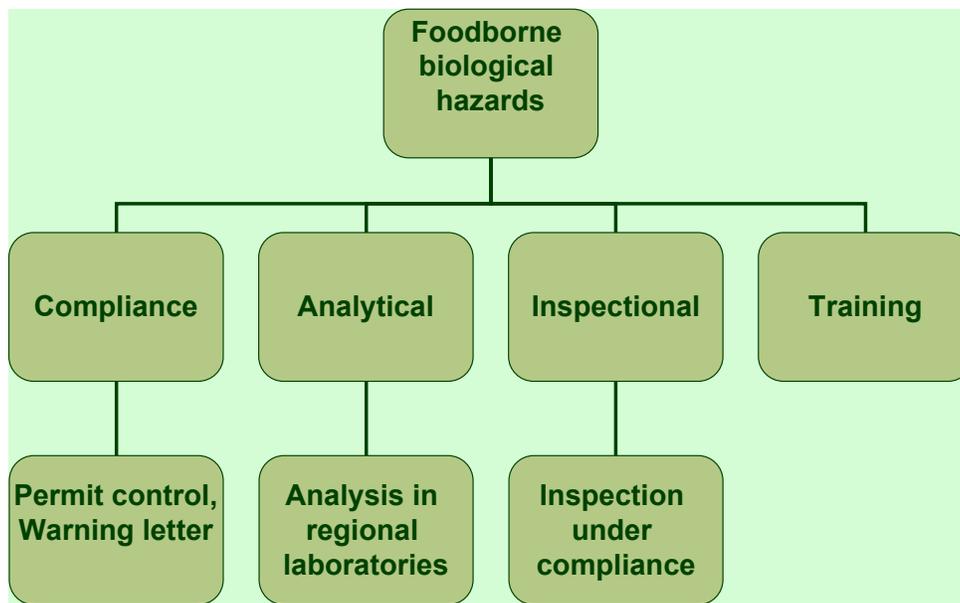


Current Testing and Practices for Botulinum Toxin Prevention in Foods

Shashi K Sharma
US Food and Drug Administration



Clostridium botulinum

Proteolytic (A,B,F)
Growth, 10°C (50°F)

Non-proteolytic
(B, E, F)
Growth, 3.3°C(38°F)

FDA regulatory concern and compliance

- The FDA's requirements for registration, manufacturing, and process filing of low-acid canned foods (LACF) and acidified foods (AF) are codified in Title 21, Code of Federal Regulations, Parts 108, 113 and 114.
- The purpose of 21 CFR 108, 113, and 114 is to ensure safety from harmful bacteria or their toxins, especially the deadly *Clostridium botulinum*.

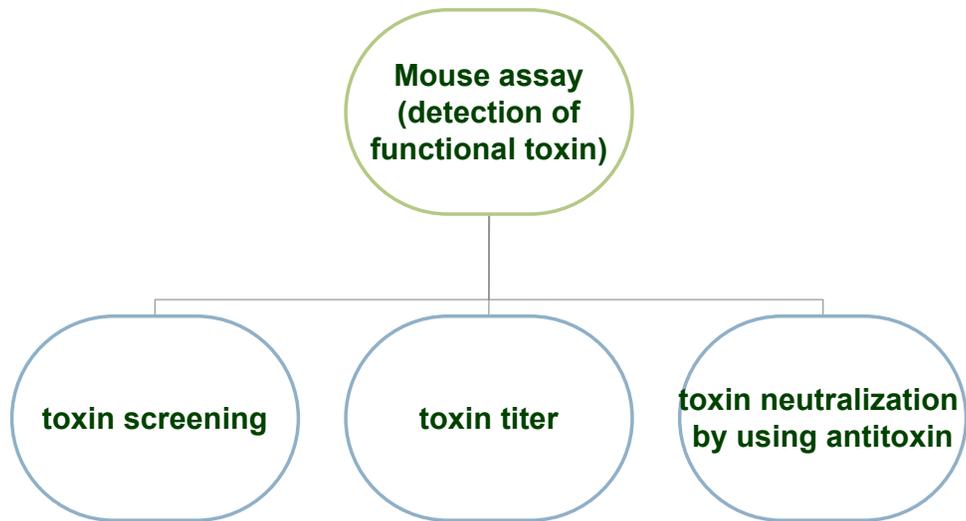
Controlling growth

- Adequate processing of food,
- Manufacturing controls,
- Appropriate processing methods, such as cooking the food at the proper temperature for sufficient times,
- Adequately acidifying the food, or controlling water activity. (pH of 4.6 or less, according to FDA's Good Manufacturing Practices, inhibition of the growth of *C. botulinum*).

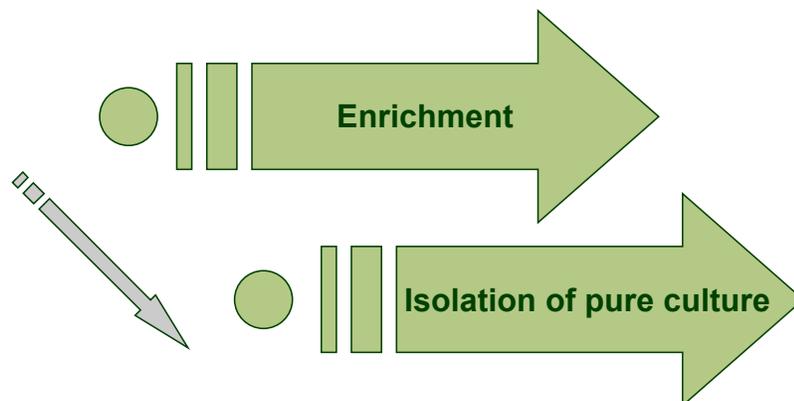
Regulatory requirements for testing

There are no regulatory requirements for testing *C. botulinum* in finished products (unless there is a follow up to clinical symptoms).

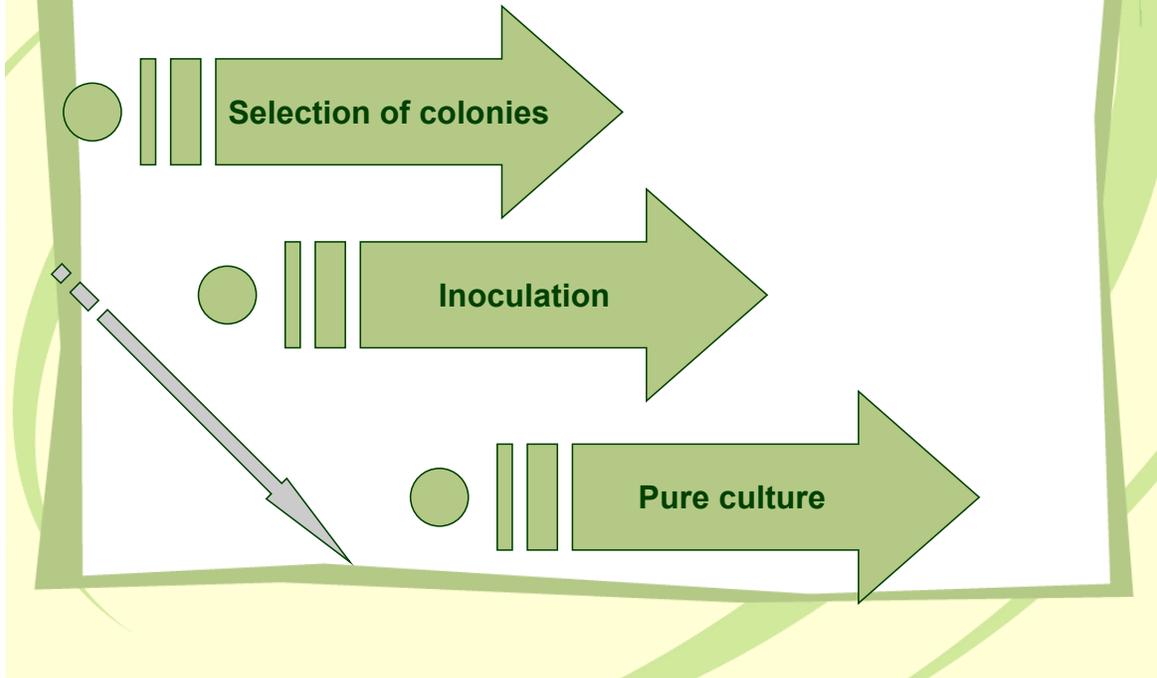
Types of testing



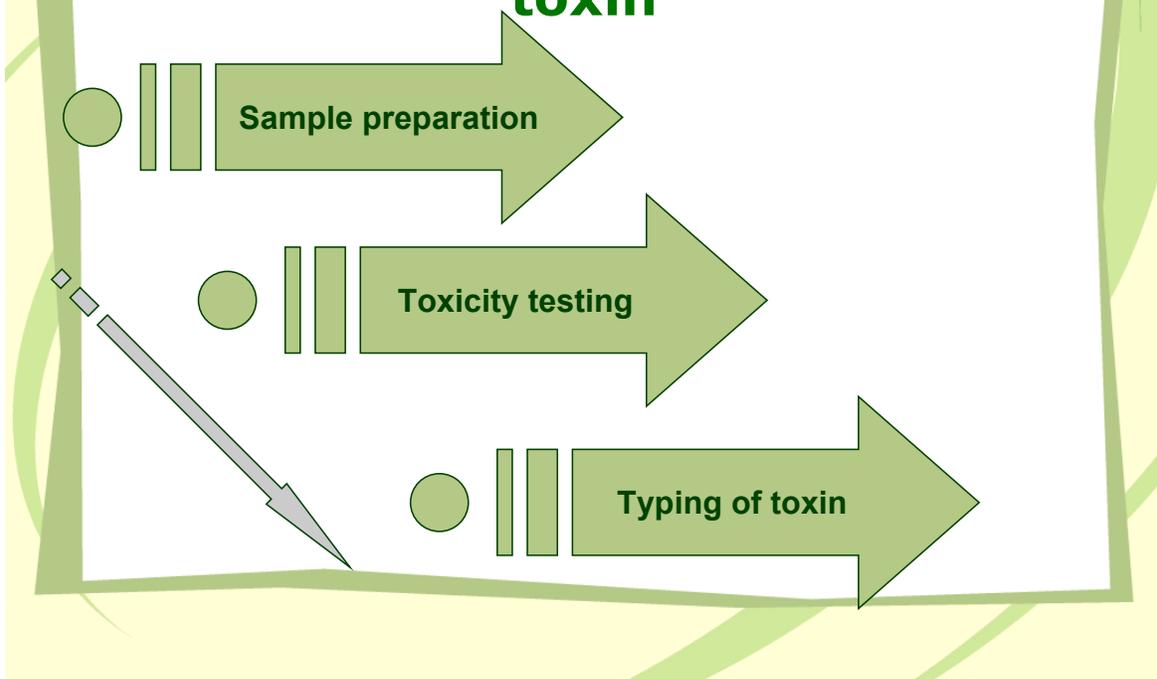
Detection of viable *C. botulinum*



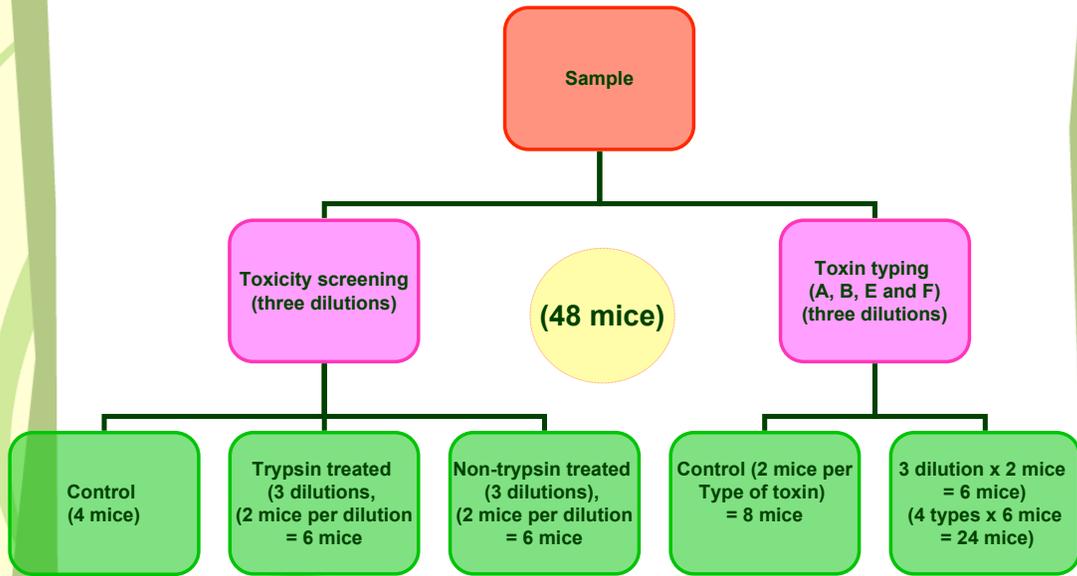
Selection of *C. botulinum*



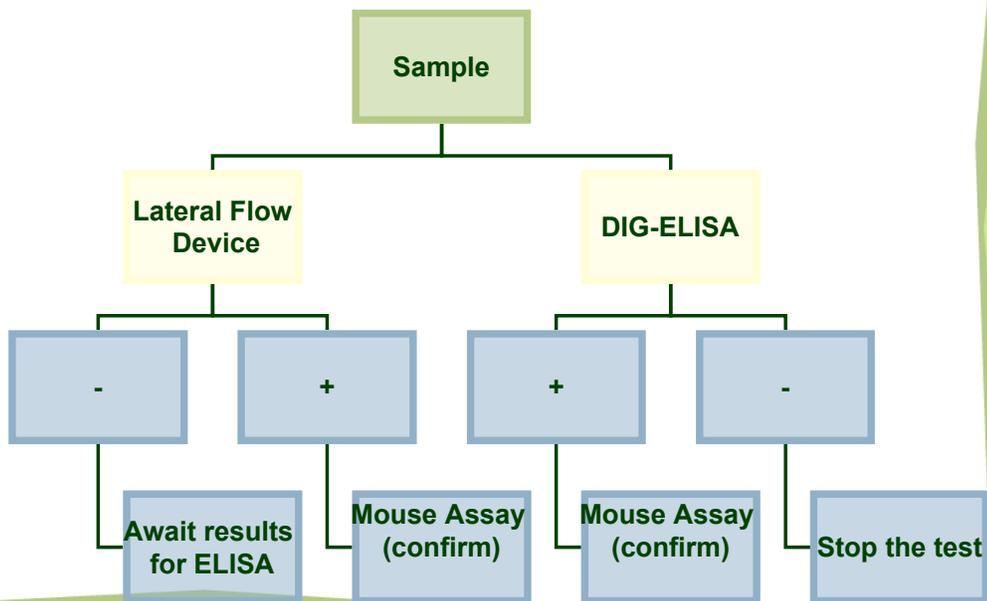
Detection and identification of toxin



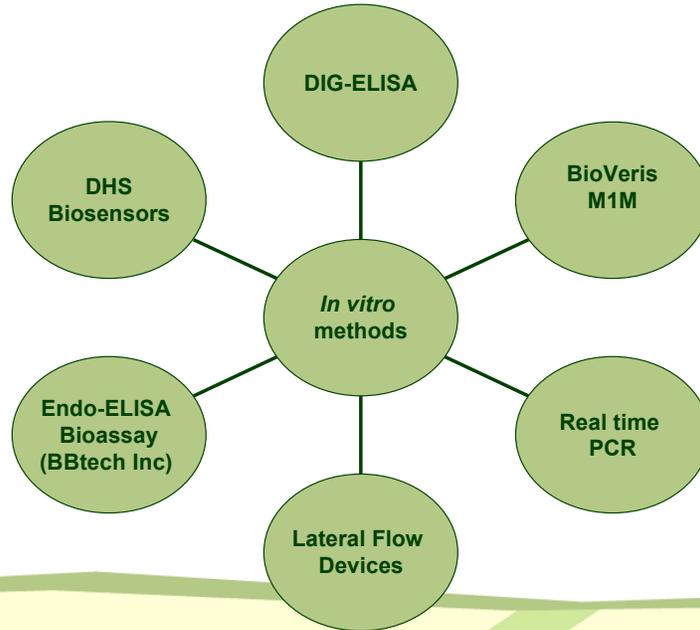
Animal requirements



Botulinum toxin testing in food contamination investigation



Alternate methods



Developed by Southeastern FDA regional lab

Dig- ELISA

CFSAN

CDC

Validated for toxin types A, B, E and F with 35 food samples, 77 outbreaks strains

Validated for toxin type A, B, E and F with 63 Clinical, Culture and Food specimens

34 Laboratories (member of LRN, FERN, Public Health Laboratories, PulseNet) have been jointly trained by CDC and CFSAN for running ELISA method

Contract with Roche Diagnostic for bulk production for CDC and FDA

Validation

**DIG-ELISA method
has been submitted for
AOAC validation
studies
(A joint effort by FDA and CDC)**

***C. botulinum* detection measures**

- **Assessment and validation of sensitive rapid methods for detection that can replace mouse bioassay.**
- **Methods development for food matrices suitable for rapid methods.**
- **Development, improvement of a sensitive rapid kit.**

Acknowledgement

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