FDA Norovirus Risk Profile

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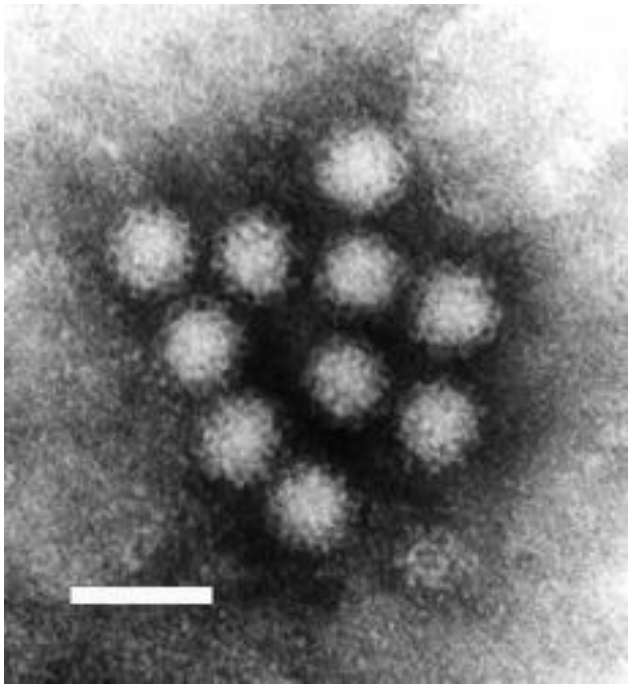
Outline

- What is a Risk Profile?
- Focus & Scope of the Norovirus Risk Profile
- The Science
  - Factors that influence stability
  - Sources of Norovirus
  - Transmission Routes
- Control Options
- Conclusions



Single stranded, non-enveloped RNA virus belonging to the family *Caliciviridae*

Risk Profile

A science-based document that…

1) Describes the current state of knowledge about a specific food safety problem or issue

2) Provides an evaluation of the data and information to support current interventions or new approaches to reduce or prevent illnesses

Ref: Codex Alimentarius Commission, 19th Procedural Manual, *http://www.codexalimentarius.net/web/ procedural_manual.jsp*, accessed April 13, 2010

Risk Profile

A science-based document that….

Provides qualitative answers to questions about the hazard and options for controlling it, based on available data

How will FDA Use a Risk Profile?

- FDA has adapted this tool as a new approach to assist the agency in its regulatory decision making.
- The information in a risk profile may affect a range of decisions, such as whether or not to commission a quantitative risk assessment or a request for research, or whether or not to implement an immediate and/or provisional regulatory decision.
- In some cases, it may reveal that no further action is needed.

Scope of Norovirus Risk Profile

The objectives of the risk profile are 3-fold:

- Provide a comprehensive review of the available science on NoV and its mode of transmission
- Provide information for decision-making in relation to potential options to interrupt the NoV transmission pathway
- Identify knowledge gaps for the purposes of research planning

Team Members

Core Risk Team

- William Burkhardt
- Wendy Fanaselle (Team lead and Project Manager)
- Biswendu Goswami (retired)
- Karl Klontz
- Michael Kulka
- Marianne Miliotis

- Sherri Dennis (Risk Analysis Coordinator)
- Lori Papadakis (Program Analyst)
- Susan Cahill (Editor)

Risk Management/ Advisors

- Ted Elkin
- William Jones
- Andrew Jacobson
- Angela Lasher
- Don Zink
- Kevin Smith
- Tom Hammack
- Jack Guzewich

- Retired: Robert Buchanan, Faye Feldstein, George Hoskin, Terry Troxell, and Jack Guzewich

Why is NoV so Hard to Control?

- **Acute onset of vomiting (often explosive) and diarrhea (also often explosive)**
- Inability to culture human NoV has limited our ability to identify effective controls
- All Surrogates have differences from human NoV and strains within Genogroups may also react differently
- **There are many different sources and transmission routes**
- **The virus is shed in very high levels and has a very low infectious dose**

Transmission of Norovirus

- **Fecal-Oral Route**: Primary route responsible for causing foodborne outbreaks
- **Airborne Inhalation of microscopic droplets**:
- **Person-to-Person**: Important means of sustaining & spreading an outbreak
- **Environment-to-Person**: Important means of sustaining & spreading an outbreak

Norovirus: An Infectious Disease in the Community

- May be more than one genogroup circulating
- Immunity is short-lived
- About 1/3 of population is asymptomatic
- Can’t overlook role that contaminated food & water plays in community outbreaks
- Role of biofilms?
- Genogroup II – May differ from NoV GI strains in infectivity, amount shed in the stool, stability outside of the host and disinfection properties
- Genogroup II.4-- Most widespread genogroup globally in communities

Questions?