Verification of the control of microbiological, chemical and physical hazards in food processing

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Challenges with verification programs

- Statistical limitations of detecting contaminant in finished product and raw materials
- Distribution of contaminant may limit ability to detect non-conformance
- Environmental monitoring represents a point in time
- Sensitivity of methodology may limit effectiveness in monitoring to standard
- Cost of verification testing may limit application

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Limitations to testing

Sampling by presence / absence testing for pathogens

# samples	Prob. accept.	Prob. reject	Proportion of lots rejected
10 % defective units in lot			
5	59%	41%	1 / 3
10	35%	65%	2 / 3
60	0.5%	99.5%	199 / 200
2 % defective units in lot			
5	90%	10%	1 / 10
10	82%	18%	1 / 6
60	30%	70%	2 / 3

Source: ICMSF, 1986

- Constraints for sampling and examining a sufficient number of samples
- The constraints of time and cost to obtain results
- Testing only identifies effects and often neither identifies nor controls causes

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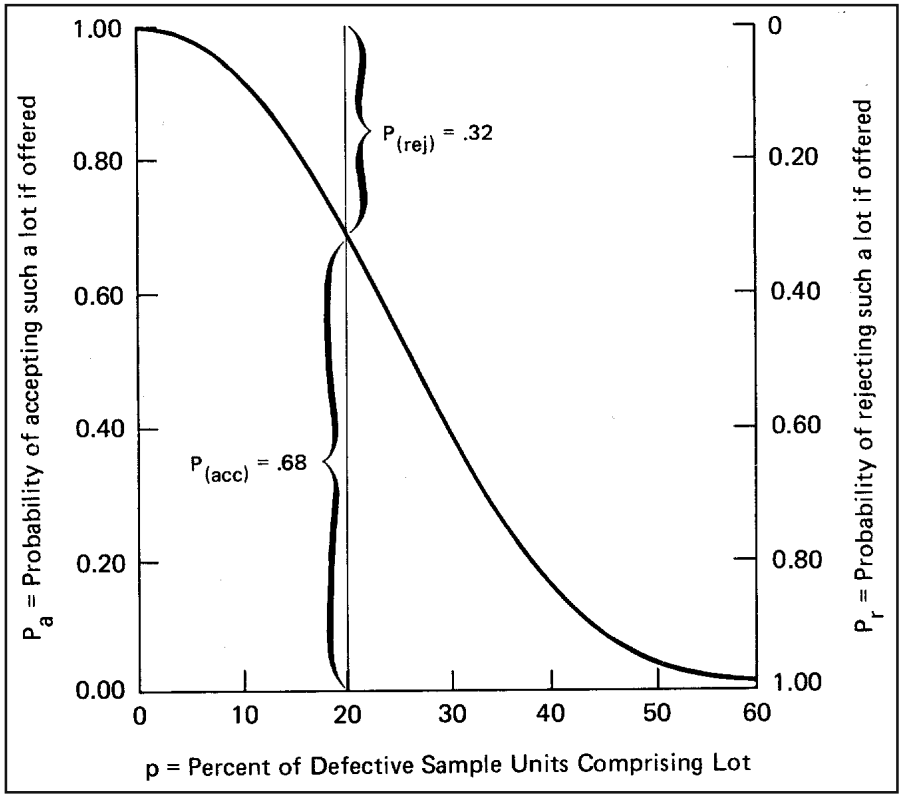
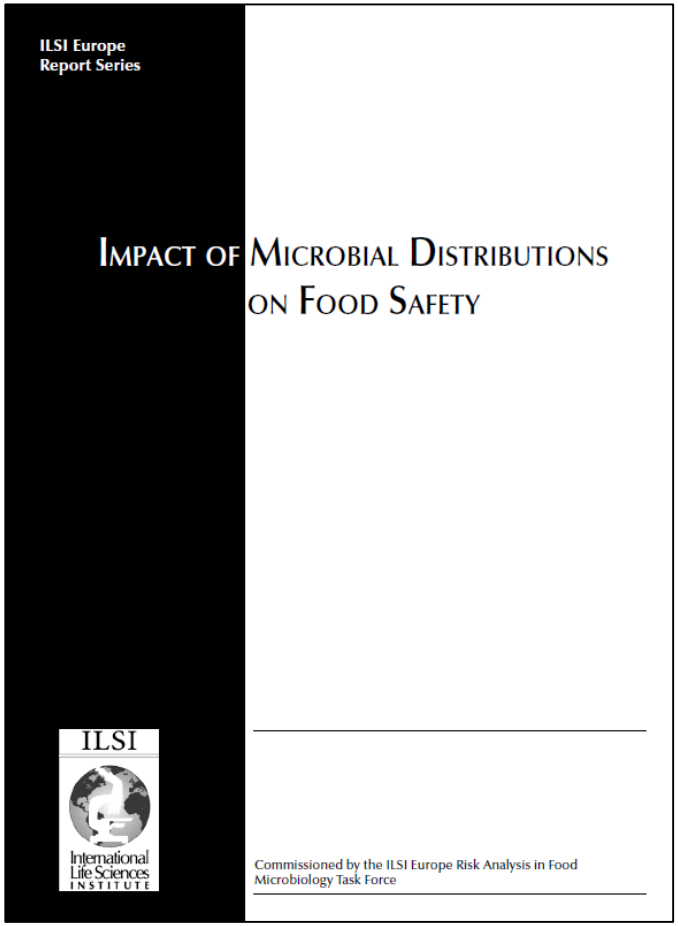
Tools for developing sampling strategies



ICMSF, 1986

Operating Characteristic Curve

n = 10, c = 2



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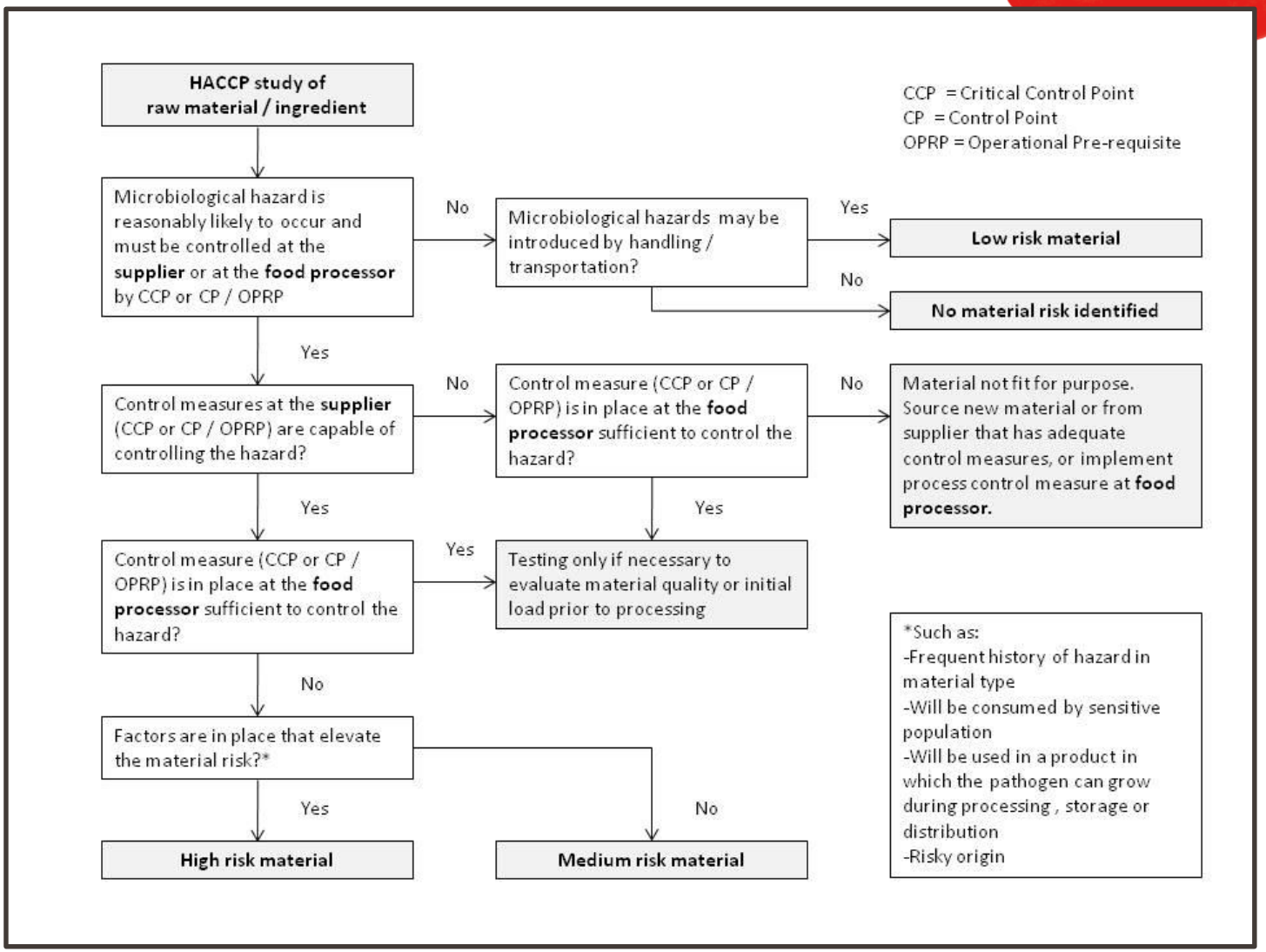
Example of a decision tree for categorizing raw material risk to determine verification activities



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T. Jackson 2013 Microbiological verification. *In* Food Safety Management. In press. Elsevier

Example of a decision tree for categorizing raw material risk to determine verification activities

Table 7. Example of a raw material verification program based upon raw material risk and supplier confidence.

Material risk	Supplier confidence	COA	Pre-shipment possible	Testing upon receipt
High	High	Each lot	Yes	Each lot
	Medium	Each lot	No	Each lot
	Low	Disqualify vendor		
Medium	High	Each lot	Yes	First 15 lots, then quarterly
	Medium	Each lot	Yes	Increase frequency (e.g., monthly)
	Low	Each lot	No	Each lot
Low	High	Quarterly	Yes	First 10 lots, then quarterly
	Medium	Each lot	Yes	Monthly
	Low	Each lot	Yes	Increase frequency

Jackson, T. 2014. Ch. 33. Management of Microbiological Hazards: Role of Testing in Verification. in Food Safety Management. Y. Motarjemi, H. Lelieveld eds. Elsevier, San Diego

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Environmental sampling modification based upon risk

Recommended minimal sampling frequencies per sampling site			
Environment priority rating	**Control level**		
	Minimum	**Medium**	**Maximum**
First	Once / week	Twice / week	Investigative
Second	Once / month	Once / week	Investigative
Third	None	None	As needed

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Methods for verification of allergen control

- Surface swab for detection of protein (3-20 µg)
- ATP bioluminescence
- PCR (2.5-10 mg/kg)
- Lateral flow, dipstick, ELISA (5 ppm)
- Proteomic Mass Spectrometry

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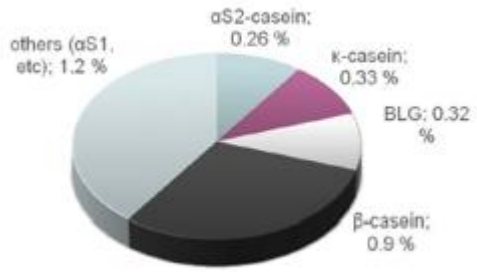
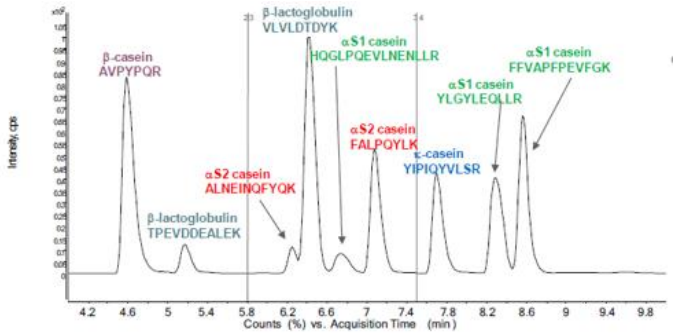
Developments in allergen detection





- LC/MS/MS has unique advantages of multiple allergen detection and quantification
  - High sensitivity and specificity allow detection of multiple allergens in one analysis
  - Suitable for evaluation of cooked foods:
    - Not dependent on proper folding of proteins
  - Internal standard improves precision and reliability
  - No need for antibody production
  - Multiplexing saves time and cost

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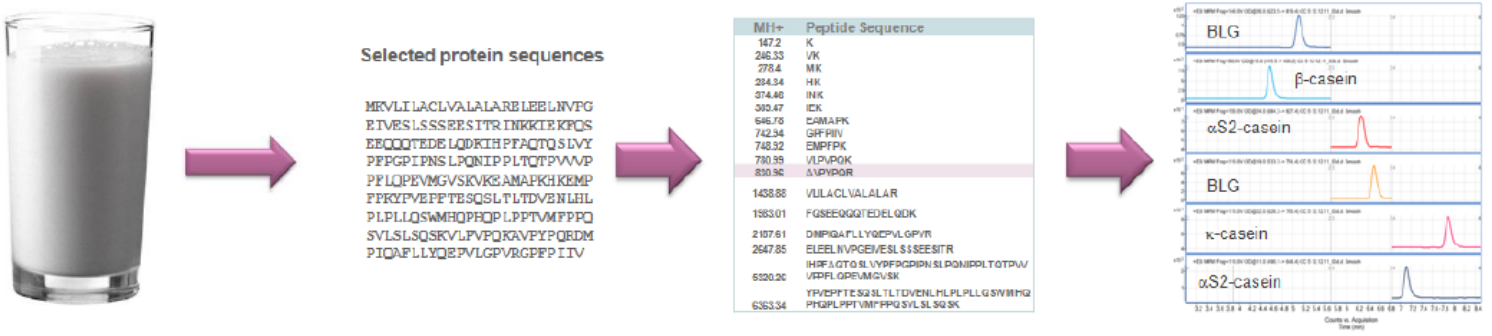
P. Lutter 2015. ILSI Safety Assessment Workshop Beijing

Developments in allergen detection

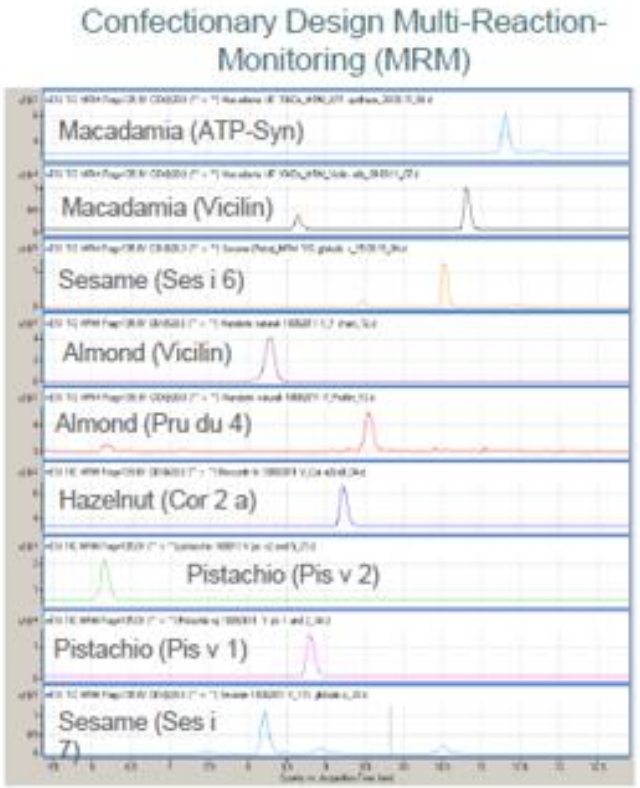
- Selection of “marker proteins”
  - Specific for milk proteins from different species (cow, buffalo) but not specific for other food ingredients (e.g. egg)
  - Ideally 2-3 marker proteins per allergenic compound
  - Good extraction properties and solubility (no membrane proteins)
  - None to few posttranslational modifications, modifications during food processing



Lutter P et al. *Journal of AOAC International* 2011; **94**, 1043-1059.

Developments in allergen detection

- LC/MS/MS multiplex allows the combination of allergen targets based upon needs:
  - Confectionery set:
    - tree-nuts, sesame, peanut
  - Culinary set:
    - lupine, mustard, celery, soy, gluten, egg
  - Infant nutrition set:
    - whey, casein, soy, gluten



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P. Lutter 2015. ILSI Safety Assessment Workshop Beijing

Methods for foreign body verification

- Visual inspection
- Separation systems (sieves, filtration)
- Magnets
- Optical sorting
- Metal detection
- X-ray

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In-line monitoring systems

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Sources: Foodengineeringmag.com; Unitec, ipinimg.com; bbctechnoloties.com

Glass in spinach recall

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Business

DiGiorno pizzas, Stouffer's meals recalled for glass in food

Nestle, which makes DiGiorno frozen pizza, issued a recall for 3 million boxes of pizza, Stouffer's lasagnas and Lean Cuisine meals after customers said they found pieces of glass in their food. (Bob Fila / Chicago Tribune)

By **Tribune news services** · **Contact Reporter**

MARCH 10, 2016, 2:09 PM | NEW YORK

Nearly three million boxes of frozen DiGiorno pizzas, Stouffer's lasagnas and Lean Cuisine meals are being recalled after customers said they found pieces of glass in their food.

Nestle USA, the company behind the brands, said no injuries have been reported.

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Whole Genome Sequencing is increasingly used in food safety microbiology

GenomeTrakr: > 35 sequencing labs in and outside US providing to the FDA sequence information of foodborne pathogens

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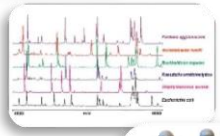
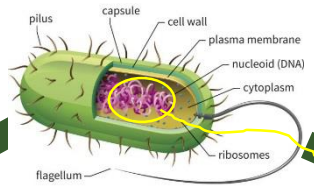
Bacterial Source Tracking By WGS Is More Discriminatory than other methods

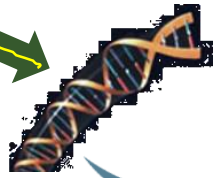
API:
Enzyme

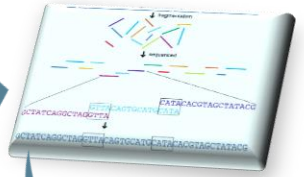
Maldi-TOF:
Chemical



Serotyping:
Antigens







DNA-Based Typing Methods

DGE, HRM | PCR-RFLP | MLVA | Rep-PCR

RAPD | AFLP | RFLP

PFGE

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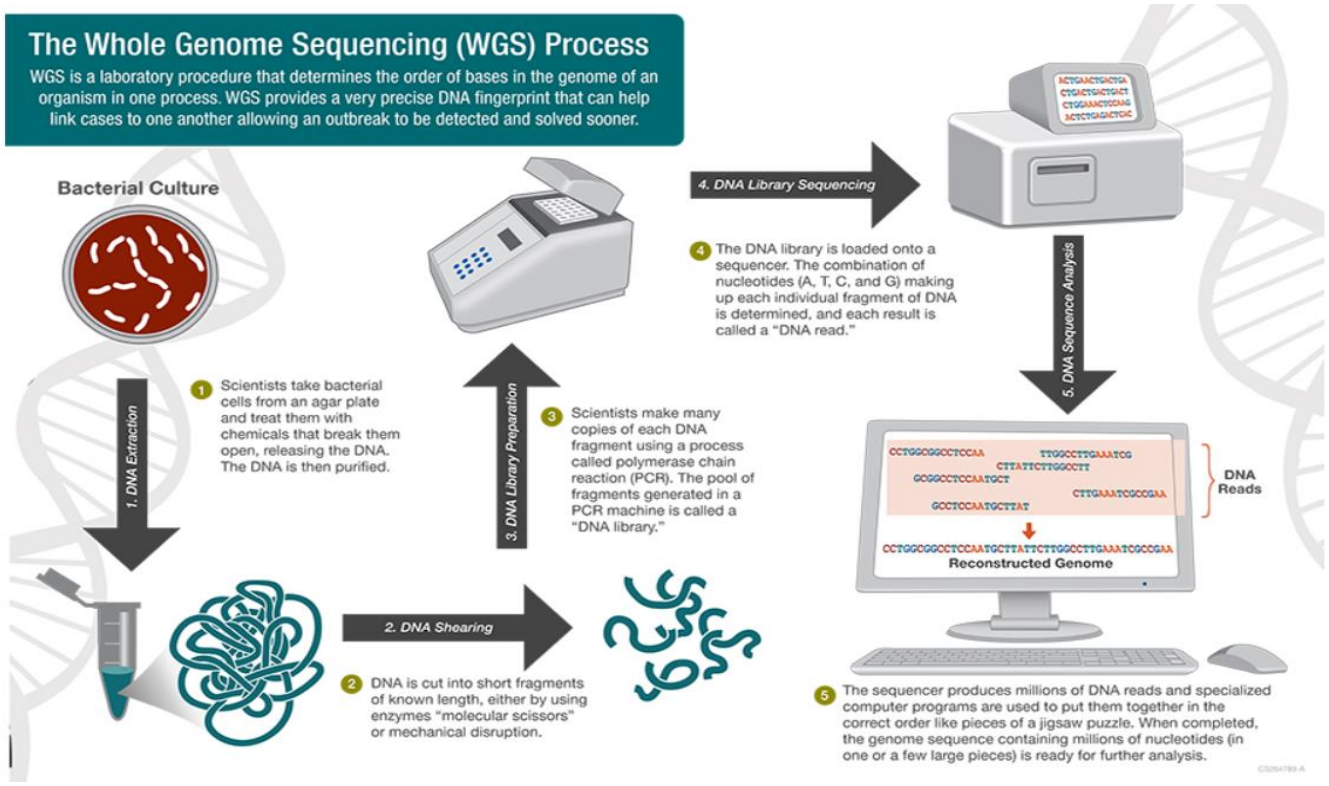
WGS – It Requires Technical Competencies Beyond Traditional Microbiology



'Wet' Processing WGS

'Dry' Processing WGS

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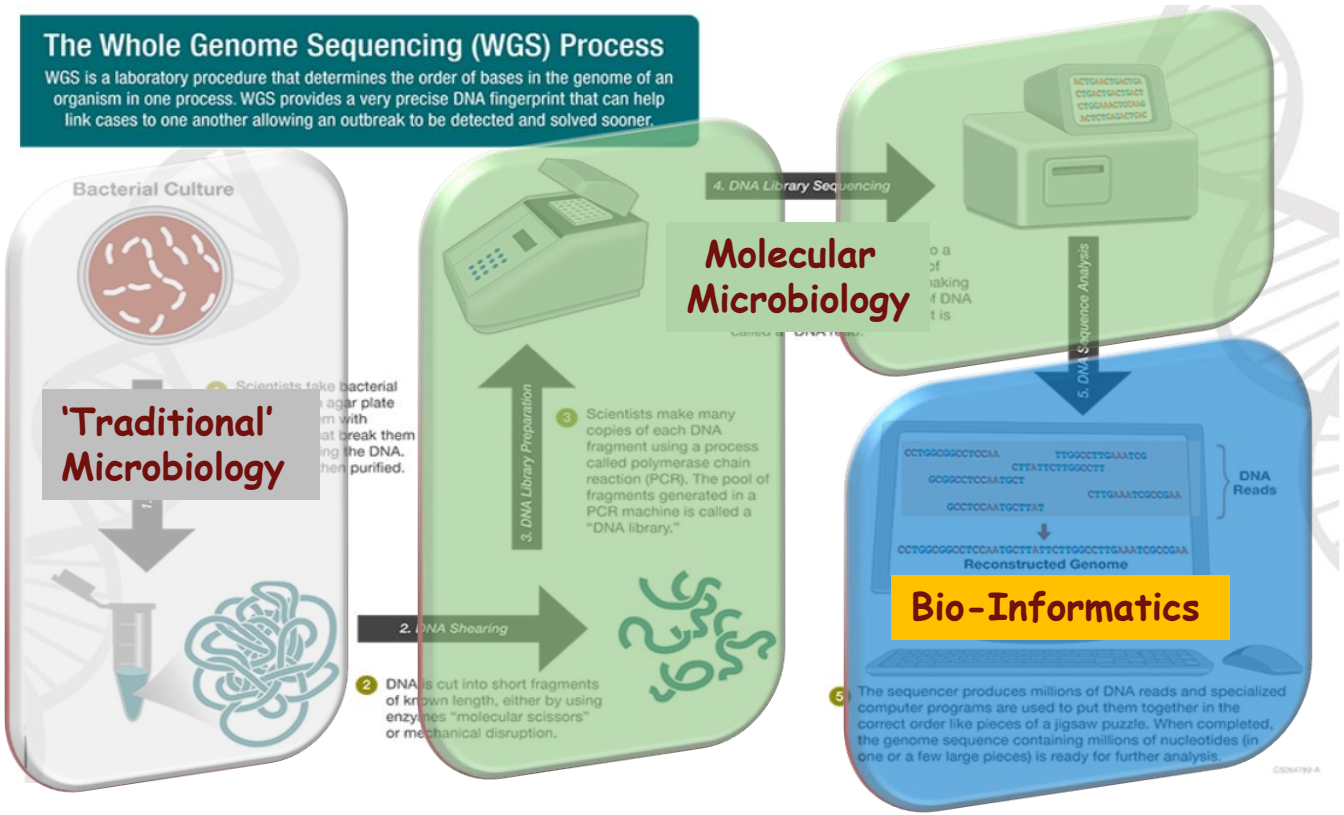
WGS – It Requires Technical Competencies Beyond Traditional Microbiology



Slide source John Donaghy Nestec

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Opportunities and barriers for Whole Genome Sequencing and Metagenomics

Opportunities

- Investigation of recurrent issues in factory environment
- Evaluation of spoilage issues
- Economic adulteration
- Characterization of micro-organisms to develop effective interventions
- Characterization of cultures for use in validation studies

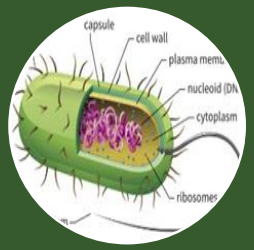
Barriers

- Cost
- Time for results / interpretation
- Expertise to interpret results
- Evolving interpretation understanding of context of findings
- “Data lives forever”

Considerations for WGS in Food Safety Management

Quality assurance - Standards

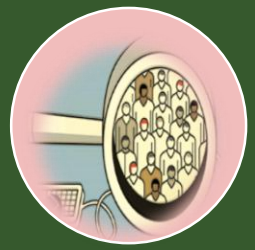
P- Test



WGS is not just another typing tool - Robust Underpinning Science

Protocol Harmonization Stakeholder Guidelines on Decision-making /Interpretation

Technical competence: authorities, industry, labs, academia



WGS is ONE tool: epidemiology must also be used

Sharing of data: legal, political, psychological constraints

Food safety is global – WGS will be a global tool

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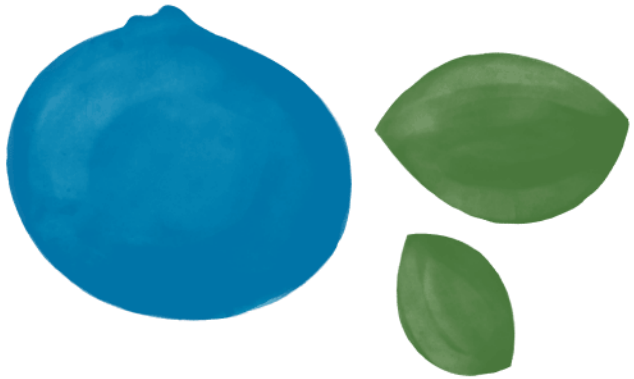

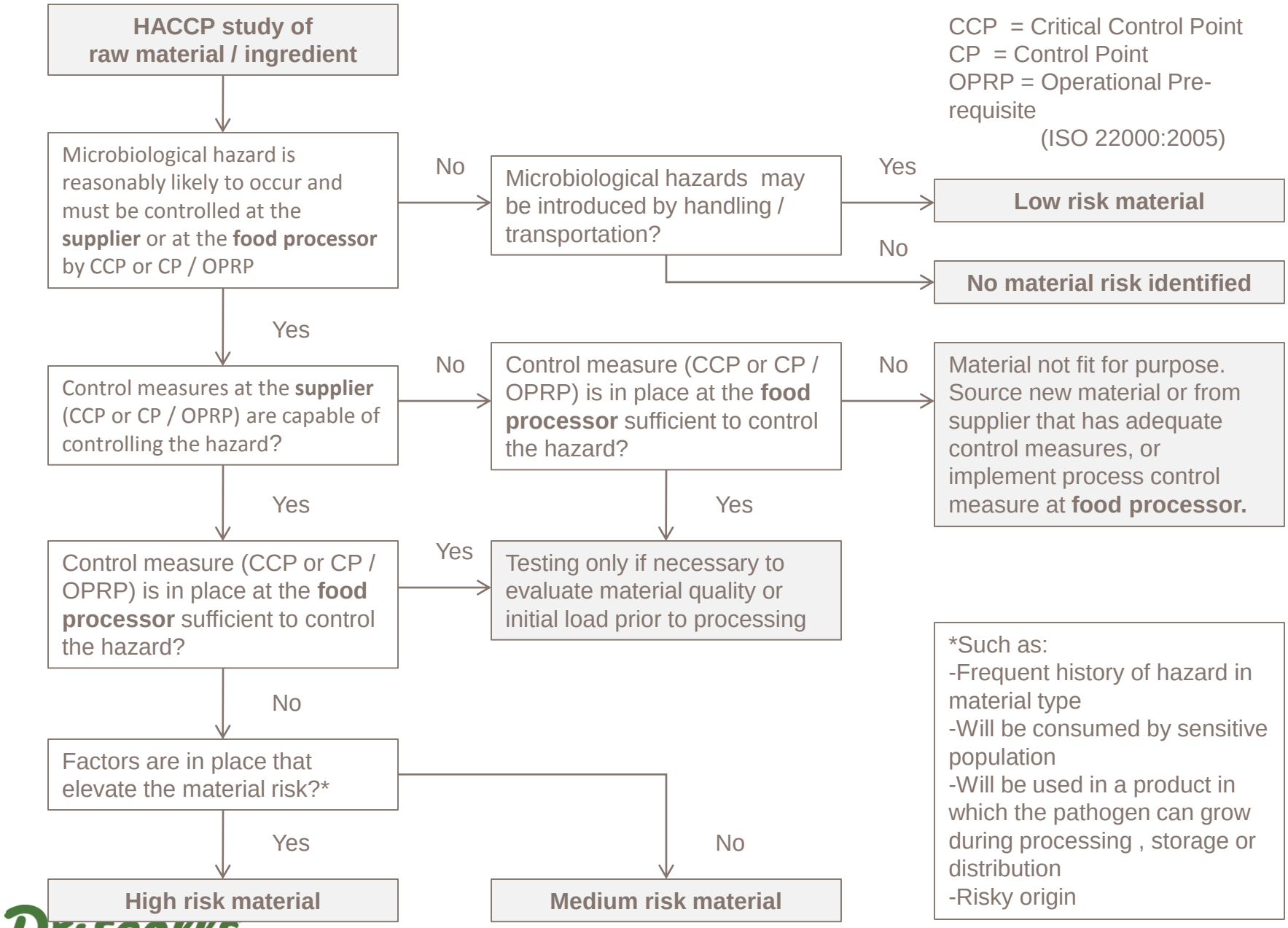

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Jackson, T. 2014.