

Guidance for Dairy Product Enhanced Traceability

Voluntary Practices and Protocols for
Strengthening the U.S. Dairy Supply Chain

Issued April 1st, 2013, revised 2016

Version 3 --- July 15th, 2020



The information provided herein is for informational purposes only. The Innovation Center for U.S. Dairy (“The Innovation Center”) makes no representation or warranty with respect to the completeness, accuracy, reliability, or suitability of any information contained herein. We recommend that practitioners consult an attorney concerning the laws applicable to any particular situation as well as their own scientific experts to evaluate the applicability of any recommendation to their particular situation. By utilizing the materials contained herein, you agree to release the Innovation Center from any and all liability that may result from your use of the information provided.

Acknowledgements

2013 Guidance contributors (company affiliation at the time): Jeff Acker (Dairy Farmers of America), Dermot Carey (Dairgold Inc.), Barney Krueger (Glanbia Foods, Inc), Clay Detlefsen, (International Dairy Foods Association), Craig Nelson (Food Automation LLC), Vikki Nicholson (US Dairy Export Council), Jeremy Travis (Hilmar Cheese and Ingredients), Edith Wilkin (Leprino Foods)

2020 Update: Edith Wilkin (Leprino Foods), Tim Stubbs (Innovation Center for U.S. Dairy)

Reviewers: Niaz Bakhtyar (Hilmar Cheese & Ingredients), Michelle Ferry (Saputo USA), Rylee Sterrett (Prairie Farms), Susan Zucker (Agri-Mark)

This Traceability Guidance is one part of the **U.S. Dairy Stewardship Commitment**, a voluntary pledge through which the U.S. dairy community can document and demonstrate its progress to consumers, customers and other stakeholders. Companies that adopt the U.S. Dairy Stewardship Commitment meet defined criteria for important areas including animal care, the environment, food safety, traceability and other important initiatives to report on impact in a transparent and meaningful way. Learn more about the Stewardship Commitment at commitment.usdairy.com

The Innovation Center for U.S. Dairy® is a forum that brings together dairy farmers, cooperatives, processors, retailers and trade associations to address the changing needs and expectations of the marketplace and consumers through a framework of shared best practices and accountability. Initiated in 2008 by dairy farmers, Innovation Center companies collaborate on efforts that are important both to the dairy community and our customers – issues including animal care, the environment, food safety, nutrition and health, and economics. The Innovation Center is committed to continuous improvement from farm to table, striving to provide the world responsibly produced dairy foods that nourish people, strengthen communities and foster a sustainable future.

Foreword

In order to share best practices and ensure the global competitiveness of U.S. products, a work group comprised of U.S. dairy processors was convened by the Innovation Center for U.S. Dairy to:

- 1) Gain a better understanding of the variety of approaches being used for traceability by the entire industry, and
- 2) Provide guidance to help all companies refine and improve their programs

These practices were compiled and validated in a one-year pilot program and published in 2013 as this Guidance Document. In 2016 and 2020 the guide underwent minor updates including language updates from Food Safety Modernization Act (FSMA) implementation.

This document contains information and guidance to help implement traceability at your company. The following pages will guide you through a process of comparing your current practices to a set of minimum requirements for traceability and identifying areas that may need improvement. The areas detailed include:

- Record keeping
- Data collection - Lot Numbers, ingredient information
- Efficacy of traceability protocol for verification on content of final product
- Testing and validation of traceability in mock trace/recall exercises

When this industrywide traceability effort began, five processors who comprised more than 20 percent of U.S. milk production took part in a year-long pilot study that benchmarked and identified practices which met both customers' and processors' needs. When the Guidance was issued in 2013 these companies (Darigold, Glanbia Foods, Hilmar Cheese Company, Leprino Foods, and Michigan Milk Producers Association) were joined by many others in committing to, adopting, and applying these traceability best practices. At the time of this update 35 companies, representing 70% of U.S. milk production, have committed to follow this guidance by making the Traceability Commitment. This commitment is now a key part of the Innovation Center's broader "U.S. Dairy Stewardship Commitment".

The companies each agreed to the "U.S. Dairy Traceability Commitment," which reads:

"(Name of processor) commits to adopt and apply the recommended best practices for traceability outlined in the Innovation Center for U.S. Dairy's "Guidance for Dairy Product Enhanced Traceability." The best practices include these three pillars of dairy traceability for processors:

- *Modeling physical plants to know where new Lots enter and where products transform*
- *Creating a Lot identifying mark that will be recognized and used by customers*
- *Record-keeping that will assist in expedient and effective recall capability*

(Name of processor) will support the Innovation Center for U.S. Dairy's goal of increasing the percent of the U.S. milk supply using enhanced dairy traceability practices."

For more information, and to download this document, please visit the Innovation Center for U.S. Dairy website at www.usdairy.com/traceability. If you have specific questions, please email innovationcenter@usdairy.com. Our sincere thanks for your willingness to join us in this important effort.

Table of Contents

These guidelines can be accessed and downloaded at
www.usdairy.com/traceability

Overview	6
The Basics of this Guidance Document.....	7
Understanding the Components of a Traceability Process	10
Modeling the Physical Process for Traceability.....	14
Key Data Elements (KDEs) - Lot Entry Points in Your Process	14
Special Considerations	
Raw Milk Receiving	14
Milk Hauler Responsibility	15
Using Farm ID.....	15
Raw Milk Pooling.....	15
Whey Pooling	15
Rework	15
Packaging Materials	16
Common Lot Entry Points Missed	16
Disposed Ingredients or Products.....	16
Examples	
Skim Milk Powder Facility	16
Nonfat Dry Milk Powder Facility	17
Fluid Milk Facility.....	17
Ice Cream and Frozen Dairy Facility	18
Cultured Products Facility	18
Cheese Manufacturing Facility.....	19
Butter Manufacturing Facility.....	19
Whey Products Manufacturing Facility.....	20
Critical Tracking Events.....	21
Special Considerations	
Storage that is not cleaned/CIP'd on a frequent basis	22
Continuous Processes.....	22
Adding Rework into the Process	23
Examples	
Skim Milk Powder Facility	23
Nonfat Dry Milk Powder Facility	24

Fluid Milk Facility.....	24
Ice Cream and Frozen Dairy Facility	25
Cultured Products Facility.....	25
Cheese Manufacturing Facility.....	26
Butter Manufacturing Facility	26
Whey Products Drying Facility	27
Product Labeling.....	28
Making Your Lot Identifying Mark Stand Out.....	28
Recommended Lot Identifying Mark Content	29
Including SKUs and Weights into the Lot Identifying Mark.....	29
GTIN/GS1 as the Lot Identifying Mark	30
What Not to Do	30
Record Keeping.....	31
General Information	31
Recall Report.....	32
Traceability Record Content.....	32
Basic Record Content	32
Daily Records	33
Specific Record Recommendations	33
Post Production	34
Record Retention, Security and Back-up	34
Appendices	35
Conducting a Recall Using this Guidance Document	36
Story-based Mock Recalls	38
Working with Vendors to Reduce the Liability of a Recall	39
Limiting Exposure by Processing Methodologies	40
A 21-point Traceability Checklist.....	42
Glossary of Traceability Terms.....	43
Example Records	45

Overview

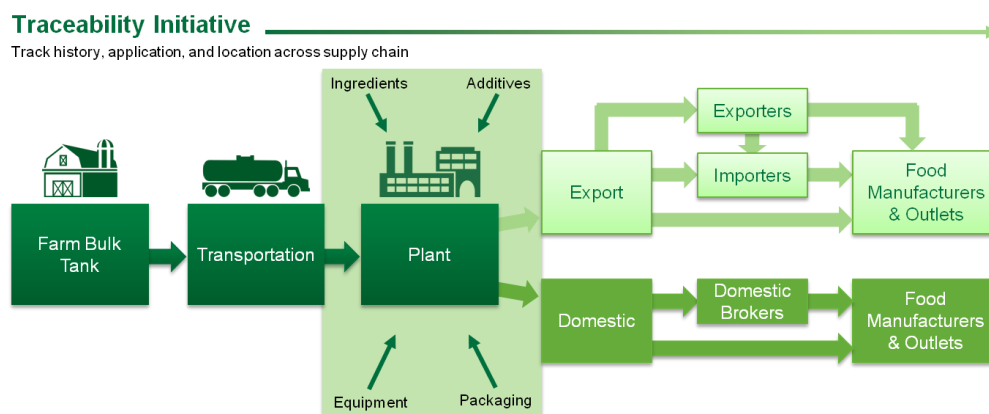
Purpose of this Guidance Document

This Guidance Document is intended to guide management and supervision at both corporate and plant levels in developing and maintaining a traceability process that will: 1) satisfy the requirements of the Food Safety Modernization Act (FSMA), 2) align traceability records to meet customer needs and 3) ensure successful recall audit outcomes. Moreover, this document will provide guidance on creating a model to enhance traceability practices. This guidance has been tested by U.S. dairy processors of various sizes and sectors such as fluid milk, cheeses, nonfat dried milk and whey powder. No matter how advanced a firm's current practices, each may identify new methods to enhance current traceability practices.

This Guidance Document is intended to be used in tandem with a reliable, three-pronged process to create a complete and robust traceability system: Quality Assurance systems to minimize the chance of ever having a food safety incident; Food Safety processes to identify an adverse incident quickly, possibly before the food has even left the facility; and Traceability to isolate product in question and reduce or prevent brand damage in the event a firm or one of its vendors experiences a food safety issue.

As you begin working with this Guidance Document, you will start with a modeling exercise to determine where all Lot Entry Points exist. This is followed by an examination of how materials flow through your process and identification of points where product is transformed. Next, current product labeling practices are examined, primarily those that are used to identify each Lot. How these numbers are collected, used and communicated through the supply chain will also be assessed using this Guidance Document. It is important to appreciate that processing aids that do not appear in ingredient labeling also need to be identified and tracked as part of traceability program.

Recordkeeping needs that may arise from enhanced labeling and information collection are addressed. Near the end of this document you will find a handy 21-point checklist of important components of a traceability protocol that are critical to the mock recalls used to test any traceability system.



The Basics of this Guidance Document

How to Use This Document

This document will guide you through the following basic steps to achieve a robust traceability system for your facility:

1. Model your physical plant to understand where new Lots enter and where products are transformed.
2. Create a Lot Identifying Mark that will be used in all your records and will also be recognized and used by your customers.
3. Create a record set that will assist in expedient and effective recall capability.

Modeling your physical plant will feed the design of your recordkeeping requirements. Then, you will choose your Lot Identifying Mark or Product Label to finalize the information you will need to develop the record sets. The Lot Identifying Mark is the unique number that identifies this product and its Lot, and it is the mark both you and your customers will use for your traceability records. The Food Safety Preventive Controls rule requires that food safety records must tie to specific product or ingredient Lots, these are the same Lots referred to in this guidance.

Many examples of typical industry manufacturing paradigms are included in each section of this Guidance Document for your reference. Use them as examples for designing your process. None of the examples are perfect, but they should give you a good starting point for your facility.

For IT professionals, this Guidance Document is also a guide for the development of an electronic traceability system for organizations implementing electronic tracking. The same examples apply.

Who Should Use This Guidance?

This guidance is intended for those involved in the receiving, storing, processing and shipping of dairy products. This includes employees who are responsible for product quality, safety and/or traceability. Senior and mid-level managers of operations and supply chain management will also benefit.

Minimum Standards for Traceability

This Guidance Document is intended as a minimum level of standards for implementing a robust traceability process. A more complex solution can be designed, which will allow smaller recalls with decreased peripheral impact. Most electronic implementations will support the more complex traceability protocol.

While electronic traceability is an advantage, no specific platform or operating system is recommended in this guidance. This Guidance Document will allow all manufacturers to design a process and choose individual solutions based on their financial and other internal justifications.

Use of Lot Identifying Mark

The importance of having consistency in the way products are identified cannot be understated. Consistent identification that provides sufficient information for full traceability can be a challenge for many facilities. While a level of automation improves consistency and proper product identification, hand-writing this information is common and is addressed in this document.

It is recommended that Lot identification is specified for each product type manufactured at the facility and included in the product description section of the Food Safety Plan.

The findings of the research that informed this document demonstrate that both barcodes and handwritten records are pervasive in the dairy foods industry. In our pilot testing, even plants with the lowest level of automation were able to create good traceability processes and track product through processing when following the methods of this Guidance Document. This document provides guidance and examples of implementing consistent Lot Identifying Mark technology that also provides human readable information to keep automation requirements to a minimum.

Important Principles of a Traceability Process

This Guidance Document covers the concepts you need to understand and implement to create a successful traceability process. With this Guidance Document, a facility can establish a robust and effective plant-wide traceability process with minimal time and expense.

To establish a traceability process, you will need to take the following steps:

Identify and Record Lot ID's (Key Data Elements, KDEs)

1. Identify the places in your facility where bulk products, ingredients, or packaging materials are added to make your final product.
 - a. Create a method of recording the Lot ID's for each of these places.
 - b. Decide which identifying mark will be used for the Lot ID on the various materials.
 - c. Train your employees to be consistent and accurate when recording Lot ID's.
 - d. Keep your records in a way that makes the Lot ID's easy to find.

Identify and Record Flows (Critical Tracking Events, CTEs)

2. Identify the main flow paths in your facility that products pass through from beginning to end.
 - a. Create a method of recording each of these flows and ensure they are reflected in your food safety plan.
 - b. Train your employees to be consistent and accurate when recording these flows.
 - c. Keep your records in a way that makes it easy to relate the above recorded Lot ID's with the flows.
 - d. Track your flows between the facilities within your company or cooperative. Keeping good records of your inter-location transfers, or a system that can link the traceability of your products and materials in-process (including rework) between facilities will reduce your time to identify products or exclude your company from a recall.

Place a Standard, Human Readable Lot ID on Your Products (Lot Identity, Lot ID)

3. Label your final products with a simple, human-readable Lot ID so everyone using your products in their manufacturing can also maintain consistent and accurate records. This LOT ID is a critical part of a good traceability system, and the ability to recall quickly and effectively.
 - a. Use this Lot ID in your records as either a primary identity, or at least a searchable field in your electronic or ERP system.
 - b. Use this Lot ID in every record, both manual and electronic (ERP)
 - c. Add “**LOT**” or “**Lot ID**” near the human-readable Lot ID so the operators in your customers’ facilities can easily record the correct identity.

The following pages explain the above steps for creating a traceability process you can rely upon. Use this Guidance Document and the examples provided as a guide for your facility. Involve your management, quality, and information services staff to trace your processes and compare your processes to the examples in this Guidance Document. Based on your results, create your own enhanced traceability process at a standard level that has been proven to work.

Understanding the Components of a Traceability Process

Before we get into the details of the Guidance Document, we will first outline the most important components of an effective traceability solution. Essentially, a good traceability process should allow a manufacturer to perform three key tasks:

- Find the source of an issue.
 - The records of the bulks/ingredients/materials should be able to identify when and where a suspect lot entered the process. It also should be able to quickly identify which Lot ID's contributed to a final product Lot ID.
- Find the common point of convergence of all products that are (potentially or actually) unsafe or noncompliant in the regulatory sense. This Guidance will refer to these going forward as “affected”.
 - As soon as more than one final product is identified as affected, you will need to identify the common origin or source of the problem quickly. The affected products could be multiple packages or lots in one facility, or different products across several facilities in a company. The origin could be a bulk material, ingredient, equipment or packaging materials.
- Once the origin of the issue is identified you should find all the products that contain that common point of convergence across your corporation.
 - This will significantly help expedite and accomplish the control of affected materials and/or products to be recalled

Performing a product trace in these two directions depends upon your ability to quickly categorize your production into three groupings.

1. Inclusion

Inclusion is the ability to *INCLUDE* any product(s) that could contain any amount of affected material. This includes products that are associated with the same pipes, tanks, silos, and processing equipment that could have residual amounts of the suspect material because they had not been cleaned since the affected material was present. Keep in mind that good inclusion traceability requires knowing when and where each ingredient or product entered your production environment and the process it traveled through.

The simplest method of guaranteeing full inclusion is to recall all products made within a range of dates. However, this also has the highest financial impact, the largest potential impact on your customers' inclusion assessment, and your vendors. A good traceability process should narrow the *INCLUSION* as much as possible.

2. Exclusion

Exclusion is your ability to *EXCLUDE* unaffected products that do not contain any affected material. This reduces the recall scope to just the products that could be affected. This process requires more complete records, including resetting the status of tanks, silos, and processing equipment when they are cleaned/emptied or the acceptance of a biological test effectively eliminating any preceding product from mixing with the next.

This process will create a second category or grouping for your final products to test against. Samples can be taken from the warehouse, cold box, or retail locations to confirm that the excluded products are safe to be sold.

3. Dilution

Dilution is your ability to separate the products that may have significant contamination, and those that may only have possible trace amounts. For example, a silo that received a load of affected milk would have the lowest *DILUTION*. If the silo was emptied but wasn't washed, this would leave possible traces to be carried into additional finished goods.

If your products can be divided by *DILUTION*, it might possibly narrow the scope of the recall. However, it is important to research and consult with experts and possibly regulatory on this. As in *EXCLUSION*, finished goods and products can be sampled and tested to determine what needs to be held or destroyed.

While the final decision of which products to hold and which products to recall and destroy will need to be made with your appropriate regulatory agency, the recalls will generally be narrowed considerably if you can separate your products accurately and quickly (within a few hours) into the categories above, and third-party lab tests confirm the accuracy of your traceability process results.

A good traceability process, whether electronic or manual, should be able to separate your production into these three groups. This will allow your management and quality staff to pull samples and begin testing quickly.

A good traceability solution can also be used as a proactive tool to enhance your company's quality process. Small changes to improve quality tests can result in quicker and more accurate tracing to the 'commonality,' or source of contamination, possibly avoiding the need for a recall entirely.

Coupled with a good quality assurance process and quality controls, good traceability solutions can identify and remediate potential issues before a recall becomes necessary. Traceability can be used as a work-in-progress process to isolate and possibly remove products proactively, long before they become a regulatory issue.

The following graphics demonstrate the concept of a Powdered Skim Milk facility that separated final products into three groups of Inclusion, Exclusion, and Dilution and as a result was able to reduce the amount of a recall.

Each graphic identifies product resulting from six farm loads. Figure 1 identifies every product resulting from those loads. In Figure 2, good sanitation records prove that the condensed could contain any part of those farm loads. In Figure 3, thorough traceability and sanitation records prove only trace amounts could be in nearly half of the final products. While each of these groups will need to be held and tested, it's possible they could be released, as we mentioned earlier in this document.

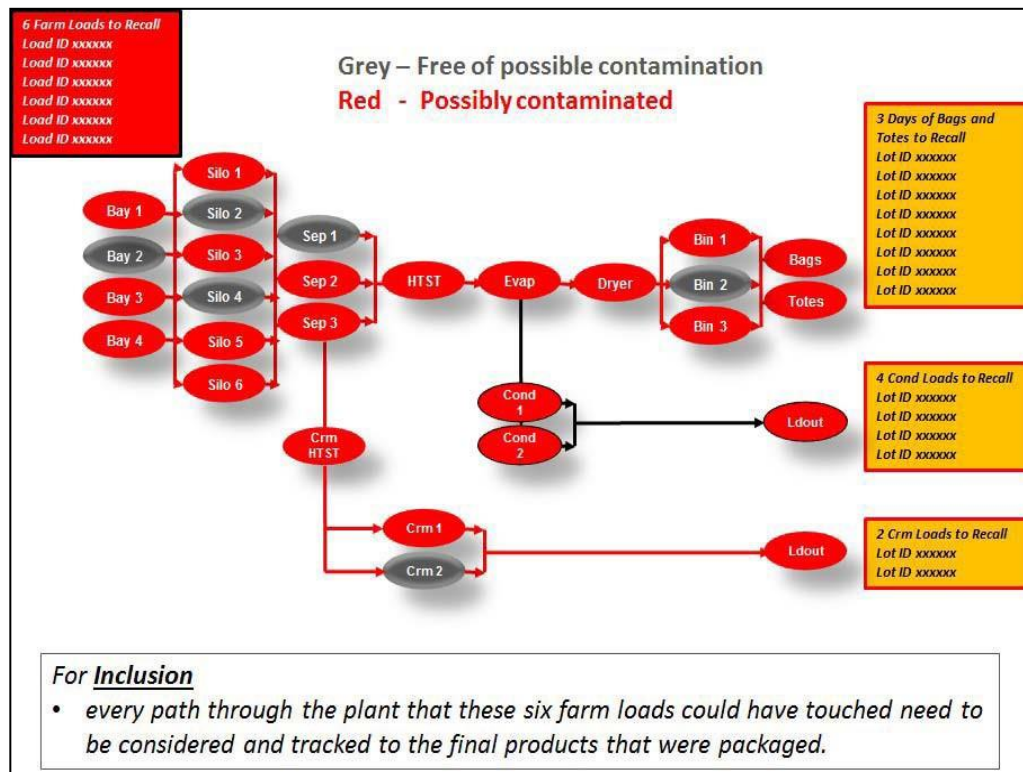


Figure 1 – Example of a Powdered Skim Milk Facility recalling to full Inclusion

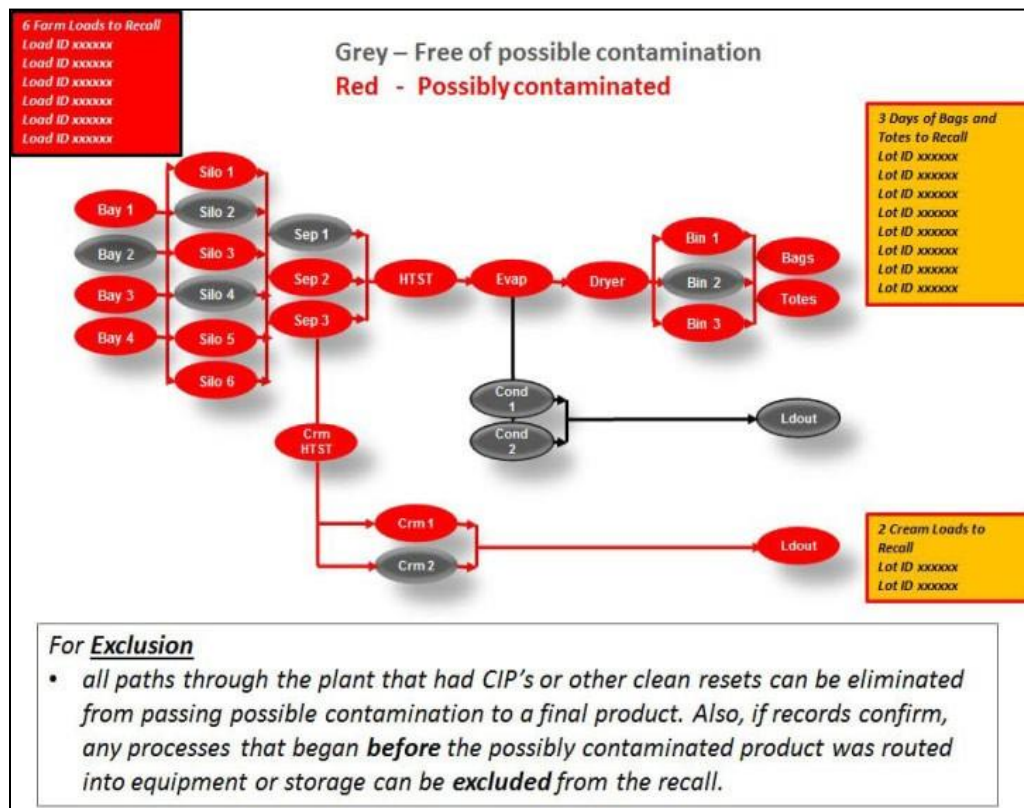


Figure 2– Example of a Powdered Skim Milk Facility recalling and excluding product not possibly affected.

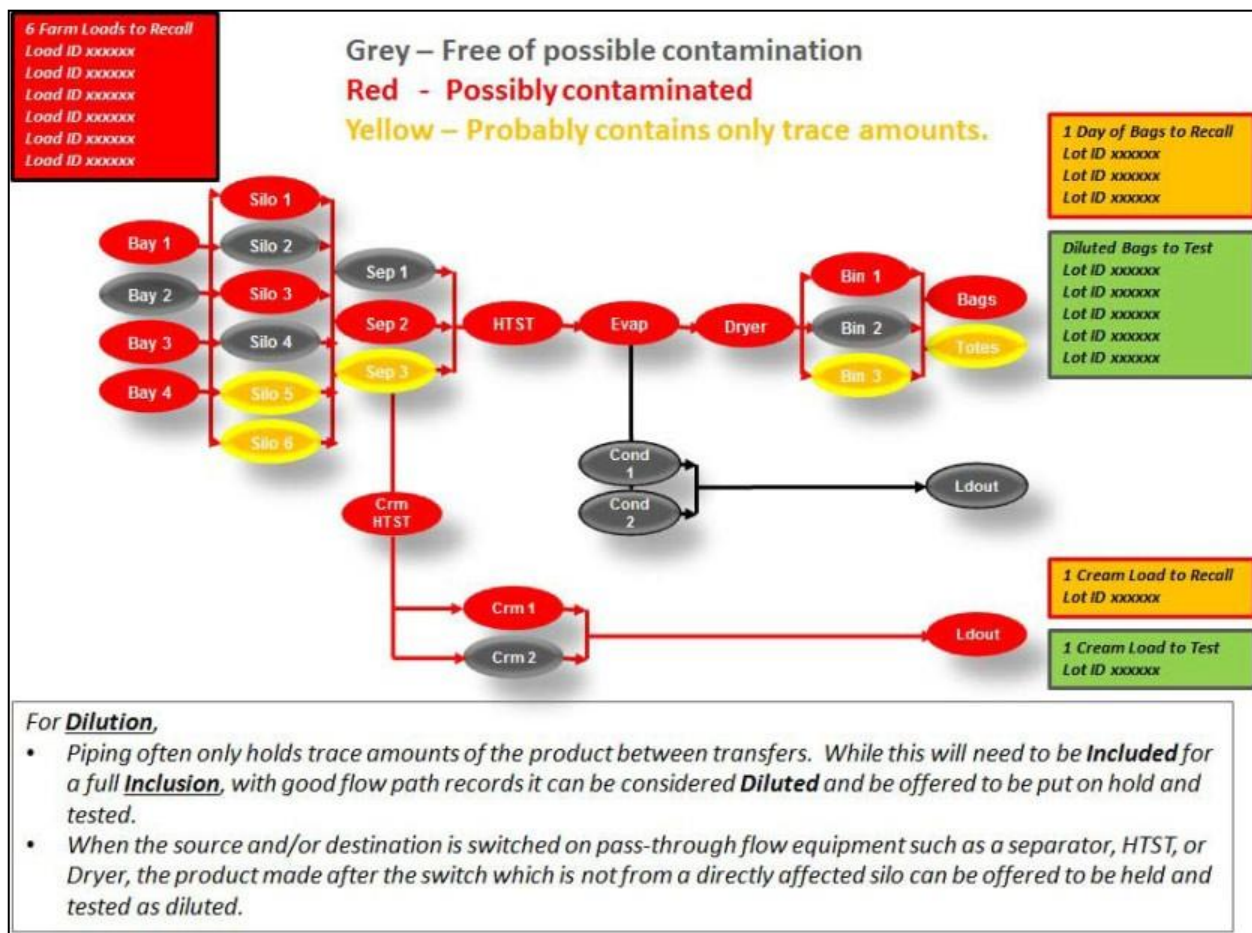


Figure 3– Example of a Powdered Skim Milk Facility identifying product that only has diluted contamination.

Modeling the Physical Process for Traceability

Modeling of the physical facility is used to create the best scenario for grouping your production into the three categories mentioned previously—Inclusion, Exclusion, and Dilution. To accomplish this, the modeling should be done in two parts:

- Identify the points in the process where bulk products, ingredients, and packaging materials enter (Lot Entry Points)
- Identify key points in the physical process where product is transformed, or lots can be discretely separated (Critical Product Flows)

Key Data Elements (KDEs) – Lot Entry Points in your process

These are the points where Lot Numbers need to be entered as the bulk products, ingredients, and packaging materials are brought into the process. While items received in the warehouse are important to track, good traceability rests on being able to first identify the Lots used in the process.

To begin, simply list the process points where a new Lot Number enters the process, such as the receiving bay, batch tank, liquefier, etc. If you are recording the Lot Numbers manually, you will need to create entry forms for these points. If you have an electronic system, you will need to create automation interface points at the KDEs - Lot Entry Points.

Some facilities will have several production areas, manufacturing different types of products like cheese, powder and butter. For traceability purposes, we recommend that these are modeled as individual facilities.

Equally as important as identifying the points where Lot Numbers are collected is planning which identifying mark the operators will collect for traceability. This is where many traceability solutions break down. Typically, there are multiple numbers on the bags or containers and the operators could choose the wrong identifying mark to put on the form (see section on Product Labeling for further information).

Special Considerations

The following specific areas are common in the dairy foods industry and should be considered when listing KDEs - Lot Entry Points:

- *Raw Milk Receiving*
 - When receiving raw milk, the receiving facility should consider each farm on a truck as a Lot of product received. The facility should have, or have access to, the farm name and address of the farmer. Model the receiving bay as a Lot Entry Point, and record each farm received and the silo that it was received into. This can be accomplished in three ways:
 - o The receiver records the load information only and turns the farm tickets into the office where the individual tickets are correlated with the load information. This would be used when multiple farms' pickups are accumulated on a single delivered load.

- Only the route information is recorded by the receiver because the load is co-mingled by a cooperative. In this case, the cooperative would need to have the farm information for each load and would be involved in the traceability effort if a recall were required.
- The receiver records the individual farm tickets that are received with the load information.
- *Milk Hauler Responsibility*
 - The records of the Milk Hauler performing the farm pickups are paramount to making a recall work and are the first step in creating a successful traceability process. Accurate identification of the farm, quantity, sanitation records, and sample of milk is essential.
- *Using Farm ID*
 - The Farm ID is often used as the identifier for the farm load. This can be helpful to trace the loads, since this number is issued by a State Department of Agriculture and is used in inspections and other records. However, many cooperatives and other dairy businesses assign their own farm ID as well. It is important that your haulers' and receivers' records are consistent and accurate.
- *Raw Milk Pooling*
 - When milk is picked up from the farm, loaded into silos or tanks and reshipped to dairy foods plants, it is the responsibility of the milk pooling facility to keep the records of the farm loads as they relate to the tankers shipped. This facility will be modeled as any other facility.
- *Whey Pooling*
 - When whey or permeate is pooled from various cheese manufacturing facilities, it is treated as a bulk loadout product at the cheese facility and is received by the whey processor as any other bulk product. The Lot identity is created at the cheese facility, and the same Lot identity is used to receive the whey into the processing facility. If the whey is pooled at a pooling or reloading station, the station must keep the correlated records as would any other dairy processing facility.
- *Rework*
 - Rework is common but complicates traceability. Consider and model rework as you would for any other ingredient or product. Rework is best handled in the following manner:
 - List the points where rework could be collected in the process. Identify and label the rework as a final product.
 - If the rework is not a final product, create a Lot Identifying Mark on the rework. If it is a bulk rework situation, create a Lot Identifying Mark and mark or tag the tank with this identifier.
 - If the rework is a final product, use that Lot Identifying Mark.
 - List the points where the rework is added back into the process. Record the Lot Identifying Marks as you would with any other ingredient. (KDE – Lot Entry Point)
 - Take note of the Rework narrative in the following section, “Critical Tracking Events.”
 - Limit rework from one day added into another as much as possible to reduce the co-mingling of lots.

- Examples of Rework:
 - Fluid milk filler flushes saved for use in chocolate milk.
 - Skim milk powder off-spec and reworked into the dryer.
 - Cheese fines added back into the cheese.
 - Ice cream batches either off-spec or excess is added to other batches.
- *Packaging Materials*
 - Any packaging materials that touch the product should be recorded.
- *Common Lot Entry Points Missed*
 - CO₂ addition, or other gases
 - Bags and liners for product packaging
 - Vitamins and small quantity additives
- *Discarded Ingredients or Products and Human Food By-Products for Animal Food*
 - Records should be maintained for ingredients, products, and packaging materials that are disposed. The quantity discarded, and the Lot Identifying Mark should be recorded as any final product.
- Shipping records for finished goods and materials in process.
 - Include quantities and bill of lading elements (customer/receiver)

Examples

The following pages are examples of simple manufacturing processes common in the dairy industry. In each example, we identify the places in the process where a new KDE - Lot Identifying Mark will have to be recorded, and list typical bulks/ingredients/materials that would need to be added to the process. In most cases, there are relatively few places in the process where Lot Identifying Marks need to be recorded. You should create a Lot Entry Point record for each of the points identified. In these examples they are listed in the text boxes.

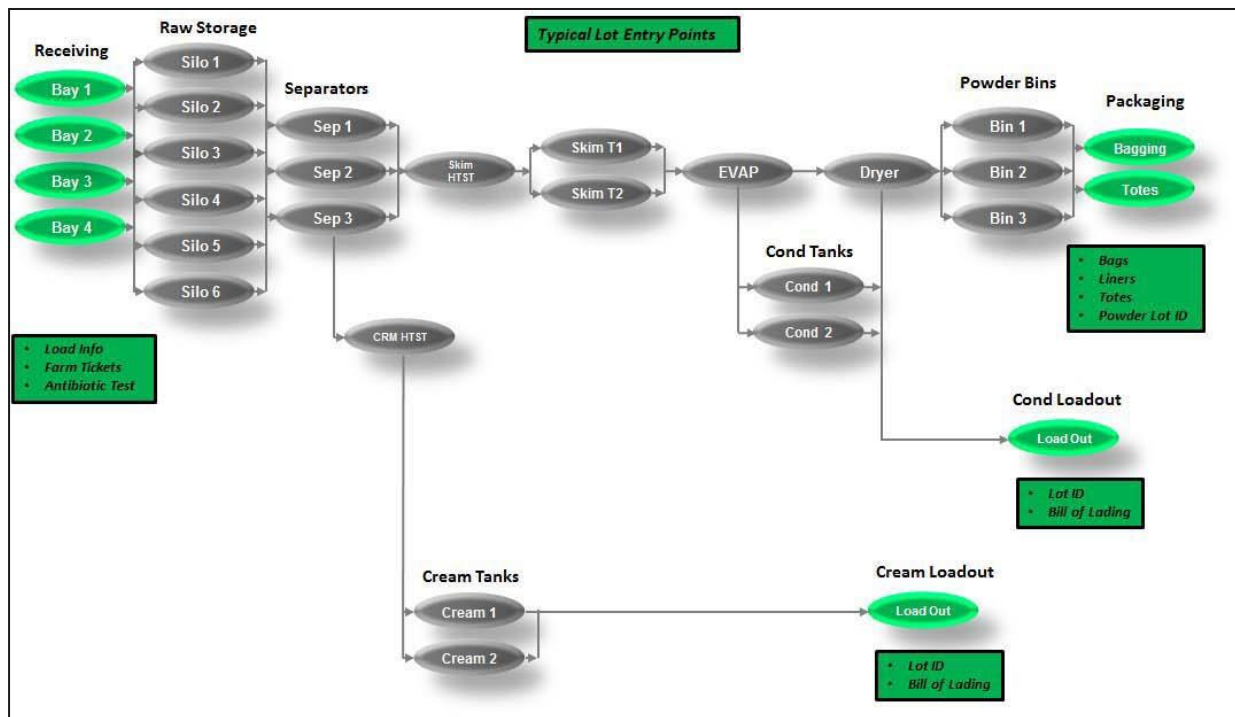


Figure 4 - Skim Milk Powder Facility

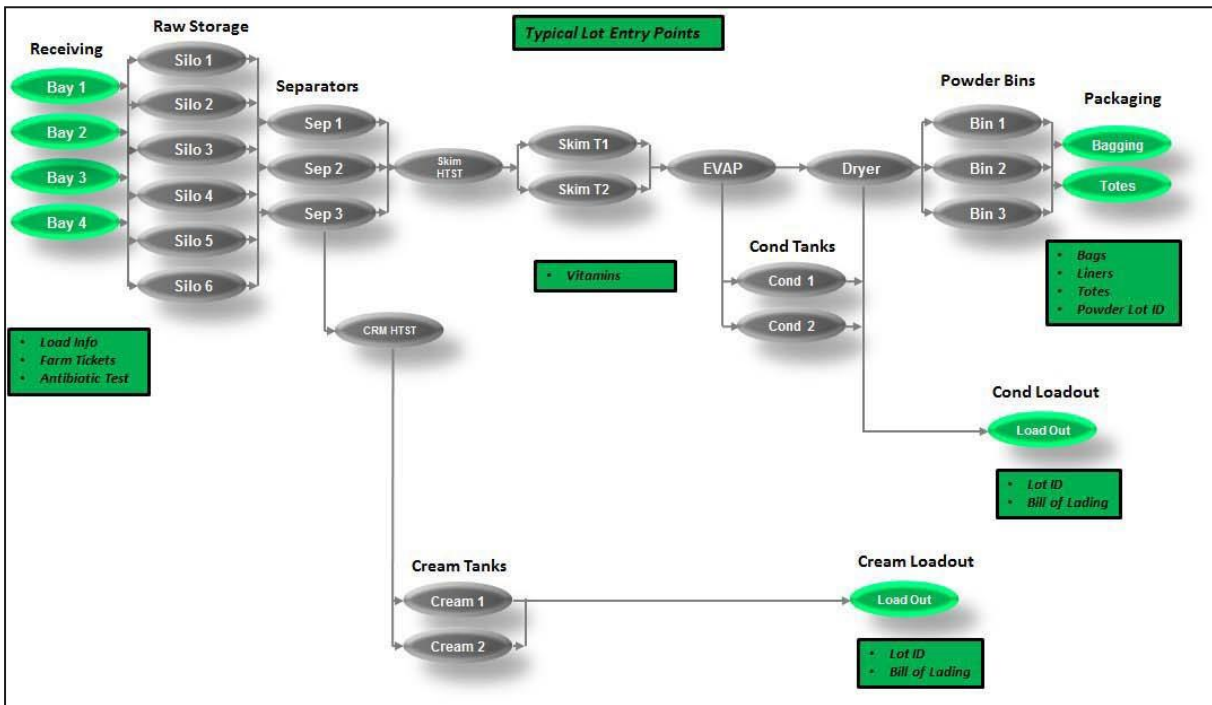


Figure 5 – Nonfat Dry Milk Facility

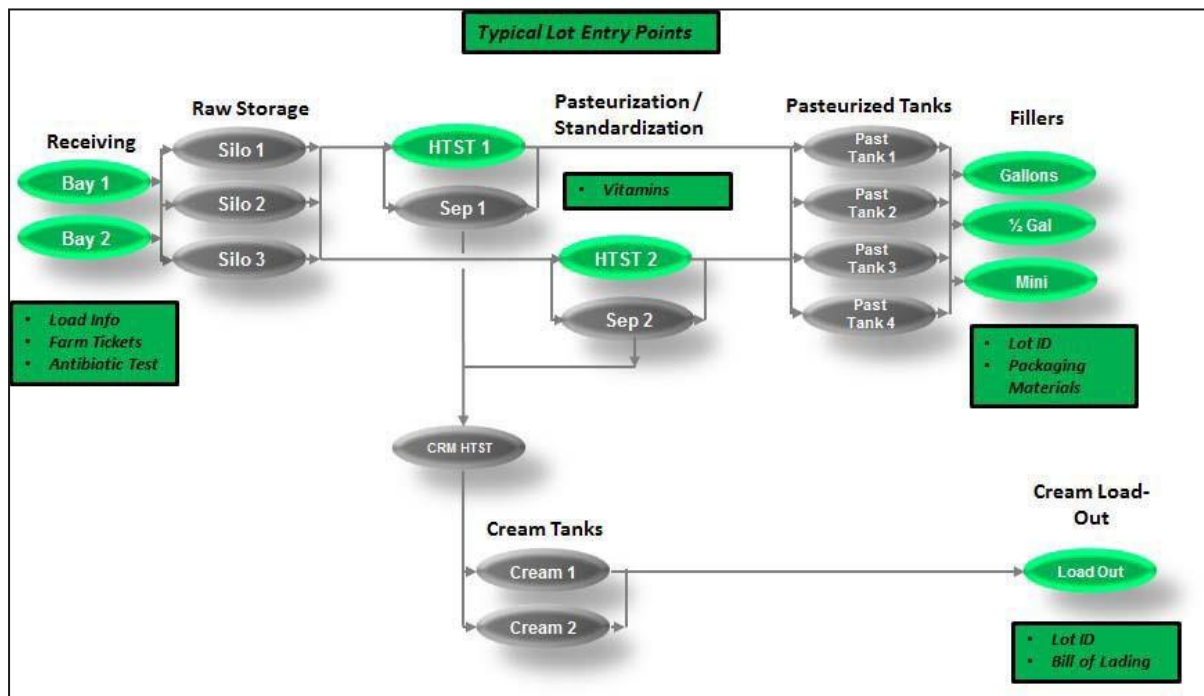


Figure 6 – Fluid Milk Facility

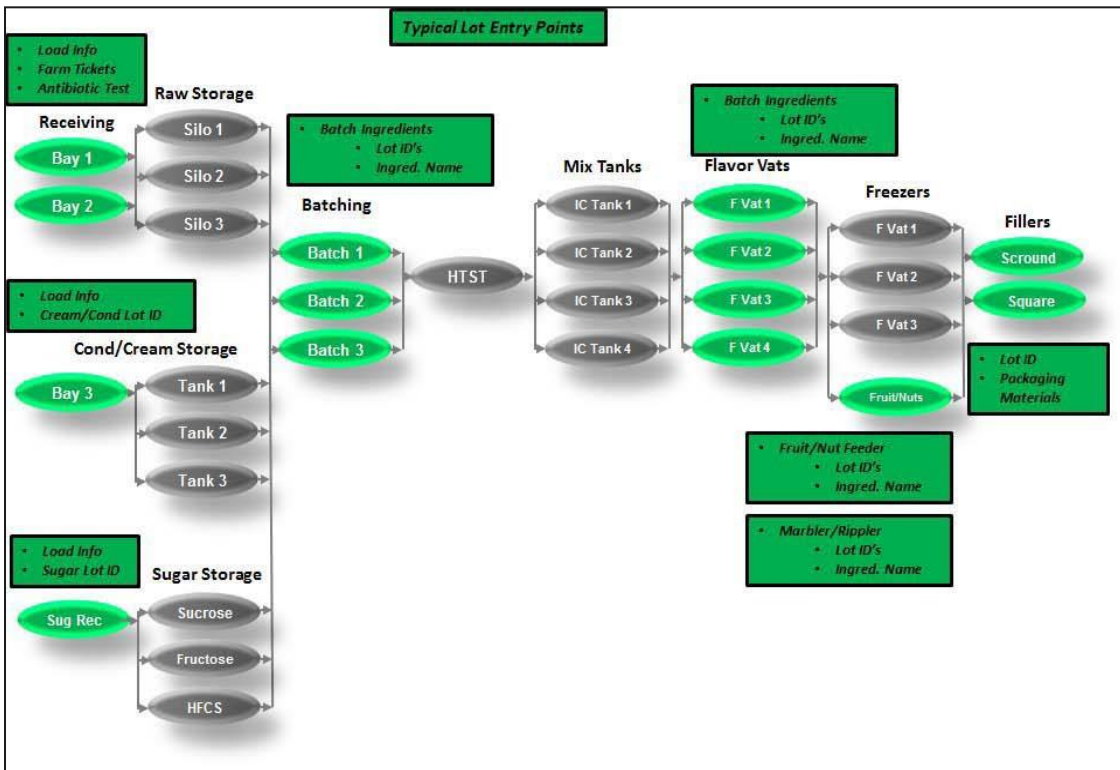


Figure 7 - Ice Cream Facility (Common template for most frozen dairy foods)

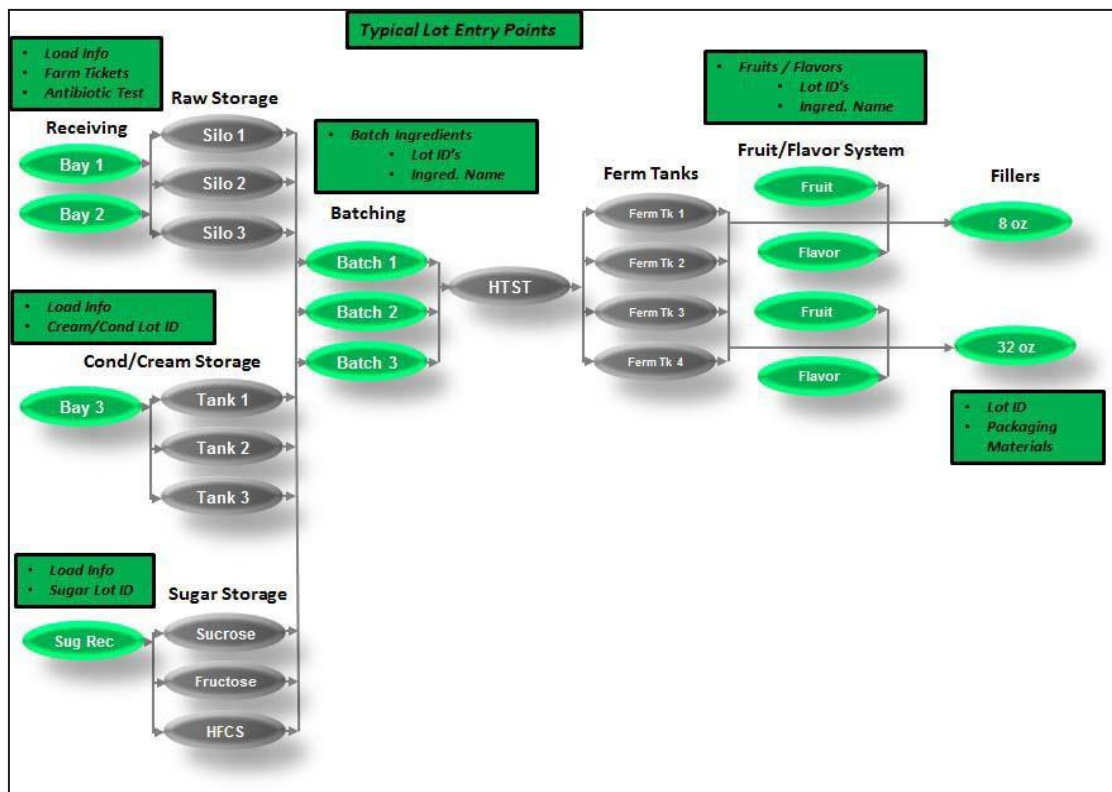


Figure 8 - Cultured Products Facility

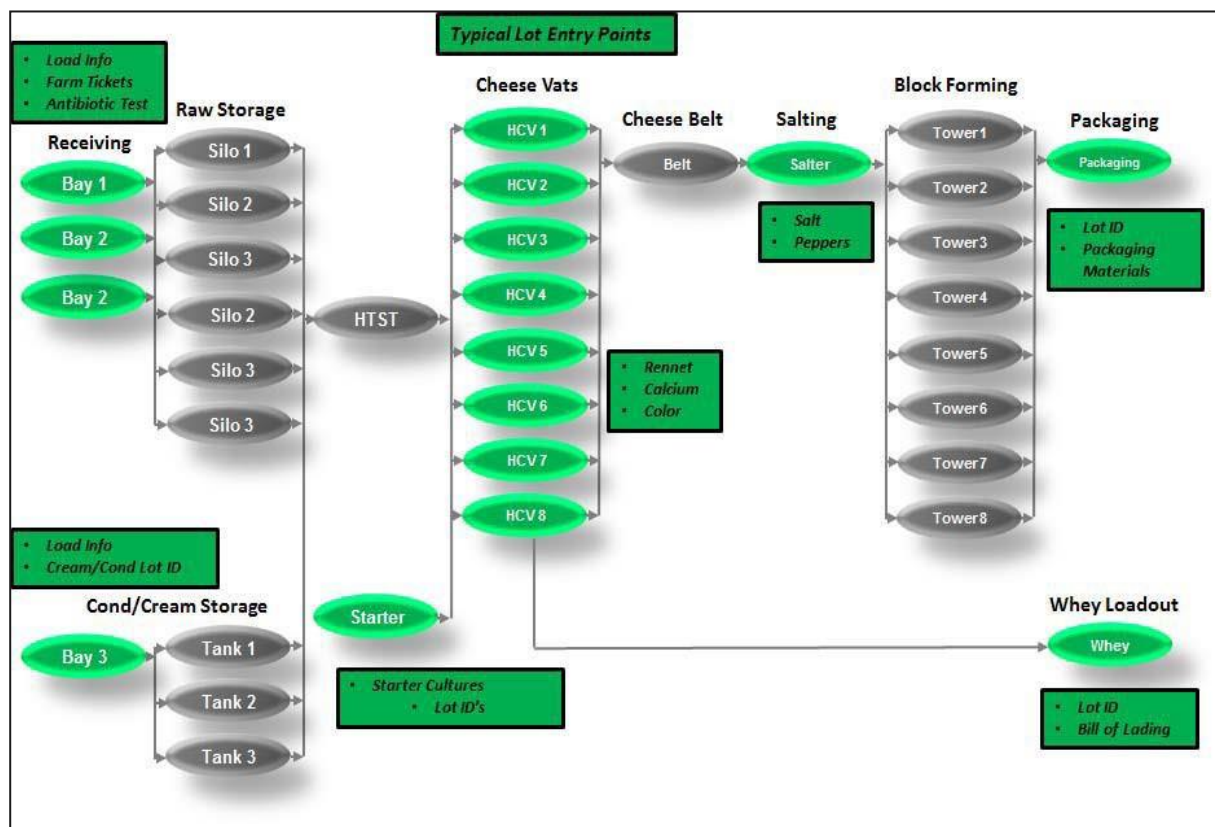


Figure 9 - Cheese Manufacturing Facility

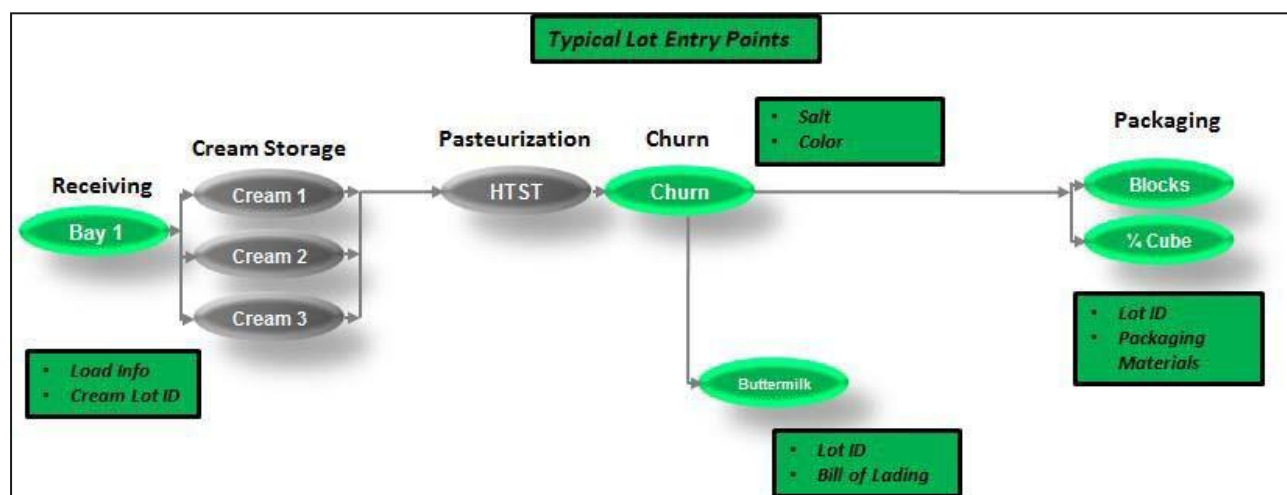


Figure 10 - Butter Manufacturing Facility

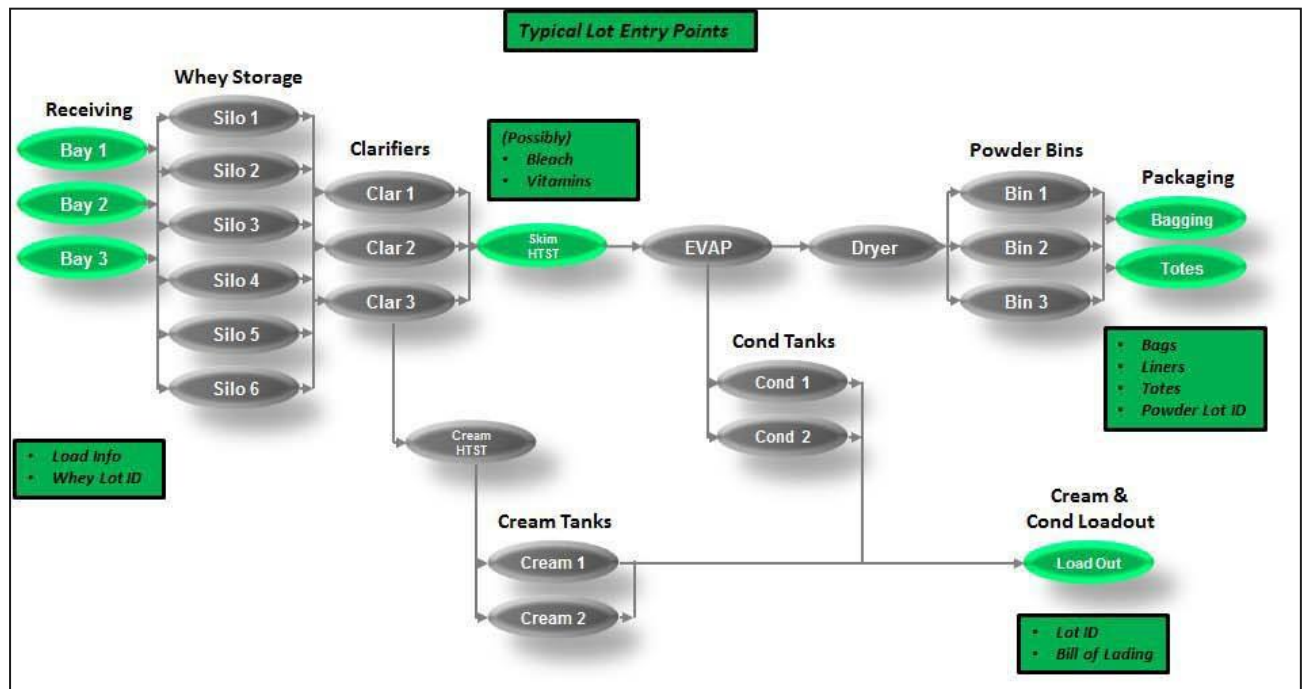


Figure 11 – Whey Products Manufacturing Facility

Critical Tracking Events

Critical Tracking Events are the points where product is transformed. Transformation for the dairy industry is where different Lot Numbers get combined, or where heating and cooling products get transferred, or where cleaning could create a break in the final product genealogy.

Following is a flow chart of the product as it starts from raw material and continues through the process to become a final package or bulk truck that leaves the facility. Plants often use their HACCP flow documentation for this purpose. The HACCP flows tend to have more details than you will need for your traceability Critical Tracking Events document, but you can group the HACCP flow steps into the Critical Tracking Events for traceability. Figure 12 illustrates this concept.

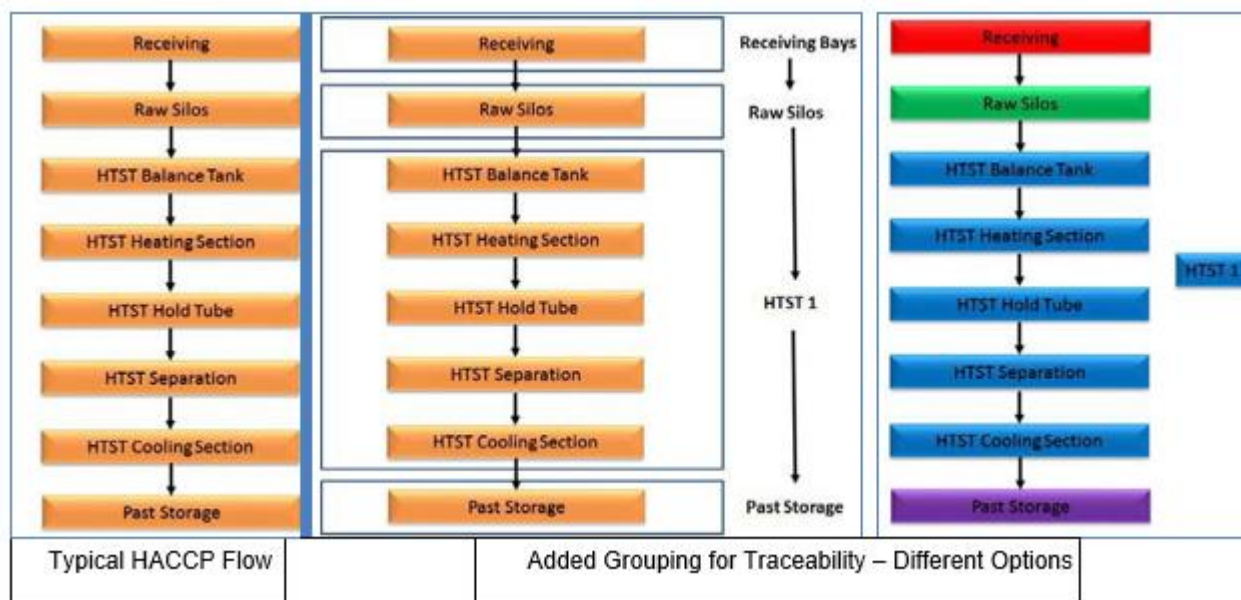


Figure 12 – Options for turning HACCP Flow Diagrams into Critical Tracking Events

When starting this exercise, keep in mind that the purpose of physical modeling is to identify each flow that will need to be recorded to track the farm loads/ingredients/materials through your facility. If your system is manual, the operator will need to write down the flows. Simple and accurate record keeping is best for flows in and out of an area of your facility, or between your facilities. Either group the flows or ignore the equipment that the product flows straight through from one storage vessel to another. The following illustrations show examples of this method.

If you are employing a sophisticated ERP traceability solution that interfaces directly to the plant automation, the flow model can be designed as granular as desired. The greater the granularity, the narrower the recall will be. However, the greater the granularity, the more complex the system will be, increasing the chance for errors that will broaden the recall. Many manufacturers adopt the method that simplifies system programming and assures fewer errors even with a fully automated ERP system.

When modeling the facility, some commonalities apply to most dairy foods processing:

- Any points where ingredients get added (KDEs - Lot Entry Points) should be listed in the model. This can be equipment, such as a liquefier, or the destination, such as a batch tank.
- Any time the product is heat treated, such as with pasteurizers, is a good place to list as a Critical Tracking Event.

Special Considerations

There are a few areas of special consideration for modeling the Critical Tracking Events in a dairy foods facility:

- *Storage vessels and other equipment that are cleaned periodically*
 - Oils, sugars, and other bulk ingredients are stored for long periods of time without being completely emptied or cleaned. This is common and safe but breaks a granular model of traceability. Several options exist to solve this. Choose the one that fits your product, and the risk you feel it poses on the final consumer product. Then, document this method for each storage vessel in the physical model. Keep in mind that your records will allow identification of surrounding products to test. Two of the most common methods of dealing with long term storage:
 - Reset the trace for this vessel on a calculated first-in, first-out method. For example, 65,000 lbs. of oil were delivered, so the first 65,000 lbs. used exhausts that Lot. On a reoccurring basis (possibly monthly), true up the calculated inventory to actual inventory.
 - Reset the trace based on a reoccurring time period. This is a common practice for city water, since there never is really an interruption. For city water, many reset the trace every 24 hours.
- *Continuous processes*
 - Some processes run for longer periods of time than is practical for consideration as a single Lot of finished product. Spray dryers, powder silos or, other processes may run for several days without cleaning/CIP. Yet the flows through these processes need to be documented either manually or automatically to provide good traceability. A few solutions exist to create Critical Tracking Events:
 - Reset the Critical Tracking Event whenever a source or destination changes. For instance, on a dryer, create a new flow record when the powder bin selection changes. In the case of an evaporator, change the flow record whenever the silo feeding the evaporator changes. If these two are combined, the quantity of product under one Critical Tracking Event becomes much smaller, reducing the size of the Lot that will be considered for a recall. Now consider the earlier section “Understanding the Needs of a Traceability Solution”. When the Critical Tracking Event is reset as described, the following traceability can be accomplished:
 - **Inclusion**—Depending on the risk of the contaminant, the entire list of final product Lot Identifying Marks can be held, recalled, or tested during the clean to clean cycle of the dryer.
 - **Exclusion**—Depending again on the risk of the contaminant, the final products that are within the narrowest scope of a single silo crossing to a single powder bin can be isolated. This may be the highest risk product.

- **Dilution**—Depending once again on the risk of the contaminant, final product that contains items such as a common silo, powder bin, a common rework Lot Identifying Mark, can now be isolated to find those product lots with trace amounts of the contaminant. In fact, this method can be used, especially in an automatically collected traceability solution, to find the source of the contaminant.
- *Adding rework into the process*
 - Rework addition should be handled as any other ingredient additions. However, where creation of rework is possible, the points in the process should be modeled as a Critical Tracking Event, with a final Lot Identifying Mark so when it is added back it can be traced.

Examples

The following are examples of typical facilities in the dairy foods industry, represented in flow diagrams. As mentioned earlier, the HACCP drawings can be modified to create the Critical Tracking Event documents. Each shows the flows that you should record, highlighted in red, and the typical names for these flows. You should also create and keep a Critical Tracking Event record for each flow identified. In the following examples, they are listed in the text boxes.

Each graphic contains equipment highlighted in light and dark grey. “Pass through equipment” is not normally recorded, especially if the Critical Tracking Events are being recorded manually. For instance, with the flow from one silo to one pasteurized tank, and from that silo to a cream tank, minimal traceability is needed. This “Source and Destination” record is typical in dairy processing, for example in a pasteurizer record, unless something new is added between these silos and tanks. If something new is added between the silos and tanks, the extra flows should be recorded as Critical Tracking Events.

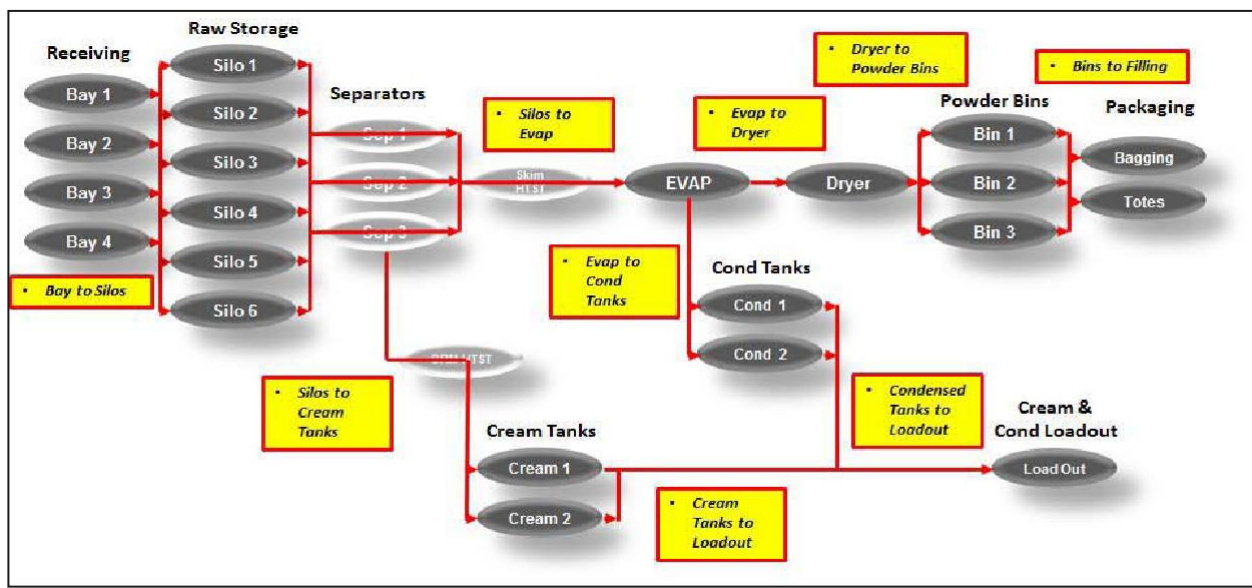


Figure 13 – Skim Milk Powder Facility

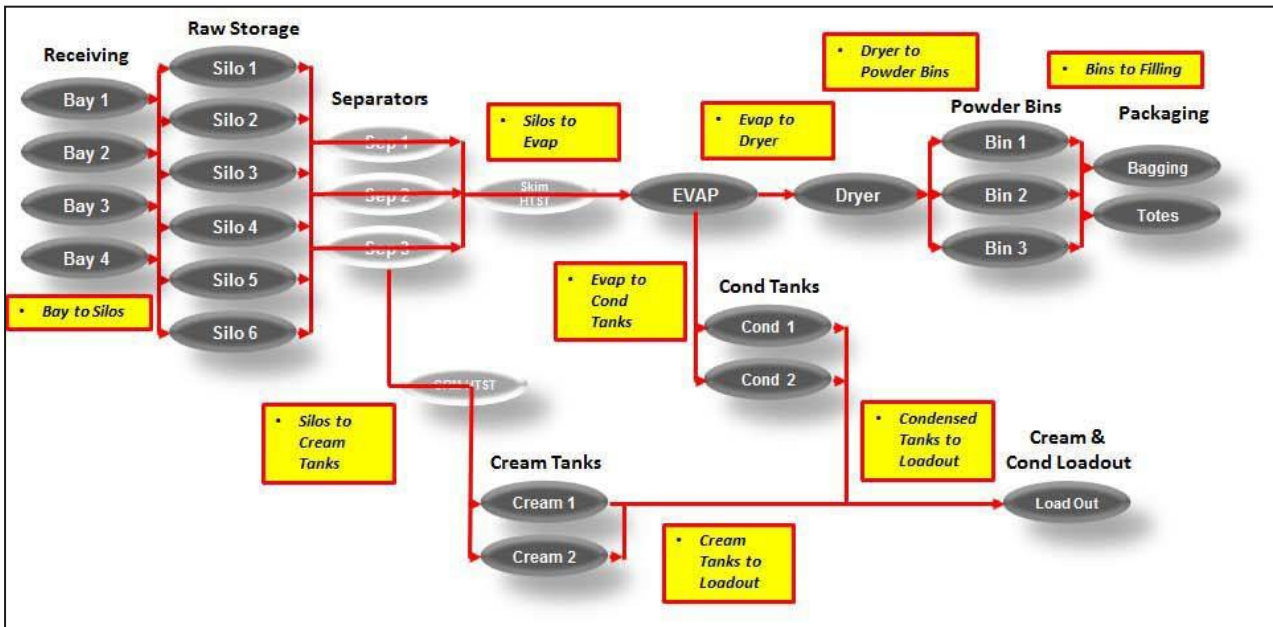


Figure 14 – Nonfat Dry Milk Facility

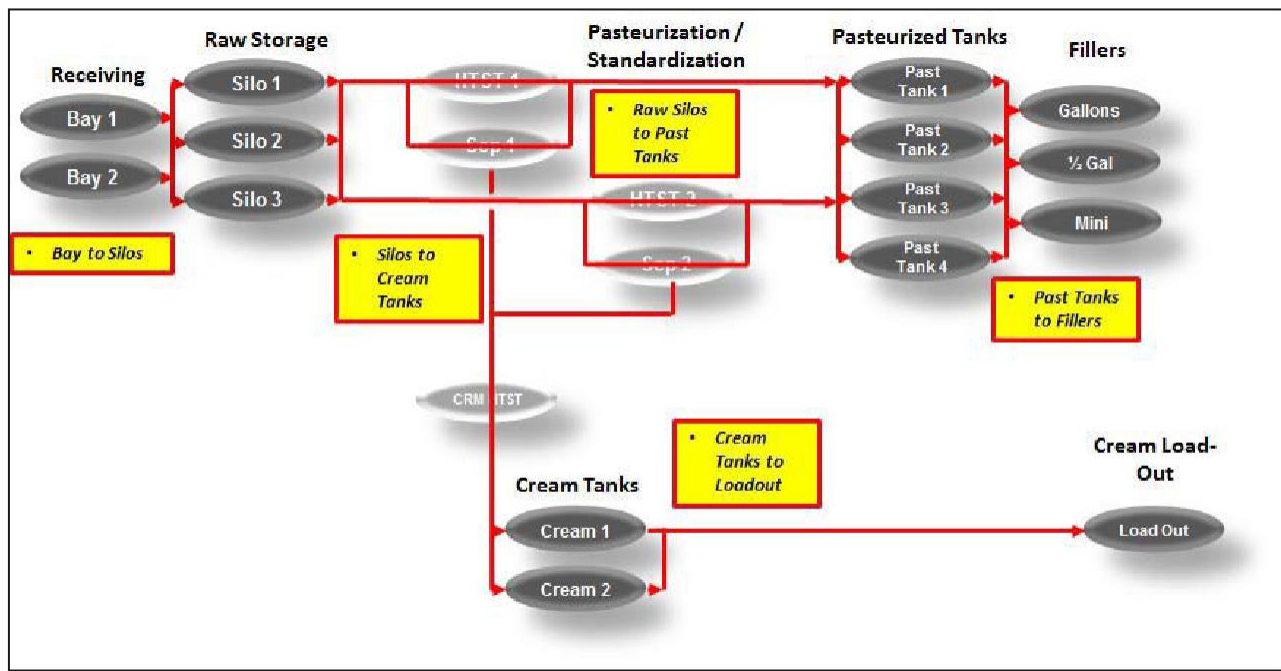


Figure 15 – Fluid Milk Facility

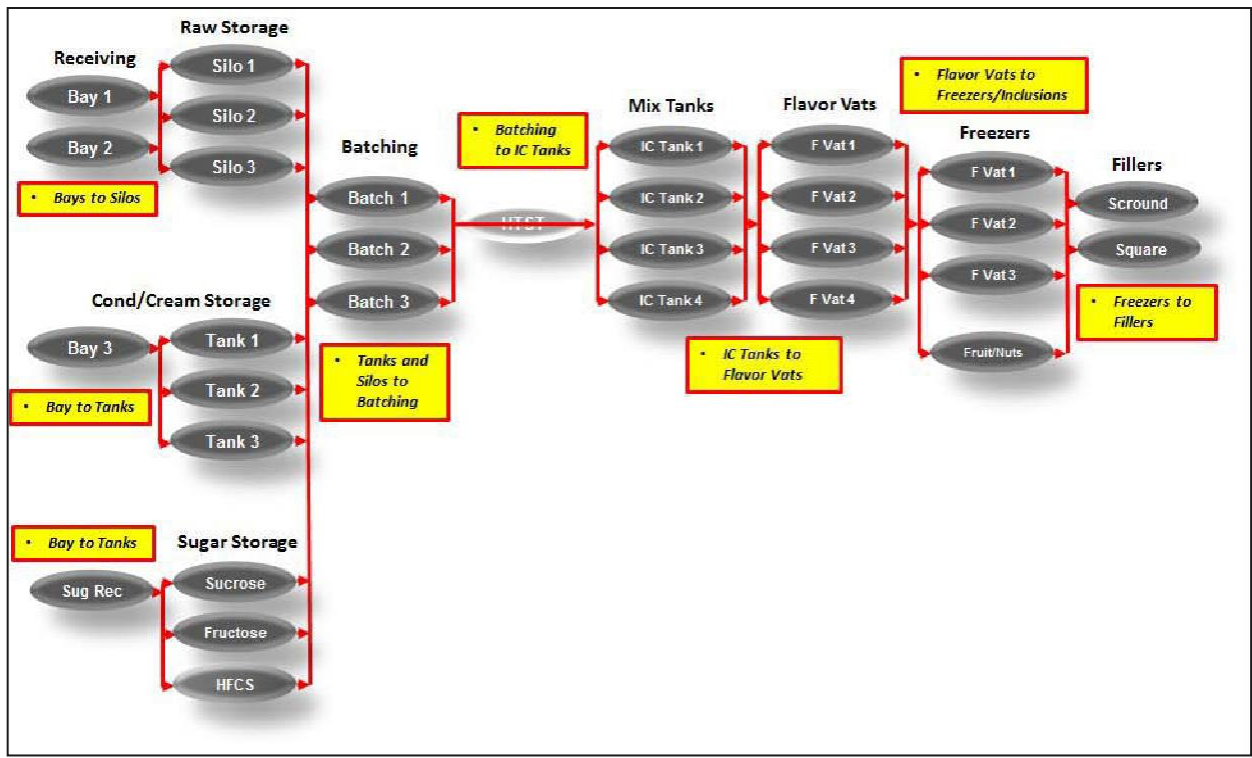


Figure 16 - Ice Cream Facility (Common template for most frozen dairy foods)

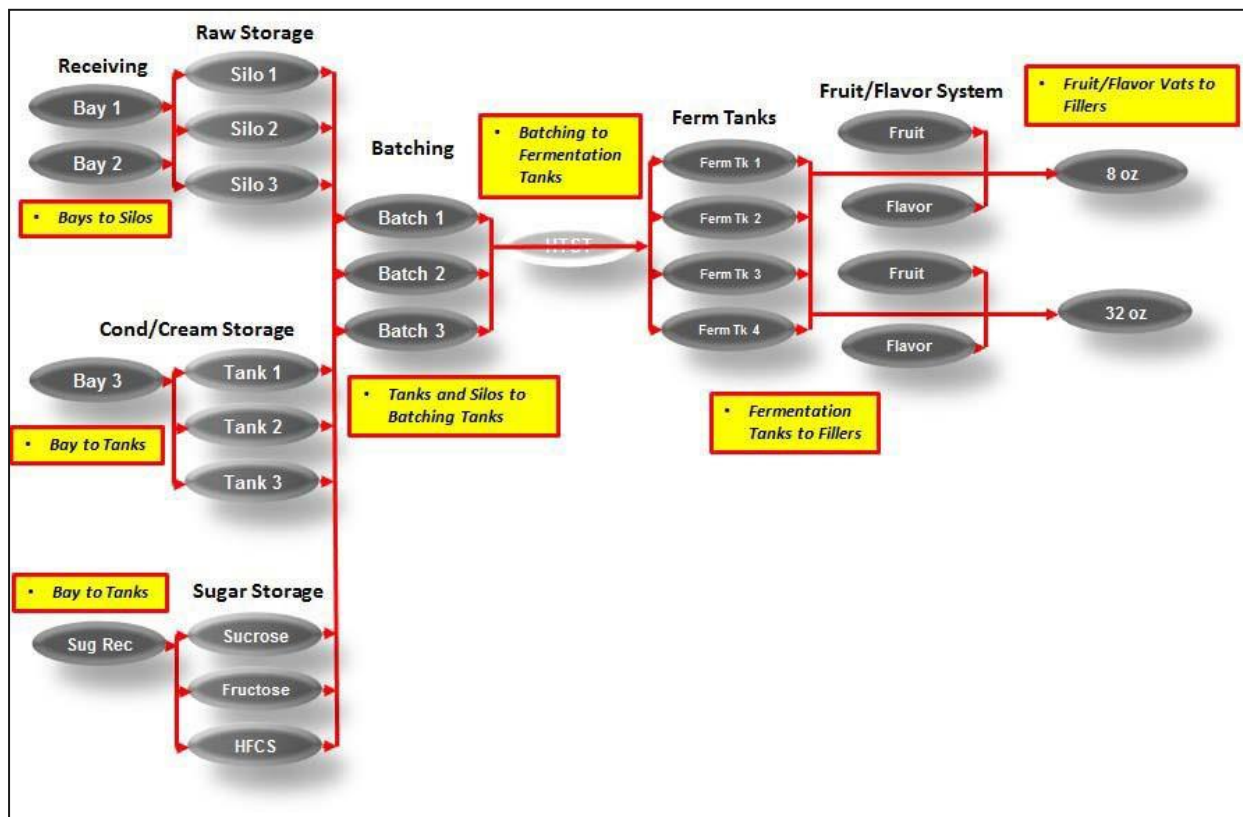


Figure 17 - Cultured Products Facility

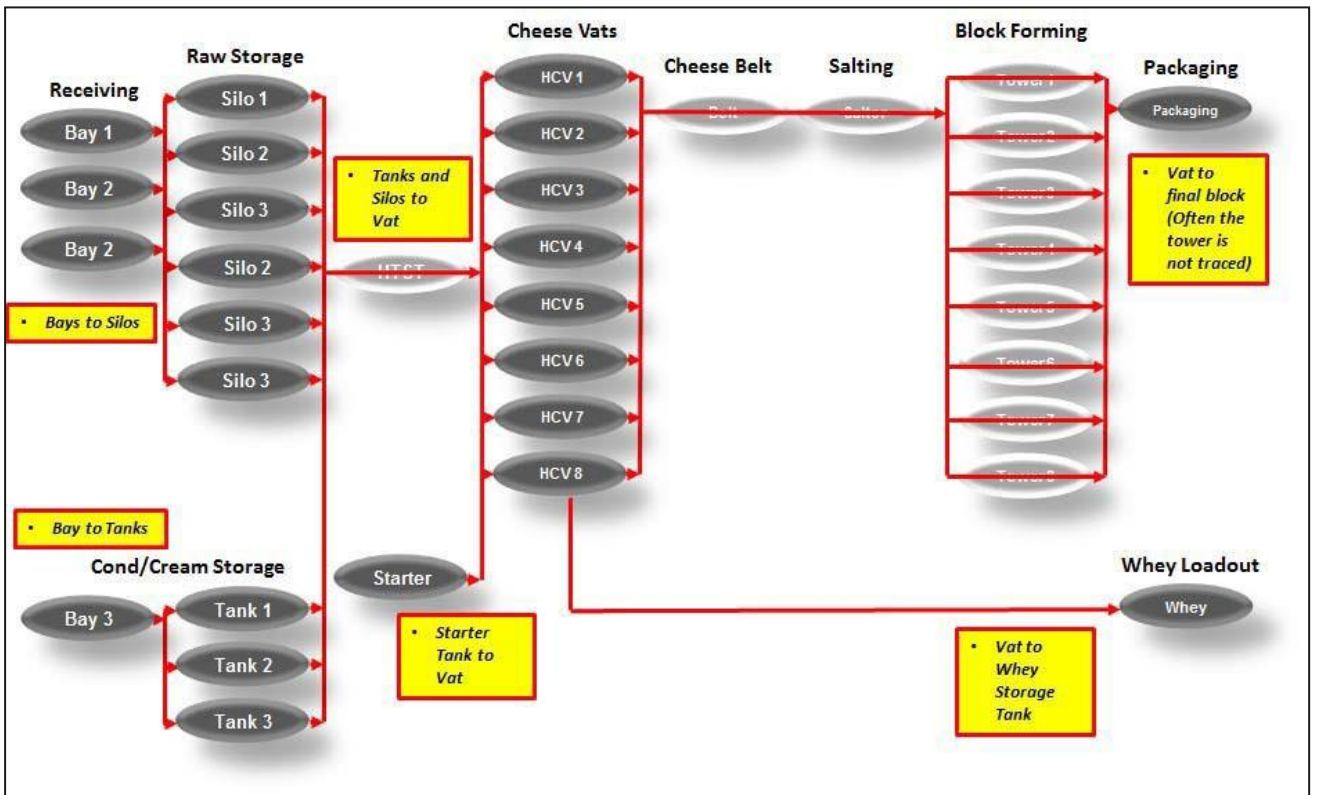


Figure 18 - Cheese Manufacturing Facility

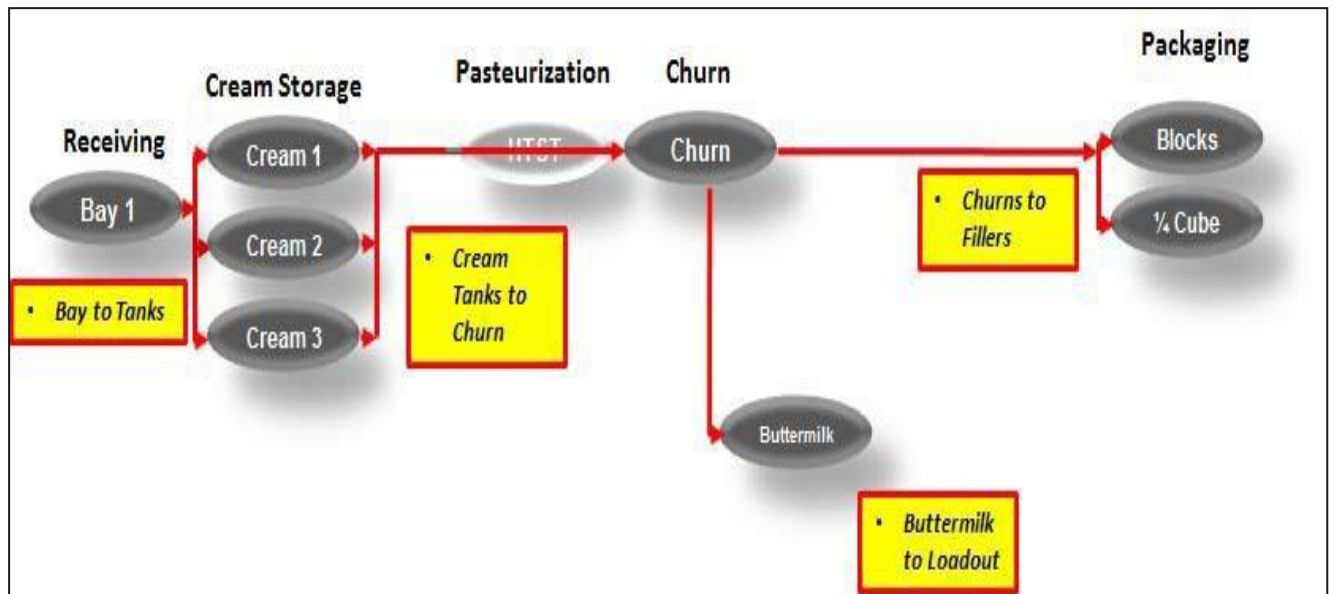


Figure 19 - Butter Manufacturing Facility

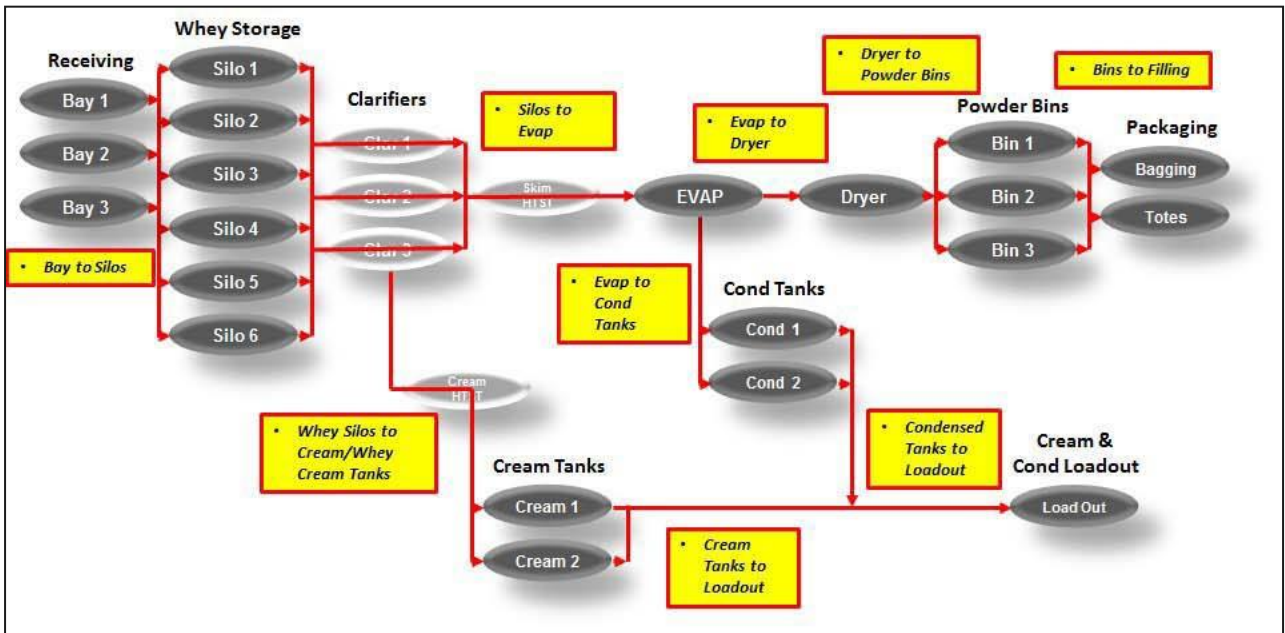


Figure 20 – Whey Products Drying Facility

Product Labeling

A simple, readable LOT ID that is accurately recorded is the key element in a successful traceability system. Almost every recall or trace back starts with this identity. Inconsistency in the way Lot ID's are recorded is the top cause of difficulties in successful traceability for many food manufacturers. The real goal of product labeling for the purposes of traceability is to have a Lot code that **identifies this container as a unique Lot of product for your facility.**

The Lot Identifying Mark can be a challenge for many facilities to manage because they often contain other information about the product including the weight, product type, SKU number, etc. While this creates greater clarity, it could make the Lot Identifying Mark number nearly impossible for operators to write down repeatedly with accuracy. Also, Purchase Order numbers, while identifying a product, often must be manually linked to a lot of product between manufacturers.

There are also several bar codes and numbers on the package in most cases. This often causes the wrong identity to be recorded. This has slowed product traces and recalls.

To allow efficient and expedient traceability, the Lot Identifying Mark should:

- Be human readable for your customers that use manual Lot tracking records. It is estimated at this time that in nearly 80% of the places the dairy industry adds ingredients such as powders, protein concentrates, etc., there is no electronic means to capture the Lot Identifying Mark. Additionally, the non-dairy additives that are added to dairy foods, such as vitamins, flavors, fruits, stabilizers, nuts and thickeners, do not have electronic capture means in most cases. Your Lot Identifying Mark must be easily identified, easily and accurately readable and simple enough to be written down correctly by an hourly employee.
- Stand out on the package, pallet label, and bill of lading so that customers can clearly determine the Lot Identifying Mark they should use in their traceability records.

If you are incorporating a bar code that is used by all customers into your records, ensure that both the distributors and the final customers are bar code scanning the Lot Identifying Mark, and integrating it into their traceability records as well.

Making Your Lot Identifying Mark Stand Out

The Lot Identity should be obvious on every package, container, pallet and bill of lading that leaves your facility. This is of the utmost importance and will probably be mandated in the coming years. One of the most important points that this Guidance Document makes is that a single Lot Identifying Mark should be used in every record. If the product is meant for use by another manufacturer or processor, the text "**LOT**" or "**Lot ID**" should be printed boldly and visibly next to the Lot Identifying Mark.

Alternatively, for a small manufacturer, the GTIN/GS1 number should be applied in human readable form. To reiterate, the text "**LOT**" or "**Lot ID**" should appear near the code.

If your customer has requested or accepted more extensive Lot Identifying Marks, this is also acceptable, just make sure the mark is clear. The Lot Identifying Marks should be used in all correspondence, and in both your facility and your customers' electronic and manual traceability systems. And don't forget, if there is any chance a pallet will be split and used, add the human readable Lot ID to the packages.

The Lot Identifying Mark should be a field entered into an ERP or accounting system because it is the key to a quick and narrow trace.

Recommended Lot Identifying Mark Content

There are some simple suggested methods to create a Lot Identifying Mark:

- The state plant number, the date and a process identifier.
 - A state plant number is the number assigned by your State Department of Agriculture. The plant numbers are typically 4-6 digits, depending on your state. Using your plant number guarantees that no one else will have the same Lot Identifying Mark.
 - The date—For example, July 26, 2012 could be in a plain date, like 20120726 or the month and day in Julian which would be 2012207. This will create a unique Lot Identifying Mark because the date will never repeat. We also recommend shortening the year to two digits.
 - An additional identifier for the product created in a specific day—this identifier could be a line identity, a series number assigned for the batch or a series number assigned for the final production run of the day. The purpose is to create a final Lot Identifying Mark unique to the product run.

Including SKU and Weights into the Lot Identifying Mark

Many companies add important information into the Lot Identifying Mark to make it useful to their ERP systems, and/or their customers' systems. However, this information typically renders the Lot Identifying Mark nearly impossible to be read by a human. It can be difficult, to say the least, for operators having to write down a lengthy series of digits accurately and legibly while they batch, load the fillers with packaging materials, or make product. When incorrect Lot Identifying Marks are included in traceability records, the system does not produce viable traceback information.

Keep in mind that information about the product, including the type of product, is NOT critical to performing a trace. If you are called to trace a simple number, and have the means to refer to records, your trace will begin in minutes and your trace backwards to find that product's contributing ingredients, bulk products, and farm loads will be quick and accurate. You will, of course, have recorded this Lot Identifying Mark against a product name, and included it with the shipping records. The customer receiving it will record the product name and company manufacturer as they receive it. A simple, accurate, identifier will link all information together.

More complex codes have valuable functions for both the manufacturer and the receiving customer. But we recommend that a simple Lot Identifying Mark be clearly labeled and then added to the package with any other bar codes or information you desire.

GTIN/GS1 as the Lot Identifying Mark

This Guidance Document does not recommend moving away from bar code technology, or even slowing the dairy foods industry in adopting this technology. Many manufacturers already have bar codes printed on packages and pallets.

As mentioned earlier, because bar code scanning is not used at many mixers, batch tanks, blenders, or other locations where bulk ingredients and packaging materials are added in a dairy process, a human readable code is still needed. While many dairy food companies incorporate the Lot Identifying Mark into an electronic system, sometimes the operator first writes down the Lot Identity Marks on a piece of paper on the production floor; then later manually enters it into a computer station in a dry environment remote from the production area. Therefore, a human readable Lot Identifying Mark, which stands out and contains large print, is still essential.

When using the bar code as your Lot Identifying Mark, make sure your customers will be electronically scanning as they add your product to their process.

If there is any doubt whether all users of your products will be electronically scanning, add the simple human-readable Lot Identifying Mark on your package in addition to the bar code. Place the “**Lot ID**” or “**LOT**” near the human-readable Lot Identifying Mark. In most cases, this only requires a small amount of setup on an existing ink jet or laser printer.



Figure 20 – Example of a GS1-128

What Not to Do:

- During audits of traceability records and systems, ERP systems often assign their own identity to the product either received or produced and shipped. While this is common and may be required for the ERP system to function, make sure the Lot Identifying Mark is both on the package and that an operator at another company will later record it. Note that in the ERP system the Lot Identifying Mark can be searched and then found quickly in all systems and can be traced quickly both forward and back. Changing the identity without at least having the extra field with the true Lot Identifying Mark will break the traceability chain as a packaged product leaves one dairy foods processor and is used by the next in the supply chain.
- Don't make the Lot Identifying Mark too long. Decide on the least amount of information needed to find the lot if contacted by another manufacturer or a regulatory agency. Often this is only the plant number, date of manufacture and, possibly, another one or two digits to identify a production line, cheese vats, tanks, etc.

Record Keeping

General Information

While recordkeeping can be done in a wide variety of ways and formats by both sophisticated ERP systems and manual means, some commonalities need to exist.

- Any final product, bulk or packaged, should have a listing of the Lot Numbers that it contains.
- The Lot Numbers that these records contain should match the Lot Numbers in the warehouse records.

We can't stress enough that the Lot Identifying Marks need to be in every part of your system. If your traceability system is stored in a database, the Lot Identifying Marks should link or associate all the records. FSMA also requires that food safety records tie back to specific Lots of product.

Recall Report

The report made for a mock or actual Recall Report should contain information from your traceability records:

- A listing of the information of the ingredients, bulk products, and packaging materials contributing to the final product(s) considered in the recall.
- A listing of the information of the final products that could be included in the Inclusion and Dilution group.
- Ant final disposition or outbound shipping records for "affected" products

The mock or actual Recall Report is recommended to contain:

- Event Owner (firm submitting information)
- Date/Time
- Event Location (address of facility for each product listing)
- Trading Partner (if an ingredient/bulk/packaging material, the shipper or manufacturer information; if a final product, the subsequent receiver of the product)
- Item (the Product)
- Lot ID
- Quantity
- Unit of Measure

It is also recommended that this information be either exported into a spreadsheet or database (e.g. Microsoft Excel or Access) or be entered into a spreadsheet to be emailed. PDFs and boxes of handwritten documents have been sent in a recall situation requiring investigators to visually locate the common points of convergence. This can take days or even weeks. If the dairy industry submits just the beginning and end points of its possible involvement in electronic format, as simple as a spreadsheet, the investigators can expedite the search.

This can improve the elimination of companies not involved by finding the common point of convergence quickly. Most electronic traceability solutions already allow export of a final report into a spreadsheet, and facilities with manual record systems can quickly enter the final report.

Traceability Record Content

Your traceability records should enable you to find a Lot Identifying Mark and any contributing Lot Identifying Marks quickly and accurately. The traceability records need to only contain the information to accomplish this.

Additional information such as other ingredients, product process information (temperatures, levels, pressures) and formulations do not typically improve a traceability system. Also, this is often proprietary information that does not need to be exposed and can be looked up once a suspect product has been identified. In fact, the inclusion of additional information in the prime traceability records makes the system more complex and can cause additional errors and confusion.

Your traceability records need to only have basic information for regulatory officials if your facility is involved in a recall. Having access to simple records that quickly and accurately show the movement of the suspect Lot Identifying Marks through your facility -- and the ability to be able to isolate based on **Inclusion**, **Exclusion**, and **Dilution** -- will minimize your exposure. Including process and formulation has little advantage to minimize a recall. Typically, regulatory agencies only want to find products to hold, test, prevent human consumption and destroy. Keeping your records to show simple traceability will expedite the process and can reduce recall impact.

For a dairy foods manufacturer's internal records, it is useful to have the basic traceability information linked with the full record of the process and the quality assurance records. This Guidance Document is only recommending that records that are presented in a recall situation should remain simple and effective for a regulatory recall.

Basic Record Content

Earlier in this Guidance Document we explained how to do a physical model of your facility for the Lot Entry Points, Critical Product Flow, and the Lot identifying Mark. These exercises are used to create your record sets. Your records should contain:

- KDEs - Lot Entry Points
 - An up-to-date listing of the KDEs - Lot Entry Points for your facility or process area. This shows that you can track where other Lot Identifying Marks enter your process. It will also correlate to the daily records you keep of the Lot Identifying Marks that you incorporate into your final products. These records can be either text or flow charts. Be sure to match raw ingredients and packaging lots to receiving records.
- Critical Tracking Events
 - An up-to-date listing of the physical flows in the process, or Critical Tracking Events. This will correlate to the daily records of the flows in your facility and

will be used to find the path of the Lot Identifying Marks through the process. These records can be either textual or flow charts. These will also include any transfers or shipment records for finished goods.

- Lot Identifying Mark
This record is only a short, written description of how your Lot Identifying Mark is structured and what the digits represent.

Daily Records

These are the records of the process that the operators will keep or that will be kept by the electronic system.

- KDEs - Lot Entry Points
 - For each KDE - Lot Entry Point listed, there should be a record for every batch, shift, or day, as is appropriate to reflect the events of the process. For example, the receiving bay records would be by day, while an ice cream batching tank should have a separate record for each batch made.
- Critical Tracking Events
 - For each Critical Tracking Event listed there should be a record of the flow of events. These should be kept as appropriate to reflect the events of the process. For example, the flows from the receiving bays can be recorded as the silo into which the truck is unloaded. The ice cream batch can be recorded based on the HTST process in which it was pasteurized.

Specific Record Recommendations

Farm Milk Records should minimally contain:

- | | |
|--|-----------------------------|
| • Farm Number | • Antibiotic Test Result |
| • Carrier/Hauler Identification | • Receiver/Tester |
| • Driver Identification | • Milk Temperature |
| • List of Farm Identifications in Load | • Silo Destination for Load |
| • Date & Time Load was Received | • Quantity Received |

Bulk Receipt Records should minimally contain:

- Bill of Lading Number
- Carrier Information
- Supplier identification
- Supplier Lot Identifying Marks and Quantities of each Lot
- Date & Time Received

Ingredient Addition Records should minimally contain:

- Lot Identifying Mark from Supplier
- Carrier Information
- Manufacturer Name (If manual system; if electronic, this can be joined in the database from the Lot Identifying Mark.)
- Ingredient Name (If manual system; if electronic, this can be joined in the database from the Lot Identifying Mark.)
- Date & Time of Addition
- Quantity added

- Operator

Final Product records should minimally contain:

- Lot Identifying Mark
- Product Name
- Date & Time of product run start
- Date & Time of product run end
- Quantity produced
- Operator

Outbound Shipping records should minimally contain:

- Bill of Lading Number
- Carrier Information
- Customer Name
- Lot Identifying Mark
- Product Name
- Date and Time Shipped
- Quantity shipped

Post-Production (Storage Warehouse, Distribution Centers, Shipping Records)

Outside the physical processing environment (within the supply chain), traceability becomes discrete, meaning each product that can be affected is contained in one package. The complex part of traceability is in the processing of a food. As long as an easily identifiable Lot Identifying Mark is contained in the Bill of Lading, Shipping Records, Receiving Records, Warehouse system, etc., when suspect product(s) are traced and identified, each can be quickly held, tested, removed from the food chain or destroyed.

Record Retention, Security, and Backup

Your traceability records should be retained for the same duration as your other regulatory records, such as sanitation and pasteurization records. FSMA Preventive Controls regulation states that food safety records must be maintained for 2 years from the time when the record was created. Because recalls fall under this regulation, traceability input records are also subject to 2 years retention. These records are also expected to be made available to the FDA or its designated inspector upon demand. Your internal record retention policies may be longer but need to at minimum be kept for 2 years beyond when the record was created.

It is important that these records are signed, dated, not lost, not edited, and otherwise follow FSMA recordkeeping requirements.

- If the records are manual, they should be stored in files that are:
 - In an office that is locked when it isn't staffed or after business hours, OR are locked in a file cabinet.
- If the records are electronic, they should be:
 - Backed up once every 24 hours and stored in a database or data archival system in a Write Once, Read Many (WORM) format.

Appendices

Appendix 1: Conducting a Recall Using the Guidance for Dairy Foods Traceability Methods

Overview

Two basic recall scenarios cover most of the needs for traceability:

- Getting one or more final product KDEs - Lot Identifying Mark(s) and needing to find the contributing bulks, farms, ingredients, or packaging materials that these products contain.
- Getting a suspect alert of a bulk, farm, ingredient, or packaging material and needing to find the final product(s) that contains the possible contaminant.

Final Product Back Traceability

Once again, the consistent use of the Lot Identifying Mark is of utmost importance and will expedite trace scenario.

Conducting the trace:

- Manual System
 - Pull the record with the Lot Identifying Mark. It would be filed under the KDE - Lot Entry Point of the packaging line. Your Lot Identifying Mark should help you understand the packaging line.
 - Pull the record for the Critical Tracking Events for that packaging line. Find the source tank/silo/bin that the product came from.
 - Pull the KDE - Lot Entry Point record for the packaging line and that Lot Identifying Mark. This will give you the packaging material Lot Identifying Marks.
 - Look at the record for the Critical Tracking Event and find the source tanks/silos/bins/equipment. Pull the records for those used for the product or while the product was being made.
 - Continue this process to the origin of each path.
 - You have a complete traceability history back.
- Manual System—Common Point of Convergence Search
 - If there are multiple final products that are involved in this recall scenario, take the Lot Identifying Marks and enter them into a spreadsheet then sort for commonalities. Start your investigation with these commonalities.
 - Take the tanks/silos/bins/equipment from the Critical Tracking Events reports and enter these into a spreadsheet. Start your investigation of a possible contamination source at the common tank/silo/bin/equipment.
- Electronic System
 - Design or configure your electronic system to report the same as your “Manual System.” An electronic or ERP system can collect, store, and report much more useful information than the example reports show. However, consider outputting simple reports for the traceability process, auditing and for regulatory compliance. These simple reports will help expedite the search for the locations of suspect contaminants and will protect the proprietary nature of your process.

- **Electronic System—Common Point of Convergence Search**
 - An electronic or ERP system can be configured to output reports showing commonalities in the suspect products by various filters. With the inputs described in KDEs - Lot Entry Points and Critical Tracking Events, reports can be generated to show various views including:
 - Other products sharing the same tank/silo/bin/equipment.
 - Remaining ingredients of the same Lot Identifying Mark in storage or the warehouse.
 - Other products touching the same equipment after the suspect affected product.
 - Other products made by the same operator on the same day.
 - Other products from the same farm.

Suspect Origin Trace Forward Traceability

Once again, the consistent use of the Lot Identifying Mark is of utmost importance and will expedite the trace scenario.

Conducting the trace:

- **Manual System**
 - Decide which Lot Entry Point the bulk/farm load/ingredient/packaging material would have entered the process based on its type (Flavor in the Flavor Vats, Raw Milk in Receiving, etc.).
 - Pull the record for the KDE - Lot Entry Point. Search the records for the Lot Identifying Mark (if your records are entered into any electronic system, including Excel, this will take minutes).
 - Pull the Critical Tracking Events record for that event. Find the next Critical Tracking Event of the product and continue to pull Critical Tracking Event records forward through the process until each path has reached its end point at a final product.
 - You have a complete traceability history forward.
- **Electronic System**
 - Design or configure your electronic system to accomplish the same basic report as in “Manual System”.
- An electronic or ERP system can certainly collect, store, and report on much more useful information than the example reports show. Consider outputting simple reports for the traceability process, auditing, and regulatory compliance. These simple reports will help speed the search for the locations of suspect contaminants and will protect the proprietary nature of your process.

Appendix 2: Story Based Mock Recalls

Conducting mock recall scenarios is an essential practice to prove that your traceability system will perform if a recall situation were to arise.

When the mock recall is based on a potentially real scenario, the scope tends to spread and the investigation becomes more complex to reflect what happens in an actual recall situation. Mock recalls should be triggered without warning and should be initiated by someone outside of the quality management team to test the plant's preparedness. For example, have the initial call come into the facility's guard or receptionist and have the guard or receptionist make the call to the appropriate person to fully test your ability to protect your brand and business. Train your team to treat a mock recall as a critical incident and respond accordingly. Utilizing outside 3rd parties specializing in these types of scenarios is another way to execute realistic mock recall scenarios.

The following are several examples for story-based recalls:

Mock Scenario #1 – Pathogen Source Isolation and Targeted Product Recall (Commonality Investigation)

Recall Scenario

- Possible contamination of a complex prepared food with *Listeria monocytogenes* has caused an investigation into which ingredient(s) could be the source of the contamination, and then which other products contain the ingredient(s). In parallel, the investigations of the source ingredient(s) need to reveal the original cause of the *Listeria monocytogenes* entering the process so it can be mitigated (search for possible faulty CIP, equipment needing repair or replacement or discontinuation of service).

Background

- The subject of the recall is a ready-to-eat prepared food containing dairy products, meat products, pasta, dehydrated vegetables, spices and flavors, thickeners, colors and preservatives. Just a few cases of sickness have been reported at this point, but there is a commonality of the cases of one brand of prepared meal that was consumed. A quick investigation reveals that the storage of this product in transportation and distribution was well above recommended temperatures, allowing the *Listeria monocytogenes* to grow. This creates a concern that other foods contain the same ingredient(s) with the same potential of contamination. These need to be identified, isolated and kept from being consumed, tested and recalled if needed.

Mock Scenario #2 – Possible Adulterated Bulk Product

Recall Scenario

- All farm loads for a three-day period must be traced through the plant and all products that this milk could have contributed to must be isolated and held from the market until further testing can be done. Any product in the market must be identified and held or recalled.

Background

- A significant amount of a controlled substance was purchased in a suspicious manner, so the chemical vendor alerted the police. The suspect was identified and was found to have worked at a dairy farm. He didn't show up for work two days after the purchase and hasn't been seen since. There is no proof yet that any of the controlled substance was put into the farm bulk tank. This farm ships multiple loads of milk a day to your plant.

Appendix 3: Working with Vendors to Reduce Liability of a Recall

Your good traceability requires that your vendors can trace the materials they furnished you. A broad scope recall of one of your vendors will involve you and may put your products and market in jeopardy. Work with your vendors to make your traceability process more efficient, and to limit your liability.

- Farm Loads
 - If your milk is being supplied by someone keeping the records of individual farms and your receiving only has the route or truck information, conduct a mock recall to test the system of quickly relating your final products to their farm records. Make sure this system works after hours and on weekends and holidays. This is a common practice, especially with co-ops, and typically works very quickly and accurately. Make sure your record keeping aligns easily with theirs.
- Sugar, Oils, Resin, Powders, Other Bulks
 - Dairy foods commonly incorporate ingredients from industries outside of dairy or Grade A foods, or even from outside of the United States. Work with these manufacturers and share this [Guidance Document] to prove their traceability practices align with yours.
 - Insist on clear Lot Identifying Marks or even request a format that aligns with your traceability system or ERP system.
 - Test their traceability to make sure you are not exposed for extended times. Make sure their Lot Identities and manufacturing practices can contain a contaminant to a reasonable amount of your product.
- Packaging Materials
 - Have your packaging vendors print Lot Identifying Marks on the pallet of boxes/bags/cartons/caps/lids/liners that clearly and simply identify their run.
 - Encourage them to make the Lot Identifying Mark number relate to something that uniquely identifies your packaging materials into the smallest lot possible.
 - Have the Lot Identifying Mark printed on the individual items on the pallet, so when a pallet is used over several days, the operator still can record the lot number.
 - Make sure the Lot Identifying Mark on the individual items on the pallet or in the box match the Lot Identifying Mark on the outside of the pallet or box

Appendix 4: Limiting Exposure by Processing Methodologies

The scope of a potential recall can be significantly reduced by how one chooses to conduct processing. Many dairy manufacturers analyze how they are using their equipment and are adopting practices that limit the potential contamination by 50-75 percent. Recall scope that was once thought to be broad has been found to be quite easy to narrow.

Storage Utilization and Sanitation

The co-mingling of products can be significantly reduced by creating and enforcing policies with plant floor staff about the use and sanitation of tanks, silos, piping, and other equipment. For the following commonly found areas, lot co-mingling can be minimized by applying the following principles in your processes:

- Receiving Storage
 - Reduce the silos that one truck of farm milk can be received into. For instance, one manufacturer found operators were “topping off” multiple silos when the silos were nearly full. The real issue was that another crew did the silo CIP’s, and this was tying up storage space. After review, CIP’s on these silos were done expeditiously, and receiving operators were coached to limit one truck to be split into no more than two silos.
 - Perform some CIP on a silo or tank when it is emptied, before returning it to use, even if the silo is still under the 72-hour wash requirement. Decide about what constitutes a clean reset on the silo or tank, and perform this when it is empty, before returning it to use. Many dairy manufacturers believe this can be a rinse and sanitize, with a full wash every 72 hours.
 - Eliminate, except in absolute necessity, receiving into a silo or tank and drawing out of it at the same time. This can almost always be eliminated and allows for much clearer lot separation.
- Processing
 - Decide where product recalls can be reduced by smart use of equipment. Some of the following examples are practices done by various U.S. dairy processors. Apply these examples to your process to reduce the scope of a recall.
 - Feed Tanks to Dryers
 - By switching between two feed tanks between the evaporator and the dryer, they can lot identify their powder by the feed tank that was delivering at that time. While trace amounts could be co-mingled, this could still reduce the non-diluted powder to 6 hours instead of 4 days.
 - Powder Bins
 - One dryer manufacturer reported switching powder bins at the same time as they switched dryer feed tanks. While there will be traces of powder co-mingled across bin changes, this still reduces the non-diluted powder to recall. Typically, non-diluted powder will be the only powder recalled if the traceability practices are good.
 - Record when a powder bin has been emptied. Even if it is a paper record, a visual confirmation with an operator initial will be proof that the bin could only have trace amounts of a contaminant. This will be valuable in a recall.

- Batching Tanks
 - Perform some type of cleaning to remove the residue of one batch from another. At a minimum, clean when switching product types even if there are no conflicting ingredients.
- Pasteurization and Separation
 - Log whenever the source or destination of the pasteurizer or separator changes. If you are assigning a manual or automatic batch ID, change this at this time too. A routing change creates a good break for product genealogy.
- Packaging
 - Find ways to change the Lot Identifying Mark often.
 - Make the Lot Identifying Mark unique for each product change.
 - Make the Lot Identifying Mark unique for each filling/package line.
 - Make the Lot Identifying Mark unique for each bin/tank/silo feeding the line or know when the switch has occurred and relate it to the scope of the run.
 - Incorporate the Make Day and Vat Number on a cheese package.
 - Always record the packaging material Lot Identifying Mark from every packaging material that touches product.

Appendix 5: A 21-Point Traceability Checklist

The following is a handy, 21-point checklist you can use to evaluate if your facility has completed the parts of this Guidance Document for creation of a robust traceability process.

Receiving

- ☐ Farms on each load can be identified by receiving record or shipper.
- ☐ For cream, condensed, sugars and other ingredients, the Lot Identifying Mark ties to shipper's records.
- ☐ Loads are recorded with silo destinations.

Warehouse

- ☐ Lot Identifying Marks recorded when received matches shipper's records.
- ☐ Lot Identifying Marks recorded are same as are used by all operators at time of process use.

Process Areas

- ☐ KDEs - Lot Entry Points are identified and listed.
- ☐ Lot Identifying Marks are being recorded as ingredients are added.
- ☐ Critical Tracking Events are identified and listed.
- ☐ Critical Tracking Events (Example: Silos, Tanks, Mixers) are not filled and emptied at the same time.
- ☐ Critical Tracking Events are documented.

Sanitation

- ☐ Sanitation type designated for Critical Tacking Event equipment.
- ☐ CIP occurs on raw silos before refilling.
- ☐ Sanitation resets Critical Tracking Event lot when complete.

Final Products

- ☐ Product Lot Identity clearly identifies manufacturing lot.
- ☐ Lot Identity is human readable, and electronically readable by the customer.
- ☐ Lot Identifying Marks are recorded for packaging materials.

Outbound Shipping Records

- ☐ Product Lot Identity clearly identified in shipping records
- ☐ Shipping records include customer name, carrier information, BOL number

Records

- ☐ Critical Tracking Event listings are current.
- ☐ KDE - Lot Entry Point records are current.
- ☐ Final products can be linked to Lot Identifying Marks they contain.
- ☐ Lot Identifying Marks recorded are consistent throughout the facility.
- ☐ Common points of convergence in products (Lot Identifying Marks) can be identified.

Appendix 6: Glossary of Traceability Terms

Sanitation Lot Resets	When cleaning and sanitizing is completed successfully, all traces of previous product is removed.
Common Point of Convergence	The common ingredient, vendor, or piece of equipment that is revealed when multiple finished product trace backs are performed. This commonality is typically the source of the issue and will be the starting point of a trace forward. The commonality often spans across multiple manufacturers and industries, requiring multi-company traces to be able to be performed quickly to find this commonality.
Critical Tracking Events	Key flows in the plant's production process where a new bulk material or ingredient is added, or where the process would change the product. Examples are receiving silos, or silos through the pasteurizer to storage tanks.
Electronic Records	When the collection of Lot Identifying Marks or the process flow between Transformation Points are collected by scanners or are directly collected and entered into a database by the plant floor automation, control system, or information systems.
Finished Products	Products ready to be shipped from your facility to another, or to the consumer. This includes bulk products such as cream, whey or permeate.
Human-Readable	When a person needs to write down a Lot Identifying Mark on paper when they add the bulk material, ingredient, or packaging material to the process, the Lot Identifying Mark must be easily identified as the proper identifier to be recorded, and must be in a large enough font to be read in average light with average corrected vision.
IFT	Institute of Food Technologists
KDEs - Lot Entry Points	Key Data Elements – Lot Entry Points. The points in a production process where new bulk materials or ingredients are added, and their associated Lot Identifying Marks should be collected for traceability. This includes processes such as raw milk receiving, batching operations, vitamin injection.

Lot Identifying Mark	A mark on a product package that identifies it as a unique entity or as part of a unique run. This identity is used through the record systems, both manual and electronic, in the ERP system and by the customer.
Manual Records	When an operator writes in the Lot Identifying Marks or process flows between Transformation Points onto paper.
Packaging Materials	For the purposes of traceability, this is any packaging materials that touch the product. This includes items such as plastic overwrap, cups, bottles, lids, caps.
PMO	Pasteurized Milk Ordinance
Preferred Trace Model	When there is sufficient technology to track the flows in the plant between all major storage and processing equipment.
Rework	Product that is part of another Lot Identifying Mark but is now being adding back into the process. This product carries all of its contributing Lot Identifying Marks into a new final product. This is typical in processes such as chocolate milk, ice cream, and powder creation.
Simplified Trace Model	When storage and processing equipment is grouped, possibly when sufficient technology does not exist requiring the operator to write down flows manually.
FSMA	Food Safety Modernization Act of 2011
PCHF	Preventive Controls for Human Food regulation
Recall	The process of identifying specific lots of product impacted by food safety or regulatory noncompliance, withholding or retrieving from commerce and safeguarding to prevent distribution.

Appendix 7: Example Records

The following are examples of manual reports for operator recording of the KDEs - Lot Entry Points and the Critical Tracking Events. The examples below are for both batch processes and continuous processes. These examples should give you an idea of how simplicity can still accomplish traceability. You can add additional information as desired.


 Lot Transformation Points Flavored Milk Batching System							
Date	7/26/2012						
Shift	2nd						
Row	Batch No	Batch Tank	Bulk	Source	Time	Quantity	Operator
1	BT3201272612	BT 3	Cond	Tank 28	13:56		VN
2	BT3201272612	BT 3	Raw Milk	Silo 3	14:05		VN
3	BT3201272613	BT 2	Cond	Tank 28	14:06		VN
4	BT3201272612	BT 3	Sucrose	ST 5	14:20		VN
5	BT3201272613	BT 2	Raw Milk	Silo 1	14:32		VN
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

Figure 10 – Critical Tracking Events Record – Batch Process



Lot EntryPoint
Flavored Milk Batching System

Date	7/26/2012					
Shift	2nd					
Row	Batch No	Ingredient	Supplier	Lot IM	Quantity	Operator
1	BT3201272612	Choc Powder	Acme	34071206221201		VN
2	BT3201272612	Gran Sugar	Sugar Co.	45991112060715		VN
3	BT3201272613	Fudge Flavor	Flavor, Inc.	65031201020344		VN
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

Figure 11 – KDEs - Lot Entry Point Record – Batch Process



Lot Transformation Points Evaporator 1

Make Date		7/26/2012					
Row	Batch No	Milk Source	Dest	Start	End	Quantity	Operator
1	E1201272601	Silo 1	Dryer 1	5:28 AM	9:37 AM		SC
2	BT3201272612	Silo 6	Cond 27	9:37 AM			SC
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

Figure 12 – Critical Tracking Events Record – Continuous Process



Lot EntryPoint
50 Lb Powder Bagging

Make Date

Row	Batch No	Bag Lot IM	Time	Quantity	Operator
1	BIN12012072601	20481202191011	10:48 AM		VN
2	BIN12012072601	20481103253476	2:37 PM		JN
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

Figure 13 – KDE - Lot Entry Point Record – Continuous Process, Packaging

Learn more about traceability best practices and the ongoing U.S. Dairy Traceability Commitment at the Innovation Center for U.S. Dairy website — www.usdairy.com. A section of the site devoted exclusively to traceability can be accessed [here](#). If you have specific questions, please email innovationcenter@usdairy.com

