# *National Advisory Committee for Microbiological Criteria in Foods (NACMCF)*

***Role*** *– provide impartial, scientific advice to federal food safety agencies (FDA, USDA, CDC, Commerce, NMFS, DOD).*

***Members*** *– academia, industry, state and federal agencies. Nominated; vetted and selected. 2 yr term*

# *NACMCF- STEC subcommittee (2015 - 2017)*

***FDA Charge:*** *Virulence factors and attributes that define food borne Shiga toxin-producing E. coli (STEC) as severe human pathogens*

- *Current knowledge on virulence and pathogenicity of STEC*
- *Methods available for STEC and virulence testing*
- *Criteria for assessing severe health risk*
- *Criteria for distinguishing STEC pathogens from non-pathogens*
- *Data gap for molecular risk characterization.*

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# *NACMCF- STEC subcommittee* (2015-2017)

***Chairs*** – *Alison O'Brien (USUHS) and Carolyn Hovde (U of ID)*

***Members*** – *P. Feng (FDA); R. Tauxe (CDC); B. Cloutier (US Army); T. Onifade (Fl. D.A.); L. Goodridge (McGill U.); P. Muriana (Ok.SU); O. Oyarzabal (U.Vt.); D. Gombas (Uni. Fresh Prod.); J. Ruby (JBS); M. Koohmaraie (IEH); L. Post (Deibel Lab.); W. Ocasio (Nat. Food Lab); V. Coffman (Safe Antibiotics Coalition)*

***Adhoc advisors*** – *A. Melton-Celsa (USUHS); N. Strockbine (CDC); M. Iwamoto (CDC);C. Elkins (FDA/CDC); J. Kase (FDA); M. Allard (FDA)*

***3 Workgroups*** – *1. Health burden; 2. pathogenesis and virulence; 3. methods – detection/risk characterization.*

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# *1. Burden - Clinical & epidemiological features*

- ***Epidemiology and infections***
  - *Surveillance; incidences; serogroups; clinical features*
- ***Burden of disease***
  - *Health & economy; International*
- ***Trends in incidences***
  - *Surveillance artifacts; improved safety measures; food sources of STEC*
- ***Prevalence***
  - *Cattle, fresh produce, dairy*

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# 2. STEC – Virulence and pathogenesis

- **Serotypes in human disease**
- **Virulence factors**
  - *adherence factors*
  - *Shiga toxins - subtypes*
  - *Other toxins - subAB, Ehly*
- **Acid tolerance**
- **Approaches to predict disease**
  - *SPT, tissue culture and animal models*

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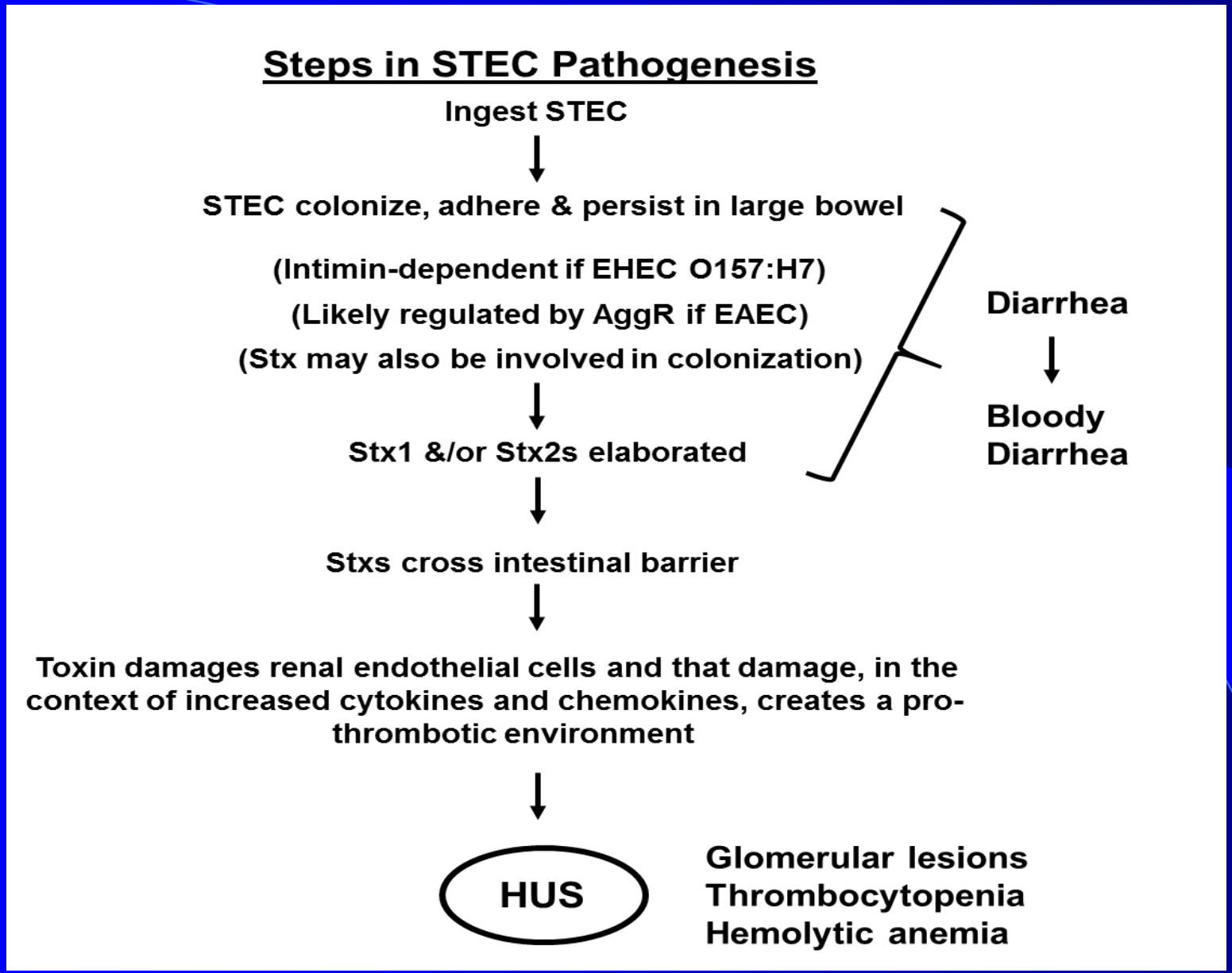
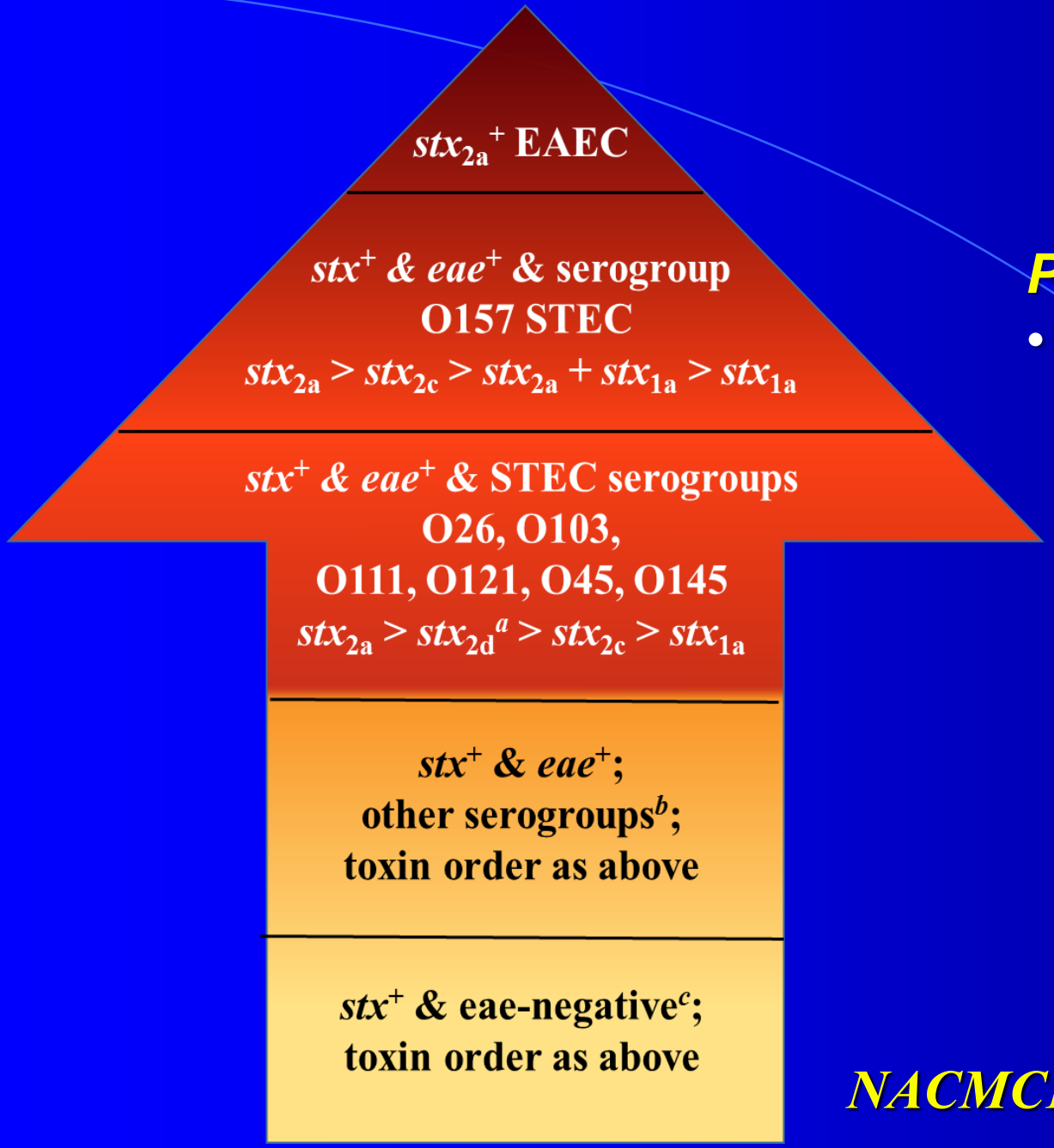



*NACMCF STEC report*




***Potential for severe risks***

- *Virulence factor-based with consideration for:*
  - *Stx subtype*
  - *Adherence factors*
  - *serogroups*

***NACMCF STEC report***

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# 3. Detection & characterization

- **USDA, FDA & clinical**
  - *enrichments, mPCR, EIA, IMS, culture, biochem, serology*
  - *Industry – screen: sensitivity and sampling*
- **Risk characterization (pros/cons)**
  - *Virulence genes & serotype (FSIS)*
  - *Virulence genes (FDA)*
- **New and high-throughput methods**
  - *WGS, digital PCR, biosensors, arrays; genomics & risk prediction; CIDT, transcriptomes, proteomics*

# 4. Gaps & recommendations

**Annex 1.** *high profile case studies - worldwide*

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# *NACMCF Report*

*(Adopted 2018 Aug. 07, Washington, DC)*

## *Response to Questions Posed by the Food and Drug Administration Regarding Virulence Factors and Attributes that Define Foodborne Shiga Toxin-producing Escherichia coli (STEC) as Severe Human Pathogens*

*(96 pages, 348 citations)*

***How to access report -***

- ***Browser – "NACMCF"***
  - ***Click "Reports and recommendations issued"***
  - ***Click "Responses to questions ….."***

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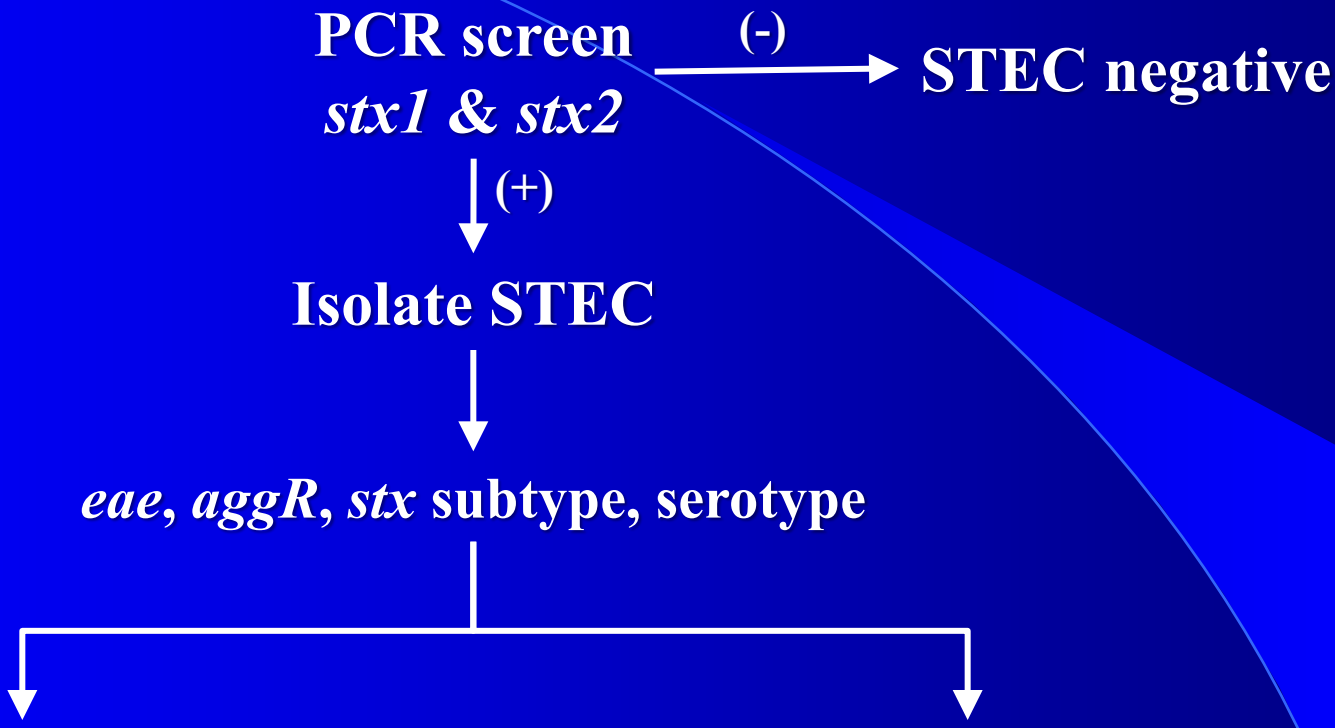
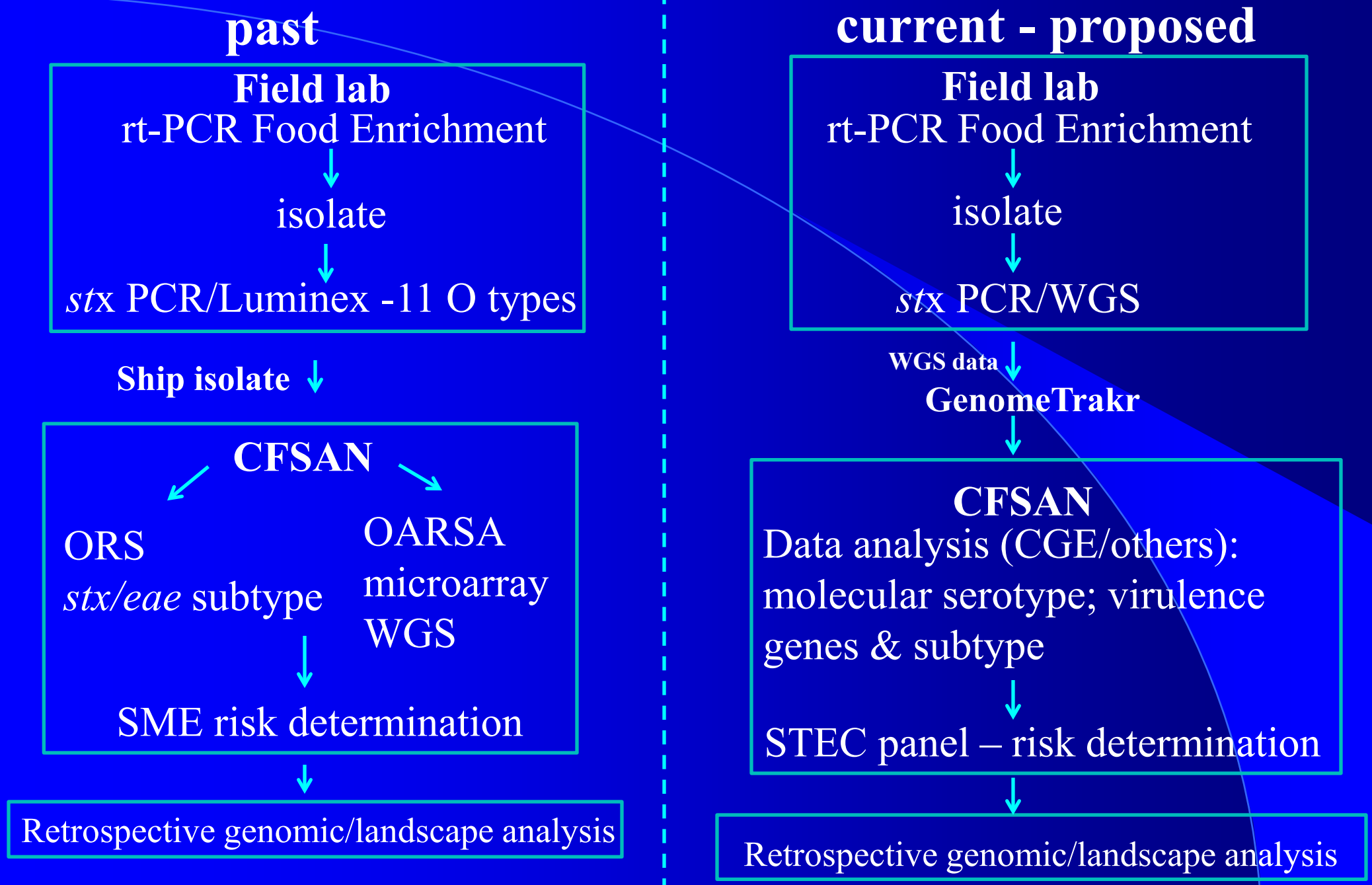
# *U.S. FDA*

*how to deal with STEC findings in foods*

# *FDA - non-O157 STEC health risk strategy*




past
Field lab
rt-PCR Food Enrichment
isolate
stx PCR/Luminex -11 O types
Ship isolate
CFSAN
ORS
stx/eae subtype
OARSA
microarray
WGS
SME risk determination
Retrospective genomic/landscape analysis
current - proposed
Field lab
rt-PCR Food Enrichment
isolate
stx PCR/WGS
WGS data
GenomeTrakr
CFSAN
Data analysis (CGE/others):
molecular serotype; virulence
genes & subtype
STEC panel – risk determination
Retrospective genomic/landscape analysis

# *STEC - health risk strategies*

- ***JEMRA (FAO/WHO) STEC Report***
  *(http://www.fao.org/3/ca0032en/CA0032EN.pdf)*
  - *Highest risk: Stx2a + aggR or eae (any serotype)*
    *(General Interest Paper, J. Food Prot. – in press)*

- ***NACMCF***
  - *Highest risk: Stx2a + aggR or eae*

- ***U.S. FDA – STEC SOP (approval process)***
  - *Highest risk: Stx2a + aggR or eae (any serotype)*
  - *Process - detect & isolate all STEC; WGS for health risk*

- ***CEN TAG18 – revision of ISO/TS 13136 – method for STEC in food and feed (in process)***
  - *Part 1 – detect & isolate all STEC*
  - *Part 2 – characterize*

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# *STEC Serotypes in produce*

- ***Basil*** – *Ont:H38, OX25:H11, O6:H10, O168:H8*
- ***Thai basil*** – *Ont:H7*
- ***Clover sprouts*** – *O130:H11*
- ***Habañero peppers*** – *O17/44/73/77/106:H45, O73:H45*
- ***Thai pepper*** – *Ont:H19*
- ***Persian cucumbers*** – *O142:H27*
- ***Parsley*** – *Ont:H14, O82:H8*
- ***Kale*** – *O8:H28, O22:H8, O17/44/73/77/106:H45, O17:H18*
- ***Microgreen*** – *O159:H19, O91:H21*


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# *STEC in foods - produce*

- ***Cilantro –*** *O101:H9, O20:H9, O168:H8, O15:H16, O20:H9, O26:H11, O165:H25*
- ***Cherry tomato*** *- O8:H19*
- ***Chives –*** *O157:H7*

- ***Lettuce –*** *O98:H21, Ont:H30, O8:H19, O2:H27, O121:H19, O163:H19, O157:H7, O165:H25, O174:H21*

- ***Spinach*** ***(0.5–0.8%) –*** *O157:H7, O8:H19, O26:H11, O82:H8, O91:H21, O98:H36, O113:H21, O116:H21, O174:H2, O174:H21*

# *STEC in foods - others*

- ***Cheese*** – *Ont:H52, O81:H21, O2:H1, O21:H10, O174:H27, O91:H14, Ont:H21*
  - ***Goat cheese*** – *O111:H8, O9:H19*
  - ***Roquefort*** – *O6:H10, O9:H9, O146:H21, O8:H30, Ont:H4, O111:H16, O20:H16*
- ***Frozen shrimp*** – *Ont:H25*
- ***Soy Nut Butter*** – *O8/O46/O134:H19, O180:H14, O157:H7*


- ***Feed*** – *O8:H19, Ont:H16, Ont:H32, O15:H45, O8:H19, O103:H2*
- ***Flour*** – *O8/B17:H19, Ont:H19, O8:H28, O8:H19, O9:H7, O157:H7, O121:H19, O103:H2, O103:H11, O26:H11, O111:H8*

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***Mille grazie.***

***Questions?***

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