Risk Assessment and Risk Management: A Perspective From FDA

Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
U.S. Food and Drug Administration
November 2008

Purpose

- How do we improve government's use of the results of risk assessments in making risk management decisions?

Principles of Risk Assessment

- Peer-review
- Best Available Science
- Full Consideration of Uncertainty
- Separation from Risk Management Decisions
- Public Input Wherever Feasible

Principles of Risk Management

- Careful Consideration of Alternatives
- Public Input Wherever Feasible
- Adherence to Statutory/Regulatory Authorities (including solicitation of public input)
- RM decisions should be based on RA
- Policy Directives (EO 12866)

FDA Examples

- Animal Cloning
- Melamine

Animal Cloning – US

- FDA decision: meat and milk from clones of cattle, swine, and goats, and the offspring of clones from any species traditionally consumed as food, are as safe to eat as food from conventionally bred animals.
- History of risk assessment
  - VMAC 11/2002
  - Draft RA for public comment issued December 28, 2006
  - Peer Reviewed
  - Finalized on January 15, 2008 along with final guidance and final risk management plan.
- Consensus and support for conclusion "as safe as."
- Current status—USDA-requested voluntary moratorium on clones in food, but not on offspring.

Animal Cloning - EU

- EFSA Risk Assessment on cattle and pig clones
  - Food safety conclusion similar to FDA's
- European Group on Ethics in Science and New Technologies
  - Doubts cloning for food supply is ethically justified due to suffering and health problems
- Eurobarometer
  - Generally oppose cloning for food use; some support for some other uses
- European Parliament
  - Recommends prohibition on food-related uses

Animal Cloning - EU

- Next Steps – Decision will take into account reports of EFSA, Ethics Group and Eurobarometer

Melamine: June 2007 Safety/Risk Assessment

- Concluded that consumption of pork, chicken, domestic fish, and eggs from animals inadvertently fed animal feed contaminated with melamine and its analogues is very unlikely to pose a human health risk.
- Issued for peer review May 24, 2007.
- Notice of availability published May 30, 2007.
- Peer review report issued on June 7, 2007.
- Presented to Science Board in June 14, 2007.

Melamine: October 2008 Safety/Risk Assessment

- Conclusions
  - Infant formula: FDA unable to establish any level of melamine and melamine-related compounds that does not raise public health concerns.
  - Food products other than infant formula: levels of melamine and melamine-related compounds below 2.5 parts per million (ppm) do not raise concerns.
- Sent to peer-review and for public comment.
- Consistent with assessments of other international regulators.