



**2005 CSL/JIFSAN Joint Symposium on Food Safety and Nutrition:
Bioactive Food Components**

**The science behind labeling issues and health
claims – a European perspective**

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Overview

1. Elements of Food Labelling

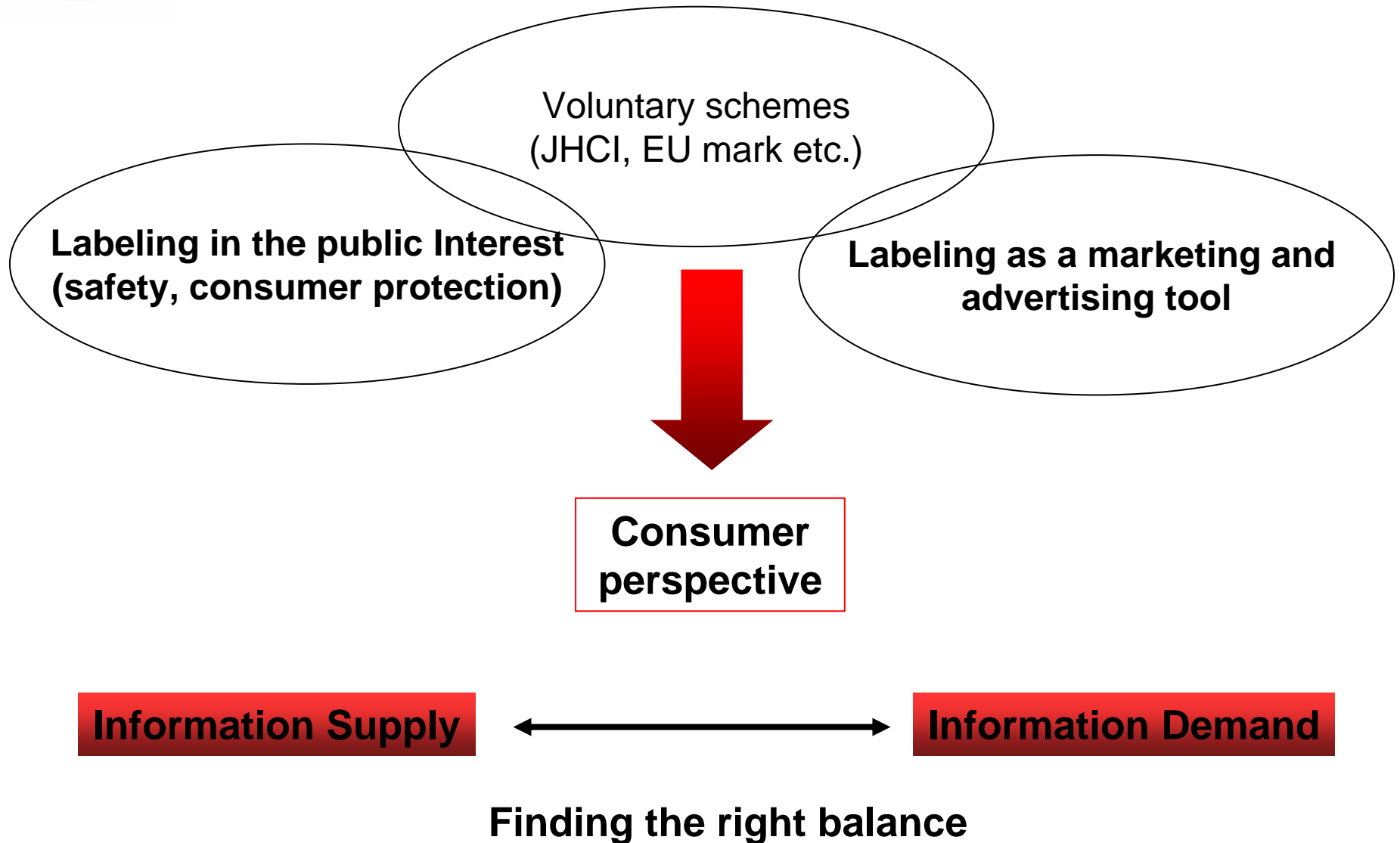
- Purpose of Food Labeling
- Labeling Policy in the Context of Current Global Issues
- Status of Proposed EU Regulations

2. The European Research Agenda

- Why
- Research on Food and Health
- Research on Targeted Consumer Communication



Purpose of Food Labeling





Set the stage: the EU Commission's View of Labeling

Markos Kyprianou, European Commissioner for Health and Consumer Protection

Labeling and its implications for consumers, Conference on Consumer Policy Perspectives, Luxembourg, 2 May 2005

“...Labeling is a central part of the communication of information to consumers...”

“...Consumer information is absolutely central to health and consumer policy, to ensure consumers can effectively take responsibility for their lives...at the moment of purchase...of use and disposal...”

“... We know that consumers do not always react to labeling in the way which we want them to. They do not always read the information on labels...”

“... There is much work to be done here, both in understanding how labeling works and how it can be improved to the benefit of all, consumers and businesses in the marketplace...”



Labeling: The EU Commission's View

Commissioner Kyprianou, European Commissioner for Health and Consumer Protection, Labeling and its implications for consumers, Conference on Consumer Policy Perspectives, Luxembourg, 2 May 2005

“...Understanding Consumer Attitude...”

“...labeling does not come for free. Every regulatory labeling requirement has to be paid for by the manufacturer and ultimately the consumer...”

“...proliferation of national voluntary labeling schemes and marks may hinder the development of the internal market...”

“... Every square centimeter of label contains a regulatory requirement is also one less for marketing and advertising. So we have to be alive to scope for simplification of labeling requirements for both businesses and consumers...”

WHO

Media

Public

IOTF

“...European Platform for Action on Diet, Physical Activity and Health – a useful multistakeholder process...”



European Platform for Action on Diet, Physical Activity and Health – A Political Manifesto with Shared Objectives

- Recognition of beneficial effect of healthy diet and physical activity on prevention and treatment of obesity and improvement of quality of life
- At both consumer level and national public health system level
- Obesity is of multifactorial nature and requires a multistakeholder approach
- Allow consumers to make healthy choices. Healthy diets must be accessible, affordable and available
- Information to consumers on link between diet & health
- Ban misleading advertising and advertising to children
- Facilitate professional advice on healthy diet and physical activity
- Enclose and responsabilize initiatives by all stakeholders (producers, retailers)
- Monitor the nutrition and physical activity trends in the population and promote appropriate scientific research



In a diverse EU25, how does this translate to legislation in relation to food?

- **Proposal for a regulation on addition of vitamins, and other substances**
- **Proposal for a regulation on nutrition and health claims**
- **Anticipated proposal for a Regulation on Nutrition Labelling**
- **Novel Food regulation**



Proposal on Addition of Vitamins and Minerals and Certain Other Substances: Status as of EP Plenary Vote May 26th

- **Vitamins and Minerals**

- **Positive List**
- **Justifiable with nutritional population status**
- **No nutrient profiles**
- **Transition period: 7 years**
- **Not for fresh foods or alcohol (>1.2%) containing beverages**
- **Minimum significant amount (7.5% RDA)**
- **Compulsory nutrition labelling**

- **Other substances (Fatty Acids, Fibers, Amino Acids, Antioxidants,..)**

- **Based on submission to and scientific evaluation by EFSA**
- **Safety assessment procedure unclear**
- **Intended use**
- **Negative list**
- **Producers to establish RDI**

- **Public Register**

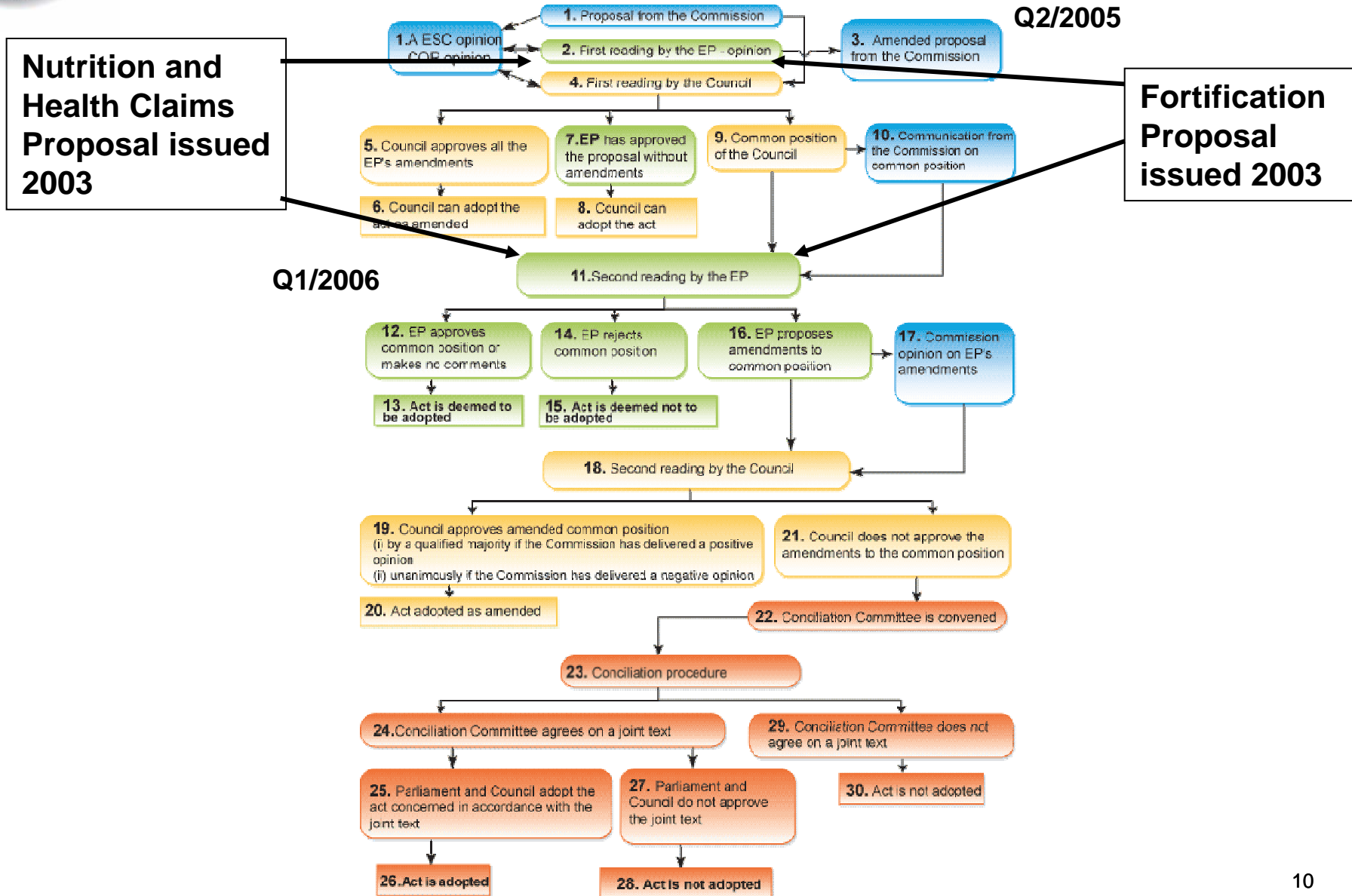


Nutrition and Health Claims Proposal – Current Status of EP and Health Council Opinions

- **EP vote on May 26th 2005. EU Health Council vote on June 3d 2005 and reaches Political Agreement. EP and Health Council have different positions.**
 - **Nutrient Profiles rejected by EP but insisted on by EU Health Council a week later.**
 - **Pre-Market Approval replaced by Notification Procedure by the EP; EU Health Council insists on pre-Market Approval.**
 - **Comparative Claims between Food Categories should be allowed**
 - **EP suggested that wording of submitted claim should not be in all community languages but one proposal is sufficient**
 - **EP vote significantly improved situation for slimming claims and reference to health professional endorsements**
 - **EP suggested to use Consumer Panels to assess claim perception**
 - **EP suggested to ban claims exclusively directed at children**



EU Co-Decision Process





Despite a Shared Vision, the Emphasis Remains on Nutrient Profiles and Lengthy Pre-Market Approval...

Commissioner Kyprianou welcomes Council agreement on Health Claims

Markos Kyprianou, Commissioner for Health and Consumer Protection, welcomed the unanimous political agreement on the proposed Health and Nutrition Claims Regulation at the Health Council today. In particular, the Council has backed harmonized rules for the use of health or nutritional claims on foodstuffs based on nutrient profiles, and has supported the requirement for health claims about disease reduction to be authorized based on scientific evidence.

“It is not in the interests of consumers to allow food products to promote claims about their nutritional and health benefits if such claims are false or misleading and obscure the overall nutritional value of the food” Commissioner Kyprianou said. “The proposal endorsed by Ministers today guarantees citizens clear, truthful and reliable information on the food they are eating. It also enables those companies whose products offer genuine health and nutritional advantages to EU citizens to compete fairly in the internal market.”



Consumer Information on Nutrition

- **We share the objectives and visions in the European Platform for Action on Diet, Physical Activity and Health, helping the consumer to make healthy food choices and to adopt a healthy lifestyle...**

...however, we think the application of **nutritional profiles** for labelling purposes such as in proposed “signposting” could be **misleading and difficult to use for the consumer**, due to its many paradoxes (i.e....calcium in full fat cheese). We don't think the application of nutritional profiles is based on sound science and application thereof could have a negative nutritional impact.

In addition, the introduction of **nutritional profiles** into European draft legislation was made **without any risk assessment, public consultation and with a lack of transparency**, ie. in violation of the basic principles of EU Food Framework Regulation 178/2002.

If **nutritional profiles** were applied to the use of **claims and fortification** this would very significantly **inhibit innovation** in the drink market in Europe.

In Europe we adhere to **voluntary nutritional labelling** on all our products because we believe consumer information is paramount.

We believe there are also other ways to provide information to consumers (web,..)



Food Intake, Diets and Lifestyle have changed

	From	To
What we consume	calorie intake	healthy, wholesome and varied diets
When we consume	regular meals	grazing and snacking
Where we consume	domestic	out-of-home
With whom we consume	social events	individual food intake
How we prepare	raw materials	ready-to-eat and heat-to-eat

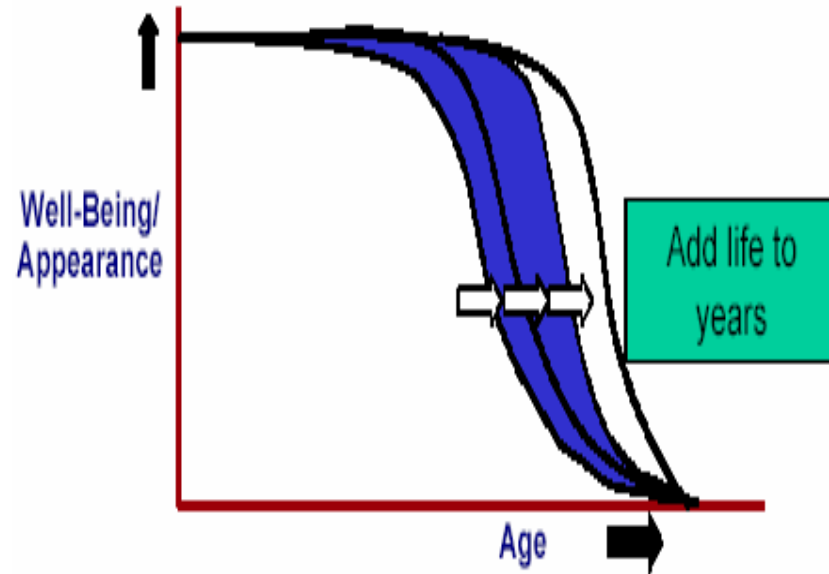
Food and Drinks bring a major contribution to the well-being, healthy ageing and pleasure of European citizens.



Poor Nutrition is an Important Public Health Factor

	DALYs (Disability Adjusted Life Years)
Poor Nutrition	4.5%
Obesity	3.7%
Physical Inactivity	1.4%
Total	9.6%
Ref.: Smoking	9%

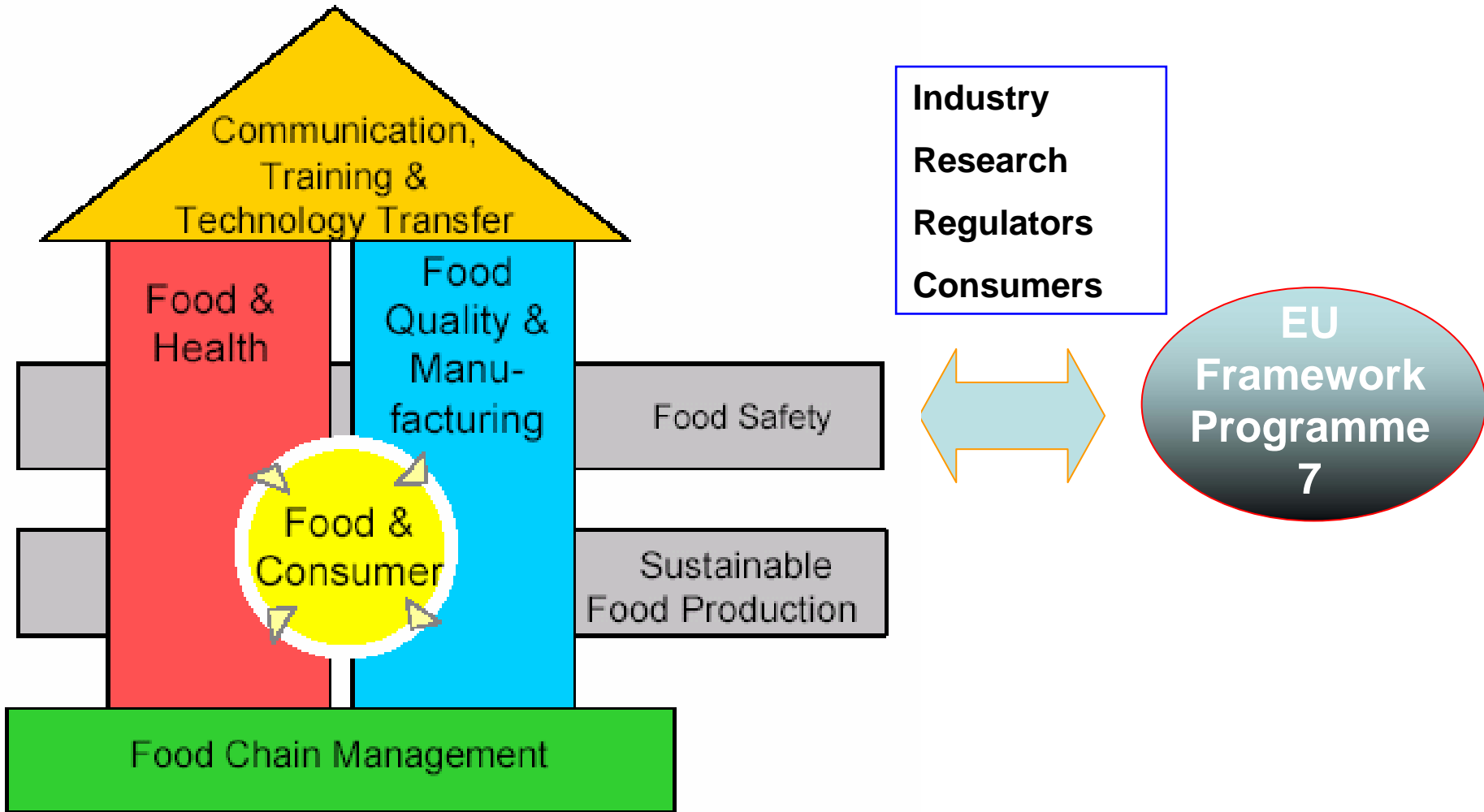
Healthy Ageing: Goal





A Coherent Research Strategy for the Future must be Developed Based upon the Shared Vision of the Diverse Stakeholders – the Consumer is at the Centre

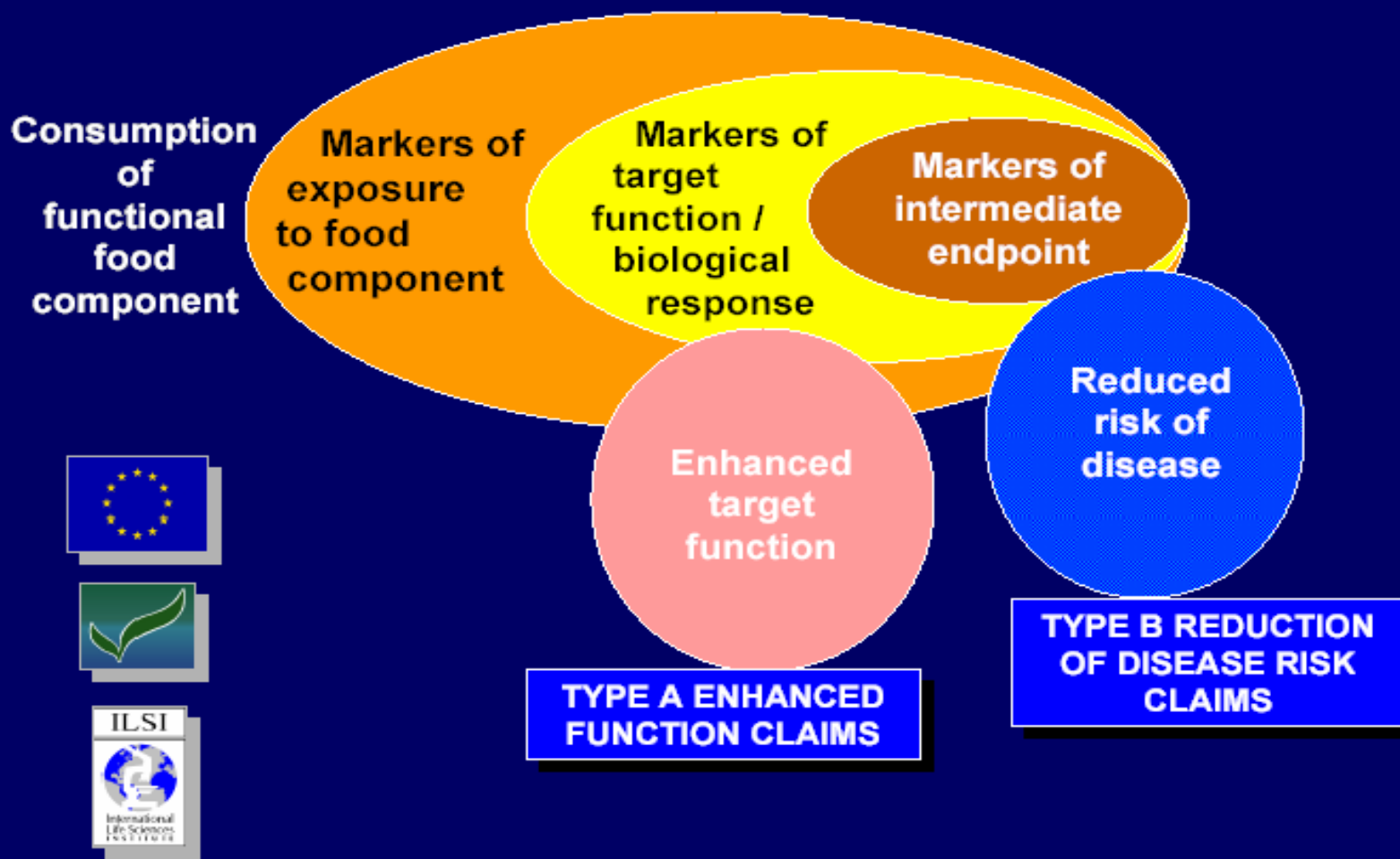
European Technology Platform Food for Life





Food and Health – Solid Foundation Exists - FUFBOSE

Functional foods: a proposal for a scientific basis for claims (ILSI-Europe)





Food and Health - Health Related Claims Structure in Europe

TYPE OF CLAIM	definition and <i>example</i>
NUTRITION CLAIM	suggests or implies nutritional properties
Nutrient content claim	describes the level of a nutrient: <i>high, low, does not contain</i>
Comparative claim	compares the level of a nutrient: <i>less, reduced, more</i>
HEALTH CLAIM	suggests a relation between a food and health
Nutrient function claim	promotes the role of a nutrient: <i>product X builds strong bones</i>
Enhanced function claim (sometimes referred to as 'physiological claim')	refers to specific beneficial physiological or psychological effects: <i>food or food component Y lowers blood cholesterol.</i>
MEDICAL CLAIM	suggests that a product can treat or cure a specific disease: medical claims are not allowed in the EU
NEW DEVELOPMENTS ON MEDICAL CLAIMS:	
Reduction of disease risk claim	The proposed EU Legislation for Health Claims allows "reduction of disease risk" claims. Until now these were considered as Medicinal Claims: <i>Food or Food product Z, when used in the context of a healthy diet, may reduce the risk of cardiovascular disease.</i>

**Bioavailability
Nutrient Status**

**Established Structure
Function Relationship**

**Human Intervention
Data**

**Intervention Study
with Markers of
Intermediate Endpoint**



Food and Health – PASSCLAIM – Criteria for Claim Substantiation

...builds upon results obtained in FUFOSE, which suggested that claims for “enhanced function” and “disease risk reduction” should be based on well designed studies using appropriately-identified, characterized and validated markers.

1. The food or food component to which the claimed effect is attributed should be characterised.
2. Substantiation of a claim should be based on human data, primarily from intervention studies the design of which should include the following considerations:
 - 2(a) Study groups that are representative of the target group.
 - 2(b) Appropriate controls.
 - 2(c) An adequate duration of exposure and follow up to demonstrate the intended effect.
 - 2(d) Characterisation of the study groups’ background diet and other relevant aspects of lifestyle.
 - 2(e) An amount of the food or food component consistent with its intended pattern of consumption.
 - 2(f) The influence of the food matrix and dietary context on the functional effect of the component.
 - 2(g) Monitoring of subjects’ compliance concerning intake of food or food component under test.
 - 2(h) The statistical power to test the hypothesis.
3. When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers.
4. Markers should be:
 - biologically valid in that they have a known relationship to the final outcome and their variability within the target population is known;
 - methodologically valid with respect to their analytical characteristics.
5. Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported.
6. A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence.

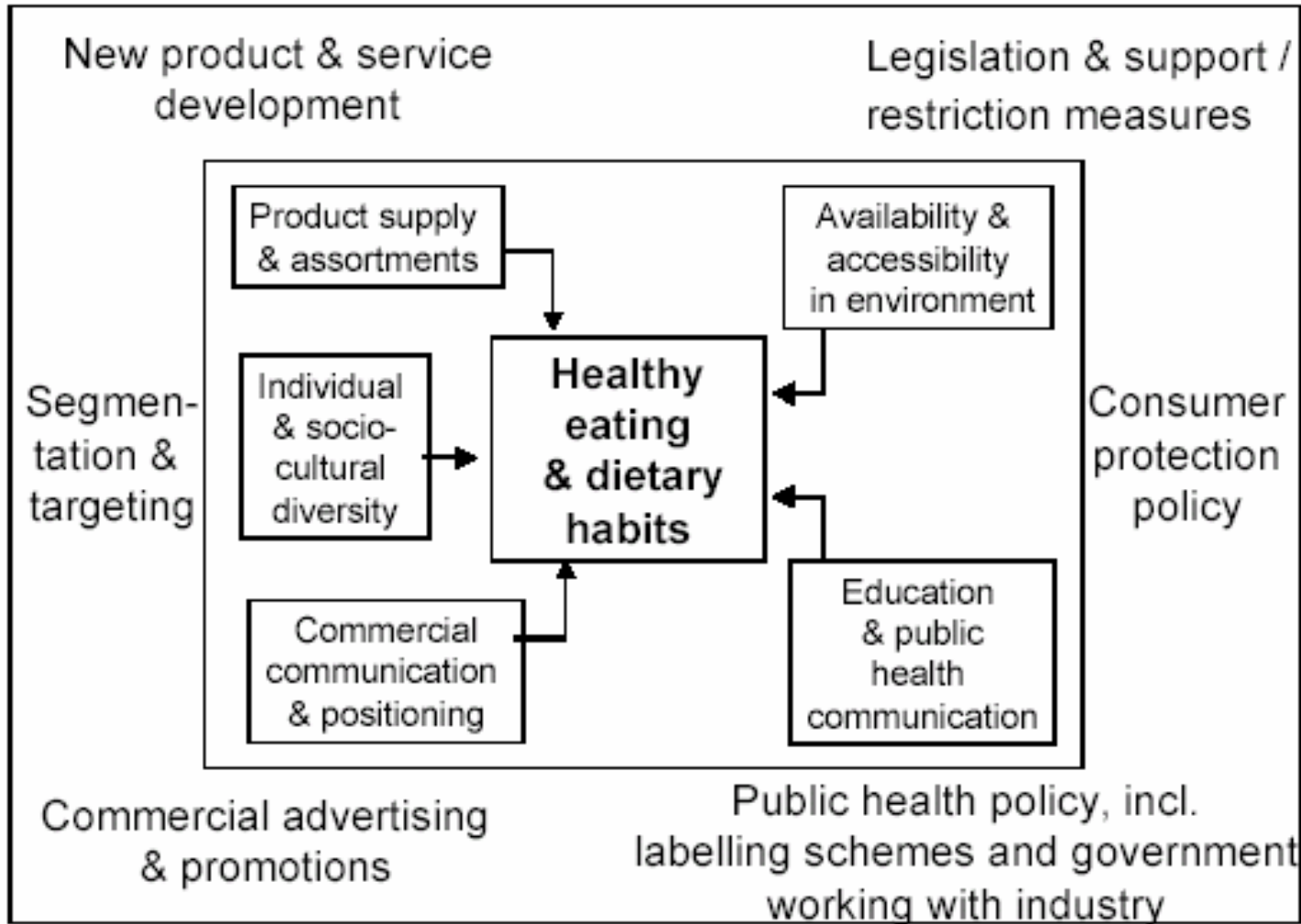


Food and Health – Research Topics

1. New and **effective food-based strategies** to optimise:
 - *children's growth and development;*
 - *lean body mass in adults including prevention of obesity;*
 - *immune, cognitive function in the elderly;*
 - *healthy gut for improved well-being and resistance to diseases.*
2. Basis **key strategic research area** in food and health: biomarker discovery and validation (epidemiology; systems biology/nutrigenomics; intervention trials).
3. New and effective food-based strategies for **reducing the risk of diet-related diseases**, such as cardio-vascular disease, diabetes, osteoporosis, obesity and cancer.



Food and Consumer: 'to make the healthy choice *the easy choice*'. Determinants of Healthy Eating.



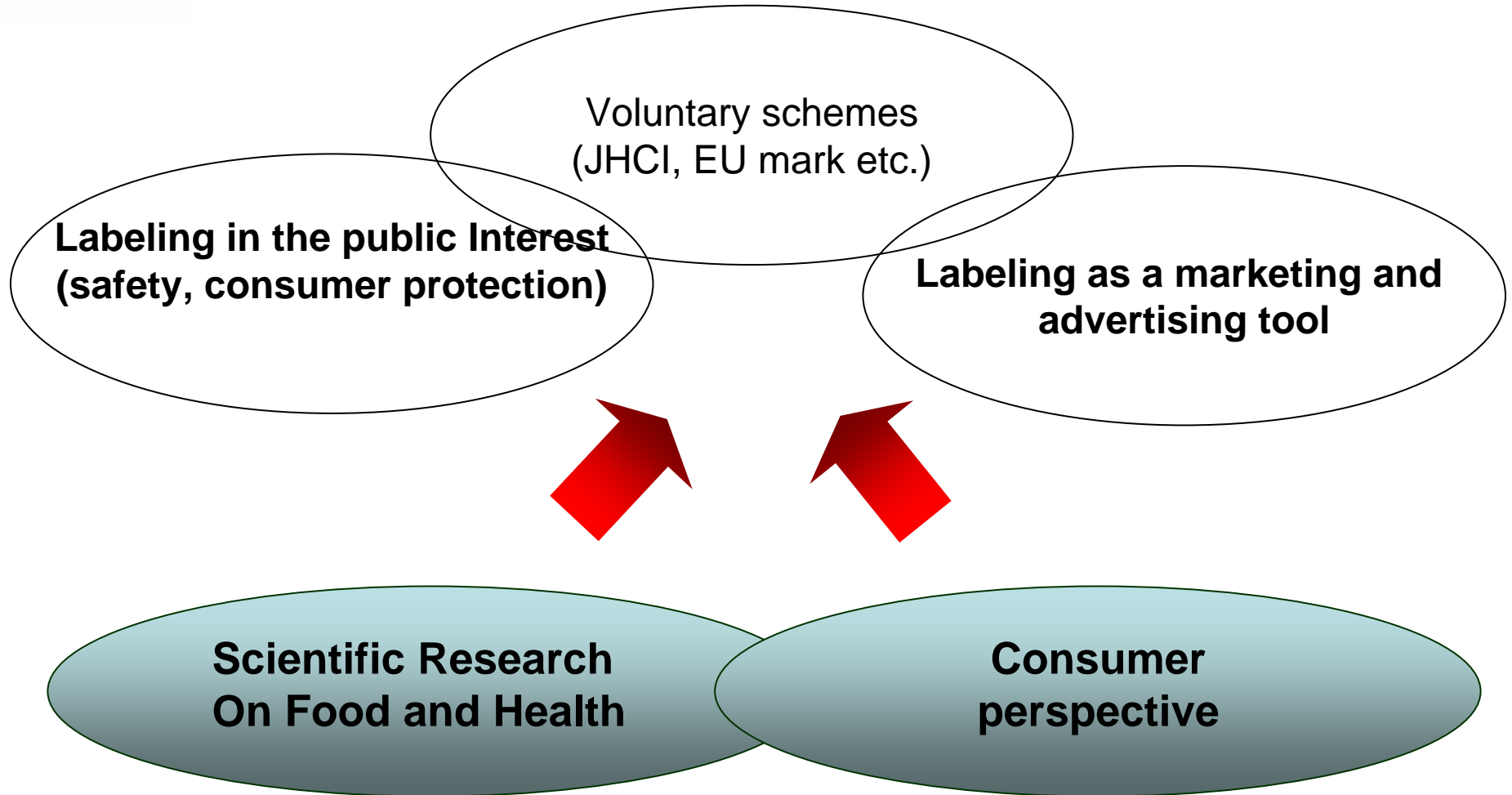


Food and Consumer – Research Topics

- How to change or influence food choice through effective **health-orientated intervention** strategies in order to optimise measurable positive effects on consumer health and quality of life.
- The design and validation of new ways to effectively communicate and **target information** at various population groups with different information needs
- **Mapping the dietary habits** of ethnic and immigrant populations in Europe and most effectively exploiting this new knowledge.
- Mapping food culture in Europe and in the global market.
- Understanding the **determinants of consumer acceptance of food technologies**, and how this varies according to individual consumer benefits.
- **Are new technologies the answer** to health requirements of consumer
- Understanding and predicting the selection and sustained **acceptance of healthy foods**, and assess the possibilities of **changing** ingrained **dietary and purchasing** habits.



Science and Communication





Thank You!