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Integrating new methodologies: Challenges for risk assessment, food policy and communication

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Protecting Health, Saving Lives—*Millions at a Time*

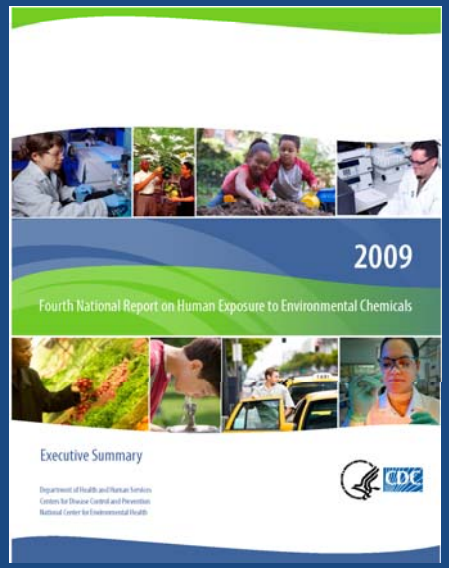
Challenges for Risk Sciences, Policy, and Communication

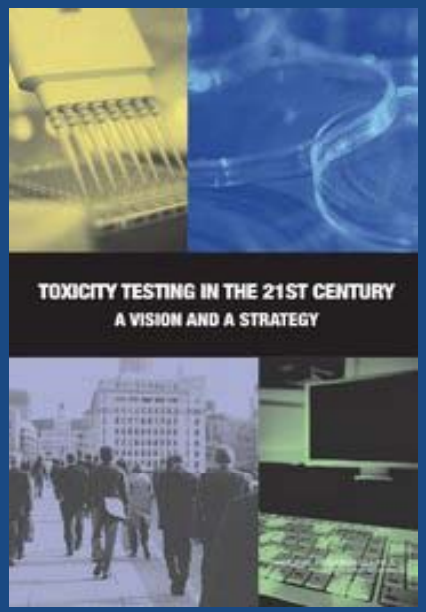
- New methods and approaches to risk assessment
- Implications of high throughput toxicity testing – upstream perturbations?
- New biomonitoring for contaminants and population exposures
- Questions concerning credibility of the science
- NGOs and consumer groups taking more active role in food issues
- Political and economic pressures for less regulation
- Communication of emerging science to the public and policy makers

Risk Assessment is Evolving

Silver Book **Tox Testing**

CDC Biomonitoring Reports

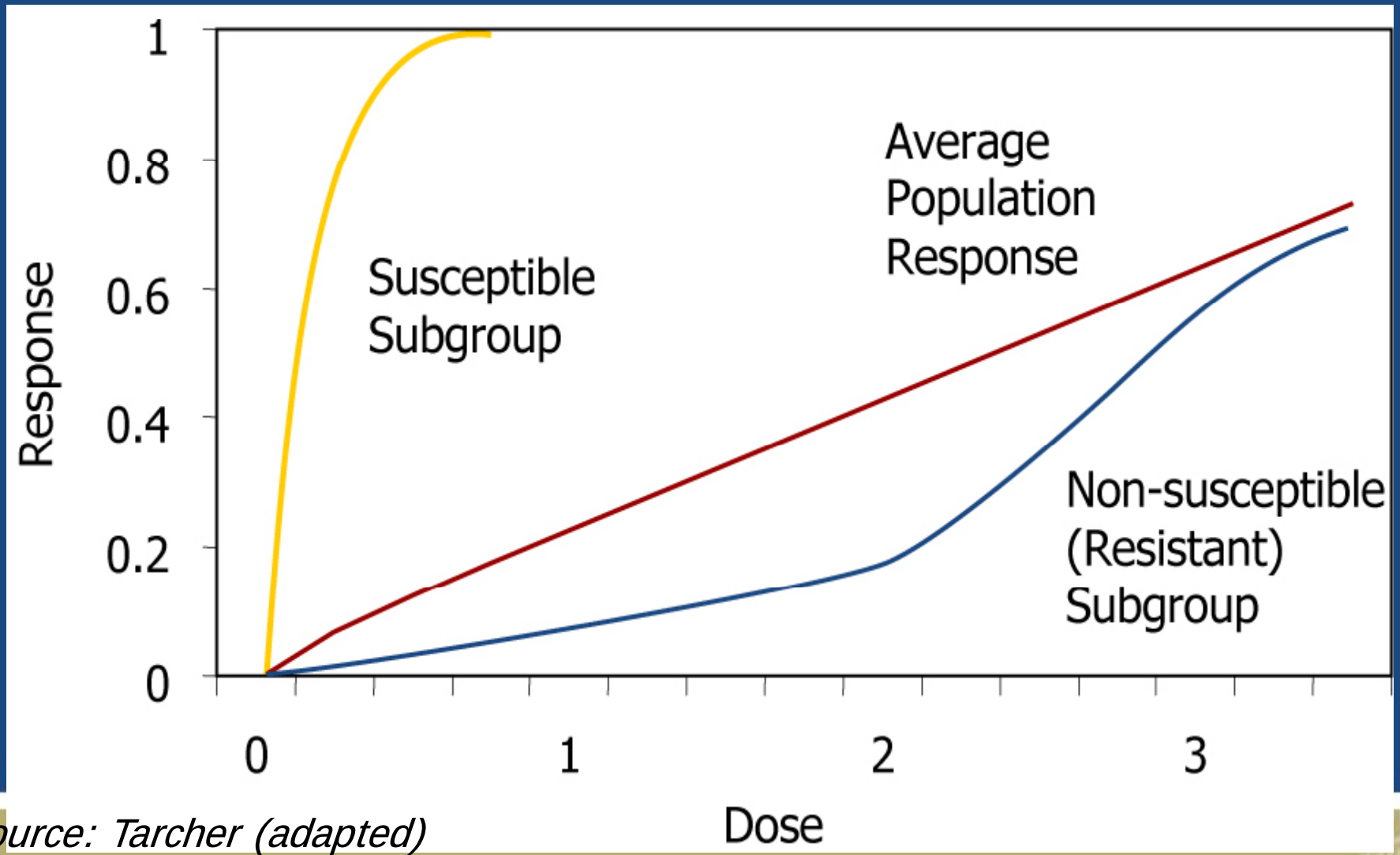




“Silver Book” Themes

- Problem Formulation – asking the right questions
- Susceptibility, population variability
- A unified approach to dose-response assessment Thresholds? Quantifying non-cancer risks
- Cumulative risk assessment, multiple contaminants, including social determinants of risk
- Improving the utility of risk assessment – EPA fit for purpose – evaluation of results
- Stakeholder involvement – how?

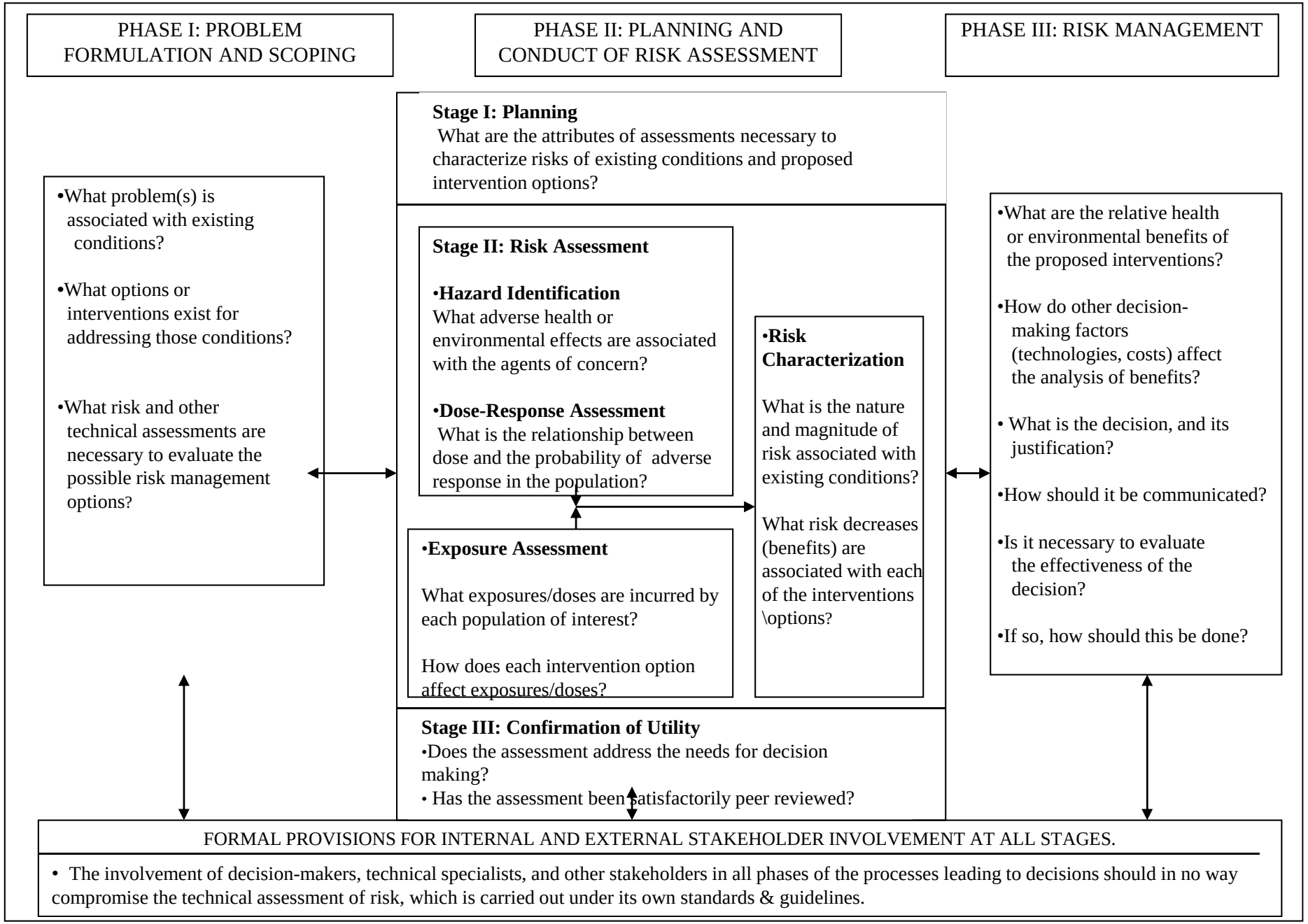
Low dose exposures and susceptible Subgroups in the Population



Source: Tarcher (adapted)

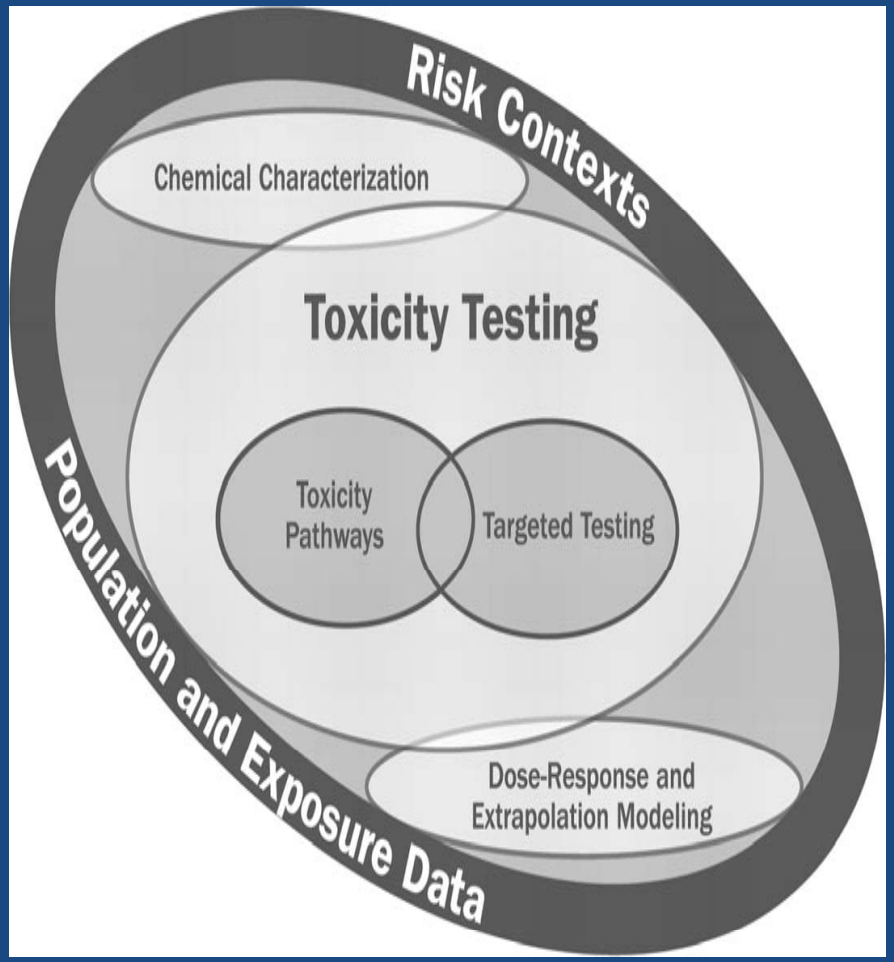
Rethinking measures of safety?

- Life stage and susceptibility - 10x or modeling with adjustment factors?
- Calculation of RfDs and HBGVs?
- The quantification of risk versus “bright lines” or margins of safety
- One at a time approach for contaminants? Mixtures?
- Most difficult question – what is “acceptable” risk



THE SILVER BOOK framework for risk-based decision-making that maximizes the utility of risk assessment.

NAS Report- Toxicity Testing in the 21st century



- Creates a new vision for the future of toxicity testing that relies less on animal studies and instead focuses on in vitro methods that evaluate chemicals' effects on biological processes using cells, cell lines, or cellular components, preferably of human origin.

New Toxicity Testing

- Fills data gap on untested chemicals
- Provides insights regarding low exposure and early signals of toxicity
- Low costs and timely results
- May confirm “safety” of chemicals of concern
- Prevention – early identification and control of potential hazards

Answers needed…

- What do cellular responses and perturbations mean for food safety decision making?
- Are these ADVERSE effects, as in NOAEL…..
- Will they provide the basis for dose response and risk characterization?
- Do the predict actual health outcomes in the population?
- Will they be accepted as credible by decision makers and stakeholders?

CDC 4th National Report

- CDC's Environmental Health Laboratory measured over 220 chemicals – 75 of which have never been measured in the U.S. population.
- The samples were collected from approximately 2500 people who participated in CDC's National Health and Nutrition Examination Survey (NHANES).
- The report provides exposure data on the U.S. population by age, sex, and race or ethnicity.
- The report includes extensive data for such chemicals as mercury, lead, cadmium, and other metals; phthalates; organochlorine pesticides; organophosphate pesticides; pyrethroid insecticides; herbicides; polycyclic aromatic hydrocarbons; dioxins and furans; polychlorinated biphenyls; perflourinated compounds, phytoestrogens and perchlorate.

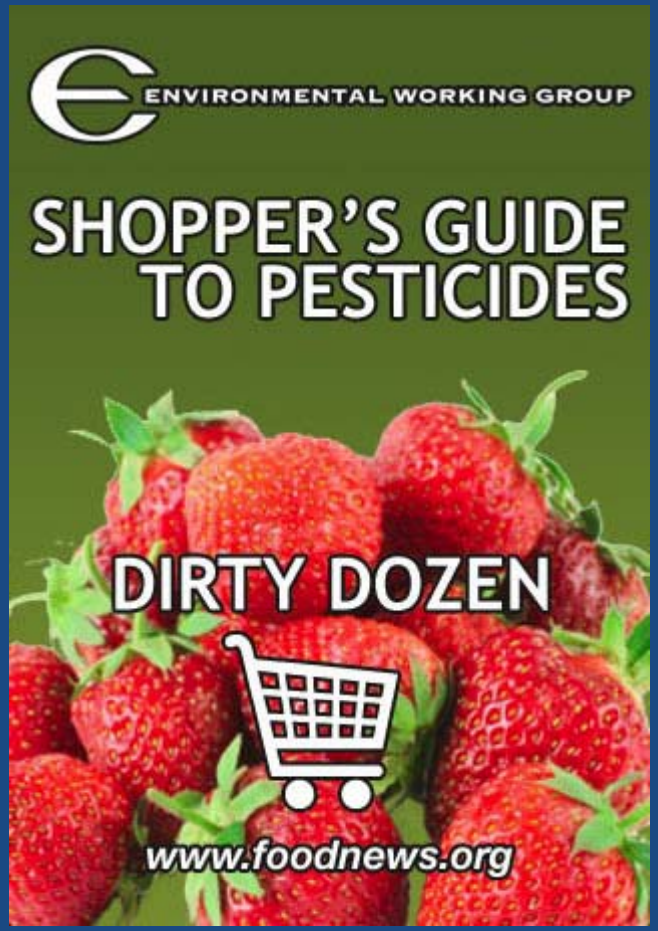
CDC Biomomitoring Example - PFCs

- CDC scientists found four PFCs in the serum of nearly all of the people tested, indicating widespread exposure to these PFCs in the U.S. population
- Fluoropolymer coatings can be used in such varied products as, adhesives, food packaging, heat-resistant non-stick cooking surfaces
- People are mostly likely exposed by consuming PFC-contaminated water or food
- Serum levels of PFCs, particularly PFOS, appear to be higher in the U.S. than in some other countries: about two to threefold higher than in Poland, Belgium, Korea and Japan; and about eight to sixteen fold higher than in Italy (Kannan et al., 2004);

Biomonitoring Results

- Findings of widespread exposure to food related contaminants have major implications for food safety efforts
- Mixtures of multiple contaminants with common toxic endpoints – endocrine, neurodevelopment, cancer
- Public health implications?
- Cumulative risks?
- Quantified risk or margin of safety approach?

The rising role of consumer groups



Stakeholders and Decision Makers

- Food safety advocates have had a major impact on public perceptions of risk
- The credibility of regulatory science is being questioned by stakeholders and decision makers alike.
- There is increasing criticism and questioning of the validity of animal and human studies in the risk assessment and regulatory decision process.
- The successful application of new methodologies will require outreach to identify and address concerns.
- Expectations and applications will need to be realistic, scientifically valid, and defensible.

Foundation for Progress

- We have a lot of work to do…
- Gaining acceptance and moving beyond research findings to practice will take a concerted effort to demonstrate the utility and applications, and define the limitations.
- New toxicology will not replace the need for exposure science, traditional tox testing, epidemiology, and surveillance in public health
- New methodologies in risk assessment, toxicity testing, and biomonitoring can provide a framework for the public health applications and improved decisions

The Public Health Possibilities

Near Term Food Safety Applications	Future Research and Applications
Problem formulation Hazard Identification/exposure assessment Mechanisms of action Disease endpoints of concern Design of epidemiologic/ toxicological investigations Weight of evidence	Dose response assessment Identification of most susceptible Cumulative effects/mixtures Linkage to disease/causality Risk characterization Policy and prevention applications

Bottom Line

- The future of food safety will depend upon new tools to identify hazards, understand the impacts of exposures, and guide policies.
- The next generation of risk assessment and toxicity testing can provide a **bridge** between the reaction based regulatory approach and the prevention based public health approach.
- Strategies to advance the application and translation of the science will be key to establishing credible food policies.
- The promise is great, but so too are the challenges.