

Wellcome from Minnesota



History and future of TTI & RFID

Traceability, Safety and Shelf Life

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Industrials
Paint
Adhesives
Solder
Paste



Blood, Vaccine, Pharma,
DoD Meals Ready to Eat,
Film



Fish, Deli, Coffee, Wine, Dairy, Cut Salad,
Organics

What do we want to do now and in the future (Traceability) ?

- Get the location of a lot of food in the distribution chain in case of an event (recall or bioterror event) ?**
- Where did ingredients come from?**
- What about the ingredients in ingredients?**
- What line, batch #, date, time was it made on?**
- What is the shelf life left of the product?**
- Is the food safe when we eat it, either by sensing agents or by modeling?**

ISO 9000-2000 Clause 3.5.4 Traceability is the ability to trace the history or location of what is under consideration

Passive -Information only food labels

- Kroger 1960's - starts putting "sell by " on milk
- Denmark 1970's required
 - Pack date
 - Sell by date
 - Use by date
- GMA v Mass. Dept. Public Health -
 - 393 NE2nd 881 (1981)
 - Court agrees state can require dating

U.S. Regulatory Stance on Shelf Life

- **Federal Laws**
 - **Required for drugs, OTC and infant formula**
 - **Drugs 10% loss below label value on lower 95% CL line**
 - **All other food products voluntary - no mention in regs**
- **State laws**
 - **30 states regulate some dates (dairy, meat)**
 - **Minnesota \leq 90 days**
 - **None based on safety more for commerce**

Types of food dating

Code date

Born on date

Sell by date

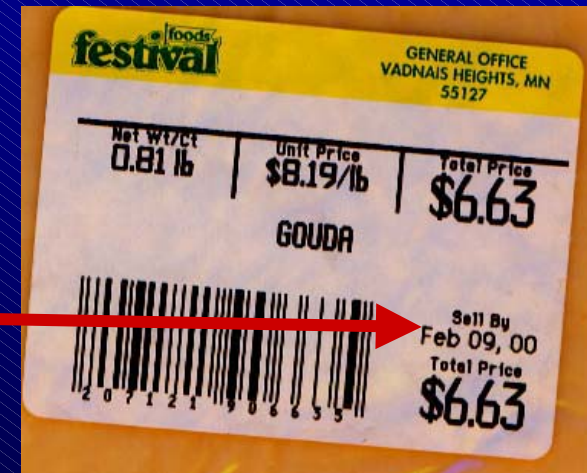
Better if used by

Freeze by

Best when purchased by

Best if used by - minimum durability

Death date - use by (expiration)



EU Dating Rules

Directive 97/4/EEC Article 9 of 79/112/EEC.

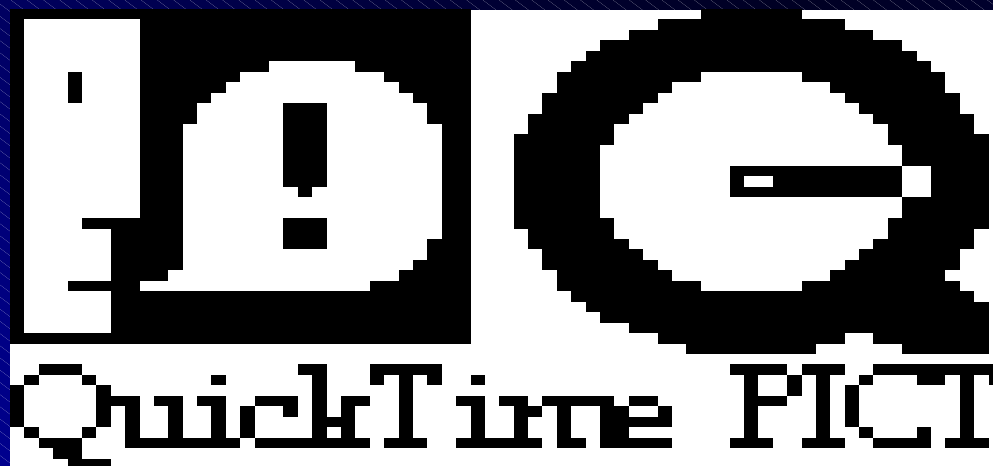
1. *The date of minimum durability of a foodstuff shall be the date until which the foodstuff retains its specific properties when properly stored. It shall be indicated in accordance with the provisions of this article.*

2. *The date shall be preceded by the words:*

--“Best before...” when the date includes an indication of the day,

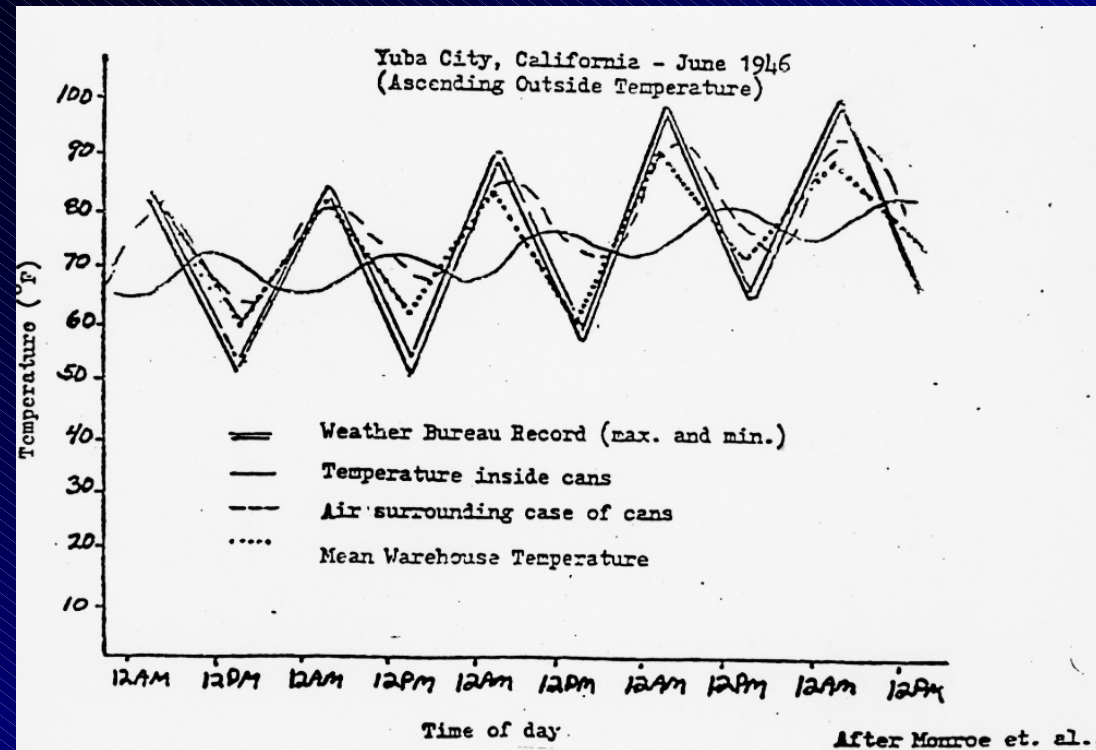
--“Best before end...” in other cases

3, *In the case of foodstuffs which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the “use by” date.*



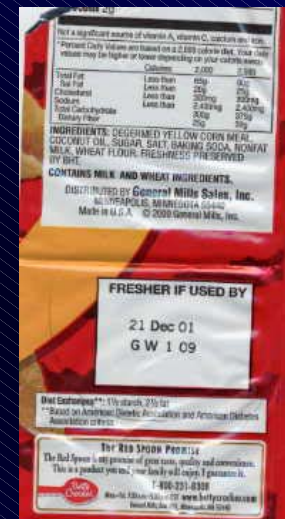
But: dates by themselves ignore t-T history in distribution

So



Development of TTI

- 1977 WHO issues report on need to improve cold chain because of vaccine distribution problem in LDCs (84% ineffective)
- Wendel Manske @ 3M
 - Monitor-Mark Diffusion tag
 - US patent 3,954,011 5/76 3M
- K. Blixt -Swedish patent for i-Point device
- Byrne (General Foods) & Kramer (UMD) 1977
 - presented correlation study of tags vs food change for frozen foods
 - Used i-Point and 3M Monitor Mark missed the key kinetic point



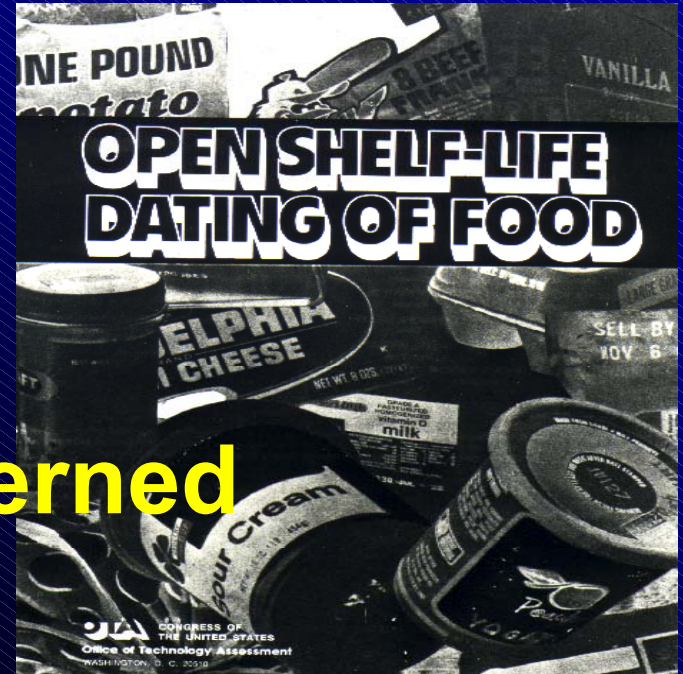
Shelf Life Dating

- **OTA Study on Open Shelf Life Dating of Foods 1979-81**
 - Open dating is state driven (~30 in 2002)
 - No federal requirements on food but required on drugs, OTC and infant formula
 - Open shelf life dating of foods is desirable
 - Open date compromised if temperature abused
 - Federal Govt should support TTI research



OTA Study 1978

- 96% consumers concerned with quality
- 1 in 10 felt some food they bought was spoiled
- most were aware of dairy food dating
- 62% sorted for freshest (date)



NSF Food Loss Survey 1979

- **frozen foods 1 to 2.9% loss**
- **dairy products 0.7 to 3.5%**
- **fresh beef ~ 5% loss**
- **fresh produce 9 to 16.6% loss**

A.C. Nielsen 1983

- **58% of consumers found defective food when they got it home**
- **5% complained to store**
(1 in 20)
- **30% did not re-buy brand**
- **15% did not re-buy food type**
- **worst was fresh and frozen food**

The 3 Company Trio

- **3M wax diffusion tag**
- **Vitsab (I-Point) - enzyme reaction tag**
- **Lifelines -- Pt polymerization**
- **3M WL□LF diffusion tag**

The kinetic break-throughs

- **Singh & Wells 1988 (U.C. Davis) - correlation studies for DOD**
- **Taoukis & Company at Univ Minnesota 1989**
 - 1st quantitative work on TTI-tag kinetics
 - Shows need for kinetics based on E_a or Q_{10}
 - Need for run out time of food
 - Concept that change at time to end must be same for constant or variable temp

Chemical Tag Design parameters

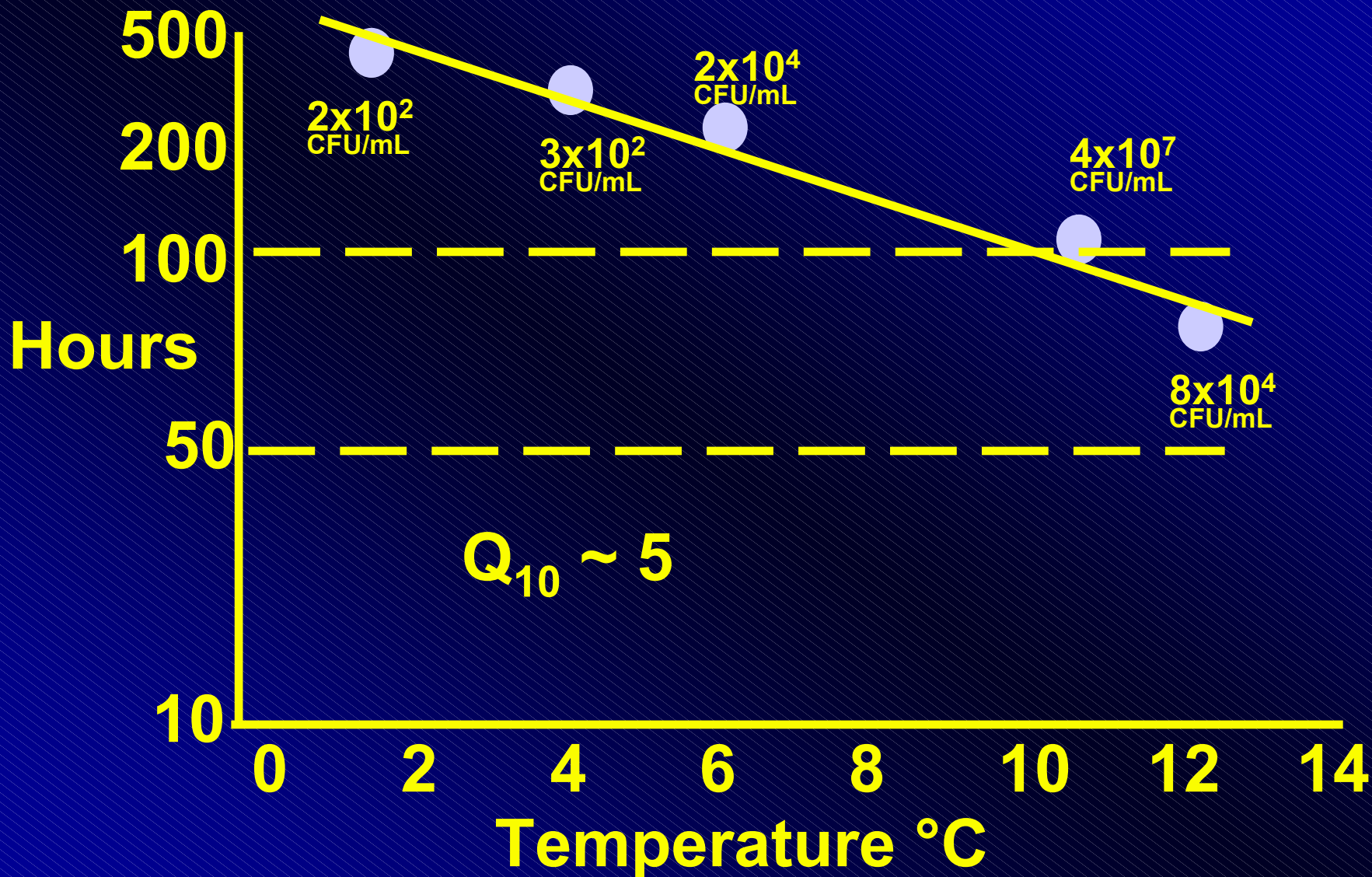
- TTI - time-temperature integrating tag
 - Chemistry of reaction in tag must follow food or drug kinetics
 - Rate of degradation as $f(T)$
 - Arrhenius function
 - Similar E_a or Q_{10}

$$k = k_o e^{\frac{-E_a}{RT}}$$

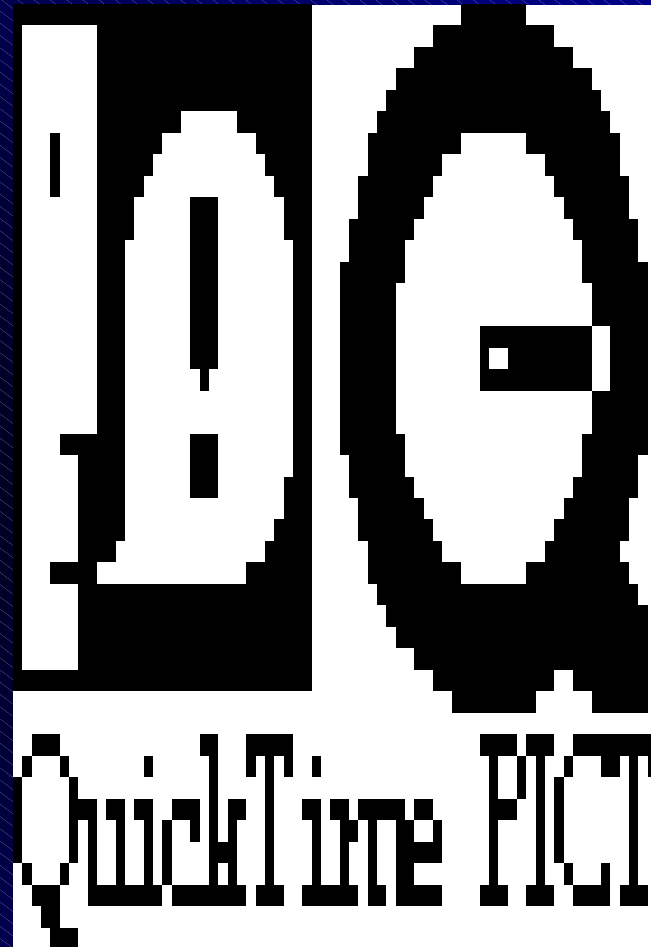
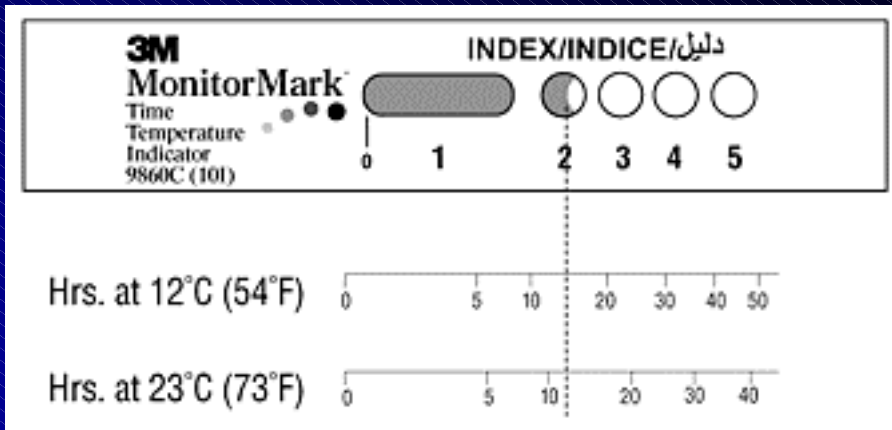
$$\ln k = \ln k_o - \frac{E_a}{RT}$$

$$\text{or } \ln \tau = \tau_r - bT$$

Sensory Shelf Life of Specialty Skim Milk

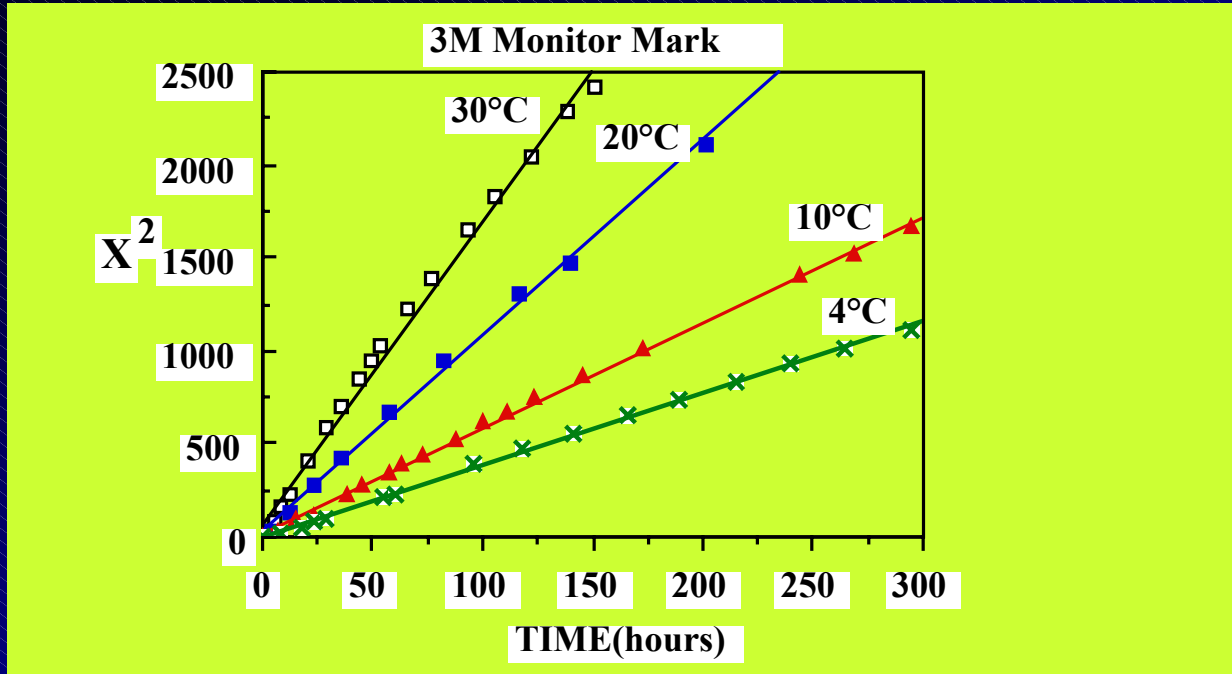


3M Diffusion Tag



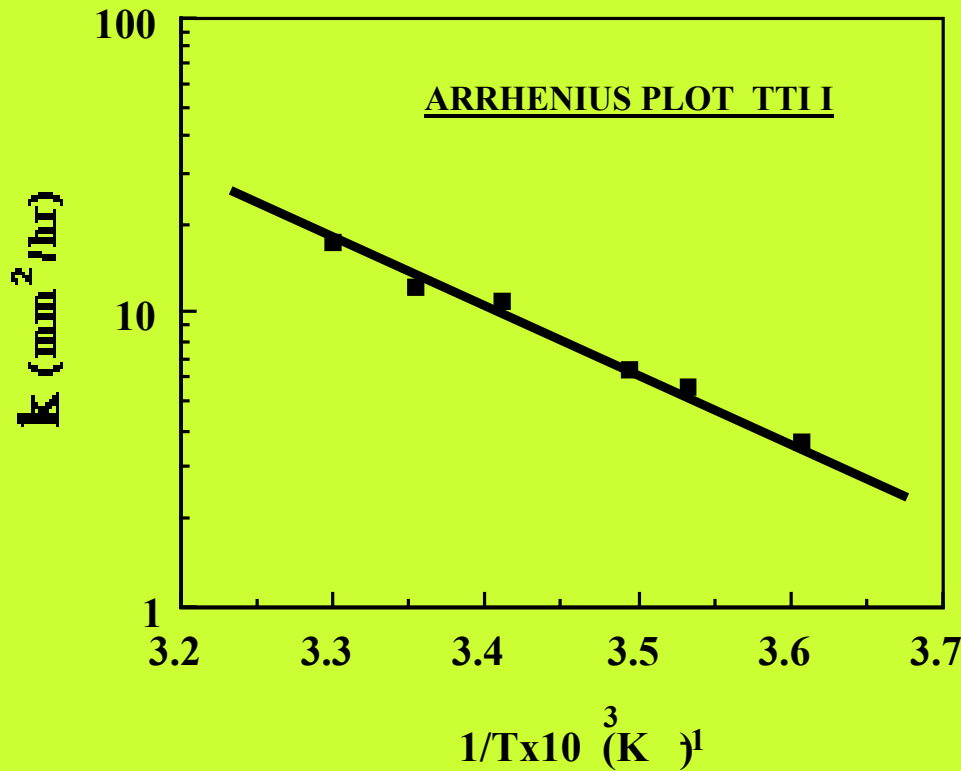
http://www.fdcpackaging.com/temperature/time_indicators.html

Diffusion Kinetics for 3M tag



Crank derivation $x^2 = k t$

3M MonitorMark



$$\ln k = \ln k_0 - \frac{E_a}{RT}$$

$E_a \sim 5$ to 9 Kcal/mole vs food at 12 to 40 Kcal/mole

Shelf Life plots food or drug vs tag

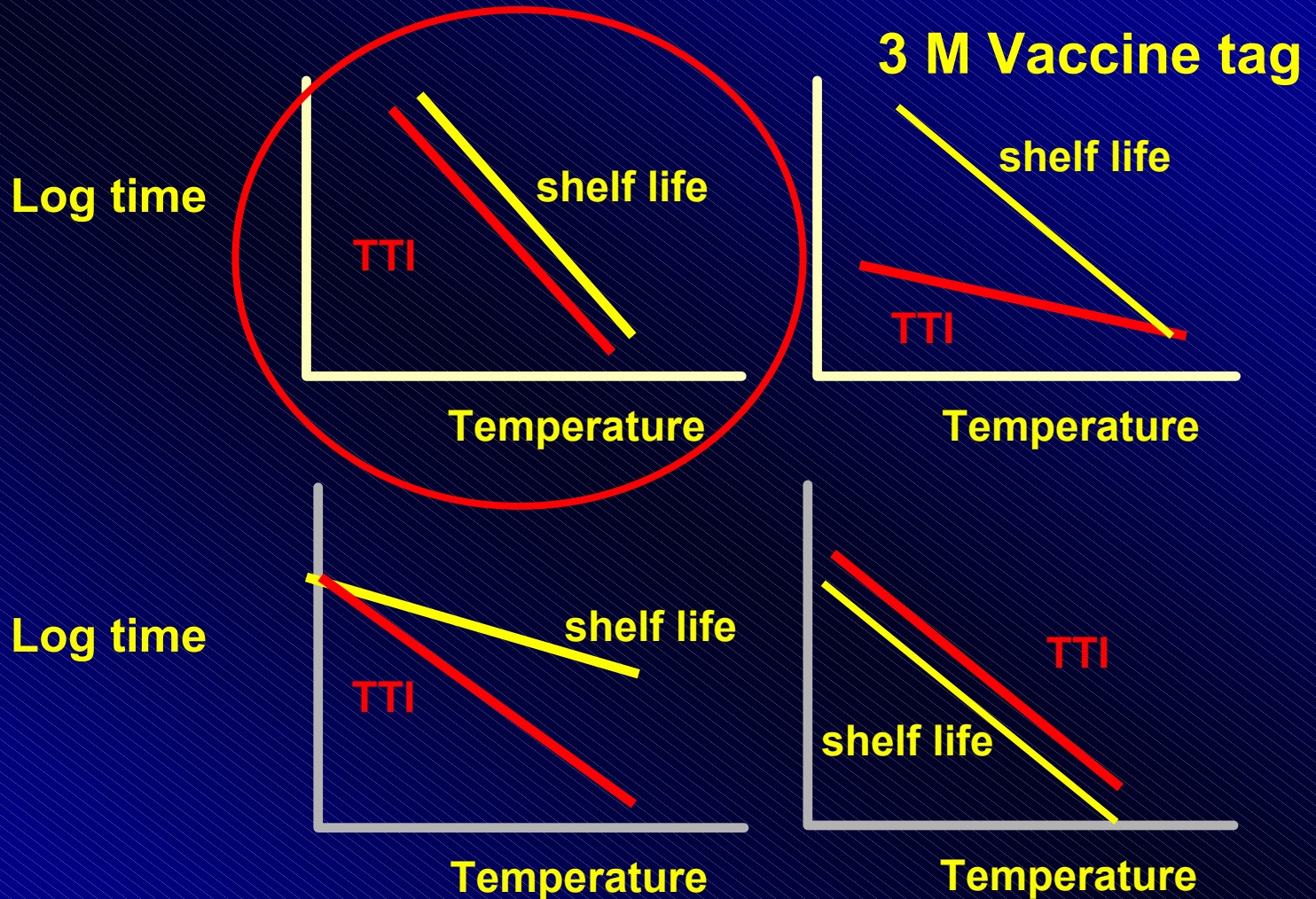
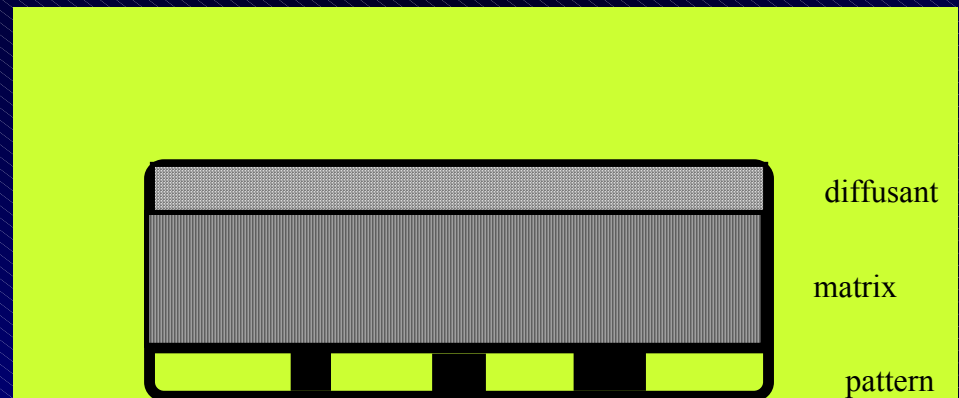


Illustration of proper and improper TTI design

US Patent 5,667,303

- Time-Temperature Integrating Indicating Device Arens et al. 3M
- Issued in September 1997
- New concept of a diffusion tag with variable E_a based on WLF kinetics
- Range 15 Kcal to 30 Kcal/mole



Full scale change



3M Commercial Tests of 2nd Gen Monitor-Mark



CUB Foods

An advertisement for the 3M MonitorMark Smart Label. It features a man in an orange safety vest holding a large sign that says "STOP &". Below the sign, the text reads "Check it out!" and "Check out the 3M™ MonitorMark™ Smart Label on specially marked bratwurst packages. It will tell you if your bratwurst has been properly refrigerated." At the bottom, there are two columns of images. The left column shows a green thumbs-up icon and the text "OK" and "Food is OK". The right column shows a red thumbs-down icon and the text "Not OK" and "Food is Not OK". Below these are four images of the Smart Label, two for "OK" and two for "Not OK", showing the label's response to temperature changes.

Johnsonville Brats

Lifelines acetylenic monomer tag polymerization catalyzed by Pt



Fresh-Check® Indicator

Do not use if center is darker than ring.

Fresh-Check® Indicator

- FRESH
- STILL FRESH
- STILL FRESH CONSUME IMMEDIATELY
- FRESHNESS NO LONGER GUARANTEED IF CENTER IS DARKER THAN RING.

Color of center shows remaining shelf life.

Activation Energy ~ 19 - 30 Kcal/mole

MonoPrix France 180 stores



Freshness Chip

MONOPRIX



LA FORME

fine
fromage frais



Poids net 1 kg

0 POUR CENT DE
MATIÈRE GRASSE

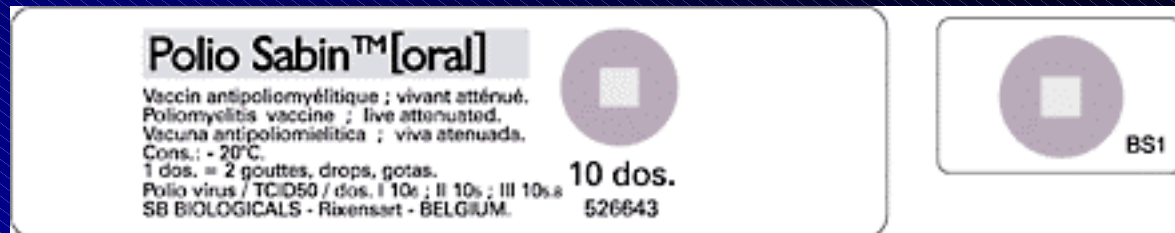
10 DEC

Freshness Point



Vaccine Vial Monitor (VVM)

- WHO mandated programs for health care and food safety.
 - Vaccine Vial Monitors mandated by World Health Organization and UNICEF
 - ISO 9001.2000 and HACCP
- Sold > 120 million “Heatmarker” labels for polio VVM (100% of WHO requirement)
- http://www.fsci.umn.edu/Ted_Labuza/PDF_files/papers/Vaccine_TTluse.pdf



VITSAB enzyme reaction tag

Activation Energy ~ 20- 35 Kcal/mole



Many uses and part of
S□MAS

Point Out Your Freshness

freshpoint.

very fresh



fresh



still fresh



not fresh



The FreshPoint
TTI Label

Reference Color

www.freshpoint-tti.com



freshpoint.

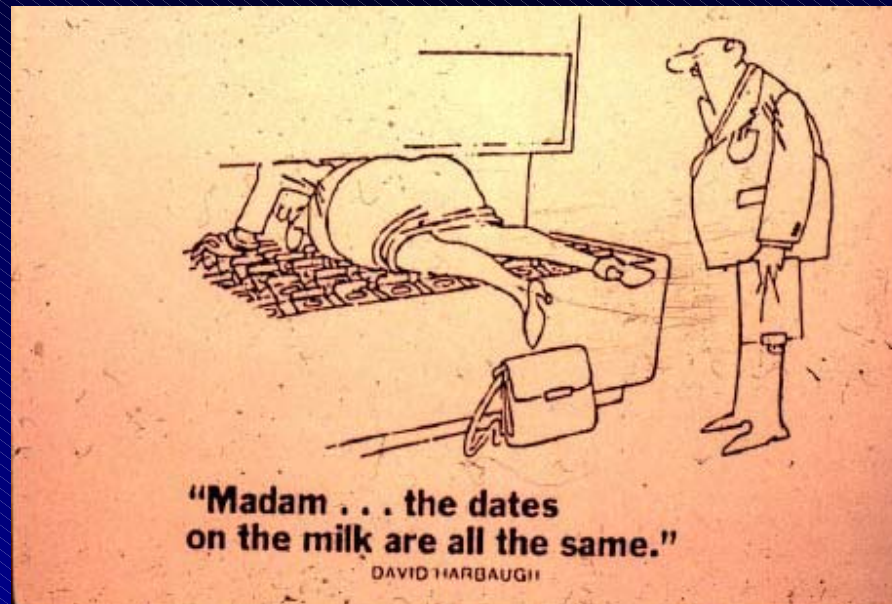
Active Matrix

Days of Shelf life of milk

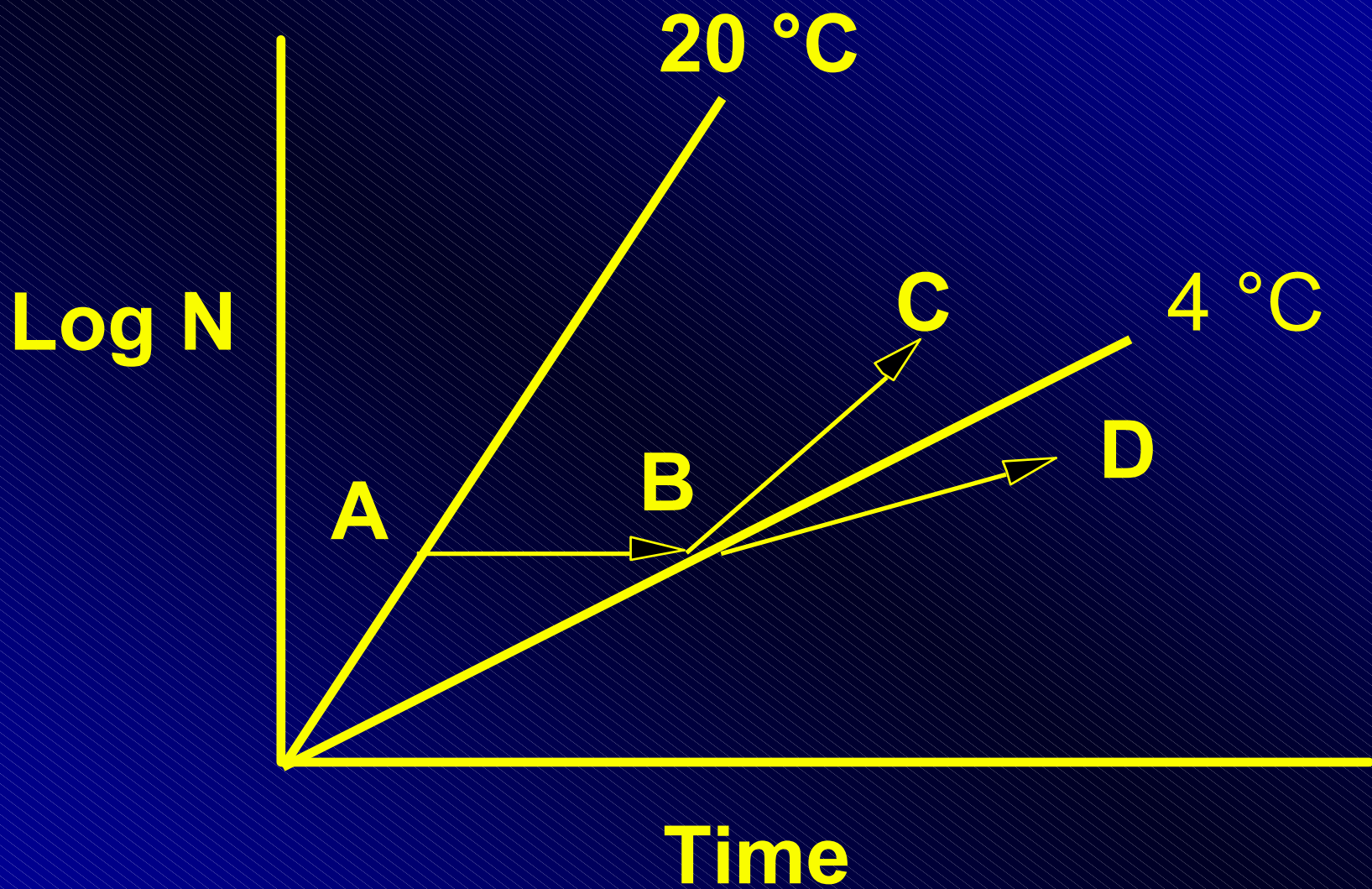
System	Predicted	actual
Lifelines	9.8	10.3
3M	10	9.5
VITSAB	10.6	9.8
Sensory	8.1	9.9

TTI Problems

- need to collect food E_a data
- Must match tag kinetics to activation energy and run-out time of food - time consuming
- ease of reading end point
- sorting



- Food (or tag) must not have history effect



TTI Problems

- ease of reading
- need to collect food E_a data
- need to match tag kinetics to activation energy and run-out time of food
- food must not have history effect
- **marketer's resistance to cost**
- **liability for implied safety**

Consumer demand for dating

- 1998 Joanne Gage (Price Chopper)
 - * **Consumers want simple and basic information**
 - * **“Sell-by” and “use-by” date sought after**

(Dowdell, 1996; Williams, 1998)

From Lifelines FAQ

13) Why have we not seen the same success with TTIs in the United States as in Europe?

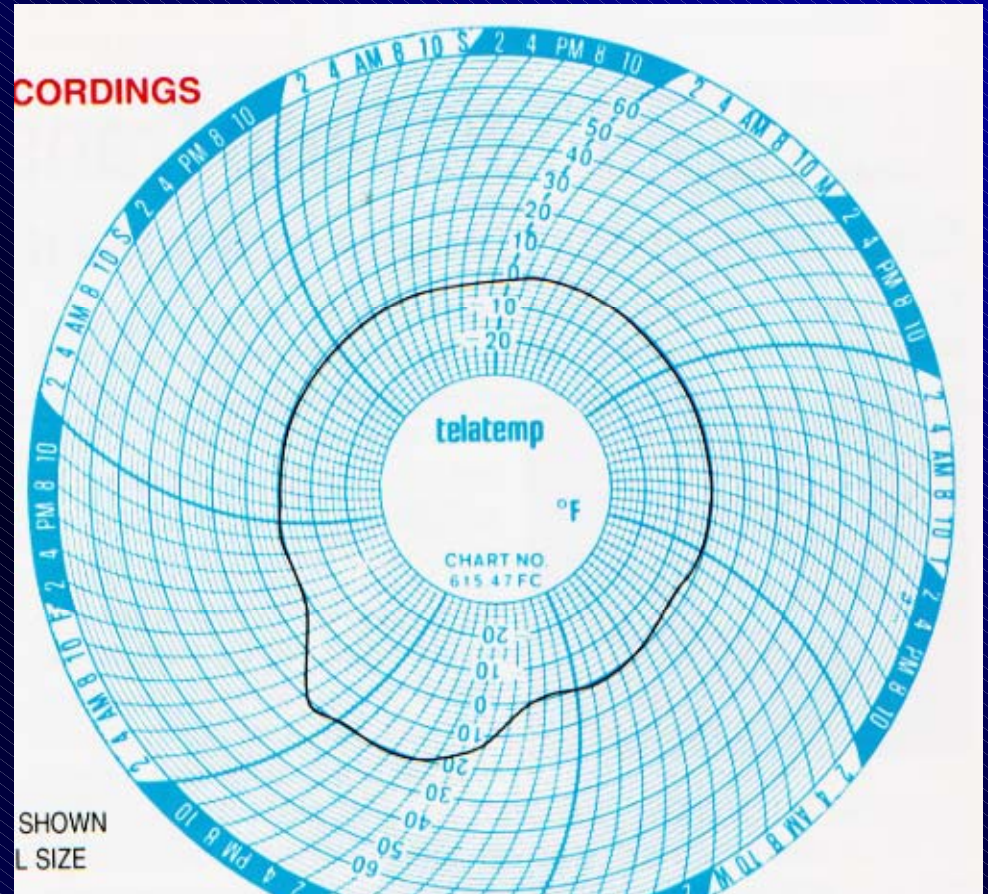
For the past several years, **many U.S. supermarket chains have elected to compete for market share based primarily on pricing, leading to eroding margins**, whereas, European food retailers have focused on marketing and merchandising strategies to create a point of difference. European Retailers have also built very strong Private Label product lines which command a significant share of category mix and contribute significantly to company profitability. The development of strong Private Label programs is now an important part of the business strategy of many U.S. supermarket chains. TTIs can be an integral part of that strategy and can help to differentiate a chain's Private Label program.

Other early systems



Optional
counting
racket
04

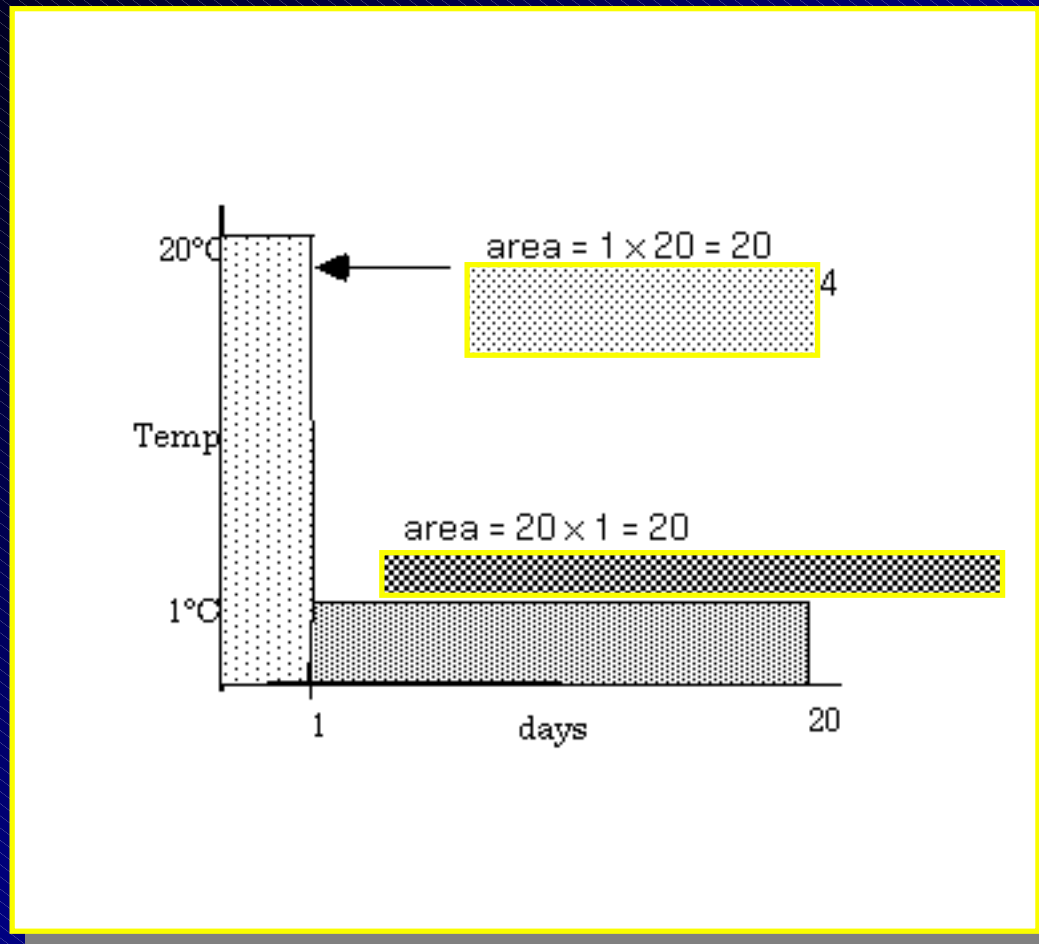
CORDINGS



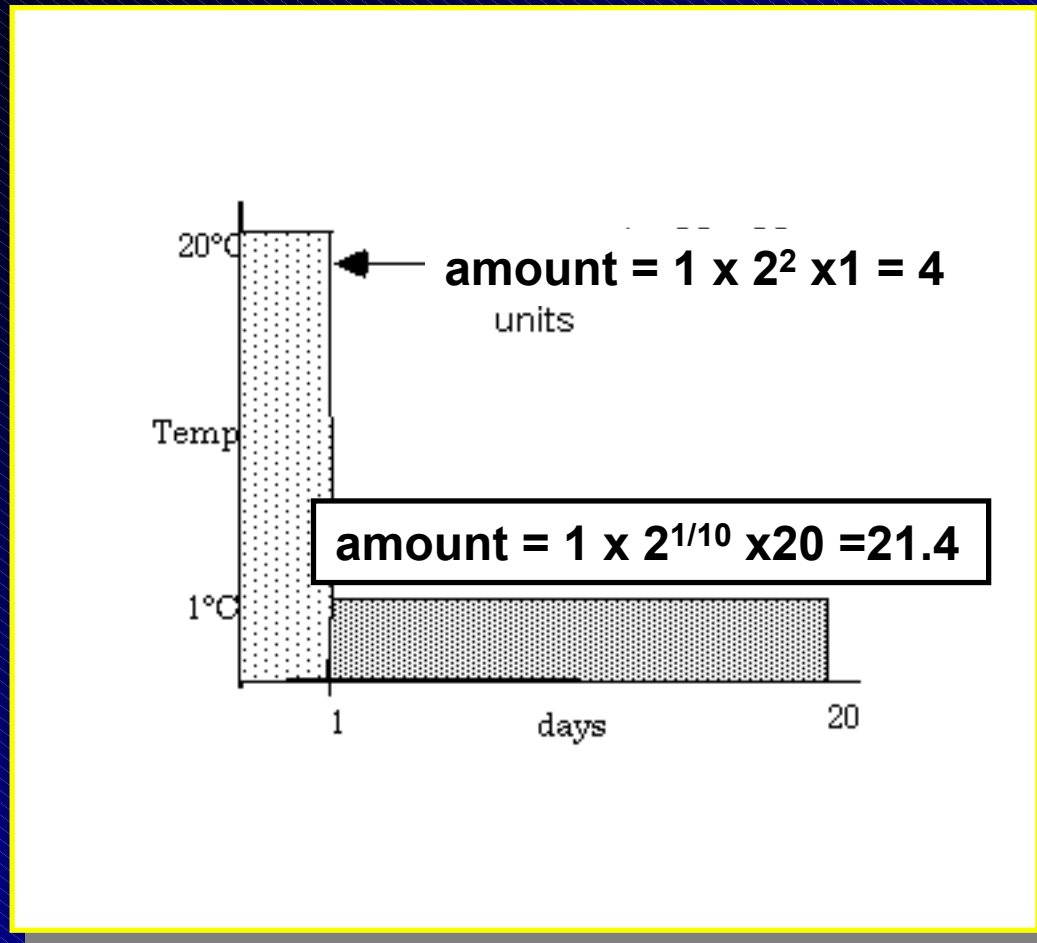
SHOWN
L SIZE

measures area under the T vs t curve = degree days
Area not = to quality lost

Area under T vs t curve



Area under T vs t curve



$$Q_{10} = 2 \quad \text{Rate}_{0^\circ\text{C}} = 1 \quad \text{Amount} = \text{Rate}_{0^\circ\text{C}} \times Q_{10}^{\Delta T/10} \times \text{time}$$

Amount of Change for $Q_{10} = 6$

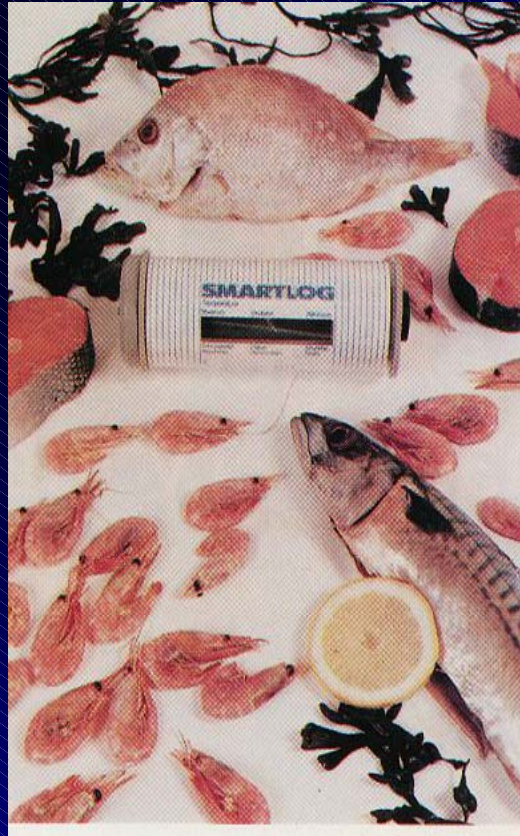
- for 1 day @ 20°C

- Amount = $1 \times 6^{20/10} \times 1 = 36$

- for 20 days at 1°C

- Amount = $1 \times 6^{1/10} \times 20 = 23.4$

Reymomsis Fish Shelf Life Data Logger Integrator 1970



For fresh fish

Tropicanna Fresh OJ

Food Tech June 1991 pg 119-120

- **72% of consumer complaints due to temperature abuse**
- **lack of accountability in distribution**
- **~37% retail storage above recommended 32-38°F**
- **stock rotation poor**

1996 USDA FSIS Transportation Technical Analysis group

- **current regulation of t-T is passive**
- **logistics of handling perishable foods is vague**
- **what are the transportation hazards?**
- **how to apply HACCP**
- **who is liable ?**
- **use of time-temperature monitoring systems**
- **use of vehicle tracking systems**
- **new technologies for T control**

61 FR 59372-82 Transportation and Storage Requirements for Potentially Hazardous Foods

- **Options for Regulatory Action**
 - **Set time-temperature performance standards**
 - **Require shipper record keeping**
 - **Create Mandatory HACCP-type systems**
 - **Create voluntary guideline**
 - **Combination of approaches**
 - **Do nothing**

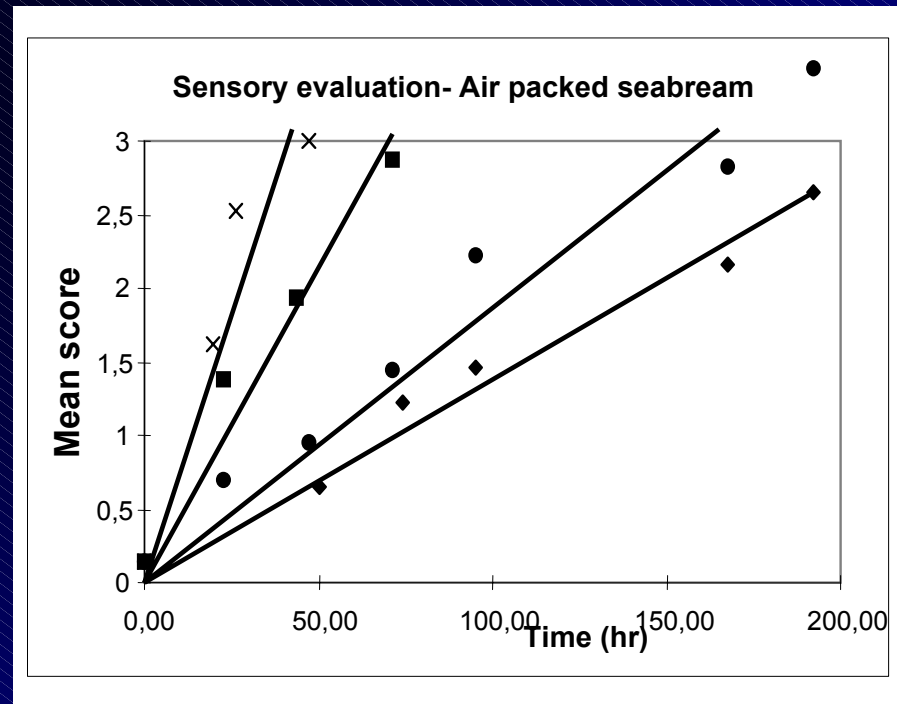


- **FIFO vs LIFO system (Wells and Singh 1988)**
 - **Would make for better distribution using least shelf life left**



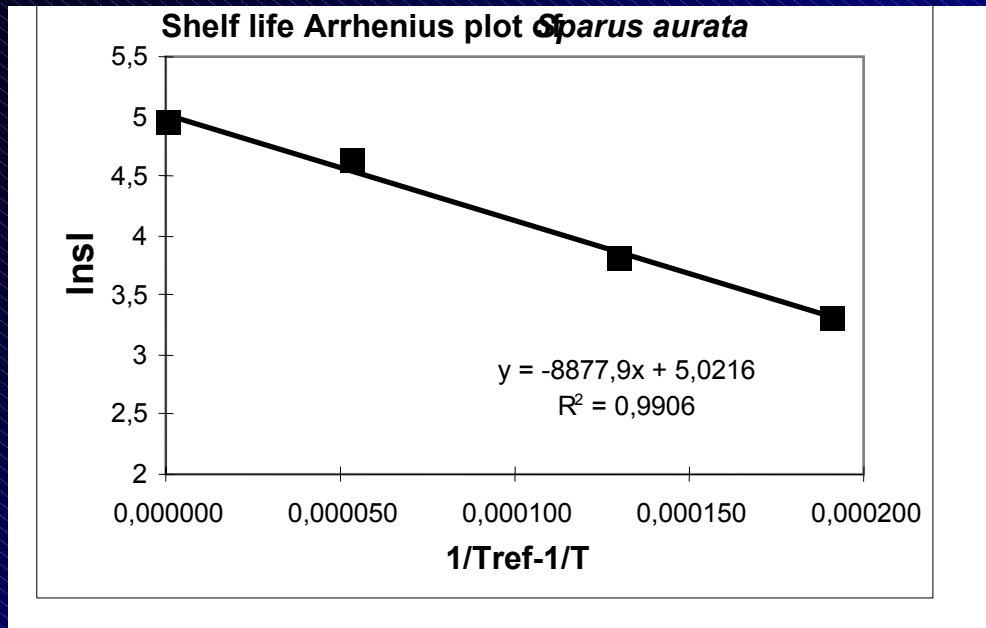
- **FIFO vs LIFO system Taoukis et al**
 - **≥15% savings (EU programs including SMAS)**
 - Taoukis, P.S., Bili M., Giannakourou M. (1998). “Application of shelf life modelling of chilled salad products to a TTI based distribution and stock rotation system.” Proceedings of the International Symposium on Applications of Modelling as an Innovative Technology in the Agri-Food-Chain Ed. L.M.M. Tijskens, Wageningen, Netherlands, p. 131-140.
 - **Case study with fish**
 - **Basis for formation of SMAS**
- <http://www.vitsab.com/htdocs/default.htm>

FISH SENSORY TEST ISOTHERMAL STORAGE



Giltheaded Seabream (*Sparus Aurata*) shelf life kinetics

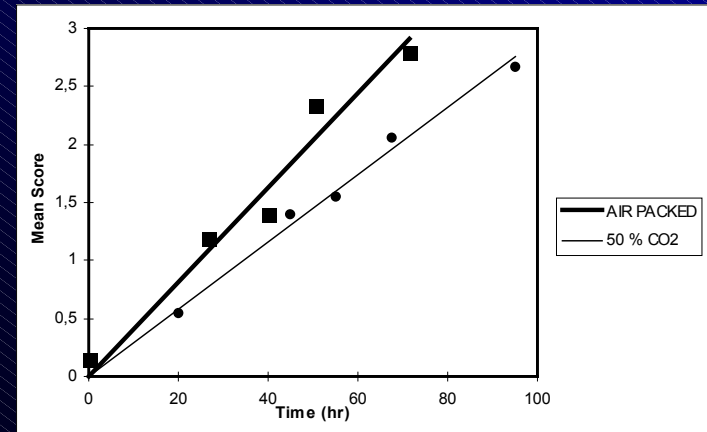
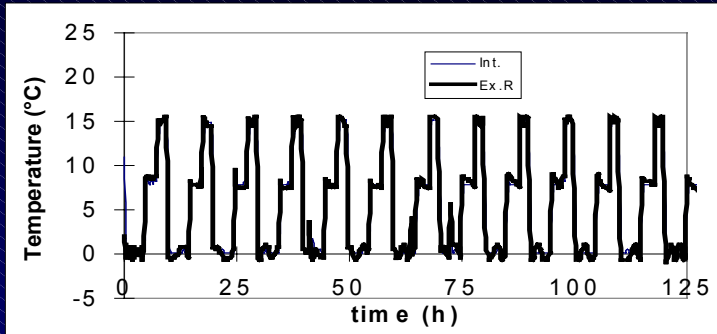
TEMPERATURE DEPENDENCE OF FISH SHELF LIFE



$SL_{0^{\circ}}$ (hr)	E_a (kcal/mol)	R^2
170-200	17.8	0.99

Giltheaded Seabream (*Sparus Aurata*) - Arrhenius plot

FISH SENSORY TEST : NON -ISOTHERMAL STORAGE



VARIABLE TEMPERATURE VALIDATION

$T_1 = 0^\circ \text{C}, 5\text{h} - T_2 = 8^\circ \text{C}, 3\text{h} - T_3 = 15^\circ \text{C}, 2\text{h} \Rightarrow T_{\text{eff}} = 6.55^\circ \text{C}$

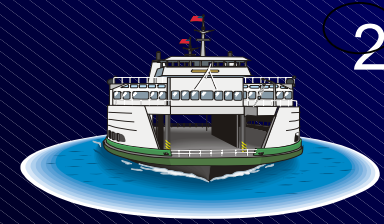
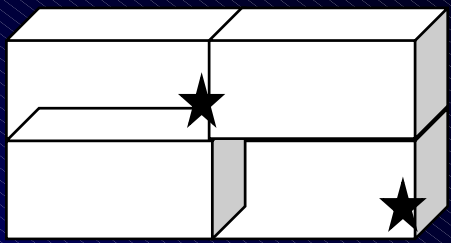
Air packed: Experimental shelf life = 69 h

Predicted shelf life = 71 h (68-74)

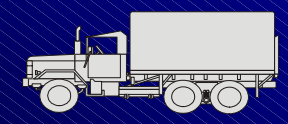
Sparus aurata shelf life kinetics-

Application in dynamic conditions shows no history effect

1 Chios island



2 Piraeus port (27 h)



3 Patra port (33 h)

Distribution center

External TTI expiration

(48 h)
(59 h)
(68 h)

Italy



4
5 (78 h)

(101 h)
(120 h)

6
Retail outlet and Local consumers

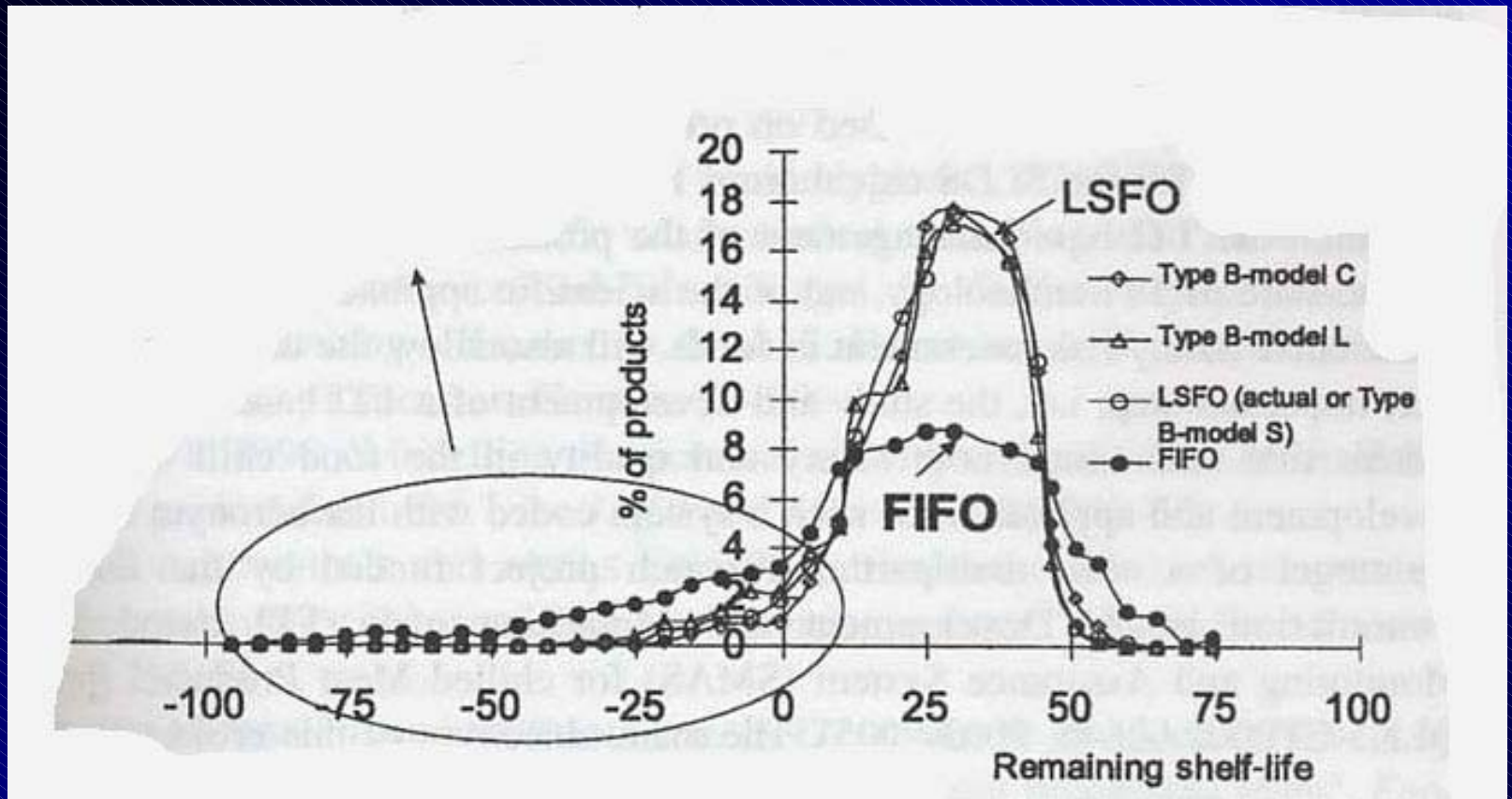
Field Test : Monitoring seabream exported from Greece to Italy

% Life Consumed

	TTI Center Box			TTI Top Box		
Time (h)	out	Inside box	Center of box	out	Inside box	Center of box
48	60%	40%	20%	70%	45%	25%
78	85%	50%	25%	>100%	75%	40%
120	>100%	90%	45%	>100%	>100%	60%

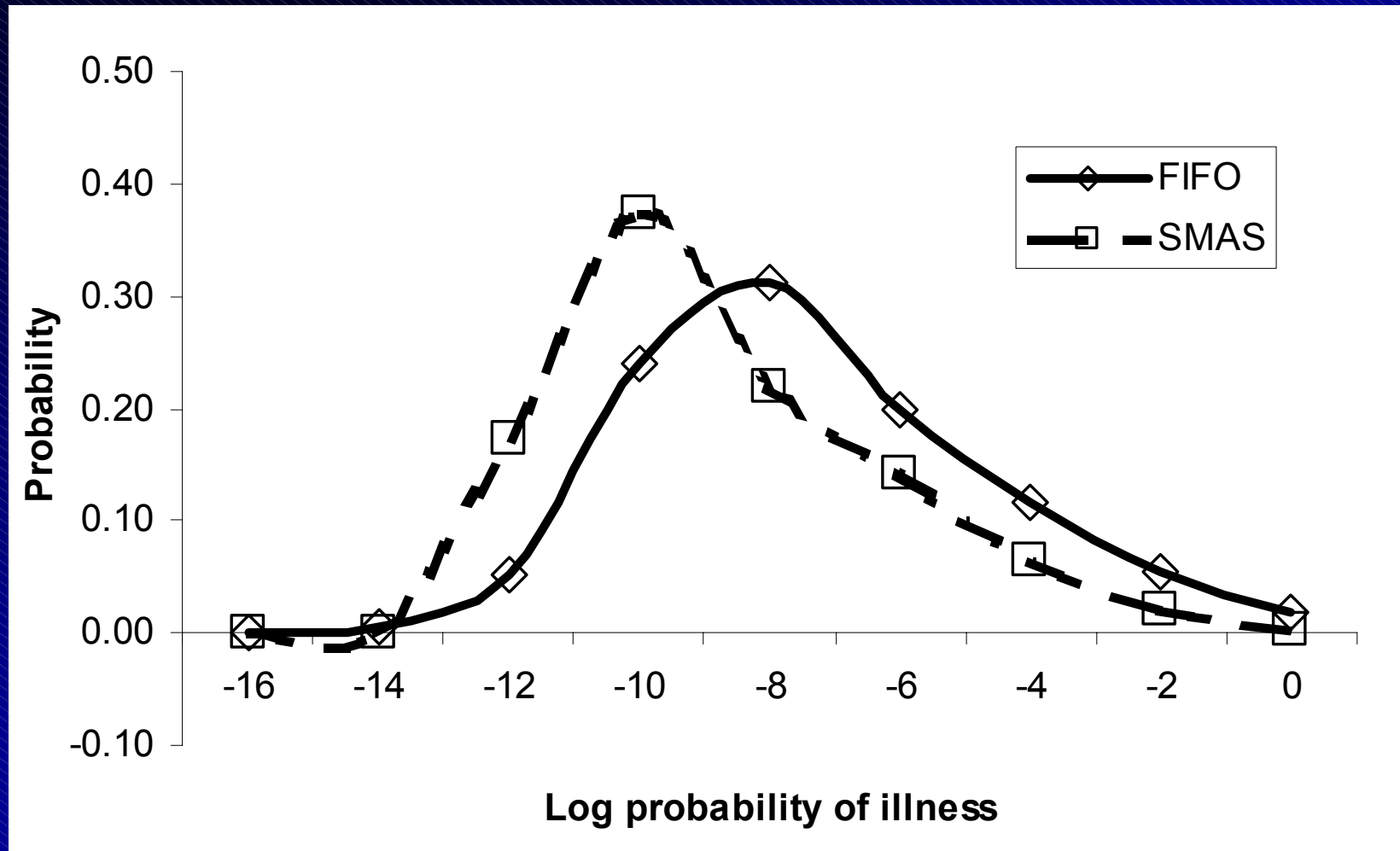
Field Test : Monitoring seabream exported from Greece to Italy

Note test showed if use LSFO increase profit by 15%



Ship based on least shelf life left (LSFO)
JFS 68(1):201-9
J Food Protection 64(7): 1051-57

Reduction in illness using LSFO



Commercial Application Problems

- Don't want to know about problem
- Liability if tied to safety
- Marketer's resistance to cost
- BUT!!!! Tracing with time-temperature logging is insurance policy and gets "who did it"

So portable active "data loggers" critical

Other chemical TTI vendors

- **Bioett - Sweden - biosensor system**
- **Food Guardian (UK)**
- **Deltatrak (US) - diffusion tag**

Generation III

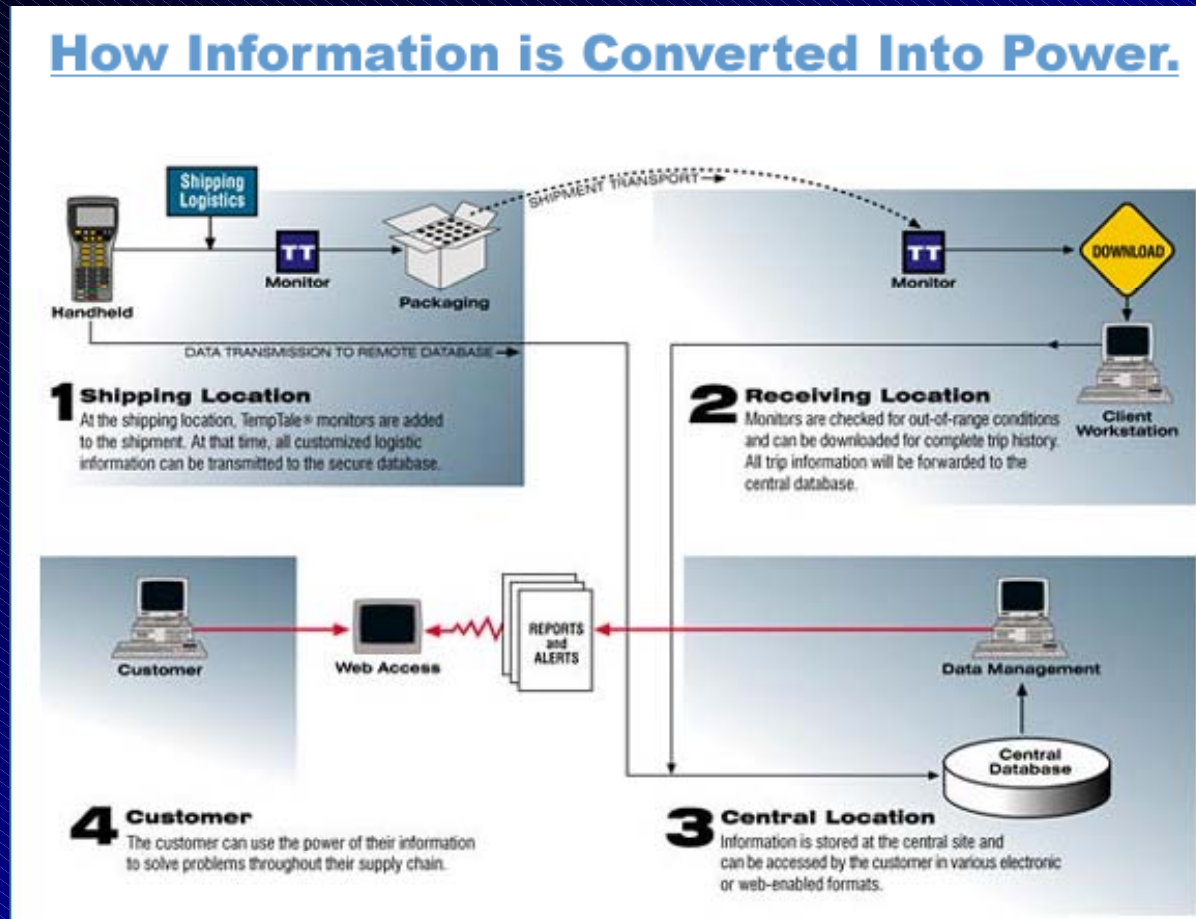
- **Electronic data loggers tied to computer analysis**

Data loggers

- Reusable
- \$10-\$15 cost
- Designed for distribution system



Sensitech Logistics and Temperature Management



http://www.sensitech.com/h_index.html

Determination of Effect of Time/temperature Distribution on Shelf Life or quality loss

Input the product name or code here **Salmon Shelf Life** Reference:

Data limited to three temperatures

Input the initial and final quality values (cannot be zero for 1st order) for most foods use As=2

Define: Initial Quality Ao = **100** End Value As = **2**

Note a key here is what you choose as an endpoint

This should be discussed with an Infratab scientist

Input the temperature and shelf life time

Input		hours
Temp °C	Shelf life time in	
0	242.4	
5	132	
10	62.4	

Kinetic parameters

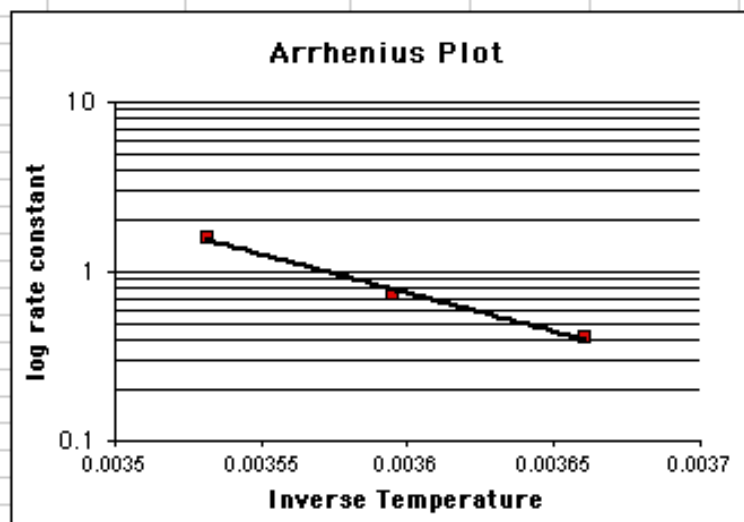
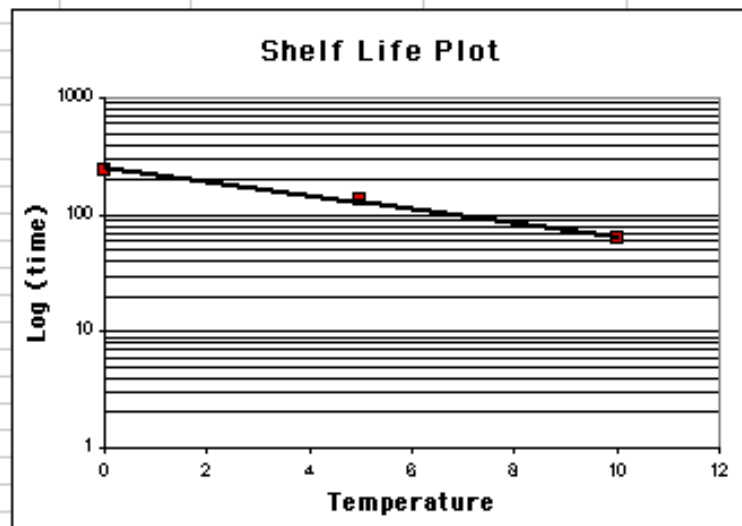
Shelf Life Constants		Shelf life equation $ts=to(\exp(-bT))$	
t ₀	248.18	shelf life at T= 0°C	r ² = 0.98
b	0.14	slope of shelf life plot	
Q10	3.88	rate increase for a 10°C increase in temperature	
Ea	20.82	kcal/mole	
k ₀	1.82E+16	zero order preexponent of $k = k_0 \exp(-Ea/RT)$	
Ea	20.82	Kcal/mole	
k ₀	7.28E+14	first order preexponent of $k = k_0 \exp(-Ea/RT)$	
r ²	1.00		

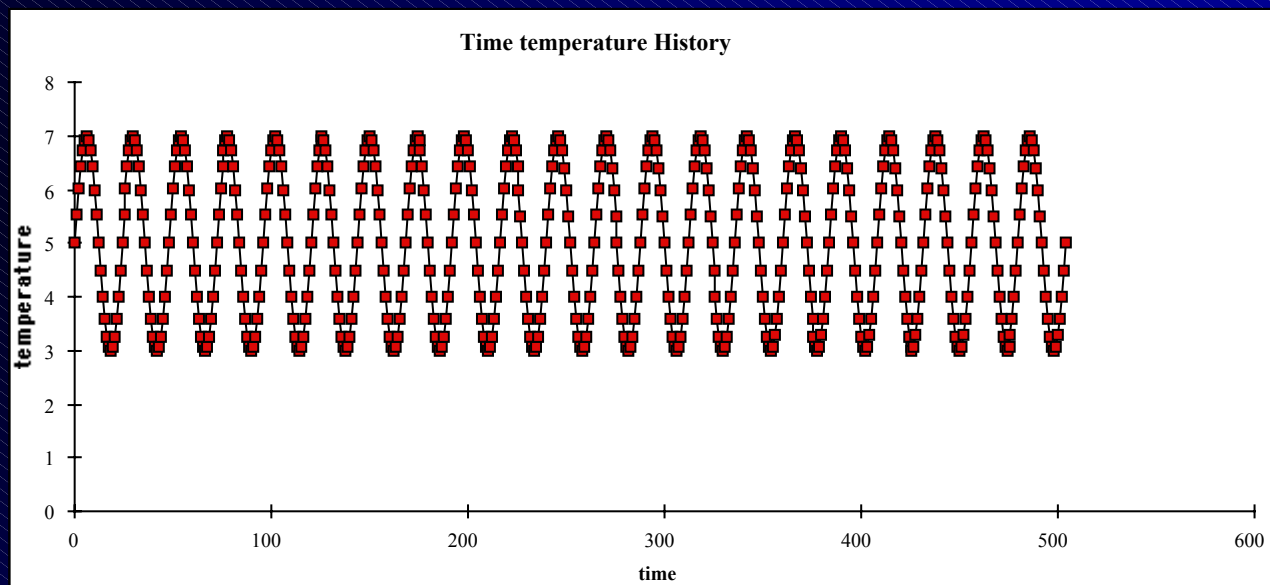
zero order

first order

Temp °C	inverse temp	zero order rate constant	In k
0	0.003660992	0.404290429	-0.905621776
5	0.003595182	0.742424242	-0.297834444
10	0.003531697	1.570512821	0.451402203

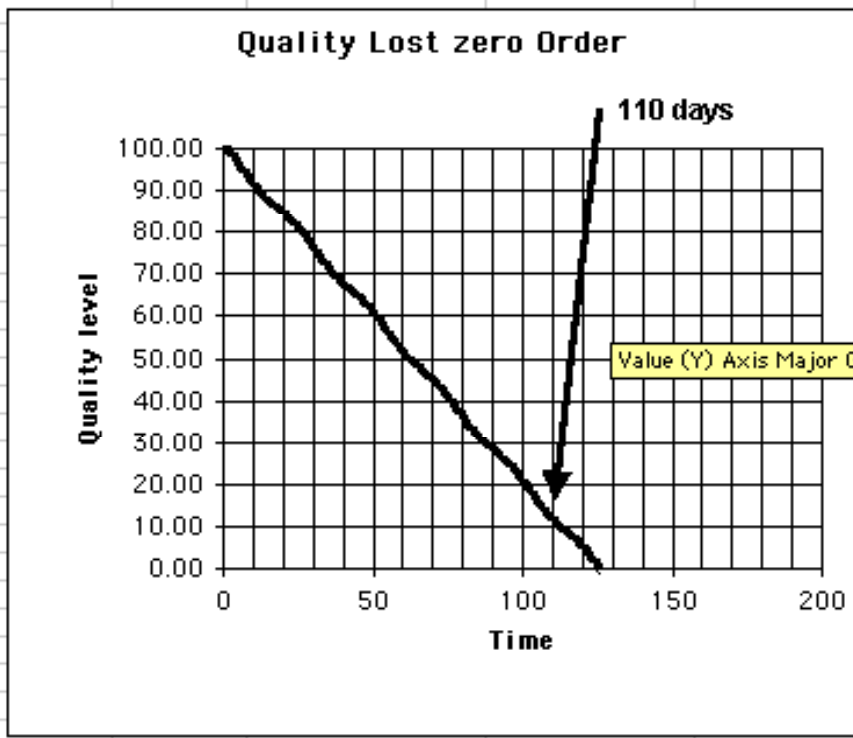
k first	Ink first
0.0161387	-4.12653462
0.0296365	-3.51874729
0.0626927	-2.76951064



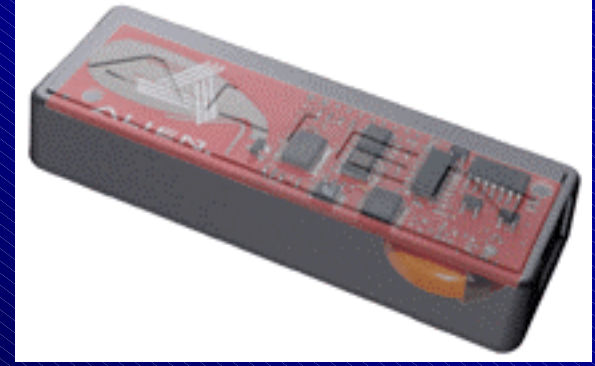


Download		Delta time (Δt)	zero-order			Zero Order	first-order			1st Order
Time	Temp.		kT	kT Δt	Sum(kT Δt)	A	kT	kT Δt	Sum(kT Δt)	A
0	5		7.85E-01			100.00	1.75E-02			100.00
1	5.517655	1.00	8.42E-01	0.84	0.84	99.16	1.77E-02	0.017673	0.01767252	98.25
2	6.000031	1.00	8.98E-01	0.90	1.74	98.26	1.78E-02	0.017813	0.03548519	96.51
3	6.414252	1.00	9.50E-01	0.95	2.69	97.31	1.79E-02	0.017941	0.05342617	94.80
4	6.732087	1.00	9.91E-01	0.99	3.68	96.32	1.80E-02	0.018045	0.07147095	93.10
5	6.931875	1.00	1.02E+00	1.02	4.70	95.30	1.81E-02	0.018112	0.08958343	91.43
6	7	1.00	1.03E+00	1.03	5.72	94.28	1.81E-02	0.018136	0.10771946	89.79
7	6.931819	1.00	1.02E+00	1.02	6.74	93.26	1.81E-02	0.018112	0.12583192	88.18
8	6.731979	1.00	9.91E-01	0.99	7.73	92.27	1.80E-02	0.018045	0.14387666	86.60
9	6.4141	1.00	9.49E-01	0.95	8.68	91.32	1.79E-02	0.017941	0.1618176	85.06
10	5.999845	1.00	8.98E-01	0.90	9.58	90.42	1.78E-02	0.017813	0.17963021	83.56
11	5.517448	1.00	8.42E-01	0.84	10.42	89.58	1.77E-02	0.017672	0.19730267	82.09
12	4.999785	1.00	7.85E-01	0.78	11.21	88.79	1.75E-02	0.017532	0.21483511	80.67
13	4.482137	1.00	7.31E-01	0.73	11.94	88.06	1.74E-02	0.017402	0.23223749	79.28
14	3.999783	1.00	6.85E-01	0.68	12.62	87.38	1.73E-02	0.017289	0.24952699	77.92
15	3.585597	1.00	6.47E-01	0.65	13.27	86.73	1.72E-02	0.017199	0.26672552	76.59
16	3.267806	1.00	6.20E-01	0.62	13.89	86.11	1.71E-02	0.017132	0.2838578	75.29
17	3.06807	1.00	6.03E-01	0.60	14.49	85.51	1.71E-02	0.017092	0.30094992	74.01
18	3	1.00	5.97E-01	0.60	15.09	84.91	1.71E-02	0.017079	0.31802862	72.76
19	3.068236	1.00	6.03E-01	0.60	15.69	84.31	1.71E-02	0.017092	0.33512078	71.53
20	3.268128	1.00	6.20E-01	0.62	16.31	83.69	1.71E-02	0.017132	0.35225312	70.31
21	3.586052	1.00	6.47E-01	0.65	16.96	83.04	1.72E-02	0.017199	0.36945176	69.11
22	4.000341	1.00	6.85E-01	0.68	17.64	82.36	1.73E-02	0.01729	0.38674138	67.93
23	4.482759	1.00	7.31E-01	0.73	18.38	81.62	1.74E-02	0.017403	0.40414391	66.75

	A	B	C	D	E	F	G	H	I	J	K
601	497	3.065866	1.00	6.03E-01	0.60	397.68	-297.68	1.71E-02	0.017092	8.73447178	0.02
602	498	3.00002	1.00	5.97E-01	0.60	398.28	-298.28	1.71E-02	0.017079	8.75155048	0.02
603	499	3.070478	1.00	6.03E-01	0.60	398.88	-298.88	1.71E-02	0.017093	8.76864308	0.02
604	500	3.272439	1.00	6.20E-01	0.62	399.50	-299.50	1.71E-02	0.017133	8.7857763	0.02
605	501	3.592139	1.00	6.48E-01	0.65	400.15	-300.15	1.72E-02	0.0172	8.80297624	0.02
606	502	4.007788	1.00	6.86E-01	0.69	400.84	-300.84	1.73E-02	0.017291	8.82026754	0.01
607	503	4.49106	1.00	7.32E-01	0.73	401.57	-301.57	1.74E-02	0.017405	8.83767208	0.01
608	504	5.009017	1.00	7.86E-01	0.79	402.35	-302.35	1.75E-02	0.017535	8.85520693	0.01
609											
610											
611	time	temp		zero-order			Zero Order	first-order			First order
612			Delta time (Δt)	kT	kT Δt	Sum(kT Δt)	Quality Left	kT	kT Δt	Sum(kT Δt)	Quality Left
613											
614											
615											
616											
617											
618											
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639											
640											



Alien Technology



- 915 MHz RFID tag read @ 15 meters
- User defined time intervals - 1000 values
- Introduction soon for perishable foods
- No integration but data logging of t/T
- Reusable with 5 year life
- <http://www.alientechnology.com/>

iButton



- Thermistor (-40 °C to +80°C) in Δ 0.5 C
- Clock/calendar (seconds up to years) @ \pm 1 min/month
- Thermal history logger ~ 1 million points
- Extra memory for manifest
- <http://www.ibutton.com/ibuttons/index.html>
- Cost \$2 to \$53



Freshloc

t/T and t/%RH logging

How FreshLoc Works

The FreshLoc system is based upon tiny wireless sensors (shown here) that transmit continuously. It automatically and continually collects data such as temperature, humidity and other measures via a unique secure Internet connection.

In a given facility, FreshLoc sensors are arrayed and transmit wirelessly (for up to hundreds of feet) to a small reader / receiver which is connected to a gateway device allowing Internet connection.

With Internet connection, data is available for alerting and reporting via pager, fax, phone or email.

Wireless Sensor Array

Reader / Gateway

Internet / Multi-Media



What Is Freshloc?

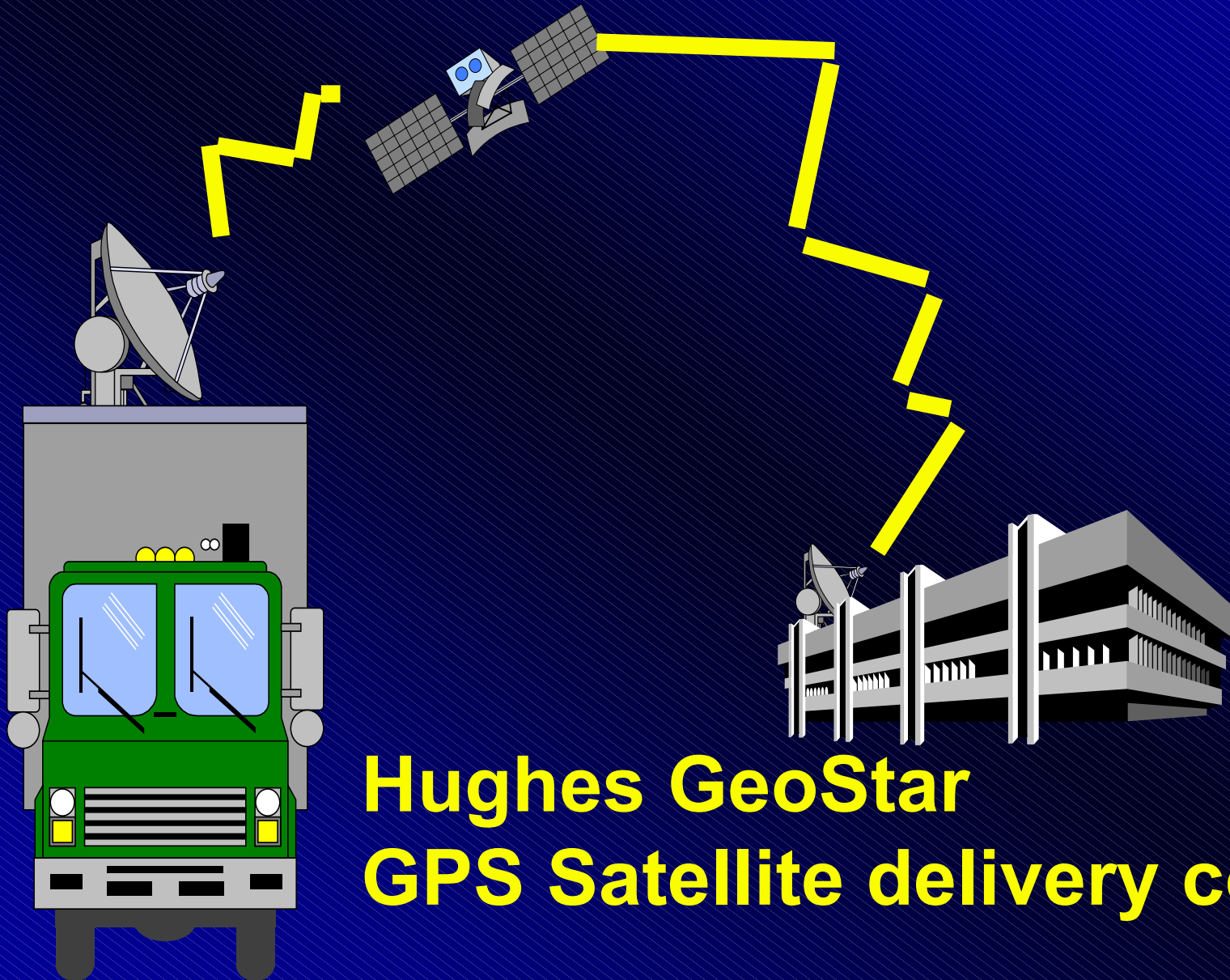
Dec. 13, 2002 - 7-Eleven Installs FreshLoc Technology in Combined Distribution Center for 692 Southern California Stores To ensure the freshness and quality of its fresh food and sandwich offerings, 7-Eleven, Inc. (NYSE:SE) is installing Cold Chain Control™ technology, a wireless, automatic monitoring system from FreshLoc Technologies (www.freshloc.com), in the Combined Distribution Center located in Fullerton, Calif. 7-Eleven aims to increase fresh food sales nationwide over the next five years. Cold Chain Control technology from FreshLoc helps to manage safe temperatures from a single distribution facility that serves Los Angeles/San Diego-area 7-Eleven stores.

<http://www.freshloc.com/>

Many other companies

- **3M Chile**
- **Clinesense US**
- **Sysco - US**
- **Ceebron - Australia**

Logistics management and Profitability ECR



**Hughes GeoStar
GPS Satellite delivery control**

Other driving forces

- **Traceability - safety**
 - **Bioterror**
 - **Product recalls**
 - **Allergens**
 - **Expiration date based on safety**
- **Traceability - label truth**
 - **GMO identity**
 - **Country of origin**
- **Economics**

Terrorism-> Bioterrorism



HEALTH & MEDICINE

Food Fright

Terrorism spotlights the risks in the food supply

BY AMANDA SPAKE

The supervisor's E-mail message looked innocent enough, even generous: The laboratory's 45-person staff was invited down to the break room at the St. Paul Medical Center in Dallas to have some doughnuts and muffins. A dozen staffers took up the offer, polishing off the better part of two boxes of pastries.

It was night before the cramps, diarrhea, fever, and vomiting began. All 12 employees got sick, nine went to the hospital, and four were admitted. Doctors found they were all infected with a type of *Shigella dysenteriae*, a pathogen rarely seen in the United States. Where had it come from?

The lab's own freezer, as it turned out. About a year after the October 1996 incident, Diane Thompson, a 26-year-old coworker, pleaded guilty to engaging in her own personal act of food-borne terrorism by intentionally contaminating the pastries. She had access to the highly toxic bacteria stored in the lab, and she had sent the bonus E-mail message while the supervisor

kitchen was stocked with foods grown on small farms, distributed locally, and, with the exception of canned goods, mostly unprocessed. A disease outbreak on one farm affected few people and was fairly easy to figure out.

Nowadays, farms and livestock companies are enormous enterprises here and abroad owned by international firms and

servicing a multitude of retail supermarkets, discount stores, and fast-food outlets. Microbial contamination—unintentional or deliberate—at any point in the production, processing, or distribution of food spreads quickly across states and even beyond national borders.

In the United States, food-borne pathogens cause an

A sandwich's story

Six separate federal agencies, with different inspectors, regulations, protocols, and legal authority, are supposed to ensure that a ham and cheese sandwich is properly produced, processed, packaged, and made safe for human consumption.

BREAD

The FDA has responsibility for the safety of wheat, flour, and bread. But at least three other federal agencies are responsible for the quality and safety of wheat crops.

September 11, 2001

Bioterror

- Intentional delivery of adulterant
- Early identification and traceability key to stopping before major damage
- Agriculture 1/6 of GDP 24 MM people
 - If 10% hit lose \$9.6 billion/month



US News and World Report 12/24/01

<http://www.fda.gov/oc/bioterrorism/titleIII.html>

Biosecurity Act 2002

One Hundred Seventh Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Wednesday,
the twenty-third day of January, two thousand and two*

An Act

To improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Public Health Security and Bioterrorism Preparedness and Response Act of 2002”.

(b) **TABLE OF CONTENTS.**—The table of contents of the Act is as follows:

Sec. 1. Short title; table of contents.

**TITLE I—NATIONAL PREPAREDNESS FOR BIOTERRORISM AND OTHER
PUBLIC HEALTH EMERGENCIES**

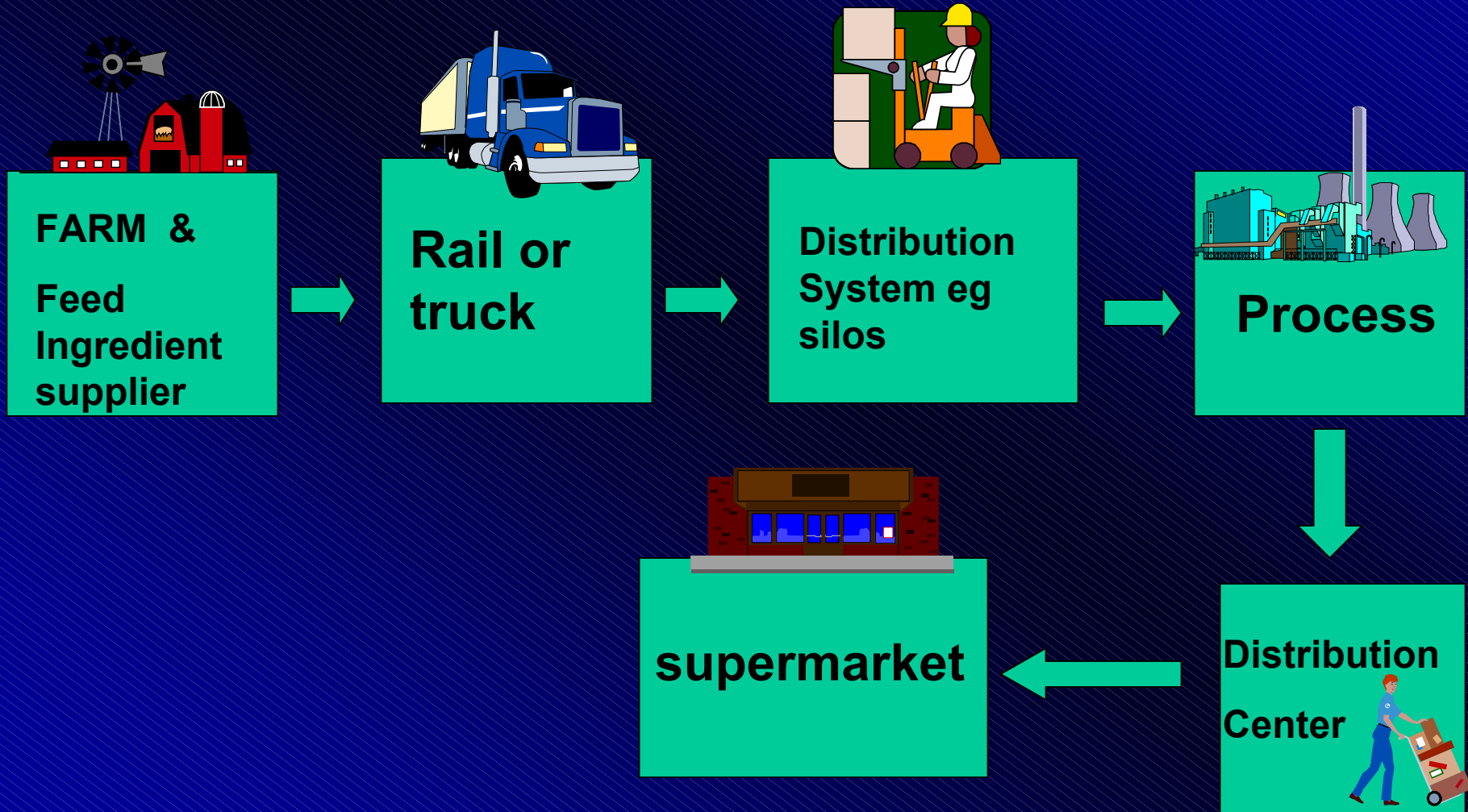
**Subtitle A—National Preparedness and Response Planning, Coordinating, and
Reporting**

Regs under Biosecurity Act

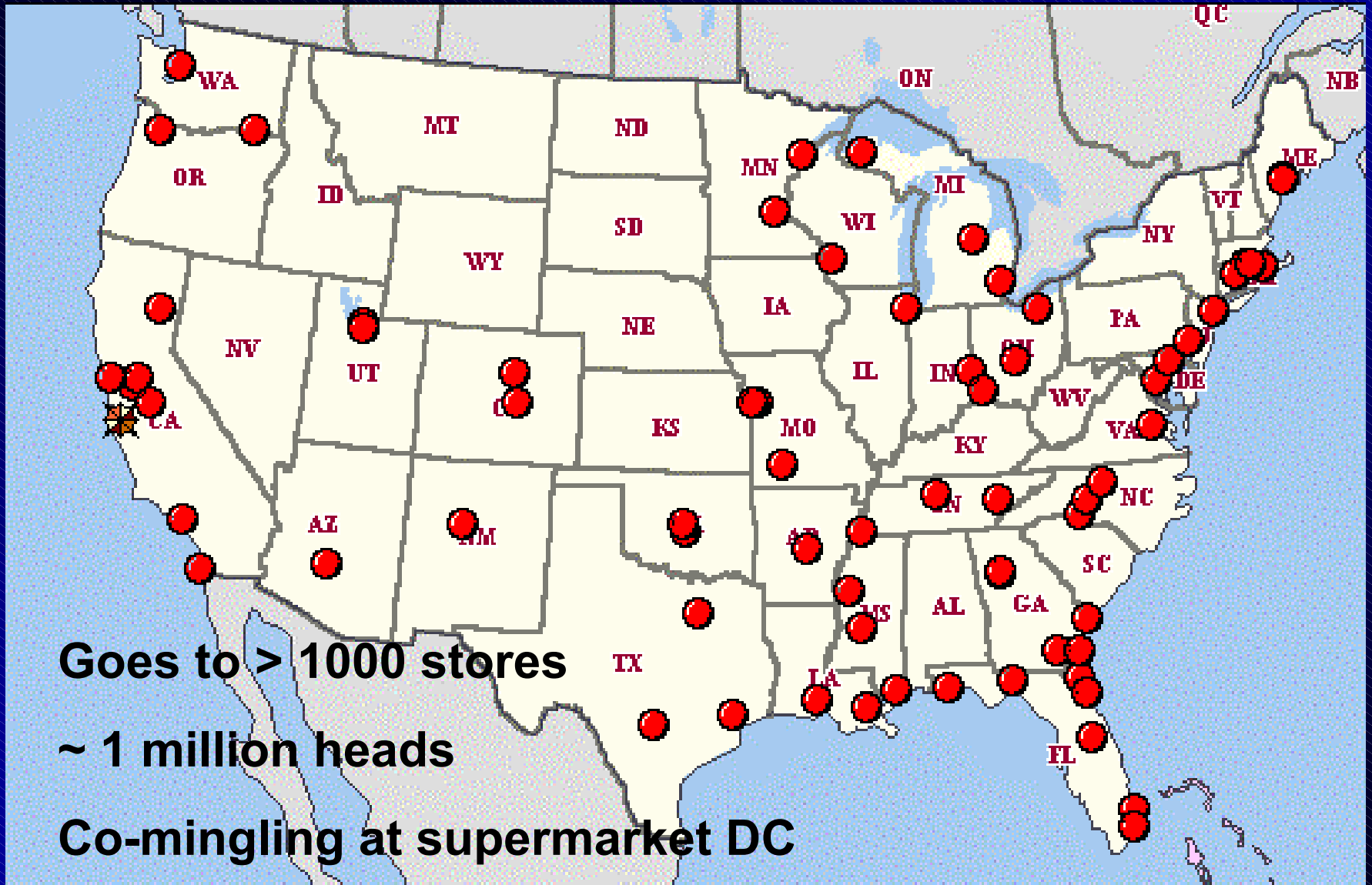
- Registration of all processing and holding
- Notice of Import within 24 hours of entry
- Detention authority (30 days) if suspect
- Record keeping - ASAP but within 24 hour identity of one step forward and backward for all foods including transport vehicles See Q&A
- <http://www.cfsan.fda.gov/~dms/recguid.html#sec-f>
- Final rule <http://www.cfsan.fda.gov/~lrd/fr04d09a.html#l11e4>



Food Process Distribution Chain



5 day Lettuce orders



EU Requirement

178/2002 Article 18 Traceability 1/1/05

According to comments received, firms exporting from the European Union (EU) are already subject to similar recordkeeping requirements under EU regulation 178/2002. Article 18: *Traceability* of the EU regulation states:

* * *

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

(2) Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures, which allow for this information to be made available to the competent authorities on demand.

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

(Ref. 14).

**All stages-
production,
processing &
distribution**

**Food, animals,
ingredients and
feed**

**Info available on
demand**

**Forward and
backward**

Key Questions

- **What is in the food, ie can we trace all ingredients?**
- **Where is it at and how much at any point in time ?**
 - Chain traceability - ie location info rather than ingredient info
- **When will the product reach consumers?**
 - Distribution (supply chain) and sales logistics
- **How soon can/will the government react if they need to, ie data collection, transfer and management systems?**
 - Data is food movement and public health reports

Drivers

- **Recalls**
 - Majority are meat and allergens

News and Trends

Washington Watch

[More Washington Watch articles](#)

By J. Mark Huffman, *Washington correspondent*

Dairy Foods, April 2002

New Allergen Recall Regulations

Government food safety regulators are placing more responsibilities on processors for keeping consumers informed when problems occur. FDA has announced it will begin automatically classifying most allergen-related food recalls in the Class I category, requiring companies to notify the public. A Class I recall is one where "reasonable probability exists that the use of or exposure to a product will cause serious adverse health consequences or death."

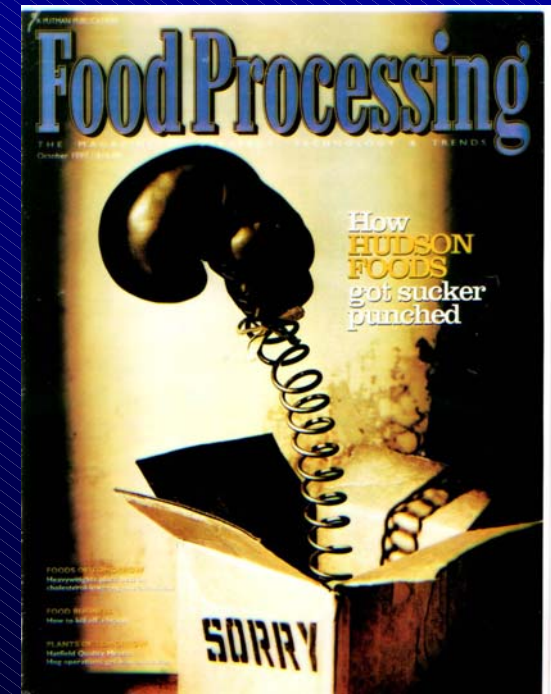
FDA's Class I recall rule goes into effect when foods are not properly labeled that they contain one of the following allergens: peanuts, tree nuts, milk, eggs, soy, crustaceans, fish and wheat. These allergen categories, known as the Big Eight, make up 90% of all food allergies.

The International Ice Cream Association recently tackled the issue head on, presenting a roundtable for processors, led by Dr. Sue Hefle, University of Nebraska Food Allergy Research and Resource Program, and Dr. Kenneth Falci of FDA. Processors were urged to develop a recall preparedness plan, mapping out clear communication channels with both the public and government officials.

Dairy processors have already implemented a number of



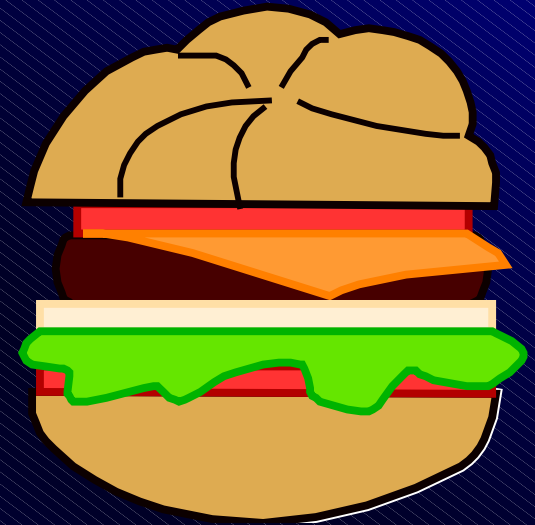
J. Mark Huffman
Dairy Foods' Washington
correspondent



In April 2002 FDA began classifying most allergens as Class 1 recalls

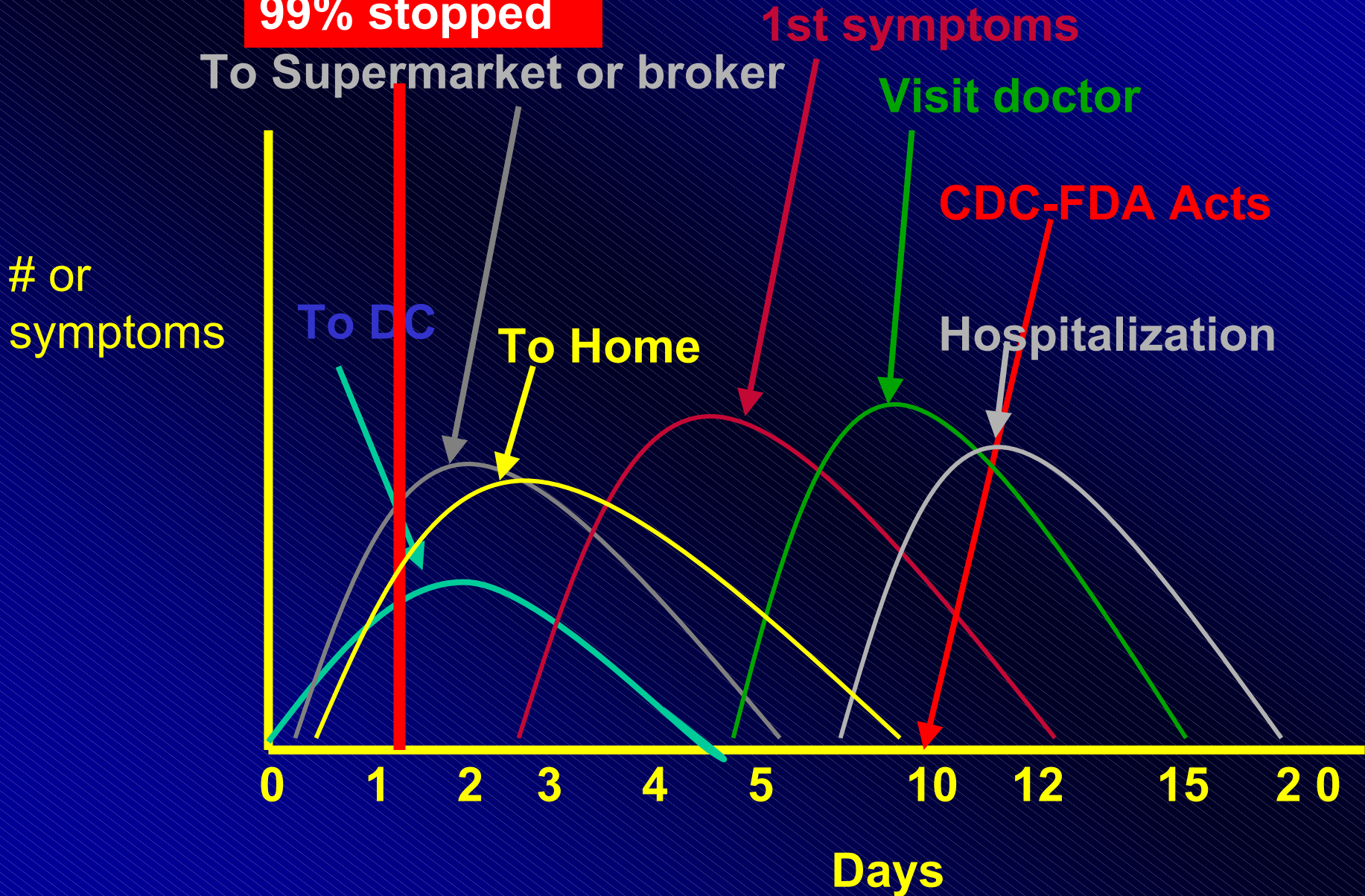
Meat traceability

- **August 2002 19.8 MM lb hamburger recall**
 - 30 ill with E coli O157:H7
 - 1 death
 - Only 8000 lbs back
 - Had a 3.5% rework policy

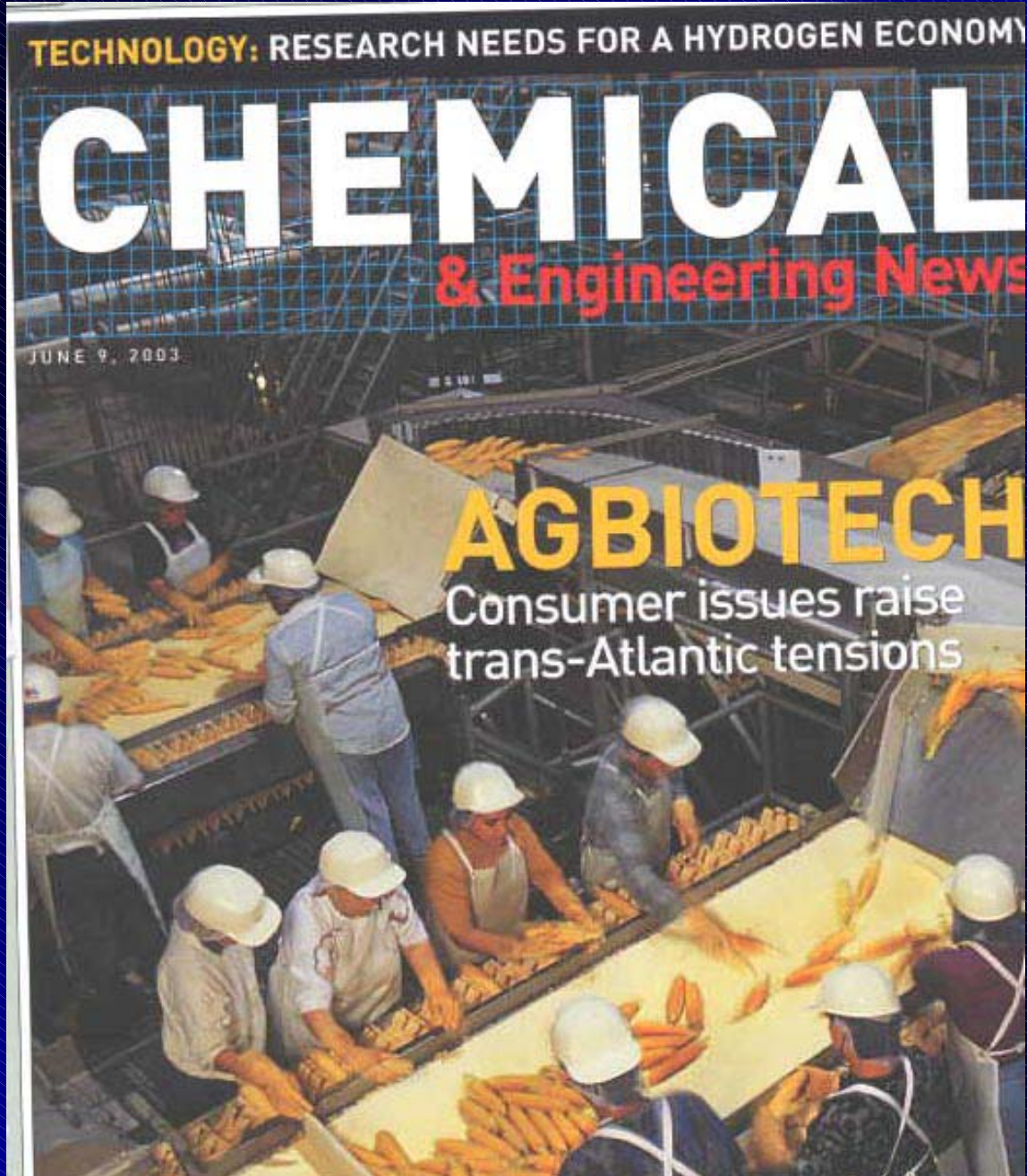


Time to Event

99% stopped



Drivers GMO



EU labeling initiative 2003

- **EU will accept US GMO if labeled with complete traceability to farm**
- **Label if $\geq 0.1\%$ content**
- **US claims a trade barrier and files in WTO court**
- **US rep says “traceability not worthwhile” will lose \$4 Billion in exports**
- **EU argues but same as FDA new powers**
- **C&E News 6/9/03 pg. 25-33**

damage

- In 2002 Canadian exports of beef were \$4 billion
- On first day (5/20/03) McDonalds lost \$1.2 Billion in stock market
- Canadian farm losses are \$11 MM/day
- Feedlot losses (1st month \$400 MM)
- in July \$3.1 billion outstanding loans
- August 2003 total loss \$42 billion
- Today \$11 MM per week
- GNP reduction ~1%

Drivers

- Country of Origin Labeling (COOL) 2003

The image shows a screenshot of the On Politics website from 2003. The main article is titled "House GOP Targets Law on Meat Origin Labels" by Dan Morgan, dated Wednesday, June 25, 2003. The article discusses the House Republicans' attempt to undo legislation requiring stores to label meat products with their country of origin. It mentions that the legislation is nicknamed "COOL" and was included in the 2002 farm bill. The article also notes that the House Appropriations Committee will take up a version of the 2004 agricultural appropriations bill today, which would bar the Agriculture Department from implementing the law.

Three maps are overlaid on the page:

- A 3D map of the United States on the left, with a red arrow pointing to the "2003-2004" link in the left sidebar.
- A map of Europe on the right, with a red arrow pointing to the "Congress" link in the right sidebar.
- A map of Asia on the bottom right, with a red arrow pointing to the "Economic Calendar" link in the right sidebar.

The left sidebar contains a navigation menu with the following items:

- Front
- Elections
- The Issues
- Federal Page
- Administration
- 2002
- 2003-2004
- Supreme Court
- Today in Congress
- Players
- Post Series
- Polls
- Cartoons
- Online
- Galleries
- Car
- Real Estate
- Other News: Nation, World, Metro, Sports, Business

The right sidebar contains a search bar and several links:

- SEARCH: News
- Congress
- Executive
- Electoral
- On the Web
- Safety Tips
- Web Special
- Economic Calendar

Country of Origin Labeling

- Federal Security and Rural Investment Act of 2002 HR 2646 2002 (Farm Bill)
- COOL Sec 10816
- Identity required by 2004
- Retailer must ensure (indemnification)
- Fine \$10,000 per violation
- 6/17/03 Japan asks 26 countries for beef traceability
- EU 104/2000 for fish
- Rest delayed until 9/30/2006



Cool Record keeping



Country of Origin Labeling

Examples of records that may be useful for COOL verification purposes

The examples of documents and records listed in the attached tables, although extensive, are not inclusive of all documents and records that may be useful to verify compliance with the Country of Origin Labeling provisions of the 2002 Farm Bill. Additionally, maintaining documents and records such as those listed as examples will not necessarily ensure compliance. The documents listed are examples only and are for the sole purpose of providing information for producers, processors, and retailers to consider when establishing records for verification purposes. During a compliance audit conducted by USDA, auditors will review any and all documents to the extent necessary to arrive at an accurate decision on the level of compliance.

- [Cattle, Beef, Muscle Cuts of Beef, Ground Beef - PDF file](#)
- [Farm-Raised Fish - PDF file](#)
- **NEW** [Farm-Raised Shellfish - PDF file](#)
- [Hogs, Pork, Muscle Cuts of Pork, Ground Pork - PDF file](#)
- [Peanuts - PDF file](#)
- [Perishable Agricultural Commodity - PDF file](#)
- [Sheep, Lamb, Muscle Cuts of Lamb, Ground Lamb - PDF file](#)
- [Wild Fish - PDF file](#)

Food Allergen and Consumer Protection Act 8/3/04

- Title II S741
- Requires all allergens to be declared including hidden
- Identity in common language use 8 major food categories
- Report to Congress on allergen inspections and methods to reduce contact
- Guidelines for restaurants and food service to prepare allergen free foods
- Investigate the “may contain” label
- Takes effect 1/1/2006

Indicates the need for an electronic active tag system that records and forwards info to next step

Economics

- **Retail shrink ~ 2.3% vs 0.7% profits**
Damaged and spoiled goods ~ 0.5%
- **Employee theft (49%) ; Shoplifting (32%)**
- **Most spoilage is refrigerated produce**
- **U Arizona 40% food waste**
- **ERS estimates 27% waste**
- **Nat. Supermarket Research Group**
 - **2002 estimate \$31 billion**
 - **EU shrink ~ \$25 billion**

Expiration Dating of foods & Safety

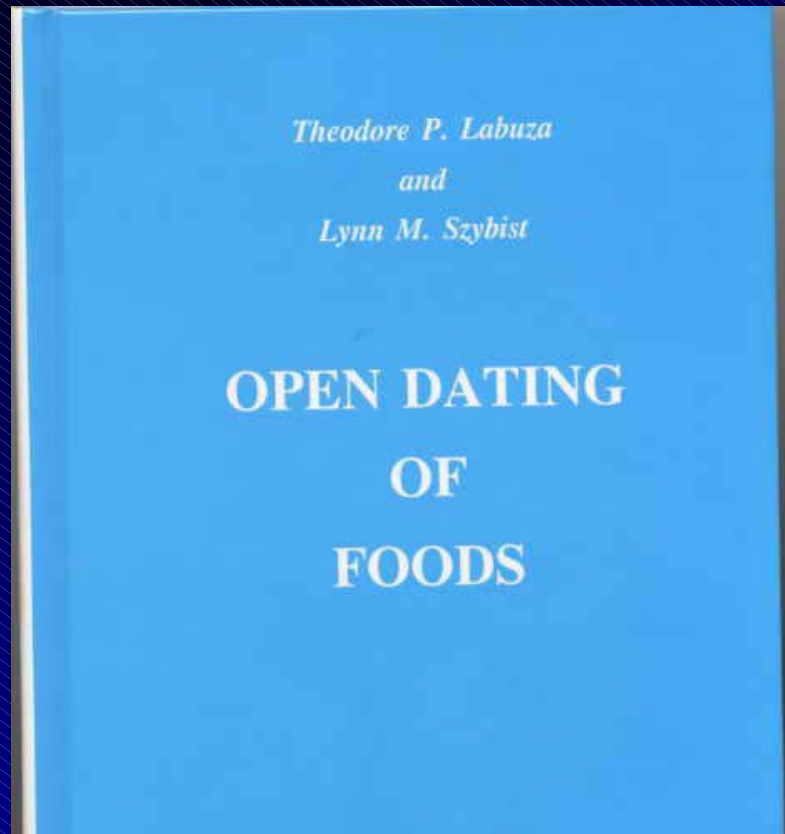


Question of safety vs food quality

Value of life = \$6.5 MM

Consumer Open Dating Survey

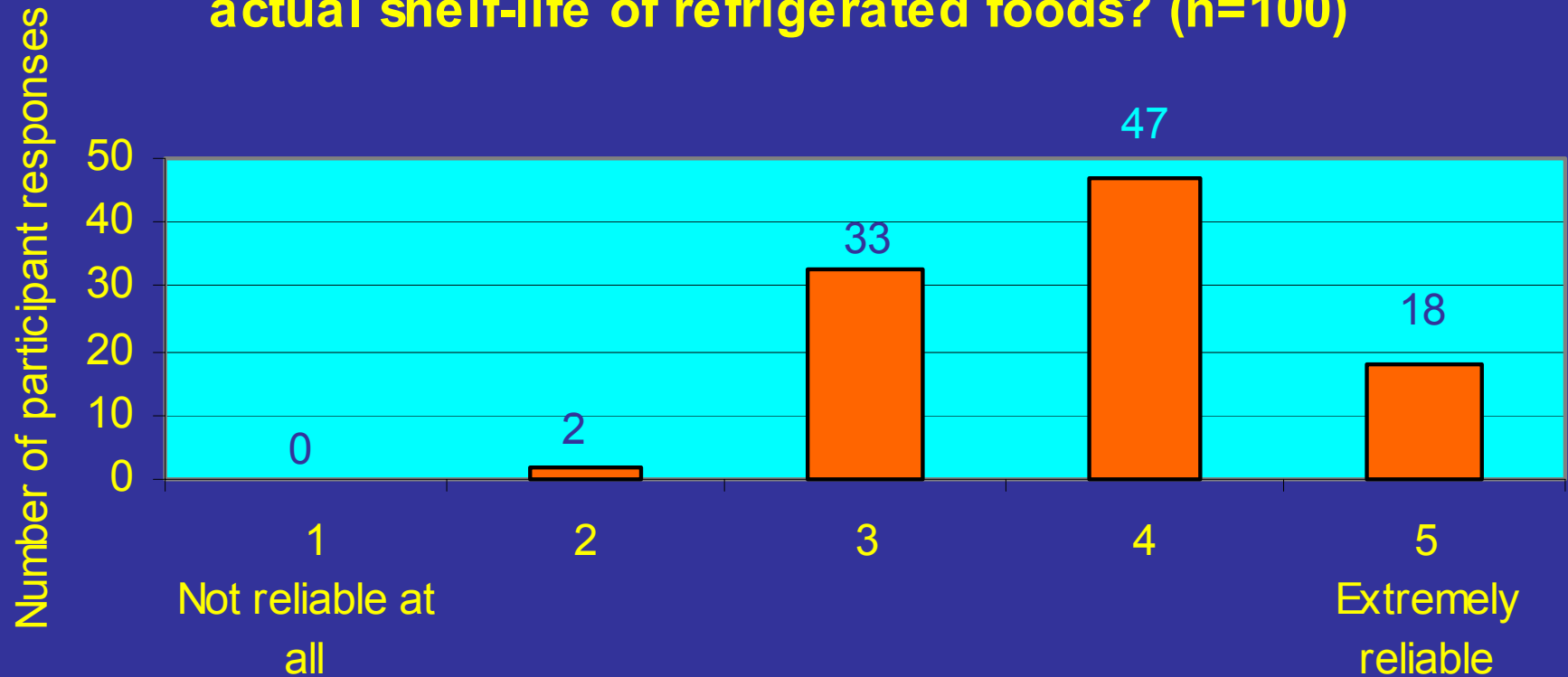
http://fscn.che.umn.edu/Ted_Labuza/tpl-books-main.html



Survey Part I

Open dates

Q: How reliable is the open date in regards to the actual shelf-life of refrigerated foods? (n=100)



Listeria monocytogenes

- Major concern for RTE refrigerated foods
- 354 billion servings per year in US
- 2500 illnesses
- 500 deaths or long term kidney damage
- Bil Mar Foods - major incident 20 deaths-hotdogs
 - Tom Billy of FSIS implicated that those that made people ill or died were consumed at or near “use by” date and were temperature abused
 - Many manufacturers now set date shorter and good product discarded

Shelf Life Dating Confusion

Safety vs Quality

- **August 1998 Prevention Magazine - NBC survey**
 - **61% feel sell by is last date to safely sell**
 - **34% feel use by is last date to safely use**
- **1999 IFT document to RCs related to safety and open date**
- **1999 National Enquirer**
 - **Use by date is a stern warning on meats, poultry and other perishables. Pay close attention and do not use once date is passed**
- **Food Technology July 1999 “Playing the Open Dating Game” Ted Labuza and Lynn Szybist**

Interest in potential information cues

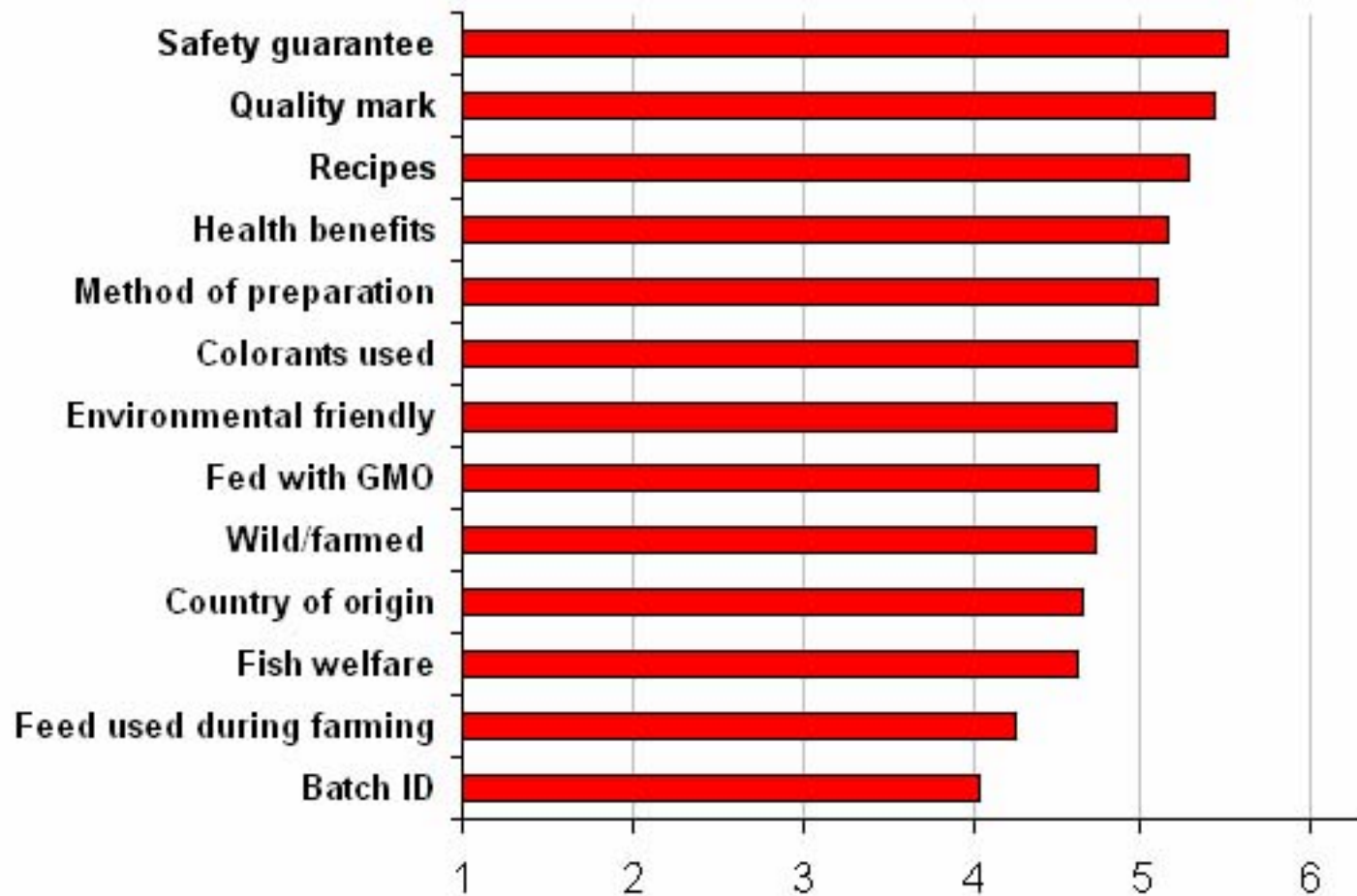


Figure 3. European consumer's interest in additional information about fish (mean scores; n= 4786)

□ USDA -FSIS 1998
Guidance for Beef Grinders to Better Protect
Public Health

Guidance for Minimizing Impact Associated with a
Food Safety Hazard in Raw Ground
Meat and Other FSIS Regulated Products

Install a time-temperature indicator on the package to indicate adequate temperature of storage, distribution, and display (in grocery and other retail establishments).

Journal of Food Protection, Vol. 68, No. 8, 2005, Pages 1761–1775 Supplement

Considerations for Establishing Safety-Based Consume-By Date Labels for Refrigerated Ready-to-Eat Foods†

**ADOPTED 27 AUGUST 2004, WASHINGTON, D.C.
NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL
CRITERIA FOR FOODS**

***NACMCF Executive Secretariat,* U.S. Department of
Agriculture, Food Safety and Inspection Service, Office of
Public Health Science, Room 333***

***Aerospace Center, 1400 Independence Avenue S.W.,
Washington, D.C. 20250-3700, USA***

MS 05-701: Received 7 February 2005/Accepted 1 March 2005

1. What are the scientific parameters for establishing safety-based “use-by” date labels for refrigerated RTE foods?

2. What effect do the multiple factors that influence the growth and survival of *L. monocytogenes*, i.e., strain differences, food matrices, production and distribution systems, consumer susceptibility, etc., have on the establishment of safety based “use-by” date labels for refrigerated RTE foods?

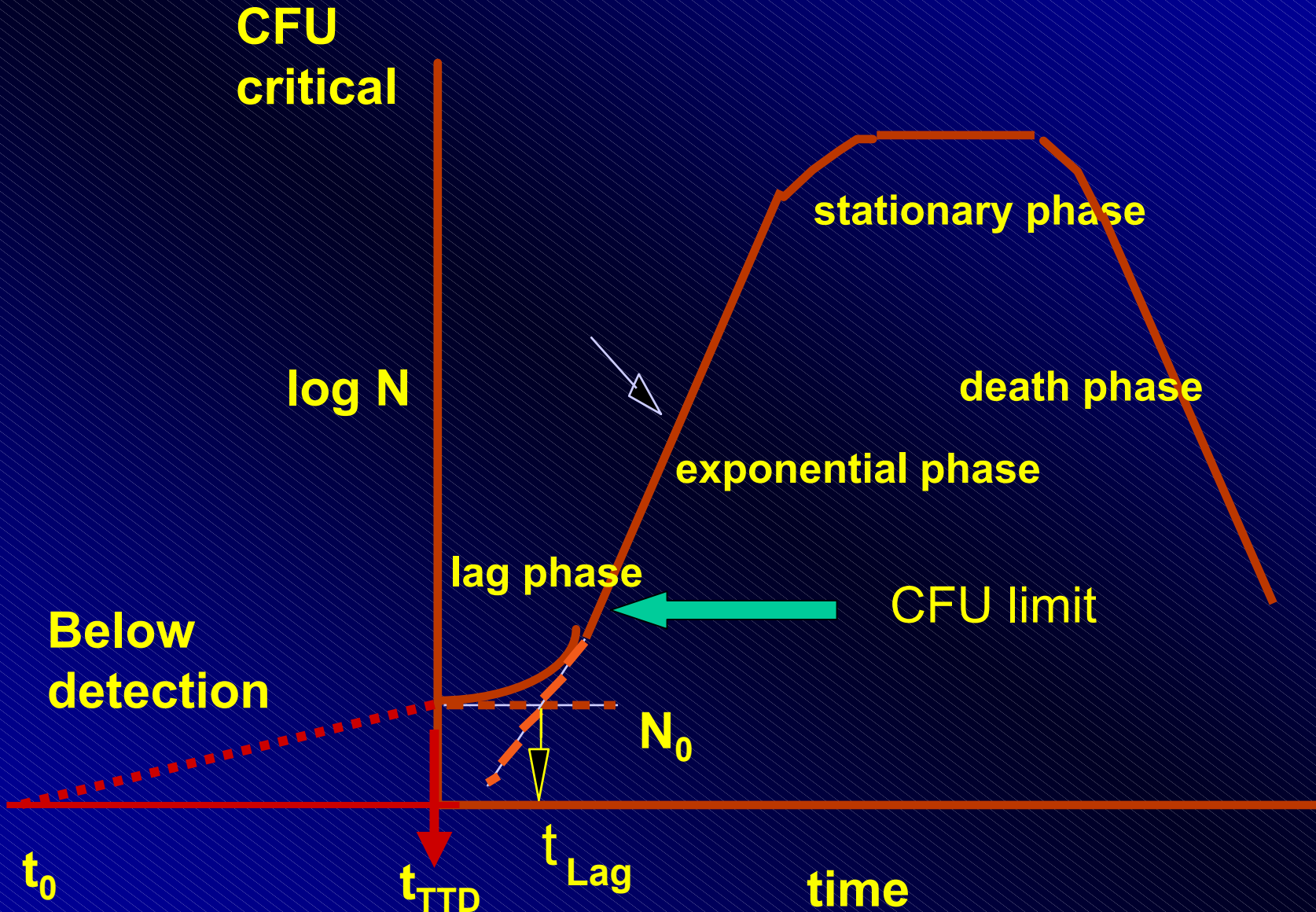
3. What data need to be acquired to scientifically validate and verify the adequacy of a proposed safety-based “use-by” date label for a refrigerated RTE food?

4. Should safety-based “use-by” date labels for refrigerated RTE foods be established using mathematical modeling techniques? If so, what modeling approaches are best suited to the development of labels for refrigerated RTE foods?

5. What impact would safety-based “use-by” date labels created for one psychrotrophic pathogen, e.g., *L. monocytogenes*, likely have on the control of other foodborne pathogens in refrigerated RTE foods?

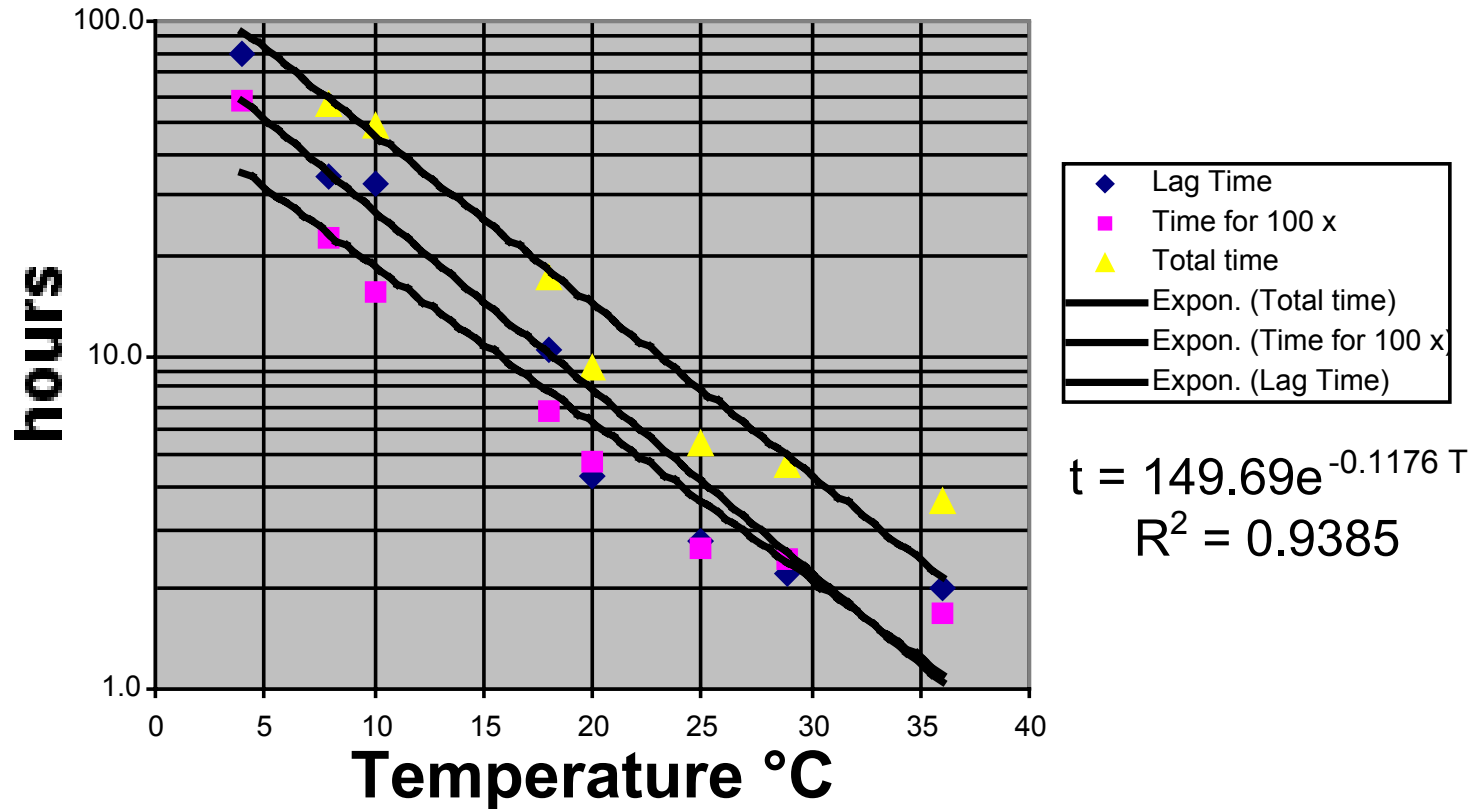
Disappointment - will set based on single temperature and no mention of TTI work

Microbial Life cycle



Each has a different temperature sensitivity

Listeria Shelf Life (100 CFU/g) on hotdogs



Electronic tags can handle all three periods of growth

***Clostridium botulinum* fish study (Genigeorgis group)**

5 years

types B, E and F

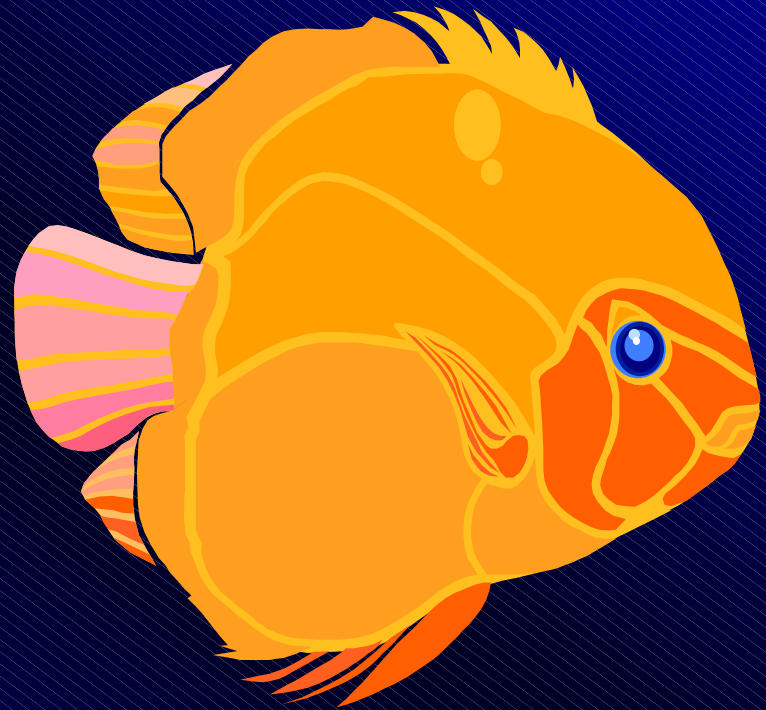
4 to 30 °C

60 days maximum

927 experiments

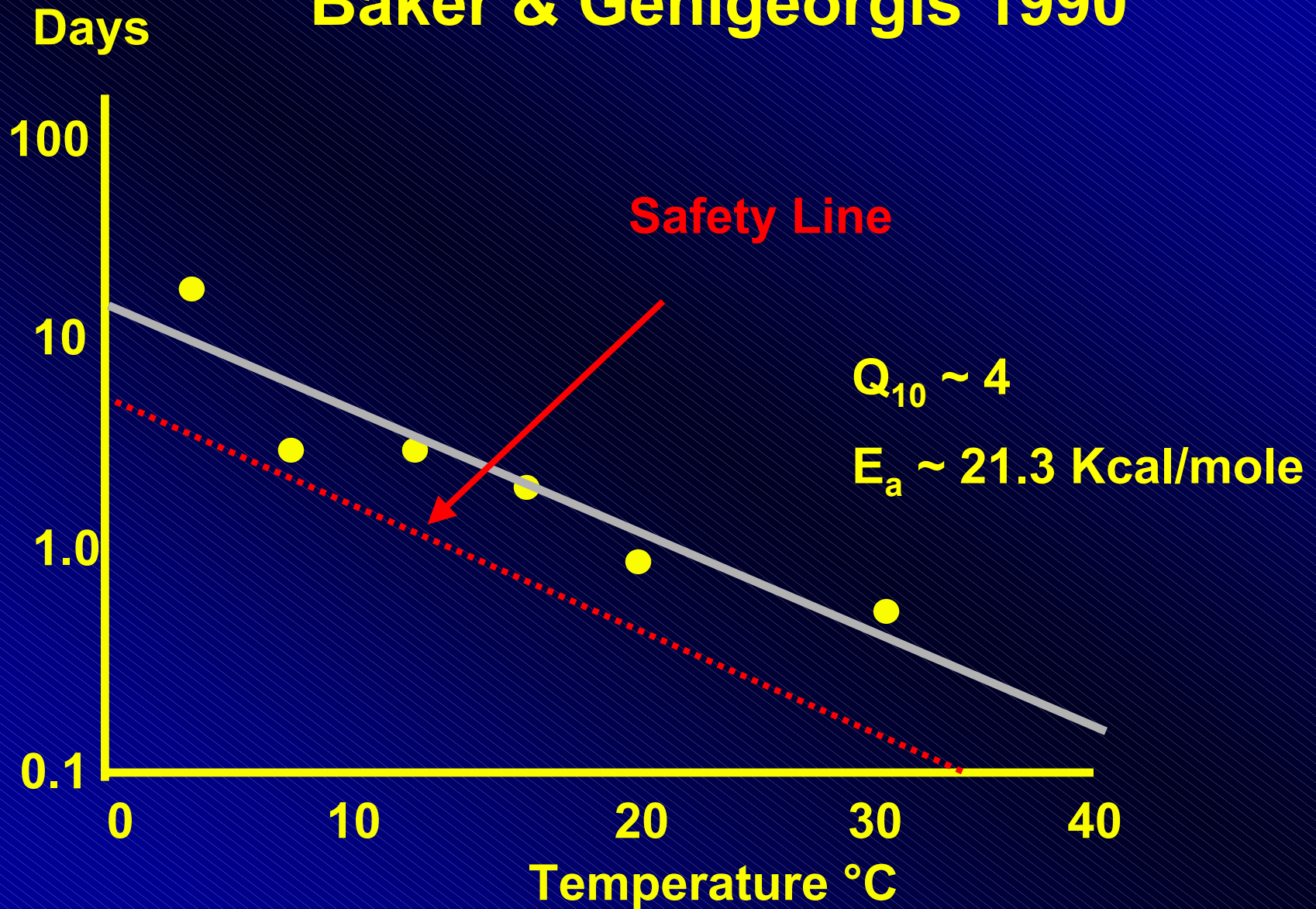
18700 samples

187,000 mice

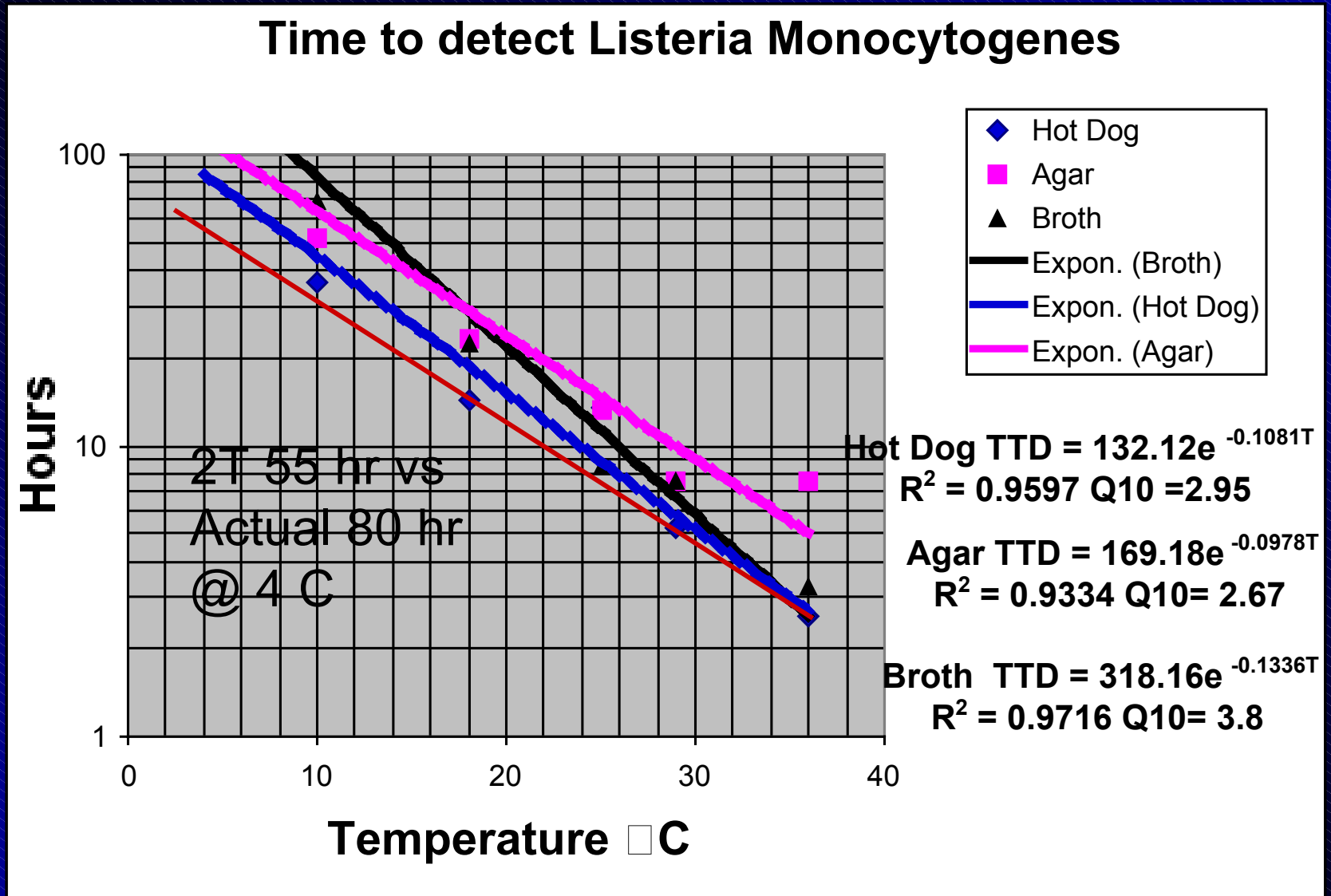


Days to detect botulinum toxin

Baker & Genigeorgis 1990



Log TTD vs temperature



Using 29 and 36 °C TTD @ 5 °C is 50 hr vs 72 hour

New Driving sectors Generation IV

Active “RFID Labels” for t-T management

- includes

- Foods \$4 billion



- Cut flowers - potential \$58 MM global



- Drugs DOD study on dates



- Mail order/ web drugs

- Adhesives

- Photographic film



- Cosmetics

- Explosives

- Paint

Wal-Mart sets date for RFID adoption

One hundred key suppliers to tag pallets by 2005

June 16, 2003
Frontline Solutions

Frontline Solutions

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RIGHTS LINK

Wal-Mart Stores Inc. will roll out an RFID-based pallet-tracking system by 2005, a move that will force the hand of other retailers and consumer packaged goods manufacturers that have waffled on rolling out the technology. In a standing-room-only presentation at last week's Retail Systems conference in Chicago, CIO and senior vice president Linda Dillman outlined the world's largest retailer's implementation roadmap for RFID, and issued a challenge to the technology provider community to help overcome the obstacles of widespread adoption.

"We believe very strongly in the potential of this technology to do wonderful things for our customers and suppliers," Dillman says, noting that Wal-Mart has opened an RFID Lab in Rogers, Ark., and has

Electronic “Smart Labels” for TTI



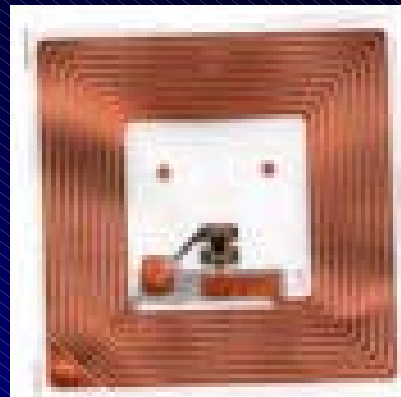
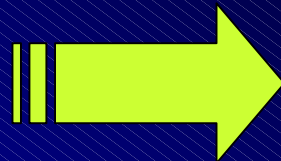
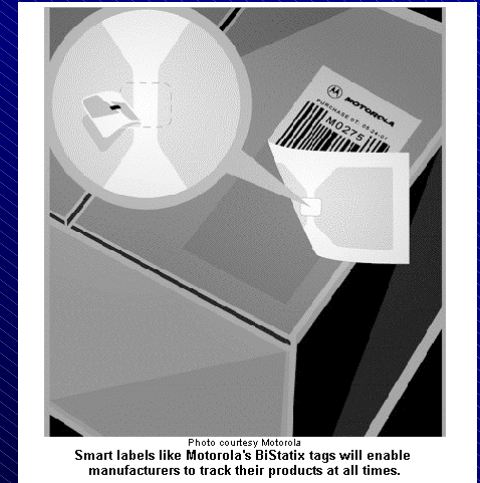
- **Driven by**
 - **Current TTI- No data storage to find weak link (insurance)**
 - **Electronics got smaller**
 - **Move towards electronic tags with RFID to replace bar codes with traceability**
 - **Can build in run out time and activation energy on computer chip so kinetics match is easy to do**
 - **Can create sharp end point**
 - **Electronics does not have history effect**
 - **Includes traceability at same time (RFID)**
 - **Ability to follow multiple steps with different E_a (microbes)**

The kick- start of RFID

- **Wal-Mart**
 - 2004 sold \$1.7 billion retail out of \$7.5 billion total (22%)
 - Required top 100 suppliers to use RFID by 1/1/05
 - All suppliers required by 2006
 - Already found that RFID helps reduce inventory requirements and out of stock situations
- **2004 Retailers worldwide spent \$400 MM on RFID**
 - High costs limits RFID to retailers with >\$5 billion sales
- **Military to switch by 2006**
- **RFID manufacturers in 2005 release new tags at < 10 ¢ (Avery Dennison and Alien)**
- **US will adopt EU ISO standards**
- **Frost & Sullivan predicts >\$4 billion RFID sales by 2011**

Achieving RFID Traceability

- **Tag-reader compatibility**
 - frequency
- **Data standardization ePC**
- **Traceable resource unit (TRU)**
 - One fish vs 1 case vs 1 pallet



Shelf Life Consumed Approach to reduce memory space

t_i — the time a product is held at some constant temp T_i for a given time segment

t_{si} — the actual shelf life of the product held at that constant temp T_i

Electronic TTI solutions and problems

- ~~ease of reading~~
- need to collect food kinetics data
- ~~match TTI to activation energy of food~~
- Food ~~or tag~~ must not have history effect
- ~~marketer's resistance to cost~~ (can be < \$0.05)
- liability for implied safety

KSW TempSense

www.ksw-microtec.de



TempSense®



To verify the temperature conditions during complex logistic processes a unique identification of the product and a low cost documentation of the temperature curve during transportation and storage is necessary. Especially nowadays where most companies receive and send international deliveries, a well documented quality of the shipped product is a major business advantage. The TempSense® label from KSW offers you not only the documentation of the temperature curve, it also determines for you if the product has been exposed too long to a certain temperature.

TempSense® documents exceptions in the storage temperature and tells you when and for how long the product was exposed to a certain temperature. Only with these data a high quality of chilled and frozen products can be proved.



Micro-electronic TTI tag vendors

- **Technopuce (France)**
 - **Acti-Tag** RFID TTI for t/T integration
 - **Hemo-Tag** TTI for blood (two technology awards)
 - <http://www.technopuce.com/>



Micro-electronic TTI tag vendors

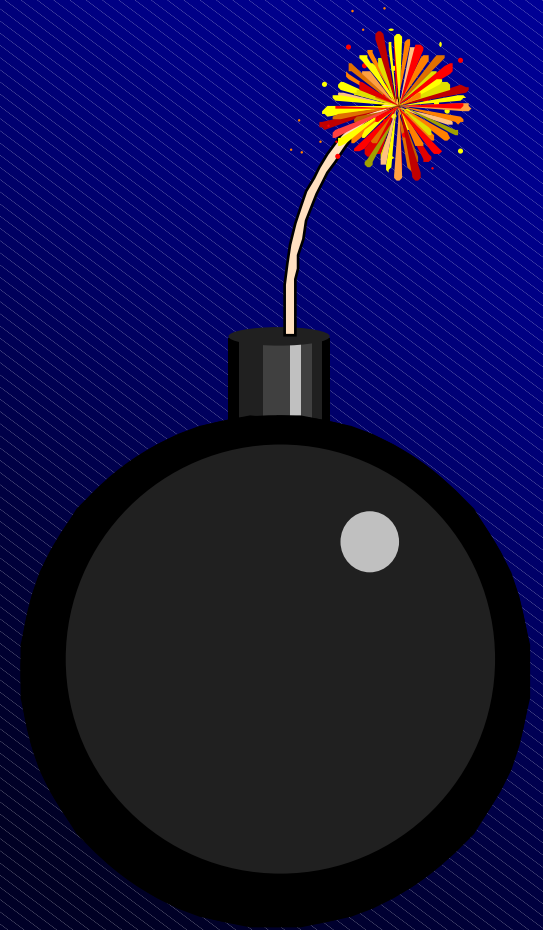
- **Infratab (US) skaye@infratab.com**
 - **Micro-electronic TTI integrator**
 - **RFID capability for traceability**
 - **US Patent # 5,442,669**
 - **For food and other perishables**
 - **Prototype design stage**



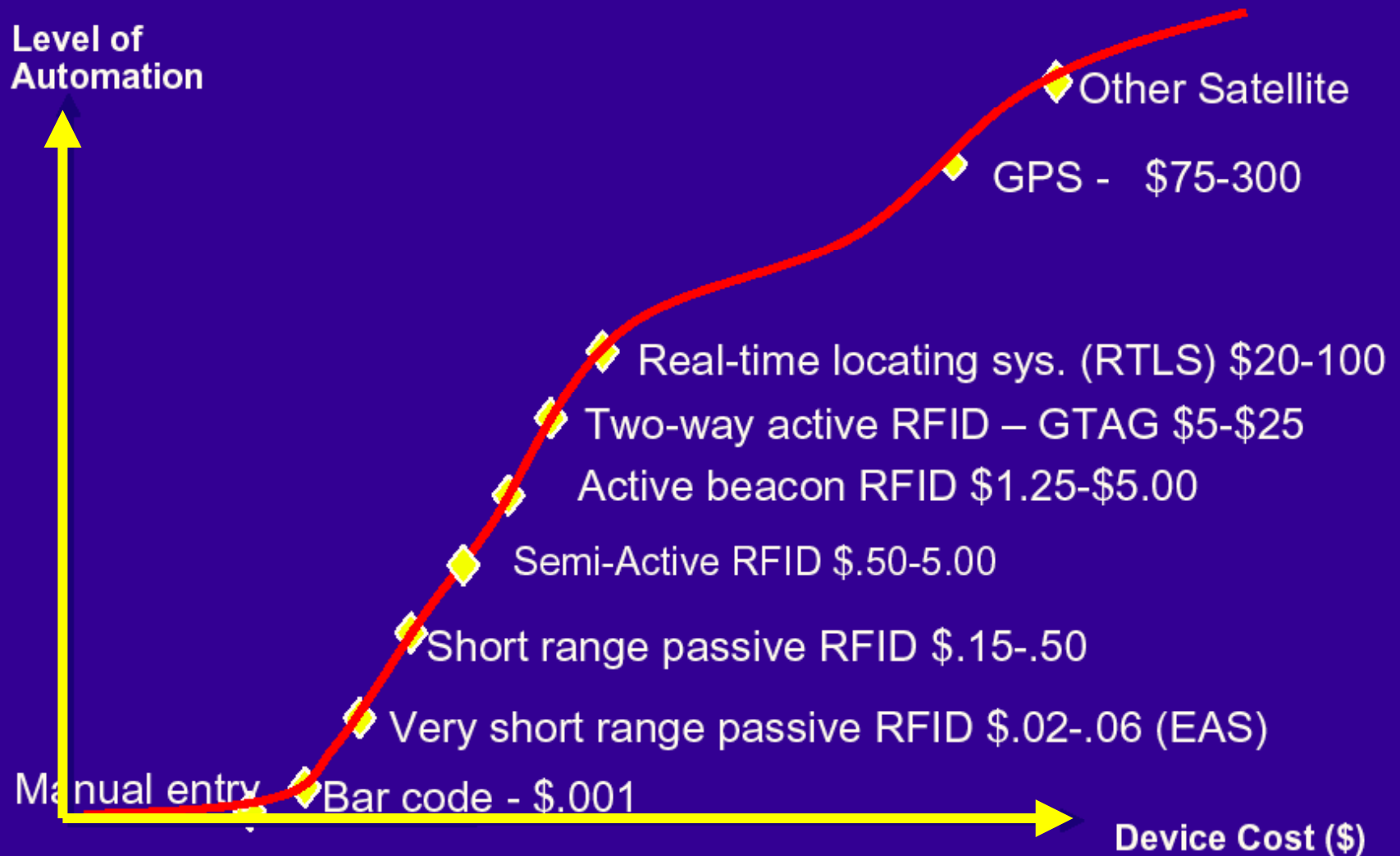
End points

- **Color change**
- **Lights up red**
- **Beeps**
- **LED - don't use**

- **Or if listeria then blows up food**



Critical Factor - Cost



Critical Factors - technology

- **Choice of frequency ISO standards**
- **Data standards ePC**
- **Water absorption of μ -wave reduces power**
- **Reflectivity of metal**
- **Standards for readers**
- **Software compatibility**
- **Data security**

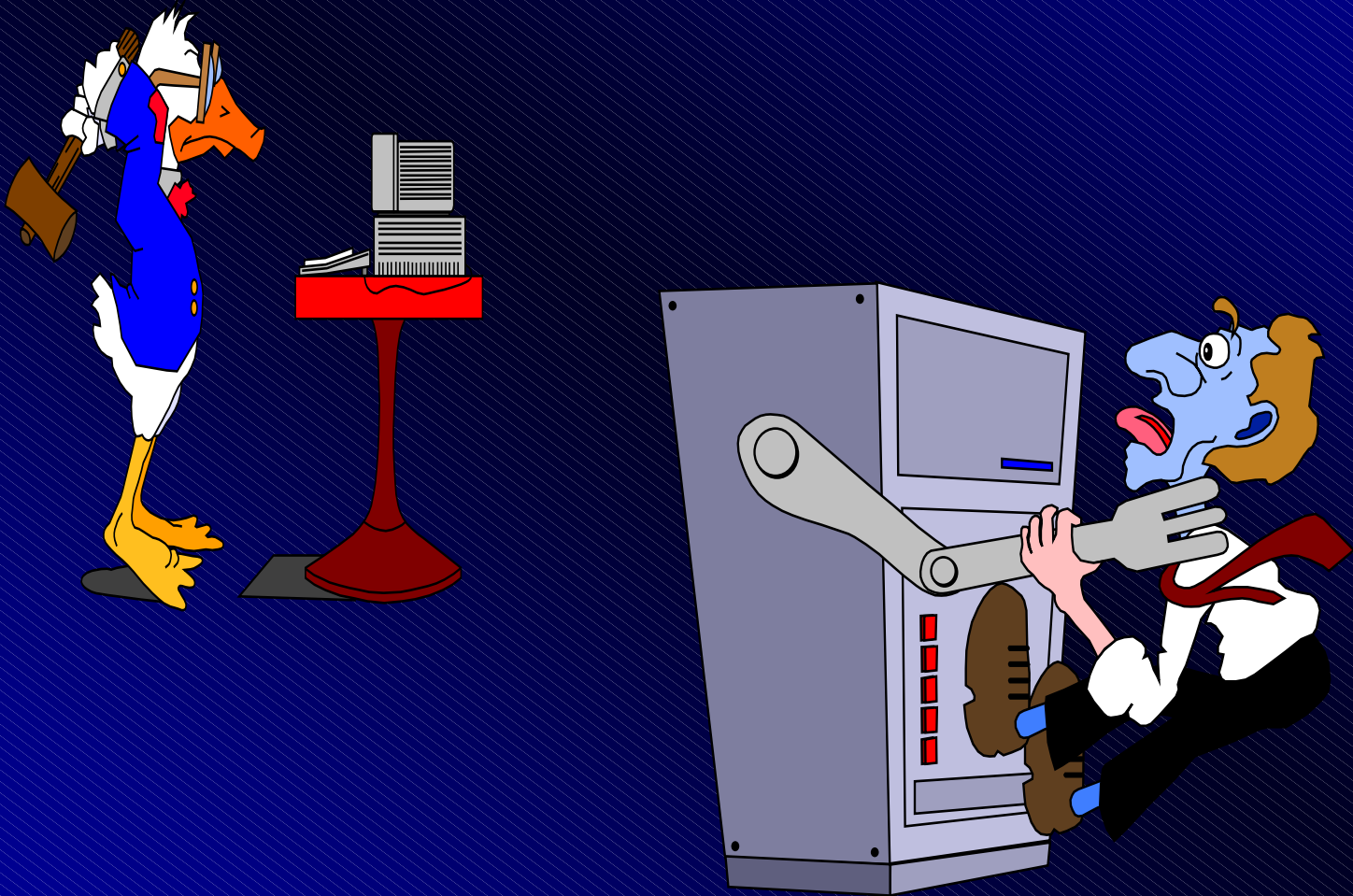
Use concerns

- **Influence of environment on tag**
- **Recycling prohibitions if on primary package**
- **Environmental disposal (EPA)**
 - **Heavy metals in battery**
 - **organics**

Traceability concerns

- 4th amendment rights of privacy
- Cost of implementing RFID vs paper files
- Pallets vs cases vs packages (TRU)
- Tag reliability in environment
- Standards for data security during collection, management and sending
- KISS software
- Palm compatibility

That's all folks



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