

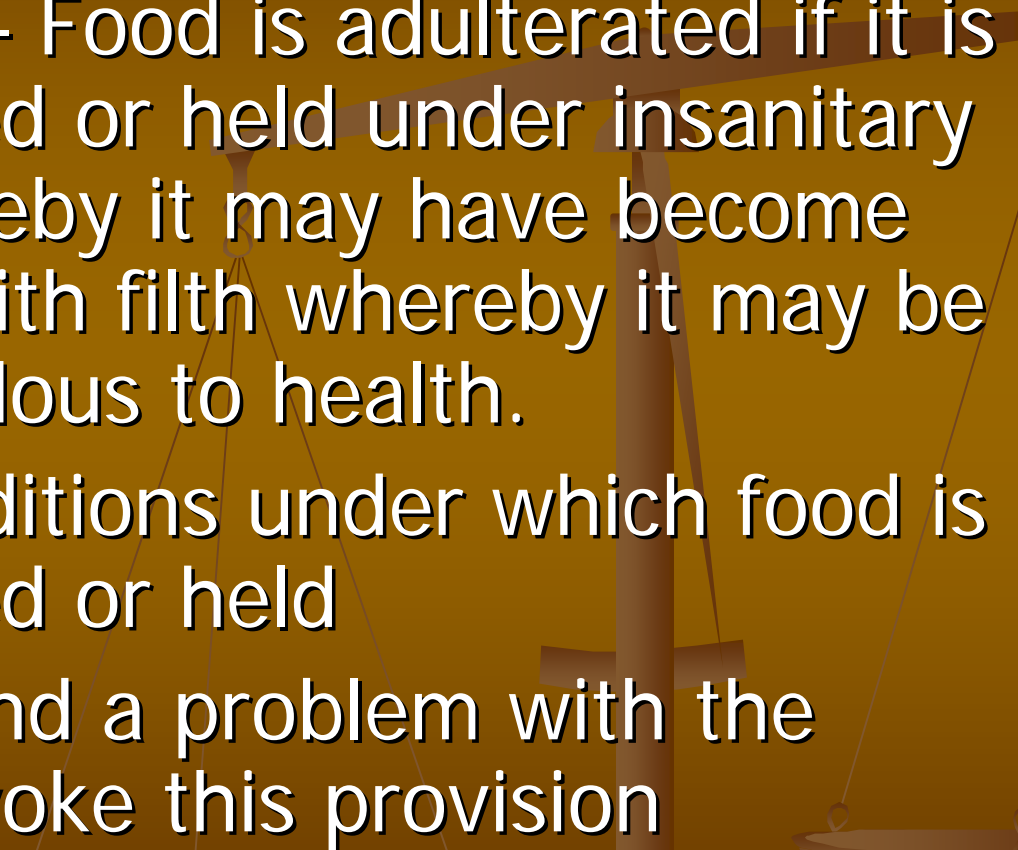
Food Sanitation, GMPs and GMP Modernization

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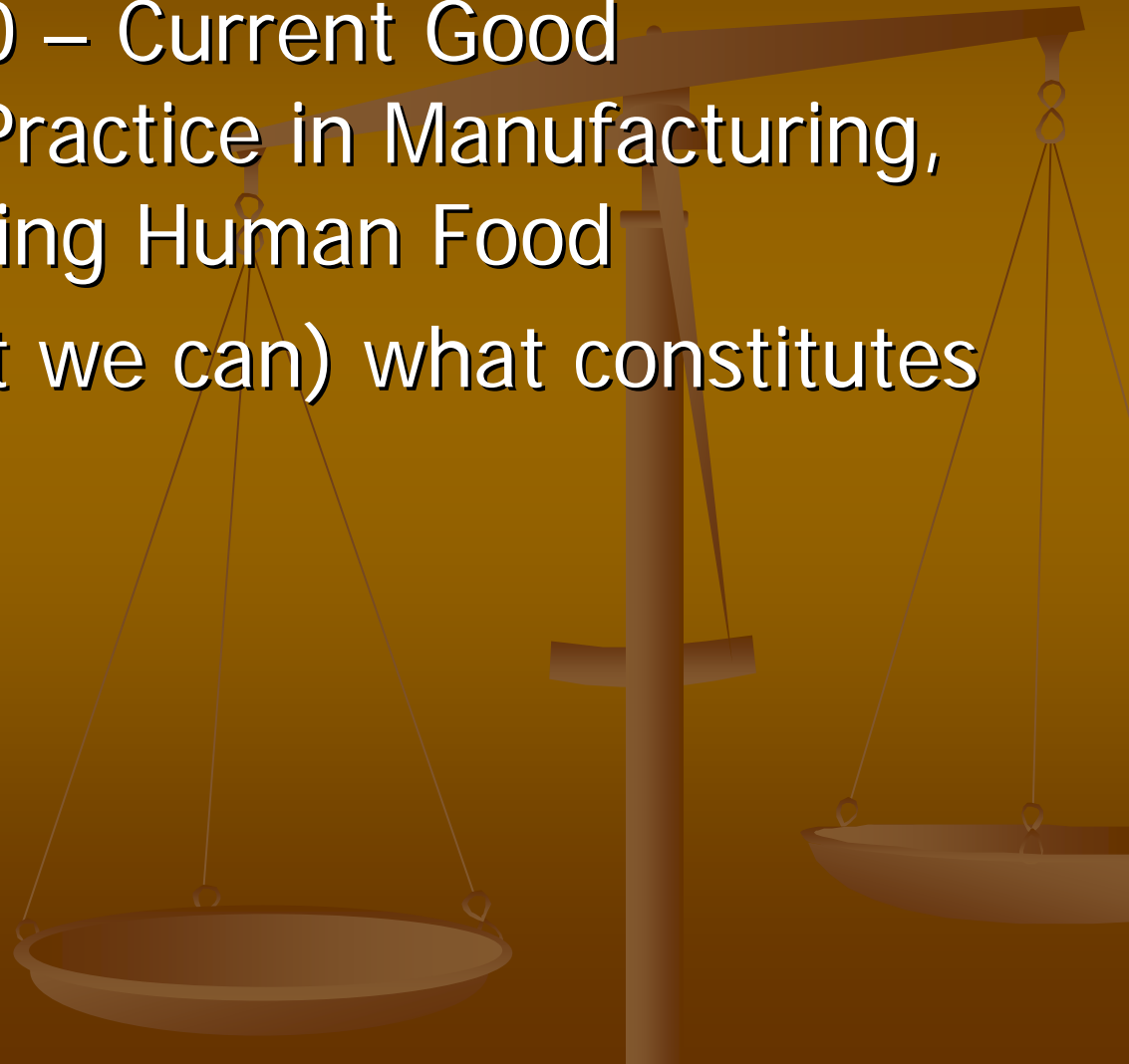


Federal Food, Drug and Cosmetic Act

- Sec. 402(a)(4) – Food is adulterated if it is prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth whereby it may be rendered hazardous to health.
 - Focus is on conditions under which food is prepared, packed or held
 - FDA need not find a problem with the food itself to invoke this provision
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FDAs cGMP Regulation

- 21 CFR Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food
- Defines (as best we can) what constitutes insanitation



FDAs cGMP Regulation

- Subpart A – General Provisions
 - 110.3 Definitions
 - 110.5 Current Good Manufacturing Practice
 - 110.10 Personnel
 - 110.19 Exclusions



FDAs cGMP Regulation

- Subpart B – Buildings and Facilities
 - 110.20 Plant and grounds
 - 110.35 Sanitary operations
 - 110.37 Sanitary facilities and controls
- Subpart C – Equipment
 - 110.40 Equipment and Utensils



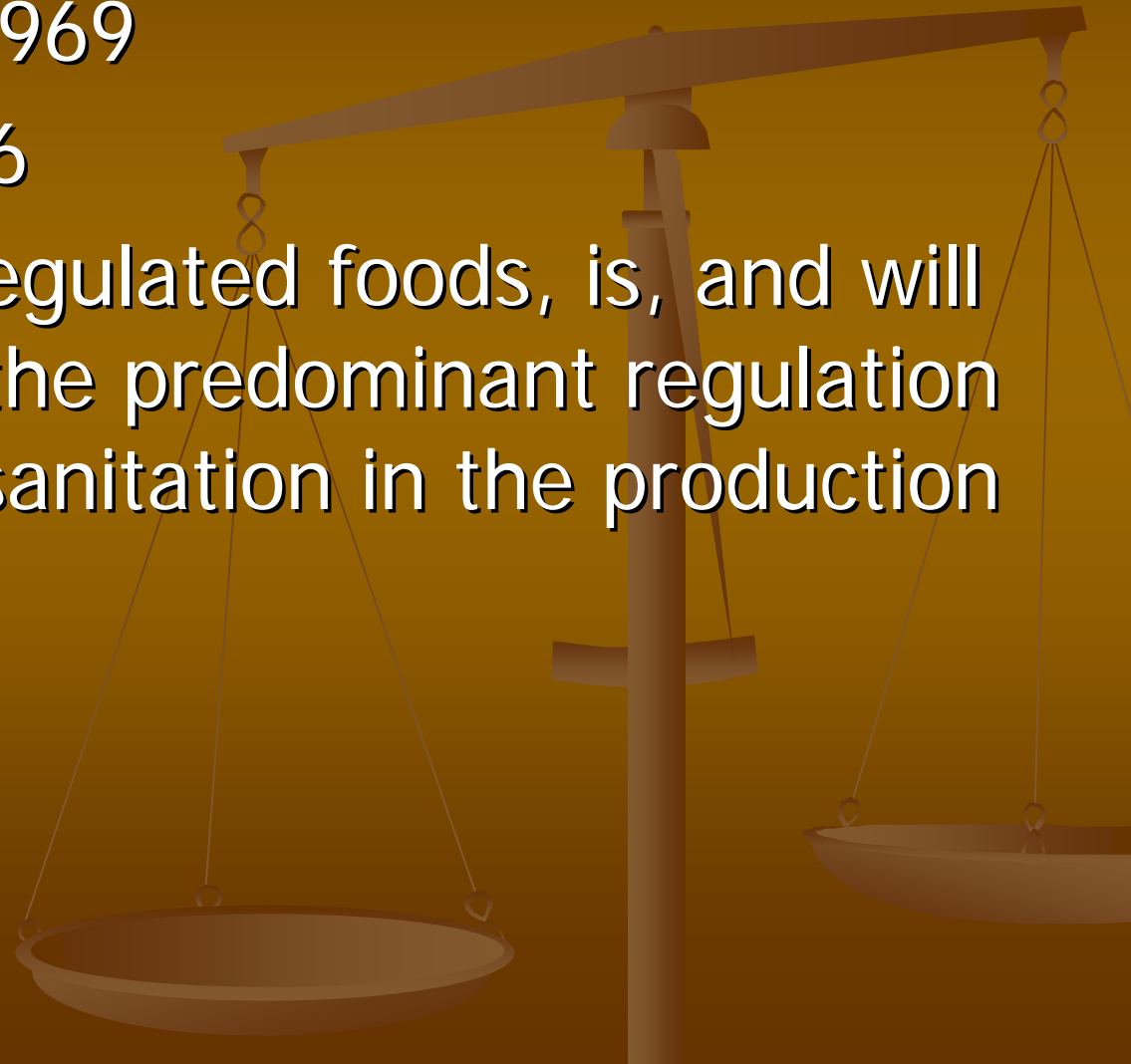
FDAs cGMP Regulation



- Subpart D – Reserved
- Subpart E – Production and Process Controls
 - 110.80 Processes and Controls
 - 110.93 Warehousing and Distribution
- Subpart F - Reserved
- Subpart G – Defect Action Levels

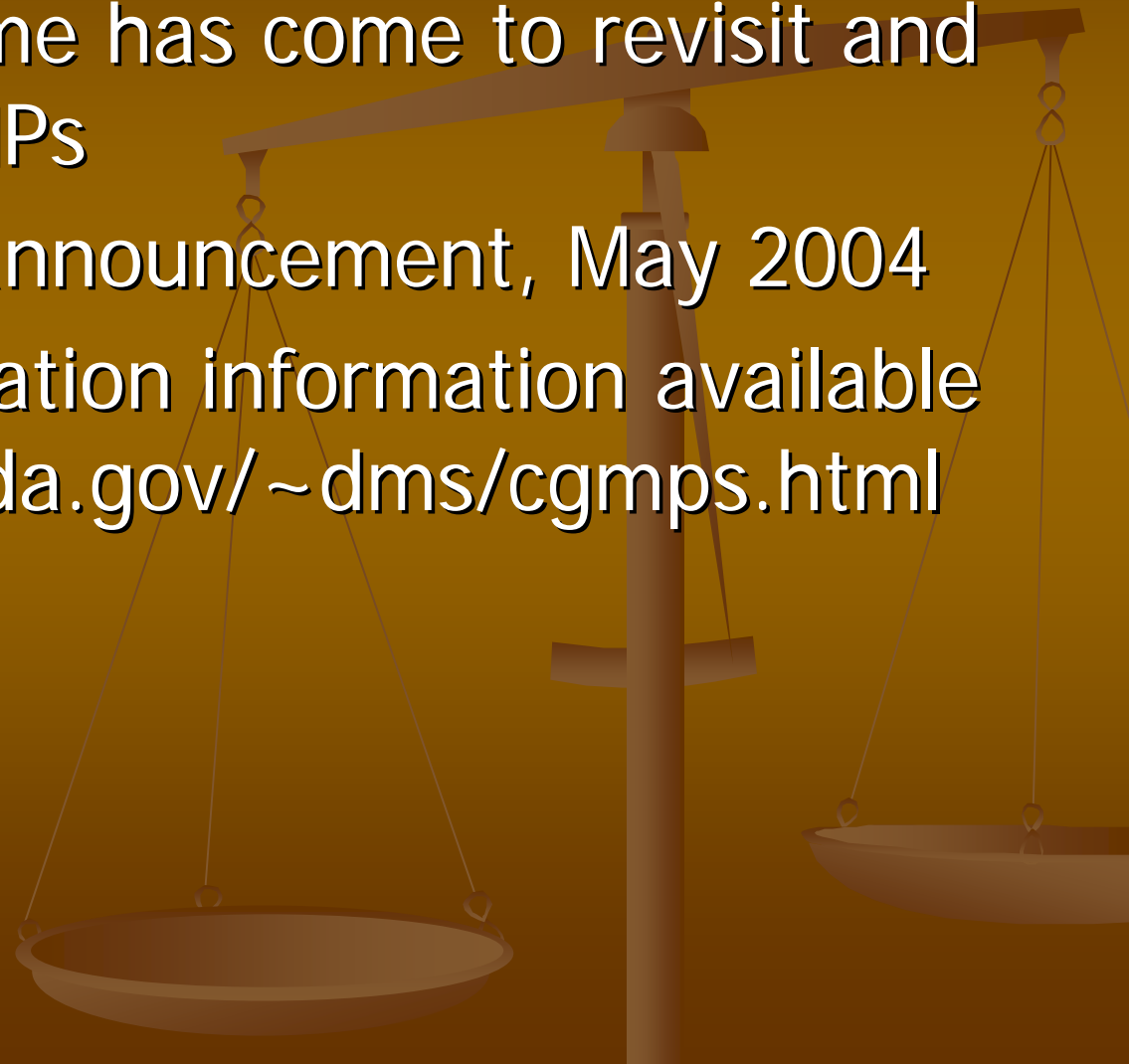
FDAs cGMP Regulation

- First issued in 1969
- Updated in 1986
- For most FDA regulated foods, is, and will continue to be the predominant regulation for addressing sanitation in the production environment



FDAs cGMP Regulation

- FDA believes time has come to revisit and update the cGMPs
- Commissioner announcement, May 2004
- cGMP modernization information available at www.cfsan.fda.gov/~dms/cgmps.html



FDA GMP Modernization Working Group



- Research

- Impact of the food GMPs on food safety
- Impact of revised regulations on food safety and the likely economic consequences of such revisions

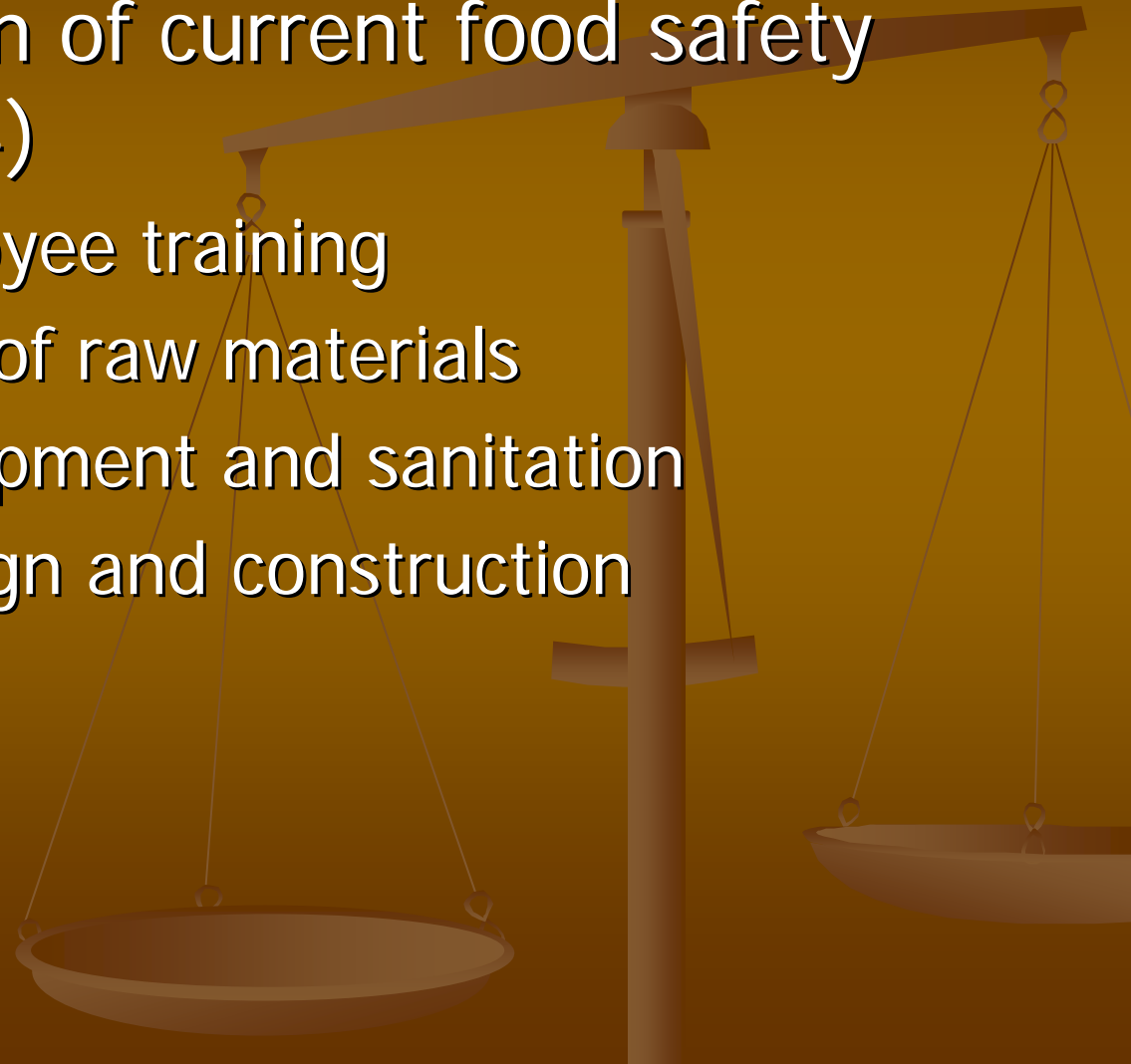
- Public Meetings, 2004

- College Park, Chicago, San Jose

- Will issue White Paper

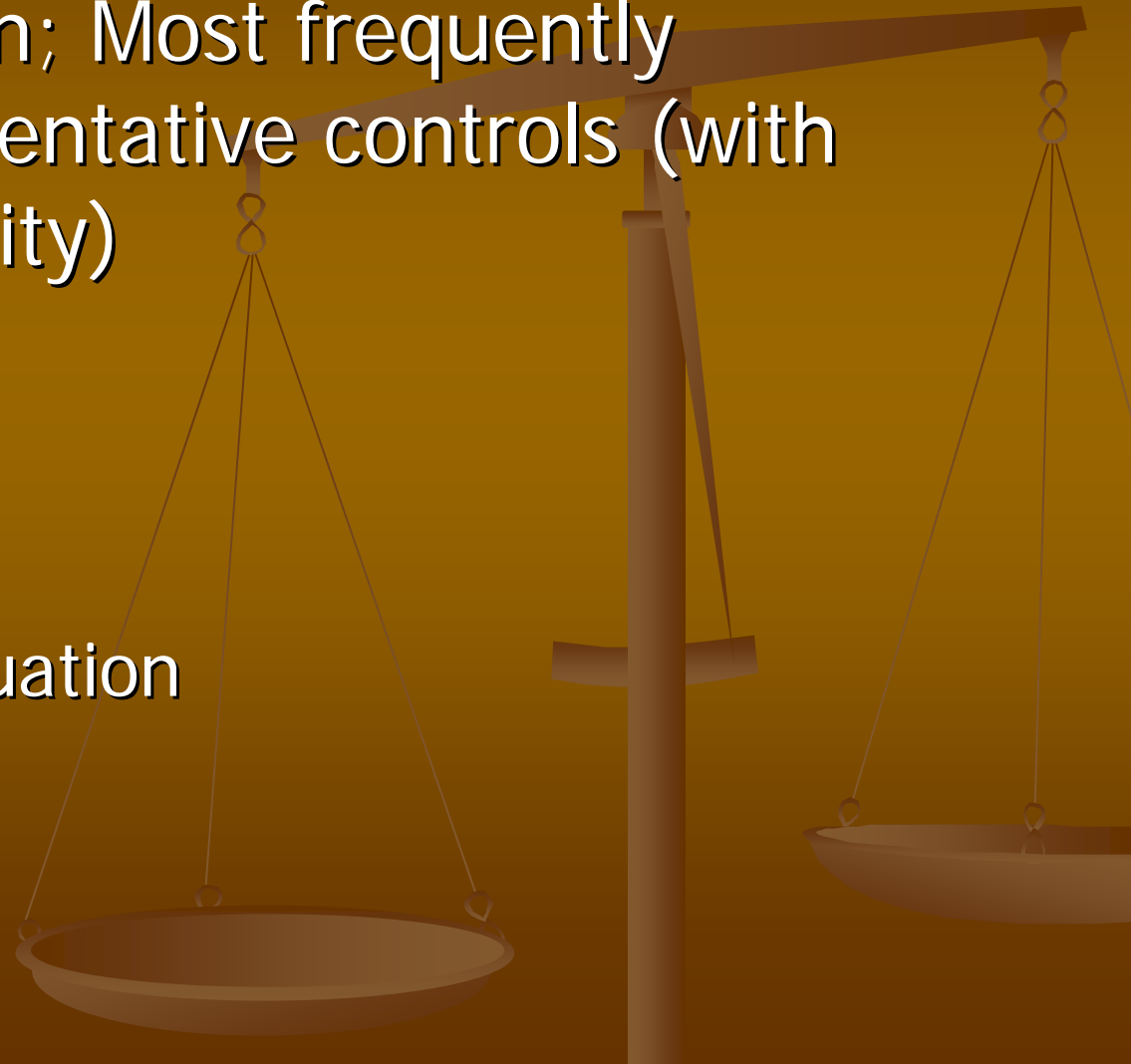
FDA GMP Modernization Working Group

- Expert elicitation of current food safety problems (top 4)
 - Deficient employee training
 - Contamination of raw materials
 - Poor plant equipment and sanitation
 - Poor plant design and construction

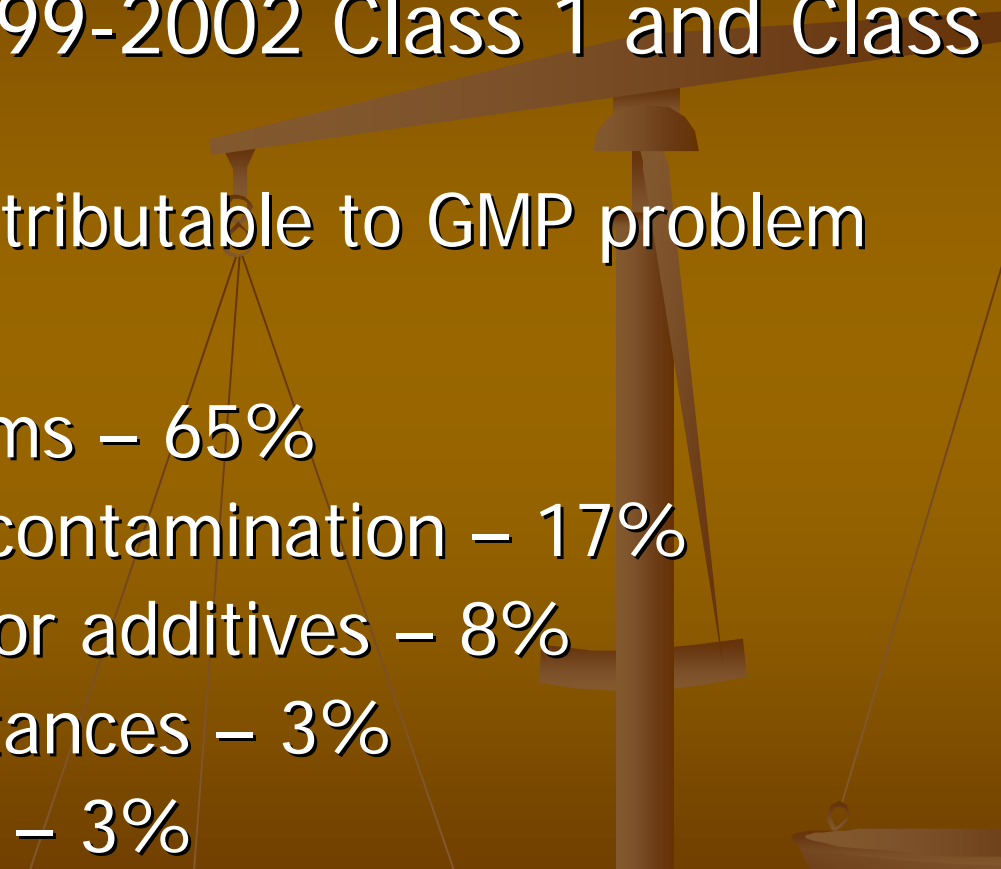


FDA GMP Modernization Working Group

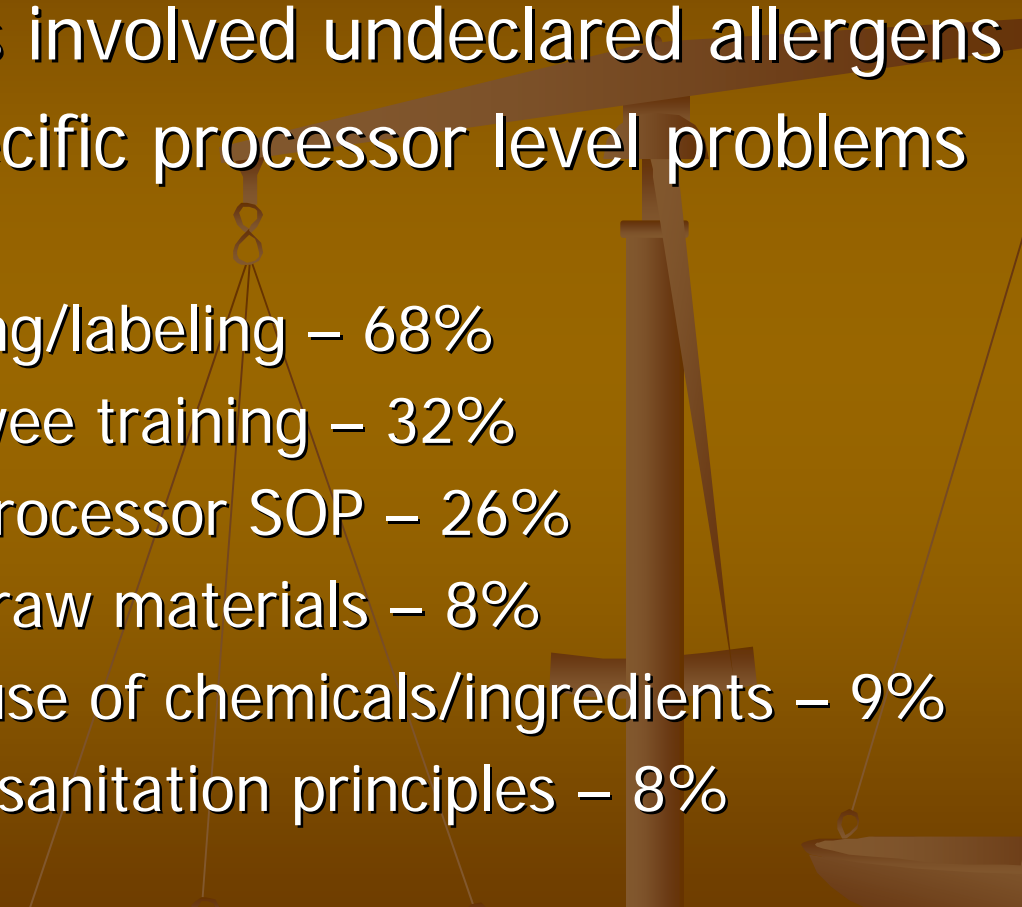
- Expert elicitation; Most frequently mentioned preventative controls (with broad applicability)
 - Training
 - Audits
 - Documentation
 - Validation/Evaluation



FDA GMP Modernization Working Group – Recall Study

- Recall study; 1999-2002 Class 1 and Class 2 Recalls
 - 1146 of 1307 attributable to GMP problem
 - Recalls involved
 - Labeling problems – 65%
 - Microbiological contamination – 17%
 - Unapproved color additives – 8%
 - Poisonous substances – 3%
 - Foreign Objects – 3%
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FDA GMP Modernization Working Group – Recall Study

- 34% of the recalls involved undeclared allergens
 - Most common specific processor level problems involved in recalls
 - Incorrect packaging/labeling – 68%
 - Ineffective employee training – 32%
 - Failure to follow processor SOP – 26%
 - Contamination of raw materials – 8%
 - Excess/mistaken use of chemicals/ingredients – 9%
 - Ineffective use of sanitation principles – 8%
 - Unknown – 4%
- 

Commenters

- 19 Written comments
 - 11 Industry trade associations
 - 5 companies
 - 3 food manufacturers
 - 2 food industry equipment/chemical suppliers
 - 3 Consumer/Professional associations



Most Common Themes

- Training
- Food allergen controls
- Written sanitation procedures
- Environmental monitoring
- Temperature controls
- The need for guidance



Scope of Comments

- Definition of terms
- Use of lubricants
- Lot size
- Filtration
- Inclusion of raw agricultural commodities
- Finished product testing
- Allergen controls
- Manufacturing operations
- Warehousing and distribution
- Written sanitation practices



Scope of Comments, cont.

- Environmental monitoring (microbiological)
- Maintenance of records
- HACCP and CGMP Regulations
- "Shall" vs. "Should"
- Training
- Temperature Requirements
- Validation of preventive controls
- Employee health
- Cleanliness
- Plant and grounds
- Imported foods



Conclusion

- FDA believes time has come to revisit and update the cGMPs
 - Some overlap between agency research findings and public comments
 - Next Step: GMP Modernization Working Group to Issue White Paper
 - Will state findings and recommendations
 - FDA will solicit public comment
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