



# IMPLEMENTING TRACEABILITY IN THE FOOD SUPPLY CHAIN

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## References

ECR Blue Book Using Traceability in the Supply Chain to meet Consumer Safety Expectations, March 2004

CIES Global Food Safety Initiative Guidance Document

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# IMPLEMENTING TRACEABILITY IN THE FOOD SUPPLY CHAIN

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## Executive Summary

The CIES “Implementing Traceability in the Food Chain” document aims to build awareness and provide information to food businesses, enabling them to make the right business decisions regarding traceability. It describes the potential impact of the implementation of a traceability system and provides some recommendations. It is aimed at the senior management level of food companies, independent of their position in the food chain. It seeks to guide food businesses by highlighting the components of such a system, the pitfalls when designing and implementing such a system and above all how to ensure that systems can be aligned along the food supply chain. The document focuses on food and not on product safety in general.

Traceability systems cover all types of food and affect food businesses from farm suppliers to retailers. Traceability systems are or will be obligatory for all businesses in the food chain in the European Union (EU), the USA and Japan. In addition to this legislation, there are other existing requirements for traceability, particularly in standards related to quality improvement and/or food safety. There is an underlying need to define the specific information elements that each sector of the food business must agree upon. This information should then be compiled and shared between the different sectors in order to achieve chain traceability.

Traceability is multi-disciplinary in the sense that many departments of a company will be involved in its development and its implementation. In addition to the quality (or food safety) department, at least logistics and IT should be involved. A fundamental decision to take in the beginning of this process is to define who has internal responsibility. In a traceability system, information can be used to trace back to find the source and cause of a problem, to stop the problem or prevent it from happening again. Products can also be found that have already been forwarded in case of a necessary withdrawal or recall in such a system. Other added value to a food business needs to be considered.

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. The expenditure should be considered as a long-term strategic investment because it is linked to consumer's perception, the image of the company and the trust that consumers display when buying a product.

The application of EAN.UCC standards is a prerequisite for the alignment of traceability systems. Companies that implement collaborative best practices and EAN\*UCC standards should encourage their partners to do the same thing. (*See Annex 1*)

## Introduction

In January 1999, a car demolition company in Walloon, Belgium, delivered oil from a transformer to a municipal oil recycling plant. The oil contained approximately 1 gram of dioxins. The oil ended up in a vegetable oil storage tank, an ingredient for feedstuff. Through the animal feed, the contaminated product entered the human food chain. The problem could not be contained since a targeted recall was impossible. There were few records on the feedstuff ingredients, the production date or the batch identity. It was impossible to ascertain whether other feed factories were involved, which farmers had bought the contaminated feedstuff, let alone which food products were contaminated and to which countries these products had been transported. Consequently, it was impossible to launch a proper recall, due to a lack of coherent and adequate information. As a result, millions of Euros were wasted on the withdrawal and recall of products that on hindsight were perfectly safe, but that were considered to be a major public health risk at the time. Ever since, the concept of the implementation of traceability in the food supply chain has received a great deal of attention. It is about to become a legal obligation within the EU.

In the United States, the desire to protect the nation's food supply and fear of food tampering led to the enactment of the Bioterrorism Preparedness and Response Act in 2002. A record-keeping regulation has been issued to help the US Food and Drug Administration (FDA) track foods implicated in future emergencies, such as terrorism-related contamination. The obligations are similar to those in Europe.

## What is the issue?

Many food businesses will be or are already confronted with the need to build a traceability system. This document aims to build awareness on this issue and to provide information to food businesses, to enable them to make the right business decisions. It will describe the impact that the implementation of a traceability system may have and provide some recommendations. It is aimed at the senior management level of food companies independent of their position in the food chain. It seeks to guide food businesses in the implementation of traceability systems, by highlighting the nuts and bolts of such a system, the pitfalls when designing and implementing such a system and above all how to ensure that systems can be aligned along the food supply chain. It focuses on food and not on product safety in general.

## Scope

Traceability systems cover all types of food and related products in the entire food chain and affect food businesses from farm suppliers to retailers. Feedstuffs and other farm supplies needed to produce food, are included, as well as food contact materials such as packaging. As requirements for traceability systems are present in the US, Europe and Japan the implications of this document have a global reach.

## Applicable legislation

Traceability systems are obligatory for all businesses in the food chain in the EU from 1st January 2005. This means a business must be able to identify all its suppliers of food, food products and feed and all businesses it has supplied food or feed to. The information needs to be systematically stored, in order to be made available to inspection authorities on demand. (*See Annex 2*)

In the United States a similar requirement regarding the establishment of records to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, was laid down in the Bioterrorism Act (section 306) and will come into effect in three stages. The US industry will need to comply with the record-keeping requirements by either December 2005, June 2006 or December 2006 depending on the company size, i.e., the larger, the earlier. (*See Annex 3*) In the US, food safety is seen as part of food security.

In Japan traceability is obligatory for beef as from December 2004. It can be expected that this will be expanded to other agricultural products.

In the EU, traceability is related to labelling in specific cases only. For some sectors in Europe, the requirement for traceability ran ahead of the general requirement, i.e. for the labelling of beef and some beef products, fish, and for the labelling of (non) GMO's. (*See Annex 4*) However, in the case of food contact materials (mainly packaging) the requirement has to be implemented in 27 October 2006 (*See Annex 6*).

The requirement for a traceability system is in essence quite simple, but implementing an effective system that is also beneficial to the business may be difficult to put into place for some businesses to a greater or lesser extent. There are no legal requirements for in-company traceability (from door to door), to set up a complete food chain traceability system, nor to give any information to the consumer. The choice on how to set up an in-company traceability system remains with each individual company.

For some, traceability appears to be a magic word, the ultimate solution to all food safety problems and a means to create consumer confidence. In reality, it is an important tool, which assists in the management of food safety and security issues. There are many other reasons why operators should implement traceability systems.

## Requirements for Traceability

In addition to the legislation described above, other requirements for traceability exist, particularly in standards related to quality improvement and/or food safety. The use of such standards may help to reduce the chances of a food safety crisis and subsequent product withdrawal or recall. Despite best efforts at prevention however, there will always be some degree of risk of product contamination or tampering at any point in the supply chain.

### ISO 9001:2000

Traceability is mentioned in ISO 9001:2000 as one of the aspects that should be considered in a quality management system. Many businesses are therefore interested to have traceability systems, whether it's a legal requirement or not.

## Definitions

There are many definitions and different terms for traceability. In Codex Alimentarius the term Traceability/Product Tracing is used, many others speak of tracking and tracing and in the United States this is simply called record-keeping. But the effects they have are all the same.

In this document the following definitions apply to traceability:

- **Traceability** is the ability to trace the history, application or location of an entity by means of recorded identifications.

*This definition is based on the definition in the ISO 9001:2000 standard: "Traceability: ability to trace the history, application or location of that which is under consideration."*

- **Chain Traceability** is the ability to trace the history, application or location of an entity by means of recorded identifications throughout the entire food chain.

*To facilitate this, in practice the requirement for traceability is to keep records of suppliers and customers, sometimes called "one step up, one step down". If all food businesses keep these records and the information therein can be communicated and exchanged, chain traceability is achieved.*

- **Traceback or Tracing** is the ability to identify the origin of a particular unit and/or batch of product located within the supply chain by reference to records held upstream.

- **Traceforward or Tracking** is the ability to follow the path of a specified unit of a product and/or batch through the supply chain as it moves between organisations towards the final point-of-sale or point-of-service.

- **Internal Traceability** is the ability to follow the path of a specified unit of a product and/or batch within one company or company unit.

Another confusing area of terminology is the definition of "lot" and "batch". Lot is defined in EU legislation as:

- **Lot** is a batch of sales units of a foodstuff produced, manufactured or packaged under practically the same conditions (Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs).

- **Withdrawal** is a procedure to withdraw food from the market where the food has left the immediate control of that initial food business.

- **Recall** is procedure to withdraw food from the market where the food has left the immediate control of that initial food business and where the product may have reached the consumer.

In this document lot and batch are considered to have the same meaning.

## Food Safety Standards

Food retailers often require certification from manufacturers of private-label food products, for the safe production of food. Food safety standards are applied to other food products as well.

The CIES Global Food Safety Initiative has issued a Guidance Document as a benchmarking tool for food safety standards, and in effect provides requirements for food safety standards. The document can be found at [www.ciesnet.com](http://www.ciesnet.com). The Guidance Document contains the following paragraph concerning traceability:

### *6.1.17 Traceability*

*The standard shall require that the supplier develop and maintain appropriate procedures and systems to ensure:*

- Identification in any case through a code marking on container and product, to identify the source of any out-sourced product, ingredient or service;*
- Record of purchaser and delivery destination for all product supplied.”*

To date, five food safety standards have been benchmarked against the Guidance Document and were found to be in compliance with it:

- The BRC Global Food Standard
- The Dutch HACCP Code
- The EFSIS Standard
- The International Food Standard (IFS)
- The SQF 2000 Code

All five therefore contain requirements for traceability. (*Specific requirements are given in Annex 5*). They may differ in detail, but substantively the requirements are the same.

In addition to these standards, there is the need to define the specific information elements that each sector of the food business must agree upon. This information may then be compiled and shared in order to achieve chain traceability. Trace Fish, a consortium, initiated and financed by the EU is an example of a body that was able to bring together different elements of information into a CEN standard. Based on the Trace Fish standard, a generic version of the standard for use in all fresh produce in the food industry was launched.

Many customers already ask for traceability systems to be in place through the requirement of certification based on the ISO 9001 series or food safety standards. Besides the legal necessity to implement traceability systems, there often is a commercial need to do so.

The implementation of traceability systems will be increasingly a part of the usual commercial negotiations and product specifications. This will decide in how far implemented systems will be compatible.

## Functions of a traceability system

Traceability is multi-disciplinary, as many departments of a company will be involved in its development and its implementation. Besides the quality (or food safety) department, at least logistics and IT should be involved. Marketing and Auditing departments could also benefit from a traceability system. A fundamental decision to take in the beginning of this process is to define who has internal responsibility.

A traceability system may serve many purposes. Essentially, it functions as a tool for communication, making information available along the food supply chain. This information can be used for a wide variety of purposes.

In food safety, the information can be used to trace back to find what the source and the cause of a problem is, to stop the problem or prevent it from happening again. The system may also be used to find products that have already been forwarded in case of a necessary withdrawal or recall.

## Implementing a traceability system

When implementing a traceability system, the added value of such a system needs to be considered. Traceability systems can serve many purposes and may lead to the following benefits. Here are a few examples:

- Ensure a fast product withdrawal or recall, thus protecting the consumer.
- Minimise the impact of such a product recall, by limiting the scope of product implicated and providing traceability tools. The financial impact of recalling an entire commodity or brand versus a specific grouping of product (e.g., a lot) can be enormous.
- Enabling companies to demonstrate that their product is not implicated in a given product recall, by ensuring proper segregation and clear identification of product.
- Address concerns of food-terrorism or tampering of the food supply chain.
- Strengthen consumer confidence, through the industry's ability to promptly identify and recall potentially unsafe product.
- Providing internal logistical and quality related information, improving efficiency.
- Create a feedback loop to improve product quality, condition and delivery.
- Providing transparency in distribution routes and improving supply chain efficiencies and trading partner collaboration.
- Providing reliable information
  - business to business
  - to consumers
  - to government inspectors
  - to financial or technical auditors
- Establishing the responsibility and liability for a certain problem
- Facilitate protection of company and/or brand name

As the implementation of a traceability system requires upfront investments, companies are advised to take all benefits into consideration when implementing a traceability system. These benefits should be analysed as well as the risks that are managed with the system. This will also include a cost/benefit analysis.

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 immediately obvious. The expenditure involved should be considered as a long-term strategic investment because it is linked to consumer's perception, the image of the company and the trust that consumers display when buying a product.

It is of great importance to

1. decide on the exact product specification
2. decide on batch (or lot) sizes.

Batch sizes can be based on production or run time, on volume, or on the expiry date.

Generally, being able to trace to the detail (product or a small batch level) will increase the costs in the traceability system. Deciding on big batches will probably make the system less costly, but will increase the risks because if a problem arises, more products will be involved than would have otherwise been necessary. Based on the cost/benefit analysis the ideal balance should be sought between present and future costs. This analysis should then be taken into account in the design of the system.

It is difficult to recommend a suitable traceability model for retailers and food producers by looking at the most cost efficient process and the reliability of the links throughout the chain. Situations vary from case to case. In case of a recall, a retailer may not necessarily take the smallest possible batch off the shelves. Retailers will often withdraw all similar products, whether they belong to the affected lot or not. This is more efficient for the retailer, as mistakes can be avoided in-store and consumers are provided with the reassurance that everything is under control.

Many companies now have effective internal traceability systems in place. The next step is to achieve chain traceability. The main requirements for handling withdrawals and recalls across the supply chain are having reliable data, the possibility to exchange the data and properly mapped business processes. A good internal traceability system is a prerequisite to a chain traceability system. The investments in an internal traceability system will not be wasted in moving towards chain traceability. All good chain traceability software should be able to integrate seamlessly to any internal system.

As a best practice on investments: some insurance companies are offering recall insurance and free traceability software, for the same price as only the insurance.

The application of EAN.UCC standards is a prerequisite for the alignment of traceability systems. Companies that implement collaborative best practices and EAN\*UCC standards need to encourage their partners to do the same thing. A further reference is contained in the ECR Blue Book “Using Traceability in the Supply Chain to meet Consumer Safety Expectations”, March 2004, which describes the implementation process in detail. More information may be found at [www.ecrnet.org](http://www.ecrnet.org).

Bar-coding is often used as a means to transfer information. Radio frequency identification (RFID) is a growing technology that utilises radio frequencies to identify products (trade items), pallets (logistic units) and/or returnable assets throughout the supply chain. Recent EAN.UCC standardisation developments in the field of RFID are internationally known as the Electronic Product Code (EPC) Network.

## References

ECR Blue Book Using Traceability in the Supply Chain to meet Consumer Safety Expectations, March 2004



CIES – The Food Business Forum - January 2005

## ANNEX 1 - Application of EAN.UCC standards in traceability systems

From an information management point of view, implementing a traceability system within a supply chain requires all parties involved to systematically associate the physical flow of materials, intermediate and finished products with the flow of information about them.

This is best attained by deploying a common business language – the EAN•UCC standards. Their global reach and universal acceptance by consumers, businesses and governments make them uniquely positioned to provide the appropriate response to traceability system requirements.

Because of its ability to provide globally unique identification of trade items, logistic units, parties and locations, the EAN.UCC System is particularly well suited to be used for traceability purposes. The EAN.UCC standards provide a global business language that is used to enable accurate and fast communication between different internal traceability systems used by suppliers, manufacturers and retailers around the world.

EAN International has defined key traceability principles and produced an implementation grid, which links them to enabling technologies and relevant EAN.UCC System tools.

<b>TRACEABILITY PRINCIPLES</b>	<b>ENABLING TECHNOLOGIES</b>	<b>EAN•UCC SYSTEM TOOLS</b>
UNIQUE IDENTIFICATION	AUTOMATED IDENTIFICATION	GTIN, SSCC, GLN, APPLICATION IDENTIFIERS
DATA CAPTURE AND RECORDING	AUTOMATED DATA CAPTURE	EAN/UPC, UCC/EAN-128
LINKS MANAGEMENT	ELECTRONIC DATA PROCESSING	SOFTWARE APPLICATIONS <sup>1</sup>
DATA COMMUNICATION	ELECTRONIC DATA INTERCHANGE	EANCOM®/ XML

### Unique Identification

Any product that needs to be traced or tracked must be uniquely identified. The EAN•UCC globally unique identifiers are the keys that enable access to all available data about the product's history, application or location.

- Identification of Locations

Unique identification of locations is ensured through the allocation of an EAN•UCC Global Location Number - GLN, to each location and functional entity.

- Identification of Trade Items

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<sup>1</sup> Hardware and software manufacturers and vendors are not affiliated with EAN International.

Unique product identification is ensured through the allocation of an EAN•UCC Global Trade Item Number - GTIN, to each product (consumer unit). For traceability purposes, the GTIN has to be combined with a Serial Number or Batch Number in order to identify the particular item.

Identification of Lots/Batches.

Traceability of Lots/Batches is ensured through the allocation of an EAN•UCC Global Trade Item Number - GTIN and Lot/Batch Number to each product (e.g. consumer unit).

- Identification of Series

Traceability of Series is ensured through the allocation of an EAN•UCC Global Trade Item Number - GTIN and Serial Number to each product (consumer unit).

- Identification across Product Hierarchies

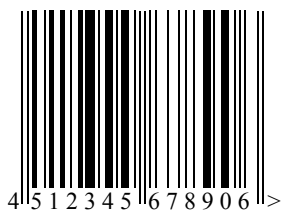
A GTIN needs to be allocated to each of the three levels of the Product Hierarchy, namely: consumer unit, traded unit and pallet – the latter only to be included if it is priced, ordered or invoiced at any point in the supply chain, in other words, if the pallet is also considered to be a traded unit.

- Identification of Logistic Units (pallets)

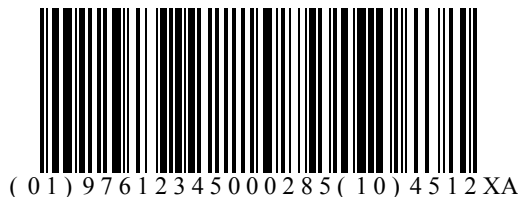
Identification and traceability of pallets is ensured through the allocation of an EAN•UCC Serial Shipping Container Code - SSCC. Any pallet, independently of its type (mixed or uniform), needs to carry an SSCC allocated at source. A new SSCC must be allocated every time a new pallet (logistic unit) is created.

### Data Capture and Recording

Products, Standard Trade Item Groupings and Pallets identified with applicable EAN•UCC standards [GTIN, SSCC, Application Identifier (AI)] must be bar coded in relevant EAN•UCC bar code symbols.



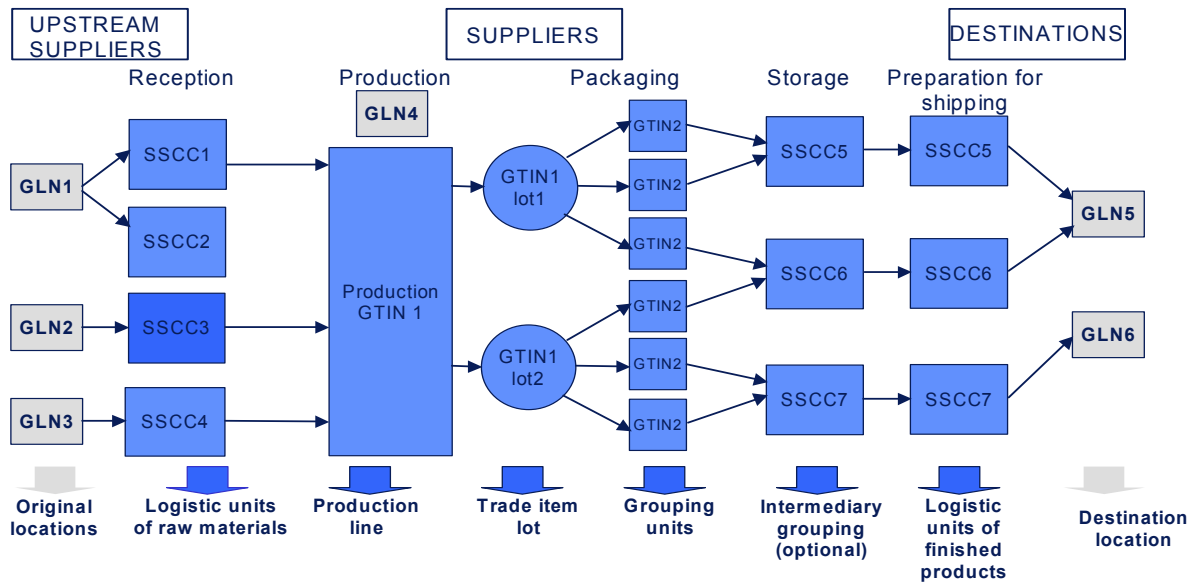
*Example of an EAN/UPC Bar Code*



*Example of an UCC/EAN-128 Bar Code*

### Traceability Links Management

In a majority of supply chains, products are tracked and traced by their production batch, which has undergone the same transformation (production process) and by their transport/storage path (distribution process). The figure below shows the use of EAN•UCC standards for identifying locations (GLN), logistic units (SSCC), manufacturing batches (AI 10) and consumer units (GTIN) in a production environment.



*Traceability data management in production*

### Identification management in a production environment is characterised by:

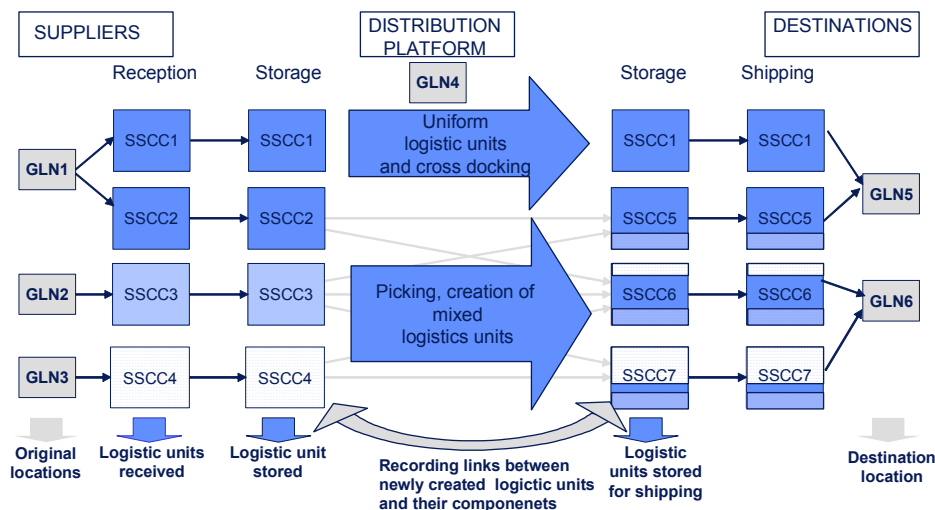
- Several supplier locations (GLN 1-3), which send pallets of materials (SSCC 1-4).
- At reception, materials are stored and/or ordered for the production process.
- At the production site (GLN 4), consumer units (GTIN 1) are produced in separate batches (each identified with a distinct Batch Number).
- In the packaging step, consumer units (GTIN 1 and its Batch Number) are packed into standard grouping units (GTIN 2).
- In the next two steps - storage and preparation for shipping, pallets are created (SSCC 5-7) and dispatched to customer destinations (GLN 5-6).

#### Application of EAN.UCC standards for traceability in a production environment:

- Reception:** the SSCC of an incoming pallet is recorded and linked to the GLN of the supplier. Each time the pallet is moved, its SSCC is recorded and linked to the GLN of its new location (e.g. to storage or production).
- Production:** Under ideal conditions the SSCC of the pallet and/or GTIN + Batch Number of materials used in the production process are recorded and linked to the GTIN of the product made and its production batch. At the end of the production process, standard trade item groupings are made from individual products. A new GTIN is assigned and linked to the production Batch Number.

3. Packaging, storage and expedition: The GTIN of a standard trade item grouping is linked to the SSCC of the pallet onto which it is packed. The SSCC of an outbound pallet is linked via scanning to the GLN of its destination. The GLN of its destination must not necessarily be displayed on the label.

*Traceability data management in distribution*



The figure above shows the use of EAN•UCC standards for identifying locations (GLN) and logistic units (SSCC) in a distribution environment, which is characterised by:

- a) Several supplier locations (identified with GLN 1-3), which send pallets of finished products (identified with SSCC 1-4).
- b) At distribution centre (GLN 4) reception, pallets are stored and sent to the order picking process.
- c) In the order-picking step, orders are fulfilled either by shipping uniform pallets, cross docking or creation of mixed pallets. They are either carried forward unchanged (uniform pallet identified with SSCC 1) or newly created (mixed pallets identified with SSCC 5-7) with products originating from different pallets (SSCC 2-4).
- d) In the last two steps - storage and preparation for shipping, both uniform (SSCC 1) and mixed pallets (SSCC 5-7) are dispatched to customer/point-of-sale destinations (identified with GLN 5-6).

Application of EAN.UCC standards for traceability in a distribution environment:

1. Reception: The SSCC of an incoming pallet is recorded and linked to the GLN of the supplier. Each time the pallet is moved, its SSCC is recorded and linked to the GLN of its new location (e.g. to storage, order-picking or distribution).
2. Order-picking and distribution:
  - a) The SSCC of an unmodified pallet picked for distribution from the storage area or cross-docked without any storage is recorded and linked to the GLN of its destination.
  - b) A newly created pallet contains standard trade item groupings originating from different pallets. In this case, a new SSCC is assigned to it and linked to the SSCC numbers of all other pallets used in its creation and/or, if applicable, the GTIN and Batch Number of each standard trade item grouping that was used. This can create the need for an enormous effort and can be solved through the application of a “time window”, to be defined by

each company when a product is packed. Newly created pallets during this time window can be linked to pallets used up within the same time frame. The SSCC is recorded and linked to the GLN of its destination.

The ability to retrieve traceability data in a fast and accurate manner along of a supply chain is critical. This requires the management of successive links between what is received, produced, packed, stored and shipped across the entire supply chain.

If one of the partners, in the supply chain, fails to manage these links, this will result in a break in the information chain and in the subsequent loss of traceability. It is impossible to attain full product traceability without correctly identifying products in all their configurations at each different point in the supply chain.

### Data Communication

The use of EDI is recommended for the fast, accurate, and cost effective communication of traceability data. Applicable EAN•UCC standards are EANCOM® and EAN•UCC XML messages. Traceability requires associating the physical flow of products with the flow of information about them. To ensure the continuity of the information flow, each supply chain participant must communicate pre-defined traceability data keys to the next one, enabling the latter to apply traceability principles.

### EAN.UCC System application: an example of a product withdrawal

1. Consumer - The consumer signals an anomaly in the sales transaction.
2. Distributor - The distributor relays the complaint to its supplier, i.e. the product's manufacturer, specifying the item reference (Global Trade Item Number - GTIN), and if possible, the Batch Number.
3. Manufacturing Plant - The manufacturer identifies the raw material associated with the anomaly and identifies the corresponding upstream supplier (Global Location Number – GLN).
4. Upstream Supplier:
  - The upstream supplier analyses the cause of the anomaly and identifies the production batches associated with it;
  - It identifies all units shipped from these production batches (Serial Shipping Container Code - SSCC);
  - Informs receiving customers about the nature of the problem and the Batch Number of the raw material in question;
5. Manufacturing Plant:
  - The manufacturer decides to withdraw the finished products related to the problem.
  - Through its traceability system, the manufacturer searches its records for batches of finished products for which the raw material in question has been used;
  - Identifies the SSCC of cartons and pallets containing batches of finished products to be withdrawn (which may be in the process of being delivered, in external storage and/or already delivered to customers);
  - Quarantines the cartons and pallets still present in its stocks;
  - Identifies customers (GLN) and provides them with information related to products to be quarantined and returned (SSCC, GTIN, Batch Numbers).
6. Retail Distribution Centre:
  - The retail distribution centre identifies the cartons and pallets (SSCC) to be quarantined and returned from the stock picking and shipment areas, and those already delivered at the retail points of sale;
  - Removes and returns affected products still within its premises (SSCC);
  - Provides retail stores with the SSCC, GTIN and Batch Number of the items to be removed.
7. Point of Sale:
  - Retail store quarantines suspect products (GTIN and Batch Number).

**ANNEX 2 - REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety**

[EXCERPT]

Article 3, 15.

‘Traceability’ means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

**Article 14 Food safety requirements**

1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health;

(b) unfit for human consumption.

3. In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

**Article 17 Responsibilities**

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

**Article 18 Traceability**

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

**Article 19 Responsibilities for food: food business operators**



1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.
2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.
3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.
3. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

### ANNEX 3 - Public Health Security and Bioterrorism Preparedness and Response Act of 2002, section 306 (USA)

Regulations Concerning Recordkeeping.--The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

((c) Protection of Sensitive Information.--The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

Proposed requirements to establish and maintain records to trace the transportation of all food (Sec. Sec. 1.351 and 1.352) would require that you keep records that trace the transportation process of all food you transport. The information that we propose as necessary to trace the transportation process includes: (1) The name, address, and phone number of the person who had the food immediately before you (the transporter's immediate previous source), and the date you received it from that person; (2) the name, address, and phone number of the person who had the food immediately after you (the transporter's immediate subsequent recipient), and the date you delivered it to that person; (3) the type of food transported; (4) the lot number or other identifier of the food if available; (5) the quantity; and (6) identification of each and every mode of transportation used (e.g., company truck, private carrier, rail, air, etc.) from the time you first received the food until the time you delivered it.

*This proposal has been implemented in December 2004 with the regulation "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002". An extensive fact sheet can be found on: [www.cfsan.fda.gov/~dms/fsbtac23.html](http://www.cfsan.fda.gov/~dms/fsbtac23.html)*

**ANNEX 4 - REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC**

[EXCERPT]

**Article 3 Definitions**

3. 'Traceability' means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains.

**Article 4 A. TRACEABILITY**

1. At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

- (a) that it contains or consists of GMOs;
- (b) the unique identifier(s) assigned to those GMOs in accordance with Article 8.

2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to the operators receiving the products.

3. In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

4. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of information specified in paragraphs (1), (2) and (3) and the identification, for a period of five years from each transaction, of the operator by whom and the operator to whom the products referred to in paragraph 1 have been made available.

**Article 5 Traceability requirements for products for food and feed produced from GMOs**

1. When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

- (a) an indication of each of the food ingredients which is produced from GMOs;
- (b) an indication of each of the feed materials or additives which is produced from GMOs;
- (c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

2. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of the information specified in paragraph 1 and the identification, for a period of five years from each transaction, of the operator by whom and to whom the products referred to in paragraph 1 have been made available.

## ANNEX 5 - Description of five food safety standards benchmarked against CIES Global Food Safety Initiative Guidance Document

### **The BRC Global; Food Standard:**

#### 2.13 Traceability

The Company shall have a system with the ability to trace materials from raw material source to finished product.

2.13.1 Where rework or any reworking operation is performed, traceability shall be maintained.

2.13.2 The system shall be regularly tested to ensure traceability can be determined from raw material source to finished product.

### **EFSIS**

23.1 The Company shall have a system with the ability to trace materials (including packaging) from raw material source to finished product and from finished product back to raw material source.

23.1.1 Where rework or any reworking operation is performed, traceability shall be maintained.

23.1.2 The system shall be regularly tested to ensure traceability can be determined from raw material source to finished product and from finished product back to raw material source.

23.1.3 The level of traceability shall be such as to enable the recall procedure to operate effectively and complaints to be traced to a defined production run.

**International Food Standard** (This is a so-called KO criterion. Non-compliance automatically leads to an inability to be certified)

#### 4.19 Traceability

The Organisation shall adequately identify all raw materials and be able to trace work in progress and finished product at all stages during manufacture, storage, despatch and, where appropriate, distribution to the customer.

Foundation level:

4.19.1 The organisation shall demonstrate the ability to trace each product backward to processing plant and raw material organisations, and forwards to delivery point.

4.19.2 Where rework or any reworking operation is performed, traceability shall be maintained.

Higher level:

4.19.3 The organisation shall maintain records of the product during the relevant stages of production.

4.19.4 From all relevant raw materials samples shall be available and kept stored till the end of the expiry date of the end product.

4.19.5 Samples from the produced charges shall be stored appropriate and kept until the expiry date of the end product.

### **Criteria for Assessment of an Operational HACCP System (Dutch HACCP)**

2.1 Product Characteristics. The traceability of the raw materials up to and including the final supply shall be described.

The documentation and data shall be systematically arranged, easily retrievable and shall consist of at least: (...)

- registration of the use of raw material up to and including the point of (final) supply, in order to ensure traceability of products.

### **SQF 2000 Code**

#### 4.6.2 Product Trace

Finished product shall be traceable to the customer. The product trace system shall be documented in a procedure with responsibilities defined. It shall provide for the identification of raw materials and other inputs that may have an impact on finished product quality and safety. Raw materials and other inputs shall be traceable through the process to the finished product. Records of product dispatch and destination shall be maintained.

ANNEX 6 - REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

[EXCERPT]

*Article 17*

**Traceability**

1. The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
2. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.
3. The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.