

Current Status of PCR Testing



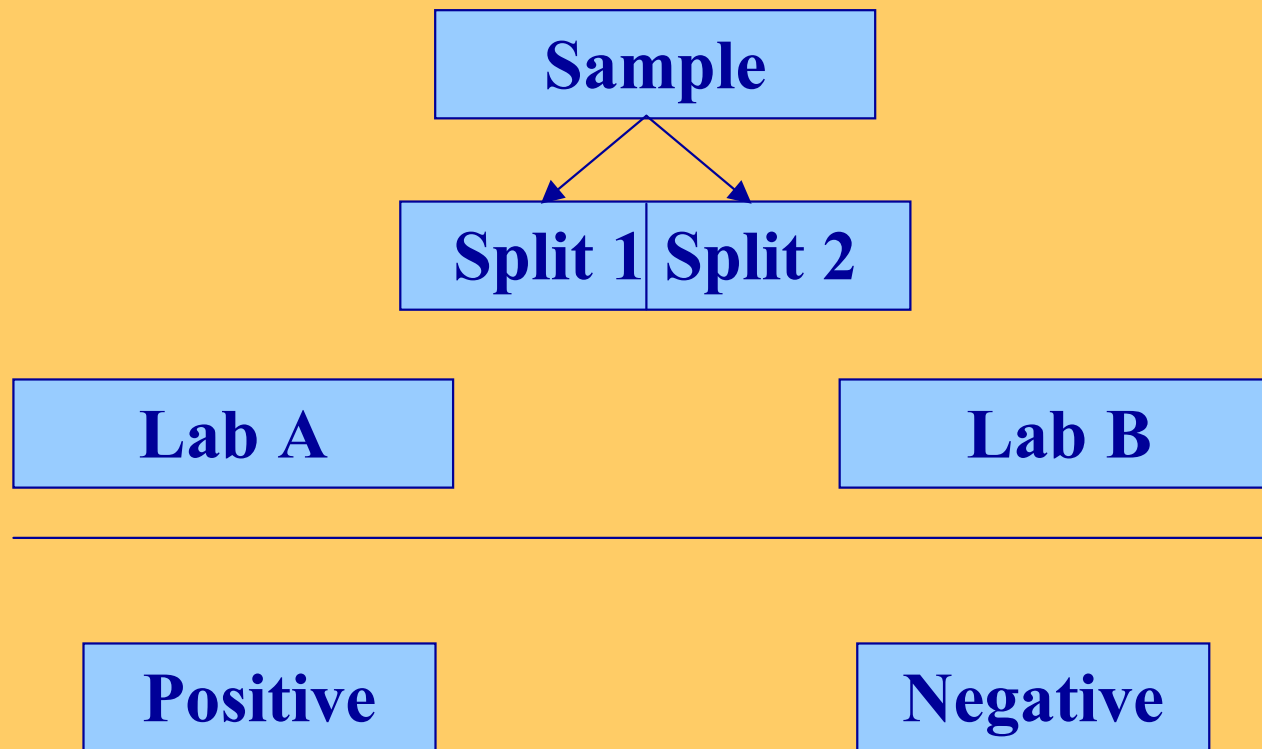
AEIC

May 4-5, 2000

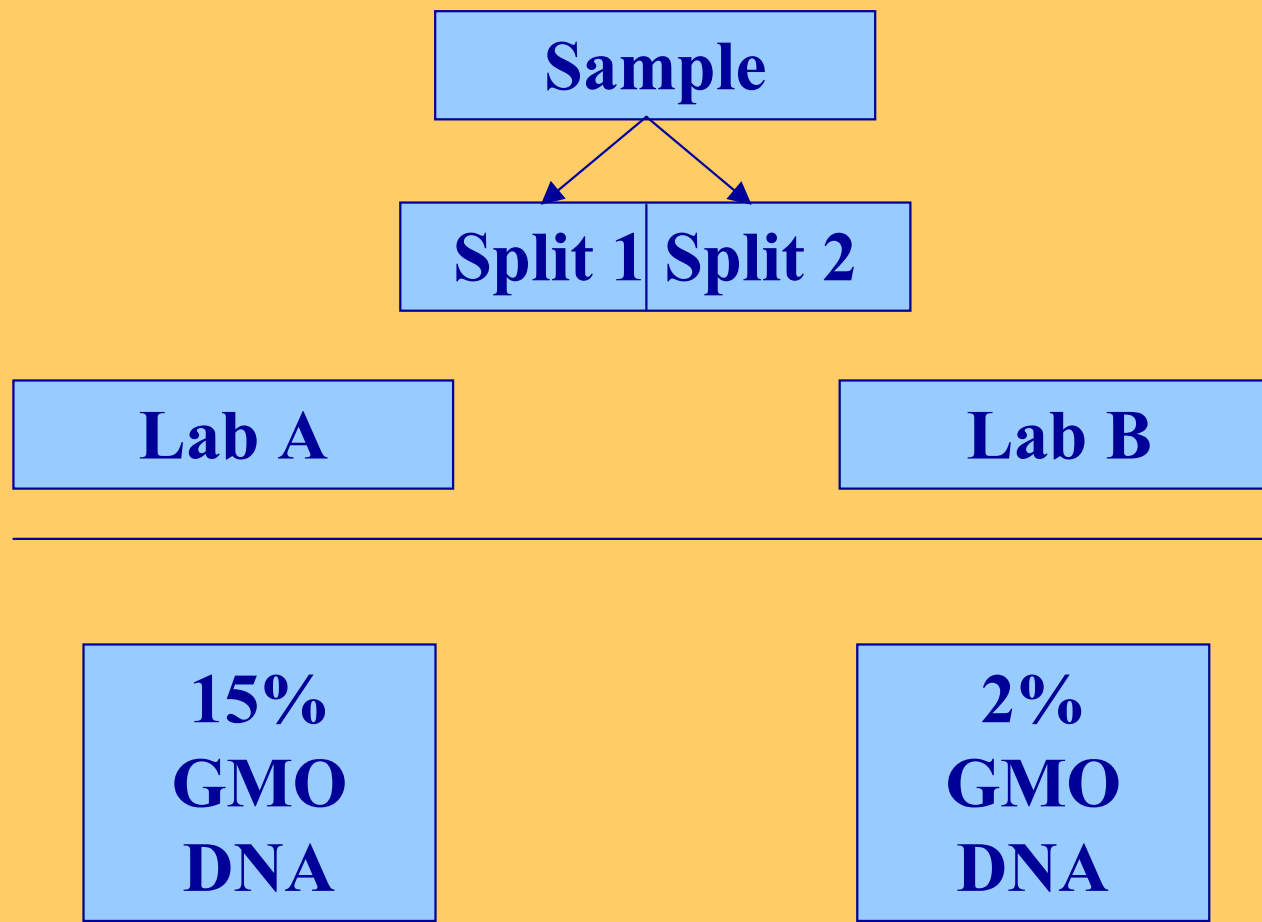
Current Status of PCR Testing

**CAVEAT
EMPTOR!!**

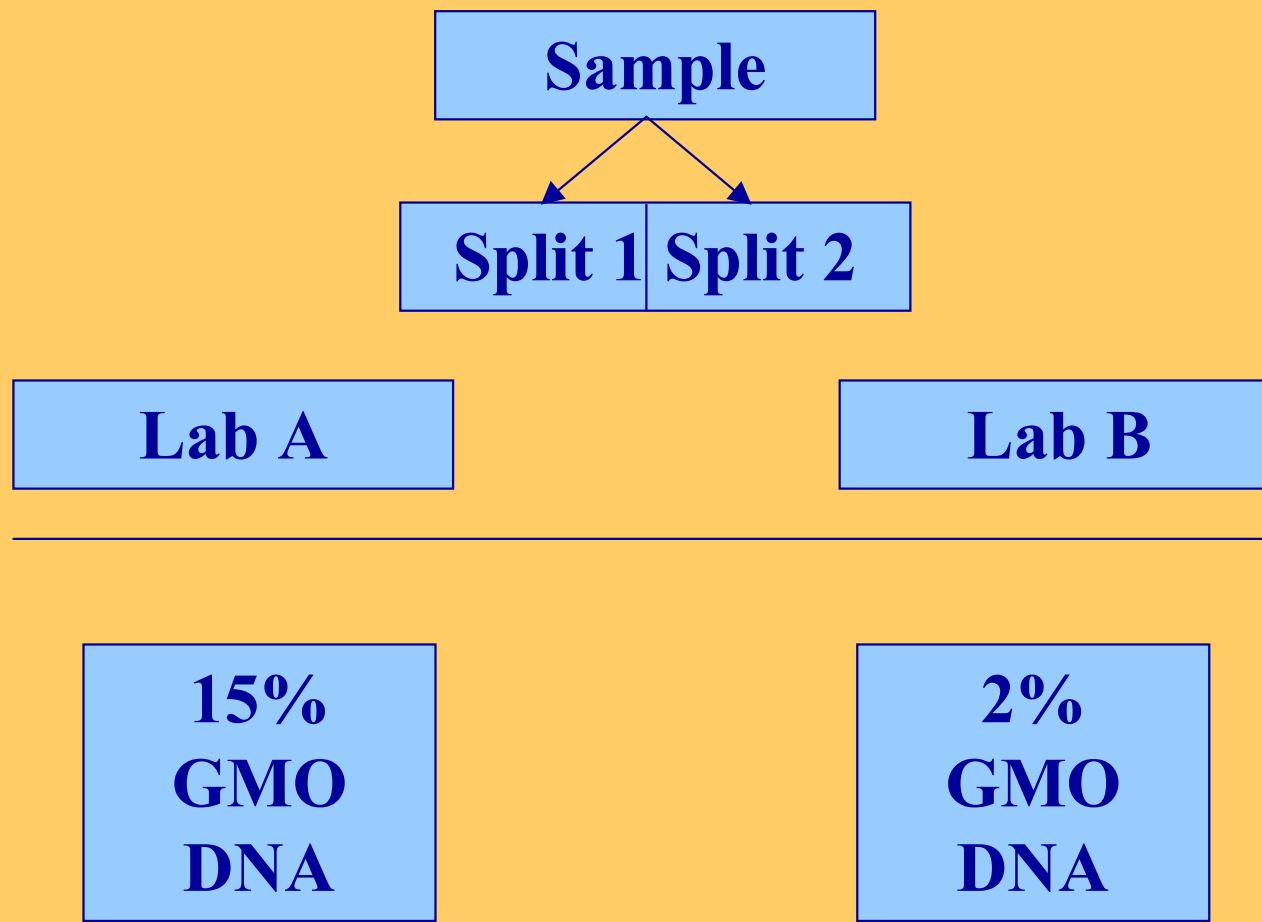
Lack of Standardization



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Lack of Standardization

What are meaningful results?

Highly Processed Samples:

...positive, but insufficient corn DNA to quantify

50% GMO DNA

(This could be 1 of 2 DNA molecules extracted)

Unexplained Variations

Inter-Lab & Intra-Lab

SOME POTENTIAL SOURCES:

- ◆ Sampling
- ◆ Sample prep
- ◆ Extraction
- ◆ PCR Routine
- ◆ Reference Materials

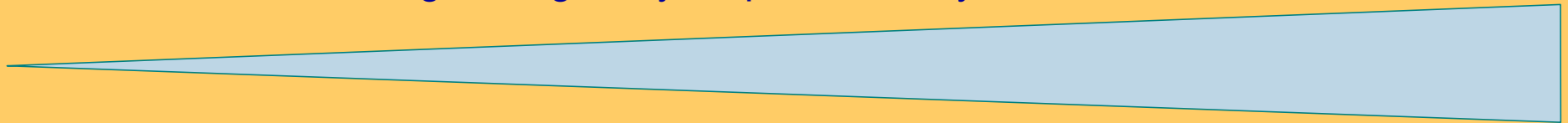
Unexplained Variations

Sampling:

- ◆ Different methods of sampling
- ◆ Size of sample taken
- ◆ Number of samples taken
- ◆ Mixing
- ◆ Contamination from Official Samples

Sampling: Representativity and Sensitivity

Increasing homogeneity / representativity



High sampling and subsampling effort

Potentially decreasing analytical sensitivity due to DNA removal

Unexplained Variations

Sample Preparation:

- ◆ **Different methods of splitting**
- ◆ **Different methods of grinding**
- ◆ **Variation in particle size**
- ◆ **Cross Contamination**

Unexplained Variations

Extraction:

- ◆ **Which procedure used**
- ◆ **Efficiency of extraction**
- ◆ **Alternative procedure available**

Unexplained Variations

PCR Procedure:

- ◆ Machine specific variability
- ◆ Number of cycles
- ◆ Presence of inhibiting chemicals
- ◆ Specificity and validity of primer sets

Unexplained Variations

Reference Materials

- ◆ **Copy numbers of inserted cassettes**
- ◆ **Polyploid status of chromosomes**
- ◆ **Similar behavior of reference & transgene**
- ◆ **Qualitative or quantitative**
- ◆ **General or specific events**
- ◆ **Is the reference material what it purports to be?**

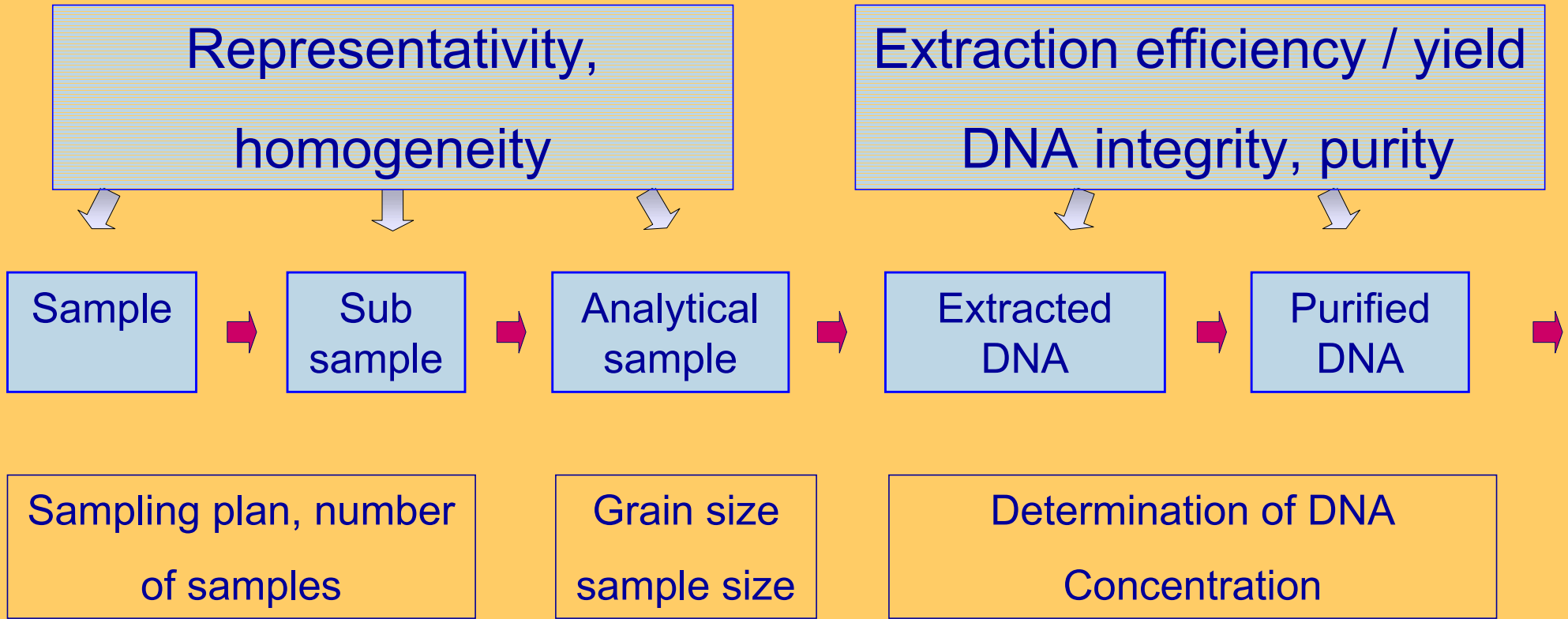
Unexplained Variations

Impact:

- ◆ **Hinders commercial transactions**
- ◆ **Negative reflection on biotech as a useful application to the food chain**
- ◆ **Legal disputes and rejection of shipments**

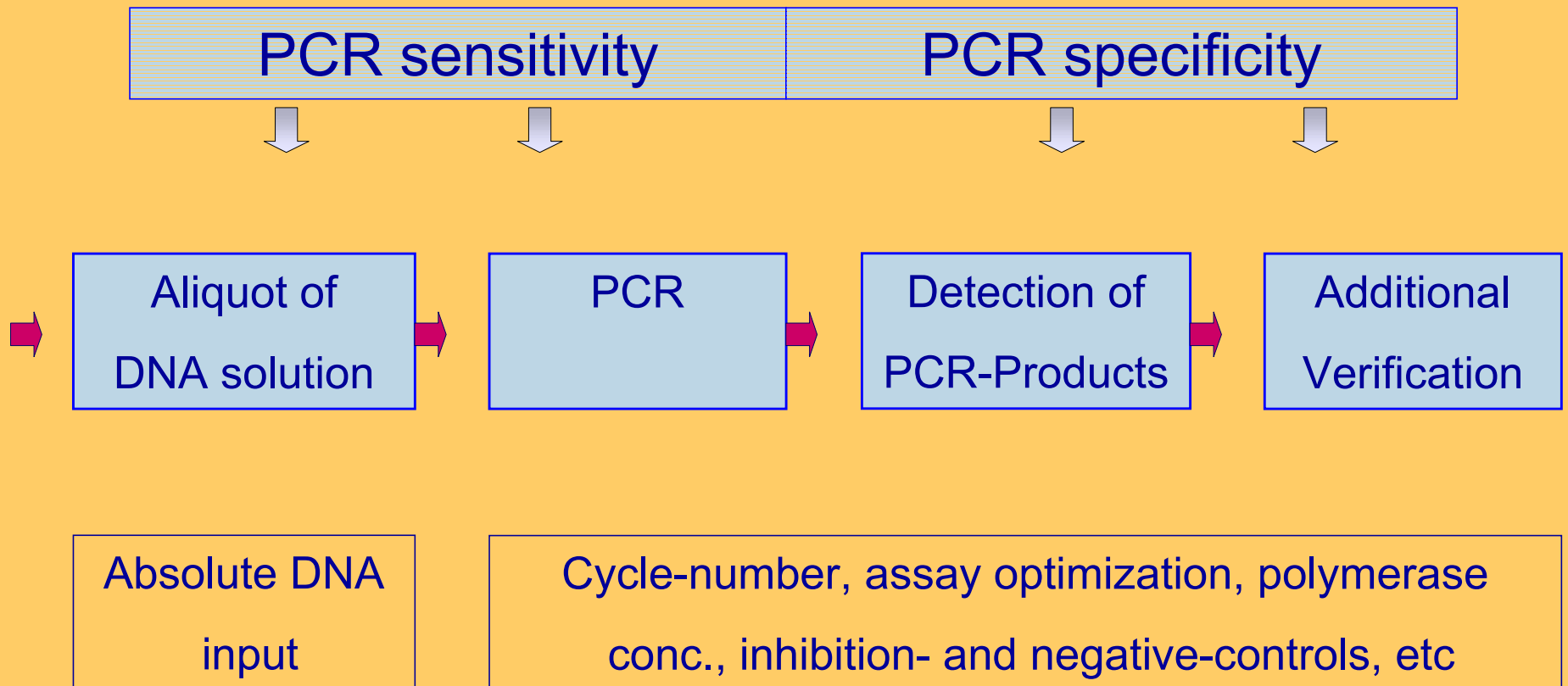
Steps of Sample Preparation

- Important Factors -



PCR Analysis of DNA

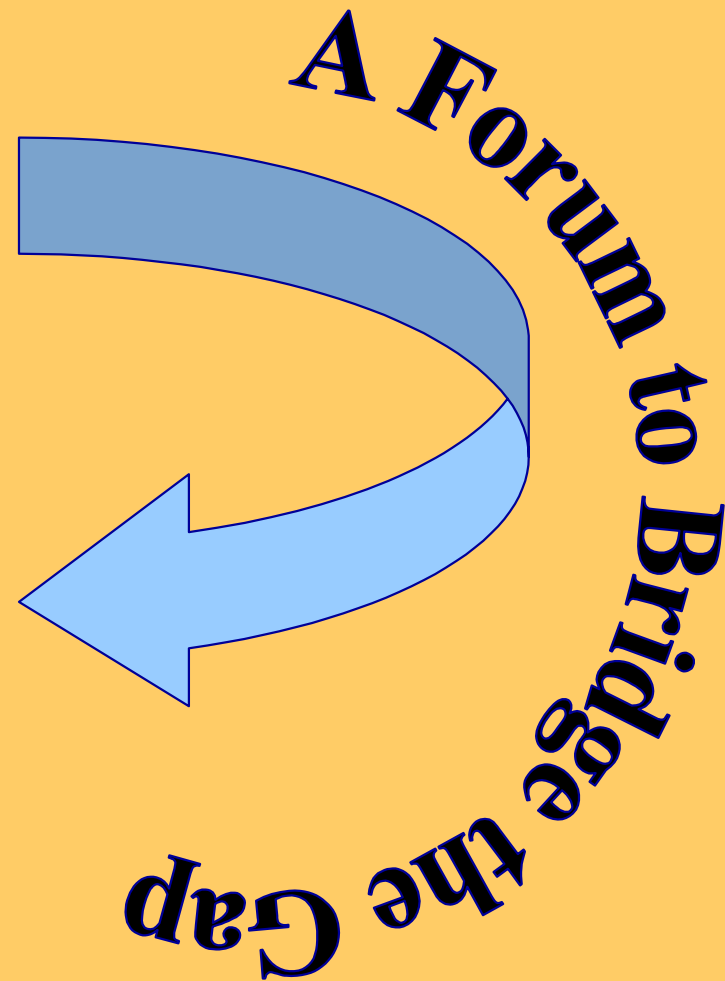
- Important Factors -



What Can AEIC Do?

**Esoteric Discussions of
Biotech in Foods**

**Commercial Applications
and General Understanding
of Biotech in Foods**



What Can AEIC Do?

A Forum for Scientific Expertise

Informal Transfer of Information

&

Formal Transfer of Information

Informal Transfer of Information

Membership Overlap

AEIC + AACCC, IFT, ACS, AOAC, etc.

**Conduit to translate technical
information to “users” and to bring the
needs of users back to “developers”**

Formal Transfer of Information

Provide a science based source of information to meet the technical needs of groups working to standardize testing of genetically engineered foods.

Formal Transfer of Information

**Develop position papers: e.g.,
Effective sampling procedures
*Minimum QA protocols***

Formal Transfer of Information

Technical Information: Test Guidelines

- ◆ **Effective sampling procedures**
- ◆ **Minimum QA Protocols (for lab and field tests)**
- ◆ **Guide for selection of a test kit or a contract laboratory**
- ◆ **Limitations of the testing technologies available**

Formal Transfer of Information

Public Voice for Technical Information

**A non-biased source of public oriented information
on biotechnical concerns**

- ◆ **Educators**
- ◆ **Regulators**
- ◆ **News media**
- ◆ **Legislators**

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