Assessment of Scientific Support for Claims on Foods
A European Perspective

Peter J Aggett
(on behalf of the EU Passclaim Concerted Action)
Lancashire School of Health and Postgraduate Medicine
University of Central Lancashire
Preston, UK

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INTRODUCTION

- Health and nutrition claims are the focus of much attention.
- Many food products on the market with claims.
- Increasingly documented effects of dietary components on body functions.
- EC introduction of regulation on health claims.

EC project FUFOSE ('95-'97) (1)

'Functional Food Science in Europe'

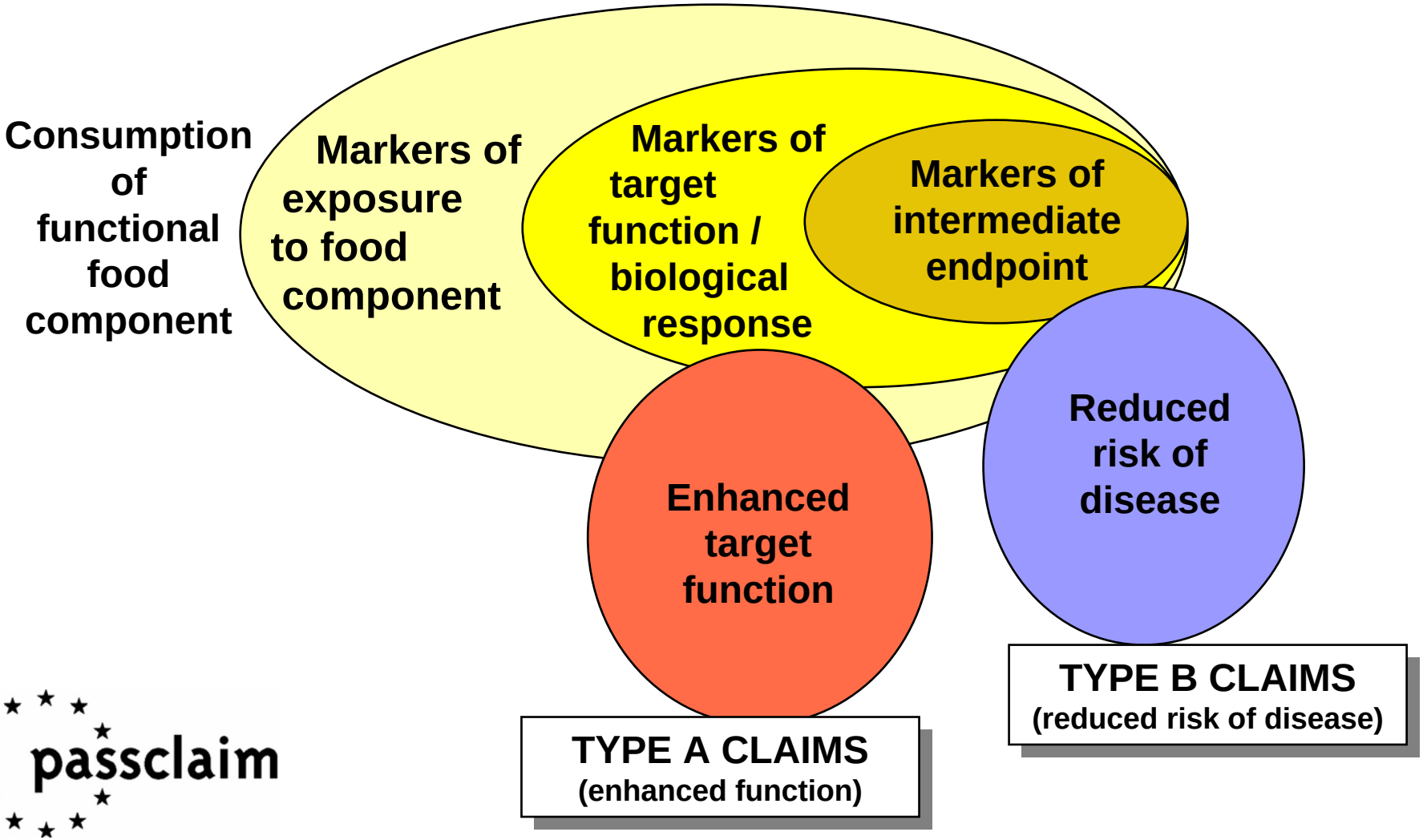
- A working definition of functional foods was developed.
- A consensus was reached on scientific evidence that specific foods or food components positively affect physiological functions.

EC project FUFOSE ('95-'97) (2)

'Functional Food Science in Europe'

- Two types of claim are of the greatest relevance:
  - Type A: Enhanced Function Claims
  - Type B: Reduction of Disease Risk Claims

FUFOSE: From evidence based on markers for functional foods to types of claims relevant to them



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…builds from
suggested claims for *'enhanced function'* and
'reduced risk of disease'

- …and that claims should be based on well-designed studies using appropriately-identified, characterised and validated markers.

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EUROPEAN NEEDS

- No European/EC regulation on health claims in 2000.
- EC regulation on nutrition and health claims made on foods *« Scientific substantiation should be the main aspect to be taken into account for the use of claims »*

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GLOBAL NEEDS

No harmonised approach for scientific substantiation of claims.

Three key benefits:

- Satisfy regulatory requirements.
- Support consumer confidence in foods with claims.
- Promote fair market competition.

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Objectives

- To evaluate critically existing schemes that assess scientific substantiation of claims.

- To produce a generic guidance tool for assessing the scientific support for health claims for foods

- To establish criteria which can be used to explore the links between diet and health.

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Output

- Set of criteria to facilitate review of scientific evidence submitted for substantiation of a health claim.

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SUPPORT

1) European Commission

Fifth Framework Programme (FP5)
Concerted Action

Key action 1: Food, Nutrition and Health
Thematic programme 1: Quality of life and management of living resources.

2) ILSI Europe Functional Foods Task Force.

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European Commission Concerted Action

Coordinated by ILSI Europe

Jan 2001- March 2005

- 191 experts from 26 countries
  - 45 academia
  - 63 industry
  - 83 public interest groups and regulatory bodies

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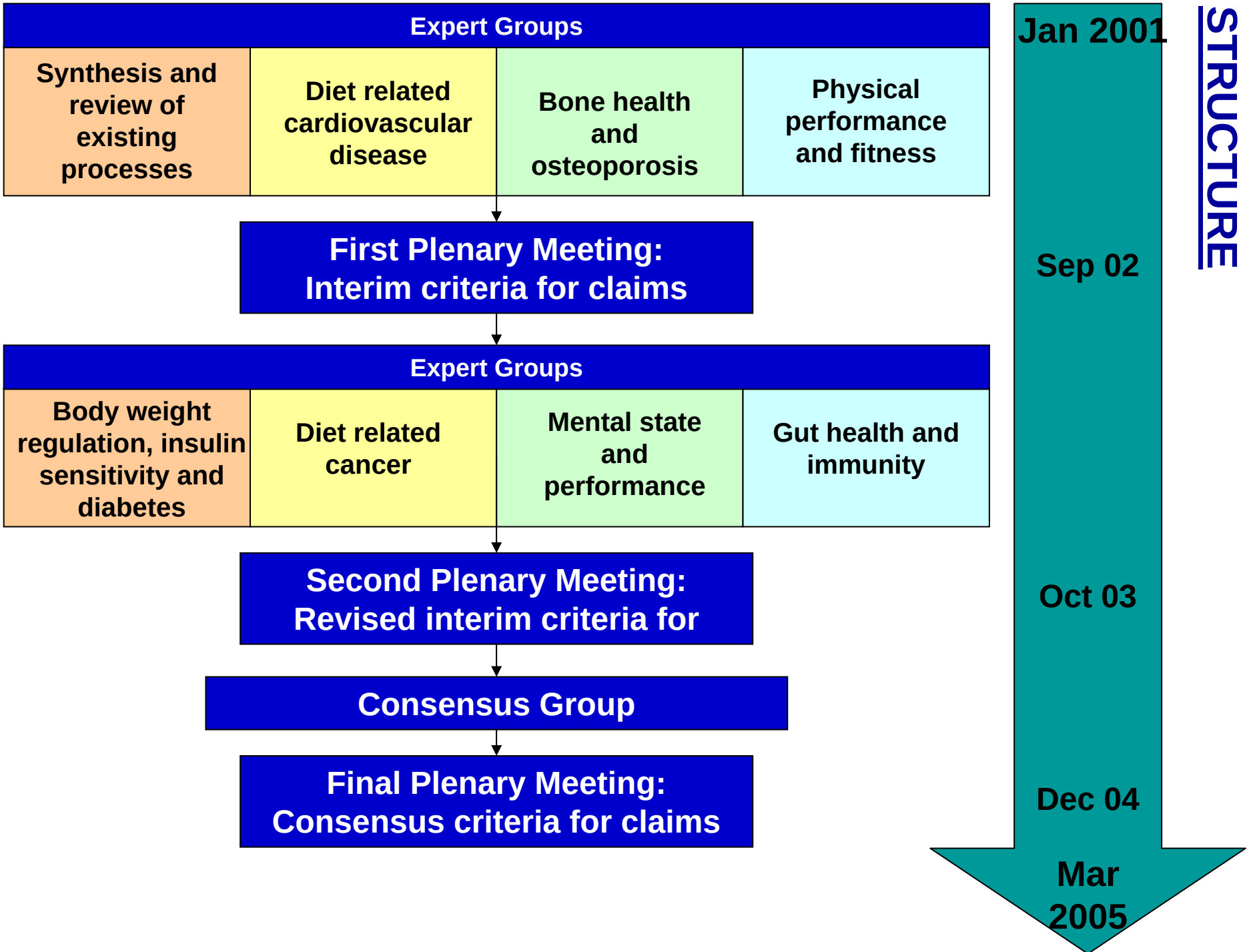
Steps followed

Collate potential types of claims.

Describe scientific support needed and evaluate relevance.

Assess usability and validation of markers.

Develop list of criteria to evaluate the substantiation of claims.


Expert Groups
Synthesis and review of existing processes
Diet related cardiovascular disease
Bone health and osteoporosis
Physical performance and fitness
First Plenary Meeting: Interim criteria for claims
Expert Groups
Body weight regulation, insulin sensitivity and diabetes
Diet related cancer
Mental state and performance
Gut health and immunity
Second Plenary Meeting: Revised interim criteria for
Consensus Group
Final Plenary Meeting: Consensus criteria for claims
Jan 2001
Sep 02
Oct 03
Dec 04
Mar 2005
STRUCTURE

Objectives of the consensus group

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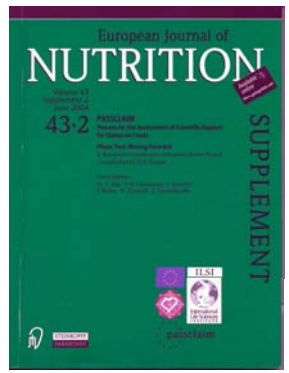
- To further elaborate and refine the criteria

- To review the comments made in the first two Plenary Meetings

- To assess and validate the criteria against the scientific information in the ITG reports

Publications

PASSCLAIM publications:



- Phase One – Preparing the way

European Journal of Nutrition, Vol 42, Suppl. 1, March 2003

- Phase Two – Moving forward

European Journal of Nutrition, Vol 43, Suppl. 2, June 2004

- Consensus on Criteria

European Journal of Nutrition, Vol 44, Suppl. 1 June 2005

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Context: Claims

- Foods and Food Components for which a claim is made should comply with existing legislation and fit into a healthy diet.
- Regulations should reflect the evolving science base taking into account new scientific developments as appropriate.
- A claim should reflect its scientific basis, be understandable, and not mislead the consumer.

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Criteria for the scientific substantiation of claims

1. The food or food component to which the claimed effect is attributed should be characterised.

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Criteria for the scientific substantiation of claims: 2

2. Substantiation of a claim should be based on human data, primarily from intervention studies the design of which should include the following considerations:

Criteria 2:

- 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.

Criteria 2

- 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.

Criteria 2

- 2(g)Monitoring of subjects' compliance with concerning intake of food or food component under test.

- 2(h)The statistical power to test the hypothesis.

Criteria 3

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3. When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers

   (Address:

   - delayed impact or appearance of key benefit,
   - feasibility or ethical issues limiting access to tissues
   - resource constraints: expensive assays)

Criteria 4

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.

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Criteria 5 and 6

- 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.

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Overall

The criteria emphasise the need for

- Direct evidence of benefit to humans
- Markers of intermediate effects when ideal endpoints are not accessible to measurements
- Markers of proven validity
- Magnitude and character of effects to be statistically and biologically meaningful

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The Portfolio

Overall, there should be:

- consistency of results across the various categories of evidence and methodologies
- valid dietary methods
- randomised sampling
- a dose response relationship between intakes of food or food components and the effects and health effect, if relevant
- biological plausibility

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The Portfolio

- Selective presentation of studies and their outcomes is acceptable only if this is transparent and done on the basis of the quality of the data

- All published studies should be reviewed and unpublished data, including those that have been held back from publication for reasons of confidentiality, must also be considered.

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Weight of evidence;1

- The submission may leave questions unanswered. Do these need to be answered by additional research, or does the evidence overall support the proposed claim?

- Claims may need to draw on the broad spectrum of scientific data. However, there is no definite rule, each claim would need to be assessed in its own right.

Comments and Discussion:1

Passclaim has

- Involved pre competitive collaboration of all relevant sectoral interests: Consumers, Health and Social Care, Regulators, Legislators, Education, Industry

- Drawn on best practice in investigative studies to monitor health and well-being and the reduction of disease risk, and of existing regulatory and advisory processes for the evaluation of claims

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Comments and Discussion:2

Passclaim has produced

- consensus on the objective and transparent assessment of scientific evidence submitted to support a claim related to a food or food component.

- core issues and separate criteria that will facilitate the objective assessment

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Comments and Discussion:3

The Passclaim criteria

- facilitate the compilation of guidelines on the preparation of submissions.
- emphasise that the overall consistency and coherence of all the evidence, i.e. the totality of the evidence, should be assessed.

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Comments and Discussion:4

The Passclaim criteria

- should help those who are
  - responsible for evaluating evidence providing feedback to those submitting portfolios
  - submitting evidence
- Should improve the efficiency of regulatory review

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Passclaim: Caveat 1

The Passclaim criteria

- Provide only a guidance template for the evaluative process
- Need to be applied intelligently on a case by case basis with respect both to gaps in knowledge and to the development of new knowledge

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Passclaim: Caveat 2

Expert judgement may be needed for assessment

- of the validity of markers, study designs, the influence of dietary matrices, etc.

- of the totality, consistency and complementarity of evidence and the extrapolation of effects across gender and generation groups

Thus there will still be a need for informed scientific advice in the advisory and regulatory process.

Passclaim: Caveat 3

- Limitations of existing markers.
- Need to improve the characterisation of populations, and the early detection of responses to interventions with foods and food components (molecular biology).
- Better markers may enable more practicable and cost-efficient study protocols and timescales.

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Passclaim did not

- Consider the process, regulation or classification of claims.
- Consider in depth the grading of evidence.

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Other Issues: Agrifood;1

Intellectual Property Rights

- Substantiated claims may be important for the the competitiveness of food industry and the incentive for its investment in healthy foods.

- Producers may wish to assert intellectual property rights for their innovations based on the substantiation of claims.

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Other Issues: Agrifood;2

Small and Medium Enterprises

- Criteria would be useful for innovative SMEs to judge the feasibility of developing new products.

- There may be a strategic need for competent authorities to support SMEs by investing in scientific support and networks, e.g. to undertake human nutrition studies.

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Consumers

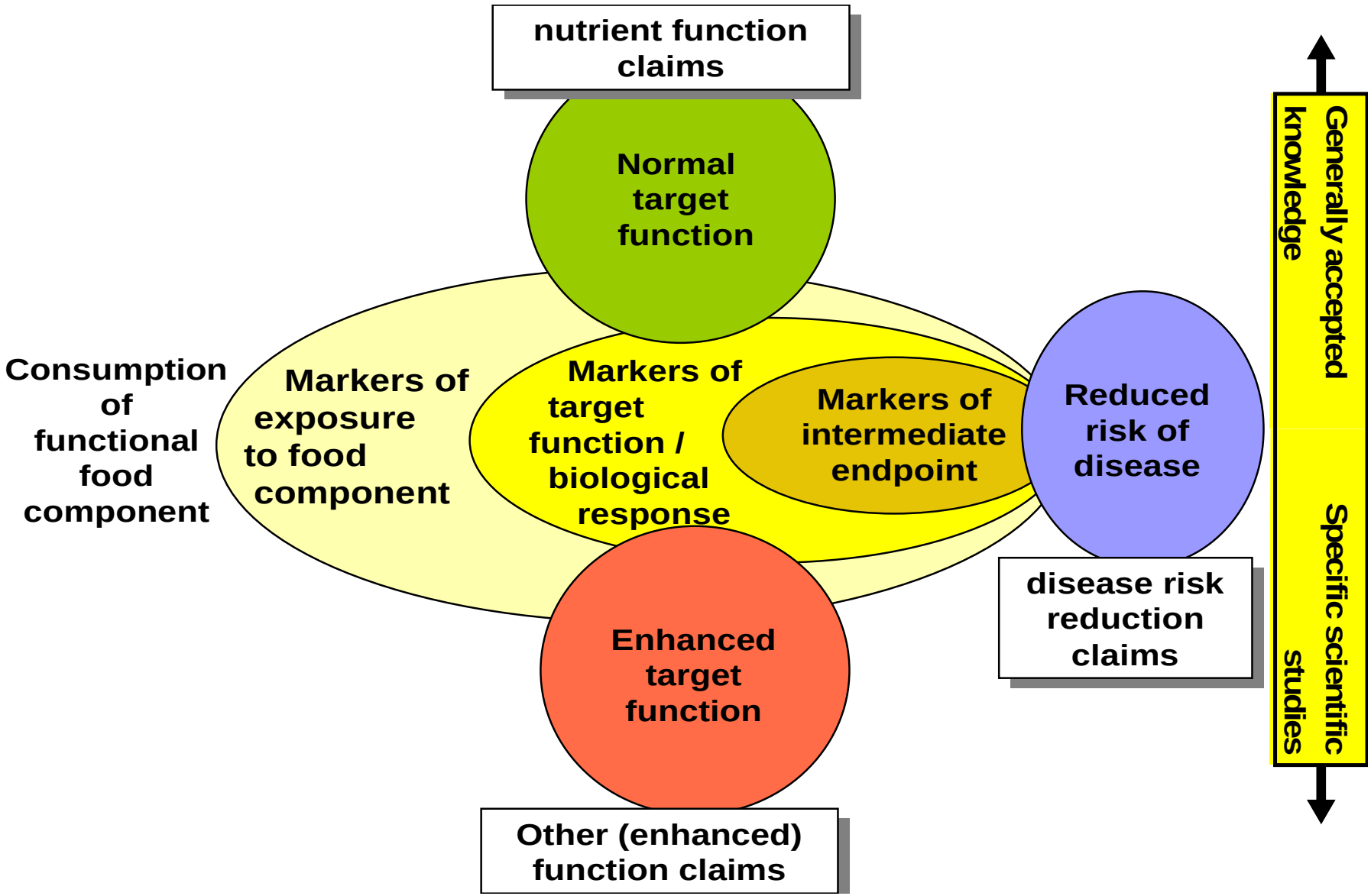
The Passclaim criteria

- Will support well-founded claims and explanations that will contribute to consumer education and confidence in science-based claims on foods.
- Develop informed consumers who will choose products with benefits for health and well-being.
- Will contribute broadly to healthier diets and thereby to a decrease in the burden of diet-related diseases .

"Generic Claims"

- The Passclaim criteria may also be applied to the substantiation of generic claims that can be made on a range of products containing the active food component.
- Conditional on standard considerations; matrix etc..

Health Claims Addressed by PASSCLAIM and the FUFOSE Concept of Underpinning Scientific Evidence



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Indicative Research Needs

- Biomarker research and validation of markers against endpoint
- Research on relation between food and mental performance
- Nutritional intakes and requirements
- Address the consumer understanding of health claims
- Risk-benefit analysis of foods
- Nutritional safety and nutrient risk assessment

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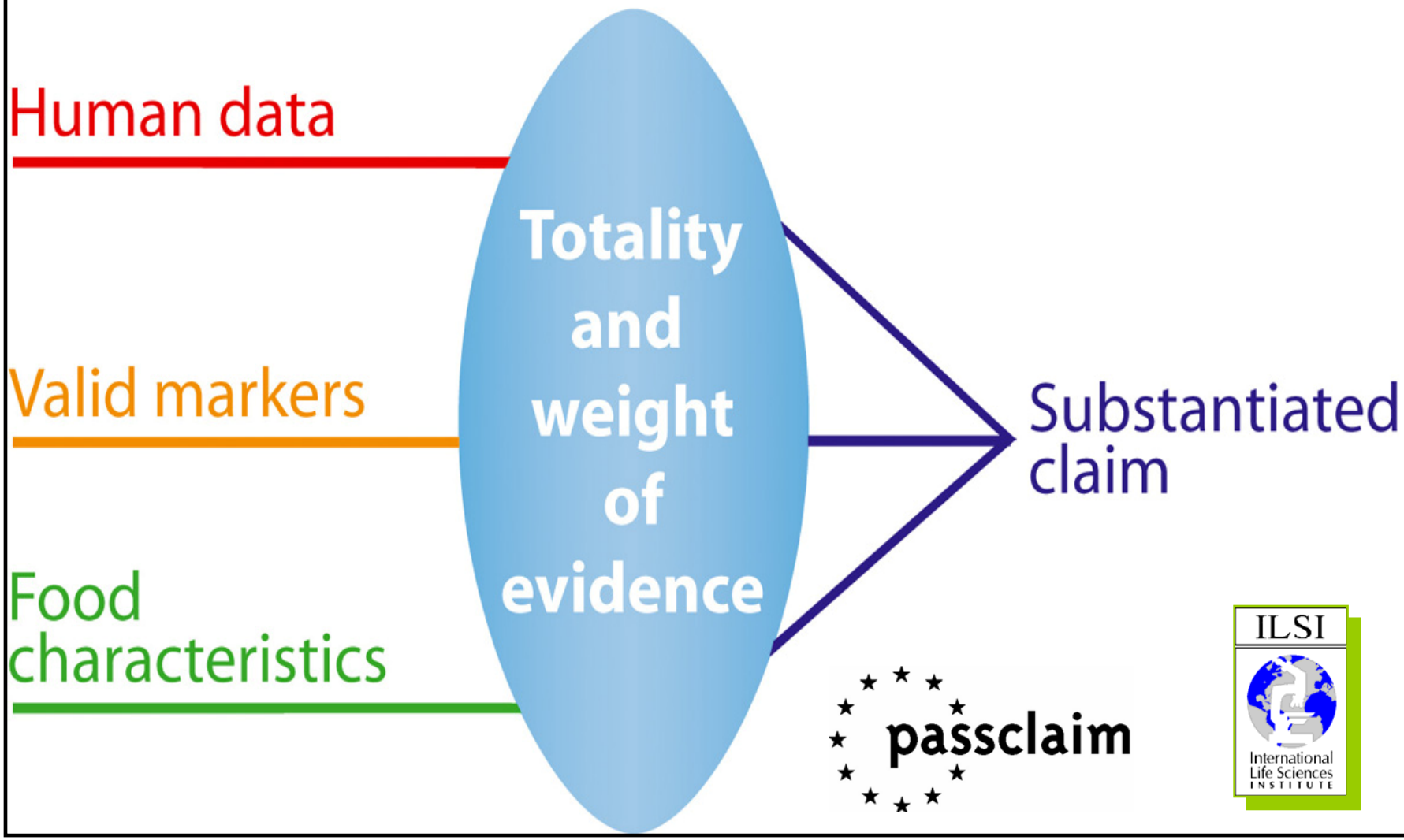
Human data
Valid markers
Food characteristics
Totality and weight of evidence
Substantiated claim
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