OUTLINE

• Introduction
• Legislative tools in EU/US on food safety
• Risk assessment
• Decision Making Process
• Risk communication
• Challenges

Introduction

200-240 Volts
50 Hertz

110-120 Volts
60 Hertz

European Food Safety Authority
The European Union/United States
Aprox. 500 / 325 Mio Habitants

23 Official languages
1 Language English (+Spanish)

What's so good about the government?
Poll says people want services, but are wary of how tax dollars are used

BY JON COHEN and DAN BALZ

If there is an overarching theme of election 2010, it is the question of how big the government should be and how far it should reach into people's lives.

Americans have a more negative view of government today than they did a decade ago, or even a few years ago. Most say it focuses on the wrong things and lack confidence that it can solve big domestic problems; this general anti-Washington sentiment is bolstered by the fact a potential Republican takeover of Congress next month.

But ask people what they expect the government to do for themselves and their families, and a more complicated picture emerges.

A new study by The Washington Post, the Henry J. Kaiser Family Foundation and Harvard University shows that most Americans who say they want more limited government also call Social Security and Medicare "very important." They want Washington to be involved in schools and to help reduce poverty. Nearly half want the government to maintain a role in regulating health care.

The study suggests that come January, policymakers in both parties
Legislative tools in EU/US on food safety
International approach

- **International trade**
  - WTO (Uruguay Round)- SPS agreement (1995)

  - Goal: To avoid use of sanitary & phytosanitary measure as unjustified barriers to trade, while recognizing the right of countries to protect human, animal and plant life and health

  - scientifically based & transparent measures using Risk assessment as set by CODEX, OIE and IPPC.

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Main Elements of Food Safety Modernization Act (FSMA)

- **Prevention**
- **Inspections, Compliance, and Response**
- **Import Safety**

  - The FSMA builds a formal system of collaboration with other government agencies, both domestic and foreign.

  - Explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals.
3 new principles of US/White House for Smart Regulation:

- Human Behavior in achieving goals
- Cost benefits according to science and economics but considering
  - i) Interest of future generations
  - ii) Distribution consideration of the benefits,
  - iii) Fairness,
- Transparency involving the public in the knowledge of the regulation

The EU Food Safety regulatory framework

- Feed Additives 1831/2003/EC 429/2008/EC
- Contaminants 1881/2006/EC Residues -96/22;96/23;2377/90 Pesticides 396/2005/EC (91/414)
- Additives 1332/2008 Flavourings 1334/2008
- Additives 1333/2008
- Pesticides 396/2005/EC (91/414)
- Enzymes
- Additives 1332/2008
- Flavourings 1334/2008
- Feed Additives 429/2008/EC 1831/2003/EC
- Plant Health 2000/29 575/2006/EC
- Animal Health including zoonosis and Welfare
- Food contact materials 1935/2004/EC
- Nutrition Lab. 90/496 Health Claims 1924/2006
- EU Food legislation EFSA and RASFF Regulation 178/2002
- Food contact materials 1935/2004/EC
- Novel Food 258/2005/EC
- Nutrition Lab. 90/496 Health Claims 1924/2006
- GMO 1829/2003
### Food safety Legislation:
**Overview of U.S. & EU**

<table>
<thead>
<tr>
<th>U.S.</th>
<th>Areas of responsibility</th>
<th>Risk management</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA/CFSAN</td>
<td>Food Allergies, Food toxicology and microbiology</td>
<td>Legislative proposals to EU member states, European Council and EU parliament.</td>
</tr>
<tr>
<td>FDA/CVM</td>
<td>Feed additives, Vet. Medicines</td>
<td>Stakeholder meetings &amp; impact assessment</td>
</tr>
<tr>
<td>USDA/FSIS</td>
<td>Microbiological risks in meat,</td>
<td>Database coordination with Member States Epidemiology</td>
</tr>
<tr>
<td>EPA /NIEHS</td>
<td>Pesticides, Env. Toxicology</td>
<td></td>
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<td>CDC and NIH/ NTP/NIEHS</td>
<td>Public health &amp; Food borne Diseases (AMR)</td>
<td></td>
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</tbody>
</table>

**FDA/ ORA, USDA/FSIS** Control their respective types of foods as legally competent

**EU Member States + FVO (SANCO) auditing EU and Third countries**

### Risk Assessment

- **Risk Assessment**
  - EFSA
    - Hazard identification
    - Hazard characterization
    - Exposure assessment
    - Risk characterisation

- **Risk Management**
  - European Commission
    - Assess policy alternatives
    - Select and implement appropriate options

- **Risk Communication**
  - EFSA+EC
    - Information - Opinions
Interagency RA Consortium member agencies (HHS/USDA/EPA …)

<table>
<thead>
<tr>
<th>Agency Name</th>
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<tbody>
<tr>
<td>Centers for Disease Control and Prevention (CDC)</td>
</tr>
<tr>
<td>Department of Defense, U.S. Army Veterinary Services (DOD/YSA)</td>
</tr>
<tr>
<td>Department of Defense, U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM)</td>
</tr>
<tr>
<td>Office of Research and Development (EPA/ORD)</td>
</tr>
<tr>
<td>Environmental Protection Agency, Office of Water (EPA/OW)</td>
</tr>
<tr>
<td>Center for Food Safety and Applied Nutrition (FDA/CFSAN)</td>
</tr>
<tr>
<td>Center for Veterinary Medicine (FDA/CVM)</td>
</tr>
<tr>
<td>National Center for Toxicological Research (FDA/NCTR)</td>
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<tr>
<td>Office of Women’s Health (FDA/QWH)</td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
</tr>
<tr>
<td>National Marine Fisheries Service (NMFS)</td>
</tr>
<tr>
<td>Agricultural Research Service (USDA/ARS)</td>
</tr>
<tr>
<td>Animal and Plant Health Inspection Service (USDA/APHIS)</td>
</tr>
<tr>
<td>Cooperative State Research, Education, &amp; Extension Service (USDA/CSREES)</td>
</tr>
<tr>
<td>Economic Research Service (USDA/ERS)</td>
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<tr>
<td>Food Safety Inspection Service (USDA/FSIS)</td>
</tr>
<tr>
<td>Food and Nutrition Service (USDA/FNS)</td>
</tr>
<tr>
<td>Office of Risk Assessment and Cost Benefit Analysis (USDA/ORACBA)</td>
</tr>
</tbody>
</table>

EFSA’s origins

EFSA established in 2002 as an independent source of scientific advice and communication on risks associated with the food chain, to:

- improve EU food safety
- help ensure a high level of consumer protection
- restore and maintain confidence in the EU food supply

EFSA started its scientific work in 2003

2003 - 2010 more than 2500 scientific outputs

Over 450 Staff, 60% engaged in science

Budget 2011 of 77.3 Million Euros
What EFSA does

EFSA’s tasks

1. Provide independent scientific advice, opinions, information, and technical support for Community legislation and policies
2. Collect and analyse data to allow characterisation and monitoring of risks
3. Promote and coordinate development of uniform risk assessment methodologies
4. Independent risk Communication related to all aspects of EFSA’s mandate

EFSA structure

Management Board + Advisory Forum + EFSA Staff + Scientific Committee and Panels

= European Food Safety Authority
EFSA Expert Data Base EU/US & World distribution

INCLUDED EXPERTS BY 09.2011: 2886

AUSTRIA; 79
BELGIUM; 107
BULGARIA; 40
CYPRUS, 9
CZECH REPUBLIC, 30
DENMARK, 99
ESTONIA, 5
FINLAND, 59
FRANCE, 216
GERMANY, 283
GREECE, 88
HUNGARY, 33
ICELAND, 1
IRELAND, 63
ITALY; 394
LATVIA, 18
LITHUANIA, 14
LUXEMBOURG, 6
NORWAY, 38
NETHERLANDS; 185
UNITED KINGDOM; 356
SWITZERLAND, 53
SWEDEN, 84
SPAIN; 175
SLOVAKIA, 26
SLOVENIA, 28
ROMANIA, 92
PORTUGAL, 82
POLAND, 38
NORWAY, 38
NETHERLANDS, 185

OTHER INCLUDED EXPERTS BY 09.2011: 232

ARGENTINA, 2
AUSTRALIA, 10
BANGLADESH, 1
BOSNIA AND HERZEGOVINA, 1
BRAZIL, 1
BHUTAN, 1
BOSNIA AND HERZEGOVINA, 1
BULGARIA, 40
CHINA, 3
CROATIA, 12
CUBA, 2
EGYPT, 1
ETHIOPIA, 1
FRANCE, 216
GERMANY; 283
GREECE, 88
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How does EFSA work?

European Commission
European Parliament
Member States
EFSA ("self mandate")

Question?
Risk Assessment
Opinion
Risk Communication
Risk Management
Consumers
Media
Industry
Professionals
EFSA’s scope - from farm to fork

- Plant Health
- Plant Protection
- Genetically modified organisms
- Biological hazards
- Animal health and welfare
- Animal feed
- Chemical contaminants
- Food additives
- Food packaging
- Nutrition

How does EFSA’s Panel work?

Panel

Mandate

Working Group

Opinion adopted
Steps in a risk assessment:

- Information gathering and decision on the approach
- Initial examination of question
- Establishment of risk profile
- Determine resources & response timeline

Evaluate and communicate results:
- Peer review of model
- Discuss results and address additional requests
- Generate report
- Feedback on implementation

Conduct a risk assessment:
- Establish risk pathways
- Collect data
- Statistical data analysis
- Qualitative RA
- Quantitative RA

Risk assessment

Number of opinions

<table>
<thead>
<tr>
<th>Year</th>
<th>2003</th>
<th>2005</th>
<th>2007</th>
<th>2009</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>0</td>
<td>100</td>
<td>200</td>
<td>600</td>
</tr>
</tbody>
</table>
Chemical Risks......

Developmental Origins of Disease: Developmental Stressors Lead to Disease Throughout Life

Environmental Exposures

Gestation | Childhood | Puberty | Reproductive Life | Middle Life | Later Life

FIGURE 2: Incidence of Campylobacter Infections by Age, 2008

FIGURE 5: Incidence of Listeria monocytogenes Infections by Age, 2008

FIGURE 3: Incidence of E. coli O157:H7 Infections by Age, 2008

FIGURE 6: Incidence of Salmonella Infections by Age, 2008


### Food safety Risk Assessments in U.S. & EU/ EFSA

<table>
<thead>
<tr>
<th>U.S.</th>
<th>Areas of risks</th>
<th>EFSA Risk Assessment Panels</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA/CFSAN</td>
<td>Food Allergies, Food toxicology and microbiology</td>
<td>FOOD ADDITIVES (2 panels)</td>
</tr>
<tr>
<td>FDA/CVM</td>
<td>Feed additives</td>
<td>FEED ADDITIVES CONTAMINANTS</td>
</tr>
<tr>
<td>USDA/FSIS</td>
<td>Microbiological risks in meat, eggs</td>
<td>BIOHAZARDS</td>
</tr>
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<td>PLH &amp; AHAW</td>
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<td>NUTRITION/ CME</td>
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<tr>
<td>FDA/ ORA</td>
<td>Control their respective types of foods as legally competent</td>
<td>Outside EFSA’s remit</td>
</tr>
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<td>USDA/FSIS</td>
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<td></td>
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</table>

### Decision Making process

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   - Hazard identification
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   - Exposure assessment
   - Risk characterisation

2. **Risk Management**
   - European Commission
   - Assess policy alternatives
   - Select and implement appropriate options

3. **Risk Communication**
   - EFSA+EC
   - Information - Opinions
Risk analysis: Decision process
EU Food Safety Structure

- EFSA
- DG SANCO (FVO)
- Commission
- Parliament
- Council

Risk communication

- 2010 Eurobarometer survey report on risk perception in the EU
- The majority of Europeans associate food and eating with enjoyment.

Introduction
EU consumer concerns on food

Chemical products, pesticides and other toxic substances are the major concerns

Source: 2010 Eurobarometer on Food-related Risks

QF3: Could you tell me in your own words, what are all the things that come to your mind when thinking about possible problems or risks associated with food and eating?

Who do consumers trust?

QF5: Suppose a serious food risk were found in a food you eat regularly such as fish, chicken or salad. How much confidence would you have in the following sources to give you accurate information about this risk?
Communication & Policies

A sirloin a day?
While the U.S. Department of Agriculture says our plates should be half filled with fruits and vegetables, most of its subsidies go toward protein, particularly grain to feed cows, pigs and chickens.

Approximate subsidies for feed crops, 1996 to 2010

<table>
<thead>
<tr>
<th>Category</th>
<th>Subsidies (billion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein and dairy</td>
<td>$91.6</td>
</tr>
<tr>
<td>Grain</td>
<td>$37</td>
</tr>
<tr>
<td>Sweeteners and additives</td>
<td>$12</td>
</tr>
<tr>
<td>Edible oils</td>
<td>$1.6</td>
</tr>
<tr>
<td>Total</td>
<td>$116.8</td>
</tr>
</tbody>
</table>

U.S. may talk fruit and fiber, but it spends big on meat

BY Arthur Allen
Special to The Washington Post

Challenges
Challenges in RA methodologies:

i) Safety assessment of chemicals, new toxicological paradigm shift & exposure assessment data
ii) New technologies (Nanotech)
iii) Genomics
iv) Use and sharing DB, modeling and impact of globalization
v) Reevaluate Quant & Qualitative RA

EFSA: Challenges ahead

- **Workload/resources**: increasing number of questions, more applications and re-evaluations, new areas of work
  - Need of leverage
- **Ring-fence resources for ongoing public health work** (zoonoses, antimicrobial resistance, chemical contaminants, etc)

- Sustainability of Panel structure and Attracting staff and external experts
- External evaluation of EFSA
- EC proposal on fees?
Noncommunicable diseases' deaths on rise globally

Food Chain
Challenges for Risk Assessment

Vehicle emission
Agricultural practices
Landfills
Industrial emissions and effluents
Crops
Livestock
Seafood
Processing
Storage
Distribution
Retail
Cooking

PPR PRAPER
GMO PLH
CEF ANS
AHAW BIOHAZ FEEDAP
BIOHAZ CONTAM
CONTAM
NDA
“...connecting the dots....”
(Steve Jobs)

Thank you for your attention

Questions ?