AN INTRODUCTION TO TRACEABILITY: PROCESSED FOODS

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Prepared by the Egyptian Traceability Center for Agro-Industrial Exports (Etrace)

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Disclaimer

While every possible effort has been made to ensure that the information in this manual is correct, Etrace disclaims all liability for any errors or omissions in this document. We do not claim that companies, which implement the best practices described here, will *de facto* achieve compliance with the Council Regulation (EC) No. 178/2002 concerning General Food Law. Companies or organisations using this document are advised to seek professional advice addressing their possible specific requirements.

1 About Etrace

The Egyptian Traceability Center for Agro-Industrial Exports (Etrace) exists to increase the competitiveness, exports, product quality & safety of Egyptian food products through the application of traceability. Toward this end, the Egyptian Ministry of Foreign Trade and Industry in cooperation with the United Nations Industrial Development Organization (UNIDO), began in Egypt the first and only multi-faceted project in the Middle East that assists fresh produce exporters, NGO's, farm associations and public institutions in their efforts to ensure high quality, safety and traceability of fresh produce. This assistance extends also to complying with international regulations on food safety including the so called "General Food Law," EC No. 178/2002.

Since July of 2004, Etrace has provided technical and financial assistance to farms, exporters, dealers, traders and other operators in the fresh produce industry in their efforts to comply with the requirements set by the importing countries.

Beginning in 2007, UNIDO/Etrace has begun an effort to extend the principles of traceability to the agro-industrial sector. This sector manufactures products that consist of fractionated or otherwise modified direct agricultural inputs. These products may be formulated from many ingredients, the components of which are frequently themselves formulated and processed from many ingredients. They may or may not contain raw agricultural inputs. Agro-industrial products are more commonly known as processed foods.

2 Introduction

Most processed foods require more complex operations than fresh produce, and implementing traceability along with other quality initiatives will necessarily be more complex. One way of looking at this increased complexity is to consider the apple. A fresh-market apple may go through many processes before it appears in the market. However, it is still an apple, not fundamentally different from when it was on the tree. It represents the ultimate in batch systems. A good traceability system could determine which tree it came from and when. However, if an apple goes into a process for the manufacture of a shelf-stable cocktail juice, that apple has almost disappeared. The apple has taken on a new form. It is a small and invisible component of a product with many ingredients and that product most likely contains juice from apples from different trees, farms and even regions & countries.

Traceability may be viewed as a burden to many Egyptian processors. However, traceability for agro-industrial products in Egypt is necessary to increase the exports of this sector and to improve the competitiveness of Egyptian products. Additionally, traceability is part of bigger systems, such as ISO 9001, or HACCP, and more recently, is also a mandate in ISO 22000 and described in ISO22005. Any manufacturer claiming compliance with such systems must have traceability in place.

As such, most Egyptian processors believe they have adequate traceability systems in place. Many do, but many have systems that are only partially effective, hence this first issue of this manual, “An Introduction to Traceability: Processed Foods.”

2.1 Scope of this Manual

This manual aims at a method to establish compliance in traceability to both the requirements and the suggestions of E.U. regulations. This aim is accomplished by presenting the fundamentals of traceability and how to apply these fundamentals to processed foods. Regulations and current scientific & trade literature on traceability generally do not specify sector-specific methods of implementing traceability since it is usually not their objective. This manual presents not only the theory of traceability but also five industry-specific models for traceability systems. After studying this manual, the reader should be able to grasp the meaning of traceability as it applies to processed foods, to have a working knowledge of E.U. regulations on the subject, and to be familiar with working models for traceability systems which may be applied, perhaps in amended forms, to his own food processing operation. Finally, the reader should be able to discern the relationship of this manual to another international standard, as sections of this manual are cross-referenced with relevant entries from the standard on traceability: ISO22005, First Edition, 2007.

2.2 Target Beneficiaries

This manual is intended for anyone with a technical or business interest in processed foods. This group includes processors, suppliers of raw agricultural produce, ingredients & packaging materials, as well as anyone associated with the distribution, storage, transportation and export of processed foods.

2.3 Objectives

This manual is intended to accomplish the following objectives:

- To acquaint the reader with the fundamental concepts of traceability and their implications to the processed food business

- To explain E.U. regulations for traceability
- To provide a model of what data are necessary for traceability and how these data should be linked through the supply chain
- To demonstrate how actual data forms might be used to establish traceability for several sub-sectors of processed foods.

2.4 Organization

The technical parts of this manual begin with a glossary of terms and a descriptive definition of what is traceability. Following is a summary of E.U. legislation on traceability, a discussion of the benefits of traceability, and then a description of the technological needs of traceability systems. Following is a description of how data should be linked through the supply chain and a model of what data should be kept and what data should be shared with your trading partners. Next is a description of internal traceability and its role in processed foods. Complementing these descriptions are several models, complete with forms, for traceability systems for several sub-sectors of the processed food industry. Finally, this manual introduces techniques of beginning and assessing your traceability system, including a summary of techniques used in management control of the traceability system for effective and sustainable traceability, an outline of procedures for verification of the traceability system and a method of verification of the traceability system .

2.5 How to Use this Manual

This manual is intended to be self-instructive, with trainer-guides available at Etrace.

- Decide what products and ingredients you want to include in the traceability system.
- Draw a flowchart of your process, identifying each process step and the documents, records or sheets currently used in each step.
- Work through the exercises in this manual for your sub-sector, keeping in mind their applicability to your own process.
- Once you have done the exercises, compare the worksheets you have completed with your company's existing sheets. Make a list of any discrepancies and justify them.
- Use the audit checklist (see Verification of the Traceability System) both now and after any changes in your traceability system to see how well the system is working, and if it is improving. The check list can also identify areas for improvement.

Other than the links given in the footnotes and in Suggestions for Further Reading, there are no specific electronic exercises given in this manual.

3 Glossary of Terms

Breadth: The amount of information that a traceability system demands.

CIP: Cleaning in-place

Common carrier: The entity, usually a third party, responsible for delivery of finished product.

Depth: How far back or forward a traceability system traces or tracks (such as one up/one down)

GMP: Good manufacturing practice

HACCP: Hazard analysis and critical control point

Ingredient: Any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

Input shipment identifier: A document created by a party receiving a shipment. It describes and uniquely identifies the shipment. It may include information found on the purchase order, bill of lading or invoice. It does include the date of shipment from the supplier and the date of its receipt. It also links the sender's output lot number with the receiver's input lot number. A single Input shipment identifier can include more than a single lot number.

Intermediate processor: A processor that manufactures a packaged food (such as mango pulp, bulk olive oil or tomato paste) that is used as an ingredient by another processor.

Internal traceability: The ability to track what happens to raw materials, ingredients, primary packages and finished products inside the processor's operation.

ISO: International Organization for Standardization

Label: A written statement appearing on each container of processed food. Typically, a label contains, at a minimum, the product name, form & style, its net contents and the identity of the manufacturer. The information contained on a label does not change on a regular basis.

Lot: A collection of materials (ingredients, raw materials or primary packaging materials) produced under conditions as nearly uniform as possible, designated by a common code for identification.

Lot identifier: A code which uniquely identifies a lot. Terms such as batch number, batch code and lot number may all be synonymous with lot identifier. A production code and information from the label may also be considered to be a lot identifier.

Output shipment identifier: A document created by a party sending a shipment. It describes and uniquely identifies the shipment. It may include information found on the purchase order, bill of lading or invoice. It does include the date of shipment and may include the sender’s output lot identifier or production code. A single output shipment identifier can include more than a single production code.

One up/one down: A description of one level of depth of a traceability system. In a one up/one down system, each participant in the food supply chain is responsible for maintaining records about the products they receive, their use (i.e. the link between inputs and outputs) and to whom they were shipped, or sold. Figure 1 is a graphic representation of the basic components of a one up/one down system including internal traceability.

Precision: The degree of assurance that a traceability system can pinpoint the movements of a particular ingredient to a single lot of finished product, or conversely, can pinpoint a single lot of raw materials, ingredients or primary packaging materials that make up a finished product

Primary producer: A farmer or grower.

Processor: A member of the supply chain that typically receives inputs from primary producers, suppliers of ingredients & packaging materials and/or common carriers and transforms these inputs into some other form. This other form is typically packaged in a way that would preclude the addition of more inputs or processing without opening it. A supply chain may have more than one processor.

Production code: The identification printed on each container of processed food at the time of its manufacture. The production code uniquely identifies when the product was packaged (the year, day and time period). It also uniquely identifies, by examination of the factory's records, which factory manufactured the product[1] and what production codes of raw agricultural commodities, ingredients and packaging materials went into the product. The production code should be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Production codes should not extend over a period of more than one personnel shift. Codes should be permanently visible to the naked eye. When the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, if the label is securely affixed to the product container.

Record keeping step: A point in a process where records are taken and new batch codes assigned for the purpose of traceability. Data taken could include input lot numbers, times and other data to link the inputs to the outputs.

Retail/store/foodservice operator: The entity that has the relationship with the ultimate consumer. The foodservice operator may be an individual restaurant or an institution, such as a school, prison, hospital or hotel chain.

Ultimate processor: The last processor in a value chain to add ingredients or otherwise process a product.

Wholesaler/distributor: A member of the supply chain that provides finished product to the retailer. The retailer then distributes to each individual store.

[1] This information is needed in the production code only in the event that multiple production sites exist for the same product for the same company. Otherwise the product's label, with the identity and address of the company, will take care of this item. It follows then that the production code can include information that is presented on the label.

4 What is Traceability?

The objective of this section is to define traceability, its components, its characteristics, its basic elements, its scope and its rationale. This section is short but rather theoretical. Keep in mind that traceability is a simple concept, one that most people are likely to understand to some degree.

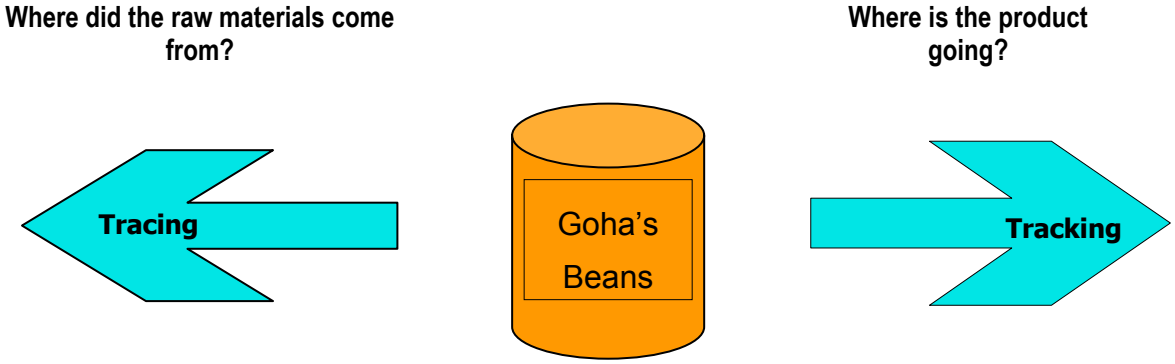
According to European Council regulation (EC) 178/220, "traceability" means:

> …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

In commercial practice, traceability includes details of what has happened to the food (its processing history) as well as the source of the raw materials and the recipient of the finished product.

Traceability has two components:

- Tracking: The ability to follow the path of a specified unit and/or lot of trade items downstream through the supply chain as it moves between trading partners. Units are tracked routinely for availability, inventory management and logistical purposes.
- Tracing: The ability to identify the origin of a particular unit located within the supply chain by reference to records held upstream in the supply chain. Units are traced for purposes such as recall and complaints.[2]



Internal Traceability

Traceability systems should be able to provide the following:

[2] Canadian Food Traceability Data Standard, version 2.0 (2006); Note: GS1 Canada is the industry custodian of the Can-Trace standard.

http://www.can-trace.org/portals/0/docs/CFTDS%20version%202.0%20FINAL.pdf

- The identity of units or batches of all raw materials, ingredients and primary packaging materials supplied
- Information on how, when and where they were incorporated into finished products[3]
- The identity of units or batches of all products manufactured and to whom these are supplied
- A documentation and record keeping system linking these data.

Tracking and tracing a processed food requires that the finished product bear a unique **Lot identifier** (**Production code** & **Label)** to define (after examination of the **Ultimate processor**'s records) the first three characteristics, above. This unique identifier does not change once the product is packed into individual coded containers. As the product moves down the value chain from the final processor it is only the **Production code** and **Label** that begins to identify the elements of the traceability system.

In a one up/one down model of traceability, no single member of the supply chain holds all the information. However, the onus is on the ultimate processor since:

- It is usually the one member of the value chain that brings most of the inputs together and has the most issues with internal traceability.
- When the product leaves the premises of the ultimate processor, the traceability game is essentially over, since
    - The production code and label should contain all the information needed to start to determine inputs and how they were processed,
    - The value chain members downstream from the ultimate processor will have no need for any product details except what is on the production code and the label and,
    - Once the ultimate processor packs the product into an individual container, there are no additional inputs or further processing.[4]

Still, each member gathers (or collects) and keeps information about production inputs from its suppliers and keeps and shares information regarding production outputs with the next member down the chain.

Collecting information from suppliers and sharing information with the next trading partner ensures a mechanism for linking all the information throughout the value chain. Failure to collect, keep or share data by a single member of the chain will result in the loss of traceability.[5]

Traceability systems are thought to have three dimensions: breadth, depth and precision. Breadth is the amount of information the traceability system demands. The individual processors must decide which information is of value since all the information is unattainable

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[3] Since traceability systems should operate in "real time," they should be able to reveal the history of any given component in a process at any point in time. Depending on the extent of the traceability system, it can not only reveal which lots of product were manufactured from which lots of raw materials, but it can also reveal the source and causes of out-of-specification product.

[4] The exceptions are products manufactured for industrial uses by **Intermediate processors**, such as tomato paste in bulk.

[5] For a discussion on how to handle dealers, see Section 10.1, below.

and much of it is not actionable. The depth of a traceability system is how far backward or forward the system traces or tracks (such as one up/one down). Although the one up/one down model complies with European Council regulation (EC) 178/220, individual customers may demand more. Precision is the degree of assurance that a traceability system can pinpoint the movements of a particular ingredient to a single lot of finished product. A traceability system with very high precision could likely trace an apple, in the trade, to its tree. A less precise system for apple juice may trace apples only to one or more of several growing areas. Conversely, in a less precise system, a single production code of apples may be tracked to one (or more) of several production codes of finished product. Reduced precision in traceability results in:

- Single lot numbers of raw materials ending up in more than a single production code of finished product (This may be thought of as dilution of a single production code of raw materials).
- More finished product codes containing more lot numbers of the same ingredient
- Uncertainty about the extent of the dilution of individual lot numbers of raw materials into more than a single production code of finished product.
    - This uncertainty leads to uncertainty about whether or not a small quantity of a given lot number of raw material is contained in a given lot number of finished product.[6]

The characteristics of a traceability system may be driven by characteristics of the raw materials and products. For example, raw materials and products that are more susceptible to pathogens, prone to chemical contamination or intended for at-risk consumers such as children may have traceability systems that are broader, deeper and/or more precise. Also, a company that makes several products may wish to give priority in traceability to those products with the greatest sales volume.

Ultimately, the complexity and even the very existence of a traceability system will depend on a cost/benefit analysis on the basis of real and perceived advantages, outlined below in Section 6.0 What Are the Benefits of Traceability?

Exercise: It may be instructional to read the European Council regulation (EC) 178/220 for yourself before proceeding to the next section:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:HTML

See that the requirement on each individual in the supply chain is one up/one down and how this basic requirement may be in conflict with its own definition of traceability.

Exercise: Review again the example given above for illustrating the precision of a traceability system for an apple and a system for apple juice. The system for the apple is more precise. How could it be possible that the systems for both could have the same breadth?

[6] We will see later that traceability systems for most processed foods are necessarily less precise than those for fresh produce. Traceability procedures are not changed by this limitation. The implications of the uncertainty are felt mostly during a recall where lots known to contain problems are removed from the trade. Uncertainty forces the processor to recall products not known, but suspected, to have problems, typically the production codes immediately before and after a problematic lot.

Summary

- Traceability includes details of the source(s) of raw materials, and the recipient(s) of finished products as well as what has happened to the product in your factory.
- Traceability has two components: tracking and tracing.
- The characteristics of traceability systems are:
  - Identification of all raw materials
  - Information on what happened to them in your factory
  - Identification of all finished products and to whom these are sent
  - A record keeping system linking the above data to each other
- In a one up/one down model of traceability, no single member of the supply chain holds all the information
- The information on the label and the production code, combined with information from the factory should contain all relevant traceability data to the point of release by the ultimate processor.
- Traceability systems for most processed foods are necessarily less precise than those for fresh produce.
- Reduced precision can cause uncertainty about the identity of problematic product. This uncertainty can expand and increase the cost of a recall.

5 E.U. Legislation on Traceability

This section will summarize two E.U. regulations, the "General Food Law," and a regulation intended to extend this law to food-contact surfaces such as packaging materials.

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.

This regulation is referred to as the "General Food Law" and went into force on 1-January-2005. The requirements apply to all food businesses.

"Food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. It includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. "Food" shall not include:

- feed;
- live animals unless they are prepared for placing on the market for human consumption;
- plants prior to harvesting;
- medicinal products within the meaning of Council Directives 65/65/EEC(21) and 92/73/EEC(22);
- cosmetics within the meaning of Council Directive 76/768/EEC(23);
- tobacco and tobacco products within the meaning of Council Directive 89/622/EEC(24);
- narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- residues and contaminants.

Food businesses must record:

- The name and address of suppliers of food to the food business
  - The details of the products supplied by them[7]
- The name and address of business customers supplied with food
  - The details of products supplied to them
- The dates of transactions/delivery

Additional information recommended to be kept:

- Volume or quantity of foods supplied

[7]The term "supplied" should not be interpreted as the mere physical delivery of ingredients (e.g. truck driver who is an employer for a certain operator). Identifying only the name of the person physically delivering the ingredients would not be sufficient to maintain traceability along the food chain.

- Batch number
- More detailed descriptors of the product
- Internal traceability information.

This traceability information must be stored and made available to an official agency on demand.

The details of the ultimate consumer do not need to be recorded.

The requirements are of a general nature and are applicable to all food business operators in the food chain.

Other more detailed traceability requirements exist and are set out in regulations specific to some products or sectors (e.g. beef labeling requirements, GMO Regulations) which may also be applicable.

Traceability should be established for food and *"any other substance intended to be, or expected to be, incorporated into a food,"* including:

> All ingredients used in the preparation, manufacture or treatment of a food, including grain, gases, water or any other substance to be incorporated into a final product
>
> Veterinary drugs, plant protection products and fertilizers are not included in the scope, though other controls may apply under separate legislation relating to the traceability of such compounds.

There are no exceptions from the requirements for small businesses. The information required to comply with the regulation is minimal and all operators should be able to comply.

Generally, records should be kept for the period of the product's shelf-life plus six months. For products with no specified durability date (such as fresh fruit and vegetables), records should be kept for a period of six months after date of manufacture or delivery. The format for the records will be decided by the food business operator, with consideration to ease of retrieval.

The traceability provisions of the General Food Law do not have an extra-territorial effect outside the EU. This requirement only covers all stages of production, processing and distribution in the EU from the importer up to the retail level. Article 11 of Regulation 178/2002 refers to imported products, but this should not be construed as extending the traceability requirement to food/feed business operators in third countries. It requires that food/feed imported into the Community complies with the relevant requirements of EU food/feed law.

It is common practice among some EU food business operators to request trading partners to meet the traceability requirements which go beyond the "one step back-one step forward" principle. It should be noted that such requests are part of food business' contractual arrangements and not of requirements established by the regulation.

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…extends traceability requirements to packaging materials.

As its title suggests, this regulation extends the General Food Law to "articles intended to come into contact with food," which in this context means packaging materials.

Exercise: Review Regulation (EC) No 1935/2004:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_338/l_33820041113en00040017.pdf

Come to your own conclusion if this regulation can be extended to food processing equipment (that contacts food) as well as to packaging materials.

Exercise: The E.U. regulations specify that food businesses must record "The details of the products supplied." What do they mean by "details"?

Summary

E.U. regulations require that food businesses record:

- The name and address of suppliers of raw materials, including packaging
- The details of the products supplied
- The name and address of customers supplied with food products
- The details of products supplied to them
- The dates of transactions/delivery

6 What Are the Benefits of Traceability?

The purpose of this brief discussion is to outline some of the obvious and less than obvious benefits (or possible objectives) of traceability. It also aims to explain the relationship of traceability to food safety.

Traceability is a tool to help achieve broader management objectives but management must define these objectives. What follows are some examples of such objectives

The most important objective for traceability might be to meet quality, customer, regulatory and industry standards. Failure to meet these standards can result in lower prices for your products or even the loss of some business altogether.

The second most important objective might be to limit the scope, and therefore the cost, of a product recall by determining the origins of products. It can also help trace and assign responsibility for defective products or raw materials.

Traceability can have other roles to fulfill depending on the company's objectives for a traceability system and its willingness to invest in it:

- To help support product claims and provide information to customers, for example to authenticate organic, non-GMO or country-of-origin claims
- To identify and implement corrective actions to regain control of a problematic process
- To provide information for the disposition of any non-conforming product, including recall if necessary.
- To serve as a tool for process control in areas such as inventory control and quality control.
- To provide a mechanism for providing product information quickly, to regulators or customers.

Traceability assures that authorities have the ability to trace all the steps taken during the preparation and distribution of food products as well as the sources of all the raw agricultural commodities, ingredients and primary packaging materials. This ability is particularly useful in cases that might present health emergencies and resulting removal of certain product from trade. Traceability, therefore, assists risk management systems in that it ensures transparency, improves supply-chain management and allows smooth and cost-effective exchanges of information.

The extent of a traceability system will be a balance between costs and benefits accrued. Any traceability system and each component of that system must have a measurable economic benefit. Otherwise it will serve no purpose.

It is sometimes tempting to suggest that traceability assures food safety. Traceability can be a tool for food safety but only that. If Quality Control and HACCP systems are not adequately implemented and linked to inputs and outputs, a traceability system becomes little more than an after-the-fact trail of paper useful only in assigning blame if a problem arises. However, if hazards[8] are monitored, recorded, controlled and LINKED to inputs and finished products, then the traceability system can become a powerful tool for food safety.

[8] Common major hazards include aflatoxin, pesticide residues, heavy metals or pathogens. Other possible hazards and concerns that could be linked to the traceability system include allergens and GMO inputs.

Exercises:

1. *Are there any ways, not mentioned above, that a traceability system might help your company?*
2. *How do you view the relationship between traceability and food safety?*
3. *The summary (below) lists seven benefits of traceability. Which ones are related to food safety, either directly or indirectly?*

Summary

Traceability, can:

- Help meet regulatory and industry standards
- Help limit the scope of a product recall
- Help support product claims
- Identify and implement corrective actions
- Provide information for the disposition of any non-conforming product
- Serve as a tool for process control
- Provide a mechanism for providing product information quickly

7 Technology Necessary for Traceability

The tools that may be applied to traceability systems can be simple or very complex. Increasing complexity brings more options. The purpose of this brief section is to demonstrate how simple and low-technology traceability can be and to point out some of the benefits of more complex technology-based infrastructure.

All traceability systems start with hand-written records. Paper-based traceability systems are still the easiest and cheapest of all the systems. They can be based on existing management and documentation systems and are flexible in terms of the many production systems to which they can be applied. Typically, traceability systems evolve first from purely paper systems, then to converting the data to electronic forms after-the-fact, then to entering data directly, and finally to a more sophisticated software/hardware system designed especially for traceability.

The adoption of various technology-based approaches to traceability can increase the following:

- Ease of data recording and retrieval, thus minimizing errors and maximizing efficiency
- Speed at which data may be collated and processed
- Number of uses for the information
- Discrimination (or precision) in product traceability, thus reducing the company's financial exposure in the event of a recall

Intangible benefits also accrue from a more technologically-based traceability system such as customer confidence, goodwill and staff morale.

The establishment of traceability can be successfully achieved using a paper-based system and these systems form the basis of many traceability systems in food business operations today. However a technology approach is increasingly being adopted to improve the efficiency and management of traceability systems. This approach, however, must be set against the capital cost of equipment and software. Although the advantages of a technology approach to traceability are minor when used in a simple production process, the benefits of using technology-based systems become more apparent where the production system becomes larger and more complex.

Exercise: Can a paper-based traceability system work at your company? At what point (from the standpoint of either volume, diversity of product line or customer requirements) do you feel that operating a paper system will no longer be desirable?

Summary

Any traceability system can operate with a clipboard, a pencil and some paper. Higher technology approaches can yield benefits but they are not necessary to achieve the fundamentals of traceability.

8 Linkage of Information

Since traceability requires some knowledge of your suppliers and your customers, they, likewise, must have some knowledge of you. This exchange of data from one step to another, or in this case, from supplier to customer and back, is called "linkage."

The purpose of this section is to illustrate the basic components of a traceability system, to define the concepts of Collect Data, Keep Data and Share Data.

As you work through these concepts and models, remember that there is no single "correct" method for establishing traceability. Any method is correct as long as the required information exists and is available. Exactly what information is required is a policy matter between your company, its customers and the regulators.

8.1 Basic Concepts: Collect, Keep & Share Data

Figure 1 shows the basic components of a traceability system. It shows (generally) information being exchanged by a processor and its immediate supplier (one step back) and by the same processor and its immediate customer (one step forward). To ensure the continuity of the flow of traceability information, each trading partner must pass on certain information about a shipment to the next partner in the production chain.

To ensure the continuity of the flow of traceability information, each trading partner must pass on information about the identified lot or product group to the next partner in the production chain. The sets of information necessary for traceability are called Collect Data, Keep Data and Share Data:

> Collect Data: The data that the participants in the supply chain are required to obtain from the relevant member of the supply chain.
>
> Keep Data: The information that each participant in the supply chain is required to record and maintain in their business records.
>
> Share Data: The information that each participant in the supply chain is required to provide to the relevant member of the supply chain.[9]

The question remains: "Which data should be collected, kept and shared?" The answer depends on what is expected from the traceability system. If the objective is simply to comply with the requirements (and not the suggestions) of E.U. Legislation, then the information an individual supplier (such as an ingredient supplier) would be obliged to share with its customer (say a processor) would be minimal:

- Their names and addresses
- Some details (unspecified) of the products supplied by them
- The dates of transactions/delivery

Likewise, the processor would be obliged to share similar information about itself to the ingredient supplier and to its immediate customers. More rigorous traceability requirements will demand that more information be collected, kept and shared.

[9] Can-Trace, see footnote 2

8.2 Methods of Linking Data

It should be emphasized again that there is no single and correct method for traceability except for those that may exist to satisfy some regulation or standard.[10] Therefore, there is no single and correct means of linking data for traceability. One method of linking data in a traceability system is shown in the Canadian Food Traceability Data Standard, version 2.0 (2006).[11] This standard is voluntary and suggests a model of what data should be collected, kept and shared for different industries.

A somewhat different model, for the processed food industry, is suggested in Figures 2 through 5 which covers data to be collected, kept and shared by growers, ingredient suppliers, processors, distributors & exporters, retail establishments & foodservice operators and common carriers. This model demonstrates one method by which data is to be collected, kept and shared in order to link data and thereby establish traceability. It should be remembered that this too is a model only and is shown here for illustrative purposes only. This model is not mandatory.

For both models, it is imperative to record the links between the received and the finished products and to record the links between the processed and the shipped products. Within a company, the control of all these links and accurate record keeping make it possible to connect what has been received with what has been produced and/or shipped.

Exercises:

1. *Refer to Figure 3, Data Requirements for Ingredient Suppliers, Processors, Distributors and Exporters, and notice the symmetry of the data collected from the suppliers with the data shared with the customers. Why does this symmetry exist?*
2. *Same question for Figure 5, Data Requirements for Common Carriers.*
3. *Why does this symmetry not exist for growers, Figure 3, or for retail establishments, Figure 4?*

[10] Two such example are Regulation (EC) No 1830/2003 concerning the traceability and labeling of genetically modified organisms and (EC) No 1760/2000 establishing a system for the identification and registration of bovine animals and regarding the labeling of beef and beef products.

[11] Can-Trace, see footnote 2

Figure 1: The Basic Components of a Traceability System

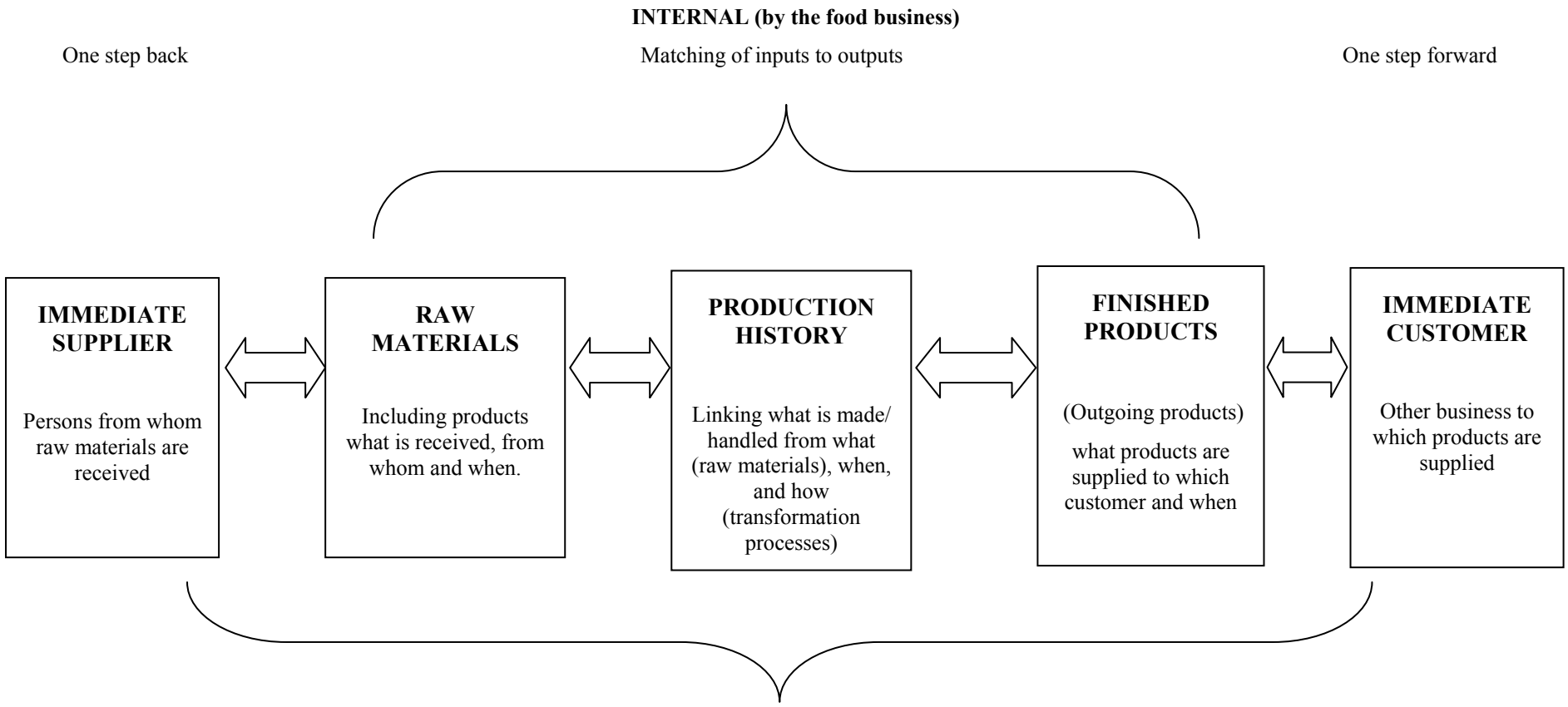

Figure 2: Data Requirements for Growers

Data to Collect (from Your Trading Partners)	Data to Keep (Record and Maintain)[12]	Data to Share (with Your Trading Partners)
From Your Immediate Suppliers None[13] **From Your Immediate Customers** Their Identity Their Shipping Address	Product Description Output Lot Number[14] Quantity (and Units of Measure) of Each Lot Output Shipment Identifier	**With Your Immediate Suppliers** None **With Your Immediate Customers** Your Identity and Address Product Description Quantity (and Units of Measure) of Each Lot Output Shipment Identifier[15]

[12] The word "Keep" is somewhat misleading here since all data (from your trading partners and the data you take) should be "kept," that is, maintained at least throughout the shelf-life of the product.

[13] The primary producer, such as a farmer, has no previous trading partners in the same sense that a processor might have previous trading partners. However, primary producers also have raw materials in the form of seeds, fertilizers, pesticides and other chemicals which bear on traceability but are, for now, beyond the scope of this document. Until on-farm safety and quality programs are implemented, this document will rely on the identity of the farmer and the pesticide residue analysis (as part of a Quality Control program).

[14] The Output Lot Number should uniquely represent the batch and should also contain the following information: grower code, plot number and harvest date.

[15] Remember that in this model, the Shipment Identifiers (input & output) contain both the date of shipment and the input or output lot number.

Figure 3: Data Requirements for Ingredient Suppliers, Processors, Distributors & Exporters

Data to Collect (from Your Trading Partners)	Data to Keep (Record and Maintain)[16]	Data to Share (with Your Trading Partners)
From Your Immediate Suppliers Their Identity and Address Product Description Output Lot Number[17] Quantity (and Units of Measure) of Each Lot Output Shipment Identifier **From Your Immediate Customers** Their Identity Their Shipping Address	Identity and Address of Supplier Product Description Input Lot Number Input Shipment Identifier Output Lot Number Quantity (and Units of Measure) of Each Lot[18] Output Shipment Identifier	**With Your Immediate Suppliers** Your Identity Your Shipping Address **With Your Immediate Customers** Your Identity and Address Product Description Output Lot Number (Production Code) Quantity (and Units of Measure) of Each Lot Output Shipment Identifier

[16] The word "Keep" is somewhat misleading here since all data (from your trading partners and the data you take) should be "kept," that is, maintained at least throughout the shelf-life of the product.

[17] Although the Output Lot Number should be included in the Output Shipping Identifier, you suppliers may not adhere to this practice. Therefore, Output Lot Number is kept as a separate item here.

[18] Input and output

Figure 4: Data Requirements for Retailers & Foodservice Operators

Data to Collect (from Your Trading Partners)	Data to Keep (Record and Maintain)[19]	Data to Share (with Your Trading Partners)
From Your Immediate Suppliers Their Identity and Address Product Description Output Lot Number[20] Quantity (and Units of Measure) of Each Lot Output Shipment Identifier **From Your Immediate Customers** None	Identity and Address of Supplier Product Description Input Lot Number Input Shipment Identifier Output Lot Number Ship Date Quantity (and Units of Measure) of Each Lot[21] Output Shipment Identifier	**With Your Immediate Suppliers** Your Identity Your Shipping Address **With Your Immediate Customers** None

[19] The word "Keep" is somewhat misleading here since all data (from your trading partners and the data you take) should be "kept," that is, maintained at least throughout the shelf-life of the product.

[20] Although the Output Lot Number should be included in the Output Shipping Identifier, you suppliers may not adhere to this practice. Therefore, Output Lot Number is kept as a separate item here.

[21] Input and output

Figure 5: Data Requirements for Common Carrier

Data to Collect (from Your Trading Partners)	Data to Keep (Record and Maintain)[22]	Data to Share (with Your Trading Partners)
From Previous Trading Partner Shipment Identifier Product Description Quantity (and Units of Measure) of Each Lot Ship From Location Identifier Ship to Location Identifier	Shipment Identifier Product Description Quantity (and Units of Measure) of Each Lot Ship From Location Identifier Ship to Location Identifier	**With Your Previous Trading Partner** Ship Date Receive Date **With Your Next Trading Partner** Shipment Identifier Product Description Quantity (and Units of Measure) of Each Lot Ship From Location Identifier Ship to Location Identifier[23]

[22] The word "Keep" is somewhat misleading here since all data (from your trading partners and the data you take) should be "kept," that is, maintained at least throughout the shelf-life of the product.

[23] Note that in the case of a third party transporter, the data to collect, keep and share are all the same. This is because no transformation of the product is supposed to occur in transport.

9 Internal Traceability

The purpose of this section is to introduce the concept of "internal traceability," to describe how a single lot of an input can become blended with other lots of the same input in the process, how to maintain internal traceability in the face of this blending, and to present a method to determine which steps in the process require record keeping and new batch codes for traceability.

"Internal traceability" is the ability to track what happens to raw materials, ingredients, primary packages and finished products inside the processor's operation. Internal traceability matches inputs to outputs. This means that when 1000 kg raw material (or 10,000 primary packages) goes into a process, the records must be able to account for[24] the disposition of all this material. In the case of processed foods, this "accounting for" can be especially difficult since they involve operations which seemed designed to obscure their traceability. The biggest difference between traceability for fresh produce and processed foods is that internal traceability is more complex for processed foods:

- Processed products usually have more than one ingredient
- The processes tend to be more complex, and
- During manufacture, ingredients from different lot numbers are frequently blended into finished products with the same code.

Additional complexity from more ingredients and more complex processes should be self-explanatory. What may not be so obvious are the source and the necessity of blended lot numbers.

9.1 Blending of Product Codes

Most food processing operations result in the blending of different production codes of agricultural commodities and ingredients.

Some of this blending results from the nature of a **continuous** process where there is no stoppage between different production codes of raw materials. For example, if an olive oil process is receiving and processing olives continuously and the lot number of the incoming olives changes, the process is not stopped. Some mixing of different lots of olives may occur, especially during crushing and centrifugation. The end result is that some fraction of the finished product will contain two lot numbers of incoming fruit. Another example of **continuous** blending is as simple as a casing operation. After filling the last whole case in a production code, there will usually be a few primary containers of the same lot code that can not fill a case. These containers are not thrown away and a case is not partially filled. The case is filled to its capacity with these "left over" containers as well as some containers from the next production code. This case will contain two production codes. The same analysis may be applied to palletizing. **Continuous** mixing usually results in the blending of two or three lot codes only.

Blending may also be **purposeful**, such as the blending of olive oil while in storage to achieve certain finished product specifications.

Blending may also result from **idiosyncratic** design features of a particular processing line. Any time a process has, in-line, a tank (or any vessel with liquid capacity) into

[24] This not only means in the accounting sense, but also accounting for which materials ended up in what production codes.

which a stream is fed continuously, and out of which a stream is taken continuously, blending of many product codes will usually occur at that point. One example is recycling product away from the filler to an earlier point (or tank) in the process and using that same tank to feed the filler continuously. Another example is the use of surge capacity (such as an aseptic surge tank) to keep a continuous process running continuously when it is fed with batch-wise inputs. Both examples are likely to cause mixing of many product codes.[25]

Idiosyncratic blending can be especially troubling for traceability systems since it might affect a large amount of production and many lot codes. For example it could affect all the production of a continuous evaporator from one CIP to the next.

Idiosyncratic blending usually requires a fluid medium in a continuous process. Most batch and dry processes are free of **idiosyncratic** blending.

Any blending will necessarily reduce the precision of the traceability system.

All blending should be considered as transformations that will require a record keeping step. Keeping records of **purposeful** blending is easy enough since it results from conscious management decisions. Record keeping for **continuous** blending is only somewhat more difficult in that the blending takes place with the knowledge of the operators even though no decision was required for it to happen. **Continuous** blending requires only that more than a single lot number of a raw material be linked to a single production code of finished product. In many cases, **idiosyncratic** blending will present a record keeping problem. It takes place both without any decision by management and frequently without the explicit knowledge of the operator. Also, **idiosyncratic** blending can cause the mixing of many lot numbers.

In spite of its challenges, **idiosyncratic** blending can be handled in a way consistent with traceability through record keeping. However, it is **idiosyncratic** blending that reduces the precision of a traceability system more than any other type of blending.

Besides the standard record keeping approach, **idiosyncratic** blending requires a review of your process to determine where it might occur and what effect it might have on the precision of your traceability system. This review should be documented and made a part of the traceability system in the event of a recall. There is more on how to handle idiosyncratic blending in Section 12.5, regarding fruit juice.

9.2 Transformations in Processed Foods

Consistent internal traceability requires records be kept wherever there is a transformation of product from one form to another. In fresh produce, a transformation could be cooling, sorting, grading or any process, even storage, which may change the form or condition of the product. For processed foods, the definition of a transformation has the potential to expand greatly since there are more operations involved. It could be any operation in common with fresh produce plus any processing operation such as the addition of one or more ingredients to another, a fractionation (such as grading, evaporation, filtration, crystallization, crushing or extraction), or any processing step (such as sorting, washing,

[25] About the only time when these examples would not mix lot codes is if the lot codes represented very long times.

blanching, freezing, heating, cooling, filling) that, arguably, causes a transformation in the product.[26]

9.3 Transformations that May Not Require a Record-Keeping Step

Keeping traceability records at each point of the process may or may not be useful to a particular processor, depending on the objectives of the traceability program. It is easy to argue that almost every step in a process causes a transformation in the product and would require a record keeping step. For example, a drying step for filled, pasteurized and cooled containers is a transformation, but a record keeping step for traceability at this point will not be useful.

A more ambiguous example is the placing of individual cartons of frozen vegetables into a shipping case. It is a transformation, but keeping a record of this operation for traceability may have different utility for different processors:

- Processor A uses the same production code for the shipping case that appears on the individual cartons. He believes a record keeping step at this point is not important.
- Processor B may consider a record keeping step at this point to be desirable since it could help trace and implement corrective actions should anything go wrong in this operation that was not picked up in the trade or during production by routine checking.
- Processor C may be concerned that different production codes of cartons would end up in the same case almost every time the production code changed. This is an example of **continuous** blending, given above. This processor may want a record keeping step at this point to assure that both production codes appear on that one case that contains cartons of two production codes. The same argument could be made for a palletizing operation.
- Processor D may recognize that its traceability system lacks the precision that would make the overlapping of production codes in a single shipping case important.

Likewise, one processor may consider a record keeping step for traceability at a continuous freezing operation to be unnecessary since a record of what entered the freezer exists and nothing is added or taken away from the product except heat and has, therefore, no bearing on traceability as such. Yet another processor may believe that traceability can be used for diagnosing problems in the trade that can be linked to a production code. For this processor, a record keeping step at the freezer may be desirable.

One illustration of a transformation which is not amenable to a record-keeping step is in the manufacture of olive oil. Olives are washed, pressed, heated and centrifuged in one continuous and close-coupled operation. While a record keeping step is certainly appropriate for this series of operations, any attempt to keep separate records of a single operation will not be meaningful. These types of close-coupled continuous operations are

[26] It should be mentioned that certain transformations (such as finished product storage) that may be important for fresh produce are not as important to processed foods. The reason lies in the difference in shelf life between the two product categories. Storing fresh produce for a week will likely have a major effect on its shelf life in the trade as well as its quality on release. This effect could be described as a “transformation”. If most processed foods were stored under the same conditions for a week, the change in the product would not be measurable. No “transformation” would take place.

common in food processing. The best that can be done with such an operation is an overall material balance on each lot number entering the operation (kg raw material in, kg pomace, water and olive oil out).

9.4 Transformations that Require a Record-Keeping Step

As illustrated above, few rigid rules apply to which transformations require a record keeping step. For the purpose of this document, we will consider only the following transformations to be in need of a record keeping step for traceability:

- The addition of an ingredient (such as batching)
- Fractionation of a product stream which produces more than one useable output (such as size grading, but not sorting or evaporation)
- Any operation that results (or might result) in blending of two or more lot numbers of raw materials or ingredients into a single finished product code.

Exercises:

1. *Is there blending of product codes at your factory?*
2. *If so, which type of blending is it?*
3. *How should this blending be provided for in your traceability system?*

Summary

- Internal traceability is the ability to track what happens to raw materials, ingredients, primary packages and finished products inside the processor's operation.
- Internal traceability for processed foods is more complex than for fresh produce.
- The reason for this increased complexity is blending of product codes that occur with processed foods.
- There are three types of blending: **continuous**, **purposeful** and **idiosyncratic**.
- The following types of transformations require record keeping steps:
    - When an ingredient is added (such as in batching)
    - When a product stream is fractionated and produces more than one useable output (such as size grading, but not sorting or evaporation)
    - When any operation results (or might result) in blending of two or more lot numbers of raw materials or ingredients into a single finished product code.

10 Some Common Problems in Traceability

Implementing a traceability system will always have challenges (or problems), many of which are common to many processors. The purpose of this section is to illustrate some of these common problems and to present some possible solutions.

10.1 Dealers and other middle-men

Most processors purchase a significant fraction of their raw produce from dealers. Dealers tend not to reveal the sources of their produce, the produce at times comes with no lot code, and dealers will at times target produce they know to be high in pesticides or heavy metals to companies they know d o not test for these attributes frequently. The solution to the dealer problem is threefold:

- Keep it simple

Remember that your only responsibility may be one up/one down. If this is the case, recording the name of the dealer, the date, product description and quantity may be enough.

- Assign your own batch codes

This batch code may be any system to identify the dealer, product description, quantity and the date received. It will be necessary to track his produce through your process and to link it with the finished product.

- When this is not enough

Most dealers do not keep records for traceability and it is clear that traceability is almost always broken at the dealer level. If this situation is not acceptable to your customers, then you may have to guarantee the hygienic quality of the various lots provided by the dealers by appropriately testing them yourself. In this way, you become the first link in the traceability chain. If the lots of produce are too small for cost-effective testing, then perhaps you should cultivate larger dealers or consider not exporting that commodity altogether.

Dealers in Egypt are here to stay, at least over the short to medium term. However, many processors are either acquiring or expanding their own farmland to avoid dealers. Other processors are pushing the dealers to hold up their end of the traceability contract. Presently, the dealers have little incentive to do this and this situation will continue until either they start losing business to other dealers with traceability systems in place, or until all to begin to feel the pinch of vertical integration in the processing industry.

10.2 Ingredients and packaging materials with no production code

Frequently, some ingredients and packaging materials come without batch codes. Salt, sugar and locally-manufactured packaging materials are examples. The approach to this problem is similar to the problem of dealers:

- Keep it simple

Remember that your only responsibility may be one up/one down. If this is the case, recording the name of the dealer, the date, product description and quantity may be enough.

- Assign your own batch codes

These batch codes may use any system to identify the product, the date received and the manufacturer. It will be necessary to track his produce through your process and to link it with the finished product. Encourage your suppliers to provide batch codes and certificates of analyses guaranteeing the hygienic quality of the product.

- When this is not enough

Although the processor is carrying out his one up/one down responsibility by recording the supplier of an ingredient, any ingredient that comes without a lot number carries with it the probable risk of breaking the chain of traceability. Some processors may not be comfortable with this risk. The risk can be managed if the processor guarantees the hygienic quality of the un-coded lot by performing appropriate tests on each lot (i.e. heavy metals for salt, etc.). This may not be feasible for small lots and any processor receiving such small lots should consider the risk and, if possible, utilize for export only those lots for which the hygienic quality can be guaranteed.

10.3 Idiosyncratic blending

In most instances, this type of blending of product codes can not be tracked through the process. However, you need to know where in the process it may occur and how many code numbers could be affected. This information is necessary in the event of a recall. For example, if some tomato paste coded 2:00 P.M. was known to be contaminated and it came from an evaporator known to retain 1%[27] of product manufactured four hours ago, then a decision should be made to recall product up to 6:00 P.M. as well.

10.4 Mixing of filled containers in process equipment

Frequently, filled containers will undergo processing in such equipment as an exhaust box, pasteurizer/cooler or a retort sterilizer. Sometimes the containers are coded at this point, sometimes not. These operations, at times, mix product codes. Mixing product codes can be handled in one of two ways:

- Record the mixing

Keep track of the mixed codes and accept the resultant loss of precision in the traceability system.

- Prevent the mixing

Mixing of product codes in these types of equipment can easily be prevented through simple modification of the systems and through monitoring.

Mixing of product codes should be prevented where possible and in this case it is possible.

[27] Since most evaporators operate continuously, the remaining level of contaminated product will never be zero until the evaporator is shut down and cleaned. An acceptable figure of 1% is used here for illustrative purposes only. The actual acceptable figure would depend on the nature of the hazard and its level in the original problematic code number.

Exercises:

1. *How does your factory handle inputs without lot codes? Is there any solution other then the ones mentioned above?*
2. *Is there idiosyncratic blending at your factory? If so, what are the implications of this mixing to traceability?*
3. *Can different codes of filled containers become mixed in your process? If so, what solutions can you propose?*

Summary

- Raw materials, ingredients and primary packaging materials without batch numbers are not necessarily in conflict with a traceability system.
- Lacking input identifiers, one up/one down traceability can be maintained by assigning your own identifiers.
- Greater depth in traceability may require either upgrading the dealers or testing the unknown lots yourself.
- If your process is subject to idiosyncratic blending, you must know where this blending takes place and how various lot codes are affected by it.
- If possible, mixing should be prevented in order to maximize the precision of the traceability system.

11 How to Proceed, Generally

The purpose of this section is to present a generic (non-sector specific) guide to how to approach the establishment of a traceability system. As you go through the sector-specific examples in Section 12, note that the following guidelines are generally followed.

- Determine what products and ingredients you want to include in the traceability system and how this system would fit into the existing quality management system.
- Determine the objectives, target regulatory requirements (or other standards) and company policies that are to me met by the proposed traceability system.
- As you did at the beginning of this manual, draw a flowchart of your process, identifying each step and the documents/records/sheets currently used in each step.
- Determine what data should be collected from your suppliers, kept by you and shared with your customers. This decision will depend on the depth (one-up, two-up) desired for your traceability system.
- Assign and record lot identifiers to incoming raw materials, ingredients and primary packaging materials.
- Identify each step in the process that would require the assignment of a new batch code. Generally, these are steps in the process where either:
    - An ingredient is added (such as batching)
    - A product stream is fractionated and produces more than one useable output (such as size grading, but not sorting or evaporation)
    - The operation results (or might result) in blending of two or more lot numbers of raw materials or ingredients into a single finished product code.
- Compose a data sheet for each step identified in 11.6 (above) which would link the new batch code to its inputs.
- For each finished product, determine a procedure to assign a production code (which may include information from the label) that can be linked to lot identifiers of inputs as well as pertinent internal traceability data. It is this production code that will appear on the outside of every package of finished product. The production code should be applied to each package shortly after sealing.
    - Production codes are usually based on the time of sealing. Typically, the first bit of information is the date of production. This information usually appears on all Egyptian food products in any case.
    - The second piece of information is the time of day. This time may be expressed in any way that suits your traceability objectives. It may present the exact time of sealing (i.e. 0946) or a code (i.e. B) signifying an hour, a span of hours or a shift.
    - The third piece of information might be a factory designator in the event that the same company makes (or contracts to be made) the same product at more than one location.
    - Be sure that the finished product code is linked to all inputs and any changes that they may have undergone in your factory. This linkage may

be limited only to direct inputs and indirect inputs caused either by continuous or purposeful blending. Potential for idiosyncratic blending should be noted but not necessarily tracked through the system.

- Take care that all batching operations, primary and secondary, have batching sheets and that these sheets are linked to the finished product code.
- Link any relevant food safety data to incoming materials and finished products.
- Determine the protocol for data retrieval (where data are stored, how long they are retained, who has access to the information, etc.).
- Assign responsibilities within the organization for the various parts of the traceability system.
- Develop a training program for these individuals.
- Develop a system of auditing the traceability system, recording the results and assessing corrective actions.

12 How to Proceed, by Sub-sector

Presented in this section are a series of model traceability systems for several sub-sectors. Since there is no single standard method of implementing a traceability system, and no standard method of manufacturing within these sub-sectors, these models are only examples.

12.1 Table Olives

Table olives are chosen as the first example not only because they are common in Egypt, but also because they represent a food that is processed in a batch-wise manner. This method of processing is similar to fresh produce in that the olives in the finished product look more-or less like they did on the tree. Blending steps occur, as will be shown, but the olive process is easier than most to implement traceability. The steps are as follows:

12.1.1 Draw a flowchart of your process

Imagine you are a manufacturer of green olives, whole, pitted and sliced, packed into glass jars and tins. You have constructed Figure 6, a process flow diagram of your facility, ignoring for now documents/records/sheets currently used in each step.

12.1.2 Determine what data should be collected, kept and shared

Using Table 3, identify the information that must be collected, kept and shared:

Collect from Your Immediate Suppliers:
- Their Identity and Address
- Product Description
- Output Lot Number
- Quantity (and Units of Measure) of Each Lot
- Output Shipment Identifier

Collect from Your Immediate Customers:
- Their Identity
- Their Shipping Address

Share with Your Immediate Suppliers:
- Your Identity
- Your Shipping Address

Share with Your Immediate Customers:
- Your Identity and Address
- Product Description
- Output Lot Number (Production Code)
- Quantity (and Units of Measure) of Each Lot
- Output Shipment Identifier

Keep (Record & Maintain):
- Identity and Address of Supplier
- Product Description
- Input Lot Number
- Input Shipment Identifier
- Output Lot Number
- Quantity (and Units of Measure) of Each Lot

Output Shipment Identifier

12.1.3 Assign and record lot identifiers to inputs received

The first step in the process is the receipt of ingredients (raw materials, packaging and other ingredients). Those that come with lot numbers should retain the same identifier and for those that do not, lot numbers should be assigned. Assigned lot numbers should identify, at a minimum, the supplier, quantity, product description and the date of receipt.

12.1.4 Identify subsequent process steps that would require a new batch code

Using the flowchart for table olives (Figure 6), combined with the criteria for a new batch code (or record keeping step) on Page 33, it is apparent that the steps requiring record keeping for traceability are the following:

- Lye soak/acid rinse
- Brine batching
- Fermentation
- Size grading
- Filling/capping

What follows is a description of how these traceability records are made at each of the above steps.

12.1.4.1 Assign batch numbers and create batching sheets to the initial steps

The initial steps in the process are lye soaking, acid rinse and batching of the salt solution. Figure 7 shows a batch sheet for the lye soak. If more than a single lot number of olives is used in one lye soak, record all of them here. The output batch number can be in any form, perhaps the most convenient being a description of the step followed by the starting date and time:

L3004070700

Notice that the water has no batch number, only an associated date.

Also notice that the information regarding the various code numbers begins at the start of the process and is fed forward.

The second step is the acid rinse, which can be shown by Figure 8, a modification of Figure 7. Notice that the batch number does not change from Figure 7, since the olives are the same.

The next step is the batching of the brine solution for fermentation. This may be documented by Figure 9. As with the lye soak, this output batch number can be in any form, perhaps the most convenient being a description of the step followed by the starting date and time:

FS3005071035

12.1.4.2 Assign a batch number to the fermentation step

The fourth step is the fermentation itself, represented by Figure 10. This step might contain olives that were soaked and/or acid-rinsed in different batches and may be fed by more than one batch of brine solution. This is

not a problem as long as they are recorded and shown on the example in Figure 10.

The batch number for the fermentation process could be the same as for the soaking/rinsing processes if the olives are the same. If not, it may simplify things to assign another batch number to this process, in the same manner:

F3005071100

12.1.4.3 Assign batch numbers after size grading

The next process requiring a record keeping step is size grading. In this example, olives are classified into three sizes. Usually the size in the mid-range predominates and therefore (usually), lots from a single fermentation code may be fed to the filler. However, olives at the extremes of sizes come through the grader less frequently and are and held until an amount large enough for filling is accumulated. These "fillable" amounts usually contain more than a single fermentation lot number. Either way, the fermentation code(s) of the olives must be recorded at the time of size grading which must be recorded. An example of how this step might be recorded is shown in Figure 11. Figure 11 is intended to be placed on each container fed by the size grader. Once the barrel is full, another Figure 11 is placed on the new barrel, insuring that the lot codes of fermented olives are linked to the next step, the filling operation. After the next step is completed and the drum is empty, the completed Figure 11 is retained as a record.

Graded olives require another code number which can most conveniently be linked to their source by retaining the original fermentation code followed by an alphanumeric (a single letter) at the end to indicate grade.

12.1.4.4 Consider the pitting and slicing operations

Since no new ingredient is introduced and pitting produces only one useable fraction, no record keeping step for traceability is likely to be necessary at these points. In the event that **continuous** or **purposeful** blending of two or more lot numbers from the size grader takes place, a record keeping step would be in order. However, blending at this step can easily be avoided.

Batch numbers coming out of the size grader can be fed forward to the pitted and/or sliced product and from there to the filler by transferring the barrel tag, Figure 11, to the barrels of pitted and/or sliced product.

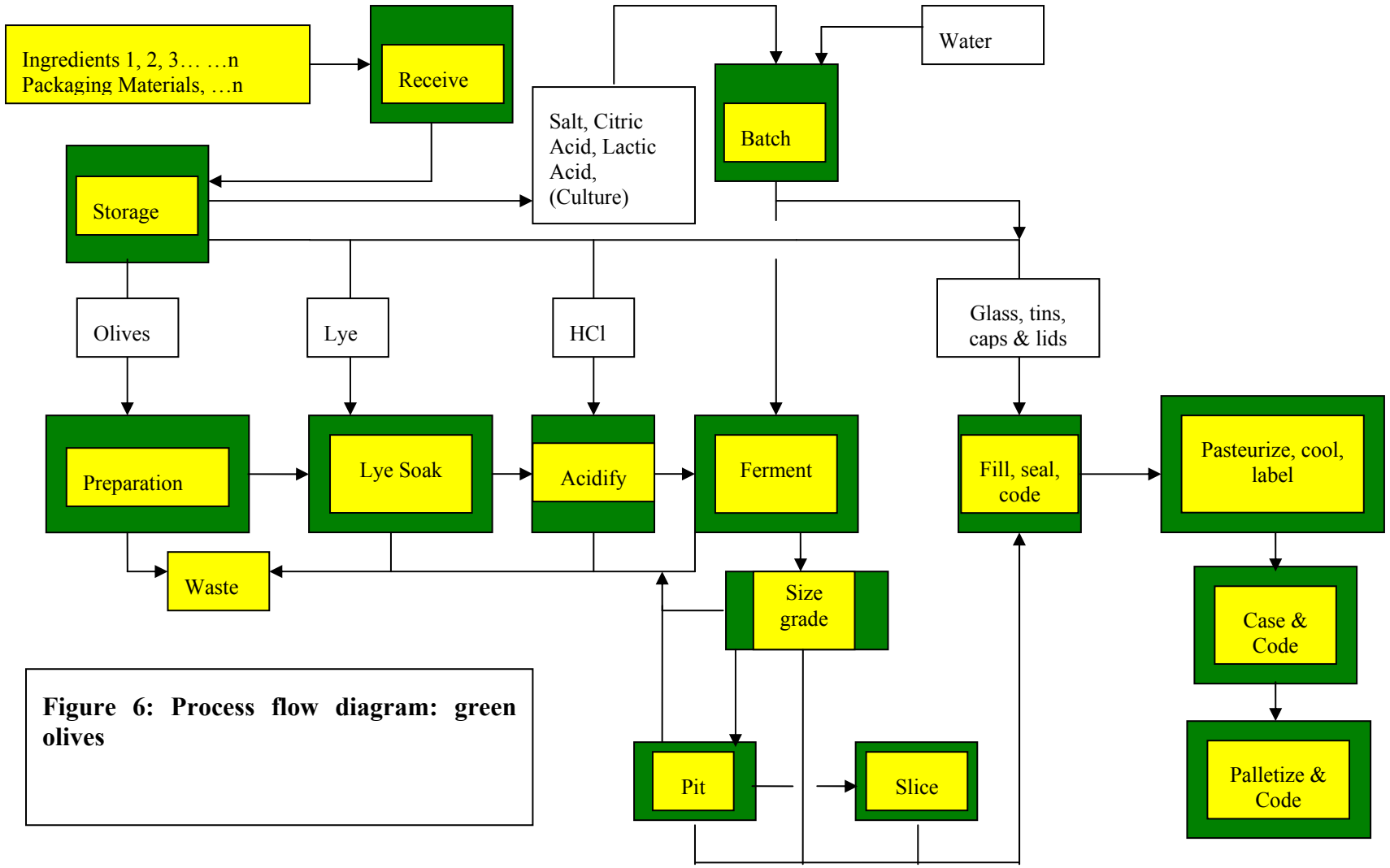

Figure 6: Process flow diagram: green olives

Figure 7: Batching sheet for lye soaking process

Date Start:	**Output Batch Number:**	**Date End:**
Time Start:		**Time End:**
Input Ingredient:	Input Lot Number	Amount (Kg)
Olives		
Lye		
Water	Not Applicable	

Figure 8: Batching sheet for acid rinse process

Date:	**Time Start:**	
Output Batch Number: (Same as Fig. 7)		
Input Ingredient:	**Ingredient Lot Number**	**Amount (Kg)**
Olives, treated with lye	Not applicable	
Acid solution		
Water	Not applicable	

Figure 9: Batching sheet for fermentation solution

Date:	**Output Batch Number:**	
Time Start:		
Input Ingredient:	**Lot Number**	**Amount (Kg)**
Salt		
Citric acid		
Lactic acid		
Culture		
Water	**Not applicable**	

Figure 10: Batching sheet for fermentation process

Date Start:	**Output Batch Number:**	**Date End:**
Time Start:		**Time End:**
Input Ingredient:	**Lot Number**	**Amount (Kg)**
Olives, prepared		
Olives, prepared		
Brine solution		
Brine solution		
Brine solution (make-up)		

Figure 11: In-process barrel tag for size grading

Date Start:				
Time Start:				
Output:	**Output Lot Number**	**Input:**	**Kg**	**Fermentation Lot Numbers**
Size:		Olives, fermented		
		Olives, fermented		
		Olives, fermented		
		Olives, fermented		
		Olives, fermented		
		Olives, fermented		

12.1.4.5 Assign a production code after filling/capping

Filling and capping brings together the finished olives, the finished product brine solution, and both elements of the primary container. This operation clearly requires a record keeping step, illustrated in Figure 12. This document links the lot numbers of the olives, the finished brine solution and the primary packaging materials.

Filling is frequently a continuous process and it is very important either to assign a new batch code (and to start a new Figure 12) whenever the code numbers of any of the inputs changes or to simply record the changing batch numbers on a single Figure 12.

Ideally, the various lot codes of finished (but un-pasteurized) jars should be separated from each other, either physically or with a marker to avoid **continuous mixing** in pasteurization and cooling.

The production code normally appears on the outside of the primary package. Remember that one item of information to be shared with your

customers is the output lot number (or this product code plus some information included on the label). Since the production date is required anyway we will use it also as part of the production code:

30/4/2007

The remainder of the production code will be represented by the time of coding:

0735

or by the hour of coding, represented by a single digit such as:

B

or by the shift, also represented by a single digit:

C

If the same or similar products are to be filled on different lines, some indication of the line should appear on the product code as well:

L1

If the company has only a single factory location so no additional code is necessary to designate location.

The filling and casing operations are separated from coding by the time of pasteurization and cooling. Because of this delay, it is important to code the containers immediately after capping since the times of pasteurization and cooling are not always predictable, owing to break-downs and occasional groups of jars becoming more-or-less trapped in the tunnels, resulting in **continuous** mixing. In order to minimize this mixing in casing and palletizing, it is desirable to assure (as much as possible) that no **continuous** mixing takes place here. If some mixing of codes does take place to the extent that mixed codes are present in many cases, the operator should so note on the casing and palletizing records.

12.1.4.6 Consider the casing and palletizing operations

Continuous mixing will occur in both operations, even without mixing in the pasteurizer/cooler. Mixing primary packages with different code dates in the shipping case is not a problem as long as both codes are marked on the case and a record is kept linking the mixed case to its pallet number. Palletizing is a similar situation.

No new lot identifier is required on each case, since the production code(s) and a label can appear on each case.

The pallets may be identified with a label shown in Figure 13. Again, the same production codes that are on the cases and individual containers may be used to identify the pallets, combined with other product information shown on Figure 13.

12.1.5 Take a note of where idiosyncratic blending takes place

Since the olive process is mostly batch-wise, no idiosyncratic blending is likely to take place.

12.1.6 Link relevant food safety data

Food safety data should be recorded at the step at which they apply. In this example, heavy metals and pesticide residue usually applies to the raw ingredient as received. These data, therefore, should be part of the receiving documents, thereby linking them to the suppliers and to the finished product.

Figure 12: Capping/Coding Sheet: Table Olives

Date:		**Product Type**
Time Start:	**Time Finished:**	**Container Size/Type**
Input:	**Ingredient Lot Numbers**	**Quantity**
Olives	(olives from size grader)	
Brine solution		
Container		
Closure		
Output:		**No. Containers in Code Number**
Production Code Number		

Figure 13: Pallet Label

Product	**Size**	**Count/Pallet**
Pallet Number:		
Packing Date:	**Production Code(s):**	

12.2 Olive Oil

Olive oil is also commonly manufactured in Egypt but is chosen here because most olive oil is manufactured using **purposeful** mixing. As will all processed foods, some continuous mixing is also present.

12.2.1 Draw a flowchart of your process

Imagine you are a manufacturer of virgin and extra virgin olive oil, packed into glass jars & tins and inerted with nitrogen. Construct Figure 14 a process flow diagram of your facility, ignoring for now documents/records/sheets currently used in each step.

12.2.2 Determine what data should be collected, kept and shared

Using Table 3, identify the information that must be collected, kept and shared. This information is the same as shown for Table Olives, above on Page 35.

12.2.3 Assign and record identifiers to inputs received

The first step in the process is the receipt of ingredients (raw materials, packaging and other ingredients). Note here that nitrogen is an ingredient. Those that come with lot numbers should retain the same identifier and for those that do not, lot numbers should be assigned. Assigned lot numbers should identify, at a minimum, the supplier, the quantity, product description and the date of receipt.

12.2.4 Identify subsequent process steps that would require a new batch code

Using the flowchart for olive oil (Figure 14, combined with the criteria for a new batch code (or record keeping step) on Page 33, it is apparent that the steps requiring record keeping for traceability are the following:

- Crushing, heating and centrifugation
- Purposeful blending of tanks
- Filling/capping

What follows is a description of how these traceability records are made at each of the above steps.

12.2.4.1 Assign batch numbers and create batching sheets for the initial steps

The initial steps are washing and removal of leaves. Since this operation does not meet the criteria of a record keeping step, no traceability records or new lot number are needed here. The next step is crushing, which is close-coupled with heating and both centrifugation steps. Since these operations are close-coupled, they will be taken as a whole, since records for each step are not feasible or necessary. Even taken as a whole, these three steps do not appear to need a record keeping step, since there is no ingredient added (water is a processing aid here[28]) and the fraction results in only a single usable stream, the oil. However, **continuous** mixing may, and most likely does, take place during crushing and heating. Therefore, a record keeping step is required and will include crushing, heating and both

[28] A processing aid is a compound added to the product stream to assist in processing but either has no function in the finished product or, in this case, is removed in processing.

centrifugation steps as a whole. The record keeping step will account for this **continuous** mixing and the material balance around these operations. It will also account for the **continuous** mixing that takes place in the storage tank which is fed by the second centrifugation operation.[29] Figure 15 hows a batch sheet for such an operation. It records the lot numbers of olives from which the oil was separated and links them with the batch number of the storage tank (and the storage tank) into which they are fed. A new Figure 15 should be started whenever a different storage tank is being filled. If a tank is left partially filled for a period of time and filled later, the same Figure 15 should be used.

The batch number for the tank can be in any form, perhaps the most convenient being a description of the step followed by the date on which the tank has completed its filling:

BN300407

Notice that the information regarding the various code numbers begins at the start of the process and is fed forward.

12.2.4.2 Track the **purposeful** mixing

In olive oil production, it is frequently desirable to blend oil from different storage tanks to achieve optimum quality for the greatest amount of product. This is purposeful blending and should be recorded to keep track of which batch numbers of oil are in each storage tank. Figure 16 can do that as well as record which lot codes of nitrogen are used in each tank. The same Figure 16 should be used for each tank until that tank is empty. As various batches of olive oil are added and lot numbers of nitrogen changed, the additions and changes may be added to the same form.

12.2.4.3 Note that filtration does not qualify for a record keeping step

12.2.4.4 Assign a production code after filling/capping

Filling and capping brings together the finished olive oil, more nitrogen and both elements of the primary container. This operation clearly requires a record keeping step, illustrated in Figure 17. This document links the batch numbers of the olive oil, the nitrogen and the primary packaging materials.

Filling is frequently a continuous process and it is very important to assign a new batch code (and to start a new Figure 17) whenever the code number of any of the inputs changes or to simply record the changing batch numbers on a single Figure 17.

Ideally, the various lot codes of finished bottles & tins should be separated from each other, and not allowed to accumulate and mix during the casing operation. This extra care will avoid **continuous mixing** after filling.

The lot identifier of containers of finished product is the product code that normally appears on the outside of the primary package combined with

[29] It should be noted that the mixing that takes place in crushing and heating is far less than the mixing that takes place as a result of filling the storage tanks. These tanks are filled with oil from many different lot numbers over several days or even weeks. The capacity of these storage tanks is usually much greater than one day's production.

information on the label. Remember that one item of information to be shared with your customers is the output lot identifier.

Since the production date is required anyway we will use it also as part of the production code:

30/4/2007

The remainder of the production code will be represented by the time of coding:

0735

or by the hour of coding, represented by a single digit like:

B

or by the shift, also represented by a single digit:

C

If the same or similar products are to be filled on different lines, some indication of the line should appear on the product code as well:

L1

If the company has only a single factory location no additional code is necessary to designate location.

Information from the label would be needed as part of the lot identifier only if the production code did not uniquely identify the product.

12.2.4.5 Consider the casing and palletizing operations

Continuous mixing will occur in both operations. Mixing primary packages with different code dates in the shipping case is not a problem as long as both codes are marked on the case and a record is kept linking the mixed case to its pallet number. Palletizing is a similar situation.

12.2.5 Take a note of where idiosyncratic blending takes place

Since the olive oil process is mostly batch-wise or straight through continuous, no idiosyncratic blending is likely to take place.

12.2.6 Link relevant food safety data

Food safety data should be recorded at the step at which they apply. In this example, heavy metals and pesticide residue usually applies to the raw ingredient as received. These data, therefore, should be part of the receiving documents, thereby linking them to the suppliers and to the finished product.

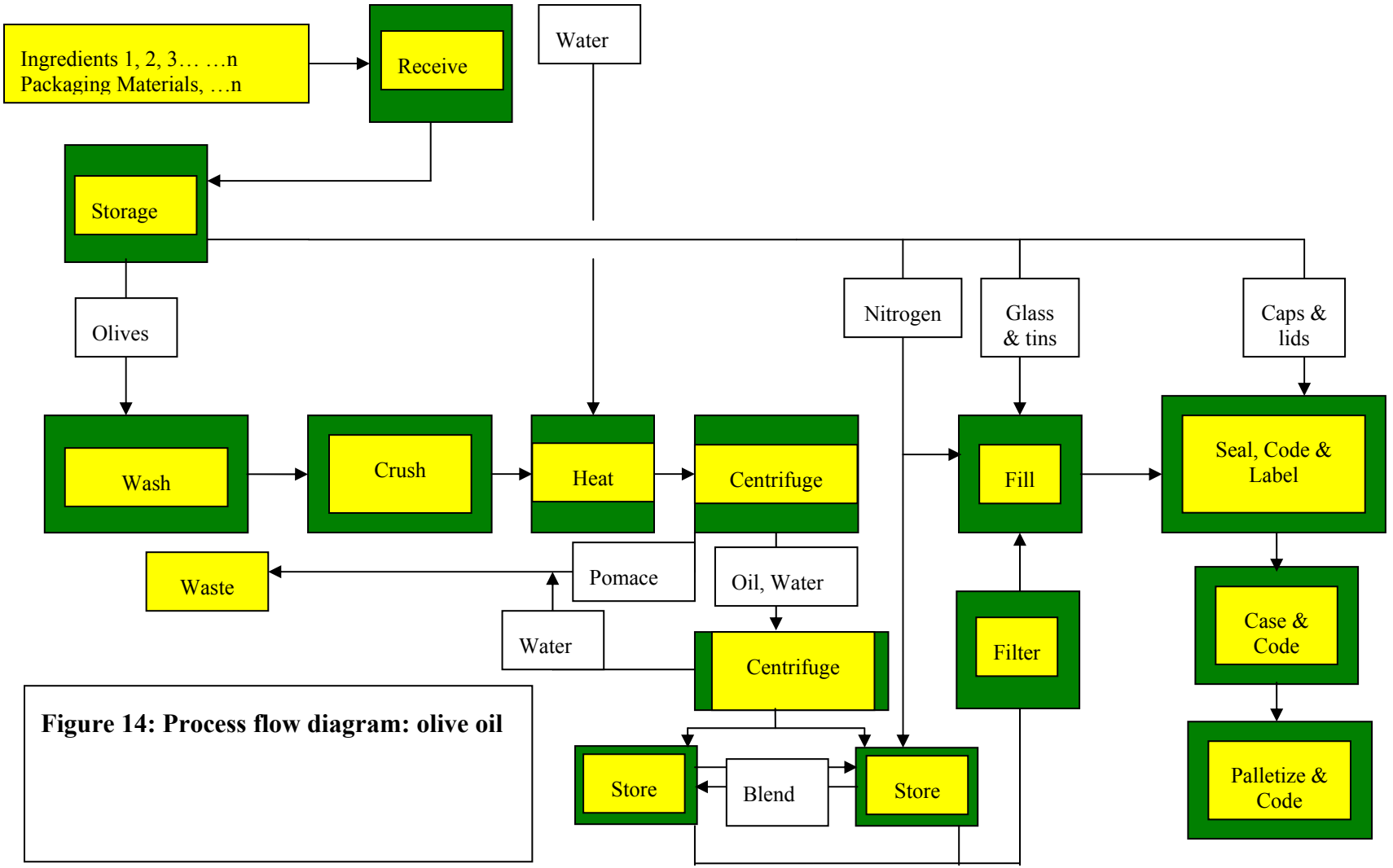

Figure 14: Process flow diagram: olive oil

Figure 15: Batching Sheet for Crushing/Heating/Separation

Input:			
Date	**Time**	**Lot No. Olives Input**	**Kg**
Output:	**Tank Number**		
Date Start	**Date Filled**	**Batch Number Olive Oil**	**Kg**

Figure 16: Batching Sheet for Storage Tank Blending

Storage Tank No.				
Input:				
Nitrogen lot number:				
Date	**Time**	**Batch No. Olive Oil**	**From**	**Kg**
			Centrifuge	
Output:				
			To Tank No.	**Kg**

Figure 17: Filling and Capping Sheet: Olive Oil

Date:		Product Type
Time Start:	Time Finished:	Container Size/Type
Input:	Ingredient Lot Numbers	
Olive Oil		No. Containers in Code Number
Nitrogen		
Container		
Closure		
Output:		
Production Code Number		

12.3 Dehydrated Onions

In several ways, processes for dehydrated onions are fundamentally the same: they have only one ingredient, there is only one fractionation process where there is more than a single usable output and they may be operated in a way that eliminates all types of mixing. Therefore, it is possible that the traceability paperwork burden for dehydrated onions could be minimal: receipt of inputs, sieving and filling. In reality, however, processes for dehydrated onions vary. The following describes a process with a continuous dryer, without holding steps that allow for mixing of product codes.

12.3.1 Draw a flowchart of your process

Imagine you are a manufacturer of several cuts of dehydrated onions, chopped, minced, kibblet and powder, packed into polyethylene bags. You have constructed Figure 18, a process flow diagram of your facility, ignoring for now documents/records/sheets currently used in each step.

12.3.2 Determine what data should be collected, kept and shared

Using Table 3, identify the information that must be collected, kept and shared. This information is the same as shown for Table Olives, above on Page 35.

12.3.3 Assign and record lot identifiers to inputs received

The first step in the process is the receipt of ingredients (raw materials, packaging and other ingredients). Those that come with lot numbers should retain the same identifier and for those that do not, lot numbers should be assigned. Assigned lot numbers should identify, at a minimum, the supplier, quantity, product description and the date of receipt.

12.3.4 Identify subsequent process steps that would require a new batch code

Using the flowchart for dehydrated onions (Figure 18), combined with the criteria for a new batch code (or record keeping step) on Page 33, it is apparent that the steps requiring record keeping for traceability are the following:

- Washing
- Sieving
- Filling

What follows is a description of how traceability records are made at each of the above steps.

12.3.4.1 Assign batch numbers and create batching sheets to the initial steps

The initial steps in the process are peeling & trimming, washing, cutting and dewatering. Provided that the different lots can be separated during peeling & trimming, the first record-keeping step will be for washing. Linkage between the input lot numbers (receipt) and washing may be maintained through the use of barrel tags. Washing represents a record keeping step because a new ingredient, c chlorine, is introduced and there exists a potential for **continuous blending** (although the process may be operated in such a way to eliminate blending here. For this example, we will assume that the process will be operated in such a manner). Note that the output lot number from washing is the same as the input, since they are

the same onions. Also note that water has no lot number associated with it, only a date. Figure 19 shows a batch sheet for the washing process. If more than a single lot number of onions is used during the time a single Figure 19 is active, then, record all of them here. However, the best way to operate this process (from the point of view if traceability) is to separate the batches by a few moments so that they are not blended during washing.

Notice that the information regarding the various code numbers begins at the start of the process and is fed forward.

The next steps are cutting and dewatering. Since no new ingredient is introduced and dewatering produces only one useable fraction, no record keeping step for traceability is likely to be necessary at these points. In the event that continuous or purposeful blending of two or more lot numbers from the size grader takes place, a record keeping step would be in order. However, blending at these steps can easily be avoided.

12.3.4.2 Consider the dehydration step

The next step is the dehydration itself. Since the washer is being operated in a manner that will keep the lot numbers separate and identifiable, the dryer could be operated in the same way so that a record keeping step is not necessary. Providing a short break between incoming lot numbers in the washer can create the same short break in the dryer.[30] The lot numbers of onions entering the dehydrator may be identified by feeding the information forward from the washer, since storing or holding of washed and/or cut onion is not advisable from a GMP standpoint. However, drying is not a record keeping step since the same onions go out as come in and the only fraction removed is water. Therefore, the lot numbers from the washer are fed to the next record keeping step, sieving, represented by Figure 20.

12.3.4.3 Assign batch numbers after sieving

The next process requiring a record keeping step is sieving (or size grading). Lot codes of onions are fed to the sieving operation separately and their identities are known by feeding them forward from the washer. Since the various fractions of onions are taken from the sieve and processed immediately, barrel tags are not an option. In this example, dry onions are classified into four sizes: chopped, minced, kibblet and powder. An example of how this step might be recorded is shown in Figure 20.

The onion fractions require another code number which can most conveniently be linked to their source by retaining the original code followed by an alphanumeric (a single letter) at the end to indicate grade.

[30] If there is no separation in either washing or drying, the precision of the traceability system will be reduced. In this example, a problem in a single lot code of inputs could affect as many as four lot codes of finished product if there were no separation in either the washing or drying steps. Without separation **continuous blending** in the dryer will be could be compounded by blending during washing, hence the decrease in precision. It is easy to see how simple procedures designed to eliminate blending at these steps can pay off in the simplicity and precision of the traceability system.

12.3.4.4 Consider inspection

Inspection is a fractionation step with only a single usable stream, no ingredients are introduced and there is no **continuous** blending.[31] Therefore, no record keeping step is required at this stage.

12.3.4.5 Assign a production code after filling

Filling brings together the finished dehydrated onions and the primary container. This operation clearly requires a record keeping step, illustrated in Figure 21. This document links the lot numbers of the onions and the primary packaging materials.

Filling is frequently a continuous process and it is very important either to assign a new batch code (and to start a new Figure 21) whenever the code numbers of any of the inputs changes or to simply record the changing batch numbers on a single Figure 21.

The production code normally appears on the outside of the primary package. Remember that one item of information to be shared with your customers is the output lot number (or this product code plus some information included on the label). Since the production date is required anyway we will use it also as part of the production code:

30/4/2007

The remainder of the production code will be represented by the time of coding:

0735

or by the hour of coding, represented by a single digit such as:

B

or by the shift, also represented by a single digit:

C

If the same or similar products are to be filled on different lines, some indication of the line should appear on the product code as well:

L1

If the company has only a single factory location so no additional code is necessary to designate location.

12.3.4.6 Consider the palletizing operation

Continuous mixing will occur in palletizing, even without mixing elsewhere in the process. Mixing primary packages with different code dates in the pallet is not a problem as long as all codes are recorded.

The pallets may be identified with a label shown in Figure 13. Again, the same production codes that are on the individual bags may be used to identify the pallets, combined with other product information shown on Figure 13. I

[31] There is no continuous blending after sieving only if there is no storage of finished product that mixes lot numbers. Any such storage would have to be accounted for in this model.

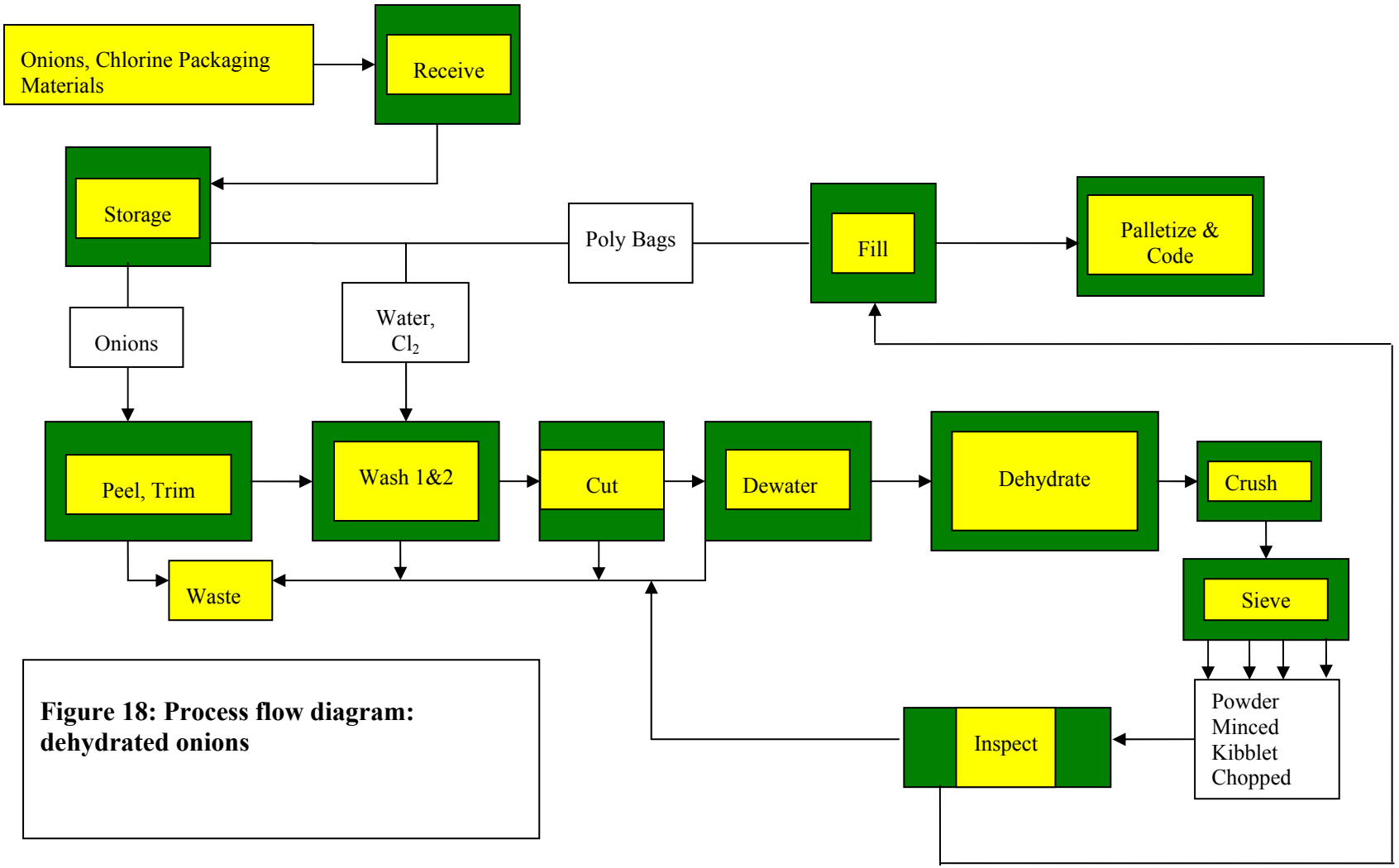

Figure 18: Process flow diagram: dehydrated onions

Figure 19: Batching sheet for washing process

Date:	**Time Start/End**	
Output Batch Number:	**(Same as input)**	
Input Ingredient:	Ingredient Lot Number	Amount (Kg)
Onions, peeled & trimmed		
Chlorine		
Water	Not applicable	

Figure 20: Lot numbers from sieving process

Date:	**Time:**	**Input Lot Number**	**Kg**
Time Lot No. Exited Washer:		**(Lot no. from washer)**	
Output:	**Output Lot Numbers**		
Chopped			
Mince			
Kibblet			
Chopped			

12.3.5 Take a note of where idiosyncratic blending takes place

Since the dehydration process does not involve liquid processing, no idiosyncratic blending is likely to take place.

12.3.6 Link relevant food safety data

Food safety data should be recorded at the step at which they apply. In this example, heavy metals and pesticide residue usually applies to the raw ingredient as received. These data, therefore, should be part of the receiving documents, thereby linking them to the suppliers and to the finished product.

Figure 21: Batching sheet for filling operation

Date:	**Product Type:**	
Time Start:	**Time Finished:**	**Container Size/Type:**
Input:	**Ingredient Lot Numbers**	
Onions		
Onions		
Poly Bags		
Poly Bags		
Output:		**No. Containers in Lot Number**
Production Code Number		

12.4 Canned Fruit

Canned fruit can be made in many ways. This process filled fruit pieces into a can, after which they pass through an exhaust (steam) box, are then topped with syrup and sealed. They then pass through a pasteurizer/cooler and are then coded. This example is given to illustrate the effect of applying the production code well after sealing.

12.4.1 Draw a flowchart of your process

Imagine you are a manufacturer of fruit pieces (perhaps peach halves), packed in syrup and canned in consumer size tins. You have constructed Figure 22, a process flow diagram of your facility, ignoring for now documents/records/sheets currently used in each step. In this example, the production code is not applied immediately after sealing but rather after pasteurizing and cooling.

12.3.1 Determine what data should be collected, kept and shared

Using Table 3, identify the information that must be collected, kept and shared. This information is the same as shown for Table Olives, above, on page 35.

12.3.2 Assign and record lot identifiers to inputs received

The first step in the process is the receipt of ingredients (raw materials, packaging and other ingredients). Those that come with lot numbers should retain the same identifier and for those that do not, lot numbers should be assigned. Assigned lot numbers should identify, at a minimum, the supplier, quantity, product description and the date of receipt.

12.3.3 Identify subsequent process steps that would require a new batch code

Using the flowchart for canned fruit (Figure 22), combined with the criteria for a new batch code (or record keeping step) on Page 33, it is apparent that the steps requiring record keeping for traceability are the following:

- Peeling
- Filling
- Sealing
- Coding[32]

What follows is a description of how these traceability records are made at each of the above steps.

12.3.3.1 Assign batch numbers and create batching sheets to the initial steps

The initial steps undertaken with the fruit are inspection & washing, peeling, halving, pitting and final inspection. Peeling is the only of these operations that meets the criteria of a record keeping step, since lye and water are introduced and there exists a potential for **continuous blending** (although the process may be operated in such a way to eliminate blending here. For this example, shown in Figure 23, we will assume that the process will be operated in such a manner). Note that the output lot

[32] Coding by itself does not fulfil the criteria for a record keeping step as outlined on page 33. However, since coding can only identify the source of the ingredients if the code is linked to the inputs, a record keeping step in necessary. This apparent breakdown of the criteria for a record keeping step is only one of the problems caused by applying the product code so far downstream from sealing.

number from peeling is the same as the input, since they are the same fruit. Also note that water has no lot number associated with it, only a date. If more than a single lot number of fruit or lye is used during the time a single Figure 23 is active, then, record all of them here. However, the best way to operate this process (from the point of view if traceability) is to separate the batches by a few moments so that they are not blended during this step and to use a new Figure 23 each time a lot code changes.

The other initial preparation step is the batching of the sugar/acid solution for filling. This may be documented by Figure 24. The output batch number can be in any form, perhaps the most convenient being a description of the step followed by the starting date and time:

BS200730050710

Notice that the information regarding the various code numbers begins at the start of the process and is fed forward.

The next steps associated with the fruit only are cutting, pitting and inspection. Since no new ingredient is introduced and pitting and inspection produces only one useable fraction, no record keeping step for traceability is likely to be necessary at these points. In the event that **continuous** or **purposeful** blending of two or more lot numbers from the peeler takes place, a record keeping step would be in order. However, blending at these steps can easily be avoided.

12.3.3.2 Assign a lot code after filling

Filling brings together the prepared fruit, the finished product sugar solution and one element of the primary container, the can. This operation clearly requires a record keeping step, illustrated in Figure 25. This document links the lot numbers of the fruit, the finished sugar solution and one of the primary packaging materials.

It is very important either to assign a new batch code (and to start a new Figure 25) whenever the code numbers of any of the inputs changes or at least to record the changing batch numbers on a single Figure 25.

Since the cans are not yet coded, it is more important than ever to separate different lot codes from each other, either physically or with a marker to avoid **continuous mixing** in the subsequent steps: exhausting, pasteurizing and cooling.

12.3.3.3 Assign a production code

The production code normally appears on the outside of the primary package. In this example, the production code is not applied until just before casing, essentially the end of the process. Remember that one item of information to be shared with your customers is the output lot number (or this product code plus some information included on the label). Since the production date is required anyway we will use it also as part of the production code: 30/4/2007

The remainder of the production code will be represented by the time of coding:

0735

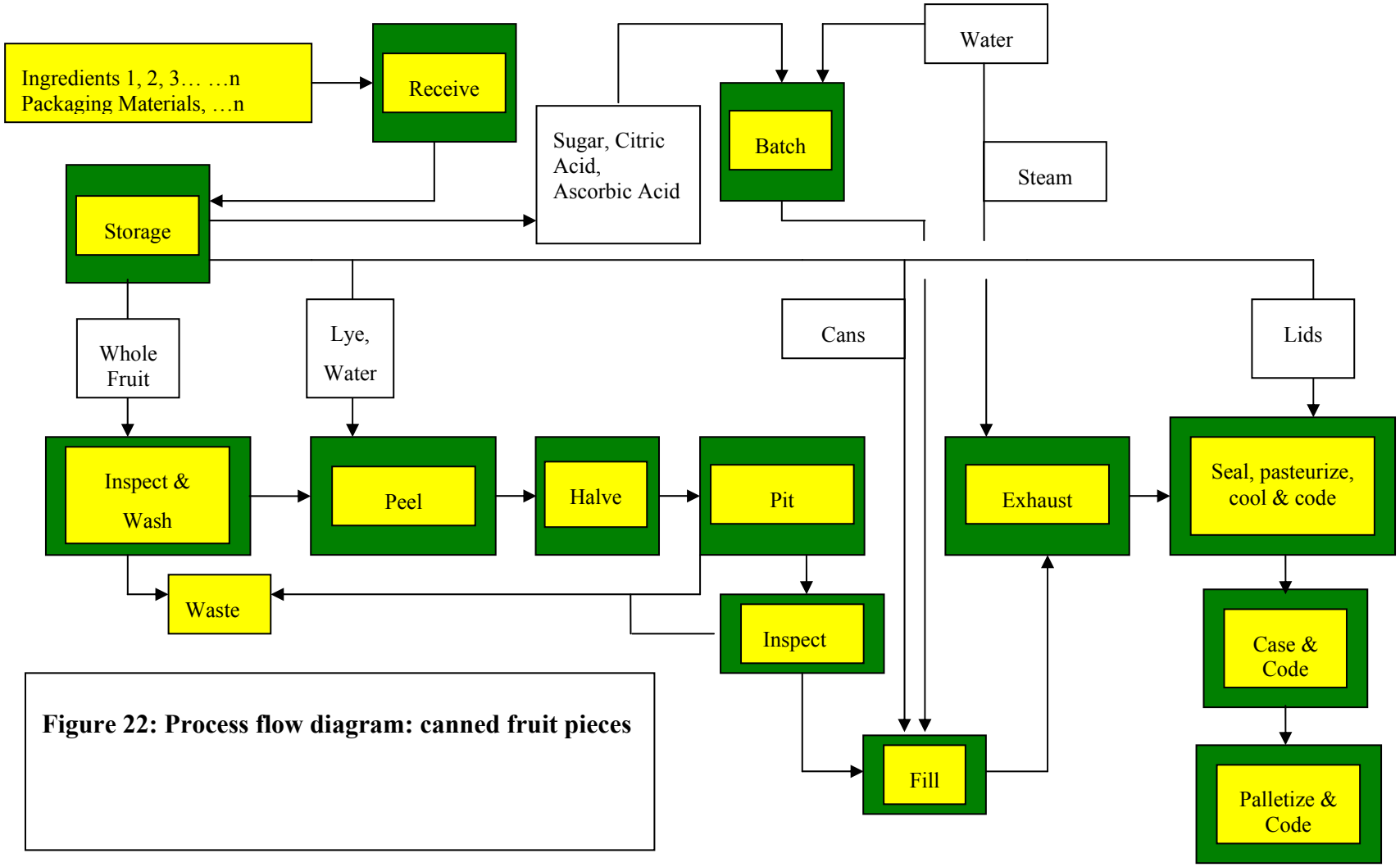

Figure 22: Process flow diagram: canned fruit pieces

Figure 23: Batching sheet for peeling step

Date:	**Time Start/End:**	
Output Batch Number:	**(Same as input)**	
Input Ingredient:	**Ingredient Lot Number**	**Amount (Kg)**
Peaches, inspected & washed		
Lye solution		
Water	**Not applicable**	

Figure 24: Batching sheet for sugar solution

Date:	**Output Batch Number:**	
Time Start:		
Input Ingredient:	**Input Lot Number**	**Input Amount (Kg)**
Sugar		
Citric acid		
Ascorbic acid		
Water	**Not applicable**	

Figure 25: Batching sheet for filling

Date:	**Product Type:**	
Time Start:	**Time Finished:**	**Container Size/Type**
Inputs:	**Ingredient Lot Numbers**	**Quantity**
Fruit	(fruit from size grader)	
Sugar Solution		
Container		
Output:		**No. Containers in Code Number**
Output Lot Number		

or by the hour of coding, represented by a single digit such as:

B

or by the shift, also represented by a single digit:

C

If the same or similar products are to be filled on different lines, some indication of the line should appear on the product code as well:

L1

If the company has only a single factory location so no additional code is necessary to designate location.

Remember that the coding operation is separated from sealing by the time of pasteurization and cooling. It is also separated from the last batch code (filling) by these operations and by exhausting. Because of this delay, it is especially important to prevent un-coded containers from mixing with each other. **Continuous** mixing may take place since the times of exhausting, pasteurizing and cooling may not always be predictable, owing to break-downs and occasional groups of cans becoming more-or-less

trapped in the tunnels. If some mixing of codes does take place the operator should so note (and link) the mixed batch numbers with the finished product code on Figure 26. The risk associated with having the coding operation so far downstream from sealing is that breakdowns and/or trapping of cans in the pasteurizer/cooler is sometimes difficult for the operator to track or even be aware that it has happened. Cans lacking a code at this point make the traceability system subject to error which results in a loss of precision.

12.3.3.4 Consider the casing and palletizing operations

Continuous mixing will occur in both operations, even without mixing in the pasteurizer/cooler. Mixing primary packages with different code dates in the shipping case is not a problem as long as both codes are marked on the case and a record is kept linking the mixed case to its pallet number. Palletizing is a similar situation.

No new lot identifier is required on each case, since the production code(s) and a label can appear on each case.

The pallets may be identified with a label shown in Figure 14. Again, the same production codes that are on the cases and individual containers may be used to identify the pallets, combined with other product information shown on Figure 13.

12.3.4 Take a note of where idiosyncratic blending takes place

Since this fruit packing operation is mostly batch-wise, no idiosyncratic blending is likely to take place.

12.3.5 Link relevant food safety data

Food safety data should be recorded at the step at which they apply. In this example, heavy metals and pesticide residue usually applies to the raw ingredient as received. These data, therefore, should be part of the receiving documents, thereby linking them to the suppliers and to the finished product.

Figure 26: Finished product coding sheet

Date:		**Product Type**
Time Start:	**Time Finished:**	**Container Size/Type**
Input:	**Input Lot Numbers**	**Quantity**
Cans of fruit	**(cans from filler)**	
Cans of fruit		
Cans of fruit		
Output:		**No. Containers in Code Number**
Output Lot Number		

12.5 Fruit Juice

Fruit juice is chosen as the final example because its process tends to be continuous and it usually has at least one operation where **idiosyncratic** mixing takes place.

12.5.1 Draw a flowchart of your process

Imagine you are a manufacturer of fruit juice from fresh fruit, packed in a 200 mL TetraPak primary container with a straw applied at the side. You have constructed Figure 27, a process flow diagram of your facility, ignoring for now documents/records/sheets currently used in each step.

12.5.2 Determine what data should be collected, kept and shared

Using Table 3, identify the information that must be collected, kept and shared. This information is the same as shown for Table Olives, above, on page 35.

12.5.3 Assign and record lot identifiers to inputs received

The first step in the process is the receipt of ingredients (raw materials, packaging and other ingredients). Those that come with lot numbers should retain the same identifier and for those that do not, lot numbers should be assigned. Assigned lot numbers should identify, at a minimum, the supplier, quantity, product description and the date of receipt.

12.5.4 Identify subsequent process steps that would require a new batch code

Using the flowchart for canned fruit (Figure 27), combined with the criteria for a new batch code (or record keeping step) on Page 33, it is apparent that the steps requiring record keeping for traceability are the following:

- Hot break[33]
- Preparation batch (water, sugar, CMC, ascorbate)
- Main batch
- Aseptic surge tank
- Filling
- Application of straws

What follows is a description of how these traceability records are made at each of the above steps.

12.5.4.1 Assign batch numbers and create batching sheets to the initial steps

The initial steps undertaken with the fruit are inspection & washing, chopping, hot break, and pulping. Hot break is the only one of these operations that meets the criteria of a record keeping step, since mixing of product codes will occur here by **idiosyncratic** blending. This means that most of the output from the hot break tank is likely to contain many lot numbers of fruit. As such, the output from this tank will be given only a single lot number, linked to the inputs by Figure 28. It is very important to note the times at which the different lot numbers of ingredients are introduced to the hot break tank. The reason for this is care is to increase the precision of the traceability system.

[33] Hot breaking is the application of heat to inactivate enzymes. It usually involves a tank of boiling pulp into which raw pulp is continuously fed and out of which "hot broken" pulp is continuously taken.

For example, if a problem were later discovered with a lot code of fruit, one could use Figure 28 to determine when this lot was fed into the hot break tank. Everything produced from pulp that was hot broken at some point before this time would be all right. Also, a knowledge of the flow rate of pulp, combined with the amount of liquid hold-up in the tank will allow a calculation of when the problem is sufficiently "diluted" so that product made from that pulp could be considered once again all right.

Notice that Figure 28 has only one output batch code for many lot codes of inputs. This is because of the mixing, mentioned above. A new Figure 28 and a new output batch number may be used only after the hot break tank has been emptied and cleaned.

The other initial preparation step is the batching of the sugar/acid solution for filling. This may be documented by Figure 29. The output batch number can be in any form, perhaps the most convenient being a description of the step followed by the starting date and time:

BS200730050710

Notice that the information regarding the various code numbers begins at the start of the process and is fed forward.

The next step associated with the fruit only is pulping. Since no new ingredient is introduced and pulping produces only one useable fraction, no record keeping step for traceability is likely to be necessary at this point.

12.5.4.2 Assign batch numbers and make batch sheets for the main batching operation

The main batching operation is where the hot-broken pulp comes together with the other ingredients from the preparation batch. Figure 30, a variation of Figure 29, may be used to document this step.

12.5.4.3 Consider heating, holding and cooling

In these close coupled and continuous processes, no ingredient is added, no fractionation takes place and there is essentially no blending.[34] Therefore, no record keeping step is necessary.

12.5.4.4 Aseptic surge tank

The aseptic surge tank in the process takes the place of a recycle line. The heat/hold/cool steps must run continuously. While the filler also runs continuously, it is sometimes stopped for short periods for adjustments. Moreover, even if the filler never stopped, it is not possible to run the heat/hold/cool line at exactly the same rate required by the filler. Therefore, a surge capacity is needed.

Unfortunately, this surge capacity introduces another source of **idiosyncratic** blending to the process and its inherent reduction in the precision of the traceability system. This means that most of the output from the aseptic surge tank is likely to contain not only many lot numbers of fruit but many different

[34] Fluid flow in a pipe always causes a certain degree of mixing. This mixing has the theoretical possibility of mixing product codes. However, in this case, the mixing that takes place as a result of this flow is much less than the idiosyncratic mixing that takes place during hot break and later in the aseptic surge tank. Therefore, this type of mixing may be ignored.

lot numbers of the other ingredients as well. As such, the output from this tank will also be given only a single lot number, linked to the inputs by Figure 31, a revision of Figure 28, the batching sheet for hot break. As with hot break, it is very important to note the times at which the different batches of finished juice are introduced to the aseptic surge tank. The reason for this is care is to increase the precision of the traceability system. For example, if a problem were later discovered with a lot code of sugar, one could use Figure 31 to determine when this lot was fed into the aseptic surge tank. Everything produced from finished juice that was batched at some point before this time would be all right. Knowledge of the flow rate of juice, combined with the amount of liquid hold-up in the tank will allow a calculation of when the problem is sufficiently "diluted" so that juice pumped from this tank to the filler could be considered once again all right.

Notice that Figure 31 has only one output batch code for many lot codes of inputs. This is because of the mixing, mentioned above. A new Figure 31 and a new output batch number may be used only after the aseptic surge tank has been emptied and cleaned.

12.5.4.5 Assign a production code after filling

Filling brings together the prepared fruit juice, the primary container and small residues of the sterilizing agent, hydrogen peroxide. It is also close to the point where the straw is applied, another food contact surface. This operation clearly requires a record keeping step, illustrated in Figure 32. This document links the lot numbers of the fruit, the finished sugar solution and one of the primary packaging materials.

It is very important either to assign a new batch code (and to start a new Figure 32) whenever the code numbers of any of the inputs changes or at least to record the changing batch numbers on a single Figure 32.

The production code normally appears on the outside of the primary package. Remember that one item of information to be shared with your customers is the output lot number (or this product code plus some information included on the label). Since the production date is required anyway we will use it also as part of the production code:

30/4/2007

The remainder of the production code will be represented by the time of coding:

0735

or by the hour of coding, represented by a single digit such as:

B

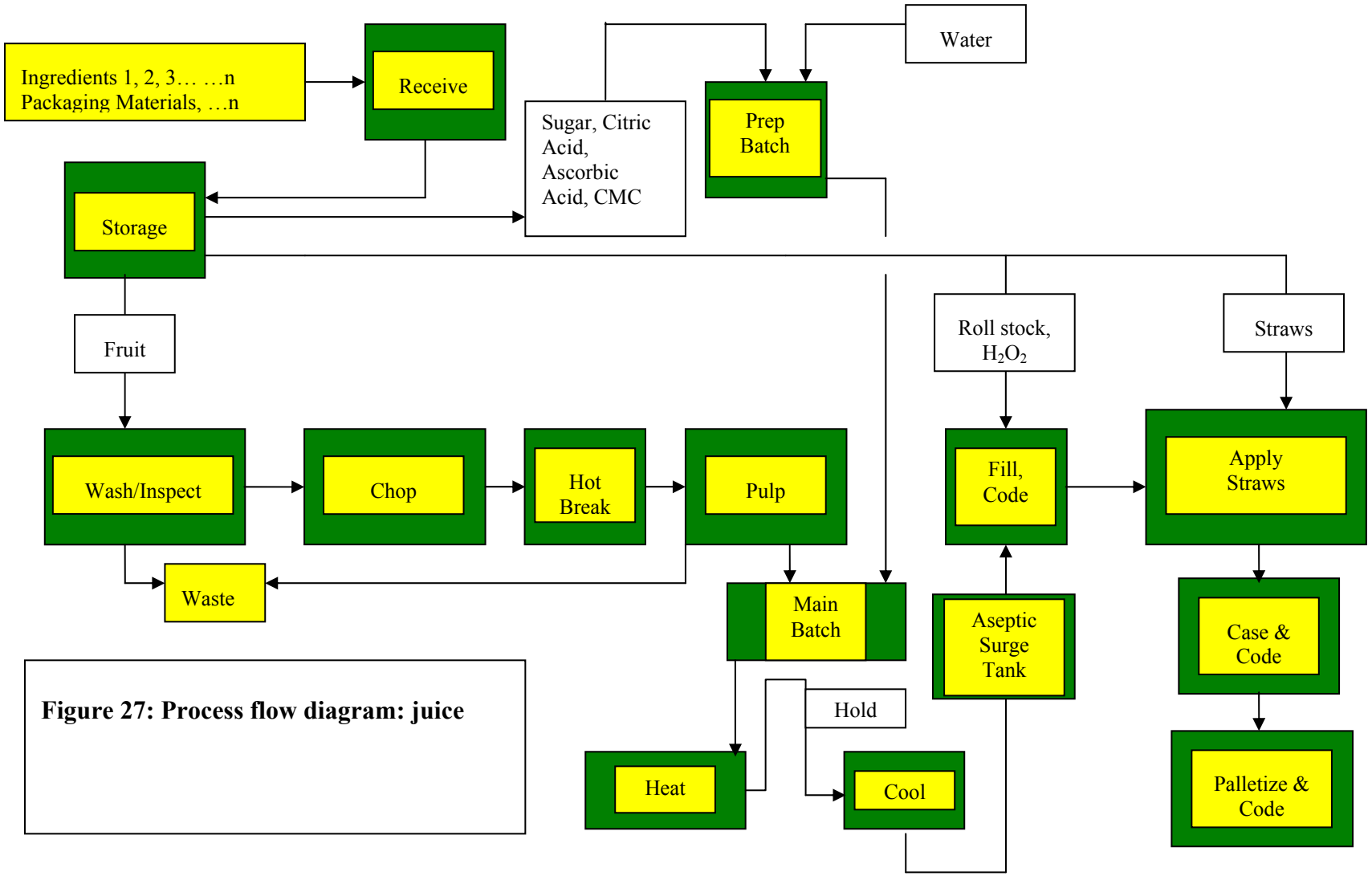

Figure 27: Process flow diagram: juice

Figure 28: Batching sheet for hot break

Product:		**Date:**	
Output Batch Number:			
Input Ingredient:	**Ingredient Lot Number**	**Amount (Kg)**	**Time Start/End**
Fruit, inspected & washed			
Fruit, inspected & washed			
Fruit, inspected & washed			
Fruit, inspected & washed			
Fruit, inspected & washed			

Figure 29: Batching sheet for sugar solution

Date:	**Output Batch Number:**	
Time Start:		
Input Ingredient:	**Lot Number**	**Amount (Kg)**
Sugar		
Citric acid		
Ascorbic acid		
Water	Not applicable	

Figure 30: Main batching sheet

Date:	**Output Batch Number:**	
Time Start:		
Input Ingredient:	**Lot Number**	**Amount (Kg)**
Fruit pulp		
Sugar solution		

Figure 31: Batching sheet for aseptic surge tank

Product:			**Date:**
Output Batch Number:			
Input Ingredient:	**Input Lot Number**	**Amount (Kg)**	**Time Start/End**
Finished juice from main batch			
Finished juice from main batch			
Finished juice from main batch			
Finished juice from main batch			
Finished juice from main batch			

Figure 32: Finished product batching sheet

Date:		**Product Type**
Time Start:	**Time Finished:**	**Container Size/Type**
Input:	**Input Lot Numbers**	**Quantity**
Fruit juice		
Container		
Hydrogen peroxide		
Straw		
Output:		**No. Containers in Code Number**
Production Lot Number		

or by the shift, also represented by a single digit:

C

If the same or similar products are to be filled on different lines, some indication of the line should appear on the product code as well:

L1

If the company has only a single factory location so no additional code is necessary to designate location.

12.5.4.6 Consider the casing and palletizing operations

Continuous mixing will occur in both operations. Mixing primary packages with different code dates in the shipping case is not a problem as long as both codes are marked on the case and a record is kept linking the mixed case to its pallet number. Palletizing is a similar situation.

No new lot identifier is required on each case, since the production code(s) and a label can appear on each case.

The pallets may be identified with a label shown in Figure 13. Again, the same production codes that are on the cases and individual containers may be used to identify the pallets, combined with other product information shown on Figure 13.

12.5.5 Link relevant food safety data

Food safety data should be recorded at the step at which they apply. In this example, heavy metals and pesticide residue usually applies to the raw ingredient as received. These data, therefore, should be part of the receiving documents, thereby linking them to the suppliers and to the finished product.

12.5.6 Why bother attempting to improve precision in traceability in a process that has so much blending of product codes?

This is an excellent question and its answer depends on what one expects from a traceability system. A company operating such a process might satisfy its one up/one down responsibility as well as trace internal traceability by assigning one lot number after any step that involves **idiosyncratic** blending. However, another company may feel that the increased precision would limit the scope of a recall sufficiently so that this extra effort in traceability is worth it. This is especially true for companies with evaporators, which may operate for weeks without being shut down, emptied and cleaned.

13 Management Control of the Traceability System

Any system in any company can not be sustained without commitment on the part of management in the form of necessary resources and integration of that system into the company's culture, procedures and other management systems. The purpose of this section is to illustrate some methods to integrate a sustainable traceability system into a company.

In order to assure that a traceability system is sustainable in the operation of the company, it must have the resources (both manpower and financial) to operate and it must be linked to the company's management's policies and procedures. Part of this linkage involves documentation that assigns roles and responsibilities regarding traceability to specific departments and individuals. This documentation would include an organization chart, job descriptions and specific budget allocation for those individuals responsible for traceability.

The company should have its own Traceability Manual specific to its needs to trace hazards and to link to applicable legislation. Key personnel should have access to copies of the manual and of applicable legislation. Company procedures should call for management to review the traceability system and its underlying assumptions at a specified frequency. Those items that should be reviewed include the manual itself, specifications of raw materials & finished products, the coding systems used by your company and your suppliers, and whatever agreements that may exist between your company and your suppliers & customers insofar as they might affect traceability. Also specified for review should be a list of key auditing records, both internal and external: the procedures (scope, checklists, frequency, and corrective action) for internal auditing of the traceability system, the results of the audits themselves, including the audits of the customers and suppliers.

The company's training plan should include traceability and the training history and experience of those responsible for traceability should likewise be documented and periodically reviewed.

At the factory level, management control of the traceability system should include assuring that the process flow diagrams and traceability procedures exist, are current, approved and stored in the correct place. The next step is to assure that the procedures have been and are enacted and that the achievement of traceability follows logically from these procedures and the process flow diagram.

Factory management must also assure that the codes for raw material, work in progress and finished product exist, are in the approved format, and are all traceable throughout the process.

Exercise: How would you integrate a traceability system into the procedures of your own company?

Summary

Traceability systems, like quality systems, must be linked to corporate policies and procedures to be effective and sustainable.

14 Verification of the Traceability System

This section describes one method of integrating a traceability system into a company's procedures. Verification is simply another word for checking that established procedures are being followed.

On a more technical level, verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the traceability system in place.

Verification that a procedure is being followed usually involves an internal audit (or checking by an individual inside your company). Internal audits may include reviewing documents, random checks and mock recalls.[35]

One component of verification might be a periodic review of status (such as the results of a mock recall or the results of an audit), changes (in your own process, package or processing, or in those of your suppliers and/or customers), or new developments (such as customer complaints, new regulations or new methods of evaluating data).

The frequency of verification usually varies by commodity, but it is recommended that fresh produce exporters make random checks daily and to conduct a mock recall once a week at minimum. Review of documents should occur at "planned intervals" to assure that the traceability system:

a) conforms to expectations and to the food safety management system requirements established by the organization, and

b) is effectively implemented and updated.

Internal audits conducted by a document review should, when possible, be compared to actual practice while the factory is in operation.

An audit program should be planned taking into consideration the importance of the processes and areas to be audited, as well as any procedural updates resulting from previous audits. The audit criteria, scope, frequency and methods should be well-defined. The auditors should be selected to ensure objectivity and impartiality of the audit process. Auditors should not audit their own work.

The management responsible for the area being audited should ensure that corrective actions are taken without undue delay to eliminate nonconformities and their causes. Follow-up activities should include verification of the corrective actions taken and reporting the verification results. Management should ensure that procedures to eliminate such nonconformities are established and followed. These procedures should include methods of documentation of such nonconformities and subsequent corrective action.

Additionally, management should establish key performance indicators for the traceability system in order to measure the system's effectiveness.

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[35] A mock recall might involve randomly identifying a case or pallet or your product at a customer's warehouse and, using the information on the label, making sure that the product can be traced through your operation to the supplier.

Exercise: Given the process documented in Appendices 1-11, how would you structure a verification program:

- *Which methods would you use?*
- *At what frequency?*

Exercise: Using the Basic Traceability System Checklist, (Appendix 13), see if the process you have documented has any deficiencies.

Summary

- "Verification" means checking
- An "internal audit" means checking that is being done by an individual inside your company
- An internal audit may include reviewing documents, random checks and mock recalls
- Internal audits, when possible, should be compared to actual practice while the factory is in operation

15 Suggestions for Further Reading

Annotated EC Guidance on the Implementation of Articles 11, 12, 16, 17, 18,19 and 20 of Regulation (EC) N° 178/2002 on General Food Law
Conclusions of the Standing Committee on the Food Chain and Animal Health
http://www.foodlaw.rdg.ac.uk/pdf/eu-05007-food-law-guidance.pdf

CODEX: Principles for traceability/product tracing as a tool within a food inspection and certification system CAC/GL 60-2006
http://www.codexalimentarius.net/download/standards/10603/CXG_060e.pdf

Improving traceability in food processing and distribution Ian Smith and Anthony Furness, eds. (CRC - Mar 31, 2006)

Food Traceability Report (weekly e-newsletter):
http://www.foodtraceabilityreport.com/home.asp

Traceability Best Practices, Fresh Produce Industry, North America; (Canadian Produce Marketing Association/Produce Marketing Association Traceability Task Force)
http://www.pma.com/view_document.cfm?docID=50

Fresh Produce Traceability, a Guide to Implementation, Version 2
Produce Marketing Association
Canadian Produce Marketing Association, October 2006
http://www.pma.com/view_document.cfm?docID=87

Guidance Note: Regulation (EC) 178/2002 (General Food Law)
Food Safety Authority of Ireland, February 2005
http://www.fsai.ie/legislation/eu_hygiene_regs/178_2002_Guide_FSAI.pdf

Code of Practice No. 5: Food Incidents and Food Alerts
Food Safety Authority of Ireland, 2004
http://www.fsai.ie/publications/codes/cop5.pdf

Can-Trace Multi-Ingredient Working Group
Multi-Ingredient White Paper, March 2006
Agriculture and Agri-Food Canada
http://www.can-trace.org/portals/0/docs/Multi%20Ingredient%20Final%20Report%20March%202006%20-%20mjf.pdf

Traceability Decision Support Tool
Agriculture and Agri-Food Canada
http://www.can-trace.org/portals/0/docs/Can-Trace%20Decision%20Support%20Template%20v1.03.xls

Can-Trace Integration Guidelines
Final Report April 2006
Agriculture and Agri-Food Canada
http://www.can-trace.org/portals/0/docs/Can-Trace%20Integration%20Final%20Report%20April%202006%20-%20mjf.pdf

Can-Trace Technology Guidelines
Agriculture and Agri-Food Canada, March 2006
http://www.can-trace.org/portals/0/docs/Can-Trace%20Technology%20Guidelines%20Mar%202006%20-%20mjf.pdf

Report on Can-Trace National Food Traceability Consultation Sessions
Agriculture and Agri-Food Canada, June 2005
http://www.can-trace.org/portals/0/docs/ConsultationSessionReport.pdf

Can-Trace Produce Pilot Project Report
Agriculture and Agri-Food Canada, 2004
http://www.can-trace.org/portals/0/docs/Can-TraceProducePilotProjectReport.pdf

Can-Trace Decision Support System for Food Traceability
Agriculture and Agri-Food Canada, 2004
http://www.can-trace.org/portals/0/docs/Can-TraceDecisionSupportSystemforFoodTraceability.pdf

Report of the Can-Trace Small and Medium Enterprises (SME) Working Group
Agriculture and Agri-Food Canada, May 19, 2004
http://www.can-trace.org/portals/0/docs/ReportoftheCan-TraceSMEWorkingGroup.pdf

International Standard ISO22005, First Edition, 2007-05/15: Traceability in the feed and food chain-General principles and basic requirements for system design and implementation

16 Cross references to ISO22005

This appendix is intended for those with access to ISO22005, First Edition, 2007-05/15: Traceability in the feed and food chain-General principles and basic requirements for system design and implementation. Below is a table which references each section of the ISO standard with the appropriate section of this manual.

It is important not to confuse this manual with the ISO standard. That standard contains just what the title says: general principles and basic requirements. It does not tell you how to achieve these requirements since methods of implementation is decided by the individual company. This manual attempts to suggest methods and models for implementation of traceability.

Any company intending to design and implement a traceability system according to the ISO standard should look first to that standard for requirements and then to this manual for suggestions on how to implement these requirements.

ISO22005		References in This Manual
	Introduction	Various
1	Scope	2 Introduction
2	Normative references	None
3	Terms and definitions	3 Glossary of Terms
4	Principles and objectives of traceability	4 What is Traceability 5 E.U Legislation on Traceability 6 Benefits of Traceability
5	Design	2 Introduction 5 E.U Legislation on Traceability 6 Benefits of Traceability 7 Technology Necessary for Traceability 8 Linkage of Information 9 Internal Traceability 10 Some Common Problems in Traceability 11 How to Proceed, Generally 12 How to Proceed by Sub-Sector

ISO22005		References in This Manual
		13 Management Control of the Traceability System 14 Verification of the Traceability System
6	Implementation	11 How to Proceed, Generally 12 How to Proceed by Sub-Sector 13 Management Control of the Traceability System 14 Verification of the Traceability System
7	Internal audits	14 Verification of the Traceability System
8	Review	14 Verification of the Traceability System

17 Basic Traceability System Checklist

When auditing a facility for traceability, the following checklist is a place to start. Please note that is intended to be illustrative, not definitive or necessarily complete.

- Raw materials should have a certificate of origin:
    - All raw materials are of known origin and approved in the country of production and in the importing country
- Any raw materials lacking a certificate of origin should at least come with a lot number (or a lot number assigned) indicating whatever information is known about the lot
- Primary packages materials should be considered a raw material
- Raw materials, work in process and finished products should have a consistent coding system
- The batch code should be known, visible and documented for all product in every step of production from entry of raw material until dispatch
- Batches or individual pallets, cases or other units should be easily traced and tracked at any given time through the established documentation and record keeping system
- Places in the process where different codes of raw materials are blended should be identified and appropriately treated in the records
- Waste should be segregated, identified and isolated from products that are not waste
- Rejected product and product undergoing inspection should be segregated from approved product
- Each unit of packaged food should bear permanent and legible code marks or lot numbers. The coding system and labeling must comply with regulatory and customer requirements
- This code should identify the establishment, the day, month and year in which the food was produced
- Code marks may be “open” or “closed.” If closed, the key to understanding the code must be in the possession of factory and management personnel
- The company should have a traceability manual (or its equivalent as part of a quality system)
- A traceability team should exist and the traceability responsibilities of everyone should be defined.