to enable corrective measures.

6.3. CONSUMER AWARENESS AND INVOLVEMENT

Consumers have the right to expect that all products on the market are safe and they can if they wish contribute to law enforcement. It may not be easy for consumers to know if a product is safe or not before purchase and unfortunately consumers may learn that a product is dangerous by the experience of using it.

Yet consumers could be better informed about basic regulatory requirements for the products of interest to them and about the risks of buying outside EU online shops. They could be better informed about why traceability is important and why it could be a wise consumption practice :

- not to buy unidentified products or products with unclear or incomplete identification
- not to buy from poorly or unidentified online shops and distributors

⁵⁷ Unlike for traditional distribution channels which always include an EU based importer known from customs (apart from fraudulent cases)

Key recommendation 7 :

Consumer associations should raise awareness on the importance of product identification and inform consumers on possibilities to alert authorities on suspicious products.

Launching a campaign to educate consumers on risks related to products without a clear identification could help impact on products distributed by actors not caring about the rules and not following good practices. Such a campaign could involve consumer associations, industry associations, advertising, schools... A first step could be to deliver a brochure explaining key information and messages.

When consumers discover an unsafe product, they should know - or have the capability to get access to the information easily from authorities and/or the industry - who they can contact so that authorities and economic operators ensure a follow up and take the appropriate corrective measures. Authorities in all EU countries have the obligation to follow up on consumers' complaints. Consumer associations could guide consumers on what to report when alerting authorities on suspicious products⁵⁸: description of the problem, brand, product name, product identification code, batch if available, date of purchase, location of purchase, etc.

7. THE KEY ROLE OF CUSTOMS

7.1. LEVERAGING THE COLLABORATION BETWEEN MARKET SURVEILLANCE AUTHORITIES AND CUSTOMS TO COLLECT AND ACCESS PRODUCT INFORMATION

The current cooperation between market surveillance authorities and customs⁵⁹ could be enhanced. By recording the product identification such as by collecting the product code from the economic operator, customs may help market surveillance authorities to establish the link between the products and the importer when they have problems finding it.

A draft document⁶⁰ from the World Customs Organization (WCO) looking at product identification says "*Product identification codes may provide benefits to customs and other regulatory agencies in their objective of protecting public health and safety, while ensuring the integrity of international trade data held in government databases.*"

The collection of the product identification by customs has already been piloted in the US⁶¹ with voluntary economic operators. The objective is to optimise the effective use of customs resources while rewarding economic operators providing additional product information.

⁵⁸ See for example the online form from the French "Commission de la Sécurité des Consommateurs" <http://www.securiteconso.org/formulaire/>

⁵⁹ *Guidelines for import controls in the area of product safety and compliance*, European Commission, Directorate-General Taxation and Customs Union

⁶⁰ *WCO Data Model, The Role of Product Identification*, Information Management Sub-Committee, 65th Meeting, World Customs Organization, 2013

⁶¹ *Leveraging e-Commerce Product Data for Smarter Cargo Admission at International Borders*, Douglas Bailey
USDA, Agricultural Marketing Service, Chair ITDS (International Trade Data System) Product Information Committee, 2013

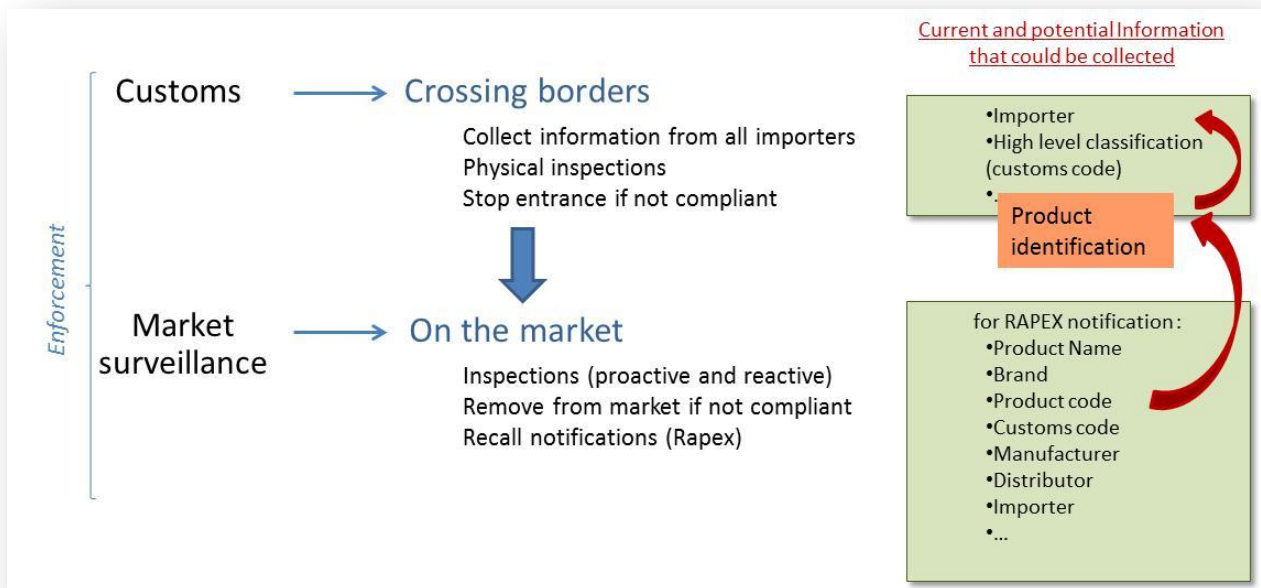


Figure 8: Product identification at customs

The benefits of customs collecting product codes on a voluntary basis from economic operators would be :

- for customs, to know which products have already been checked and focus inspections on products considered as having the highest risks
- for economic operators, a faster release of compliant products
- for market surveillance authorities, to ensure a strong traceability point at the entry of products in the EU and to help with tracing back to importers

Voluntary economic operators could provide the product codes to Customs in addition to and at the same time as the information provided in the customs declaration.

As a consequence, cooperation between services of the European Commission and competent authorities (e.g. DG SANCO, DG TAXUD, WCO) in order to explore the use of Product Identification Codes by customs should be considered. A pilot in the EU involving customs, market surveillance authorities and economic operators could bring interesting learning.

7.2. MORE AUTHORISED ECONOMIC OPERATORS : A POTENTIAL COMMON INTEREST

An Authorised Economic Operator (AEO) can be defined⁶² as an economic operator who is deemed reliable in the context of his customs related operations and, therefore, is entitled to enjoy benefits throughout the EU. An AEO status in the form of AEO certificate – Security and safety (AEOS) is envisaged for economic operators established in the Community who would like to benefit from particular facilitations related to customs controls relating to security and safety when the goods enter or leave the customs territory of the Community.

Customs authorities make the decision whether to grant the AEO status after performing a risk analysis and audit of the economic operator.

The criteria for granting of AEOS includes :

- a record of compliance with customs requirements
- a satisfactory system of managing commercial and, where appropriate, transport records, which allows appropriate customs controls
- proven financial solvency
- appropriate security and safety standards

Current criteria do not include traceability best practices as described in this document. This status of AEOS could be leveraged to include traceability best practices such as described in this report. This could encourage more Economic Operators to implement them provided they get a corresponding incentive.

8. TRENDS AND THOUGHTS FOR THE FUTURE

8.1. THE DIGITAL CONSUMER IN DEMAND FOR PRODUCT INFORMATION

Over the next decade the online channel will grow to 25% to 30% of total retail sales, up from the current 4% to 15%⁶³.

OMNI-CHANNEL RETAIL

Beyond the opposition between “online retailers” and “bricks & mortars” retailers with physical stores, consumers experiment with the multichannel or even “omni-channel bricks and clicks retail world where shoppers are comfortable hunting for deals and making purchases in virtually every manner possible — and where retailers are therefore trying to reach shoppers everywhere they’re willing to spend.”⁶⁴

⁶² *Authorised Economic Operators Guidelines*, TAXUD / B2 / 047/2011-Rev 3

⁶³ *Future Value Chain 2020*, The Consumer Goods Forum, Cap Gemini, HP 2011

⁶⁴ *The Hot New Online Retail Strategy: Pushing More In-Store Purchases*, Time Business and money, 13 May 2013

“Anywhere, anytime” is the new mantra. Smartphones are being adopted at a staggering rate. In most developed markets, over 30% of consumers have a smartphone in their pockets while they are shopping. Smartphones are accelerating e-commerce growth even further. In 2011, Amazon hit \$2 billion in mobile sales – up from \$1 billion in 2010. In 2011, eBay mobile commerce generated \$5 billion in sales; in 2012 it expects this figure to be \$8 billion.

LOW PROFILE IMPORTS

In parallel, a growing number of RAPEX notifications with missing product identification or economic operators’ details are linked to Internet sales, very often on global online market places. While the marketing world focusses on high profile innovative brands and retailers, import is sometimes performed by people with little knowledge of regulatory requirements and good practices who trade in low profile unbranded products (e.g. ”easy import” with containers bought from outside of the EU and products sold on Internet, occasional importers).

There is also an increasing incidence of products posted by air freight from China in individual packages for which it is not possible to trace the origin (no invoice, no brand name or anything else that shows the origin)⁶⁵. The emerging importance of micro-businesses and individual importers operating online is calling for a clarification of responsibilities and for potentially assessing a specific application of global traceability good practices.

MORE PRODUCT INFORMATION

Consumers have a new demand for product information. This is driven by two key trends :

- increased importance of health and well-being
- growing consumer concern about sustainability⁶⁶

Not all consumers want more information but more consumers tend to look for specific information corresponding to their lifestyle and consumer behavior (e.g. the country of origin, ingredients, chemicals...).

NEW WAYS TO GET THE INFORMATION

Consumers are becoming more empowered through the use of new communication technologies. They are demanding more digital product information to be linked to the physical products they use and consume⁶⁷. In a multichannel world, consumers are increasingly involving websites, blogs, social networks and applications in their path to purchase. The research firm Forrester estimates that 50% of all retail sales are web-influenced. IBM states that 80% of consumers use social networks to research new products. Brand and retailer applications contain good quality information, but applications from third-parties (i.e. from service providers or other stakeholders) are where consumers spend most of their time.

Barcode scanning is one easy new way for consumers to get more information about products with their mobile device (or even with their computer). Just one application provider, Scanbuy, measured over 20 million consumer scans in 2011 – a 440%

⁶⁵ See also Chapter 6.2

⁶⁶ *Future Value Chain 2020*, The Consumer Goods Forum, Cap Gemini, HP 2011

⁶⁷ The Consumer Goods Forum NGPI project (New Generation Product Identification)

increase versus 2010. Technology offers the possibility for consumers to define their profile including the type of information relevant to them.

THE CHALLENGE OF INACCURATE PRODUCT INFORMATION

In this context, inaccurate product information is a critical issue addressed by the industry. Research by GS1 into three major third-party applications indicates that correct product information is only available in 9% of cases. Consumer research shows that nearly 40% of shoppers said they would not buy a product if they did not trust the accuracy of the digital information. An industry initiative aims to become the trusted source of data to support the communication of authentic product data provided by brand owners to consumers/shoppers, retailers and Internet application providers using Internet and mobile devices⁶⁸.

With regards to all the above, traceability can support the availability of accurate information for consumers. Economic operators and solution providers should take into consideration that once in place traceability systems can support providing information to consumers as a collateral benefit, and further should consider linking Business-to-Business (B2B) systems with Business-to-Consumer (B2C) systems.

8.2. TRACEABILITY NETWORKS AND NEW TECHNOLOGIES

The best in class approach for the future tends to be considered as traceability in network or “decentralised” and based on the concept of Critical Tracking Events⁶⁹.

“In the coming decade, improved collaboration together with new supply chain / logistics technologies and information transparency will enable a more synchronised value chain with greater visibility and traceability“.[...] We will see an increasing ability to constantly read, analyse, exchange and react to information inside and outside the company boundaries.”⁷⁰

Yet current traceability solutions are still mainly built on the concept of passing along product information together with the delivery of goods to the following supply chain partner. Risks associated with that are : a tremendous amount of data for all products which must be captured during and at the end of the chain, growing information redundancies, data quality loss through chain effects, higher risks to have one actor breaking the traceability chain and higher costs for the whole chain.

Therefore, the industry is piloting systems⁷¹ making the best use of modern technology and based on global standards. The core of the approach is the decentralised archiving of the data and its recall via the product-individual identifier, carried by the product itself. The various product data will not be connected and transported directly with the final product but kept on stock decentralised during every single process step and recalled via a centralised interface/search engine. Product-related traceability systems, currently available on the market, shall get connected.

Capabilities of all companies, industry benefits and potential regulations will dictate the speed for adoption.

⁶⁸ GS1 Source and The Consumer Goods Forum

⁶⁹ IUFoST Scientific Information Bulletin (SIB), March 2012 and *Food Traceability and Pilot Projects for Improving Product Tracing along the Food Supply System –Final Report*, IFT 2012

⁷⁰ *Future Value Chain 2020*, The Consumer Goods Forum, Cap Gemini, HP 2011

⁷¹ *The German Fish Traceability Pilot Project : A future oriented traceability approach based on a network data model*, 2013

With regards to the above, legal requirements for traceability should allow the use of traceability networks of any emerging technology allowing to access product information. Inherited traceability systems will coexist with new systems and technical standards will have a great role to play in ensuring interoperability. Market surveillance authorities and customs could explore possibilities brought by 2D barcodes, smartphones and other new technologies with the example of the Interface Public-Members (IPM) tool of the WCO to fight against counterfeiting⁷².

8.3. TRIGGERING INTERNATIONAL MOMENTUM TO IMPROVE TRACEABILITY IN SUPPLY CHAINS

Supply chains are global and traceability is only as strong as the weakest point in the chain. Economic operators and market surveillance authorities depend on traceability practices from actors in other countries, within or outside of the EU, where the same regulations apply...or not. Traceability is on the agenda of several global or regional intergovernmental organisations :

- ICPSC⁷³ had a first international workshop on product traceability and tracking labels in Stockholm in 2009 and discussions are going on.
- OECD⁷⁴ Consumer Policy action plan to strengthen information sharing on product safety includes “Enhance international co-operation on traceability”.
- APEC⁷⁵ and ASEAN are looking at visibility in the chain to support food security and supply chain efficiency.

The Consumer Goods Forum⁷⁶ has started discussions around traceability⁷⁷. Building momentum at the international level and strengthening cooperation between all stakeholders – authorities, economic operators, associations – will :

- Globally align stakeholders on a common understanding of traceability
- Provide the basis for a harmonised approach of traceability implementation and potentially enforcement
- Drive and re-ensure investments from economic operators
- Enable inquiries and better results for market surveillance authorities when investigating economic operators outside of the EU
- Facilitate capacity building at the global level

Cooperation between governmental organisations, economic operators and trade associations may be the cornerstone to reach the common goal of better traceability worldwide. A first step could be to present the result from this expert group in OECD, ICPSC, APEC, ASEAN and The Consumer Goods Forum and discuss further actions and possible collaborations.

⁷² IPM *The WCO Tool in the Fight Against Counterfeiting*, World Customs Organization

⁷³ International Consumer Product Safety Caucus

⁷⁴ OECD Consumer Policy, Summary of Actions that could be taken to strengthen information sharing on product safety, 25 June 2010

⁷⁵ See for example *Challenges to Achieving Food Security in APEC*, Issues Paper No. 2, APEC Policy Support Unit, 2012

⁷⁶ The Consumer Goods Forum (TCGF) is a global, parity-based industry network, driven by its members. It brings together the CEOs and senior management of over 400 retailers, manufacturers, service providers and other stakeholders across 70 countries and reflects the diversity of the industry in geography, size, product category and format.

⁷⁷ TCGF Operational Excellence Core Team meeting in April

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ANNEXES

ANNEX 1 : SELF-ASSESSMENT CHECKLIST FOR ECONOMIC OPERATORS

	Question	Reference in the report	Yes/no
1	Do you have written procedures for traceability and recall of products ?	Chapter 4.2 Best practice 1	
2	Do you label your consumer products at least with minimum information according to best practices ?	Chapter 4.2 Best practice 2	
3	Do you record data elements according to best practices ?	Chapter 4.2 Best practice 3	
4	Do you use enabling technologies to automate data capture, data recording and data exchange ?	Chapter 4.3 Best practice 4	
5	Do you use applicable global standards to ensure the interoperability of your traceability system with your trading partners ?	Chapter 4.4 Best practice 5	

ANNEX 2 : SELF-ASSESSMENT CHECKLIST FOR MARKET SURVEILLANCE AUTHORITIES

	Question	Reference in the report	Yes/no
1	Have you been trained on barcodes / how to use product codes to get additional information ?	Chapter 5.2 Chapter 4.2. Best practice 2 and 5	
2	Do you ensure easy access to the relevant contact point details in your market surveillance authority for economic operators and consumers ?	Chapter 5.3	
3	Do you ask economic operators involved in the supply chain of dangerous products to complete a form to provide information on product identification and other economic operators ?	Chapter 5.3	
4	Do you use best practices to inquire on economic operators involved in the supply chain of dangerous products located in other Member States ?	Chapter 5.3	
5	Do you collaborate with customs to trace back dangerous products that have been imported in the EU?	Chapter 5.3	

ANNEX 3 : FOUR MODELS TO MANAGE TRACEABILITY INFORMATION ACROSS THE CHAIN

For economic operators, managing traceability information means capturing information from the label on the received products (at minimum the product identifier, this can be on grouping of consumer products), collecting information from suppliers and from internal processes, recording and storing these information, marking some information on the products delivered (at minimum the identifier for all levels of traceable item), sharing some information with at least the next economic operator. Information that needs to be communicated between partners can be communicated in parallel to the physical flow in an electronic way (usually more efficient and reliable) and does not have to be on the label.

Over the past year, various models for managing traceability information throughout the chain have emerged.

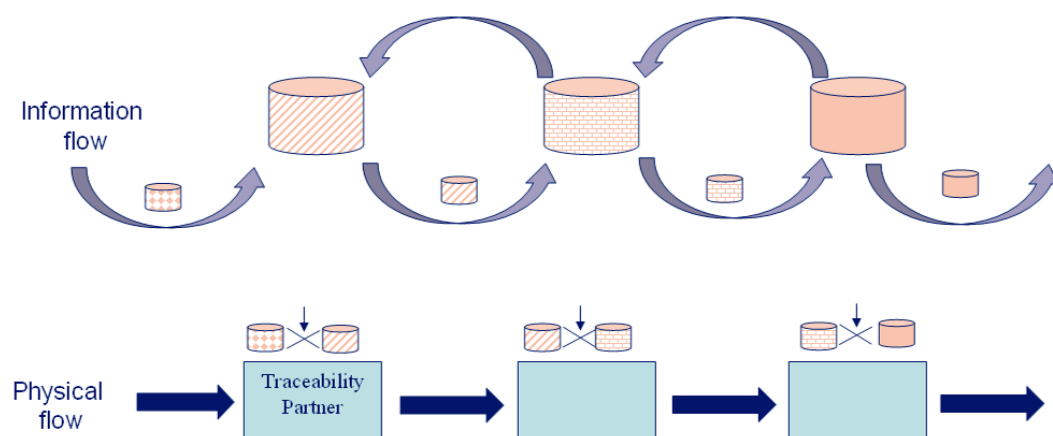


Figure 1 : one-up one-down model, source GS1

The **one-up one-down model** is still the prevalent one and is usually agreed by economic operators and authorities as the basics for any full chain traceability system. In the “one-up one down” model each traceability partner in the supply chain is responsible for linking input records to output records. The main benefit is that organisations need only be concerned with exchanging data with their immediate trading partners (upstream and downstream in the supply chain).

For several years, the idea of a **centralised database** or single source database has been discussed. In this model the traceable item source (the trading partner that provides the product) makes its traceability data available (e.g. publishes the data) to a central repository/database maintained by a third party. All partners must follow specified data standards and criteria for the privacy of information must be developed.

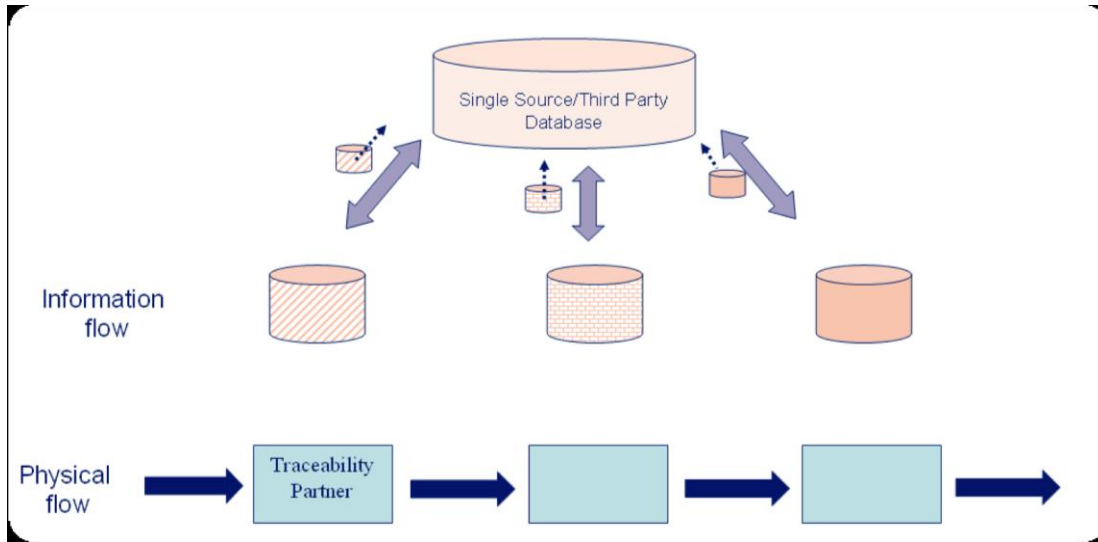


Fig 2 : centralised database, source GS1

This model can exist only in a limited community and with a limited scope as the idea of a unique global and central database for all products traceability is not realistic for many reasons (efficiency, cost, confidentiality,...). It is usually seen as the least desirable option in terms of efficiency, cost / benefit balance and carries important feasibility challenges.

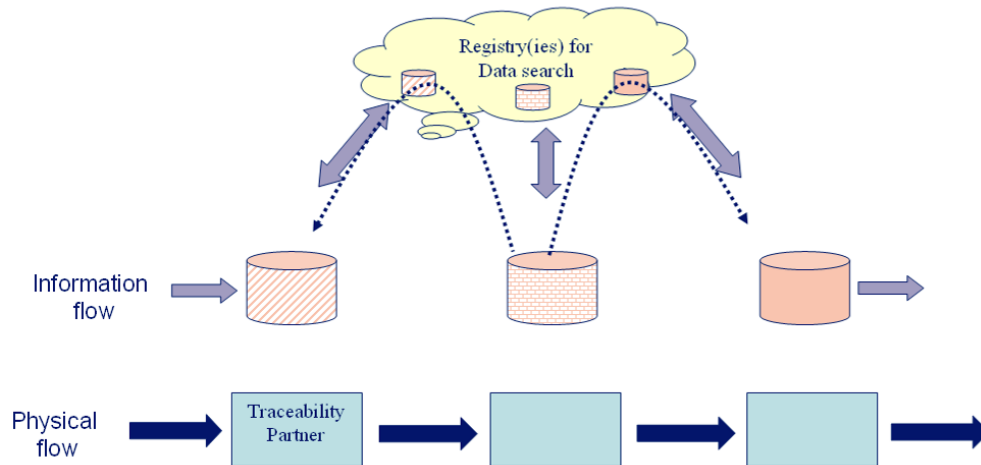


Figure 3 : traceability network, source GS1

In the **traceability network model**, the traceable item source (trading partner that provides the product) makes traceability identification keys available in a registry to enable traceability data search. This information can be stored anywhere as the registry provides the link and data search mechanism. This can be achieved with EPCIS, ONS and Discovery Services (<http://www.gs1.org/gsmc/kc/epcglobal>). The combination of RFID, serialisation and Internet actually brings the possibility of real time / event driven traceability.

This is an emerging model. It tends to be considered as the most efficient model for the future to access traceability information other than transactional data. Its ability to support anti-counterfeiting policies as well as retrace a complete pedigree of a product makes it particularly attractive. Its cost and simplicity to implement are often perceived as still to be demonstrated. Pilots can be useful when considering this model in specific industries.

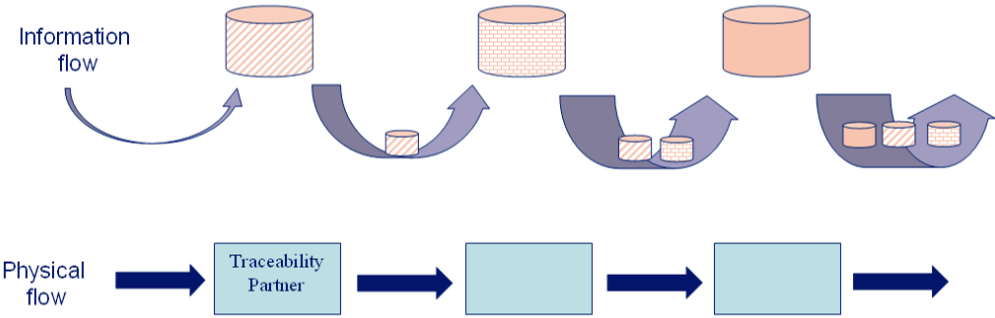


Figure 4 : Cumulative tracking, source GS1

In the **cumulative tracking model**, the traceable item source (trading partner that provides the product) makes the traceability data received from all previous upstream chain sources that have possessed (Chain of Custody) or owned (Chain of Ownership) a traceable item(s) plus its additional traceability data, available to the next downstream supply partner. Cumulative tracking is less and less considered as a traceability model in itself. It was based on very specific cases of regulatory discussions, notably in the US in the healthcare sector. It faces important challenges in terms of cost, confidentiality and implementation. It is less and less relevant as the ability to access information in an electronic manner and very fast, wherever the source of information is, increases every day (see traceability network model).

Note : The cumulative tracking model was previously called “pedigree model”. Now, a “pedigree” is considered as the capacity to retrace the full history of a product (using the various traceability models above).

These models should be seen as trends and options for the management of traceability information across the chain. Indeed they can co-exist as some information may follow the one-up one-down model while a few others may follow another model depending on the constraints and needs of an industry sector.

ANNEX 4 : CASE STUDIES

HAILU LIGHTER CASE STUDY

This case study relates to a jumbo lighter sold from a small temporary retail shop. The product was subsequently found to have been the cause of a small house fire a few days before and testing showed it to be dangerous. When it was being tested in the laboratory it created small gas cloud fires and a fire extinguisher had to be used to prevent a spread of fire in the facility.

A number of these were found on sale in the retail shop and as the stock was suspicious it was seized by officers for further testing. The trader did not have the necessary compliance documents. Unfortunately the trader gave a false supplier's address and disappeared. It became impossible to trace the chain of supply in the UK.

The only traceability was in the form of a brand name on the product. There was no barcode or compliance document with the lighters.

Using the web, the market surveillance authority was able to identify the Hailu factory address in China and that was entered on the notification form for RAPEX.

The above case illustrates the case of false supplier information but where the brand was true and enabled the factory outside of the EU to be found.

AC TO DC ADAPTOR SUPPLIED WITH LED LIGHTING CHAIN

This product was put on hold at an Enhanced Remote Transit Facility (under customs control). It was tested and found to be electrically unsafe.

This product had no brand name or barcode. The label on the adaptor had numerous approval and standard marks. For example UL, GS, CCC, Safety Mark. Although attempts were made to link the marks to this product it soon became clear that it was impossible without a brand name.

Fortunately, the Bill of Lading showed the importer's address and documents were requested from them. They provided a Certificate of Compliance with the name and address of the Chinese supplier. This information was used to complete the notification form for RAPEX.

The product did not enter the UK market and was destroyed.

The above case illustrates the case of an electrical appliance for which the name and address of the manufacturer should have accompanied the product in accordance with Directive 2003/108/EC. If it had come from the consumer, it would not have been possible to trace it back but because it was stopped for compliance audit at customs, the Bill of Lading could be found.

ELECTRIC LIGHT BULB (LED TYPE)

The product did not provide adequate protection against electric shock. The product or packaging carried no manufacturer's name or trademark. The consumer purchased the product through an Internet seller who appeared to be in the Far East. The seller information was in Chinese.

The item location indicated on the listing stated the United Kingdom. It was suspected these goods are stored in the UK by a fulfillment company who stores the goods and distributes them on behalf of the Chinese seller.

The transit packaging which the product was posted in was not marked with a return address so it was impossible to trace the location of the fulfillment company.

A RAPEX notification was issued and the Internet listing removed.



The above case illustrates the example of an untraceable product.

PRODUCT MOTORCYCLE BATTERY CHARGER

The context was a test sample purchased covertly from an Internet listing on a global online market place. On delivery, the product was discovered to have come by air freight direct from China.

It was obvious without testing that the product did not comply with regulations in that it did not carry a brand name and had a plug which was not suitable for use in the UK or in Europe.

There was no traceability on the packaging and no invoice for the product.

A notification was validated for information purposes and the listing was removed from the Internet.



The above case illustrates the example of direct air freight from China.

ANNEX 5 : GS1 STANDARDS AND CORRESPONDING ISO OR OTHER STANDARDS

<i>GS1 component</i>	<i>Corresponding ISO or other standard</i>
GTIN (Global Trade Item Number)	ISO/IEC 15459-6
GLN (Global Location Number)	ISO/IEC 6523
SSCC (Serial Shipping Container Code)	ISO/IEC 15459-1
GIAI (Global Individual Asset Identifier)	ISO/IEC 15459-4
GRAI (Global Returnable Asset Identifier)	ISO/IEC 15459-4
GSRN (Global Service Relationship Number)	ISO/IEC 15418
GDTI (Global Document Type Identifier)	ISO/IEC 15418
GINC (Global Identification Number for Consignments)	ISO/IEC 15418
GSIN (Global Shipment Identification Number)	ISO/IEC 15459-8
GCN (Global Coupon Number)	ISO/IEC 15418
Application Identifiers	ISO/IEC 15418
EPC URI Syntax	IETF RFC 3986
EANCOM syntax	ISO 9735
EANCOM content	UN/CEFACT UNSMs
GS1 XML syntax	W3C XML
GS1 XML content	W3C XML
Symbology identifiers	ISO/IEC 15424
EAN/UPC	ISO/IEC 15420
ITF-14	ISO/IEC 16390
GS1-128	ISO/IEC 15417
GS1 DataBar	ISO/IEC 24724
GS1 DataMatrix	ISO/IEC 16022
GS1 Composite	ISO/IEC 24723

GS1 QR Code	ISO/IEC 18004
UHF Class 1 Gen 2	ISO/IEC 18000-63
HF Class 1 Gen 2	ISO/IEC 18000-3,mode 3
EPC Tag Data Standard	ISO/IEC 15962, 2nd Edition
Low-level Reader Protocol (LLRP)	ISO/ICE 24791-5
Application Level Events (ALE)	ISO/IEC 24791-2
Reader Management (RM)	ISO/IEC 24791-3
Discovery, Configuration, and Initialization (DCI)	ISO/IEC 24791-3

Source : GS1 Partnerships with external Standard Bodies, May 2013