



# Anticipating Future Economically Motivated Adulteration

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## The Problem

- A pattern is evident:
  - Melamine in animal feed (March 2007): the industrial chemical melamine was added to gluten by manufacturers in China, apparently to enhance protein content.
  - Heparin (January 2008): oversulfated chondroitin sulfate found in heparin active pharmaceutical ingredient from China
  - Melamine in dairy products (September 2008): Melamine was apparently added to milk in order to enhance its perceived quality.
- Products appear to have been purposefully adulterated for economic gain.

Challenge: How can we anticipate future economically motivated adulteration of FDA-regulated products?

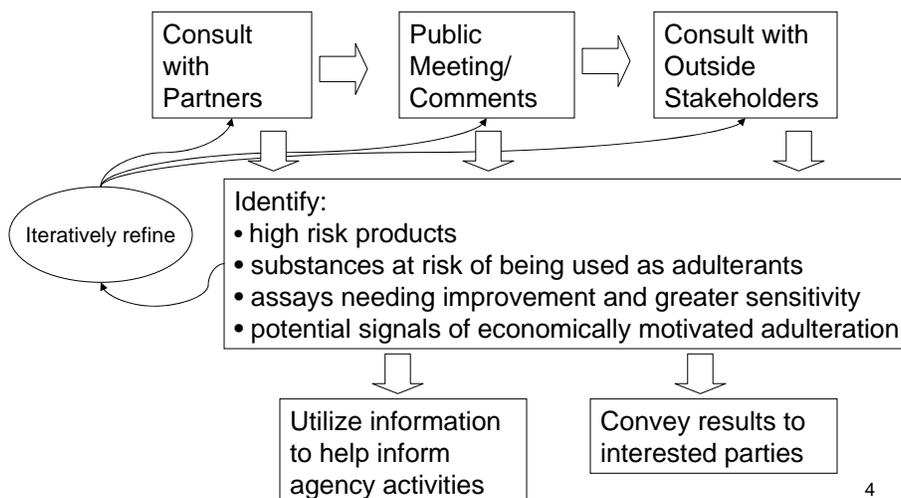
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## Strategic Approach

- Created internal workgroup to develop approach to anticipate future EMA, so as to prevent or control risk.
- Workgroup has developed a set of questions to ask federal, state, and international partners and industry pertaining to EMA.
  - Structured approach assuming adulteration may be driven by economic motivators.
- Workgroup has met with federal partners.
- Public meeting being planned for this spring to solicit more public input.

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## Strategic Approach



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## Proposed Questions

- 1) Questions pertaining to attributes of products, components/ingredients that may be faked:
  - 1a) What products or components / ingredients used in products have attributes that can be faked by using lower cost substitutes? What are such attributes and what are the lower-cost substitutes?
  - 1b) What products not reported in the press contain melamine or DEG?
  - 1c) What other known or potential adulterants have been used in the manufacturing of products or added to products for economic gain?
  - 1d) What food products are paid a premium based on measured protein content or on measured fat content?

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## Proposed Questions

- 2) Questions pertaining to changes in the marketing environment: What dramatic changes have occurred recently in:
  - 2a) the marketing environment of products or ingredients?
  - 2b) in the geographic origin of products?
  - 2c) in the prices, output, or exports of products or ingredients?
  - 2d) in the supply of ingredients or source materials for products?

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## Proposed Questions

- 3) What scientific research--published or otherwise-- indicates that a specific material could be used as a substitute for another, legitimate material?
- 4) What analytical equipment or methods, although used by industry and regulators, are in fact unable to detect faked products or ingredients?

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## Proposed Questions

- 5) Are you aware of products/ingredients with a supply chain more complicated than would appear to be necessary for distribution or where the supply chain has recently become more restricted or complicated?
- 6) What recent examples of economically motivated adulteration should U.S. regulators study and learn from?

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## Proposed Questions

7) What further information should U.S. regulators request to help predict and address economically motivated adulteration?

8) What other organizations may have information that would help U.S. regulators predict and address economically motivated adulteration?

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## Conclusions

- We welcome your comments.

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