Current Testing and Practices for Botulinum Toxin Prevention in Foods

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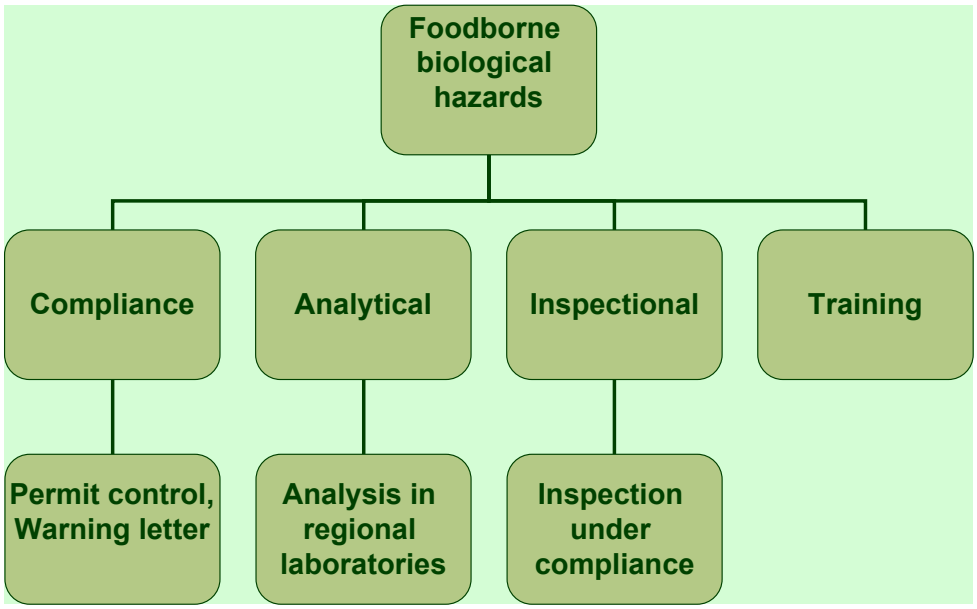
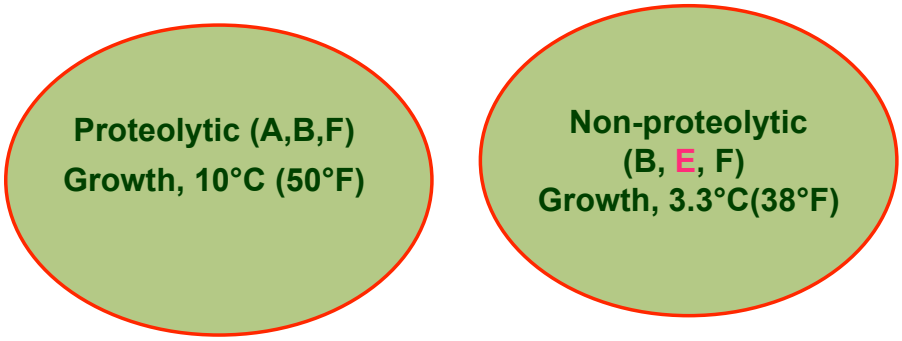
US Food and Drug Administration



Clostridium botulinum



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

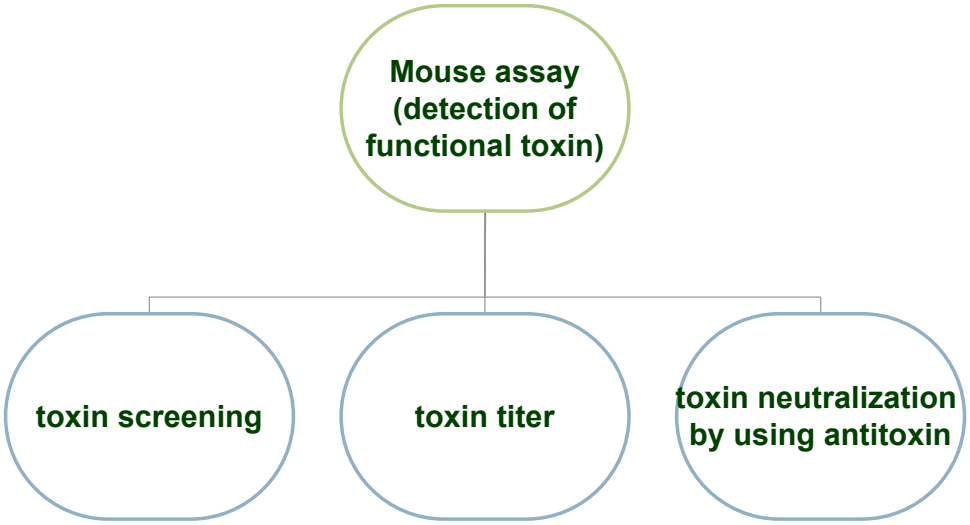
- Adequate processing of food,
- Manufacturing controls,
- Appropriate processing methods, such as cooking the food at the proper temperature for sufficient times,
- Adequately acidifying the food, or controlling water activity. (pH of 4.6 or less, according to FDA's Good Manufacturing Practices, inhibition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

Regulatory requirements for testing

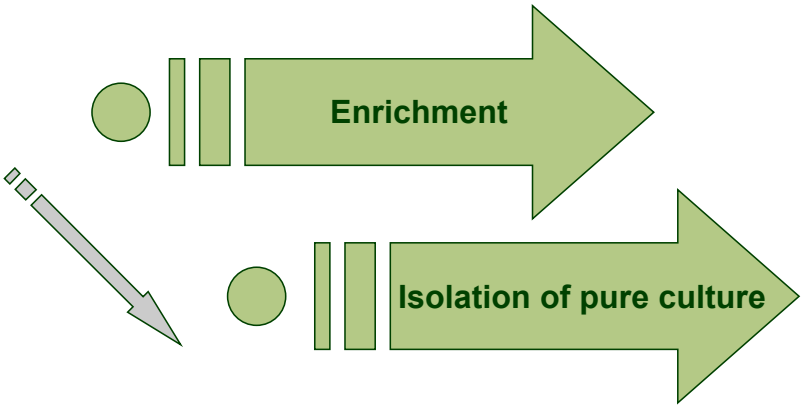
There are no regulatory requirements for testing *C. botulinum*

in finished products (unless there is a follow up to clinical symptoms).

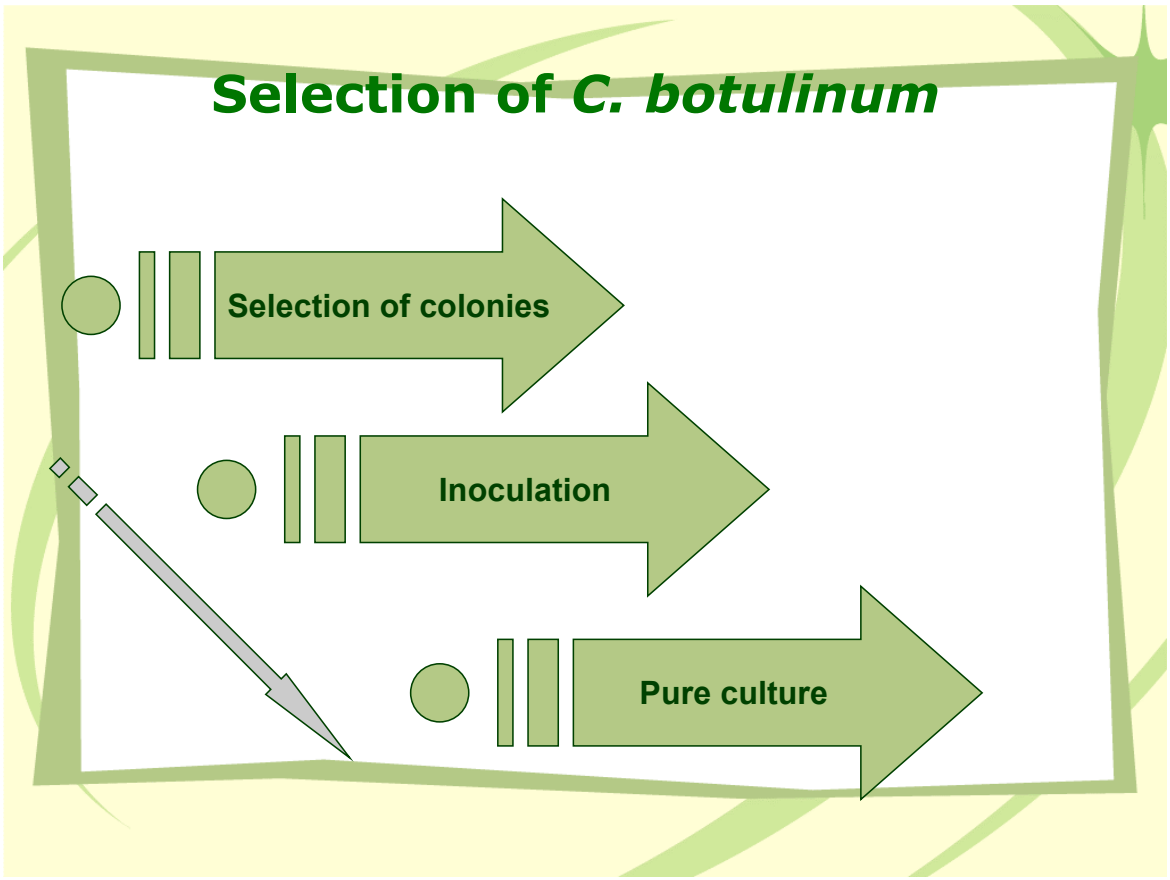
Types of testing



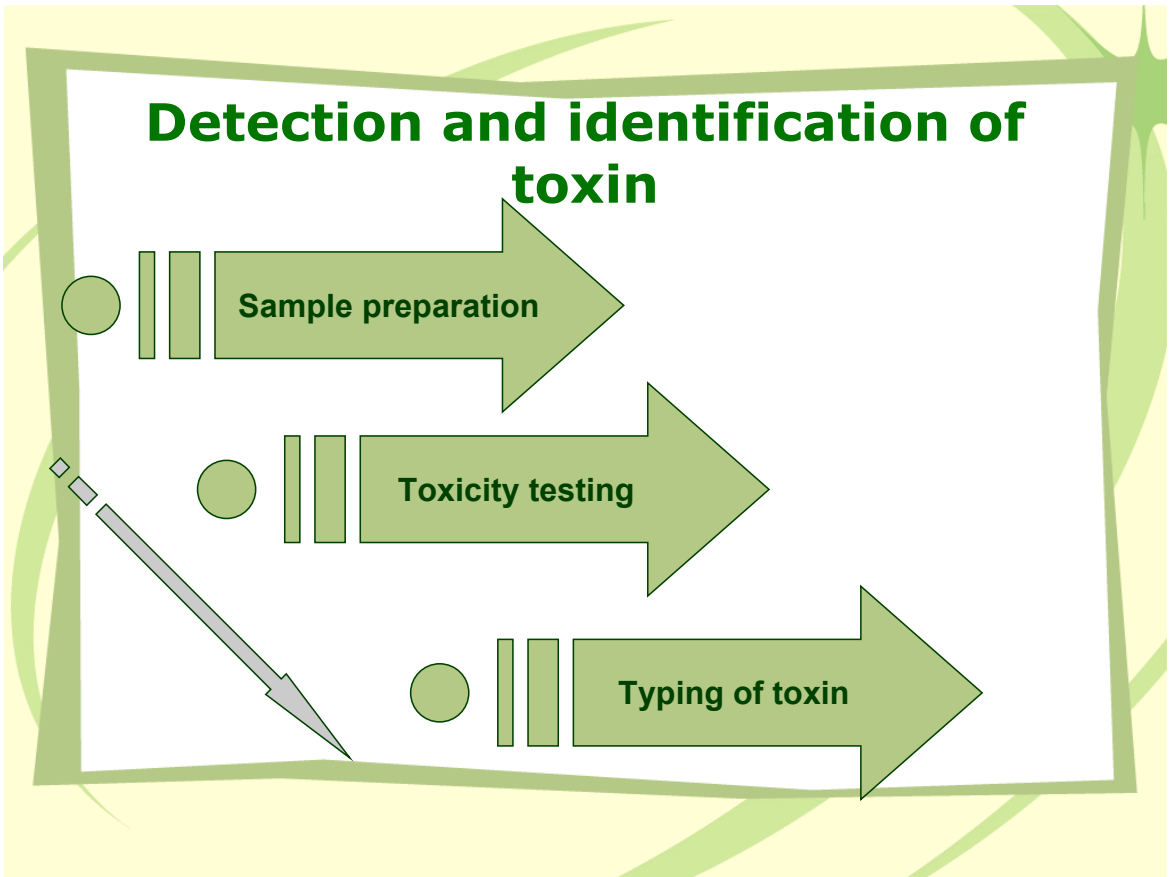
Detection of viable *C. botulinum*



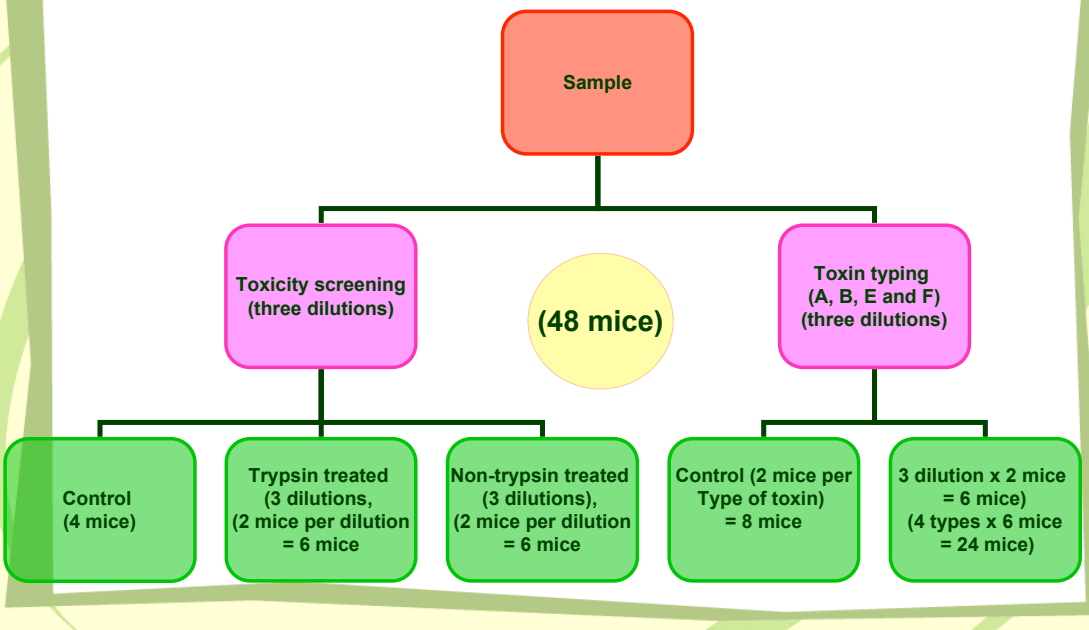
Selection of *C. botulinum*



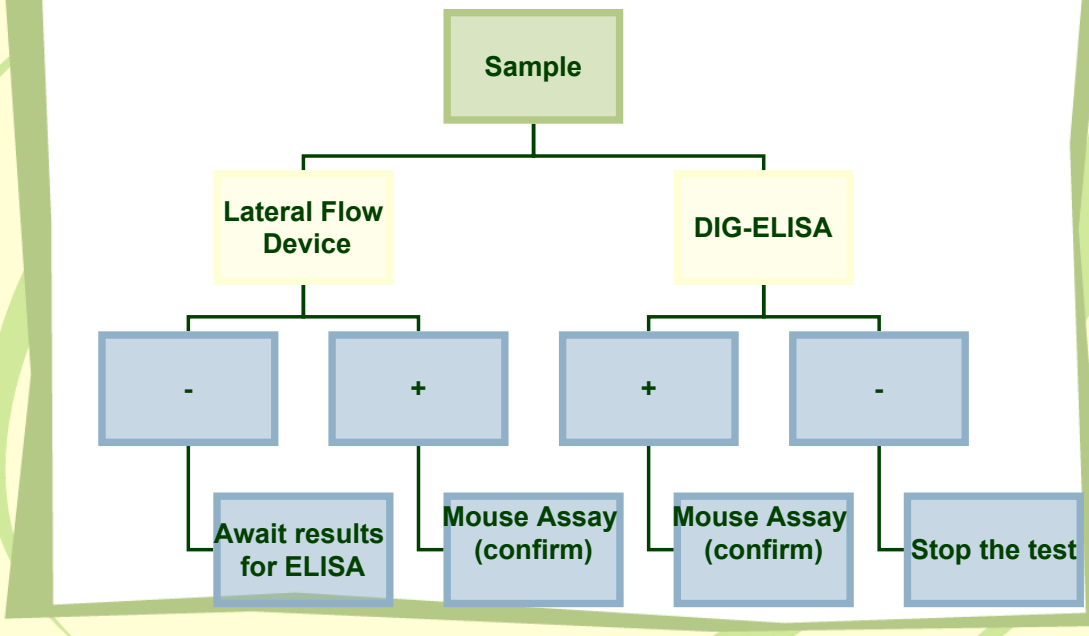
Detection and identification of toxin



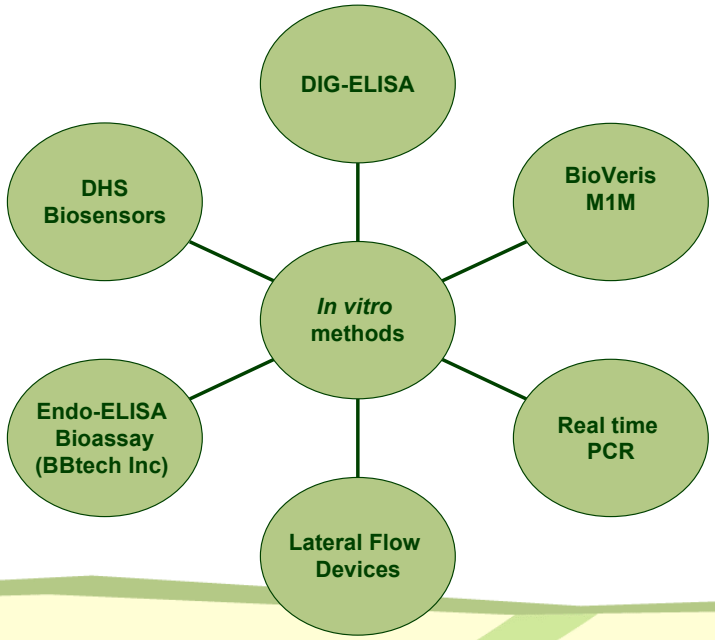
Animal requirements

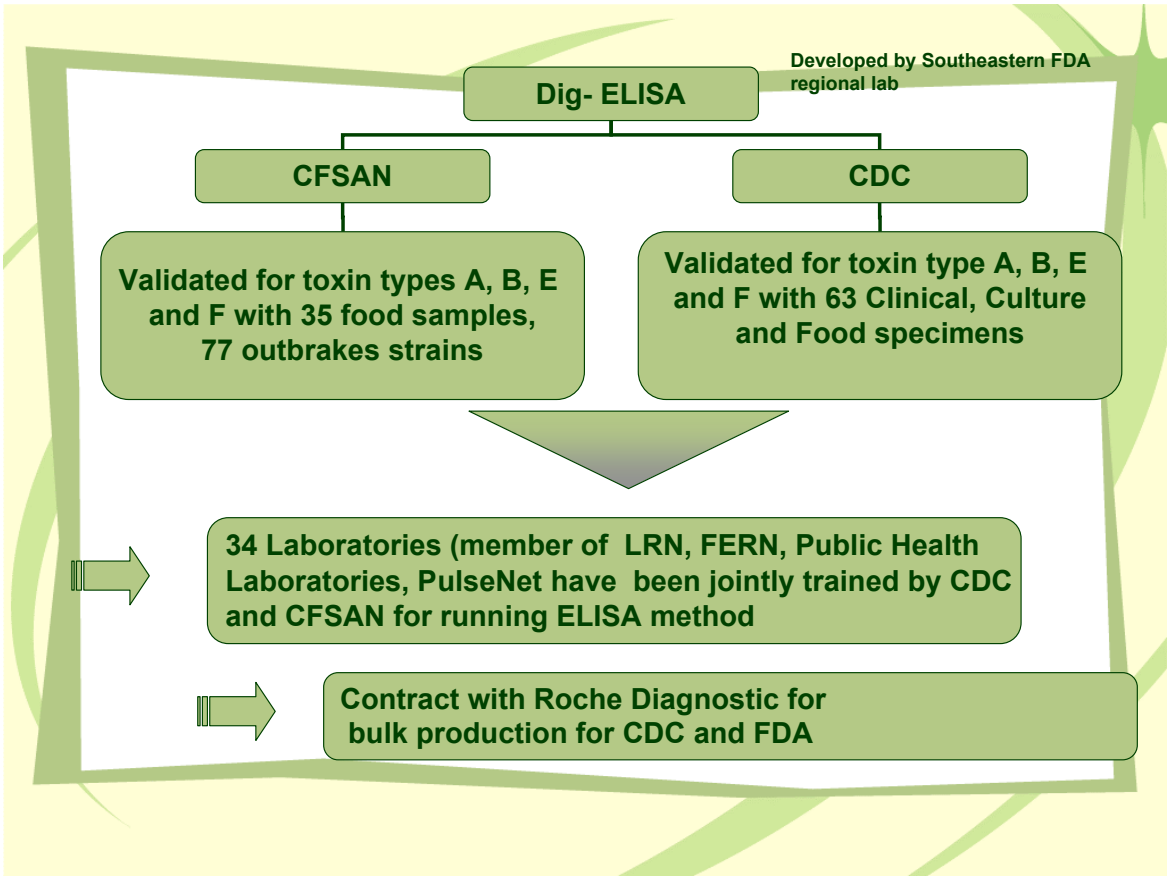


Botulinum toxin testing in food contamination investigation



Alternate methods





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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