8 September 2019

EFSA's role and remit in the area of human nutrition

Silvia Valtueña Martínez

Senior Scientific Officer

Nutrition Unit

Trusted science for safe food

European Food Safety Authority

RISK ASSESSMENT & RISK MANAGEMENT IN THE EU

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Scientific assessment

REQUEST
ADVICE

Policy, legislation, authorisation…

European Commission
European Parliament
European Council
EU Member States

MANDATE IN NUTRITION (1)

- EFSA founding Regulation (EC) 178/2002

EFSA to provide

Scientific advice, scientific or technical support on human nutrition **in relation to EU legislation**

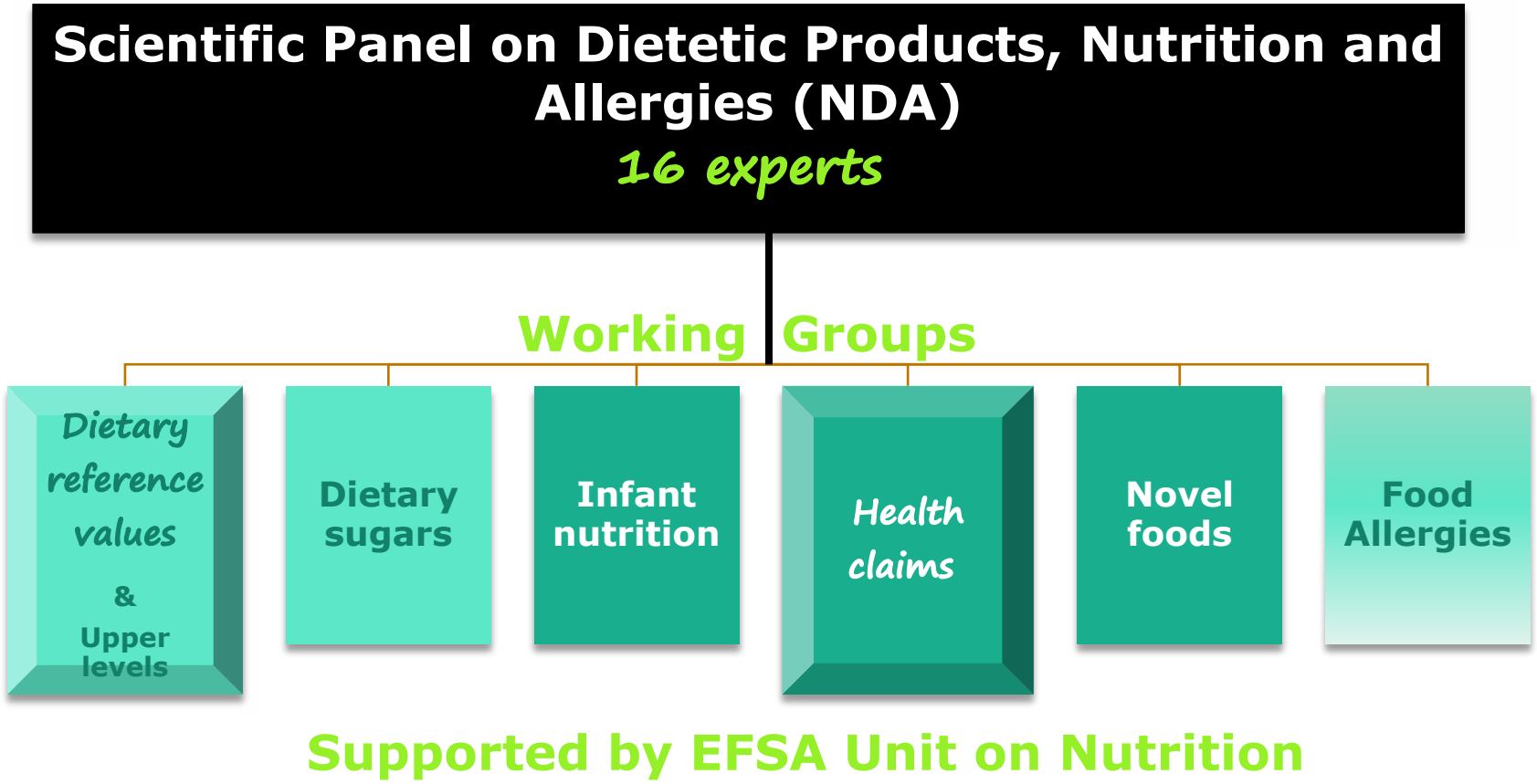
Assistance concerning **communication** on nutritional issues **linked to EU health programmes,** at request of the Commission

MANDATE IN NUTRITION (2)

EFSA does NOT

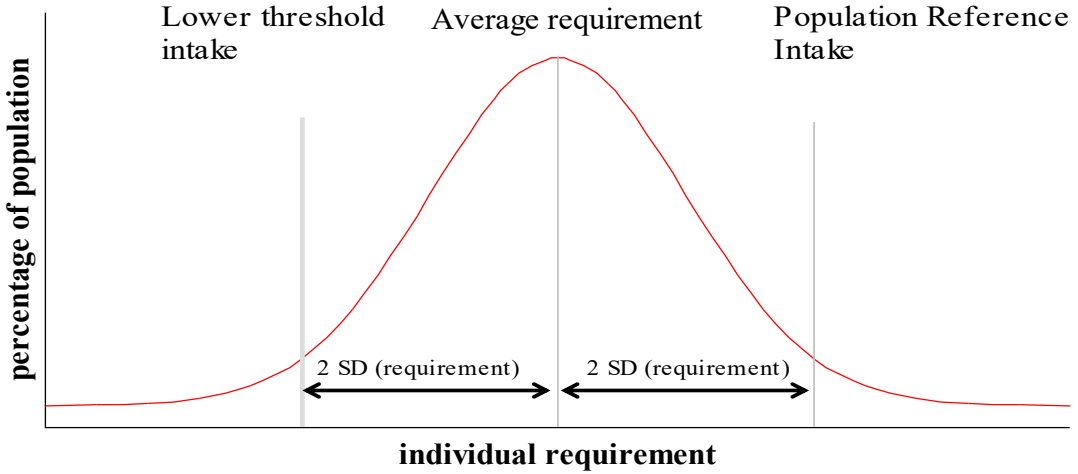
- develop or propose policies, legislation, norms and standards
- enforce legislation
- authorise products
- take charge of food safety/quality controls and labelling
- make recommendations to consumers
- monitor or assess consumers' behaviour

EFSA'S NDA PANEL

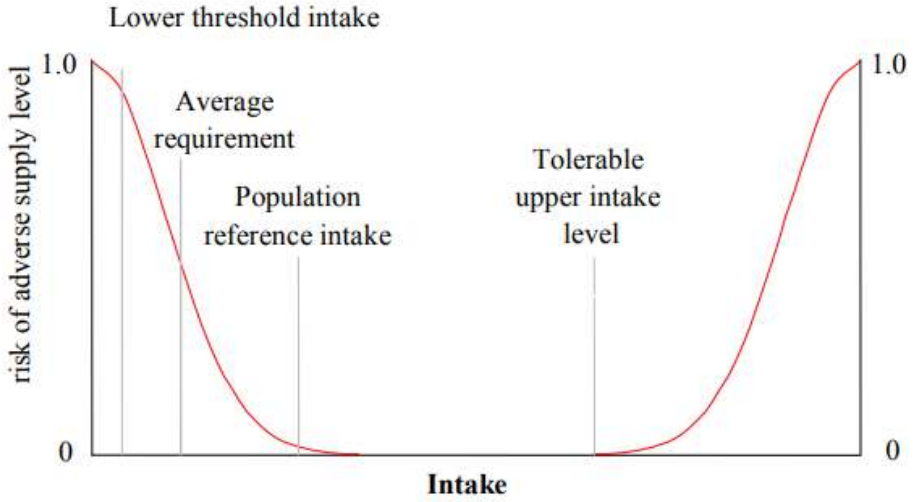


See EFSA working practices at: https://www.efsa.europa.eu/en/howwework/workingpractices

DIETARY REFERENCE VALUES FOR ENERGY AND NUTRIENTS (DRVs)



Population reference intakes (PRI) and average requirement (AR), if the requirement has a normal distribution and the inter-individual variation is known



Relationship between individual intake and risk of adverse effects due to insufficient or excessive intake

From: Health and Welfare, Canada, 1983; as adapted by Netherlands Health Council, 2000

DRVs – quantitative reference values for nutrient intakes for healthy individuals and populations which may be used for assessment and planning of diets:

Population Reference Intake (PRI)
Average Requirement (AR)
Lower Threshold Intake (LTI)
Tolerable Upper Intake Level (UL)

Adequate Intake (AI)
Reference Intake ranges for macronutrients (RI)

Safe levels of intake

DRVs – ORIGINAL MANDATE – Update DRVs from SCF (1993) (ULs excluded)

First task – to provide advice on:

- Energy,
- Carbohydrates, including sugars;
- Dietary fibre
- Fats, including SFA, MUFA, PUFA, and *trans*-fatty acids
- Protein
- + Water

Second task – to provide advice on micronutrients:

- Vitamins
- Essential minerals (- chromium)
- + Choline

Third task – if considered appropriate, provide advice on other essential substances with a nutritional or physiological effect in the context of a balanced diet which, when part of an overall healthy lifestyle, contribute to good health through optimal nutrition

Fourth task – to provide guidance on the translation of nutrient based dietary advice into guidance, intended for the European population as a whole, on the contribution of different foods or categories of foods to an overall diet that would help to maintain good health through optimal nutrition (food-based dietary guidelines - FBDG)

DRVs – CHANGES TO THE ORIGINAL MANDATE – RATIONALE

European Food Safety Authority

+ Water

- **NOT** specifically mentioned in the terms of reference (ToR)
- the NDA Panel decided that **it should be included** in the task because water and adequate hydration of the body is **essential for health and life**
- ***Adequate intakes*** established for all age groups by sex

- Chromium: Cr(III)

- postulated to be necessary for the efficacy of insulin in regulating the metabolism of carbohydrates, lipids and proteins – **IN** the mandate as **essential** mineral

- **NO evidence** of essentiality as a trace element in animal nutrition
- **NO convincing evidence** that is an essential trace element for humans
- **NO evidence** of beneficial effects associated with chromium intake in healthy humans
- **NO** Average Requirement or Population Reference Intakes could be established

DRVs – CHANGES TO THE ORIGINAL MANDATE – RATIONALE

European Food Safety Authority

+ Choline

- **SCF in 1993:** no evidence for the necessity of an intake of choline via the diet for persons older than 6 months **(NOT in the ToR)**
- **NDA Panel 2016:** Although choline can be synthesised de novo by the human body, this synthesis may become insufficient, making choline an **essential component of the diet.**
- ***Adequate intakes*** established for all age groups(NO sex-specific)

- FBDG

- **science-based policy recommendations:** guidelines for healthy eating
- should focus on the diet-disease relationships relevant to the **specific population**
- primarily **intended for consumer information and education:** should be appropriate for the region/country, culturally acceptable and practical
- **NDA Panel:** identified relevant scientific information for establishing FBDG for individual countries within the EU and summarised steps for implementation, monitoring and evaluation **(guidelines)**
- **FBDG:** to be established by each EU country/region **(NOT** by **EFSA)**

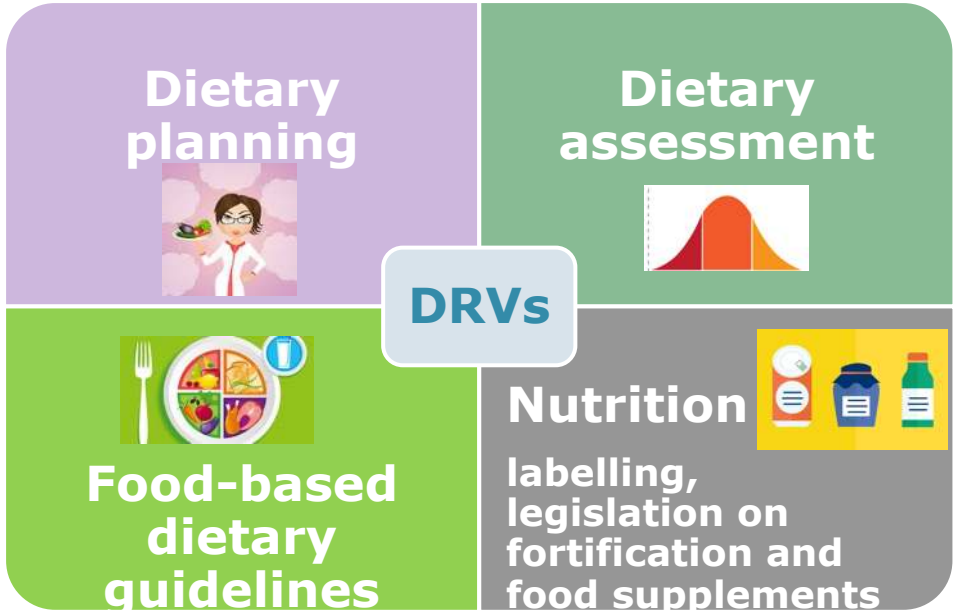
DRVs – CRITERIA AND END USERS

Criteria

- Risk of deficiency
- Functional competence
- Cell (organ) integrity
- Risk of chronic disease

Hierarchy of criteria can be established for most nutrients

Which criterion, or combination of criteria, is the most appropriate to set DRVs: matter of ***scientific judgement***



End-users

Policy makers
Public health bodies
Health professionals (dieticians, doctors)
Nutrition research community
Food and supplements industry

DRVs – WHAT IS IN THE REMIT OF EFSA AND WHAT IS NOT

Review the scientific evidence → Identify suitable indicator(s) to set nutrient requirements → Establish dietary reference values

Establish public health goals and recommendations for nutrients

e.g. establish limits for the intake of nutrients without a UL

Establish food-based dietary guidelines

Provide consumers with information and education on healthy diets

e.g. recommending regular consumption of fruits and vegetables, whole-grain cereals, etc

Adaptation to a specific context

CONTEXT

DRVs

FBDGs

Professional guidelines

Health claims made on foods

National dietary goals and recommendations

Different in aim and scope

Different scientific basis

Fulfil different purposes

Different end-users

PROFESSIONAL RECOMMENDATIONS VS HEALTH CLAIMS

WGO Practice Guideline - Probiotics and Prebiotics

October 2011

Treatment of acute diarrhea:

Hepatic encephalopathy

Allergy **Treatment of atopic eczema**

Inflammatory bowel disease (IBD)

Pouchitis:

Ulcerative colitis:

Necrotizing enterocolitis

Radiation-induced diarrhea:

Reg. (EC) No 1924/2006

- Function claims **cannot** refer to a **disease**
- Disease risk reduction claims **cannot** refer to reduction of the risk of a **disease**, but to reduction of a risk factor for disease
- Subjects with a **disease cannot** be the target population for claims made on food
  - Thus, target population for claims = **general (healthy) population or subgroups thereof**
  - Decisions on admissibility of a different target population for a claim (e.g. subjects under medications) = taken by risk managers

META-ANALYSIS FOR ASSESING PROBIOTIC EFFECTS?

European Food Safety Authority

Make clear distinction between general public health recommendations and commercial promotion of brand products through claims

Susanne Hempel, PhD
Sydne J. Newberry, PhD
Alicia R. Maher, MD

Context Probiotics are live microorganisms intended to confer a health benefit when consumed. One condition for which probiotics have been advocated is the diarrhea that is a common adverse effect of antibiotic use.

The main limitations to this result are residual unexplained heterogeneity, poor documentation of the probiotic strains, and lack of assessment of probiotic-specific adverse events.

Conclusions The pooled evidence suggests that probiotics are associated with a reduction in AAD. More research is needed to determine which probiotics are associated with the greatest efficacy and for which patients receiving which specific antibiotics.

JAMA. 2012;307(18):1959-1969

www.jama.com

No problem in clustering strains for delivering a public health message by some authoritative bodies

≠

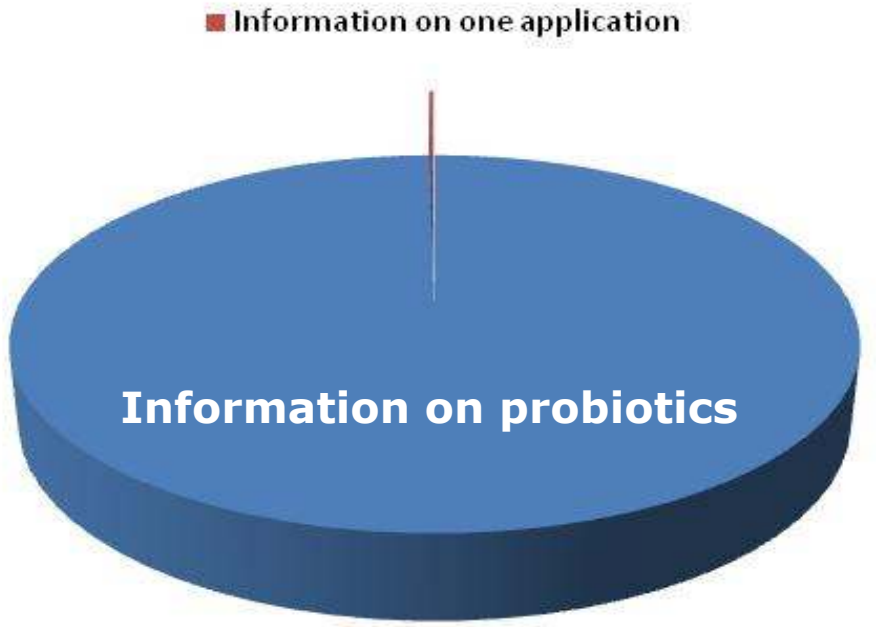
Cannot be accepted as such for commercial promotion of a brand/proprietary strain

By Ambroise Martin

HOW DOES IT WORK

"There is a wealth of scientific papers on probiotics. Why has EFSA rejected all claims?"

YES, but how much information is available for one claim application (e.g. one strain and one health effect)?



Claims are assessed case-by-case by the EFSA NDA Panel

PEER-REVIEW RESEARCH/PUBLICATIONS ON PROBIOTICS

May not provide the evidence needed for claim substantiation

Probiotics for the Prevention and Treatment of Antibiotic-Associated Diarrhea

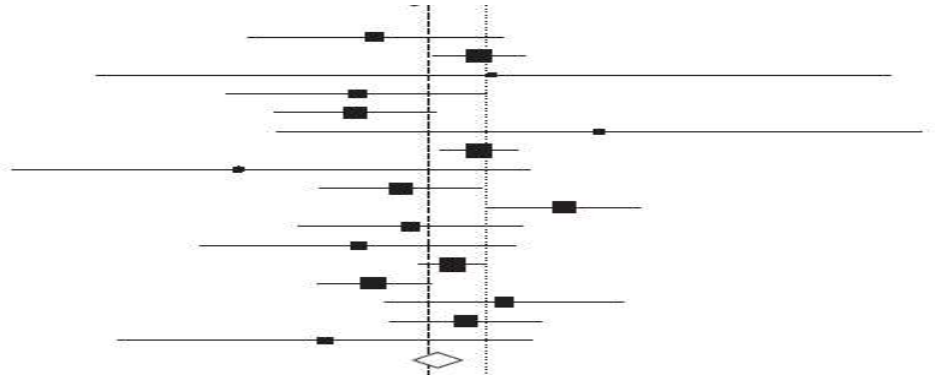
A Systematic Review and Meta-analysis

Susanne Hempel, PhD
Sydne J. Newberry, PhD
Alicia R. Maher, MD

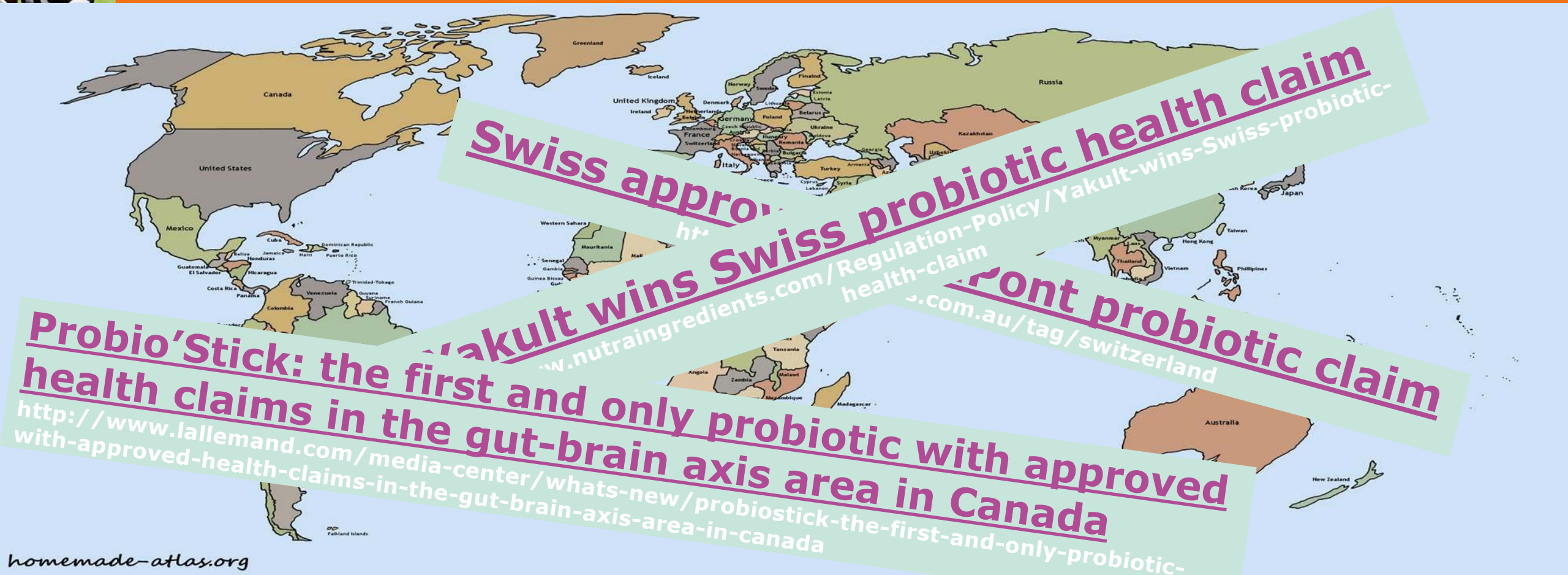
Context Probiotics are live microorganisms intended to confer a health benefit when consumed. One condition for which probiotics have been advocated is the diarrhea that is a common adverse effect of antibiotic use.

- **Aim of the publication may not fit the purpose/conditions of the claim**
- **Statistical analyses may be inappropriate** for the outcome measure of interest for the claim
- **Relevance of findings may depend on the context**

Genus, *Lactobacillus*			
Gotz,[33] 1979	3/48 (6)	9/50 (18)	0.35 (0.10-1.21)
Tankanow,[49] 1990	10/15 (67)	16/23 (70)	0.96 (0.61-1.50)
Reid,[54] 1992	0/19 (0)	0/21 (0)	1.10 (0.02-52.95)
Arvola,[37] 1999	3/89 (3)	9/78 (12)	0.29 (0.08-1.04)
Vanderhoof,[57] 1999	7/93 (8)	25/95 (26)	0.29 (0.13-0.63)
Felley,[56] 2001	1/26 (4)	0/27 (0)	3.11 (0.13-73.07)
Thomas,[50] 2001	39/152 (26)	40/150 (27)	0.96 (0.66-1.41)
Tursi,[62] 2004	0/35 (0)	5/35 (14)	0.09 (0.01-1.58)
Beausoleil,[17] 2007	7/44 (16)	16/45 (36)	0.45 (0.20-0.98)
Ruszczynski,[45] 2008	20/120 (17)	9/120 (8)	2.22 (1.06-4.68)
Safdar,[46] 2008	4/23 (17)	6/17 (35)	0.49 (0.16-1.48)
Szajewska,[48] 2009	2/44 (5)	6/39 (15)	0.30 (0.06-1.38)
Sampalis,[40] 2010	47/233 (20)	65/239 (27)	0.74 (0.53-1.03)
Gao,[41] 2010	13/86 (15)	37/84 (44)	0.34 (0.20-0.60)
Lönnermark,[44] 2010	6/118 (5)	5/121 (4)	1.23 (0.39-3.92)
Song,[47] 2010	11/103 (11)	14/111 (13)	0.85 (0.40-1.78)
Cimperman,[39] 2011	1/15 (7)	5/16 (3%)	0.21 (0.03-1.62)
Random effects model			0.64 (0.47-0.86)



PROBIOTICS IN NON-EU REGION



Health claim assessments in different jurisdictions are often driven by different legislative frameworks governing the authorisation of health claims made on food!

HEALTH CLAIMS - CRITERIA

Reg. (EC) No 1924/2006

"Health claims should only be authorised for use in the Community after a **scientific assessment of the highest possible standard**"

EFSA assessment

- **"Characterization of the food/constituent"**
- **"Claimed effect defined, beneficial, measurable"**
- **"Substantiation: human data are central"**

SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 10 December 2015

PUBLISHED: 18 January 2016

doi:10.2903/j.efsa.2016.4367

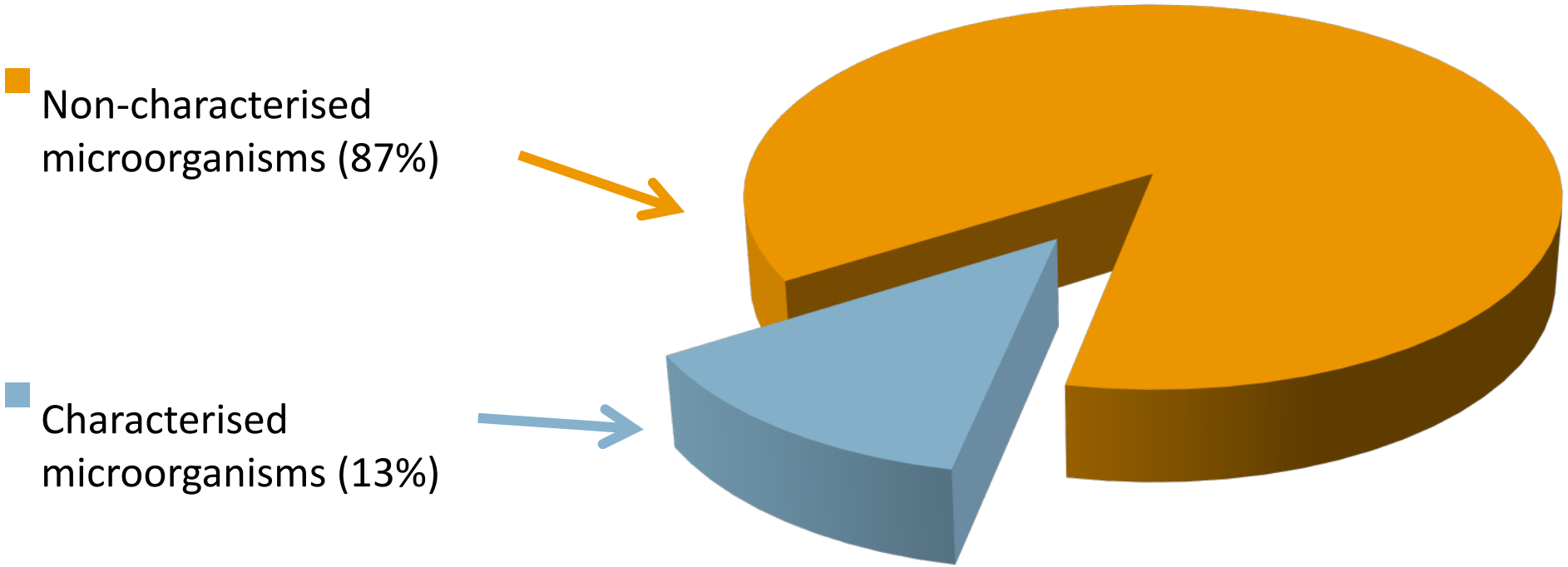
General scientific guidance for stakeholders on health claim applications

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

Scientific substantiation requires a favourable outcome in ALL

INSUFFICIENT CHARACTERISATION OF THE FOOD

A major reason for unfavourable opinions in 2009/2010



INSUFFICIENT CHARACTERISATION OF THE CLAIMED EFFECT

Other major reason for unfavourable opinions

- **Non defined claims:** 'gut health', 'digestive health', 'healthy microbiota', 'natural defences' etc.

specific and measurable ?

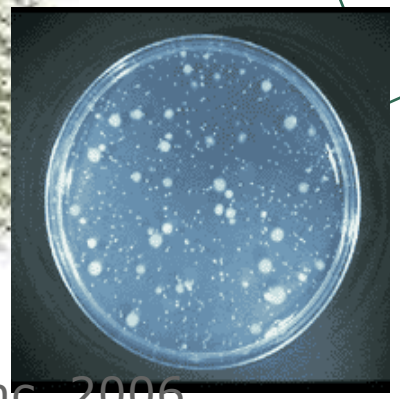
- **Non beneficial claims:** ' reduction of gastric acid levels', ' reduction of inflammation'

is a beneficial physiological effect for the target population ?

INSUFFICIENT CHARACTERISATION OF THE CLAIMED EFFECT

Not all outcomes, which can be measured *in vivo* in humans by generally accepted methods, reflect a direct benefit on human physiology

Changes in microbiota should be linked to a beneficial physiological effect or clinical outcome



Adapted from NaturalMed Apothecary, Inc. 2006

LACK OF PERTINENT HUMAN STUDIES

Altern Ther Health Med. 2011 Jan-Feb;17(1):72-9.

Clinical utility of probiotics in inflammatory bowel dise

Cain AM, Karpa KD.

York Hospital, Pennsylvania, USA.

Curr Opin Pediatr. 2010 Oct;22(5):626-34.

Probiotics and prebioti ects in allergic disease.

Tang ML, Lahtinen SJ, R

Department of Al gy, Royal Children's Hospital, Parkville, VIC, Australia. mimi.tang@rch.org.au

BMC ; 10:253.

P the treatment of acute rotavirus diarrhoea. A randomized, double-blind, co olled trial using two different probiotic preparations in Bolivian children.

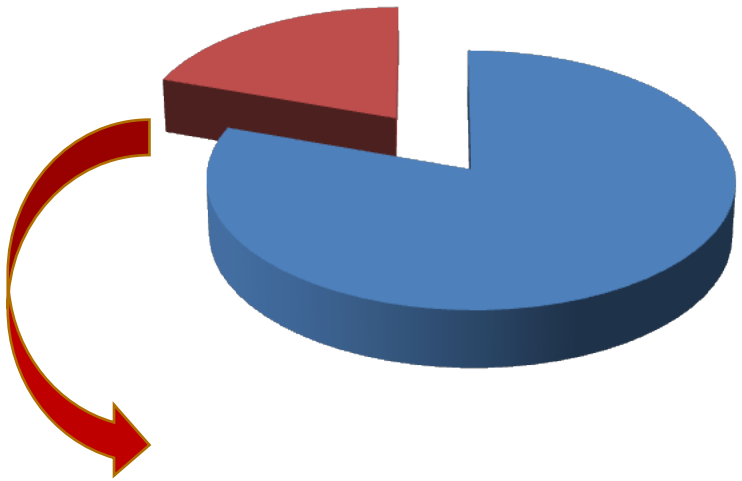
Grandy G, Medina M, Soria R, Terán CG, Araya M.

Paediatric Centre Albina Patiño, Department of Gastroenterology and Nutrition, Cochabamba, Bolivia. ggrandy@inta.cl

Studies designed for the treatment of diseases

HEALTH CLAIMS ON MICRO-ORGANISMS

Art 13.1 Claims
Lack of characterization a major reason for non favourable opinions



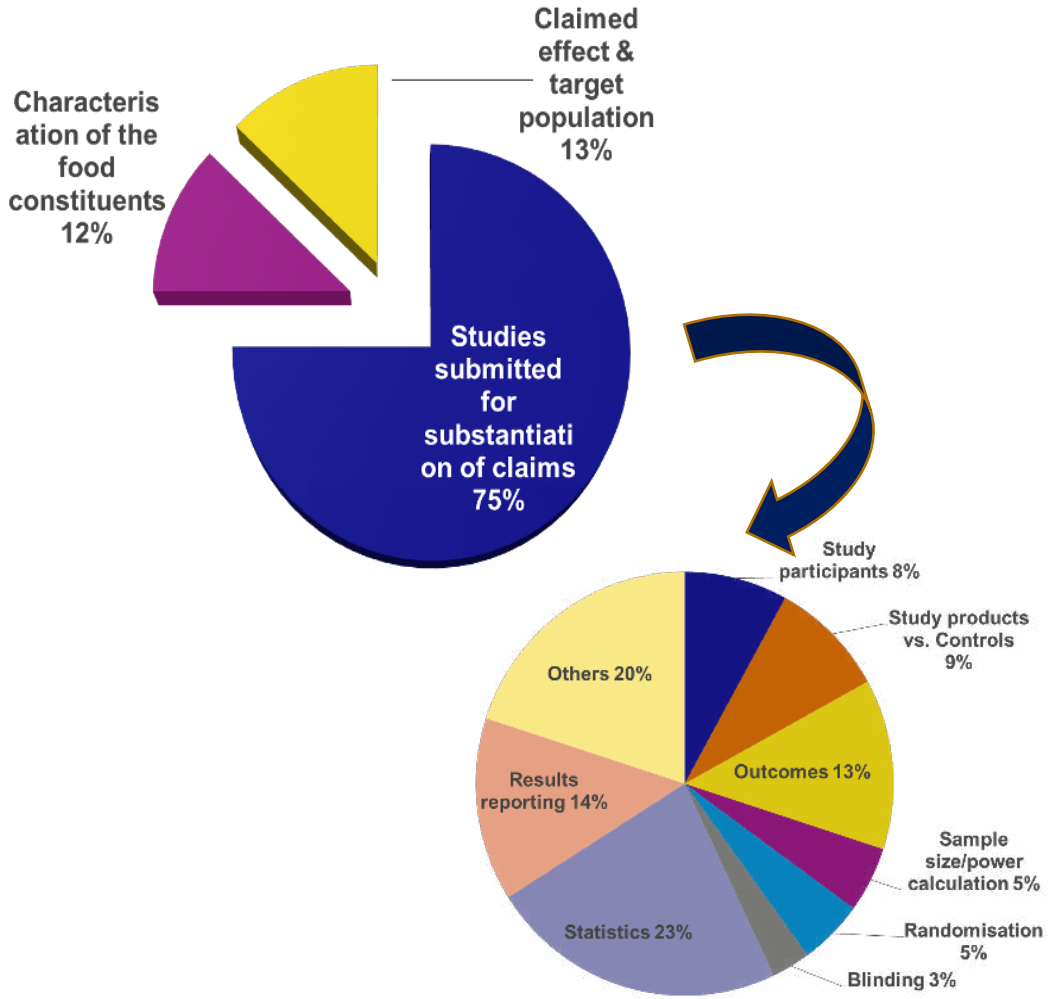
Claims effects:

- general and non-specific
- not beneficial for the target population
- not measurable *in vivo* in humans

Human studies:

- Not present
- Treatment of disease
- Uncontrolled, **etc**

Art 13.5/14 Claims (Applications)
Reasons for clock-stop



HOW TO CONCLUDE ON SUBSTANTIATION?

- ✓ **Reproducibility** of the effect of the food/constituent?
- ✓ **Consistency** of the findings?
- ✓ The **biological plausibility** of the findings?

i.e. to conclude that a cause and effect has been established between the consumption of the food/constituent and the claimed effect

FAVOURABLE HEALTH CLAIMS ON GUT/IMMUNE F(x)

- **Functions of the immune system, which were based on the essentiality of nutrients:** copper, folate, iron, selenium, zinc, vitamins C, D, A, B12 and B6

- **Bowel function/normal defecation:** dried prunes, lactulose, wheat bran fibre, rye fibre, oat and barley grain fibre, sugar beet fibre, chicory inulin and hydroxyanthracene derivatives

- **GI discomfort** caused by lactose intake in lactose intolerant individuals (foods with reduced lactose content)

- **Reduction of intestinal gas accumulation:** activated charcoal

- **Lactose digestion** (lactase and live yoghurt cultures)

- **Absorption of micronutrients** (vitamins C, D, fats)

ALTERNATIVE PROPOSALS TO HEALTH CLAIM SUBSTANTIATION

- "Probiotics" as generic descriptor
- Nutrition claim "contains probiotics"

For consideration by EU Risk Managers

(i.e. Member States and the European Commission)

- DRVs for "probiotics" ????

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