Supply Chain Communication

Optimizing Trade (eCommerce)

Dave Ulrich
QA Director Pharma Distribution (SQI)

Abbott
A Promise for Life

Agenda – Part I

1. Beyond our Borders – what the risk / issue
2. Strategic Framework for Import Safety – the assessment
3. Action Plan for Import Safety – Roadmap
4. Response from Congress (laws need to be changed)
    1. Bennett – 25 pages
        - "Drug Safety and Accountability Act"
    2. Steve Buyer (R-IN) / Jim Matheson (D-UT) – 41 pages
        - "Safeguarding America's Pharmaceuticals Act"
    3. Henry Waxman (D-CA) / Dingell (MI) – 82 pages
        - "FDA Globalization Act"

All are very similar – all have the goal to update the Federal FD&C act! Increase FDA's authority and increase Pharma supply chain controls – which includes imports

FDA Beyond Our

Each year, approximately $2 trillion worth of products enter the United States from more than 150 countries and territories around the world.

The Food and Drug Administra-

thorough in performing its over-

Commission or its European Union members, and two with the World Health Organization.

These agreements allow FDA and its counterparts to

- share human, scientific, and investi-

Interagency working group

Enhance food, drug, etc safety

Import Safety: A High Priority

International issues and import safety have been a high priority for Mike Leavitt, secretary of Health and Human Services (HHS). Leavitt led an interagency working group that created the Import Safety Action Plan in 2007. The plan supports increased collaboration with trading partners and companies exporting goods to the United States.

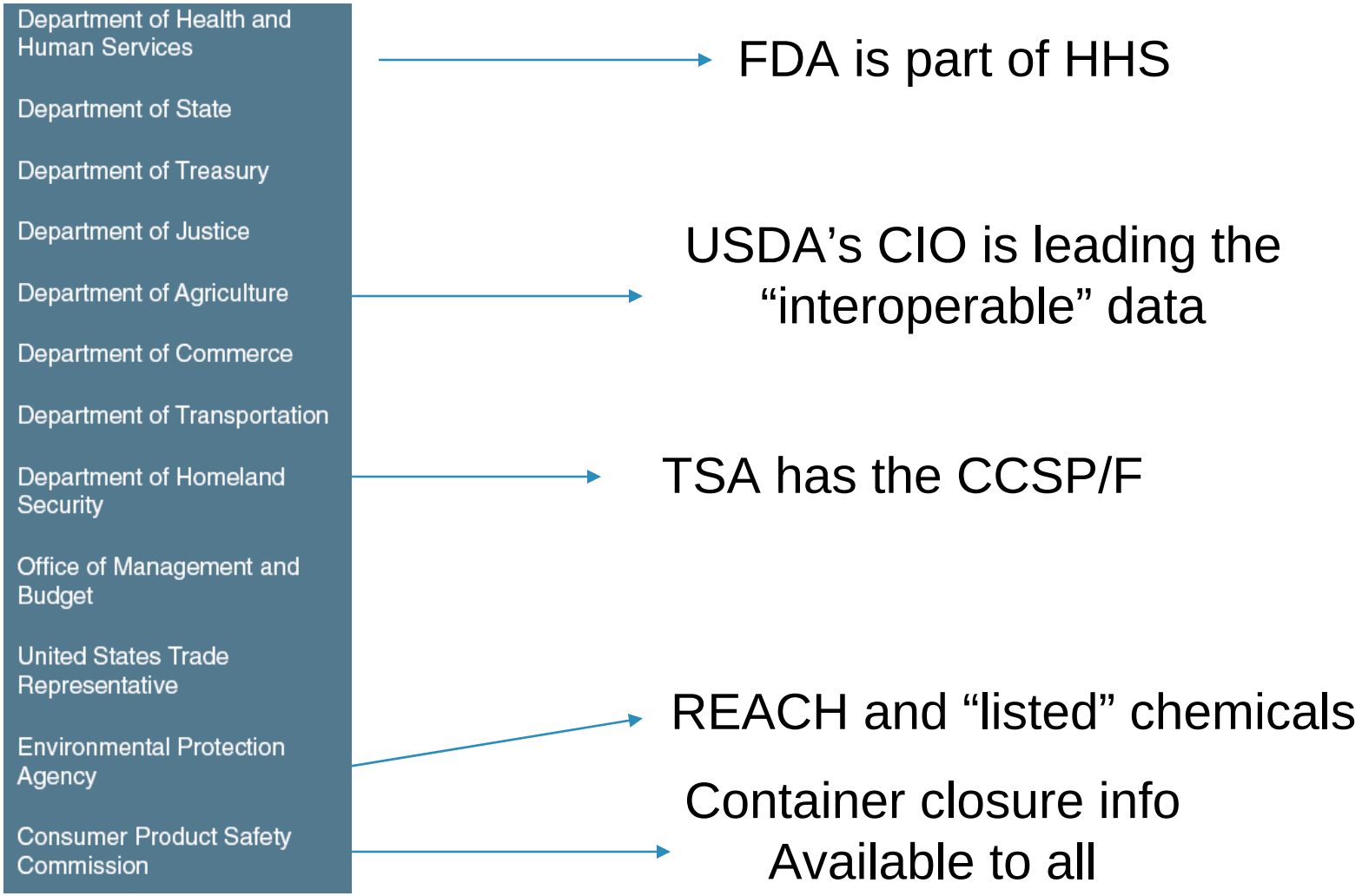
HHS also signed precedent-setting Memoranda of Agreements with FDA's counterparts in China to enhance the safety of food, drugs, medical devices, and animal feed imported into the United States from China. These legally binding agreements will build stronger cooperative relationships between U.S. and Chinese agencies, enhance technical cooperation between the agencies, and foster the flow of information between regulatory systems.

As part of these agreements, Chinese counterpart agencies will require registration of products exported to the United States. In addition, the Chinese agencies will work toward a system to certify that FDA standards are met for products before they are exported to the United States.

A Report to the President

Interagency Working Group on Import Safety
September 10, 2007

13 Agencies – lead by HHS / FDA on import safety



We’re importing more product AND more complex products

ACE

Data accuracy is crucial

Pre-alert

An Overview of the Import Process

Regulations implementing the Trade Act of 2002 require that specific information – such as a six-digit Harmonized Tariff Schedule (HTS) classification, and shipper name and address – be provided for all commercial cargo prior to arrival in the U.S. By law, exporters provide this information electronically to U.S. Customs and Border Protection (CBP) using the automated manifest system for vessels, air and rail, and the Automated Commercial Environment truck manifest for truck shipments. For maritime cargo, this information must be transmitted to CBP prior to the cargo being loaded aboard the departing vessel.

In addition, the Bioterrorism Act of 2002 requires the submission, prior to arrival, of product-specific information, such as grower and product code, for FDA-regulated food consumed by humans and animals. Failure to provide this information can result in the cargo being held at the port upon arrival.

Border officials compare the information received on the imported products with criteria provided by federal agencies and other information in

Risk Based (ICH 9 and ICH 10)

Key Features of a Risk-Based Approach

Risk assessment

- *Information gathering*
- *Surveillance and detection*
- *Information integration*
- *Risk analysis*

Risk management

- *Improving compliance*
- *Preventing entry of unsafe imports*
- *Mitigating risks*
- *Risk communication*

Correct data, instantly turned into information and transmitted securely, And accurately is the correct solution

And systems (processes) must be “interoperable”

The response (Action Plan / CI)

1. Advance a Common Vision;
2. Increase Accountability, Enforcement and Deterrence;
3. Focus on Risks Over the Life Cycle of an Imported Product;
4. Build Interoperable Systems;
5. Foster a Culture of Collaboration; and
6. Promote Technological Innovation and New Science.

GMP, GLP, GCP → GDP and soon GIP

3.1 *Develop Good Importer Practices.* The federal government should work with the importing community and other members of the public to develop Good Importer Practices and issue guidance with respect to particular product categories. The focus of these practices will be to ensure that imported products meet U.S. safety standards, as well as to promote effective supply-chain management. Development of these practices would help the importing community take appropriate steps to ensure the safety of the products they bring into the United States.
Leads: USDA, CPSC, HHS / FDA, DHS / CBP, Department of Commerce (DOC)
Time Frame: Long Term

3.2 *Partner with the importing community to foster the creation of voluntary certification programs for importers.* These programs would be private-sector based and would serve to verify compliance with Good Importer Practices. The federal government would evaluate these programs to determine whether they should be accredited by the federal government and whether certification should be required for importing certain high-risk products.
Leads: CPSC, HHS / FDA, DHS / CBP, DOC
Time Frame: Long Term

Interoperable systems

Not just IT info flow, but correct processes with change control
So that information is always, correct

Interoperability

Recommendation 7 – Complete a Single-Window Interface for the Intra-agency, Interagency and Private Sector Exchange of Import Data.

In Fiscal Year 2006, 31.3 million entries were filed with CBP for import shipments. Today, interactions between the government and importing community frequently involve time-consuming, resource-intensive paper reporting. The Automated Commercial Environment (ACE), which is currently

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9 The NTC is a CBP facility where federal officials are co-located to enable better risk-assessment and targeting of imported cargo.

Track and Trace (TnT), ePedigree at the unit level (serialization)

Not just finished Pharma goods,
but the whole mfg'ing supply chain

Track-and-Trace

Recommendation 14 – Expand the Use of Electronic Track-and-Trace Technologies.

Traceability is the capacity to identify and track a product or group of products along the import life cycle, including at all points throughout the sourcing, manufacturing and distribution chain. The ability to identify the product source and points of distribution across the import life cycle is of prime importance for the protection of consumers, particularly in the event of a product recall. If unsafe imports are discovered, effective traceability mechanisms

To be effective, tracking requirements must apply at all points along the production continuum, from point of origin to retail sale, and consumers should be given clear information to use to identify recalled products in their home.

Caroline Smith DeWaal,
Center for Science in the Public Interest

1. **Safety Standards:** Create new and strengthen existing safety standards.
2. **Certification:** Verify compliance of foreign producers with U.S. safety and security standards through certification.
3. **Good Importer Practices:** Promote Good Importer Practices.
4. **Penalties:** Strengthen penalties and take strong enforcement actions to ensure accountability.
5. **Foreign Collaboration and Capacity Building:** Make product safety an important principle of our diplomatic relationships with foreign countries and increase the profile of relevant foreign assistance activities.
6. **Common Mission:** Harmonize federal government procedures and requirements for processing import shipments.
7. **Interoperability:** Complete a single-window interface for the intra-agency, interagency and private-sector exchange of import data.
8. **Information Gathering:** Create an interactive import-safety information network.
9. **New Science:** Expand laboratory capacity and develop rapid test methods for swift identification of hazards.
10. **Intellectual Property Protection:** Strengthen protection of intellectual property rights (IPR) to enhance consumer safety.
11. **Recall:** Maximize the effectiveness of product recalls.
12. **Federal-State Rapid Response:** Maximize federal-state collaboration.
13. **Technology:** Expedite consumer notification of product recalls.
14. **Track-and-Trace:** Expand the use of electronic track-and-trace technologies.

The "legal" framework" Congressional Bills (amendments) vs. the Federal Food, Drug, and Cosmetic Act

1. Bennett – 25 pages

- **Drug Safety and Accountability Act**

2. Steve Buyer (R-IN) / Jim Matheson (D-UT) – 41 pages

- **Safeguarding America's Pharmaceuticals Act**

3. Henry Waxman (D-CA) / Dingell (MI) – 82 pages

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The Bennet Bill

111TH CONGRESS
2D SESSION

S. _____

To provide for additional quality control of drugs.

IN THE SENATE OF THE UNITED STATES

Mr. BENNET introduced the following bill; which was read twice and referred to the Committee on _____

Mr. Bennet "wrote it"

If the "Bill" gets approved it will "amend" the Federal Food, Drug, And Cosmetic Act

A BILL

To provide for additional quality control of drugs.

A BILL

To provide for additional quality control of drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Drug Safety and Accountability Act of 2010".

Know by its Short Title

SEC. 2. FINDINGS.

Recent mfg'ing quality problems

Congress finds as follows:

(1) Recent manufacturing quality problems resulting in drug recalls and warnings from the Food and Drug Administration have exposed gaps in qual-

GLN and GTIN

FEI &CFN

DUNS / GLN

Track every Establishment Involved

Track every shipment API ePedigree

"(s) TRACKING SYSTEMS.—Not later than 1 year after the date of enactment of the Drug Safety and Accountability Act of 2010, the Secretary shall develop and maintain information systems to track and assess every establishment that is involved in the manufacturing, preparation, propagation, compounding, or processing of a drug or active ingredient of a drug. The Secretary shall ensure the interoperability of all databases relevant to the

Buyer / Matheson

110TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs.

IN THE HOUSE OF REPRESENTATIVES

Mr. BUYER (for himself and Mr. MATHESON) introduced the following bill; which was referred to the Committee on _____

The goal of the bill?
Amend the FFD&C Act

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs.

Wholesalers, ADR, TnT → **WHO's GDP, July 31st**

SEC. 3. DESTRUCTION OF COUNTERFEIT DRUGS OFFERED FOR IMPORT.

1. Wholesalers
2. SNI
3. TnT / ePedigree
4. Sell to only licensed WH

[DISCUSSION DRAFT]

111TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Sept 16th, 2010

M__. _____ introduced the following bill; which was referred to the Committee on _____

Henry Waxman & John Dingell (plus Others)

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "_____ Act of

Sec. 101. Registration of producers of drugs; applicable fee.
Sec. 102. Drug supply quality and safety.
Sec. 103. Inspection of producers of drugs.
Sec. 104. Prohibition against delaying, limiting, or refusing inspection.
Sec. 105. Clarification of inspection authority related to BIMO and IRB inspections.
Sec. 106. Notification, nondistribution, and recall of adulterated or drug products.
Sec. 107. Notification.

Supply Chain Integrity

TITLE II—RESPONSE

Sec. 201. Administrative detention.
Sec. 202. Destruction of adulterated, misbranded, or counterfeit drugs offered for import.
Sec. 203. Criminal penalties.
Sec. 204. Civil penalties.
Sec. 205. Seizure.
Sec. 206. Asset forfeiture.

TITLE III—IMPORTATION AND EXPORTATION

Sec. 301. Documentation for admissibility of imports.
Sec. 302. Registration for commercial importers; fee.
Sec. 303. Registration for customs brokers.
Sec. 304. Exportation certificate program.
Sec. 305. Extraterritorial jurisdiction.
Sec. 306. Dedicated foreign inspectorate.

Import Admissibility
Registration for importer
And Broker

TITLE IV—MISCELLANEOUS

Sec. 401. Unique identification number for establishments, importers, and custom brokers.
Sec. 402. Country of origin labeling.

Pharma Imports **WILL** Change

TITLE III—IMPORTATION AND EXPORTATION

SEC. 301. DOCUMENTATION FOR ADMISSIBILITY OF IMPORTS.

(a) PROHIBITION.—Section 301 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended, is further amended by adding at the end the following:

"(ww) The submission (with respect to drugs) of information that is required pursuant to section 801 that is inaccurate or incomplete.

The Reaction → PREDCIT and eCommerce

GUIDANCE FOR USING E-COMMERCE DATA TO MANAGE PRODUCT ADMISSION AT INTERNATIONAL BORDERS

Integration Guidance for International Trade Data System Participating Government Agencies

OCTOBER 2010 – DRAFT 1.5 – FOR INDUSTRY CONSULTATION

ITDS Product Information Committee


SHOP
in a snap
INTRODUCING SCANNABLE BAR CODES
1. From your mobile phone, download the FREE ScanLife app at Target.com/scan.
2. Scan this info-rich bar code with your web-enabled, camera-ready phone to instantly receive content.
3. Can't scan? No problem! Just text TOYCATALOG to TARGET (827438).*

It’s coming at us whether we like it or not

Conclusion

The benefits of international trade are wide-ranging, yet these benefits bring with them new and complex challenges. Although they are of great value to the American consumer, the increasing volume of imports entering the United States creates an urgent need for a new, forward-looking Strategic Framework for import safety that considers risks over the life cycle of an imported product and focuses actions and resources to minimize the likelihood of unsafe products reaching U.S. consumers.

This will require shifting from the current model that relies on “snapshots” at the border to interdict unsafe products to a cost-effective, prevention-focused “video” model that identifies and targets those steps in the import life cycle where the risks of unsafe products is greatest and verifies the safety of products at those important phases. Such a risk-based, prevention-focused model will help ensure that safety is built into products before they reach our borders.

Part II
GDPs and GIPs

What does it all mean and how to expand the quality system into the supply chain
AND
What about RFID

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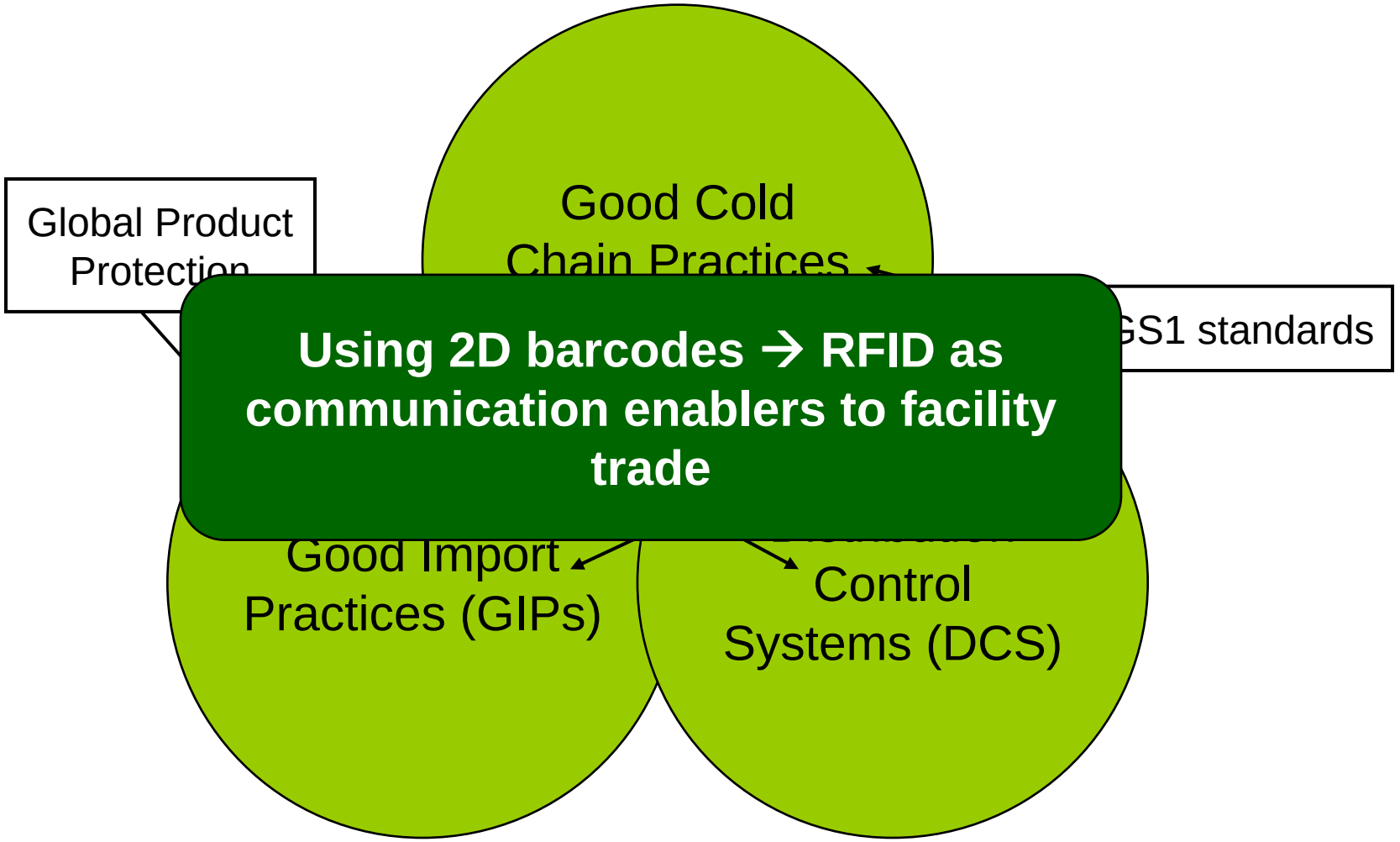
Expanding GMP into the Supply Chain (GDP)



Agenda – Part II

What is radio frequency (RF)

What is RFID, radio frequency identification

So what

Typical supply chain communication

- Linear barcodes, 1D barcodes, 2D barcodes (2D matrix), RFID
- Need faster, more accurate communication
- Why → I just showed you
  - New terminology (ePedigree, Track and trace (TnT), electronic security, eFreight)

Show and tell

RFID #1: Temperature data transmitted via RF signal to the web

RFID #2 – Import communication, RF tripped – pull data from cloud, transmit via broker to import authorities

What is RF and RFID

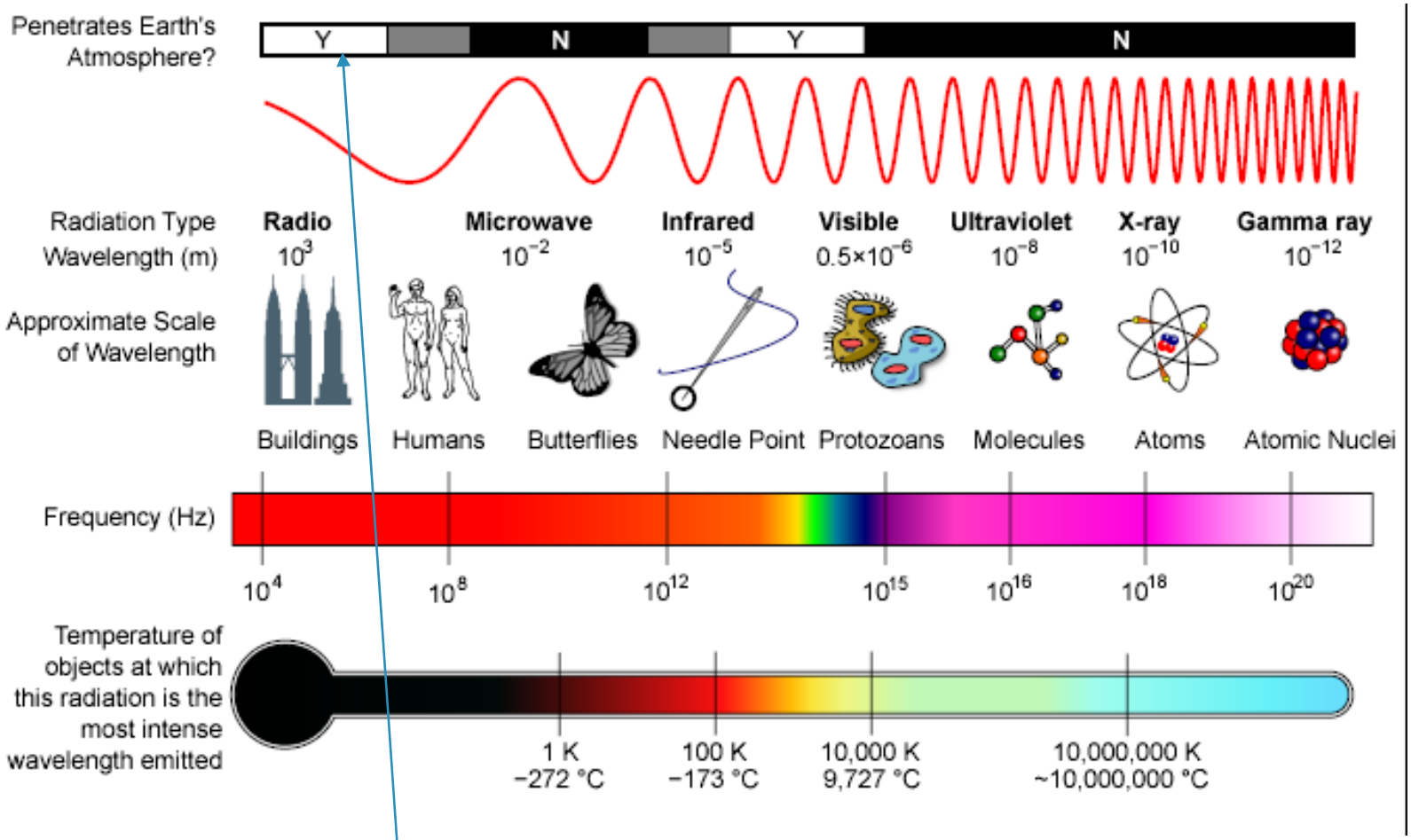
Radio Frequency (**RF**) is a frequency or rate of oscillation within the range of about 3 Hz to 300 GHz. This range corresponds to frequency of alternating current electrical signals used to produce and detect radio waves. Since most of this range is beyond the vibration rate that most mechanical systems can respond to, RF usually refers to oscillations in electrical circuits or electromagnetic radiation.*

Most Supply chain “RFID” are 13.56 to 2.5 GHz (Your cell phone is 2.5 GHz)

Active = has a battery, Passive = no battery (uses energy from the reader

* From: Wikipedia

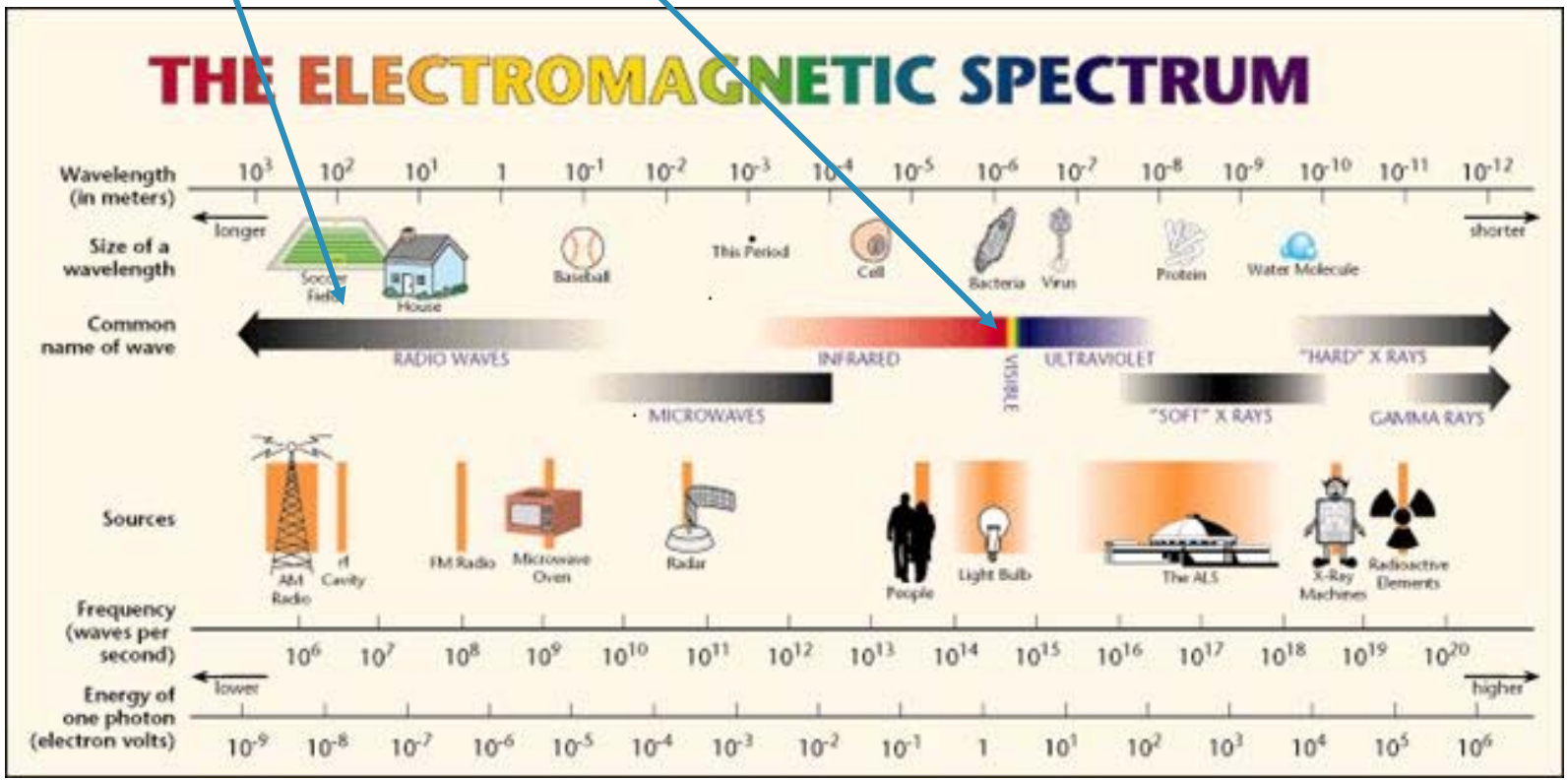
The EM spectrum
Radio waves (10^{3}) to Gamma Waves (10^{-12})



We are bombarded by RF energy

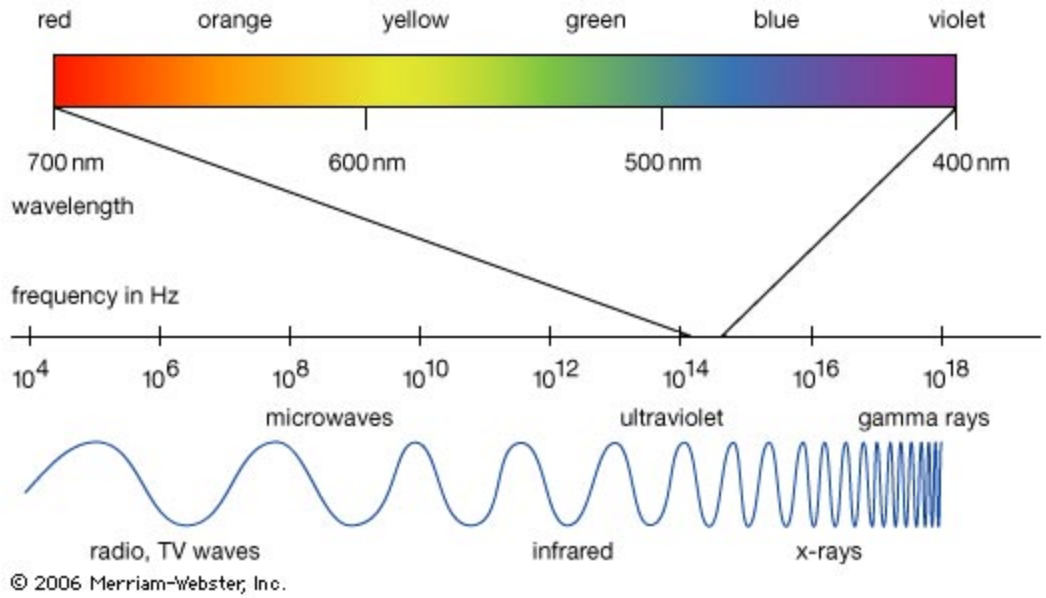
We are bombarded by RF energy

RF EM waves >> visible light waves



Visible light is a tiny sliver of the EM and >> energy RF

FDA's CPG states can't use RF for Biopharmacueticals – but we're already using it (SRx picking and RF enabled forklifts, etc)



Naturally occurring RF energy is everywhere AND we're Currently using RF in many supply chains

Supply Chain Safety: Pharmaceutical Electronic Track-and-Trace

November 17, 2008

Jeffrey Shuren, M.D., J.D.
Associate Commissioner for Policy and Planning
U.S. Food and Drug Administration

#1 Typical RF Reader Infrastructure

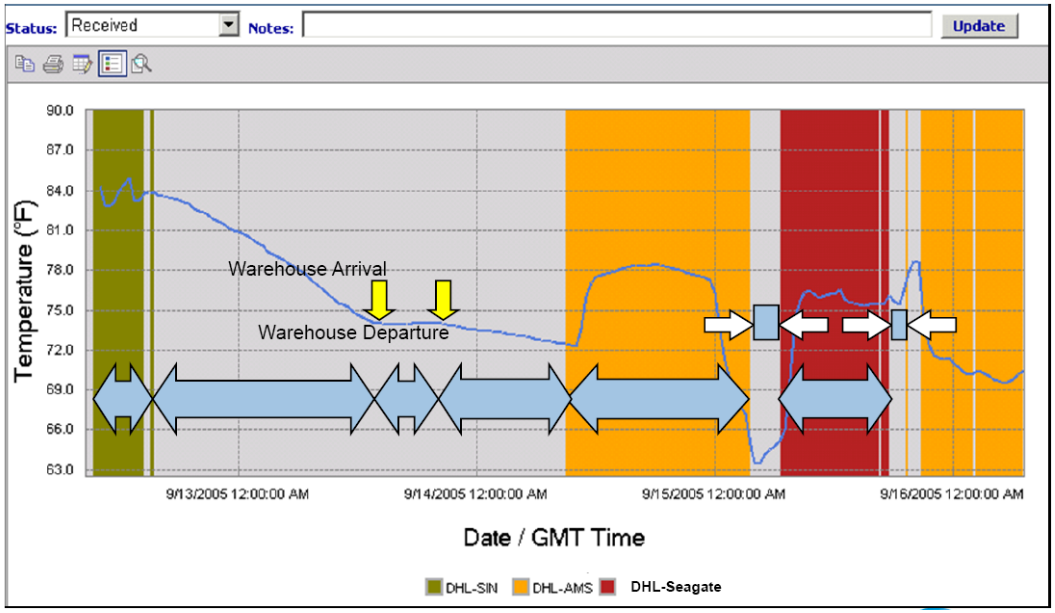
Via the web – load all shipping info onto the RF temperature Monitoring device

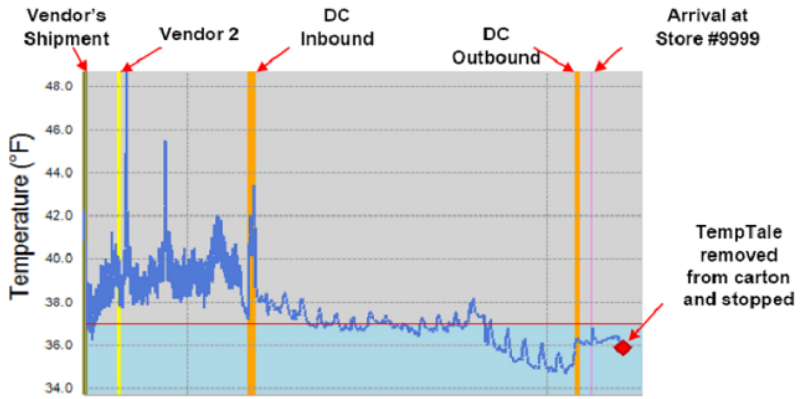
The RF Gateway and RF Repeaters form a network that provides the communications link to TempTale RF (TTRF) sensors.

#1 RF Features / Typical RF Temperature Download

RF Features

- Full temperature recording and alarming;
- Location tracking → where did the excursion happen at;
- 100 meters (line of site) read range;
- Inexpensive reader infrastructure;
- Automatic alarm notification by email (and cell phone)



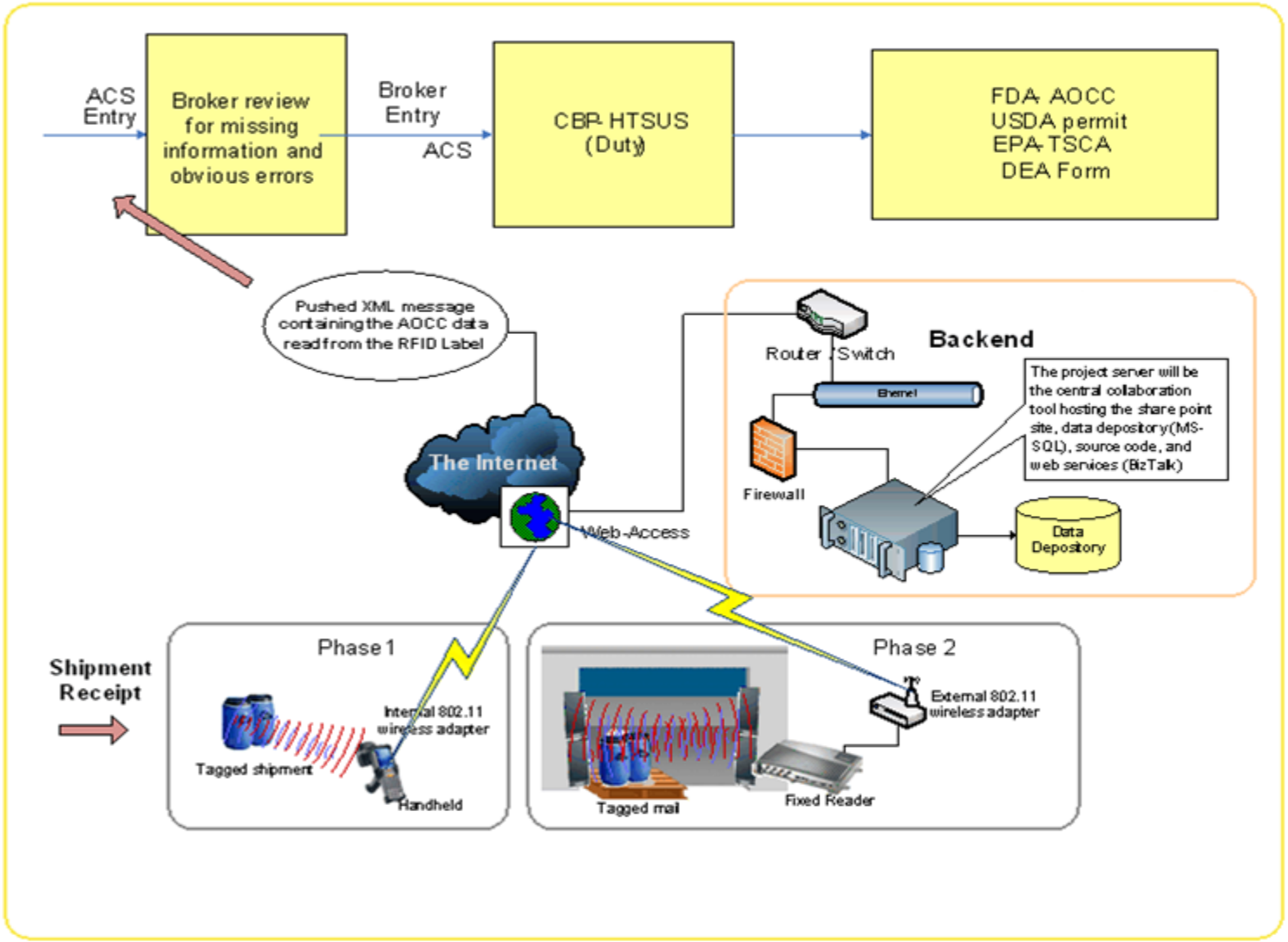


#2 Drums at our U.S. Broker after CBP clearance

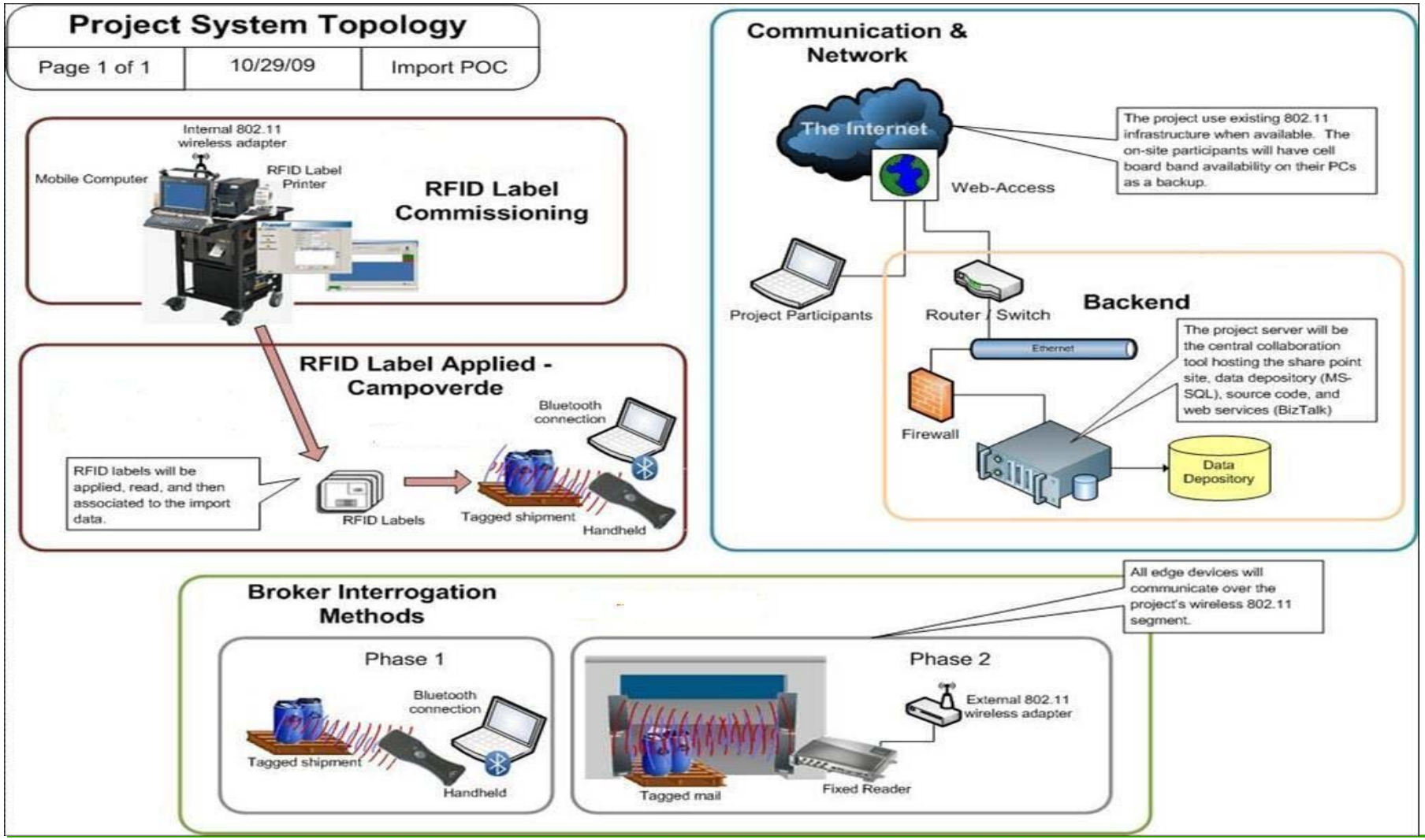
RFID Tag

© 2008 Abbott

Connectivity (Interoperability)



How to move info and point of entry from cloud to gov't (CBP, TSA, FDA, USDA, CPCS, EPA, DEA, etc)



So why RF? Vs. 1D, 2D, etc

1. Don’t need line of site
2. Automates “look-ups”
3. Quicker connectivity → faster info low
4. One more tool in the product protection category
5. WHO, FDA, MHRA, and other gov’t MOH like it
6. Can store more info (vs. 1D)
7. Matured - Has come a long way in the retail business

Questions?