A Microbiologist's Perspectives

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Why are we here

- With regards to O157 in beef, 2007 was Annus Hornbills
- Regardless of whether it was an anomaly or a fundamental change:
  - It was a tremendous setback for people who have been involved in food safety efforts in the beef industry
  - It has revealed cracks and weaknesses in our defenses against O157
  - It has also provided us with an opportunity for shoring up of the barriers
- FSIS's interest in non-O157 EHECs
- FSIS's reconsideration of issues regarding the presence of O157 in primal and subprimal

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Presentation outline

- The IEH's response to surge in O157 levels in beef
  - Addressing the sampling issues
  - Reducing the lot size
  - Use of process control
- The non-O157
- Our view of problems areas that need to be addressed by the agency
  - Reconsideration of some of the directives
  - Sampling ground beef
  - Help for grinding operations
  - Reconsideration of costs associated with food safety

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The 2007 Surge in *E. coli* O157 contamination of Beef

- Unprecedented increase in levels of *E. coli* O157 in beef trim and ground beef
- Combination of factors: change in feeding practices, climate, immigration raids, etc.
- Requires changes in approach to process control, sampling and testing
- We may need an additional firewall between slaughter operations and grinders

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Our Response to the Surge

- Intensive use of the O157 testing data in process control
- Increased monitoring of sampling protocols
- Increasing the probability of detecting an O157 contaminated lot by:
  - Increasing the number of samples
  - Decreasing the lot size

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Sampling Audits

- It is essential that each establishment asks for sample and sampling audits
- We believe this to be one of the most important gaps in the *E. coli* O157 verification protocols
- Audit should consists of auditing the sampling (SOP and the sampler's execution of the SOP), piece count and % internal vs. external pieces

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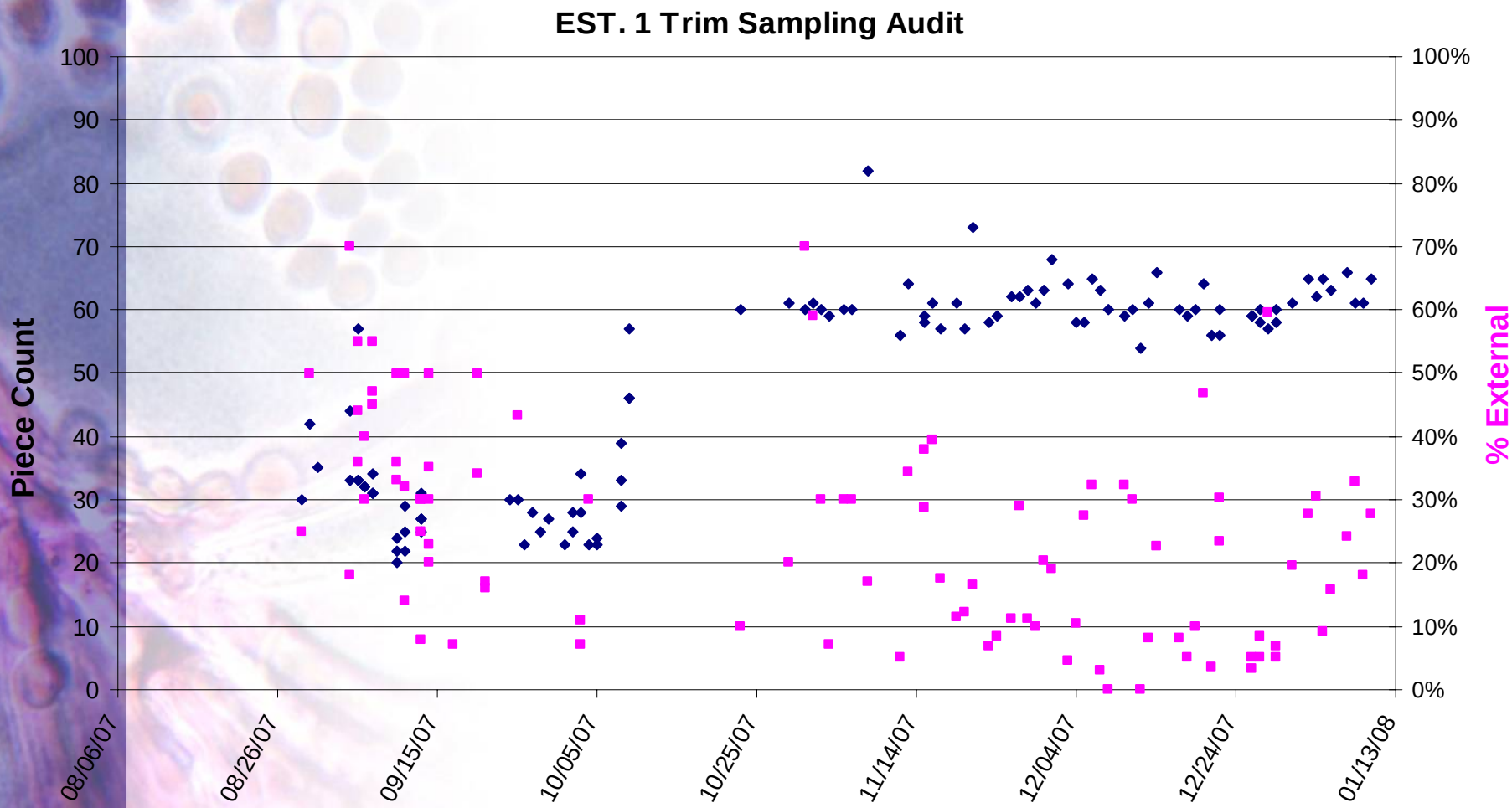

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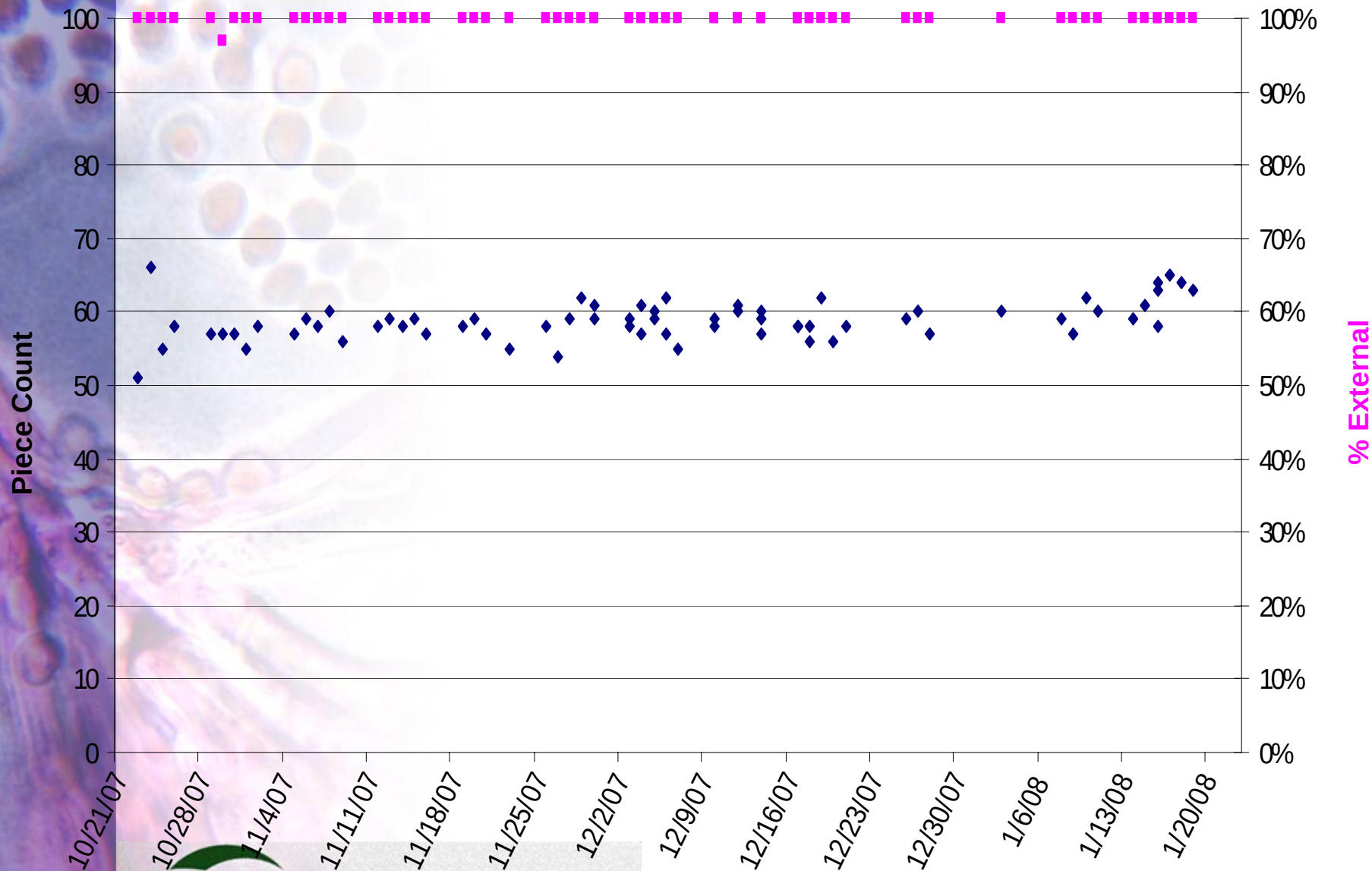
EST. 2



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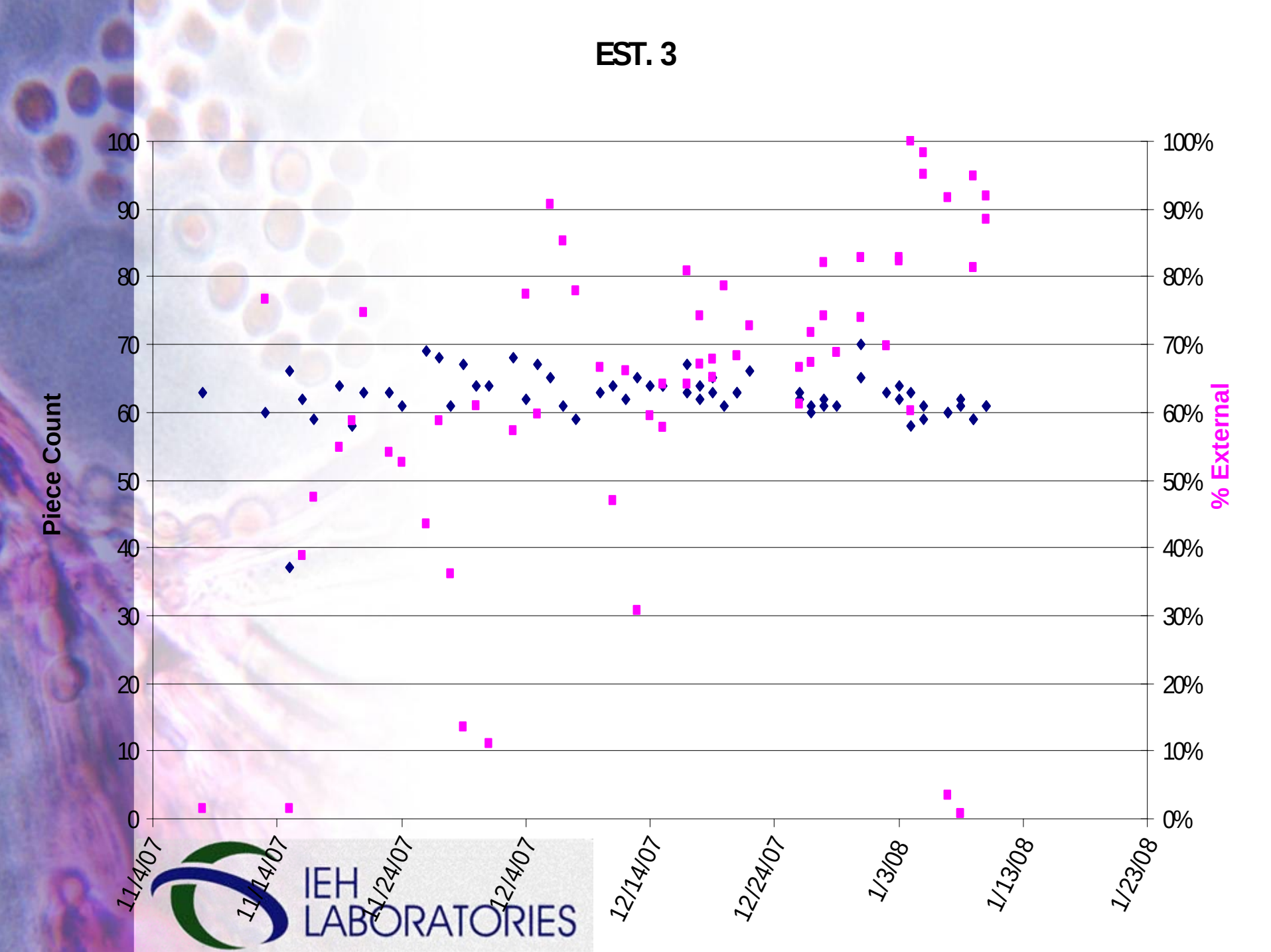
EST. 3



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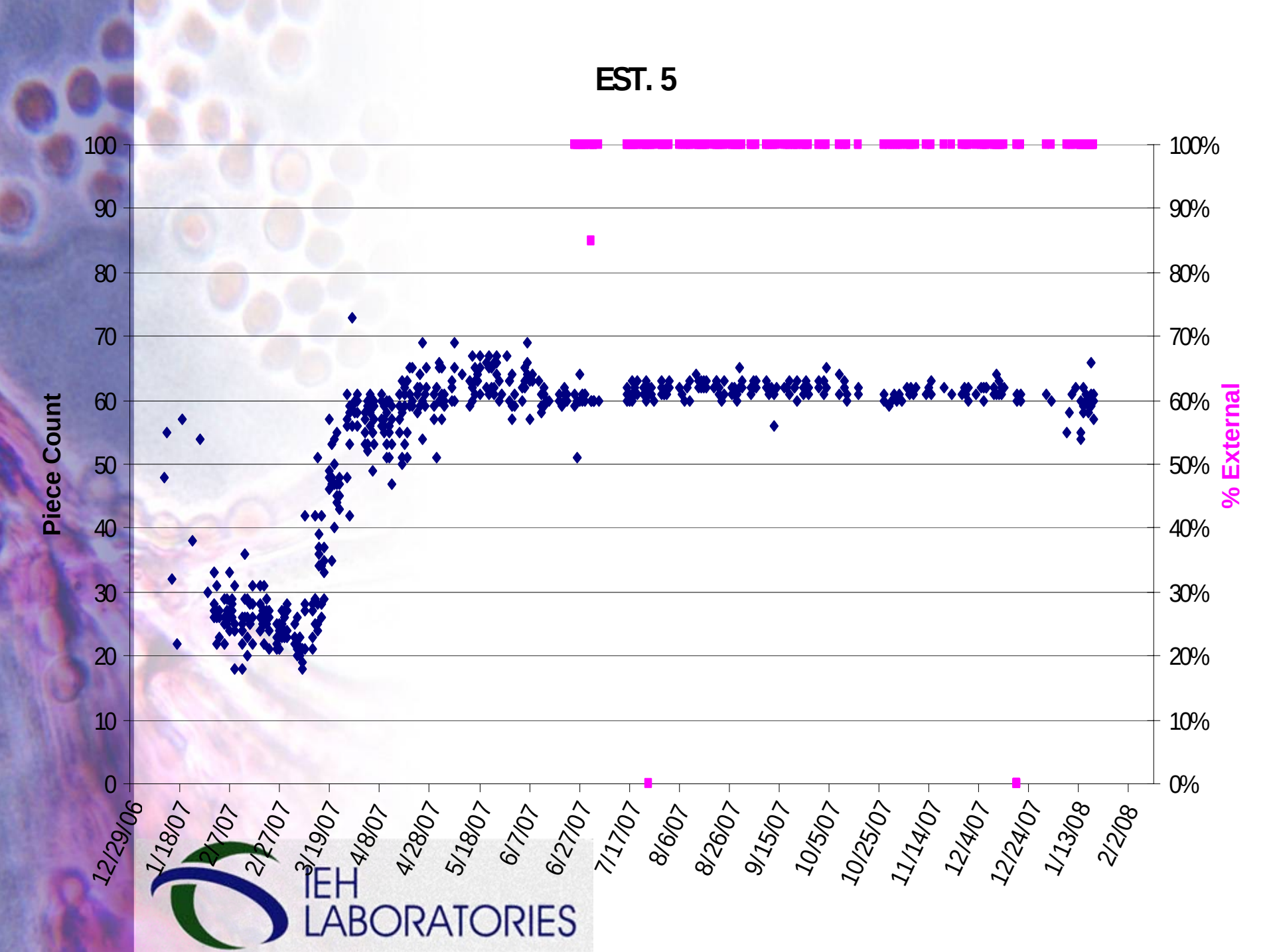
EST. 5
Piece Count
% External
100
90
80
70
60
50
40
30
20
10
0
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
12/29/06
1/18/07
2/7/07
2/27/07
3/19/07
4/8/07
4/28/07
5/18/07
6/7/07
6/27/07
7/17/07
8/6/07
8/26/07
9/15/07
10/5/07
10/25/07
11/14/07
12/4/07
12/24/07
1/13/08
2/2/08
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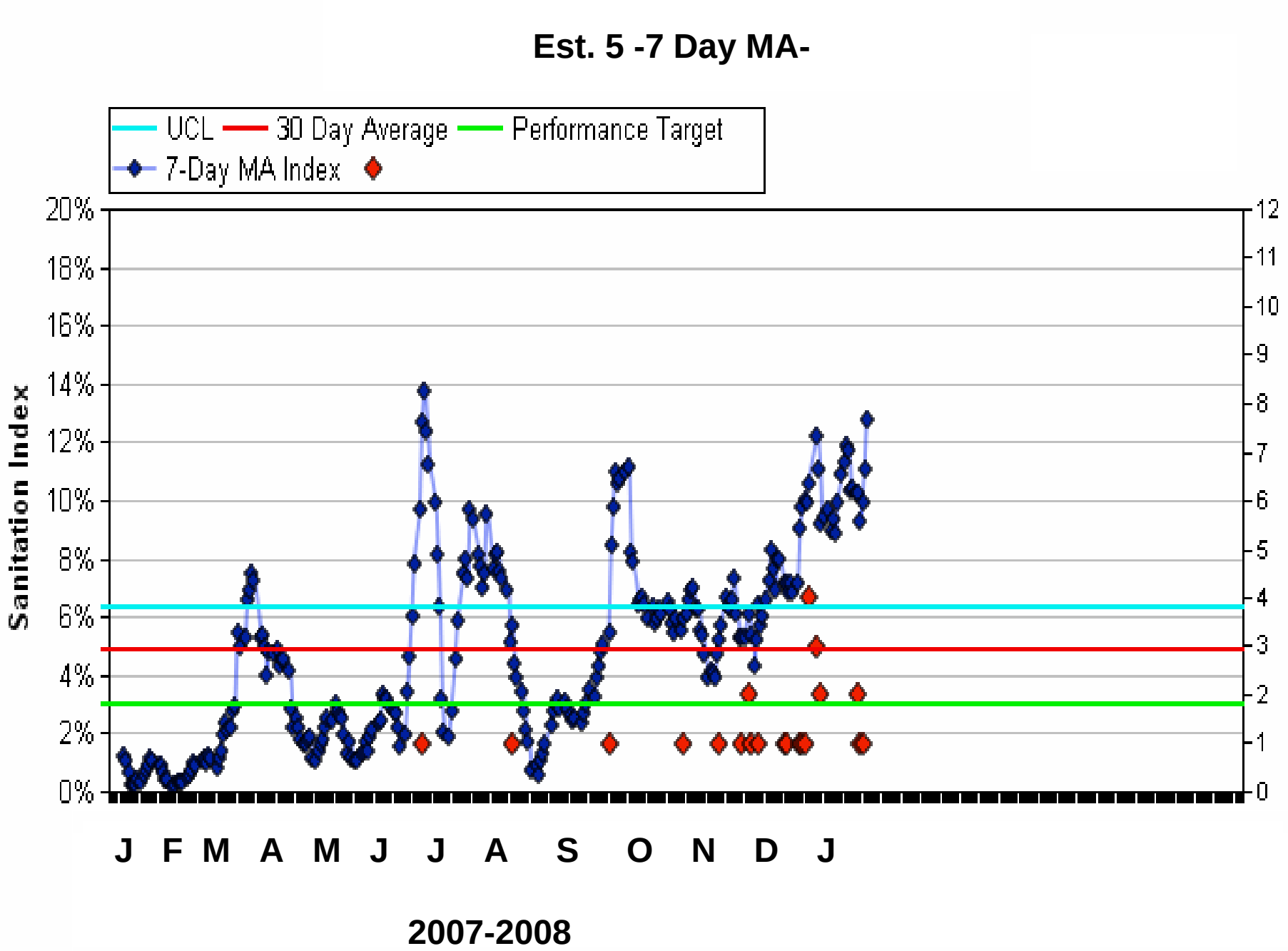
Est. 5 -7 Day MA-
UCL
30 Day Average
Performance Target
7-Day MA Index
Sanitation Index
20%
18%
16%
14%
12%
10%
8%
6%
4%
2%
0%
12
11
10
9
8
7
6
5
4
3
2
1
0
J F M A M J J A S O N D J
2007-2008

Managing the Risk

- In early 2007 we concluded that the best way to reduce the risk to our clients was to reduce the size of each lot and increase the number of samples
- "***if it is there we want to find it***"
- JBS Swift Accepted our strategy

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Trim Sampling

- *For samples capable of excision testing, N-60 represents 375 grams or more of thinly sliced exterior surface tissue (60 slices derived from trim in 5 combo bins/units 12 thin slices of exterior surface material from each combo bin/unit); a 375 gram sample is enriched and analyzed using a method at least as sensitive and specific as the FSIS method*

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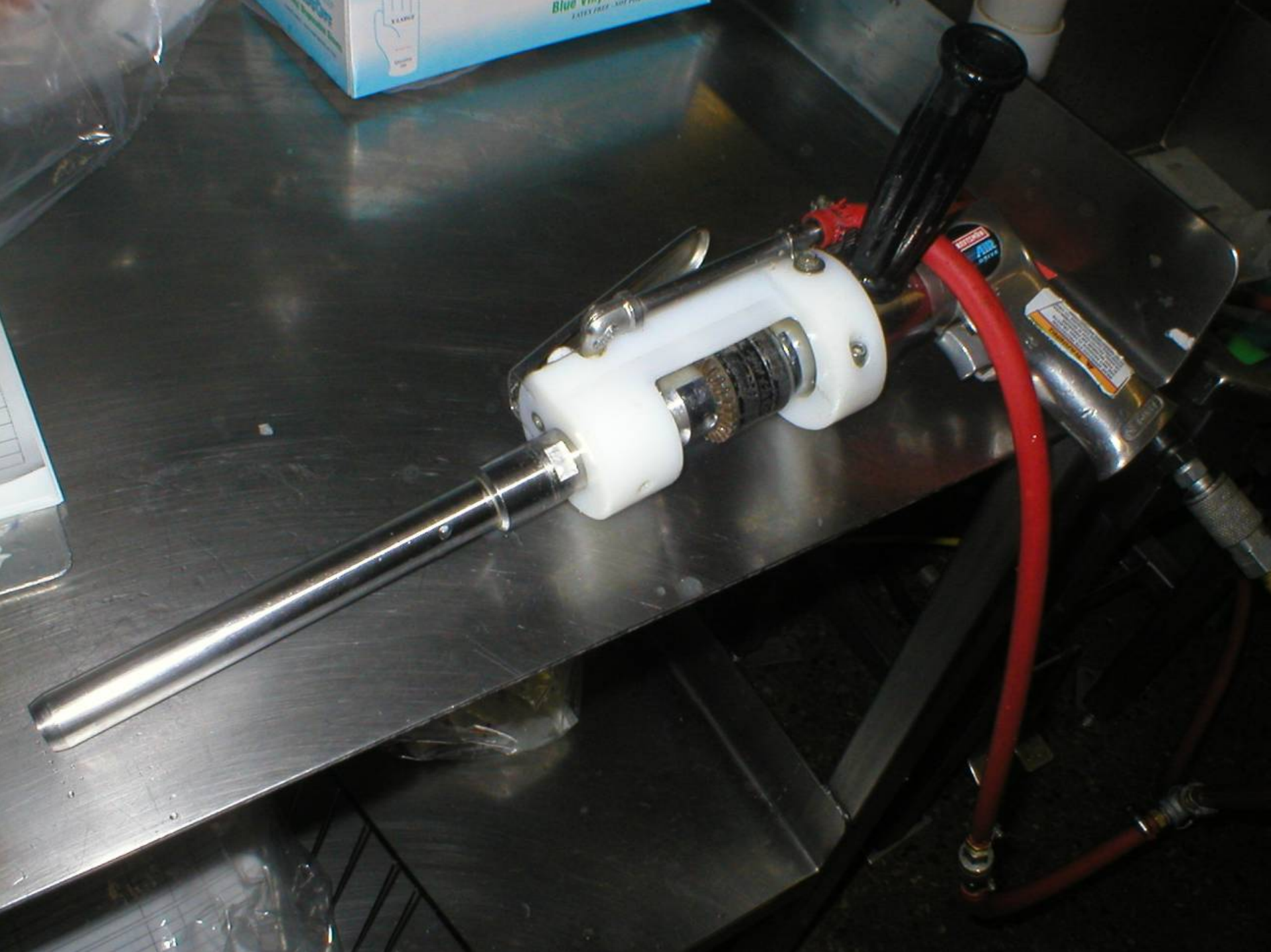
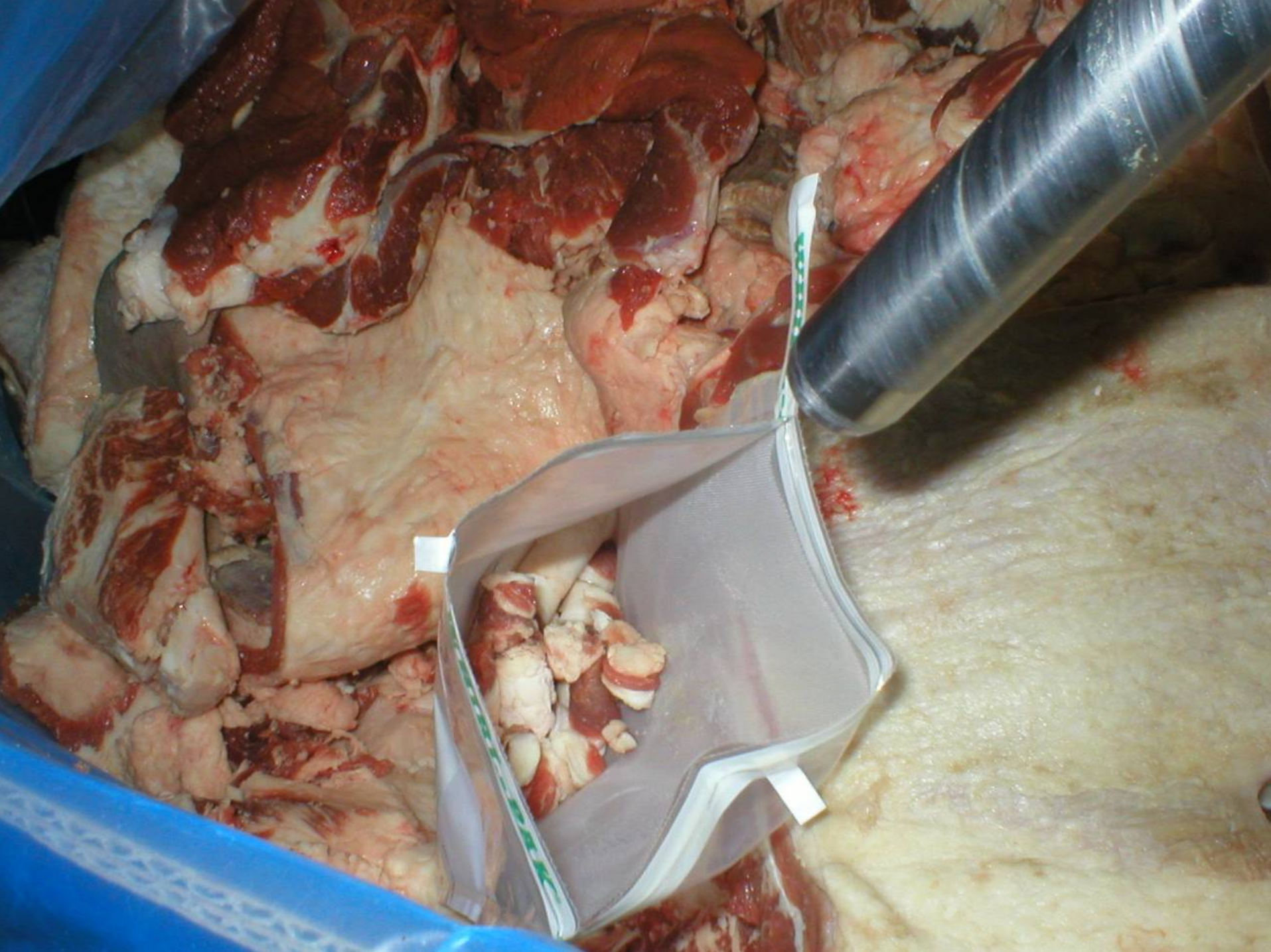
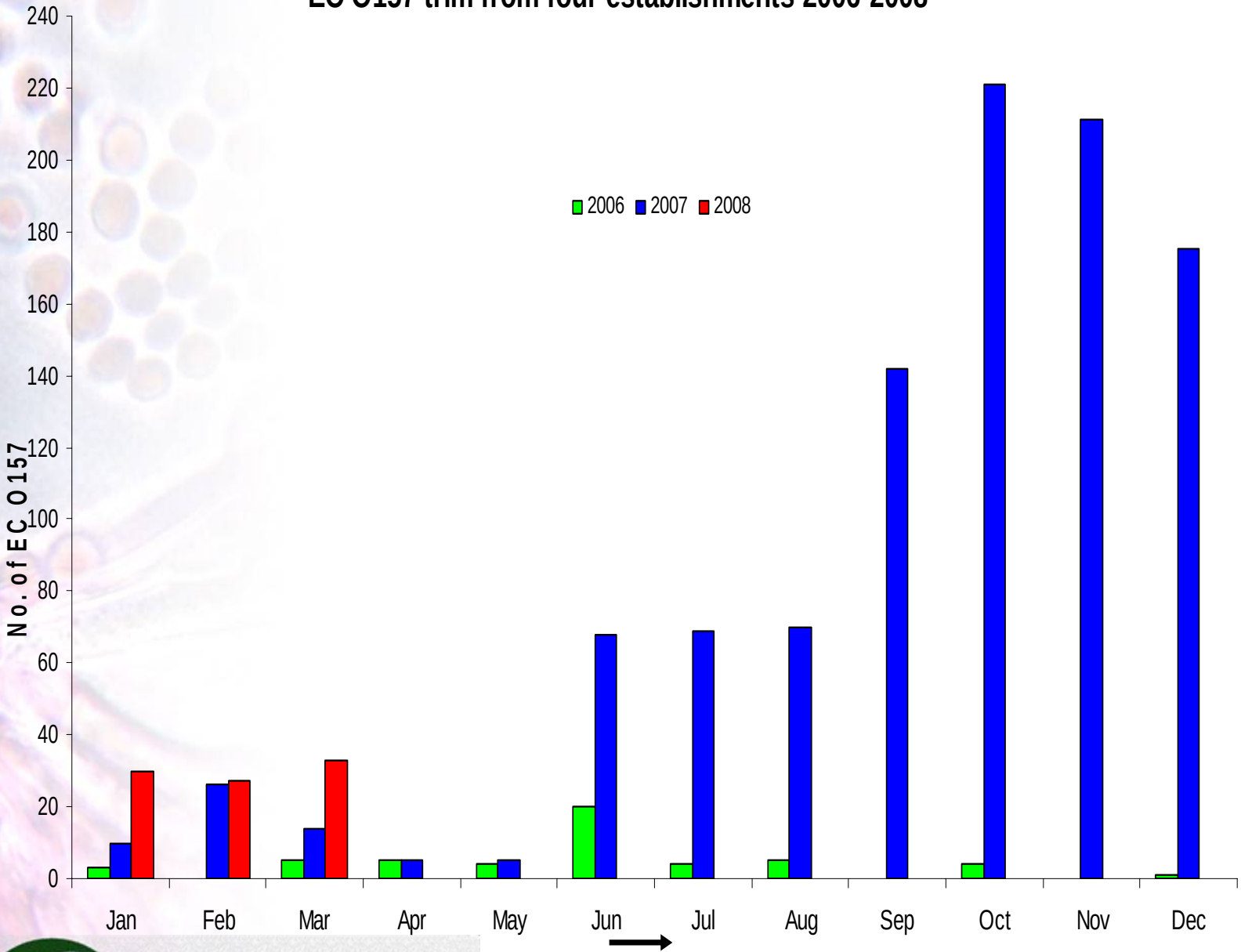



WHIRL-



Trim Type: 65/35, Sample Wt (lbs): 0.50, Piece Count: 61

EC O157 trim from four establishments 2006-2008



n=60 single combo testing

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II. Ground Beef Sampling

- *For samples not capable of excision testing (e.g., comminuted product), a composite sample is collected representing all units from a specified time period (10-30 minutes for continuous testing; one sample from the entire production lot; grab samples from each /unit); at least a 65 gram sample is enriched and analyzed using a method at least as sensitive and specific as the FSIS method*

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II. Ground Beef Sampling Continued

- Grab Samples each 10-15 minutes
- Composite 1hr to the whole production day
- Test a 65 gram
- As much as 150,000 lbs of product maybe represented by a single 65 gram test unit

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II. Ground Beef Sampling Cont.: Ground VS. Trim

- Consider a lot of 150,000 lbs:
  - Trim: 15 to 75 test units, each consist of 60 pieces (900 to 4500 pieces), the entire 375 gram sample is tested (5625-28,125 gram)
  - 8 grab samples are mixed and a 65 gram portion is tested. The test sample represent a minute amount of surface area
  - The ground beef sampling plans are not robust
  - We need to move to complete equivalency to trim testing

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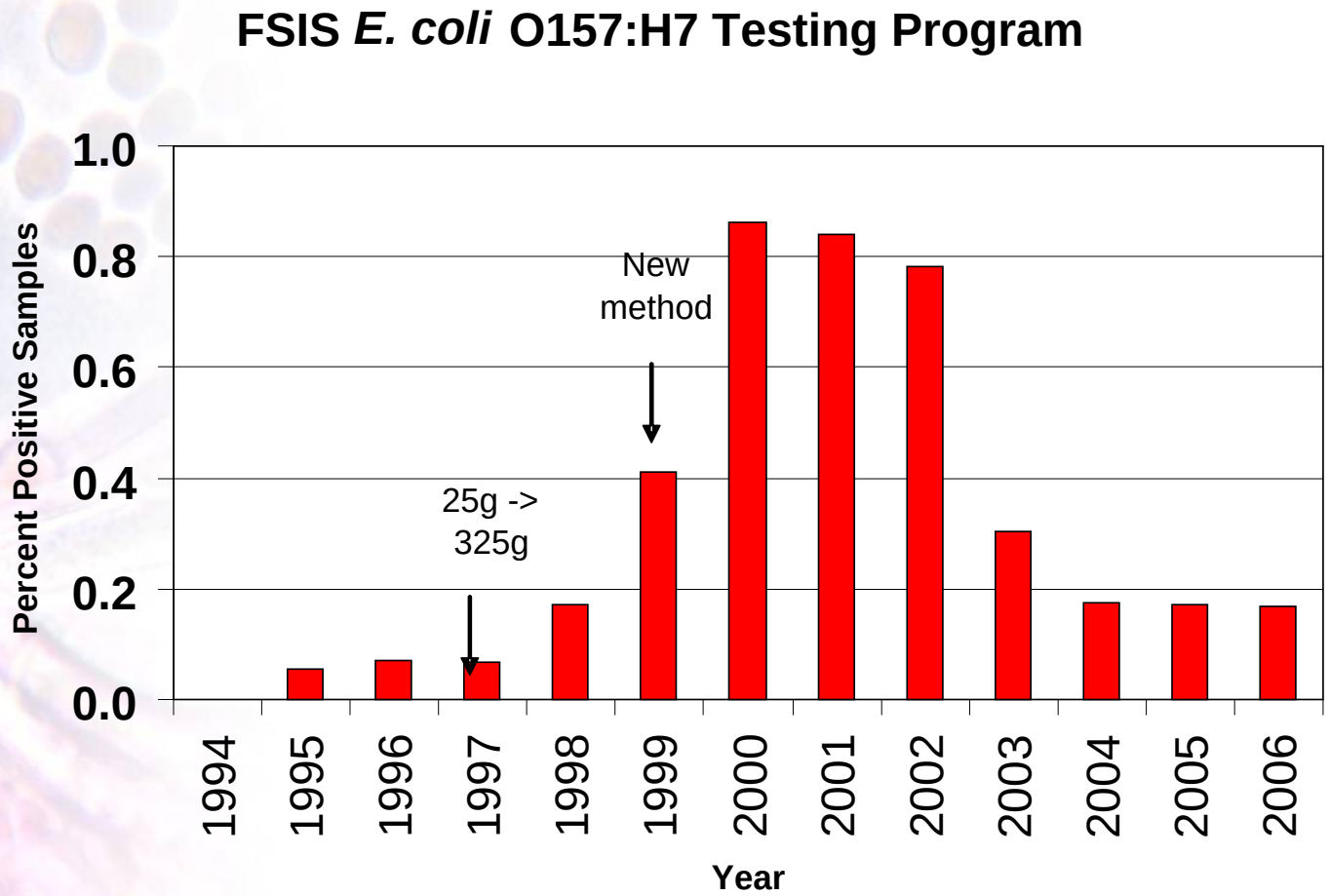
Beef Industry Success



http://www.fsis.usda.gov/Science/Ecoli_O157_Summary

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STATISTICAL PROCESS CONTROL: AN EARLY WARNING SYSTEM

IEH is the only entity able to provide SPC charts for pathogen index; All other tests only provide presence or absence

- Quantitative and Qualitative index of organisms related to *E. coli* O157
- Control limits can be set for “pathogen index”
- Increase in index is indicative of loss in control and potential pathogen event
- “Finger-on-pulse” control vs. sudden unexplained event
- Used to evaluate and compare shifts, establishments, season, suppliers, etc.
- Success in driving down the incidence of *E. coli* O157 in released product

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Use of the Pathogen Data in SPC

- The fact that a large number of samples are analyzed each day for the presence of *E. coli* O157 in abettors presents a tremendous opportunity for the use of the data in controlling the process.
- Since each sample is enriched, unlike ECC counts there will not be a large series of negative results.

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Use of the Pathogen Data in SPC

- The IEH approach of using multiplexes is the only way that SPC can be generated
- The signals that are used in SPC monitoring come from: *E. coli* O157, Salmonella, non-O157 EHEC, STEC, and EPEC
- While the incident of *E. coli* O157 is low the incident of the other index organisms is 10-100 times more

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Use of the Pathogen Data in SPC

- The carcass, trim, ground beef and environmental samples pathogen data allows for near real time. monitoring of the harvest, fabrication, and sanitation processes.
- The carcass index can be used as a true early warning system to identify process lapses before fabrication.

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Use of the Pathogen Data in SPC

- The data allows to identify sanitary dressing practice failures, and intervention failures.
- The differences between the performance of each shift can be measured.
- The performance of various establishments can be compared to each other.
- The failure of interventions due to mechanical problems can be identified.
- The process allows for a clear view of the process as opposed to the current black box approach.

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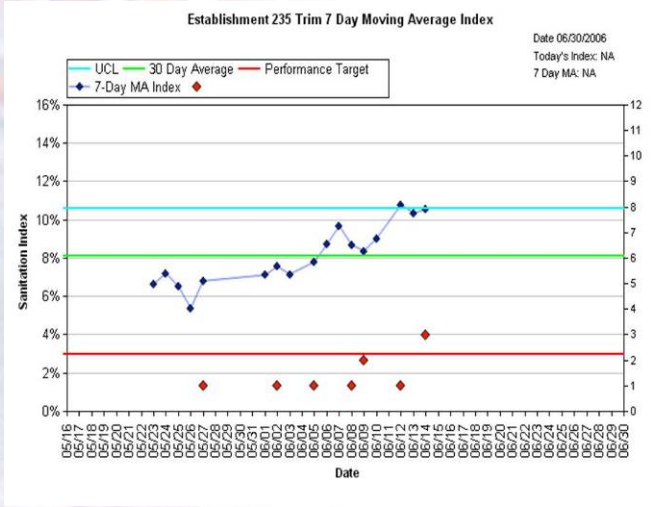
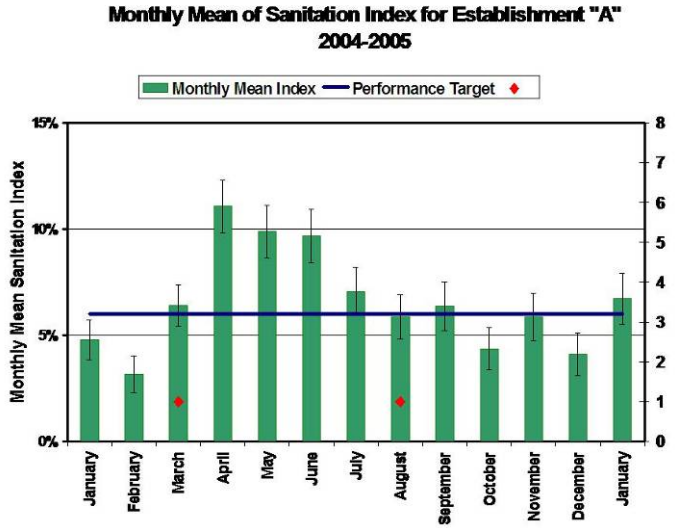
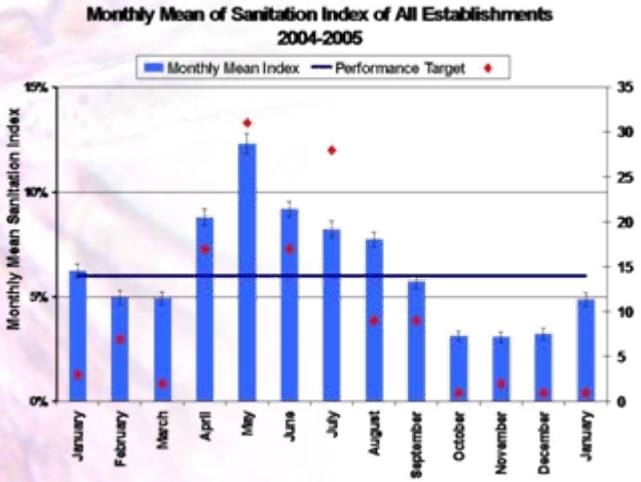
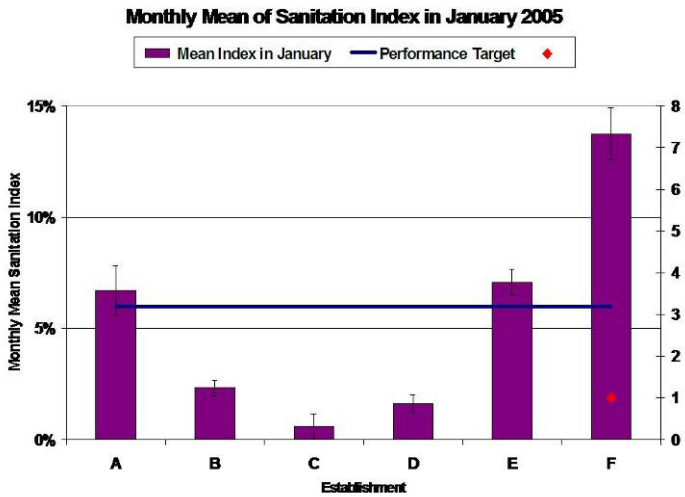
SPC - An Early Warning System









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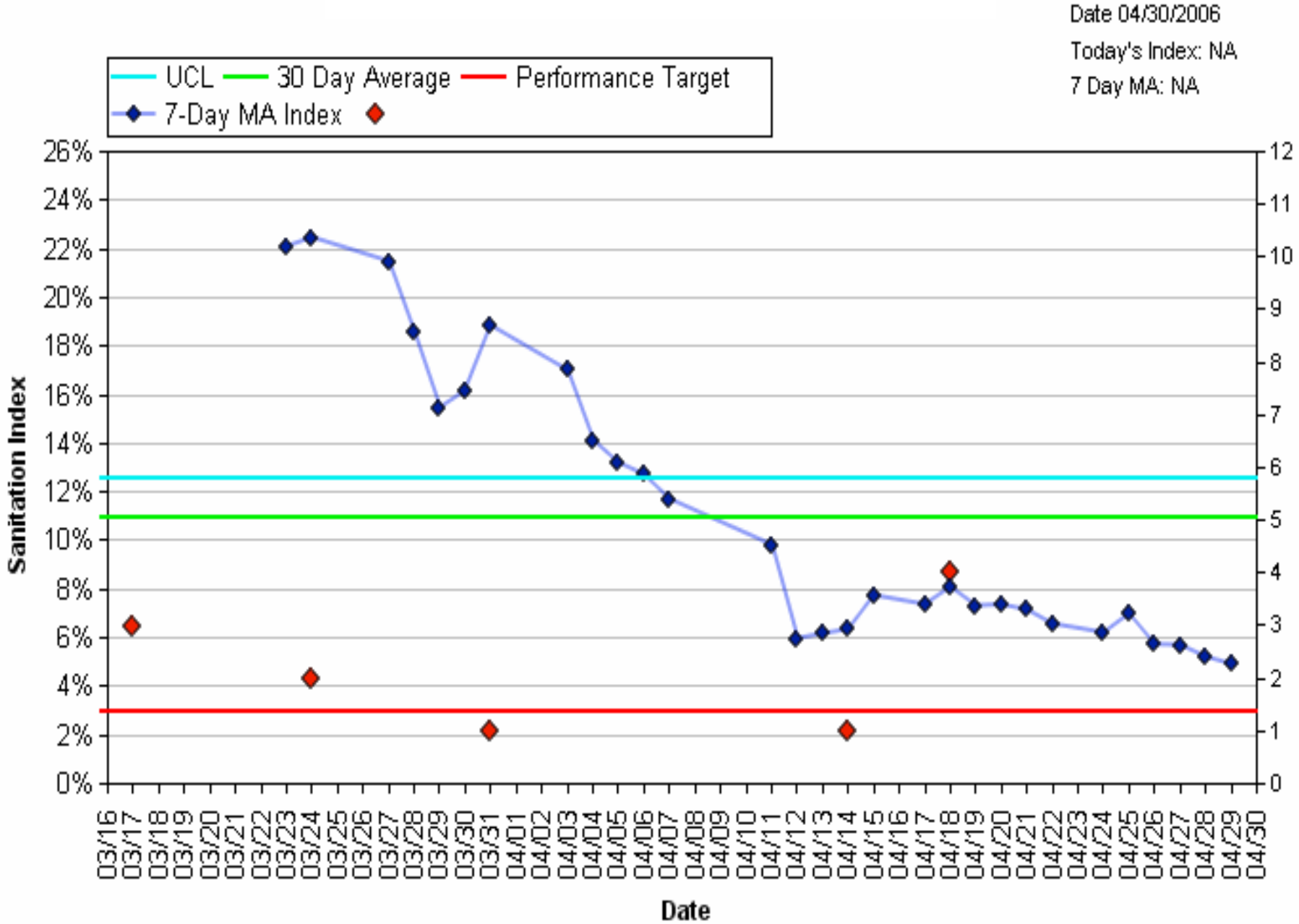
Date 04/30/2006
Today's Index: NA
7 Day MA: NA
UCL
30 Day Average
Performance Target
7-Day MA Index
Sanitation Index
26%
24%
22%
20%
18%
16%
14%
12%
10%
8%
6%
4%
2%
0%
12
11
10
9
8
7
6
5
4
3
2
1
0
03/16
03/17
03/18
03/19
03/20
03/21
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04/19
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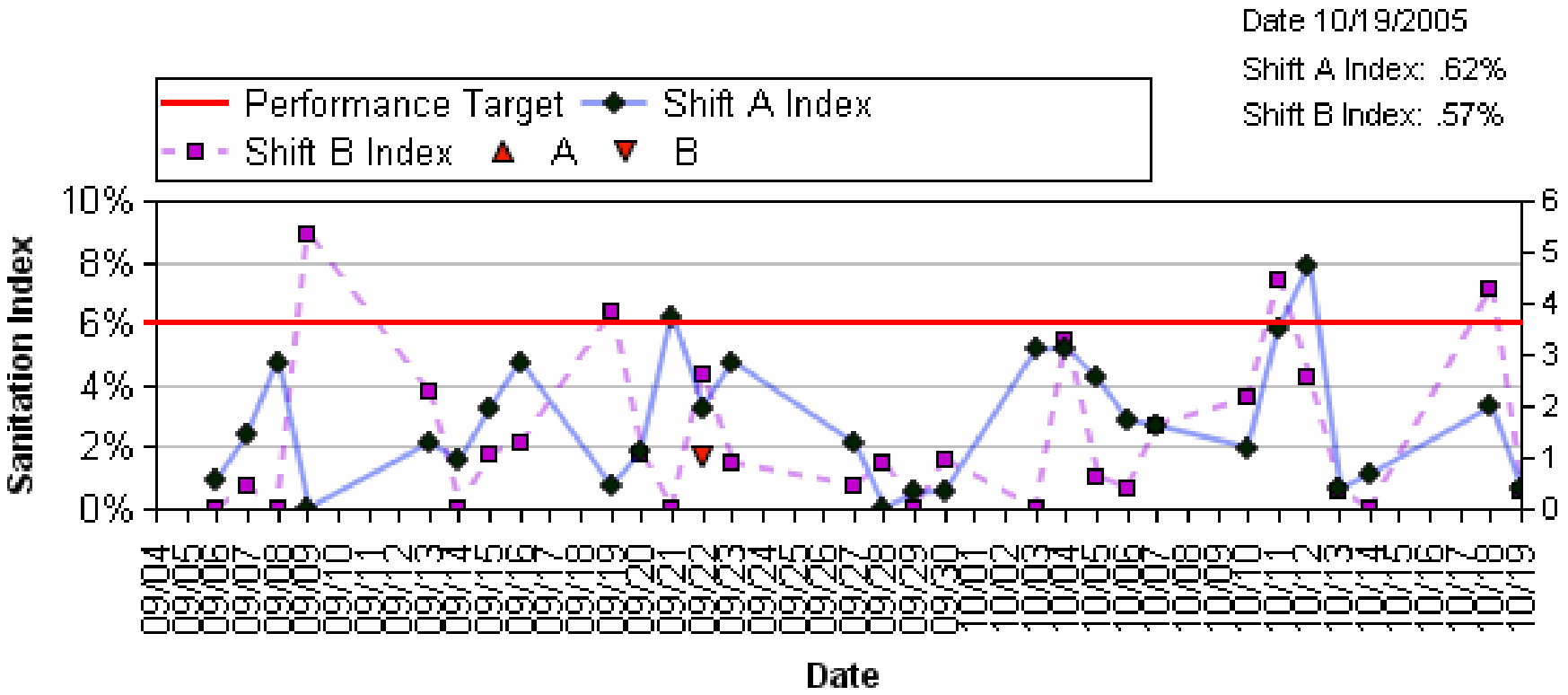
04/30
Date

STATISTICAL PROCESS CONTROL – SURROGATE INDEX



Advantages:

1. Monitor production to detect risk of exceeding control limits
2. Evaluate performance of suppliers
3. Provide warning of potential pathogen event
4. Narrow down problem, i.e. employee vs. process-induced
5. "Finger-EH-Pulse" system to evaluate processing decisions

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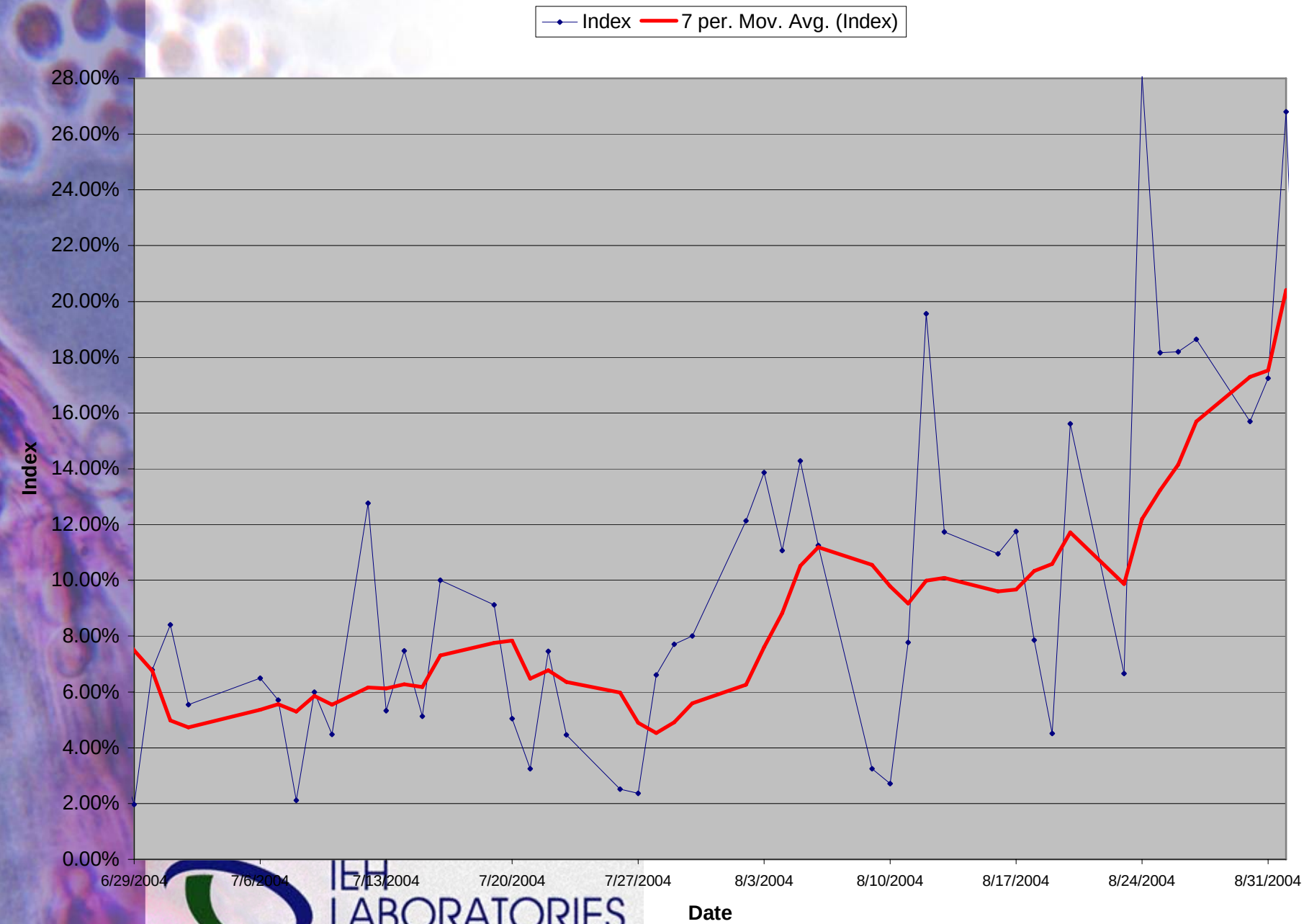
Beef Trim Index



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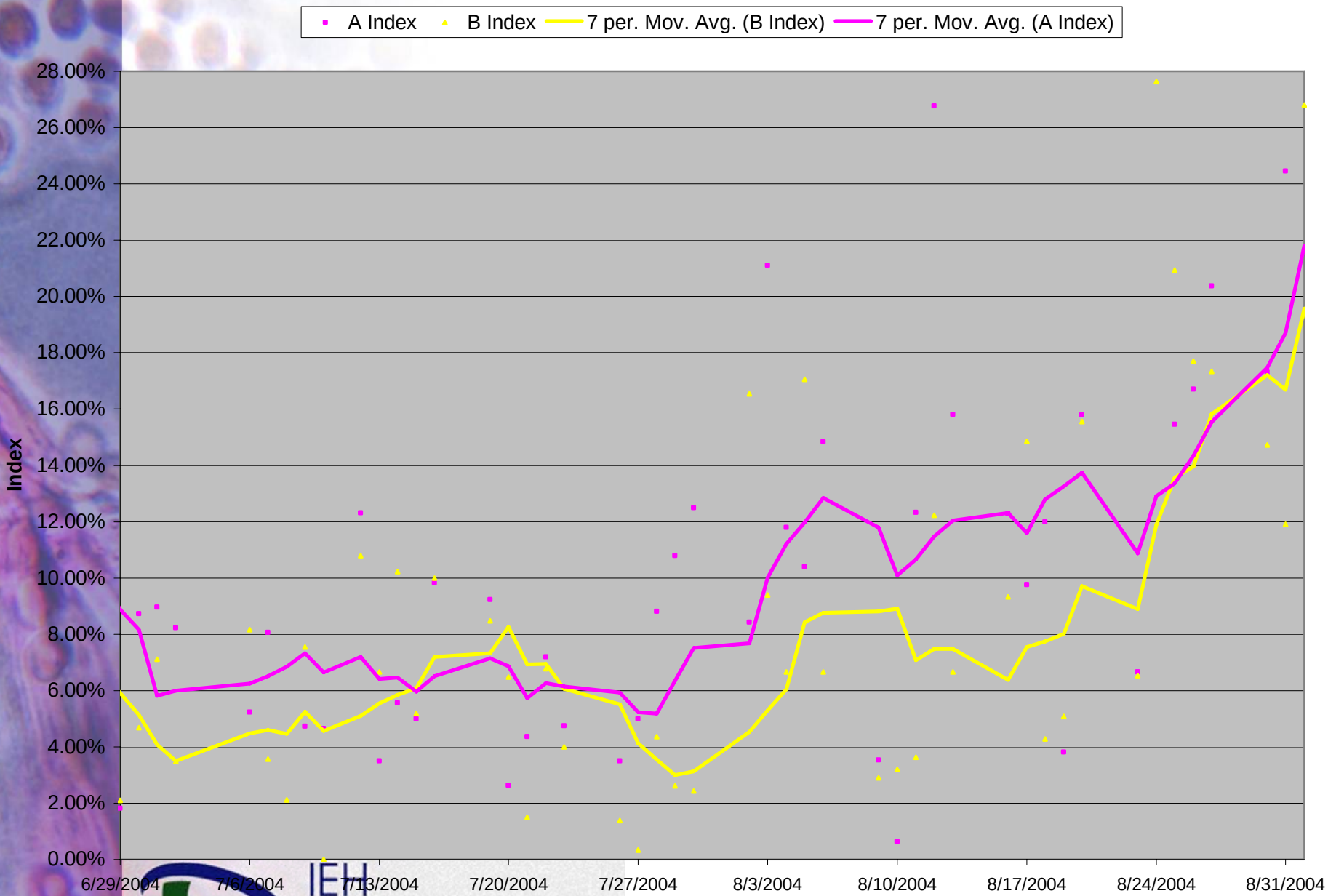
Beef Trim Index



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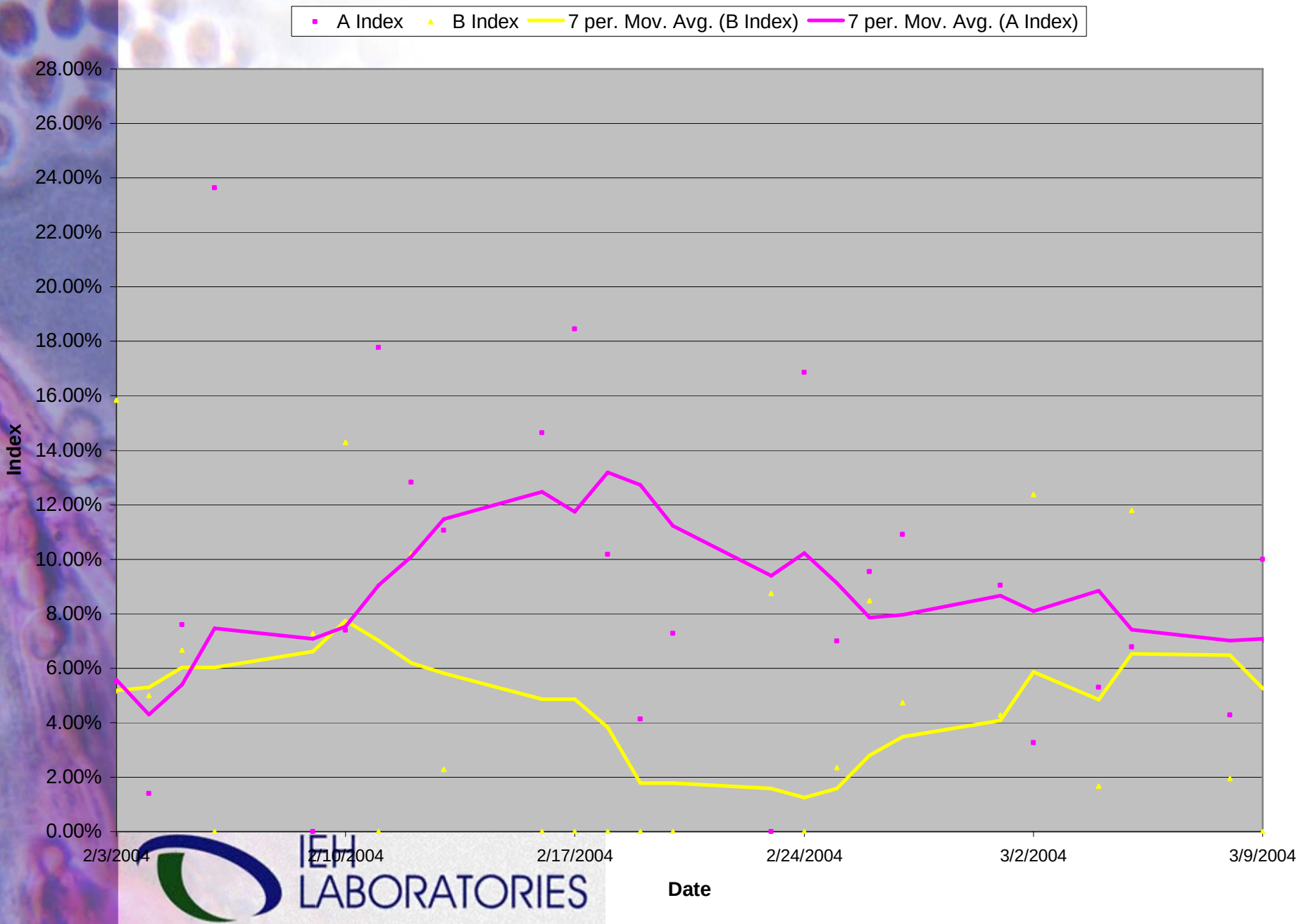
Beef Trim Index



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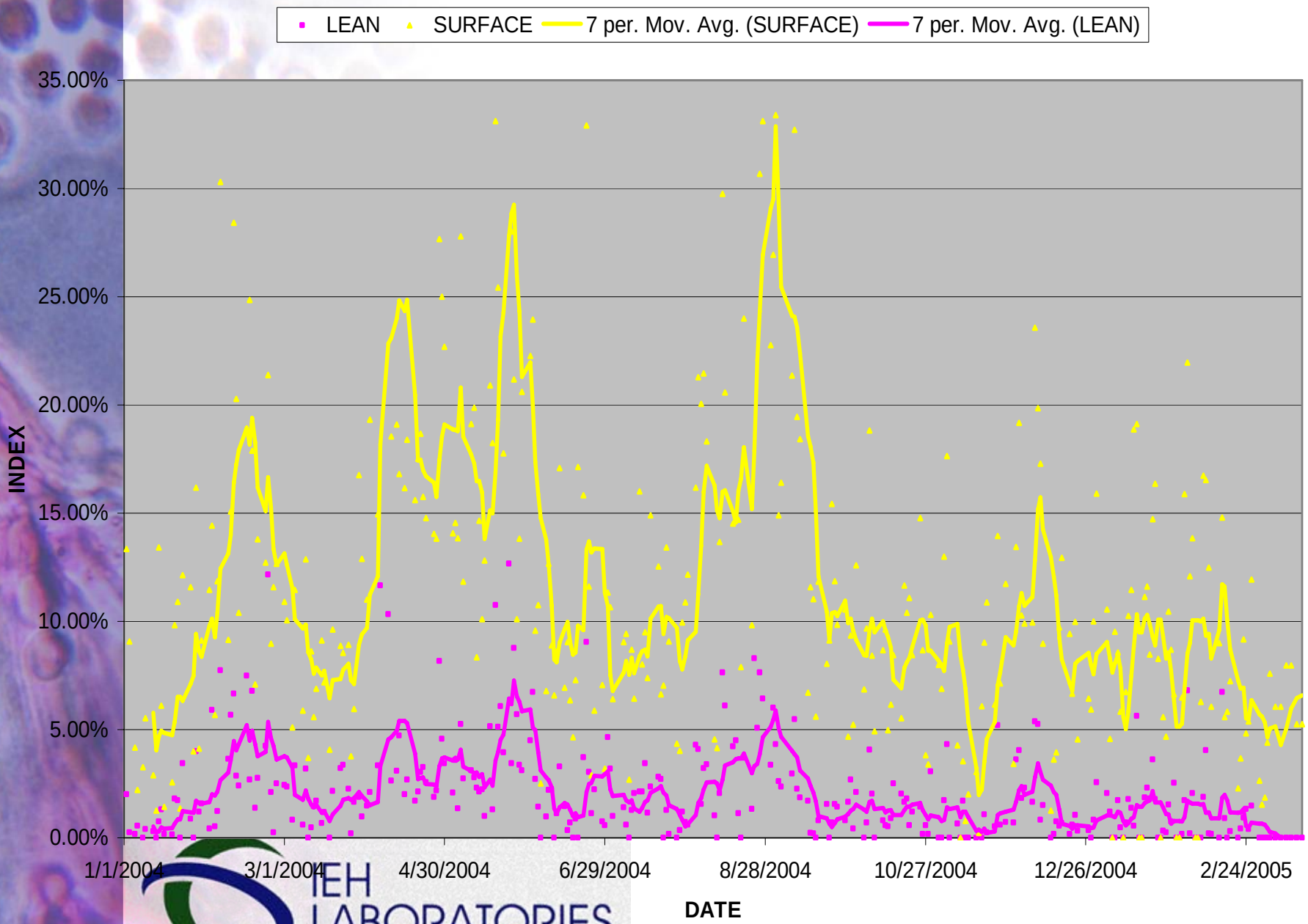
COMPARISON OF LEAN AND SURFACE INDEX VALUES



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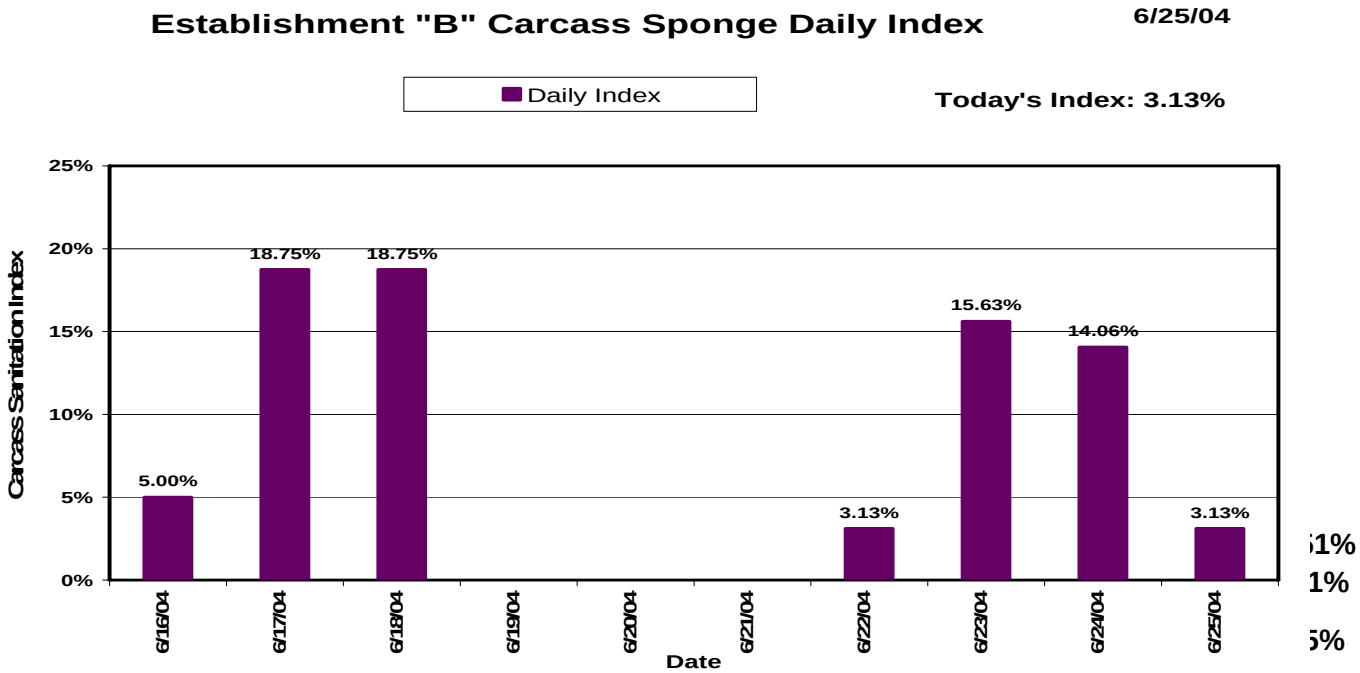
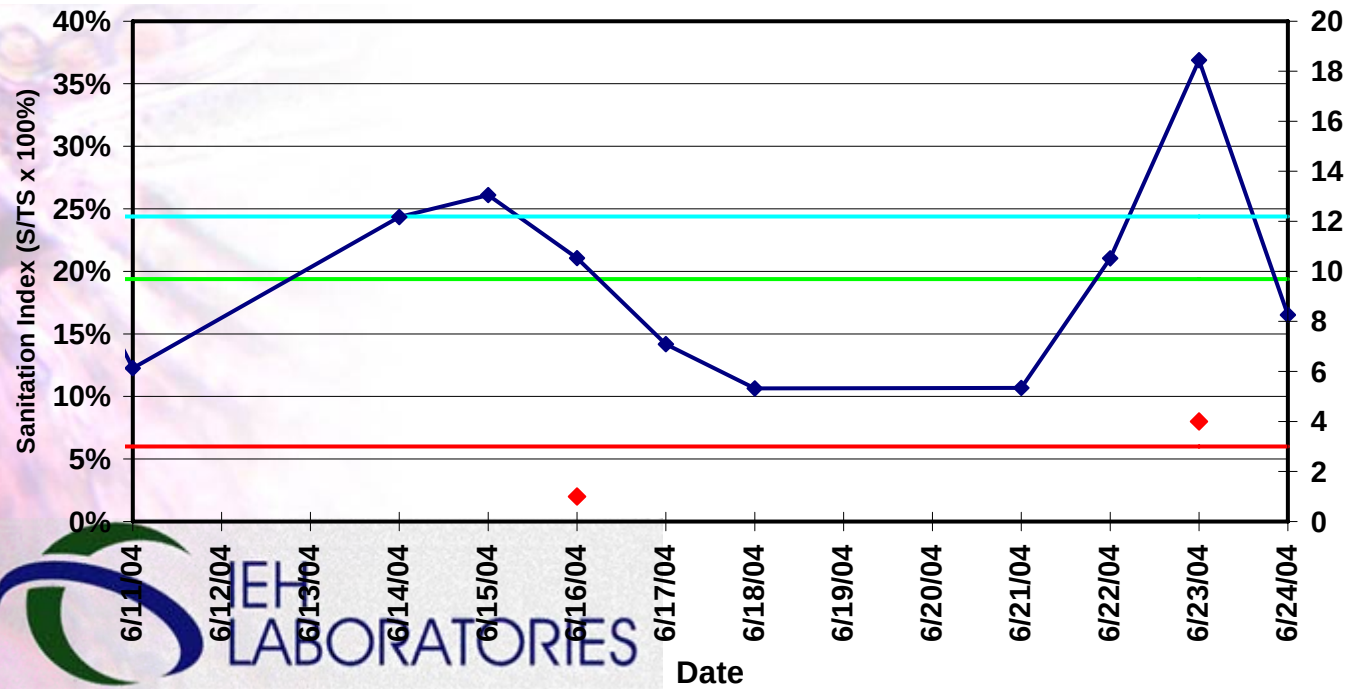
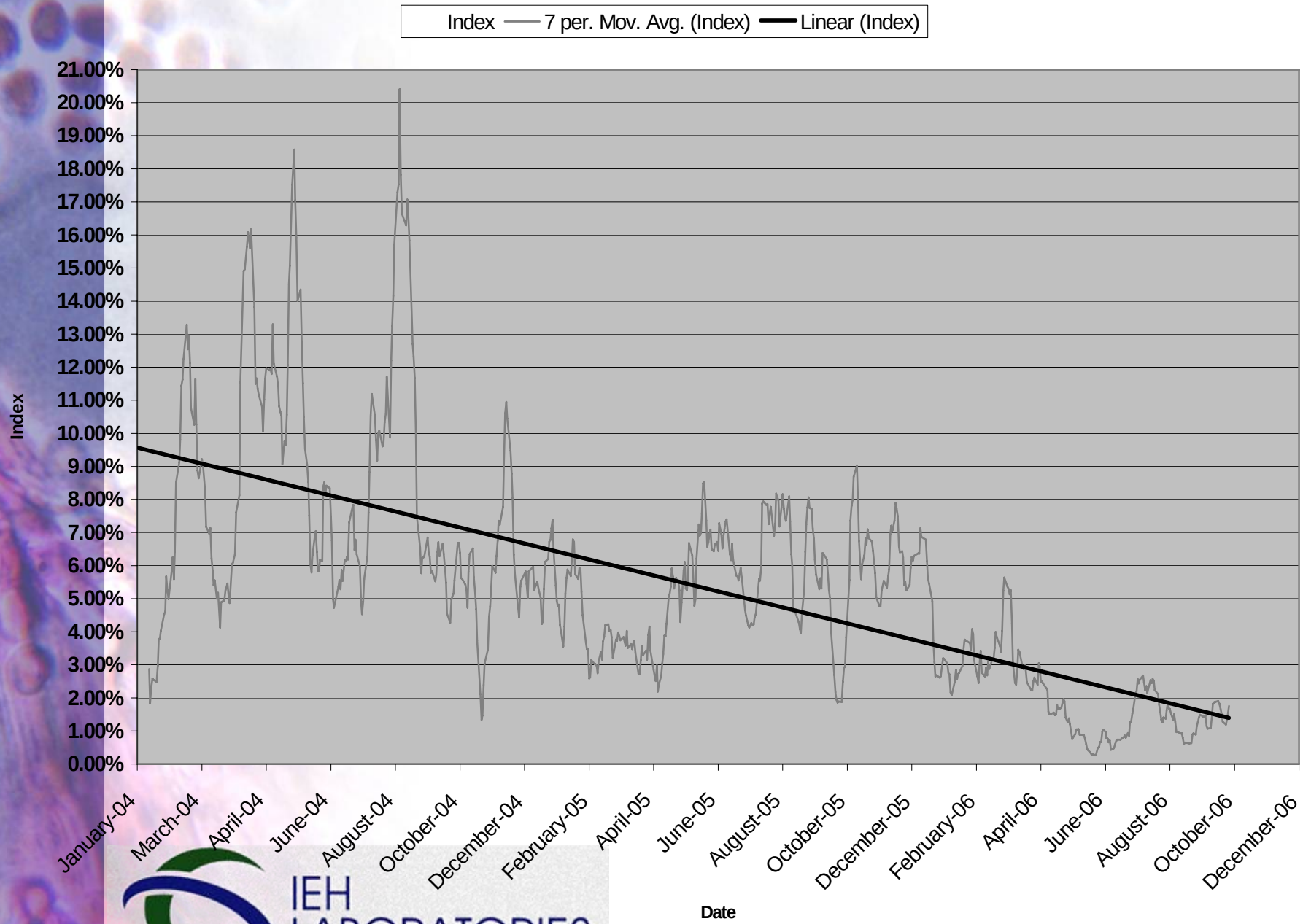
DEMONSTRATION 2: High Carcass Sanitation Index Leading to Increasing Trim Sanitat





EH LABORATORIES

Beef Trim Index



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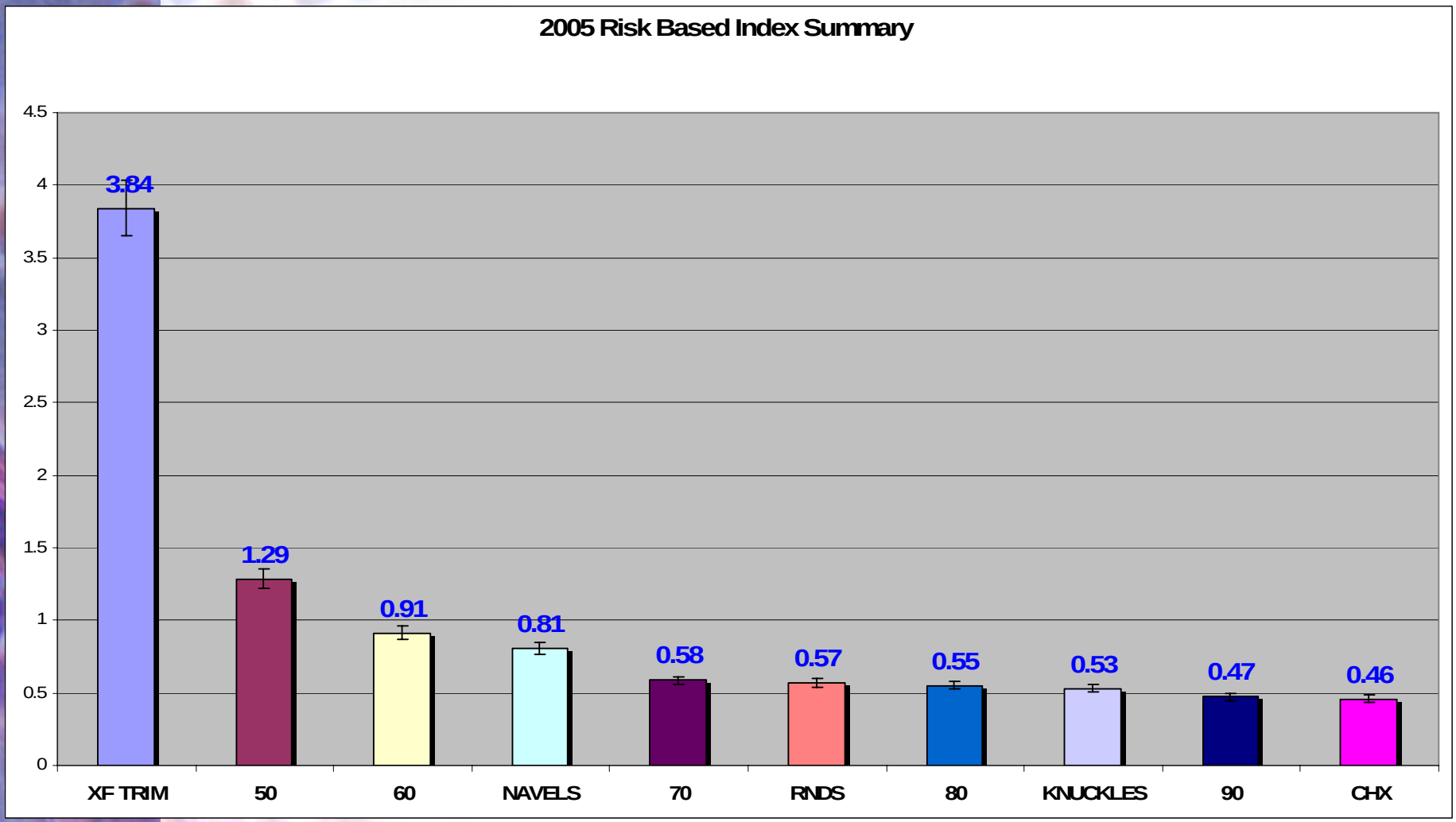

The Risk Based Index (RBI) will give us an ability to analyze risk of each sample type based on the % volume contribution and % signal contribution specific to a sample type (lean point).

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The non-O157 EHEC/STEC

- Some of the non-O157 EHECs areas pathogenic as O157
- The current infrastructure does not allow for considering these pathogens as adulterants like O157
  - There is no agreement of definition of the organisms
  - there are no official methods available to screen for them
  - There are no commercially available test kits
  - There are a few government laboratories and a few commercial labs that have the means to test for these organisms

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Intimin-negative STEC serotypes

O1:H7[1]
O1:H20[1, 2]
O2:H-[2]
O2:H8[2]
O2:H27[1, 2]
O2:H32[2]
O4:H4[2]
O4:H10[1]
O6:H10[2]
O6:H12[1]
O6:H49[2]
O8:H-[2]
O8:H21[2]
O11:H48[1]
O15:H8[1]
O15:H18[2]
O17:H47[2]

O20:H2[2]
O21:H21[2]
O22:H8[1, 2]
O26:H-[2]
O27:H30[1]
O28:H25[1]
O39:H21[2]
O42:H21[2]
O50:H8[1]
O54:H-[2]
O54:H25[1]
O55:H9[1]
O60:H4[1]
O64:H5[2]
O68:H18[1]
O71:H12[1]
O73:H18[1]

O75:H8[2]
O76:H19[1]
O77:H18[1]
O77:H41[2]
O79:H14[1]
O88:H8[1, 2]
O88:H25[1]
O91:H-[2]
O91:H10[1]
O91:H14[1]
O91:H21[1]
O104:H21[1]
O105:H18[1]
O110:H-[2]
O112:H2[2]
O113:H4[1]
O113:H21[1, 2, 3]

O114:H4[1]
O115:H10[1]
O115:H44[1]
O116:H16[2]
O116:H21[1, 2]
O117:H7[1]
O118:H12[1]
O120:H10[2]
O125:H19[1]
O125:H10[1]
O128:H2[1]
O128:H31[2]
O132:H19[1]
O141:H19[2]
O146:H-[2]
O146:H21[1, 2]
O146:H28[1]

O148:H8[1]
O153:H25[1]
O154:H31[1]
O156:H21[1]
O157:H7[4]
O162:H10[2]
O163:H19[1]
O166:H28[1, 2]
O167:H2[2]
O168:H8[2]
O171:H2[2]
O174:H-[2]
O174:H2[1]
O174:H16[1]
O174:H21[1, 2]
O178:H7[1]
O179:H8[1]
O181:H16[1]

Ont:H2[1]
Ont:H4[2]
Ont:H10[1]
Ont:H19[1, 2]
Ont:H21[1, 2]
Ont:H28[1]
Ont:H31[1]
Ont:H38[2]
OR:H2[1]
OR:H4[1]
OR:H7[1]
OR:H8[1]
OR:H10[1]
OR:H12[1]
OR:H14[1]
OR:H19[1]
OR:H28[1]
OR:H45[1]
OR:H56[1]

1. Beutin et al. J Clin Microbiol. 2004 Mar;42(3):1099-108.
2. Mora et al. BMC Microbiol. 2007 Mar 1;7:13.
3. Paton et al. J Clin Microbiol. 1999 Oct;37(10):3357-61.
4. Tatarczak et al. Vet Microbiol. 2005 Sep 30;110(1-2):77-85.

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EHEC serotypes associated with HUS

- O157:H7/H- (non–sorbitol fermenting[1, 2, 3]), O157:H- (sorbitol fermenting[1, 2] and non-fermenting[2])
- O26:H11/H-[1, 3], O111:H-[1], O145:H-[1]/H28[3], O103:H2[1, 3]/H18/H-[1]
- O4:H2[1], O8:H2[1], O8:H19[1], O11:H2[1], O23:H2[1], O55:H6[1], O70:H35[1], O77:H2[1], O84:H2[1], O92:H33[1], O92:HNT[1], O105:H18[3], O112:H2[1], O118:H2[1]/H16[3], O119:H2[1], O121:H10[1], O165:H2[1], ONT:H2[1], OR:H7[3], OR:H11[1, 3], and OR:H25[1].

1. **Friedrich et al. J Infect Dis. 2002 Jan 1;185(1):74-84. Epub 2001 Dec 14.**
2. **Schmidt et al. J Clin Microbiol. 1999 Nov;37(11):3491-6.**
3. **Beutin et al. J Clin Microbiol. 2004 Mar;42(3):1099-108.**

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STEC serotypes associated with diarrhea without HUS [1]

O3:H2, O3:H10,O6:H2 (2 strains), O8:H14,O8:H2 (2 strains),O8:HNT,O16:H32,O16:H48,O22:H8,O23:H19, O25:H2, O30:HNT,O31:H2,O40:H6,O40:H2,O60:H2 (2 strains), O60:H19,O60:H2 (2 strains),O62:H2 (2 strains),O68:H4,O70:H2, O74:H2, O75:H8, O75:H21, O75:H2, O78:H2 (3 strains), O84:H6, O91:H2 (2 strains), O96:H2, O113:H4, O113:H6, O113:H18, O113:H2 (3 strains), O120:HNT, O121:H2, O128:H2 (5 strains), O128:H2 (4 strains), O128:HNT, O129:H2, O146:H21, O146:HNT (2 strains), O152:H4, ONT:H4, ONT:H8 (6 strains), ONT:H14, ONT:H18, ONT:H2 (11 strains), Orough:H19, Orough:H2 (6 strains), and Orough:HNT

1. **Friedrich et al. J Infect Dis. 2002 Jan 1;185(1):74-84. Epub 2001 Dec 14.**

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Conclusions Regarding Non-O157 EHEC/STEC

- In the absence of official methods for this class of organisms, and a regulatory definition, at the present time, these organisms can not be considered adulterants.
- FSIS has taken the right approach in planning to conduct a baseline study
- This will allow the agency to develop methodology that can be shared with the industry
- It behooves the industry to stay proactive
- It is important to realize that the same interventions and barriers that eliminate O157 from beef are also eliminating the non-O157 EHEC/STEC

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FSIS/CDC related issues

- There are five working days in a week, recalls mostly happen on Fridays
  - If there is an outbreak, involve the industry early on, provide detailed concise epidemiologic data so the extent of the contamination can be determined.
- FSIS's demands/guidelines that don't make sense:
  - Reassess your HACCP with every O157 positive events; this can not be done scientifically, it is equivalent of asking an epidemiologist to find the source of each sporadic case of an illness.
  - FSIS's definition of robust sampling for ground beef is beyond reproach.
  - Just as you ask the industry to provide statistical justifications for their sampling plans, make sure you do the same. Please statistically justify a quarterly sampling program that you have been asking the industry to do.
  - Coordinate the food safety efforts within the agency, make sure that every foreign establishment shipping to the US has the same lot definition and testing requirement as our domestic establishments.

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FSIS
related issues - continue

- FSIS's demands/guidelines that don't make sense:
  - Please provide uniform proper training to FSIS in plant inspectors regarding cross contamination, sampling, and movement of contaminants, and sanitation of their knives and hooks, whenever they are cutting into organs for inspection.
  - Reconsider your hazard matrix, sometimes a low volume item may be the one most likely to escape interventions.
  - Don't punish plants for finding O157, worry more about the ones that are not finding the pathogens.
  - Provide guidelines when guidance is needed:
    - ✓ Give us a regulatory definition for *E. coli* O157. Should we reject a load if it has non-toxigenic, eae negative (non-pathogenic) *E. coli* O157:H7? Should we accept a load if it has O157:H-/non-motile isolate which has STX and eae? What about eae negative, stx positive O157 strains, or Stx negative, eae positive O157s?
    - ✓ What should we do if we have 1%, 5%, 10%, 15%, 20%, 25% positives (define it for a small, medium , large and very large plants)

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FSIS related issues - continue

- Bring some sense into the “Third Party Audit” situation.
- Third Party Audit’s contribution to food safety is the same as mail order diploma mill’s contribution to education. resources used on third party audits are simply wasted, you may as well hire Ph.D. who have purchased their degree from a diploma mill.

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The Pressure on Processors

- Most slaughter establishments have done everything humanly possible to control o157, to a point of wasting resources by pilling up on additional interventions that don't work.
- Grinders are the recipient of slaughter operations process failures.
- They have no control over the hazards.

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The Pressure on Processors

- If the microbial load on incoming cattle exceeds the capacity of plant intervention, product contamination is inevitable.
- It is time to encourage implementation of more pre-harvest interventions.
- Regulatory bodies should be encouraged to expedite the approval of effective pre-harvest interventions.
- We need to find other means of funding the cost associated with food safety, the current system of letting the market adjust for the cost is not sustainable and is hurting the processors:
  - Legislation that offsets the food cost associated with food safety through tax credits/incentives.
  - Retailers and food service clients paying a premium for the cost associated with food safety.

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