UNIVERSIDAD DE MURCIA

# THE FIRST STEP TO OBTAIN A HEALTH CLAIM:

## *IN VITRO* CHARACTERIZATION OF THE PRODUCT

efsa
European Food Safety Authority

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UNIVERSIDAD DE MURCIA

# Research group
# FOOD SCIENCE AND HUMAN NUTRITION

## Nutrición y Bromatología
## E098-02

# WHERE WE ARE?

Food Science and Technology Department

**FACULTY OF VETERINARY SCIENCIES AND VITALIS-PLEIADES**

**RESEARCH GROUP E098-02**

TEACHING

RESEARCH

# ACTIVITIES/FACILITIES

Food microbiology laboratory

Laboratory of Nutrition and physical-chemycal analyses

Laboratory of Sensory analyses (projects with food companies)

Satin APPetite Software

Human Nutrition Unit

**RESOURCES**

Molecular Biology laboratory

Pediatric Hospital Virgen de la Arrixaca

Animal House

Cell Culture laboratory

## Main Research Areas

### Quantification and biaovailability of micronutrientes

- Folates
- Lycopene
- Minerals
- Effect of Antinutrients/enhancers
- Influence of food matrix (thickening agents)

### Functionality of new ingredients and bioactive compounds.

- Polyamines
- Phenolic compounds
- Peptides and proteins in infant formula
- Nucleotides
- Phytases
- Pycnogenol®

### Gut microbiota & Health

- Influence of nutrition:
- Source/chemical form of minerals
- Peptides
- Nucleotides
- Thickening agents
- Geographical origin
- Disorders

## Main Research Areas

**Quantification and biaovailability of micronutrientes**

**Functionality of new ingredients and bioactive compounds.**

**Gut microbiota & Health**

# SATIETY AND SATIATION

Satin
Satiety Innovation

(thickening agents)

Pycnogenol®

Geographical origin

Disorders

## MEMBERS OF THE RESEARCH GROUP

European Food Safety Authority

EFSA Journal 20xx;x(x):xxxx

**DRAFT SCIENTIFIC OPINION**

## Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations[1]

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]**

European Food Safety Authority (EFSA), Parma, Italy

# EFSA

**Appetite**

1. Must result in changes in energy intake (if this is claimed physiological effect rather that decreased body weight)
2. Must be sustained across day – no compensation
3. Must be enduring – observable e.g. Up to four weeks during dosing
4. Biomarkers useful for proof-of-concept but not necessary for efficacy
5. Appetite ratings must be assessed using VAS.
   **Visual Analogue Scale Questionnaires (VAS).**

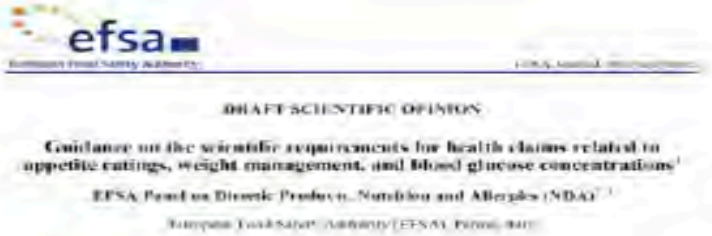
**Appetite**

1. Considered only in context of decreased body weight - *intake no longer as important but body weight is (most claims to date focus on intake – and are negative)?*
2. Must be sustained (12 weeks) with continuous consumption of food to exclude adaptation through compensatory mechanisms – *must have body weight change to make any communication on appetite (how many claims have actually been reviewed with body weight)?*
3. Biomarkers may support behavioural assessment

*'Claims on changes in appetite ratings have been made in the context of body weight. In this context evidence for a sustained effect on appetite ratings and body weight with continuous consumption of the food, should be provided'*

Blundell (2010) Nat. Rev. Endocrin 6: 53-55
Halford & Harrold (2012) Proc Nut Soc 71: 350-362
EFSA Journal 10 (2) 2604

# EFSA


efsa

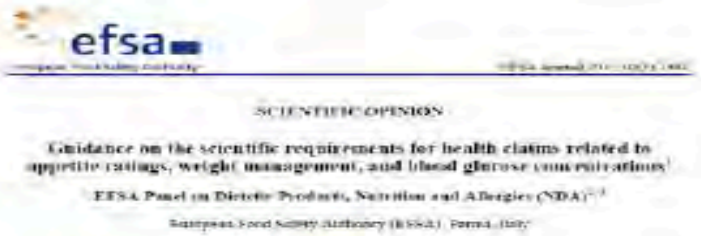
DRAFT SCIENTIFIC OPINION

Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

## Weight Management

1. Weight loss must be observed for at least 12 weeks with continuous consumption of food
2. Weight regain prevention much be observed for 24 weeks after weight loss
3. Changes in body fat not strictly required if study duration is appropriate but can be performed on subsample as supporting evidence (measures of body composition: MRI/DXA not waist circumference or bio-impedance)


efsa

SCIENTIFIC OPINION

Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

## Weight Management

1. Weight loss must be observed for at least 12 weeks with continuous consumption of food and be sufficient large not to be attributed to loss of water or lean mass
2. Weight regain prevention much be observed for 24 weeks after weight loss
3. Changes in appetite ratings, energy intake, energy expenditure or fat oxidation considered in support of mechanism to achieve weight reduction (if sustained effect) – *appetite can be used as supporting evidence*

*'Changes in energy intake etc have been proposed in the context of claims related to the reduction of body weight.*

*Evidence for a sustained effect of any of these variables with continuous consumption of the food may be considered in support of mechanism by which the food may exert the claimed (BW) effect'*

Halford & Harrold (2012) Proc Nut Soc 71:350-362

## ASSESSMENT

### 1. Introduction

To assist applicants in preparing and submitting their applications for the authorisation of health claims, EFSA and in particular its Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) has ongoing consultations with stakeholders, and has published guidance on the scientific substantiation of health claims since 2007[7]. In April 2010, a draft briefing document on the scientific evaluation of health claims was published for consultation and was followed by a technical meeting with experts from the food industry, Member States and the European Commission in Parma, in June 2010. The draft briefing document has been transformed into a Panel output, taking into account the questions/comments received. This document constitutes the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims, and outlines the approach of the NDA Panel to the evaluation of health claims in general. In response to requests from industry, EFSA is engaged in further consultation with stakeholders, and is developing additional guidance on specific types of claims.

The present guidance, prepared by the NDA Panel, on the scientific requirements for the substantiation of health claims related to appetite ratings, weight management, and blood glucose concentrations was, prior to its finalisation, endorsed by the NDA Panel on 25 March 2011 for public consultation, which was open from 26 April to 31 August 2011. All the public comments received that related to the remit of EFSA were assessed, and the guidance has been revised taking into consideration relevant comments. The comments received and a report on the outcome of the public consultation have been published on the EFSA website.

The document focuses on two key issues regarding the substantiation of health claims related to appetite ratings, weight management, and blood glucose concentrations:

- claimed effects which are considered to be beneficial physiological effects.
- studies/outcome measures which are considered to be appropriate for the substantiation of health claims.

Issues which are related to substantiation and which are common to health claims in general (e.g. characterisation of the food/constituent) are addressed in the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims [8].

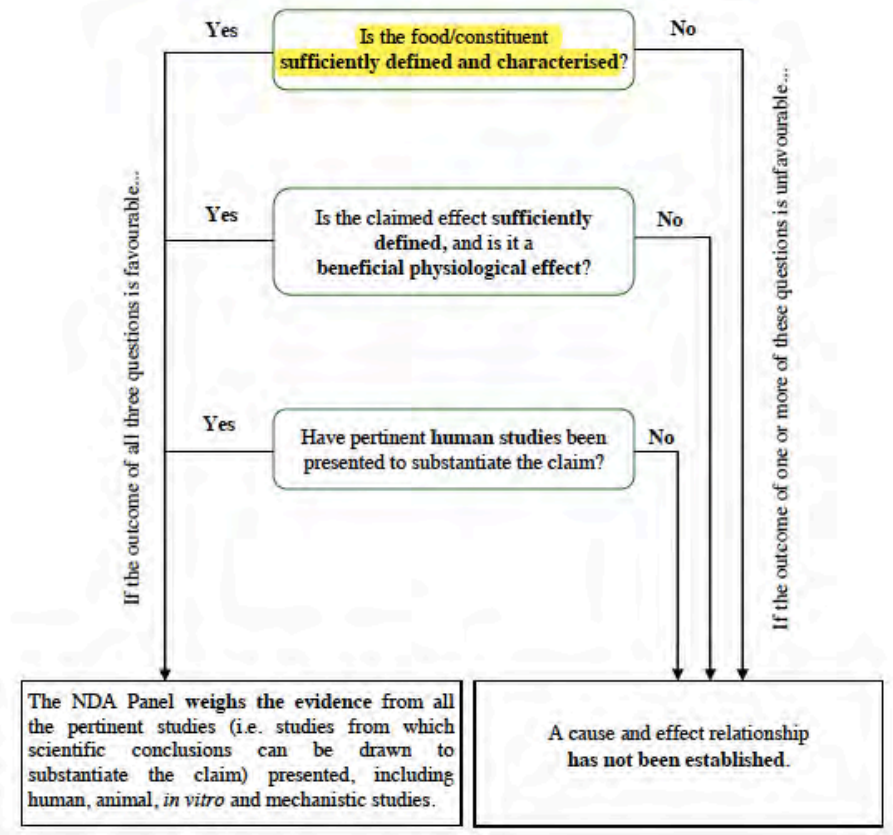
# EFSA



efsa

General guidance for Article 13.1, 13.5 and 14 health claims evaluation

**Key questions addressed by the EFSA NDA Panel in the scientific evaluation of health claims**




The *in vitro* characterization:

- Stability to GI digestion
- Solubility
- Bio-availability
- Effect on microbiota
- Intact healthy properties
- Mechanism of action.
- …

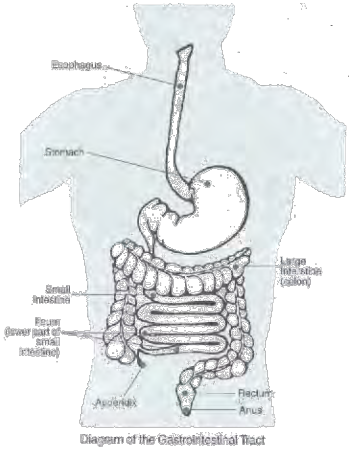


Diagram of the Gastrointestinal Tract

Satin
Satiety Innovation

Static gastrointestinal digestion model

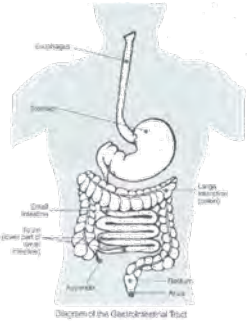
(oral, gastric, s.i. soluble, s.i. dialysis and colon fractions)

Satin
Satiety Innovation

- GI Hormone secretion & chemo-sensors
- Intestinal parameters (microbiota)
- Solubility, stability and bio-availability
- Inflammatory state

SAMPLE PROFILE

# STATIC DIGESTION MODEL



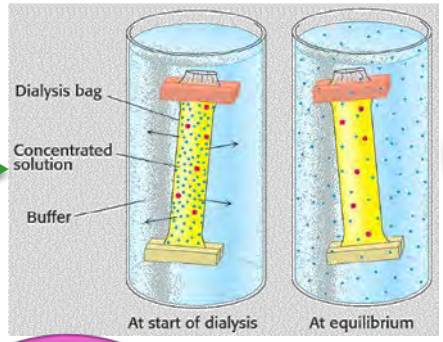
ORAL DIGESTION

GASTRIC DIGESTION

Salty solution & amilase

Pepsin & Acid pH

Bile salt Enzymes $NaHCO_3$ pH = 6




INTESTINAL DIGESTION Dialysis Fraction

**Availability test**

**Ranking**

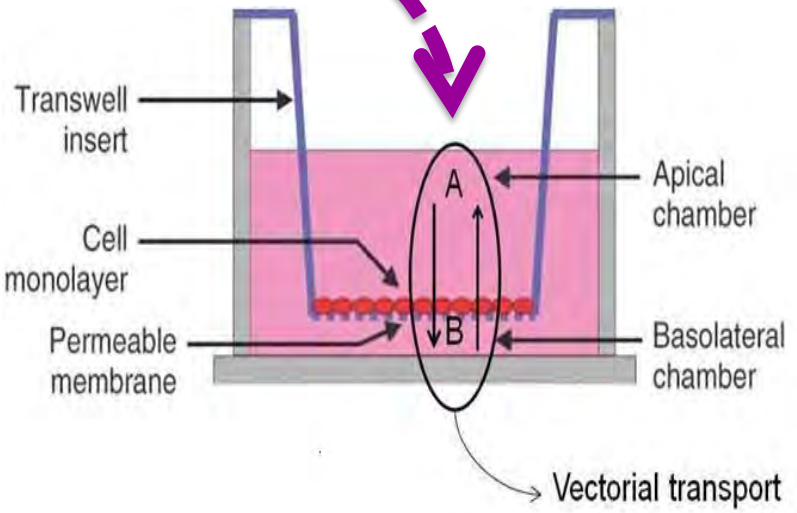
INTESTINAL DIGESTION Soluble Fraction

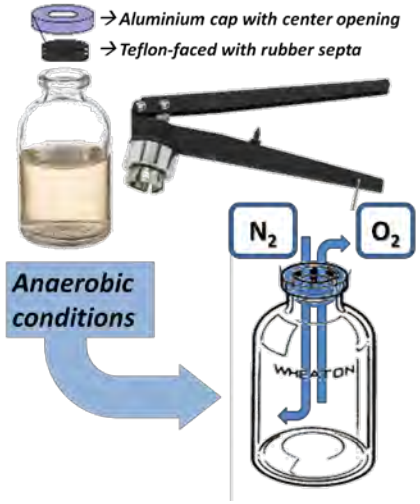
**Solubility test**

**Bioavailability test**

**MS-HPLC analysis**

| Parameter | Positive Effect |
|---|---|
| Gastric | ↑ Stability |
| S. Intestine (SF) | ↑ Stability |
| S. Intestine (DF) | ↑ Availability |
| AP Chamber | ↑ Stability |
| BL Chamber | ↑ Bioavailability |
| Colon | ↓ Stability |

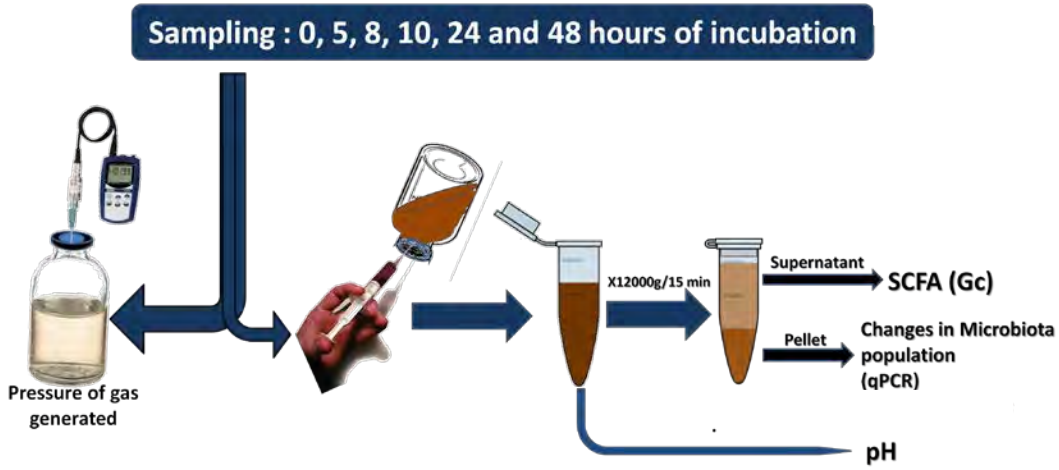





Faecal donor:

- No antibiotics
- No pre- probiotics

- Obese
- Normo-weight
- Infant
- Elderly
- …




## Ranking

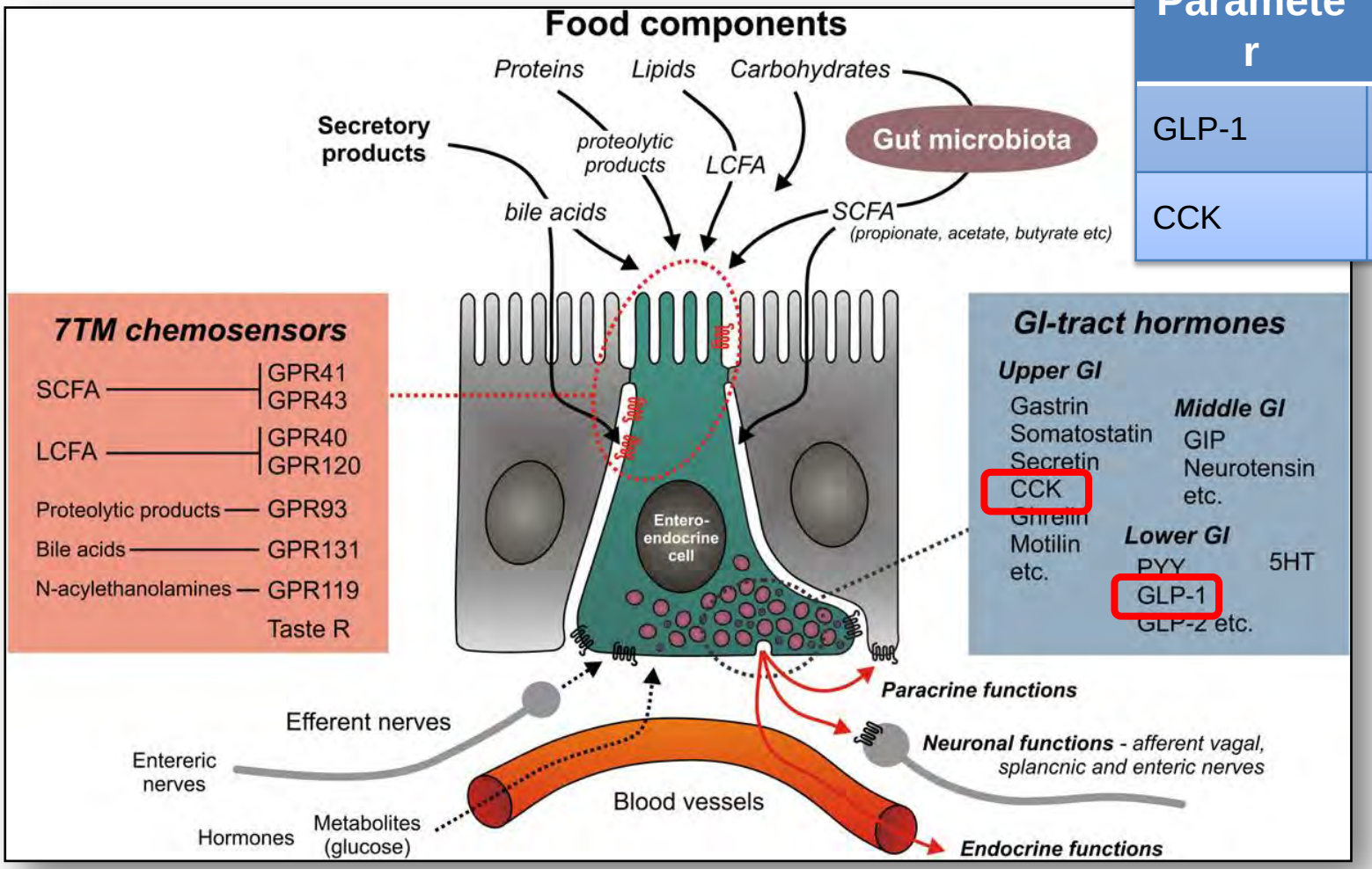
| Parameter | Positive Effect |
|---|---|
| SCFA | ↑ Butyrate and proprionate > acetate |
| SCFA | ↑ Acetate |
| Ammonium | ↓ Ammonium production |
| GAS | ↑ Low to moderate |
| Lactobacilli (LAB) | ↑ Due to increase of GABA and b-phenyl ethylamine |
| Bifidobacteria | ↑ Bifidogenic effect |

# ENTERO-ENDOCRINE CELL PLATFORM



## Ranking

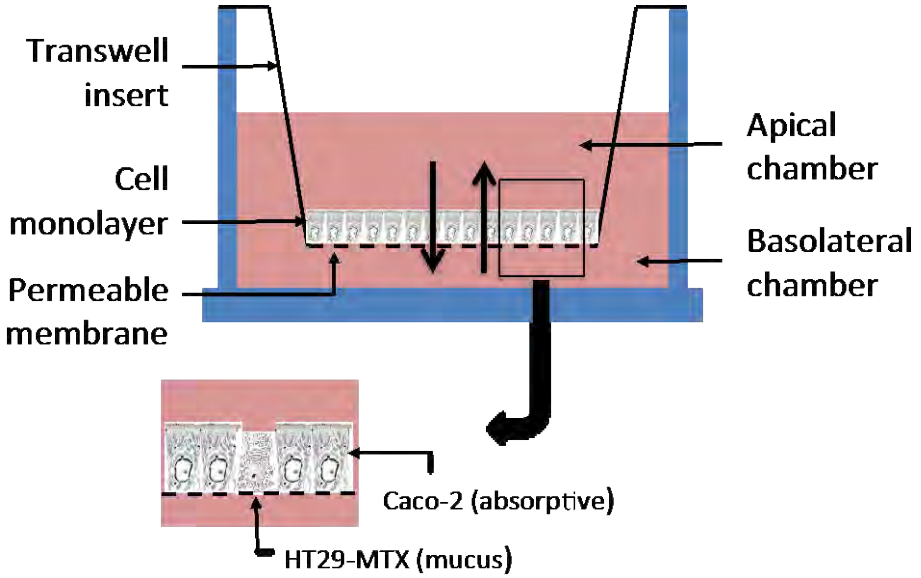
| Parameter | Positive Effect |
|---|---|
| GLP-1 | ↑ Secretion |
| CCK | ↑ Secretion |

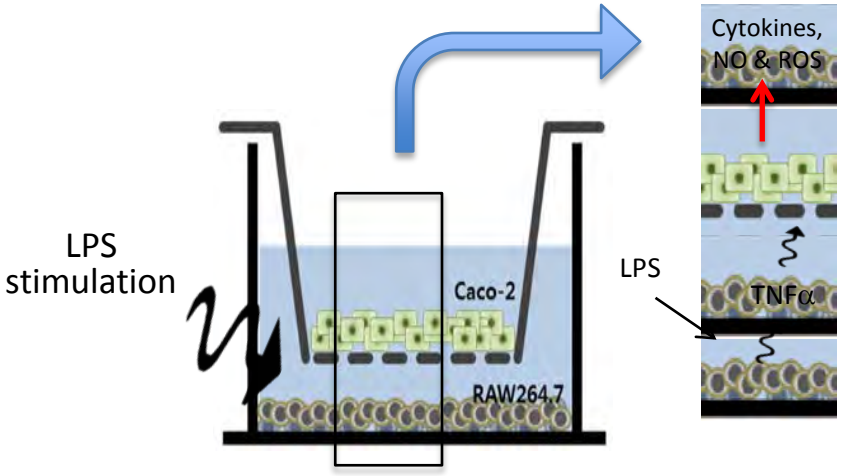


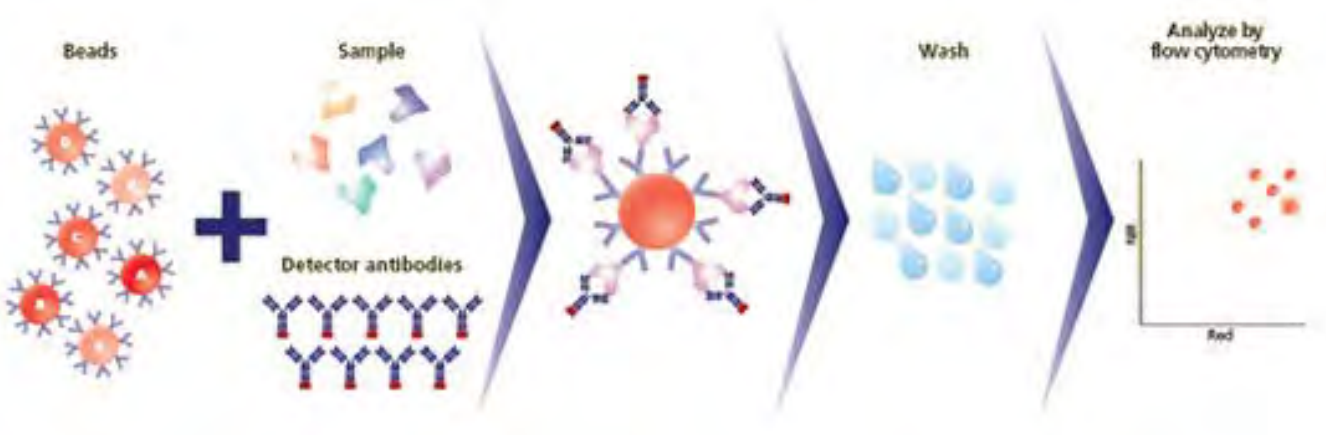

Cell Metabolism Vol.8, December 2008

# BIOAVAILABILITY AND INFLAMATION MODEL





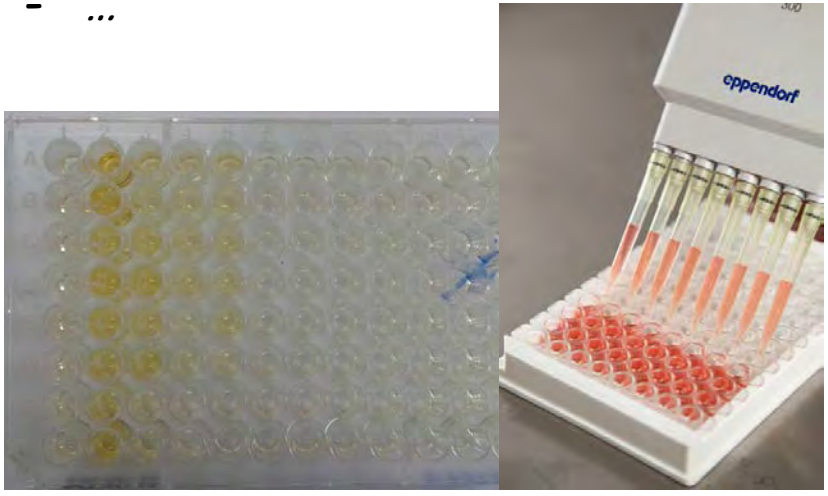



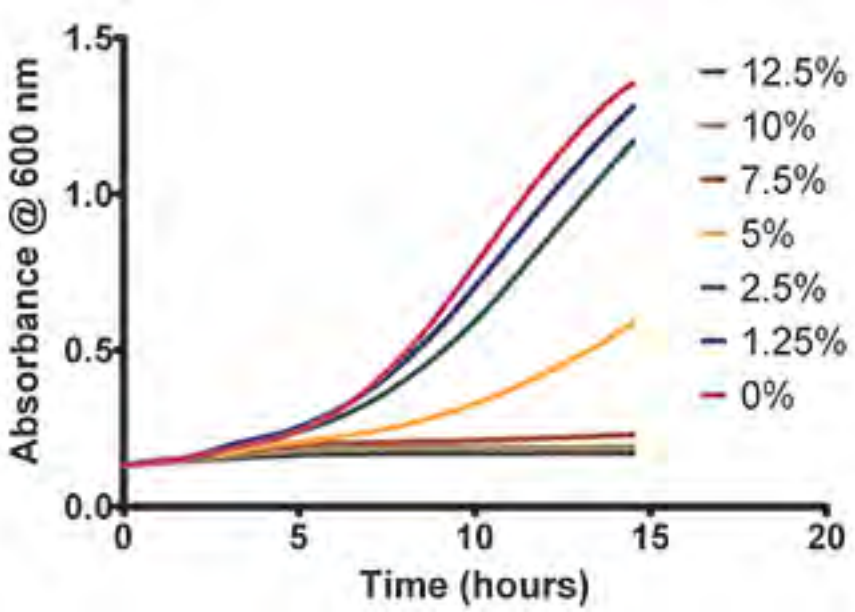

# PREBIOTIC AND/OR ANTIBACTERIAL



Pure bacteria strains:

- *Bifidobacterium sp*
- *Lactobacillus sp*
- *Escherichia coli*
- *E. coli O157:H7*
- *Stph. Aureus*
- *Listeria monocytogenes*
- *Enterococcus faecalis*
- *Enterobacter sakazaki*
- *…*

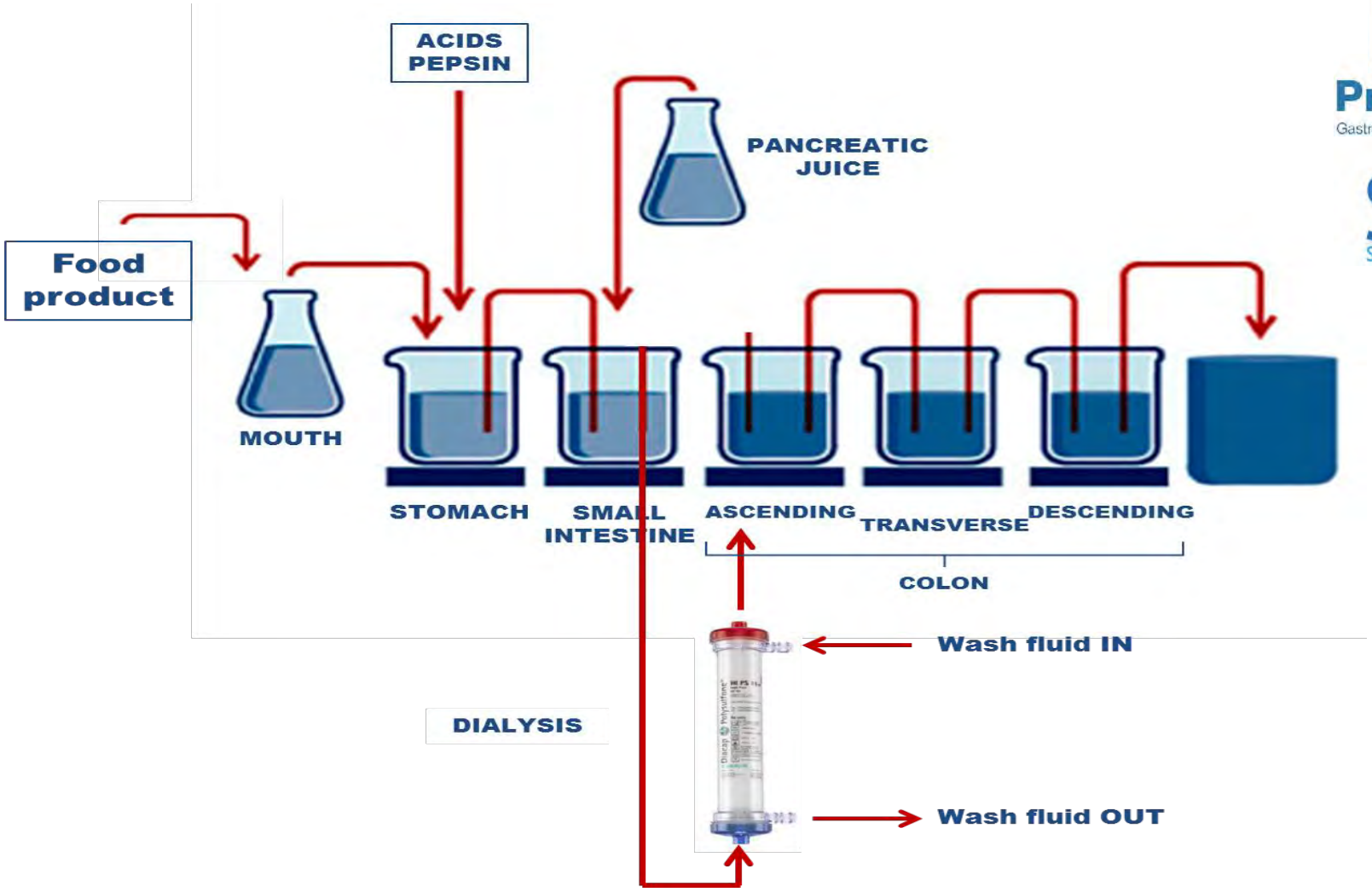



# SHIME®

## (Simulator of Human Intestinal Microbial Ecosystem)





# SHIME®

## (Simulator of Human Intestinal Microbial Ecosystem)



ProDigest
Gastrointestinal Expertise

Satin
Satiety Innovation

# Satiety Enhancing Ingredients & New Food Products Development

GOBIERNO DE ESPAÑA
MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD

MEDSatin

AGL2016-78125-R

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- Jason Halford & Joanne Harrold, University of Liverpool, UK

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# Thank You

# THANK YOU VERY MUCH

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## QUESTIONS TIME!!!