CONDUCTING AND USING RESULTS OF RISK ASSESSMENTS IN INDUSTRY

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INTRODUCTION

• Increased opportunities for sub-saharan Africa as a food exporter as well as for local markets
• Regulatory systems for food safety are needed to ensure safe and nutritious food supply for domestic and international markets
• New systems for food safety should be based on sound credible science and conducted to international standards
• As Africa grows, innovation in food science is needed to supply the consumer demand
    - Modern approaches for food safety assessment need to be adopted
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<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Company/Institution</th>
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*Scientific Advisor*
Unilever is one of the world’s leading suppliers of fast-moving consumer goods

4 Business Groups: Personal Care, HomeCare, Foods, Refreshment

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

400 brands – focussed on health & well-being
Unilever (Foods)

€ 1 billion global brands
(total = 14)

South Africa brands
Sustainability is integral to how we do business.
Sustainable growth is the only acceptable model of growth for our business.
USLP sets out how to decouple growth from environment impact, whilst increasing positive social impact.
3 Big goals for 2020:
HELP 1 BILLION PEOPLE IMPROVE THEIR HEALTH & WELLBEING
HALVE ENVIRONMENTAL FOOTPRINT OF OUR PRODUCTS
SOURCE 100% OF AGRICULTURAL RAW MATERIALS SUSTAINABLY
Our ultimate goal:
To deliver safe food
to our consumers!
(in common with other stakeholders)
Safety & Environmental Assurance Centre (SEAC)

• Centre of excellence in safety & sustainability sciences
• Provide authoritative scientific evidence & expertise to identify, assess & manage:
  • Risks for our Consumers, Workers and Environment
    • Safety of products and supply chain technology
  • Environmental Impacts
    • Sustainability of Unilever’s brands, products & supply chain

A 21st Century Approach to Science-Based Safety Risk & Environmental Impact Assessment

68% degrees or higher
27% PhDs
20+ Nationalities
15+ Languages
**Safety assessments**: We use **scientific evidence-based risk and impact assessment methodologies** to ensure that the risk / impact of adverse human health and/or environmental effects from exposure to ingredients used in our products & processing is **acceptably low**.

**Unacceptable Risk**

**Trusted Approach**: transparent, scientifically credible & discuss with stakeholders

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**Acceptable Risk**
Working with Scientific Partners Globally
How we assess food safety
A Risk-Based Approach to Facilitate Safe Innovation

We use scientific evidence-based risk assessment methodologies to ensure that the risk of adverse health and/or environmental effects from exposure to ingredients used in our products is acceptably low.

<table>
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<tr>
<th>Hazard-based</th>
<th>Risk-based</th>
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<tr>
<td>• Check-list compliance</td>
<td>• Expertise &amp; evidence-driven</td>
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<tr>
<td>• Unnecessary testing</td>
<td>• Essential testing only</td>
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<tr>
<td>• Doesn’t consider how product is used</td>
<td>• Product use / exposure determines outcome</td>
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<tr>
<td>• Yes / no decisions</td>
<td>• Transparency &amp; options to manage risks</td>
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<tr>
<td>• Overly conservative</td>
<td>• Uncertainties explicit</td>
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<td></td>
<td>• Facilitate stakeholder discussion</td>
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eg new food ingredient, incident
Establishing safe product design requires understanding:

- Product design and intended use
  - Ingredients, processing, internal/external factors
  - Processing, final formulation, handling
  - Post-process contamination, intended use or user

Key inputs to overall product safety risk assessment

1. Identify & characterise potential chemical & biological hazards
2. Understand consumers’ probable exposure (e.g. dietary intake models)
Consider the available “safety benchmarks”

- Guidelines from competent authorities
- Regulations (e.g., standards, limits, criteria)
- Industry, internal Unilever guidance
“Safe in Execution” Approach for Risk Management

- Safe execution of the safe product design:
  - Validate design: from lab-scale to operational factory-scale
  - Implement design in food safety management systems (using Good Practices, HACCP) ISO22000 → FSSC 22000 Certification in all food manufacturing sites
  - Verify control during manufacture
  - Run tracing & tracking system
  - Monitor & review as appropriate
Examples of food products with health benefits

- **Plant Sterols**
  - Natural components of the diet; lower cholesterol by blocking its absorption in gut
  - Extensive safety package generated & published
  - Worldwide regulatory approvals, including 2 EU Novel Foods approvals + 1 pending

- **Ice Structuring Protein**
  - Proteins found naturally in fish (Ocean Pout)
  - Commercialisation: use yeast to produce larger volumes
  - Key risk for consumer safety is potential to cause allergic reaction
  - Extensive safety package for regulatory approvals
Safe by Design: Safety Assessments of Food-borne Microbial Pathogens

- Extending microbiologically safe innovation space
  - Ready-to-eat cold pressed purees of fresh herbs & spices, ambient stable by formulation
  - Consumer preference: less acidic taste
  - Predictive microbial models and risk assessment approach used to establish an acidity (pH) level which produced a safe formulation and was an acceptable taste from the consumers perspective

- Safe shelf-life assessment for new markets
  - Refrigerated heat-treated pasta sauces
  - Variable cold chain temperatures; opportunities for bugs to grow
  - Probabilistic exposure assessment to evaluate maximum safe shelf-life considering temperature variability in value chain
Some common food ingredients (e.g., milk, egg) can cause food allergy.

Improving the management of consumer safety risks from food allergens is a priority.

Manage risks across the R&D/SC/consumer use continuum:
• Novel Ingredients – robust assessment of potential to cause allergy
• Product Design – exclude allergens where possible
• Supply & Manufacture – minimise cross-contamination
• Product Labelling – declare intentionally added allergens; use precautionary ‘may contain’ only when a real risk to health

Minimising the Risk for Food Allergy whilst giving Consumers Choice
Risk based approaches in food safety & scientific consensus
Food Safety Stakeholders

INDUSTRY
- Marketing
- Carelines
- Complaints

CONSUMERS

NGOs eg ILSI

GOV/ KOFs/ ACADEMIA
- Media channels
- Publications
- Scientific meetings

"science"

Building "trust"
“Science” is the Common Language

- Food is one of the most highly regulated industries in the world
  - Private standards – national – regional – global

- To build trust and assure food safety we need application of common principles and approaches
  - Consistently applied across Industry and Regulatory groups

- Science is our common language
  - Transparent ‘risk-based’ assessments (rather than ‘hazard-’) facilitate both decision making and communication
  - Stakeholders working together on risk based approaches
  - Supporting capability building across the scientific community so that these approaches are used and understood

- ILSI – partner for collaboration of experts from public and private sectors to develop scientific consensus

  science is the ‘bridge’ to develop trust with the consumer
Risk Assessment Principles

- Ensure foods placed commercially on the market are safe for the consumer and do not present undue risk

- Risk $= f(\text{Hazard} \times \text{Exposure})$

- 4 step risk assessment paradigm (NRC, 1983):
  1. Hazard identification
  2. Hazard characterisation
  3. Exposure assessment
  4. Risk characterisation

- A component of Codex Risk Analysis
Risk-based Approach to Evaluating Consumer Safety of Foods

1. Hazard identification
2. Hazard characterization
3. Exposure assessment
4. Risk characterization

Overall safety evaluation – define acceptability and risk management measures
ILSI Europe: Novel Foods Task Force

- ILSI plays an important role in developing practical approaches to how these principles of risk assessment can be applied in ‘real-life’

- Leading edge in developing the safety risk assessment approaches for novel foods (including biotechnology)
  - What is meant by ‘history of safe use?’ (Constable et al 2007)
  - How post market monitoring can be used as a tool in the development of safe novel foods (Hepburn et al 2008)
  - Framework of risk assessment for engineered nanomaterials (Cockburn et al 2012)
TTC is a threshold of exposure for chemicals of known structure, below which no significant risk to human health is expected to exist.

- A major risk assessment approach for human health for low level chemicals
  - Used by various regulatory bodies (WHO (IPCS), FAO/WHO (JECFA), USA (FDA), Japan (MHLW-PMDA), EU (ECHA-REACH, EFSA, EMA, SANCO-SCCS), ICH, CIR)
  - Uses exposure as a driver for the need for testing or not

- ILSI Europe has played a major role in advancing and promoting a broad application of the TTC concept

Recent publications

The Changing Landscape of Toxicology – impact for food safety assessment?

- Rapid advances in scientific knowledge eg genomics and epigenetics
- Technological advances
  - analytical chemistry, high throughput technologies, computational toxicology, systems biology, bioinformatics
  - The era of “big data”
- Scientific value of risk assessments based on animal testing being challenged. However, no suitable alternatives for many endpoints.
- Societal demands to move to non-animal assessment methods eg cosmetics ban in Europe

- Paradigm shift - Toxicology in the 21\textsuperscript{st} Century (NRC, 2007)
- OECD – ‘Guidance document on developing and assessing adverse outcome pathways’ (OECD, 2013)
Challenges

- What are the scientific opportunities that novel approaches present for food chemical risk assessment?
- How can they be best used to support innovation in the food industry?

Response

ILSI Europe in 2014 have set up a Task Force to address this question.

Intend to strengthen links with other scientific organisations eg ILSI HESI, EFSA, EC-JRC, Hamner, OECD, NC3Rs.
Industry and Regulatory Authorities have a common goal to deliver safe food to our consumers.

Science is the common language for stakeholders to engage on food safety. Challenge is for it to be understood by all levels of stakeholders.

Scientific risk based approaches facilitate safe innovation:
- Decision making
- Communication

ILSI facilitates collaboration between scientists from the public and private sector to advance food risk assessment.
Role of industry in adoption of risk based approaches in food safety
Food safety: adoption of risk based approaches

Challenges

- In-depth scientific knowledge of hazards and risks relating to a food
- Understanding the issues (e.g. contamination) across the food supply chain for specific types of foods
- Access to global expertise and capabilities
- Knowledge of evolving regulatory scenarios across the world

How can Industry Contribute?

- Support capability build (country & regional level)
- Provide expertise in key areas related to food safety
  - links with regulatory experts & KOFs, experts in academia and industry
  - access to Global expertise networks
  - identifying gaps in knowledge & solutions
- Provide materials, inputs and resources for training in the areas of product safety and risk assessment
- Provide support to governments and industries from both a scientific and what is ‘best practice’ at an operational level
THANK YOU
SPARES
History of Safe Use – applied to the safety assessment of novel foods

Characterisation
- Biology (origin, genetic diversity)
- Geographic distribution
- Composition
  - Proximate analysis
  - Nutritional profile
  - Chemical hazards (toxicants, allergens, contams)
  - Bioactives

Details of use
- Preparation & processing (fermentation, soaking, peeling, cooking)
- Purpose (food, supplement, pharmaceutical)
- Pattern of consumption
- Intake (ranges, populations)
- Known limitations of use (cultural practice, specific uses)

Previous human exposure
- Which populations – diversity?
- Genetic background, age groups

Health effects
- Evidence from human exposure
  - Known adverse effects
  - Case reports
  - Known precautions
  - Over-consumption
  - Mis-use
  - Specific sub-populations

Potential hazards
- Toxicology data
- Nutritional data
- Allergens
- Known contaminants
- Bioactives eg phytoestrogens

Post Launch Monitoring

**Definition:** A hypothesis driven, scientific methodology for obtaining information through investigations relevant to the safety of a (novel) food after market launch (ILSI, 2008)*.

A tool for:
- Confirming that the **product use** is as **predicted** on the pre-market assessment
- Provide reassurance that **effects observed** in the pre-market assessment occur with **no greater** frequency or intensity in the post market phase than anticipated
- Investigate the **significance** of any **adverse effects** reported by **consumers** after market launch

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**Safety Assessment of Engineered Nanomaterials**


**Summary**

- Physicochemical properties are fundamental and determine the extent of testing
- Materials of highest concern are likely to be non-biodegradable persistent particles
- Exposure – dosimetry is complex – assume 100% bioavailability as a default
- A tiered approach to testing is proposed
Threshold of Toxicological Concern

- **Foods**
  - JECFA (1997) – adopt approach to establish safety of flavouring substances
  - ILSI Europe* endorse use of TTC for low level food contaminants/ingredients

- **Pharma**

- **Cosmetics**
  - Colipa (2006) - expert group looking at TTC for cosmetic ingredients

* ILSI Europe Concise Monograph Series (2005). Threshold of Toxicological Concern (TTC
### Threshold of Toxicological Concern

- Chemicals ranked on the basis of their toxicity

<table>
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<tr>
<th>CATEGORY</th>
<th>DESCRIPTION</th>
<th>TTC (mg/person/day)</th>
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<tr>
<td>Cramer Class I</td>
<td>Low toxicity Substances with simple structures for which efficient modes of detoxification exist in our body.</td>
<td>1.8</td>
</tr>
<tr>
<td>Cramer Class II</td>
<td>Moderate toxicity Substances that are less innocuous than in Class I, but do not contain structural features suggestive of toxicity like those in Class III.</td>
<td>0.54</td>
</tr>
<tr>
<td>Cramer Class III</td>
<td>High toxicity Substances suggesting significant toxicity or containing reactive functional groups.</td>
<td>0.09</td>
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- A useful approach for risk assessing **Food Chemicals**, when:
  - Present in foods at **low** concentrations
  - Little or no toxicity data eg contaminants from processing or packaging, or flavour components.
  - A reliable assessment of intake of the chemical must be possible

- **Exclusions**
  - High potency carcinogens i.e genotoxic (aflatoxin-like, azoxy- and nitroso- compounds) and non genotoxic (TCDD and steroids)
  - Neurotoxicants
  - Allergenicity
  - Accumulation eg dioxins, heavy metals
  - Endocrine disruption