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Addressing Public Concerns in a Science-Based Regulatory System

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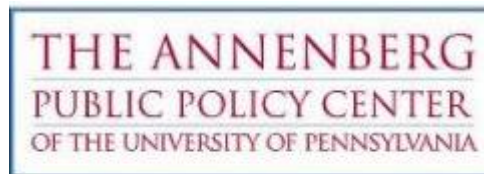
School of Environmental and Biological Sciences

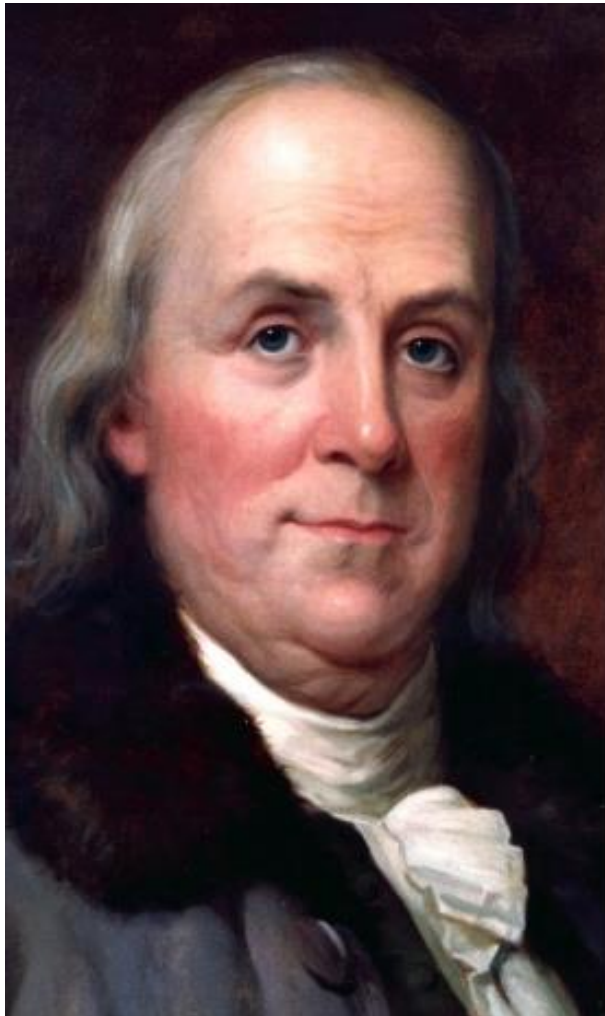
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*It is the first responsibility of
every citizen to question
authority.*

- Benjamin Franklin

Assumptions about Process

- People expect that those in charge have a duty to be:
 - Truthful / honest
 - Trustworthy
 - Credible / competent
 - Empathetic / caring
 - Helpful / provide solutions to problems
 - Responsive to requests for information
 - Willing to:
 - Take responsibility
 - Provide clear rationales for important decisions
 - Accept comments and criticism

The Importance of Trust

- Trust is essential for risk communication
 - Many of the risks we deal with are invisible
 - Bacteria
 - Viruses
 - Chemical contaminants
 - Many of the solutions we deal with are invisible
 - DNA
 - Nanotechnology
 - Antibodies
 - Information is often incomplete or uncertain
 - Much of the public cannot understand the available information themselves



The Importance of Trust

- People who distrust your messages are unlikely to believe or act on the information
 - This can have significant health, environmental, agri-food, trade, and economic implications.



Trust Components

- **Credibility** - The extent to which a source or institution is perceived to have the knowledge and expertise to assess, manage and communicate about a risk.
- **Honesty** - The extent to which a source or institution conveys information about a risk in an open, truthful and transparent way.
- **Care** - Care for the interests of the other party and that the source or institution shares the same values and concerns.

Trust and the Consumer

- Consumers are well aware that different stakeholders have different roles.
 - So, they have different expectations for them.
 - Companies need to demonstrate competence and honesty.
 - Governments need to demonstrate care for those whom they represent.



Organizational Principles

- Openness
- Transparency
- Timeliness
- Responsiveness

All are essential to *establishing* and *maintaining* trust, and contribute to *rebuilding* trust when it is low.

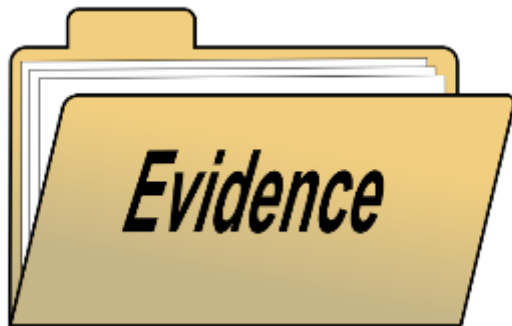
Openness

- Risk assessment, management, and communication should be conducted in an open environment,
 - including opportunities for dialogue and engagement with stakeholders at appropriate points.



Openness

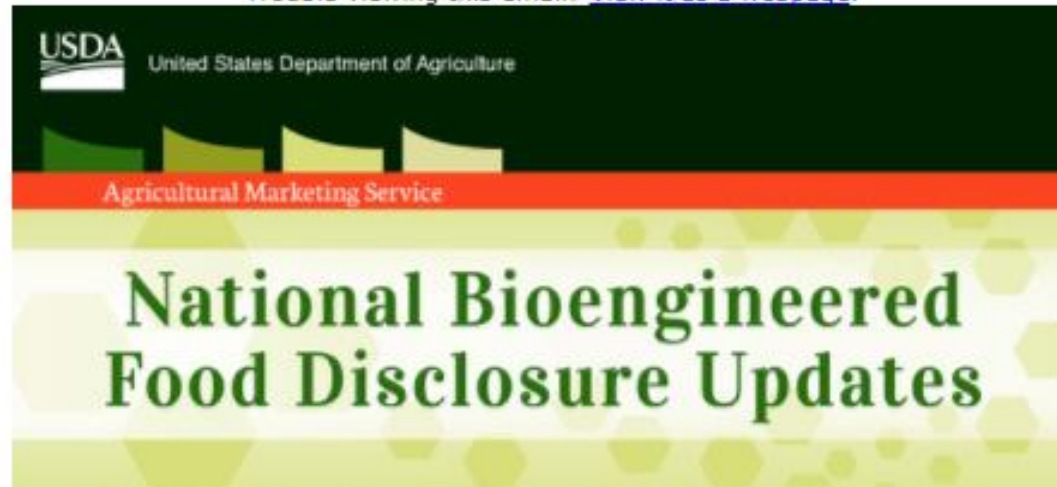
- For example, stakeholders may be invited to:
 - submit evidence,
 - participate in a meeting where risk management options are discussed,
 - comment on draft messages before they are finalized.



USDA Seeks Input on Proposed Rule

USDA Agricultural Marketing Service sent this bulletin at 06/28/2017 02:03 PM EDT

Trouble viewing this email? [View it as a webpage.](#)



USDA Seeks Input in Developing a Proposed Bioengineered Food Disclosure Rule

The U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) has posted [30 questions for stakeholder input](#) regarding the establishment of a National Bioengineered Food Disclosure Standard. USDA will use the input received when drafting a proposed rule.

Feedback related to the questions should be submitted to GMOLabeling@ams.usda.gov by July 17, 2017.

The National Bioengineered Food Disclosure Standard Law was enacted by Congress on July 29, 2016. AMS has two years to establish the standard and the procedures necessary for implementation. AMS is seeking input from stakeholders in order to establish the final rule by the mandated July 2018 deadline. The public will also have the opportunity to comment on any proposed rule during the rulemaking process.

[View The Questions](#)

<https://www.ams.usda.gov/rules-regulations/gmo-questions>

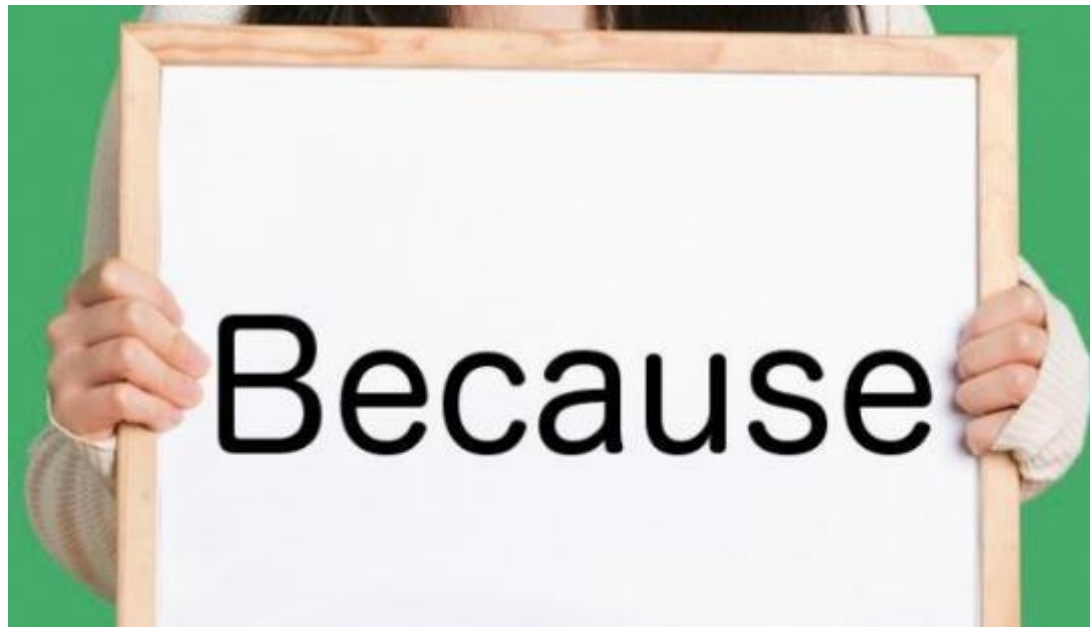
Openness

- Dialogue and engagement demonstrates **care**, and can enhance the ability of an institution to appropriately respond to public concerns.
- But,
 - Engagement in the process is not the same as seeking consensus or allowing others to make decisions.
 - Asking about, but not addressing consumer concerns can lead to anger and resentment.
- It is important to explicitly communicate how stakeholder inputs are incorporated, or how they were considered.

Question:

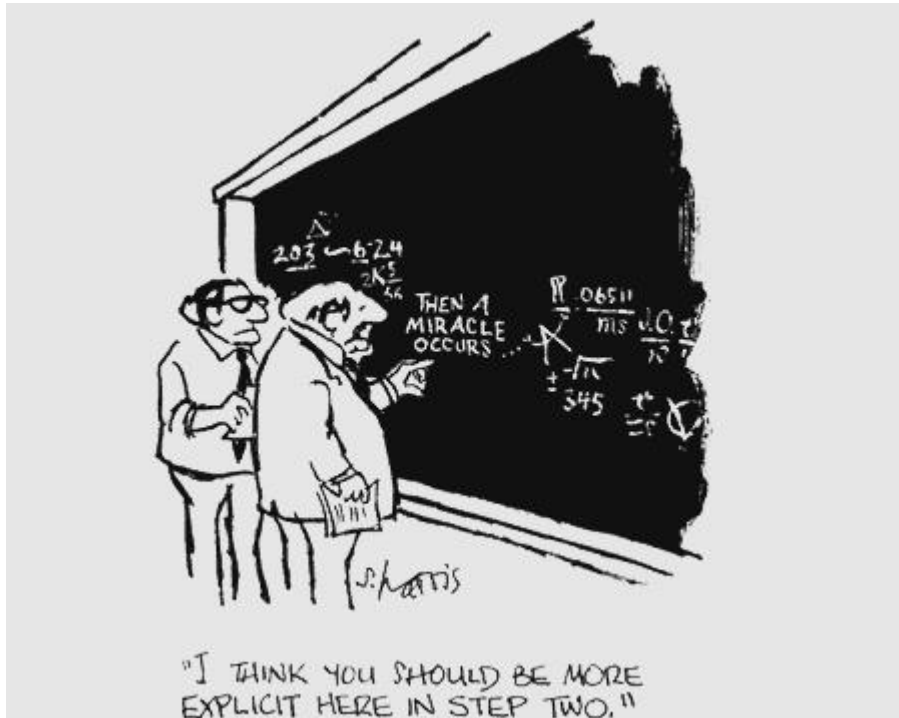
What is the Most Powerful
Word on the Planet?

The Most Powerful Word on the Planet



Explanations

- Good explanations provide evidence of your reasoning, your credibility/competency, your values, your priorities, your honesty, your care for others.



Question:

What is the Worst Possible
Explanation on the Planet?

The Worst Explanation on the Planet



Transparency

Policies, practices, and procedures that enable people to understand *how* decisions on risk assessment, management, and communication have been made.

- Make information accessible (e.g. on websites, available on request, observers):
 - Information on which decisions are made (research reports, data).
 - Documentation about the decision-making process (minutes of meetings).



openFDA

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Transparency

- ▶ **Open Government: FDA Data Sets**
- Recalls Data Sets

Open Government: FDA Data Sets

On June 2, 2014, FDA launched **openFDA** to provide easy access to valuable FDA public data. For more information:

- [Read the press release.](#)
- [Visit openFDA.](#)

The data sets listed on this page are available in a variety of different formats, including Excel, PDF, and XML. Below is the current list of data sets.



Advisory Committees

Home > Advisory Committees > Committees & Meeting Materials > Risk Communication Advisory Committee

Risk Communication Advisory Committee

- [2017 Meeting Materials, Risk Communication Advisory Committee](#)
- [Past Meeting Materials, Risk Communication Advisory Committee](#)
- [Charter of the Risk Communication Advisory Committee to the Food and Drug Administration](#)
- [Roster of the Risk Communication Advisory Committee to the Food and Drug Administration](#)

Risk Communication Advisory Committee

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Purpose

The Committee advises the Commissioner of the Food and Drugs or designee on methods to effectively communicate risk associated with products regulated by the Food and Drug Administration and in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. It also reviews and evaluates research relevant to such communication to the public by both FDA and other entities, and facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products.

Committee Resources

- [FDA's Risk Communication Advisory Committee Dates and Topics of Past Meetings \(PDF - 49KB\)](#)
- [Communicating Risks and Benefits: An Evidence-Based User's Guide](#)
- [Advisory Committee Vacancies, Qualifications, and Experience](#)
- [Advisory Committee Calendar](#)

Committee Membership

The Committee shall consist of a core of fifteen voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in fields such as social marketing, health literacy, and other relevant areas. Members will include experts on risk communication, experts

Transparency

- Transparency is important for perceptions of **honesty**
- But,
 - Transparency alone does not ensure trust
 - Trust is a result of perceptions of institutional honesty, concern for public welfare and credibility
- Transparency about how decisions are made can only build trust when the public sees that competent decisions are made to optimize consumer protection.



Diogenes the Cynic

Transparency

- Transparency can only lead to trust when it is clear that the decisions that have been made are in the public interest.

Transparent Decisions in the Public Interest → Trust

Transparency

- Not all information can be made public in all cases.
- But, this cannot be used as a justification for secrecy.
- A lack of transparency can lead to distrust.
 - The rules around transparency must be clear, well justified, and consistently applied.



Conflicts of Interest



Perceived Conflicts



Transparency and Openness

- Transparency and openness are not interchangeable
- To ensure best practice in risk communication, both openness and transparency are essential



Timeliness

- Timely communication:
 - Builds and maintains trust (credibility and care) if it appropriately informs the public.



Timeliness

- If you do not rapidly communicate, others will do so (e.g. through the Internet, social media).
 - The information they share may be inaccurate, or worse.
 - You may be perceived or portrayed as hiding information



Timeliness

- Timely communication:
 - Can prevent or reduce the development of rumors and misinformation.
 - These can disrupt trade, and have other economic impacts.



Uncertainty

- Sharing uncertain information is necessary
 - Acknowledge and explain the uncertainty
 - Talk about the implications for stakeholders
 - Say what is being done to address the uncertainty
 - Explain the logical decision given the current unknowns
 - Commit to updating when new information is available



Responsiveness

- People may distrust risk messages if these do not address their concerns and perceptions
 - Include *target audiences' information needs and communication expectations* in communication activities.
 - Revise or reinforce messages to *changes in the external environment*, including unplanned and unforeseen events (e.g. misinformation, emerging questions and concerns).

How to Build and Maintain Trust?



How to Build, Maintain or Restore Trust?

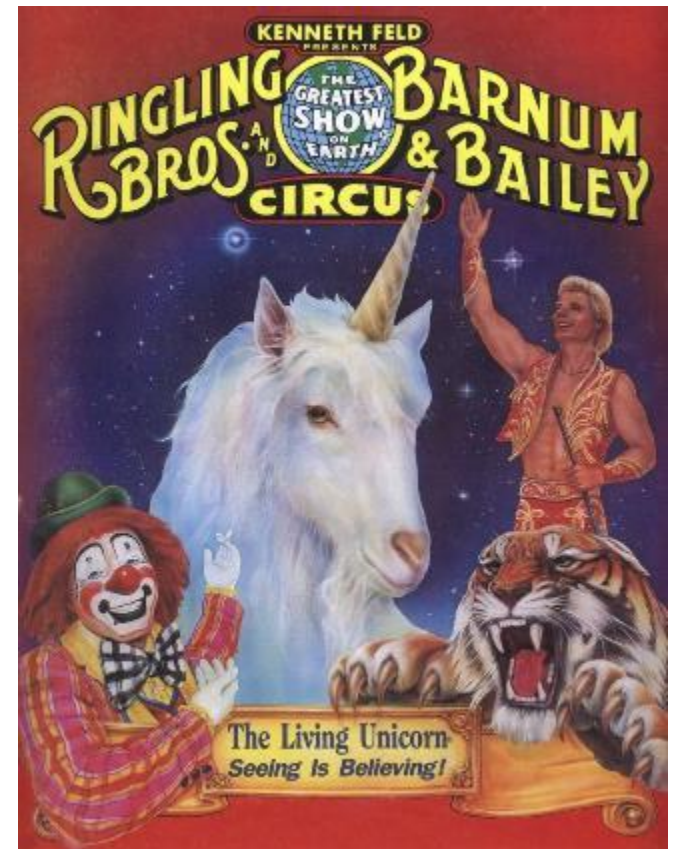
- Create opportunities for dialogue with stakeholders at appropriate times and when feasible.
- Make documents publicly available to enable stakeholders to understand and scrutinize the decision-making processes.
- Communicate in a timely manner, even when there are uncertainties. Timeliness is essential.
- Be responsive to the needs and concerns of those potentially affected by the risk.

Public Perceptions of Agri-biotechnology (1995)

- “ . . . Many recognize the potential of biotechnology to dramatically change the world. For most, understanding the mechanics of biotechnology is probably not as important as knowing that the people who use biotechnology share the same values as they do.”



“They want to be confident that people involved in this field are using common sense, taking proper safety precautions and using science to create new plants and animals in the tradition of Luther Burbank, not P.T. Barnum.”



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