MULTIDISCIPLINARY RISK ASSESSMENT AND FOOD SAFETY DECISION-MAKING

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Istanbul, 8 May 2015

OUTLINE



- Introduction to Unilever
- Codex Risk Analysis approach for governments
- Unilever Food Safety principles and processes
 - Food Safety Assurance from idea to market
 - Independent "Integrated" Risk Assessment
 - Risk assessment case study
- Risk Communication challenge

•Unilever is one of the world's leading suppliers of "fast-moving consumer goods".

自力

净含量:1千克

高浓度洗衣池

田川

Our products are sold in over 190 countries and used by 2 billion consumers every day.

A Good natural source of OMEGA 3

Light

MAYONNAISE

4

SELECTED

sheer

Infusion

NEW

BODY LOTION

6.8 fl. oz. (200ml)

STRATYS 3

wilight

80

Rama

Original

808

It's the taste

tips

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mighty



CLE/

清扬

男士 去屑洗物

日本進他が物料

TONENS

Chocolate Macadamia AFLAVOUR WITH A MISSION ICE CREAM

S ALL KNOWN GER

Chocolate & Vanilla Ice Creams with Chocolatey Covered Macadamia ki

BEN & JERRY'S

ESECANE PLAYOSED I

FAST FACTS - 2014



EMERGING MARKETS NOW REPRESENT

TURNOVER OF €48.4 BILLION TEND OF 2014 57%

€1 BILLION INVESTED IN R&D WORLDWIDE

172,000

EMPLOYEES AT THE END OF THE YEAR

UNILEVER'S PORTFOLIO OF CATEGORIES





OUR €1 BILLION BRANDS

13 Unilever brands have a turnover of €1 billion or more





SIX MAJOR R&D SITES

- more than 6,000 R&D professionals
- 92 locations globally with deploy R&D teams

Port Sunlight UK



Colworth UK



Vlaardingen The Netherlands









Bangalore India



Shanghai China



Codex Risk Analysis approach for governments

FAO/ WHO Food Standards

CODEX alimentarius



Global authority for international guidelines, standards, and recommendations on food safety

CODEX ALIMENTARIUS

- International food standards organization, established in 1963 by FAO and WHO
- Codex standards formally recognized by WTO (SPS and TBT Agreements (1995))
- 186 member States (plus EU).
- Active participation of 219 IGO/NGOs
- "Covering 99% of the world's population"

Unilower

CODEX ALIMENTARIUS



- Establishes international food safety standards to:
 - protect the health of consumers
 - ensure fair practices in trade
- Issues food safety management "principles" through its standards and guidelines
- National authorities can choose to implement Codex standards and guidelines in their regulation/law

CODEX ALIMENTARIUS



"Modern food safety management developed by Codex"

- Developed over the last 50 years an evolution!
- In many countries, food safety management evolved from control by governments to food safety management by industry.
- Evolving from "testing for safety" to "safety assurance", based on using Good Practices & HACCP principles by industry.
- Evolving from unique national standards to internationally harmonized standards.
- Evolving from focus on hazard-based decision-making to advocating risk-based decision-making.

FOOD SAFETY IS A PARTNERSHIP



GOOD PRACTICES ARE FOUNDATIONAL



- Food safety assurance is founded on Good Practices
 - Good Hygienic Practices
 - Good Manufacturing Practices
 - Good Agricultural Practices
- Concerns prevention and control measures for hazards (biological, chemical, physical) generally relevant for a manufacturing facility

GHPs/GMPs/GAPs

HACCP IS ESSENTIAL

- Hazard Analysis Critical Control Point (HACCP): a risk-based and systematic approach for food safety assurance
- All hazards (biological, chemical, physical) relevant for a specific food operation (e.g. product/processing-line) are considered and appropriate controls are put in place for significant hazards

GHPs/GMPs/GAPs

HACCP

WHAT TYPICALLY CAUSES ISSUES WITH FOOD?



RISK ANALYSIS: THE FRAMEWORK



- Risk Analysis:
 - Risk Management
 - Risk Assessment
 - Risk Communication
- Triggered by World Trade Organisation (WTO)
- Advocated by many governments and intergovernmental organisations (FAO, WHO)



RISK ANALYSIS: CODEX TIMELINE





RISK ANALYSIS: THE CODEX PROCESS







RISK ANALYSIS: SCIENTIFIC ADVICE OUTPUT

- Meeting reports
- Technical reports
 - Microbiological Risk assessments
 - Monographs for specific chemical in foods
 - Toxicological evaluations
- Summary reports
 - Rapid information dissemination for risk managers and less technical readers

Seffy evaluation of certain bod additives The seffy and the seffy additional sefere seffy additional sefere seffy additional sefere sefe	UNDERSON DEPOSITOR 913 EVALUATION OF CERTAIN FOOD ADDITIVES	Compendium of food additive specifications Volume 1	PAD POD AN HUTHIN PAREN 52/1	Pesticide residues in food - 2002 Joint FAO / WHO Meeting on Pesticide Residues	WHOLE SEALS	Hazard characterization for pathogens in food and water	Enterobacter sakazakil and other microorganisms in newstared intart formula
	Fiftysinth report of the Joint FAO/WHO Expert Committee on Food Address			EVALUATIONS 2002			
PCS Texture of Connect Barry	And the second		JECFA	IPCS International Programme on Chemical Safety	WORLD MEALDH ORGANIZATION	NH ()	JEL 0

RISK ANALYSIS: APPLICATION



Risk analysis - a tool that all governments/food safety authorities can use to achieve better food safety outcomes and improve public health

It can be used to:

- develop an estimate of the risks to human health and safety,
- identify and implement appropriate measures to control the particular risk(s),
- support and improve the development of standards

RISK ANALYSIS: THE FRAMEWORK



"Risk Management" driving "Risk Assessment"

- What is the specific issue? Is there really a risk?
- What information from a risk assessment would facilitate decisionmaking of risk manager?
- How best to mitigate realistic risks. What are the options?

Risk Assessment follows a structured and scientific approach to evaluate risks in four steps:

- Hazard Identification
- Hazard Characterization
- Exposure Assessment
- Risk Characterization



PROCESS STEPS: MICROBIOLOGICAL RISK ASSESSMENT



Hazard identification

• Identify food-borne pathogen of interest

Hazard Characterization

• Determine the dose-response relationship (volunteers, animals) when possible, or investigate outbreaks

Exposure Assessment

 Calculate the exposure to the hazard at consumption from hazard level and consumption volume/frequency

Risk Characterization

 Combine exposure and dose-response to obtain an estimation of the prevailing risk level or rate of illness

RISK ANALYSIS: ROLES & RESPONSIBILITIES



- Risk Manager:
 - Codex Committee for Food Hygiene (CCFH)

- Risk Assessor:
 - Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA)

RISK ANALYSIS: JEMRA OUTPUT













Risk assessment of *Listeria monocytogenes* in ready-to-eat foods



MRA reports



"how to" guidelines



Guidelines on principles/process

RISK ANALYSIS: JEMRA RISK ASSESSMENTS



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Food	and	Agr	icul	ture

Organization of the United Nations

for a world without hunge

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Food safety & quality

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Events & projects

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Capacity development

Scientific advice

Calls for data and experts

Microbiological risks and JEMRA

> Risk assessments Risk management Guidelines

Technology transfer

- Microbiological hazards associated with fresh produce
- Viruses in foods
- Enterohaemorrhagic *Escherichia coli* (EHEC) in meat and meat products
- Vibrio spp. in seafoods
- Salmonella in eggs and broiler chickens
- Campylobacter spp. in broiler chickens
- Cronobacter spp. and other micro-organisms in powdered infant formula
- Listeria monoctogenes in ready-to-eat foods

http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/risk-assessments/en/

RISK ANALYSIS: MRA USE IN STANDARDS



page 1



CX/FH 04/10-Add.3

codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS



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Agenda Item 10 (c)

CX/FH 04/10-Add.3 December 2003

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-sixth Session Washington DC, United States of America, 29 March – 3 April 2004

DISCUSSION PAPER ON RISK MANAGEMENT STRATEGIES FOR SALMONELLA SPP. IN POULTRY

Prepared by Sweden with the assistance of Australia, Brazil, Canada, China, Czech Republic, Denmark, France, Germany, Netherlands, New Zealand, Thailand, USA, the European Commission and ALA

BACKGROUND

At its 34th session in Bangkok, the Codex Committee on Food Hygiene was informed about the outcome of the FAO/WHO expert consultations on risk assessment on *Listeria* and *Salmonella*. It was noted that there was a need to develop a discussion paper on Risk Management Strategies for *Salmonella* spp. in broilers based upon the risk assessment document (FAO Food and Nutrition Paper 72). The committee agreed that a drafting group, led by Sweden should develop a discussion paper to be considered at its next Session. The drafting group met in Uppsala, Sweden, the 25-26th of February 2002.

RISK ANALYSIS: MRA USE IN STANDARDS



JEMRA MRAs	Codex standards			
<i>Listeria monocytogenes</i> in ready-to-eat (RTE) foods	General principles of food hygiene for management of <i>L. monocytogenes</i>			
Cronobacter spp. (E. sakazakii) in infant formula	Recommended international code of practice for foods for infants and children			
Vibrio spp. in seafood	Risk management strategies for Vibrio spp. in seafood			
Salmonella spp. in broiler chickens and eggs	Risk management strategies for Salmonella and Campylobacter in			
<i>Campylobacter</i> spp. in broiler chickens	poultry			

RISK ANALYSIS: ADOPTED BY MANY GOVERNMEN

- Unilever
- To assess the level of <u>risk</u> in a (sub-)population due to a specific hazard associated to a particular food on the market, produced by (many) businesses
- To decide on the <u>acceptability</u> of an estimated risk
- To evaluate interventions that may <u>eliminate</u> the estimated risk or <u>reduce</u> it to an acceptable level

• Role of Industry assuring safety of on-market products:

Industry has to implement proper product & process designs and manage these effectively during production (i.e. GHP/HACCP) to meet the food safety benchmarks set by governments (e.g. general food law, standards, criteria)

CODEX SAFETY AND RISK PRINCIPLES

- Safety means "no harm"
- 100% safety does not exist (i.e. no "zero risk")
- There is always a *risk* that a certain harm is caused by a specific hazard
- Risk assessment estimates the harm caused (probability + severity)
- Governments decide on risk acceptability
- Risk analysis provides a framework for assessing, managing and communicating the risk





FAO/ICD/WHO Basic awareness course of MRA, Topic 1, http://www.sp-lab.net/fao/MRA/

MODERN FOOD SAFETY MANAGEMENT MAP





Moderns risk-based food safety management well implemented and practiced

Unilever Food Safety principles and processes

- Food Safety Assurance

FOOD SAFETY ASSURANCE PRINCIPLES



- Safe performance of foods on the market needs to be assured.
- Industry uses standards / guidelines from competent authorities to benchmark product safety.
- Preventative approaches key in product innovation and marketing.
- Safe performance on the market needs to be monitored and actions need to be taken when issues arise.

UNILEVER'S SAFETY GOVERNANCE



Set out in "Code of Business Principles"

- Consumers: Products safe for their intended use
- Employees: Safe & healthy working conditions
- *Environment*: Environmental care built in product/use
- Innovation: Sound science / rigorous product safety standards

Product Safety is based on: Safety by Design & Execution



HOW DO WE MAKE SAFE FOOD?



Design of a safe product by R&D

Execution of safe design by factories

- Monitor safe market performance
- Manage issues




"SAFE BY <u>DESIGN</u> & EXECUTION"



Product safety is "designed in" into innovations

A) Specifically understanding, e.g.:

- ingredients, final formulation, external factors
- processing, handling
- post-process contamination
- intended use and intended user (consumer group)



B) Considering the available safety "benchmarks":

- Regulations (e.g. standards, limits, criteria)
- Guidelines from governments
- Industry standards/guidelines
- "History of safe use data"



"SAFE BY <u>DESIGN</u> & EXECUTION"



Steps in establishing a safe design:

- Identification of all realistic hazards
- Defining preventive measures
- Establishing effective controls for significant hazards
- Validating control measures, from lab-scale to pilot scale

SAFE DESIGN: SCALED-UP VALIDATION





"SAFE BY DESIGN & <u>EXECUTION</u>"

Safe Product and Process designs are executed by:

- Factory Level
 - Validating designs at operational-scale
 - Implementing designs in good management systems (GHP & HACCP)
 - Verifying ongoing control during manufacture
 - External audits to validate operation/management
 - Running Tracing & Tracking system
- Market Level
 - Monitoring on market performance and new insights
 - Issue Management
 - Reviewing safe design & execution as appropriate



"SAFE BY DESIGN & <u>EXECUTION</u>"

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Needs to cover all types of hazards

Microbiological hazards

• e.g. Campylobacter, Salmonella, Listeria monocytogenes

Chemical Hazards

- Industrial and environmental contaminants (e.g. heavy metals)
- Biologically derived contaminants (e.g. mycotoxins)
- Improperly used agrochemicals (e.g. pesticides)
- Improperly labelled food additives (e.g. allergens)

Physical Hazards

• e.g. Choking hazards, hazards causing burns or cuts

Unilever Food Safety principles and processes

Independent "Integrated" Risk Assessment

UNILEVER'S INNOVATION FUNNEL





Confirming Safety (SEAC)

Assessing risk (SEAC)

SEAC IS BASED IN THE UNITED KINGDOM



ROLE OF SEAC

Independent safety assessments as part of assurance of human safety and environmental care

- Toxicology
- Microbiology
- Contaminants
- Chemistry
- Physical Hazards
- Occupational Hygiene
- Occupational & Process Safety Environmental lifecycle
- Environmental management systems
- Sustainability

Risk Assessment to inform Risk Management

Design safety



Safe performance on the marketplace



CAN WE USE A NEW INGREDIENT SAFELY?



Risk-based approach:

can we use x percent of ingredient y in product z?







CAN WE USE A NEW INGREDIENT OR PROCESS SAFELY?



Will it be safe

- for our consumers?
- for our workers?
- for the environment?





RISK ASSESSMENT FOR ALL AREAS



Multidisciplinary use of Risk Assessment in SEAC:

- Chemical Risk Assessment
- Microbiological Risk Assessment
- Occupational Risk Assessment
- Environmental Risk Assessment

RISK-BASED APPROACH TO EVALUATE DESIGN SAFETY OF INGREDIENTS

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SEAC PROVIDES AN INTEGRATED RISK ASSESSMENT

Integrated COE Safety and Environmental Sustainability Impact solutions underpinned with Value Chain Thinking



Category R&D and SC Inputs are required across the value chain for our COES risk and impact assessments

Consumer, Occupational, Environmental & Sustainability (COES) **exposure scenarios & data**

SEAC Outputs and early engagement across the value chain enable us to manage risks / impacts around complex Unilever innovations



Environmental Sustainability Assessments of impacts of products and processes

Unilever Food Safety principles and processes

 Risk assessment case study



SIMULATING 'SAFE' SHELF-LIFE FOR NEW MARKETS



MICROBIOLOGICAL RISK ASSESSMENT



Newly designed "White sauce" culinary product

Key product characteristics

- Heat treatment > 90°C-10min, in-pack
- $pH= 6.0, A_w=0.997$, Stored chilled

Relevant hazard?

- Bacillus cereus
- Benchmark: 10⁵ cfu/g

Design question?

 The likely failure rate to meet benchmark on markets that differ in supply chain & consumer home chill temperatures

Disciplines involved

- Microbiologists
- Food Scientists
- Risk Assessors / Analysts
- Mathematical modellers

EXPOSURE ASSESSMENT: KEY ELEMENTS



HEAT TREATMENT ASPECTS/INACTIVATION





Profiles of Static Temperature (k) (Time=2.1000e+03)

Nov 12, 2004

Variability in spore heat resistance

Variability in heat impact

HEAT TREATMENT ASPECTS/SURVIVORS





Number of surviving spores in contaminated packs

J.-M. Membré, A. Amézquita, J. Bassett, P. Giavedoni, C. de W. Blackburn, L.G.M. Gorris. 2006. A probabilistic modeling approach in thermal inactivation: estimation of postprocess Bacillus cereus spore prevalence and concentration. Journal of Food Protection, 69: 118-129.

TEMPERATURES IN COLD-CHAIN



PREDICTED FAILURE RATES ON DIFFERENT MARKETS FOR DIFFERENT TEMPERATURE SCENARIOS



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VALUE OF RISK ASSESSMENT MODELLING



- Strengthens food safety assurance, by improving "safety by design"
- Results very informative for internal decision-making:
 - Informs on "risk" factors
 - Points out key data-gaps
 - Defines window for testing / validation
- Running what-if scenario's fast and saves resources

Risk Communication challenge

CONSUMER TRUST IS LOW



- Consumers are not confident that food is safe
- Despite efforts of government to have strong, internationally harmonized approaches to food safety control and management
- Despite all the science that is underpinning product innovation

Food Safety seems "not under control".....



The Washington Post said BSE would

U.S. facing 'grievous harm' from chemicals in air, food, water, panel says (May 7, 2010)

Tannellon

98% Of Apples Have **Pesticide Residues, USA**

Babies are being born pre-polluted



Eat at Your **Own Risk**



00,000 people

Is Anything Safe

Joe Klein Take On the GOP's

The Real Cost of Cheap Food

On Why They've On the GOP Done Nothing Wrong Scare Tactics

How two tainted grapes triggered a panic about what we eat

NT E.

MEDIA "SCIENTIST"



Various sources, Google Images

WHY CAN'T FOOD JUST BE SAFE?



- Each day consumers ingest a wide range of food; putting their faith in industry and government
- Significant erosion of general public knowledge about food safety:
 - Understanding of where food comes from and how it is made
 - Their contribution to safe food (Good handling practices)
 - Eating a varied diet / physical activity
- Consumers do not have the expert knowledge of risk managers / scientists
- Scientists don't all agree
- Risk managers may be poor at communicating acceptable risk





RISK ASSESSMENT – DIFFERENCES IN APPROACHES



Expert	Public
Scientific	Intuitive
Probabilistic	Yes / No
Acceptable risk	Safety
Changing knowledge	Is it or isn't it?
Comparative risk	Discrete events
Population averages	Personal consequences

CONSUMER RISK ATTITUDE



- Concerned, even when hazards are not relevant
- Overestimate some risks (technological risks)
- Underestimate other risks (lifestyle risks)

Example in case:

• E-numbers used for additives and commonly found on food labels throughout the European Union.



E-NUMBERS REPRESENT SAFE ADDITIVES

- E numbers are codes for substances that can be used as food additives within the EU. The "E" stands for "Europe".
- Safety assessment and approval are the responsibility of the European Food Safety Authority (EFSA)¹.
- E-numbers therefore represent additives that the EU Member States deem to be safe
- The Chemicals that E-numbers represent may be natural ingredients or artificial chemicals, categorized by function

4.1 E100–E199 (colours)
4.2 E200–E299 (preservatives)
4.3 E300–E399 (antioxidants, acidity regulators)
4.4 E400–E499 (thickeners, stabilizers, emulsifiers)
4.5 E500–E599 (acidity regulators, anti-caking agents)
4.6 E600–E699 (flavour enhancers)
4.7 E700–E799 (antibiotics)
4.8 E900–E999 (glazing agents and sweeteners)
4.9 E1000–E1599 (additional chemicals)





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HOW WOULD A LABEL LOOK LIKE?

AN ALL-NATURAL BANANA

INGREDIENTS OF AN ALL-NATURAL EGG



INGREDIENTS: WATER (75%), SUGARS (12%) (GLUCOSE (48%), FRUCTOSE (40%), SUCROSE (2%), MALTOSE (<1%)), STARCH (5%), FIBRE E460 (3%), AMINO ACIDS (<1%) (GLUTAMIC ACID (19%), ASPARTIC ACID (16%), HISTIDINE (11%), LEUCINE (7%), LYSINE (5%), PHENYLALANINE (4%), ARGININE (4%), VALINE (4%), ALANINE (4%), SERINE (4%), GLYCINE (3%), THREONINE (3%), ISOLEUCINE (3%), PROLINE (3%), TRYPTOPHAN (1%), CYSTINE (1%), TYROSINE (1%), METHIONINE (1%)), FATTY ACIDS (1%) (PALMITIC ACID (30%), OMEGA-6 FATTY ACID: LINOLEIC ACID (14%), OMEGA-3 FATTY ACID: LINOLENIC ACID (8%), OLEIC ACID (7%), PALMITOLEIC ACID (3%), STEARIC ACID (2%), LAURIC ACID (1%), MYRISTIC ACID (1%), CAPRIC ACID (<1%)), ASH (<1%), PHYTOSTEROLS, E515, OXALIC ACID, E300, E306 (TOCOPHEROL), PHYLLOQUINONE, THIAMIN, COLOURS (YELLOW-ORANGE E101 (RIBOFLAVIN), YELLOW-BROWN E160a), FLAVOURS (3-METHYLBUT-1-YL ETHANOATE, 2-METHYLBUTYL ETHANOATE, 2-METHYLPROPAN-1-OL, 3-METHYLBUTYL-1-OL, 2-HYDROXY-3-METHYLETHYL BUTANOATE, 3-METHYLBUTANAL, ETHYL HEXANOATE, ETHYL BUTANOATE, PENTYL ACETATE), 1510, NATURAL RIPENING AGENT (ETHENE GAS).



INGREDIENTS: AQUA (75.8%), AMINO ACIDS (12.6%) (GLUTAMIC ACID (14%), ASPARTIC ACID (11%), VALINE (9%), ARGININE (8%), LEUCINE (8%), LYSINE (7%), SERINE (7%), PHENYLALANINE (6%), ALANINE (5%), ISOLEUCINE (5%), PROLINE (4%), TYROSINE (3%), THREONINE (3%), GLYCINE (3%), HISTIDINE (2%), METHIONINE (3%), CYSTINE (2%), TRYPTOPHAN (1%)); FATTY ACIDS (9.9%) (OCTADECENOIC ACID (45%) HEXADECANOIC ACID (32%), OCTADECANOIC ACID EICOSATETRAENOIC ACID (3%), EICOSANOIC ACID (2%), DOCOSANOIC ACID (1%), TETRACOSANOIC ACID (1%), OCTANOIC ACID (<1%), DECANOIC ACID (<1%), DODECANOIC ACID (<1%), TETRADECANOIC ACID (<1%), PENTADECANOIC ACID (<1%), HEPTADECANOIC ACID (<1%), TETRADECENOIC ACID (<1%), HEXADECENOIC ACID (<1%) EICOSENOIC ACID (<1%), DOCOSENOIC ACID (<1%), OMEGA-6 FATTY ACID: OCTADECADIENOIC ACID (12%), OMEGA-3 FATTY ACID: OCTADECATRIENOIC ACID (<1%), EICOSAPENTAENOIC ACID (EPA) (<1%), OMEGA-3 FATTY ACID: DOCOSAHEXAENOIC ACID (DHA) (<1%)); SUGARS (0.8%) (GLUCOSE (30%), SUCROSE (15%), FRUCTOSE (15%), LACTOSE (15%), MALTOSE (15%), GALACTOSE (15%)): COLOUR (È160c. E160a), E306, E101; FLAVOURS (PHENYLACETALDEHYDE, DODECA-2-ENAL, HEPTA-2-ENAL, HEXADECANAL, OCTADECANAL, PENTAN-2-ONE, BUTAN-2-ONE, ACETALDEHYDE, FORMALDEHYDE, ACETONE); SHELL (E170), ALSO CONTAINS BENZENE & BENZENE DERIVATIVES, ESTERS, FURANS, SULFUR-CONTAINING COMPOUNDS AND TERPENES.

www.toodnavigator.com/Business/Naturally-opposed-Balancing-newtechnologies-with-consumer-perceptions

CONSUMERS ARE SCARED BY E-NUMBERS

Unilever

- They have no direct knowledge of what the system represents; they don't understand the scrutiny of safety
- They are confronted with information on apparent risks
 - increased incidence of eczema, asthma and allergies
 - Cancer, hyperactivity; decreased learning ability
 - Obesity, and millions of other illnesses
- They are unaware of the benefits / function of additives
- They are confused, getting mixed messages



BUILDING CONSUMER CONFIDENCE





Safety – integral part of Government Standard setting & Industry Innovation process



Risk – a challenge to communicate to the general public, consistently



Trust of consumers – the ultimate target for both government and industry

FOOD FOR THOUGHT





"Something's just not right—our air is clean, our water is pure, we all get plenty of exercise, everything we eat is organic and free-range, and yet nobody lives past thirty."

