Food Pharma OTC Consult

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«Approaches for better health»

3'st International Food Supplement and Nutrition Conference

Ankara-December 4-5, 2019

Prof. Dr. Manfred Eggersdorfer and Dr. Gert Krabichler

Functional Ingredients in Food and Food Supplements

Why do we need them

How

Regulation & Health Claims

Statement

The base of a healthy nutrition has to be a

Balanced Diet

Statement

The base of a healthy nutrition has to be a an appropriate lifestyle

Content

1 **The Role of Functional Ingredients**

2 **Benefits of Functional ingredients**

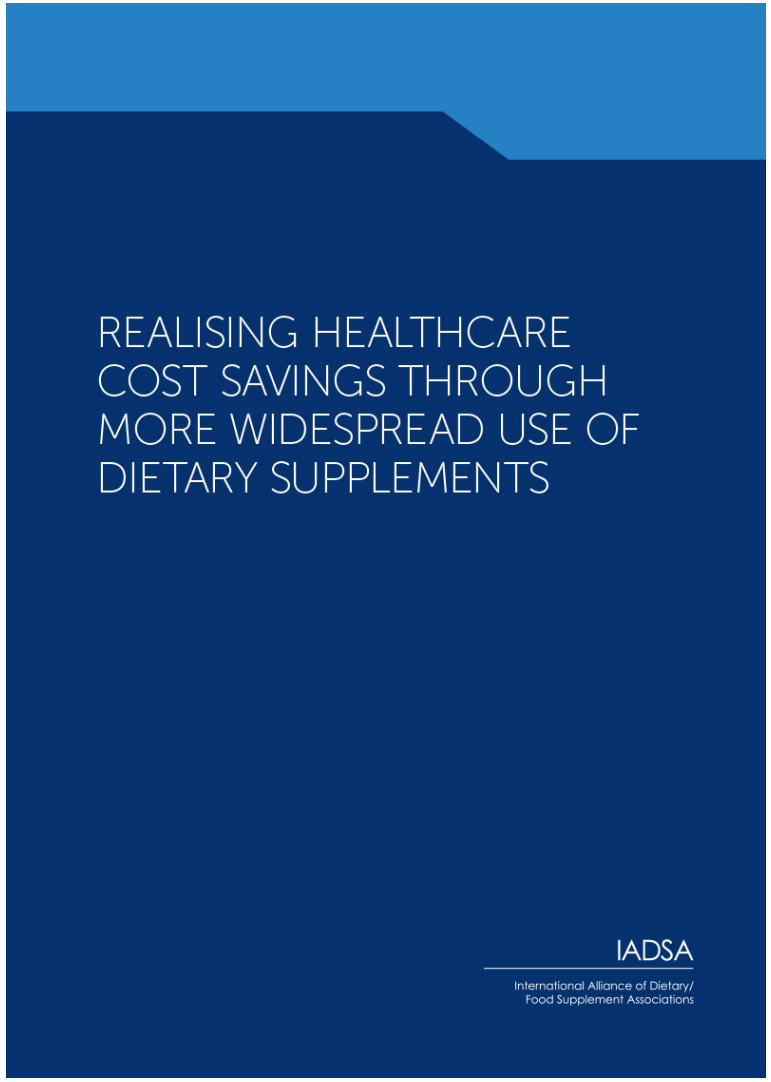
3 **Consumer understanding: Labeling and Health Claims**

4 **Innovation, Future trends, and Personalized Nutrition**

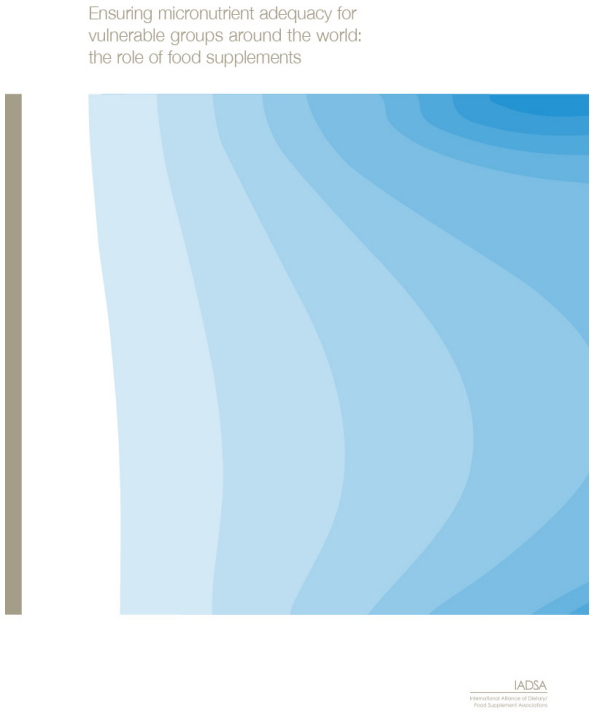
The Role of Functional Ingredients
Why is appropriate Nutrient Supply so important?

www.foodsupplementseurope.org

The Role of Functional Ingredients
Why is appropriate Nutrient Supply so important?



www.IADSA.org



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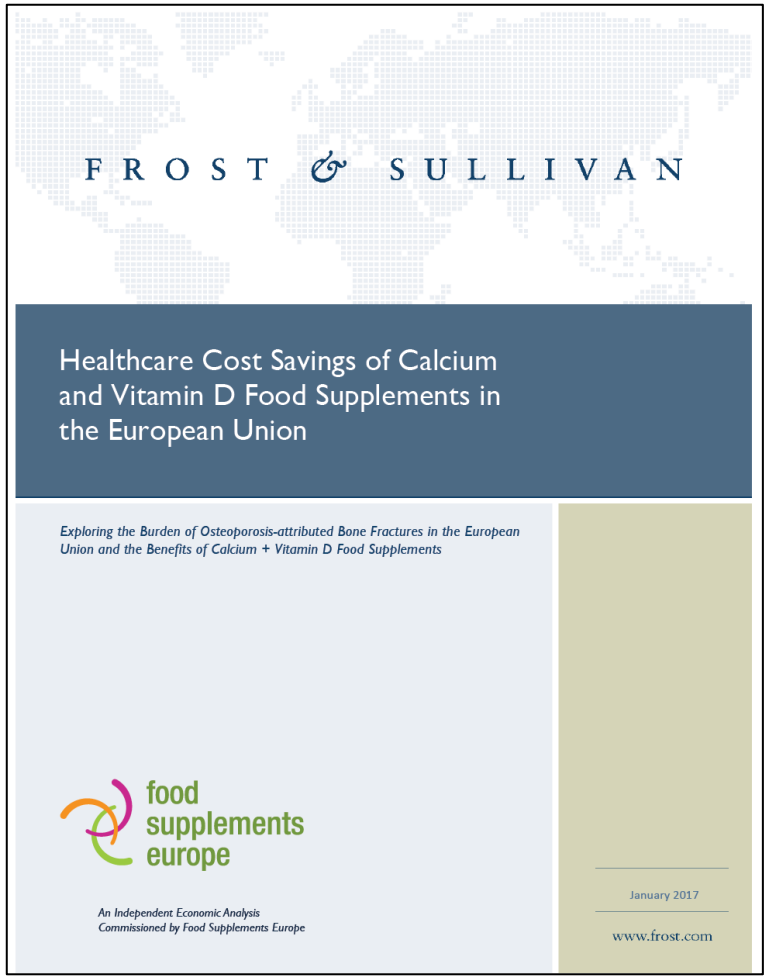


Health Care cost saving studies from Europe and the USA

- **Europe**
  - **i. Omega-3**
  - **ii. Vitamin D**
  - **iii. Phytosterols**
  - **iv. Lutein**
- **USA**
  - **i. Omega-3**
  - **ii. Vitamin D and Calcium**
  - **iii. Magnesium**
  - **iv. B-vitamins**
  - **v. Phytosterols**
  - **vi. Psyllium Dietary Fiber**
  - **vii. Chromium Picolinate**
  - **viii. Zeaxanthin**

Differentiation between Foods and Medicinal Products
Definition of Food / Food Supplements (1)

Foods / Food Supplements

Food Supplements are Foods

WHO - Codex Alimentarius
Definition of Food Supplements

1 Definition

Vitamin and mineral food supplements **for the purpose of these guidelines** derive their nutritional relevance primarily from the minerals and/or vitamins they contain. **Vitamin and mineral food supplements are sources in concentrated forms** of those nutrients alone or in combinations, marketed in forms such **as capsules, tablets, powders**, solutions etc., that are designed to be taken in **measured small-unit quantities**, but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.

Differentiation between Foods and Medicinal Products
Definition of Food / Food Supplements (1)

Foods / Food Supplements

Food Supplements are Foods

WHO - Codex Alimentarius
Definition of Food Supplements

2

Selection of Vitamins and Minerals

Vitamin and mineral food supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognised by FAO and WHO.

Differentiation between Foods and Medicinal Products
Definition of Food / Food Supplements (1)

Foods / Food Supplements

Food Supplements are Foods

WHO - Codex Alimentarius
Definition of Food Supplements

3 Contents of Vitamins and Minerals

Maximum amounts of vitamins and minerals in vitamin and mineral food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the **following criteria** into account:

(a) upper safe levels of vitamins and minerals established **by scientific risk assessment** based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the daily intake of vitamins and minerals from other dietary sources.

Definition of Foods / Food Supplements (2)

Foods / Food Supplements

Food Supplements are Foods

Definition of Food / FS (EU Regulation)

1 For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

2 Food shall not be placed on the market if it is unsafe → Food by definition has to be safe

3 'food supplements' means **foodstuffs** the purpose of which is to supplement the normal diet and which are **concentrated sources of nutrients or other substances** with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely **forms such as capsules, pastilles, tablets, pills** and other similar forms, designed to be taken in measured small unit quantities;

Definition of Medicinal Products

Medicinal Products

- Prescription Medicines
- OTC Medicines incl. Traditional Herbal Medicines

Definition of Medicinal Products (EU)

1 (a) Any substance or combination of substances presented as **having properties for treating or preventing disease** in human beings; or

2 (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

3 Medicines are

either **prescribed by doctors**
or given under **supervision of a Health Care Professional (HCP)** e.g. OTC medicines

Differentiation between Foods and Medicinal Products
Different regulatory philosophies – Comparison (1)

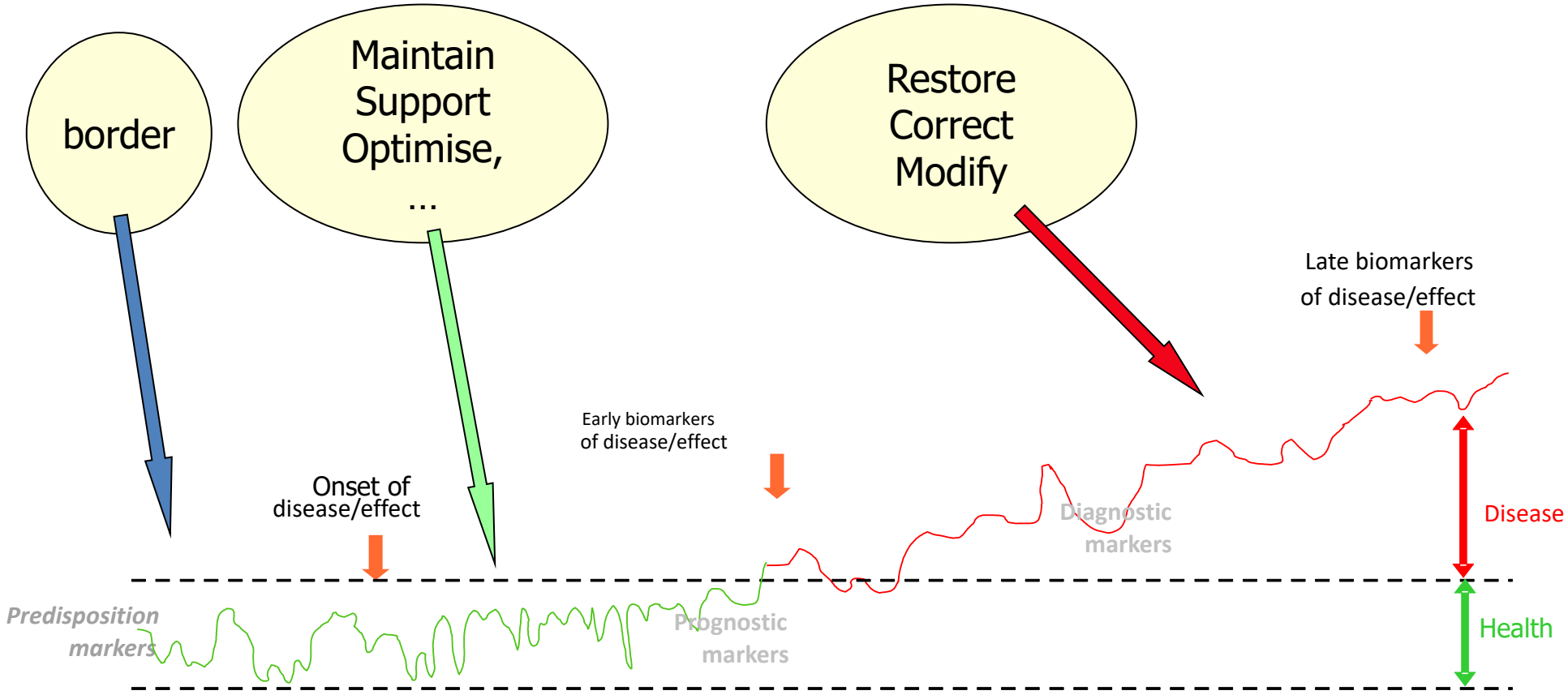
Food Supplements → Consumers	Medicinal Products → Patients
Health Claim (Function Claim): Maintenance of Health or a Health Status Reduction of a Disease Risk	**Indication:** Curing, treating or prevention of a disease
Ingredients (nutritional): Regulated list of ingredients (positive or negative lists)	**Active Pharmaceutical Ingredient:** Open, dossier requirement for each API, drug substance part
Safety driven: Risk Assessment for **long term use** by international government bodies like EFSA (EU) or IoM (US)	**Risk – Benefit driven:** Benefit has to outweigh the risk, but it can be a potentially harmful substance. **Short term use** during treatment period.
Additives: Positive list of Food Additives with proven long-term safety	**Excipients:** Excipients are part of the risk-benefit assessment during drug development
Market authorization: Many markets allow simple notification procedure, no registration (depending on market surveillance by natl. authorities)	**Market authorization:** Always pre-market authorization required, always registration with natl. authorities, dossier requirements may differ between Rx and OTC Medicines

Differentiation between Foods and Medicinal Products
Different regulatory philosophies – Comparison (2)

Food Supplements → Consumers	Medicinal Products → Patients
Quality Management: HACCP concept (EU), risk based quality management, lower requirements on single ingredient testing	**Quality Management: GMP** System approach (qualification and validation) independent of the individual risk of a product
Tolerances: Wider range of tolerances (+50% to -20%) as they are less critical regarding safety	**Tolerances:** Usually +/- 5% deviation allowed. Larger deviations could already pose a serious risk.
Monitoring of Safety: Either no monitoring required or Nutrivigilance System (national requirements)	**Monitoring of Safety:** Pharmacovigilance system, regular product update safety reports (PSURs)
Stability and Validation: Often no mandatory testing, but **manufacturer is responsible** to fulfill labelled content throughout shelf-life	**Stability and Validation:** Mandatory proof via stability batches, climatic zone requirements, continuous monitoring throughout shelf-life
Product documentation: No (drug) substance part required, but raw material specifications to be available on request	**Product documentation:** Full CTD dossier (or equivalent) required

The Role of Functional Ingredients
The Homeostasis Model

health – disease: a continuum
(Dr. Luc Demulle, Council of Europe Working Group)



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«Approaches for better health»

Why do we need food supplements and functional ingredients?

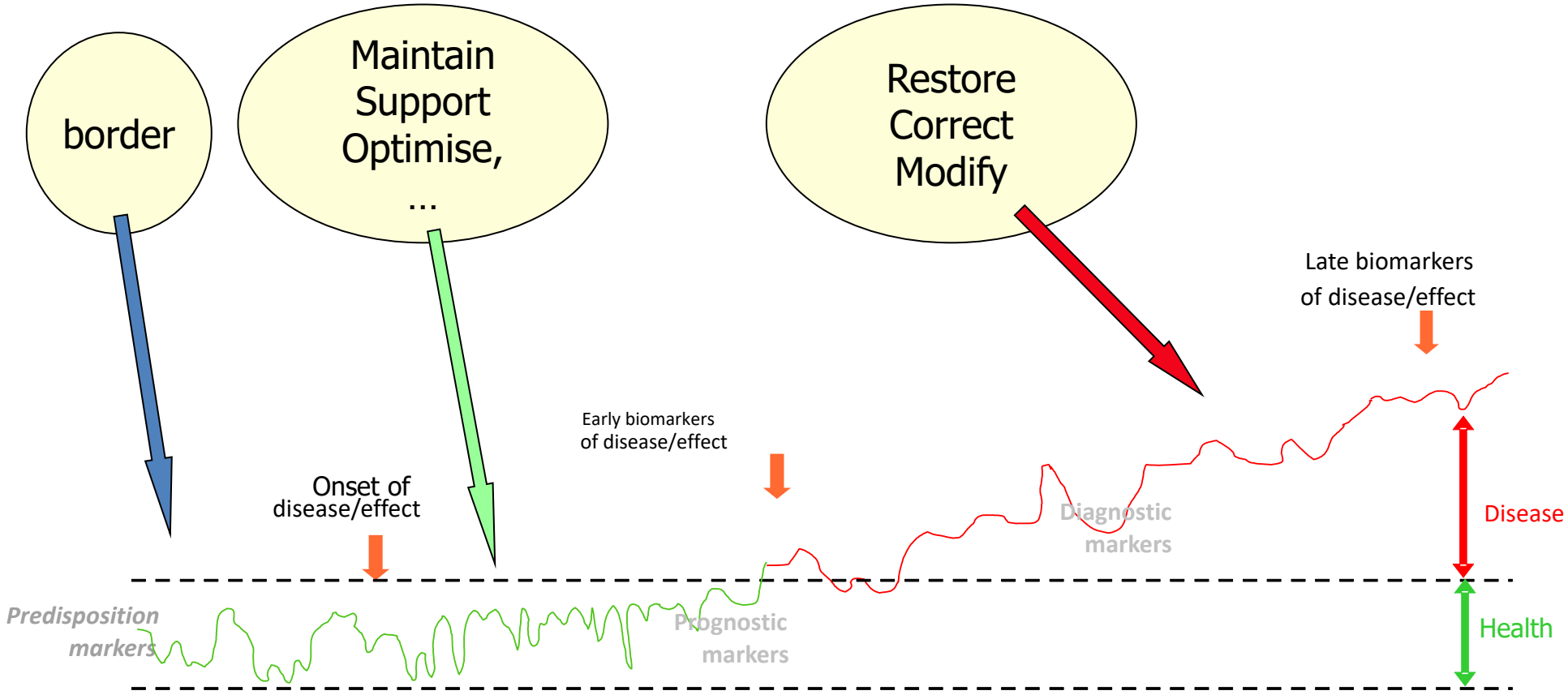
Manfred Eggersdorfer, PhD
Professor for Healthy Ageing University Medical Center Groningen
Visiting Professor at Hokkaido Information University
m.eggersdorfer@bluewin.ch

Ankara December 04, 2019

The Role of Functional Ingredients
The Homeostasis Model

health – disease: a continuum

(Dr. Luc Demulle, Council of Europe Working Group)



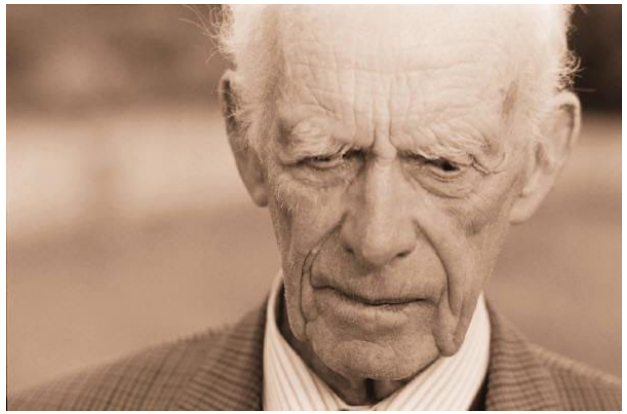
What do we basically aim with nutrition ?

- To maintain or improve normal physiological functioning (“health”)
- To reduce or modify risks (*risk factors* according to EFSA) for the development of a disease…

Health –what is it ?

Multi-dimensional

- Neither strictly defined or/nor limited
- Individually determined *and* perceived personally
- Dynamic and time-dependent

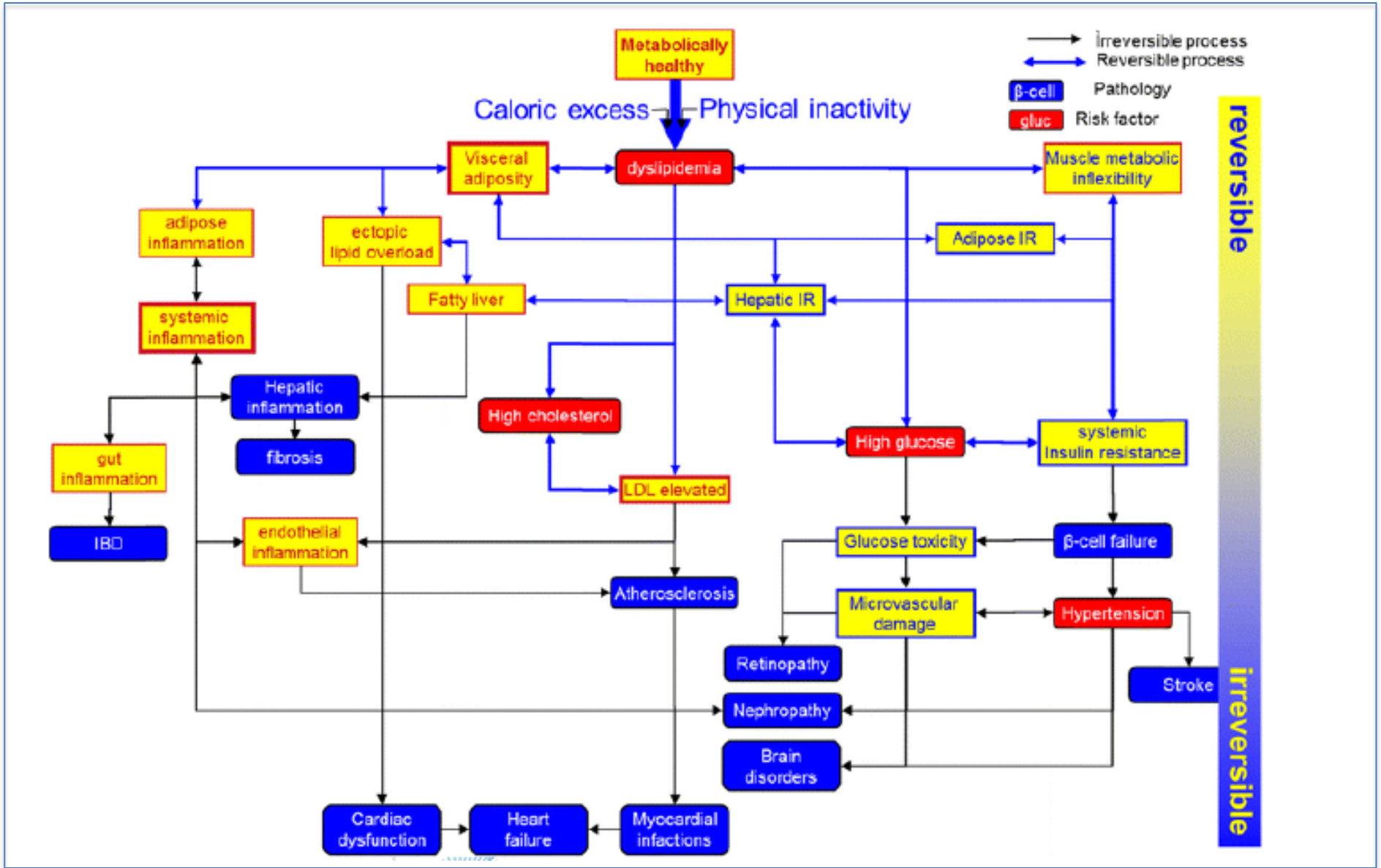


Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (WHO 1948)

→ The ability to adapt

The ability to adapt and self-manage in the face of social, physical and emotional challenges' (Lancet 2009; Huber et al. 2011).

Most chronic diseases don't develop overnight



There is a nutritional consensus with dietary recommendations built on scientific evidence

WHO recommendations:

Macronutrients:

Protein	10-15%
Fat	15-30%
Carbohydrates	55-75%
Fibers	>25g/day
Fruits and vegetables	>400g/day
Cholesterol	<300mg/day
Salt	<5g/day

Micronutrients (RDI's)

13 Vitamins

20+ Minerals

Other nutrients

9 Amino acids

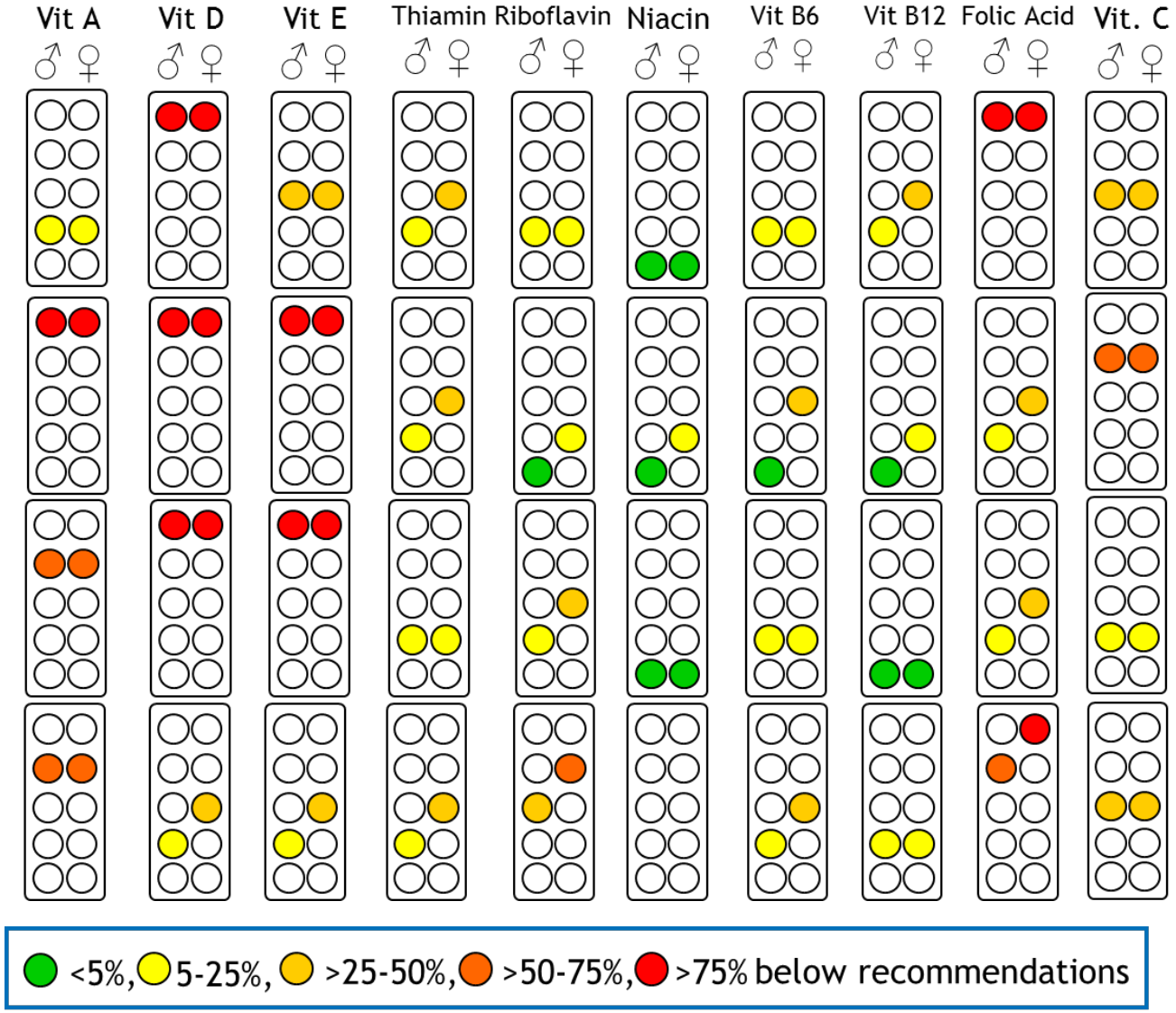
2 omega-3 Fatty acids

(moderate alcohol consumption for adults)

Macronutrient intake varies moderately,
but we see the consequences in overweight and obesity

Micronutrient intake varies considerable,
but the consequences are hidden

However nutrient intake via diet is often not according recommendations!



Barbara Troesch, Birgit Hoeft, Michael McBurney, Manfred Eggersdorfer and Peter Weber Published in British Journal of Nutrition 2012, 108, pp 692-698

Germany

United States

United Kingdom

The Netherlands

All data from intake surveys – we need status data

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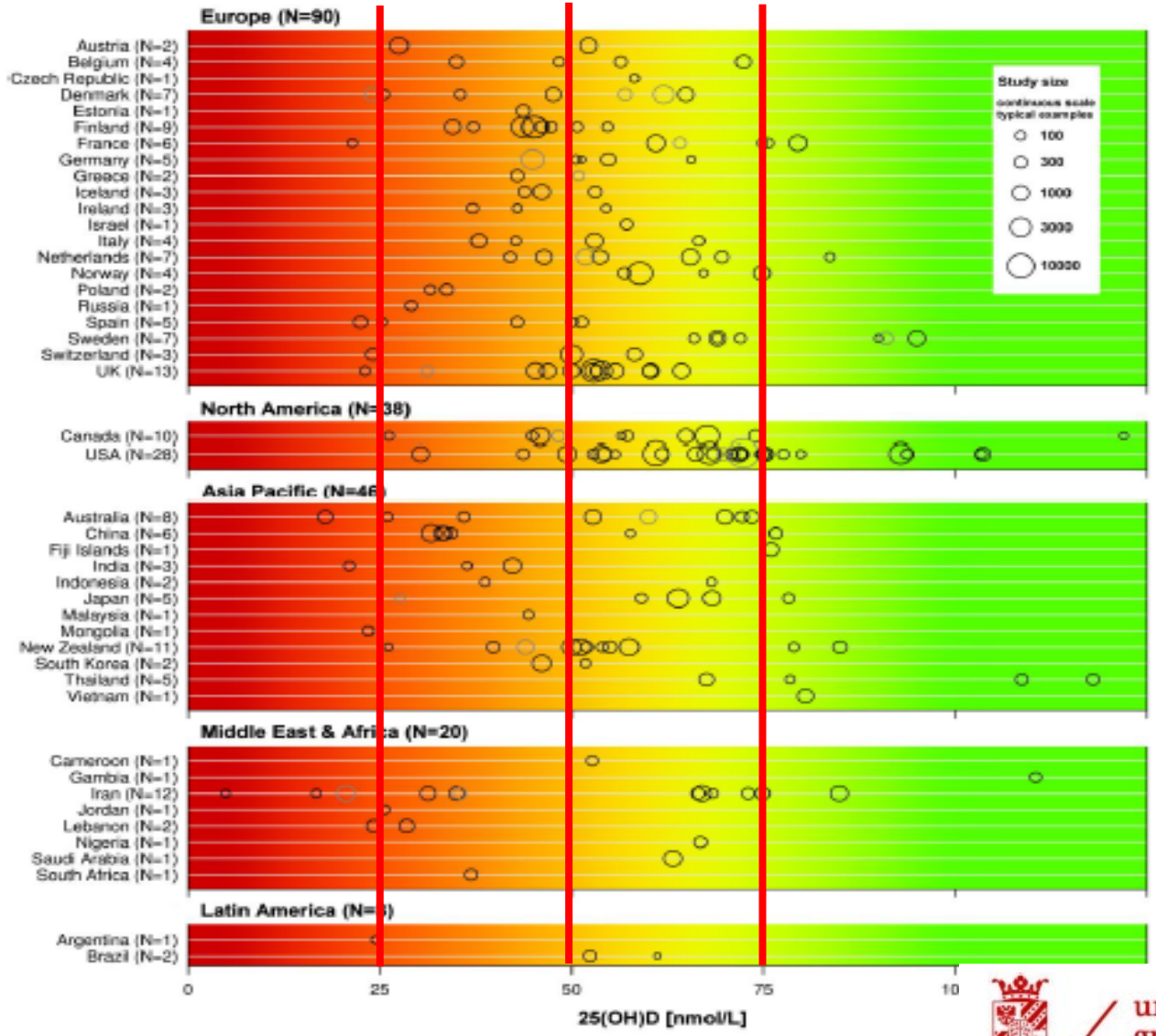
Case 1: systematic review of vitamin D status in populations worldwide

worldwide

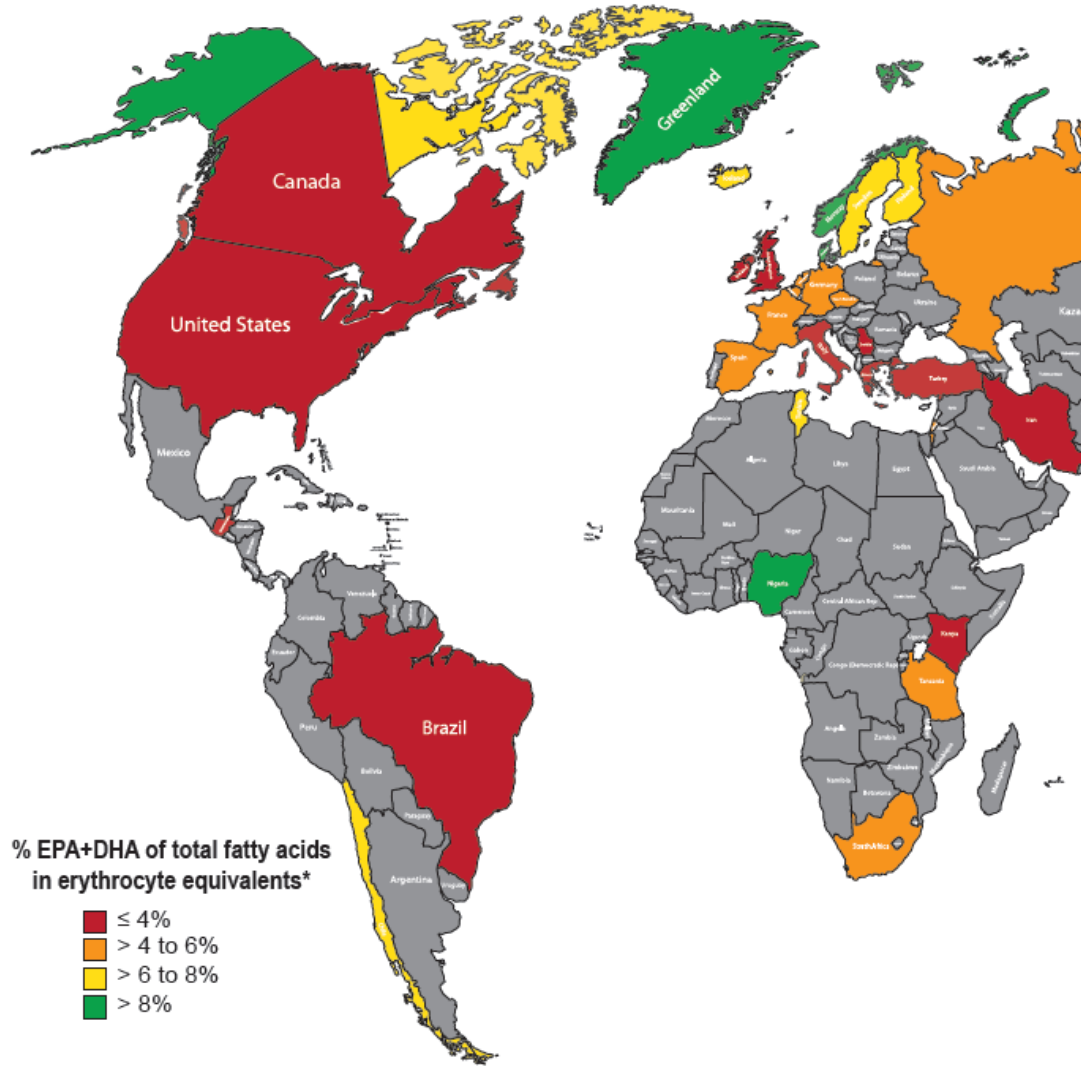
Mean 25(OH)D levels:

- 6.7% below 25 nmol/l
- 37.3% below 50 nmol/l
- 88.1% below 75 nmo/l

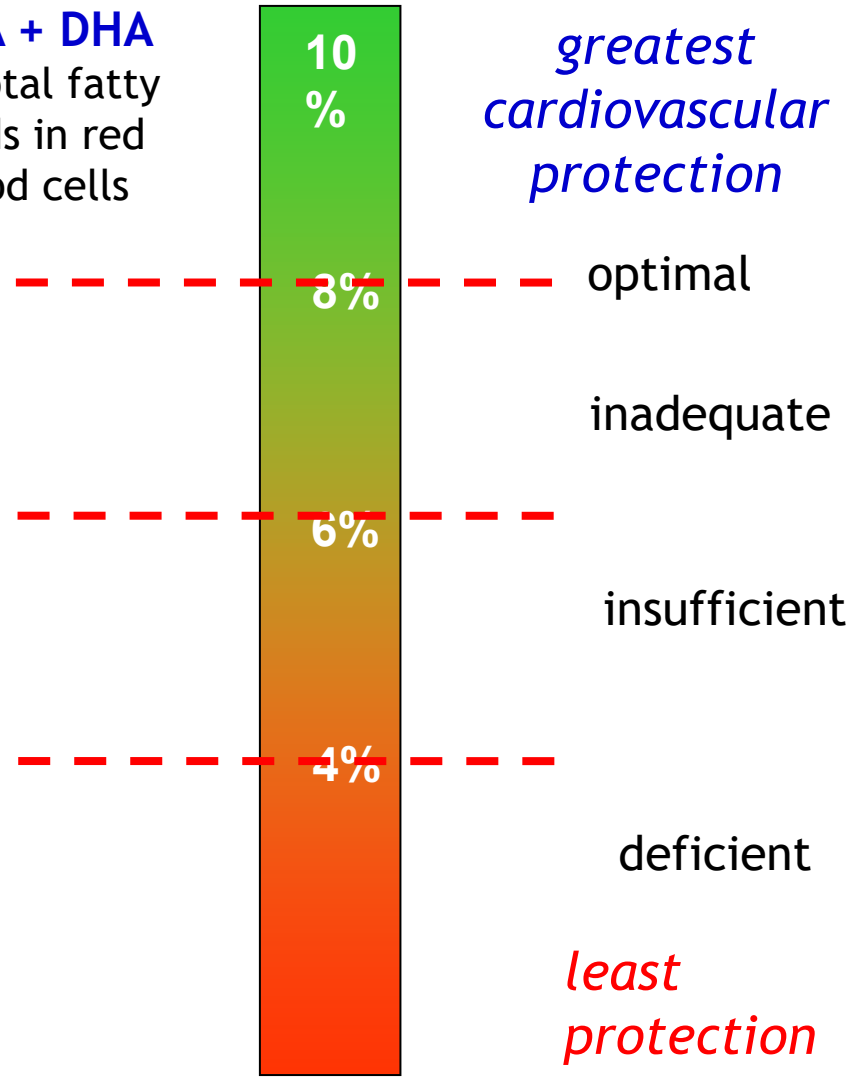
Reference:
J. Hilger, Angelika, F. Raphael Herr, T. Rausch, F. Roos, D.A. Wahl, D.D. Pierroz, P. Weber, K. Hoffmann, BJN 2013



Case 2: Omega-3 status – despite a lot of positive health data - is low in most countries



EPA + DHA
% total fatty acids in red blood cells



greatest cardiovascular protection

optimal

inadequate

insufficient

deficient

least protection

Source: Progress in Lipid Research http://authors.elsevier.com/sd/article/S0163782715300333

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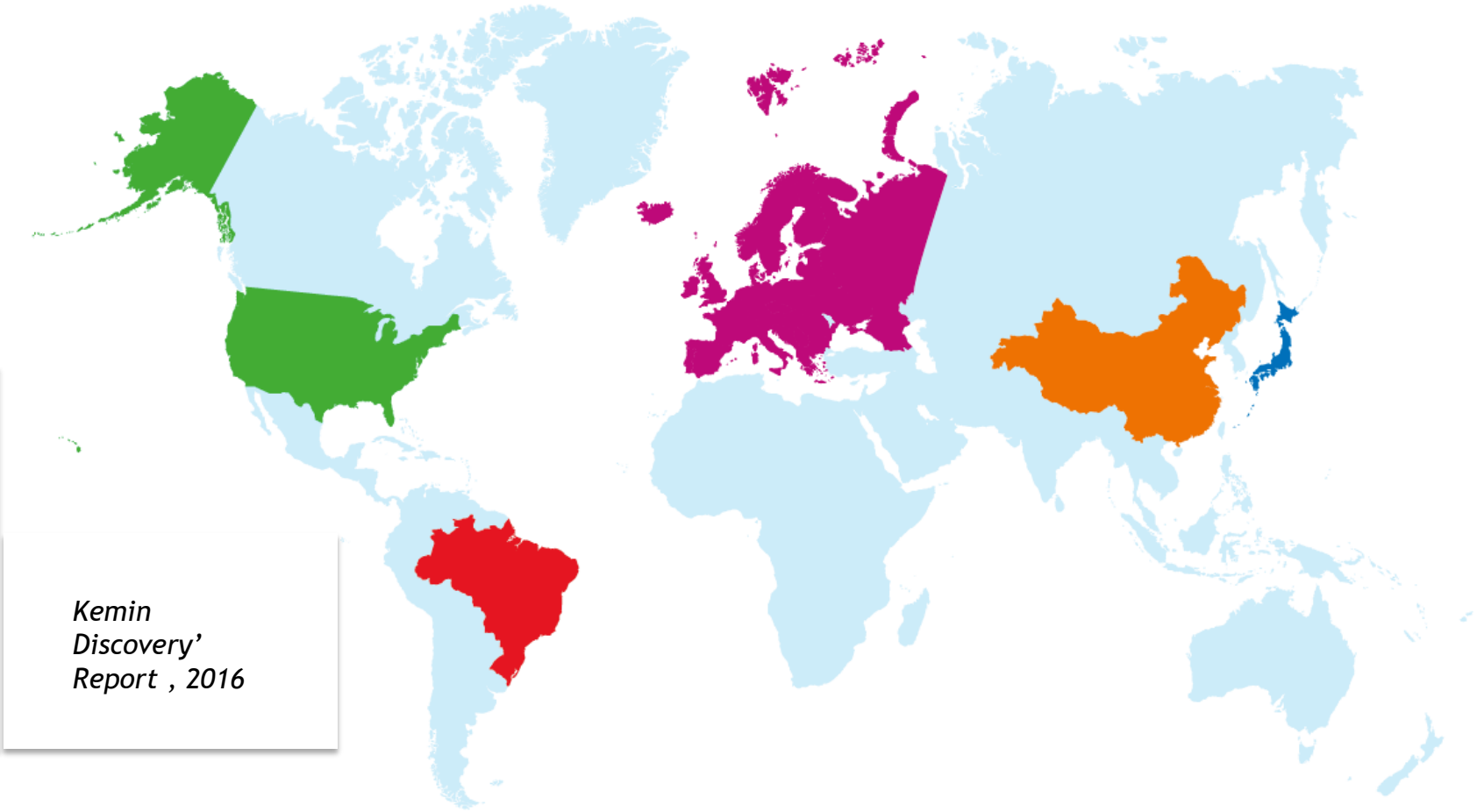
Case 3: the average daily intake of Lutein and Zeaxanthin is too low

Recommendation

10 + 2 mg/Tag
Lutein & Zeaxanthin

USA	0.8–1.1 mg /day
EUROPE	0.5–4 mg /day
CHINA	2.9 mg /day
JAPAN	0.35 mg /day
BRAZIL	0.6–1.1 mg /day

Kemin Discovery' Report , 2016



Strategies to improve nutritional status are available and partly followed

- Educate population on role of a balanced nutrition for health and well being
- Implement food fortification for nutrients of concern (country approach)
- Recommend the use of supplements to fill the gap (individualized approach)
- There is a future potential building on personalized nutrition

Still concerns about inadequate nutrient intake are not broadly accepted …..

"The medical profession itself took a very narrow and very wrong view. Lack of ascorbic acid caused scurvy, so if there was no scurvy there was no lack of ascorbic acid. Nothing could be clearer than this. The only trouble was that scurvy is not a first symptom of a lack but a final collapse, a premortal syndrome and there is a very wide gap between scurvy and full health."

–Albert Szent-Gyorgyi

…. it's not about deficiency anymore, it's about optimal status!

Content

Nutritional interventions addressing the inadequate intake of nutrients with supplements resulted in significant health benefits

Examples of recent human studies with functional ingredients demonstrating health benefits

- **Vitamin D and omega-3s** **VITAL, DO-HEALTH**
- **Folate, vitamin B6 and B12** **VITACOG study**
- **Lutein / Zeaxanthin** **AREDS II**

Heart disease is the number one reason for morbidity and mortality

- In the Europe, someone has a heart attack every 30 seconds.
- Each minute, someone in Europe dies from a heart disease-related event
- Health data from more than 190 countries show heart disease remains the No. 1 global cause of death with 17.3 million deaths each year
- Direct and indirect costs of cardiovascular diseases and stroke total more than $320.1 billion
- Nutrition and lifestyle interventions have been identified as preventive factors





VITAL study results are encouraging for the omega-3 intervention

Statistically significant reductions in secundary heart endpoints, including total and fatal MI and total CHD in omega-3 arm

- **Total MI: 28% risk reduction**
- **Total CHD: 17% risk reduction**
- **Fatal MI: 50% risk reduction**

- The greatest reductions were observed in African Americans and those who do not eat a lot of fish

These results suggest that improving omega-3 status provides a health benefit in primary prevention

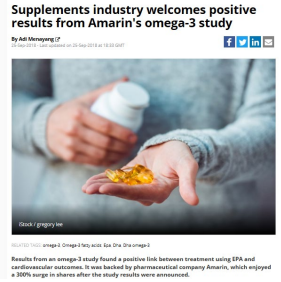
Omega-3 levels were not optimal yet in the VITAL study

Among the 15535 participants who had blood samples analyzed the mean serum n-3 index was 2.7 ±0.9 % at baseline

In 1583 participants with repeated measurement after 1 year the mean value increased to 4.1%

- The study was done in a population group which had a low omega-3 status at baseline
- Also after supplementation by 1 year the omega-3 status was in the insufficient range
- It is encouraging that under these circumstances omega-3 supplementation had shown these benefit; it can be speculated that with a higher dose ever higher benefits could have been identified (see results from REDUCE-IT study)

«REDUCE-IT» study in the US with omega-3 for CVD prevention


Supplements industry welcomes positive results from Amarin's omega-3 study

By Adi Menayang

Results from an omega-3 study found a positive link between treatment using EPA and cardiovascular outcomes. It was backed by pharmaceutical company Amarin, which enjoyed a 300% surge in shares after the study results were announced.

- Intervention in 8,179 participants with increased CVD risk, and use of statins
- Intervention with 4 g/day EPA (icosapent ethyl) (Vascepa®)
- 25% risk reduction ($p<0.001$) in primary composite end point

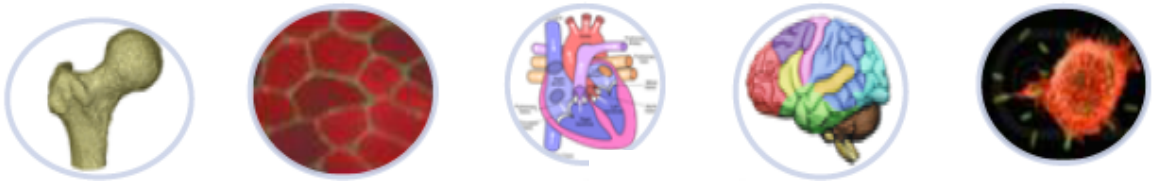
Key Secondary Composite of CV death, MI, or stroke:	26% risk reduction
Cardiovascular Death or Nonfatal Myocardial Infarction:	25% risk reduction
Fatal or Nonfatal Myocardial Infarction:	31% risk reduction
Cardiovascular Death:	20% risk reduction
Fatal or Nonfatal Stroke:	28% risk reduction
Total Mortality or Nonfatal Stroke:	23% risk reduction

«DO-HEALTH» study in Europa: with three inter-ventions for five health segments

Vitamin D
2000 IU

Omega-3
2000 mg

Physical
activity

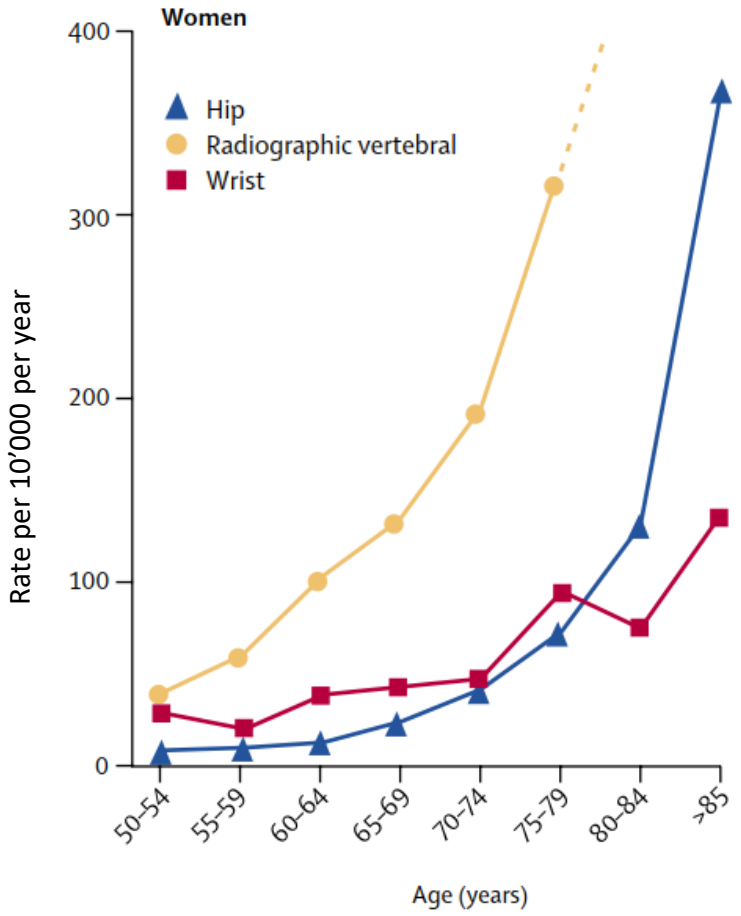


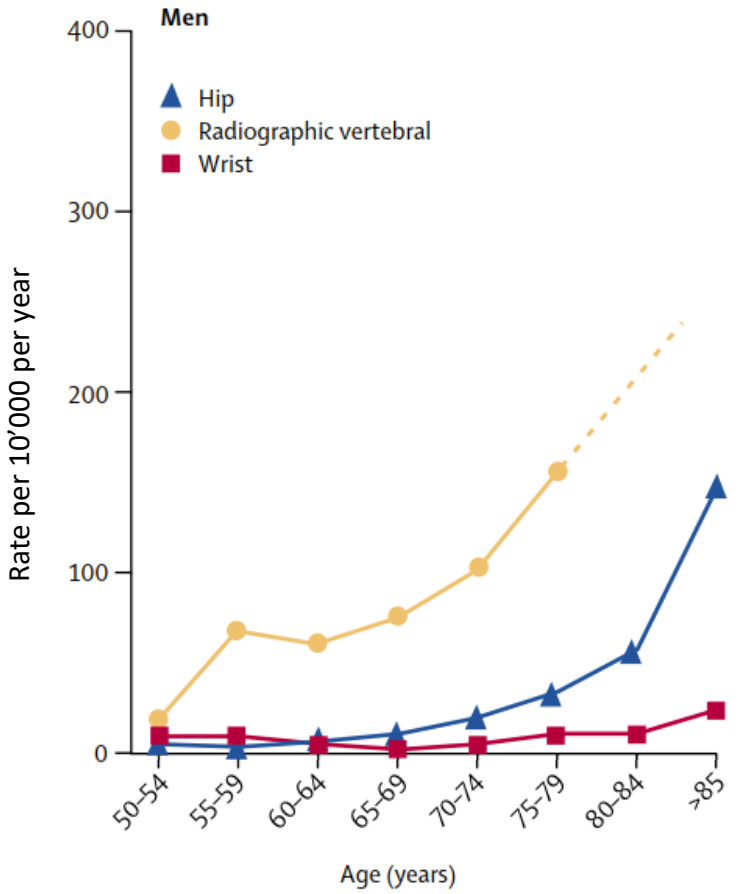
The study was performed in 7 centers in Europa over 5 years with 2152 Senioren (65+); the study is finished; the paper was submitted to LANCET for publication.

Source Heike Bischoff-Ferarri, Universität Zürich

The older, the higher the disease risk

Example: Fracture risk increase by age

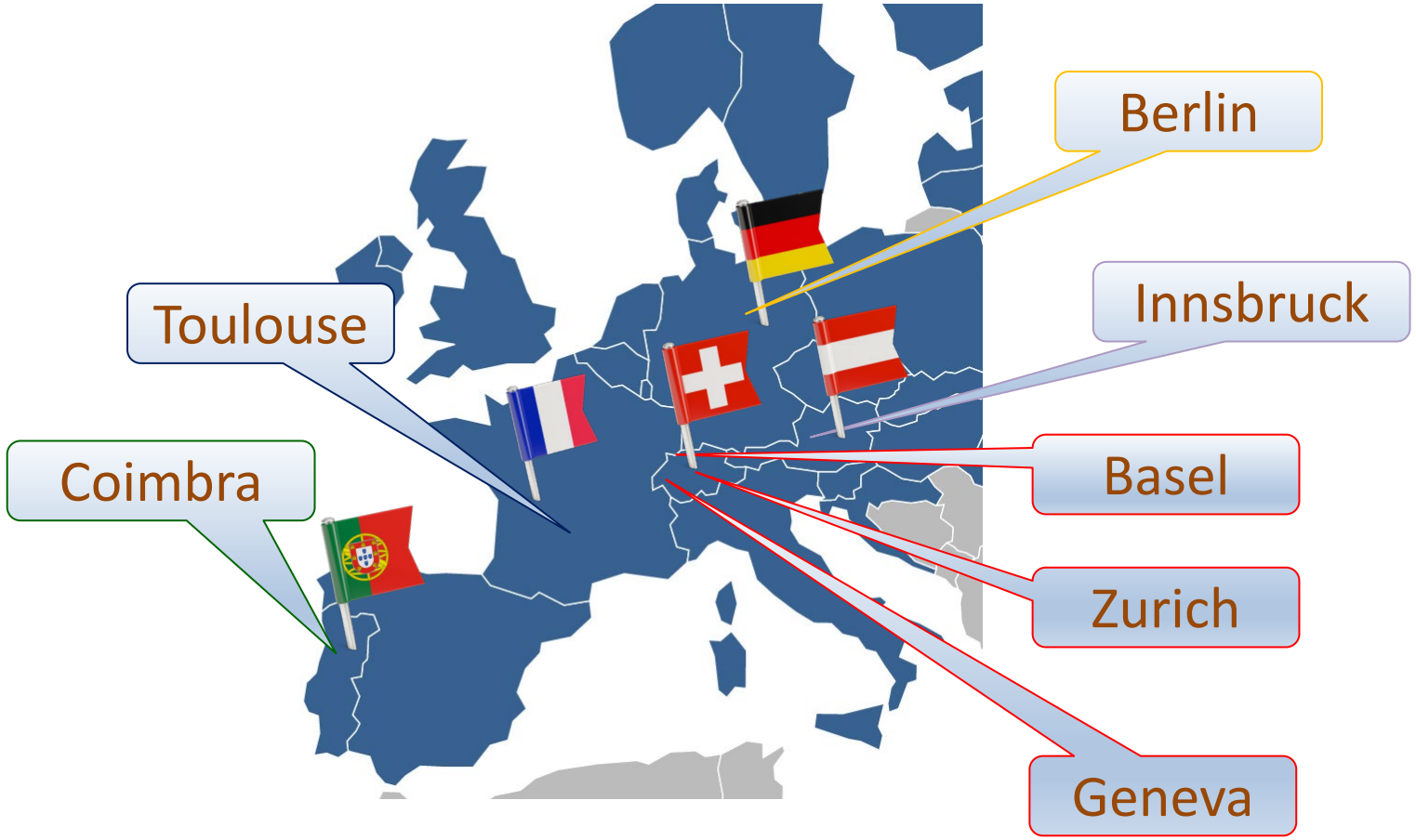




Age-specific and sex-specific incidence of radiographic vertebral, hip and distal forearm fractures. (Sambrook et al. Lancet 2006;367:2010-8)

«DO-HEALTH» Study in Europe, engaged centers

Principle Investigator :
Prof. Heike A. BISCHOFF-FERRARI, University Hospital Zurich and City Hospital Waid, Zurich, Switzerland



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Parameters assessed in the DO-HEALTH study

Primary and secondary study parameters

Heart Health

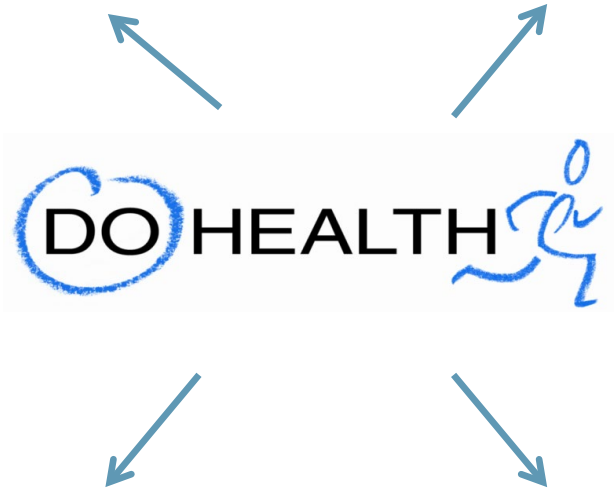
- **Systolic and diastolic blood pressure changes**
- *Risk of hypertension*

Bone Health

- **Increase of non-vertebral fractures**
- *Risk of hip/vertebral/total fractures*
- *Bone Mineral Density at spine and hip*
- *Functional recovery after fractures*

Immune Health

- **Rate of any infection**
- *Rates of any upper respiratory infection, flu-like illness or severe infections that lead to hospital admission*



Muscle Health

- **Functional decline of muscle**
- *Rate of falling*
- *Reaction time / grip strength*
- *Muscle mass upper and lower extremities*
- *Muscle Pain*

Brain Health

- **Cognitive decline**
- *Mental health decline and incidence of depression*
- *Gait variability speed when walking and counting at the same time*

Gut Health

- *Gastro-intestinal symptoms like bloating and discomfort (ROME III criteria)*

BOLD: Primary parameters

Italic: Secondary parameters

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Scientific assessment of study and results

- Largest intervention study with nutrients in seniors in Europe
- Significant findings in a number of health areas, like muscle health, heart health, brain health, immune health and even cancer reduction
- Potential to position combination of Vitamin D and algal EPA/DHA for primary prevention of diseases in the elderly
- Health economic assessment will also be done and reported in a separate publication
- Currently, three scientific publications are planned, the first one is submitted to LANCET

Cognitive impairment is a growing issue

- 44 million people worldwide live with dementia in 2013, with numbers doubling every 20 years, to reach 135 million by 2050.

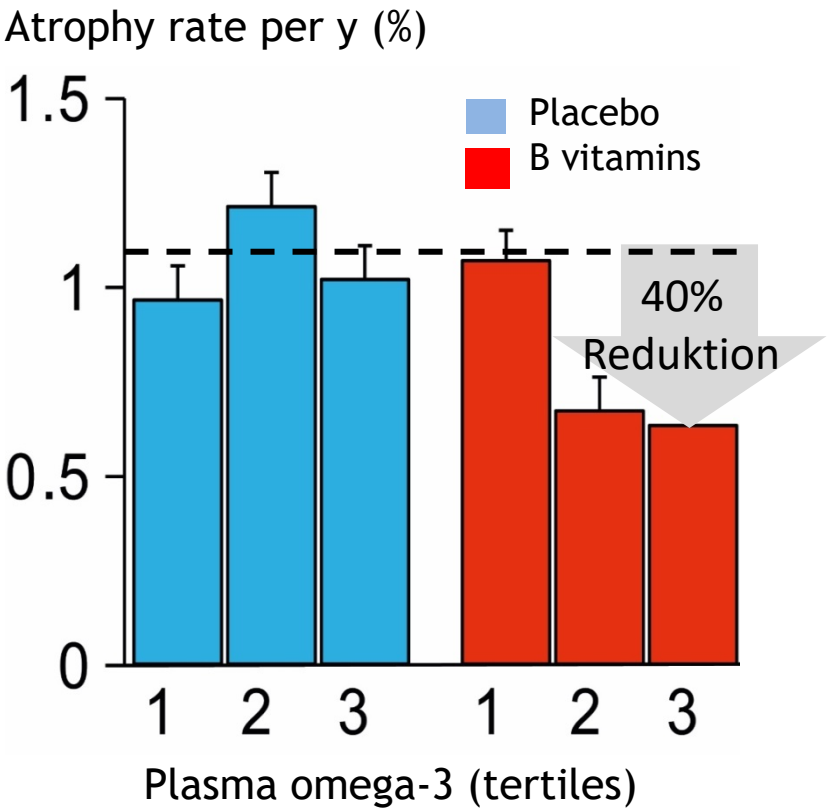
- There are 7.7 million new cases of dementia each year worldwide, with one new case every four seconds

- Dementia and cognitive impairment are by far the most important contributors, among chronic diseases, to disability, dependence, and transition into residential and nursing home care.

Of the leading causes of death, Alzheimer's Disease is the only one for which there is no way to prevent it, cure it, or slow its progression

“VITACOG” study on the role of B-vitamins and omega-3 for cognitive function

- As we age (over ~ 60) the brain shrinks at a rate of ~ 0.5% per year, i.e. ~ 7 mL per year
- Those with memory problems – ‘mild cognitive impairment’ - show a faster rate of shrinkage of ~ 1.0% per year
- In patients with Alzheimer’s disease, the rate is higher still, at ~ 3% per year



B vitamins and omega-3 fatty acids status is a marker to slow down the shrinking of the brain and memory decline

Source: Jerneren AJCN 2015

Millions of people are impacted globally by deterioration of eye health

Macular degeneration is the leading cause of severe vision loss in people over age 50 and older.
It occurs when the macula deteriorates.
Although macular degeneration is almost never a totally blinding condition, it can be a source of significant visual disability.

The loss of central vision in AMD can interfere with simple everyday activities, such as the ability to see faces, drive, read, write, or do work, such as cooking.

Normal vision

Lutein and Zeaxanthin supplementation reduces the risk of progression of Advanced AMD (AREDS II Study

4'203 AMD Participants, 5-year supplementation with 10 mg Lutein and 2 mg Zeaxanthin

- **Comparison of Lutein/Zeaxanthin vs. No Lutein/Zeaxanthin (main analysis):**

10% **Reduction in the risk of progression to AAMD**
beyond the effects of AREDS supplement

- **Sub-group analysis clearly reported the benefits of supplementation**

26% **Reduction in the risk of progression to AAMD in persons with the lowest dietary intake of L/Z at baseline**
beyond the effects of AREDS supplement

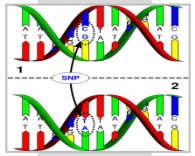
AREDS2 research Group. JAMA. 2013 May 15: 309(9):2005-15

AREDS2 research Group. JAMA Ophthalmol. 2014 Feb;132(2):142-9

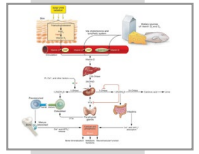
We need a new service model!

From today …

1. Regular check ups with measurement of key biomarkers and nutrients (every 1-2 years)



2. Take into account risk factors, genetics and family history



3. In case of regular drug use: care for drug nutrient interactions

4. Support and educate for a balanced diet with adequate energy and nutrient intake including use of supplements if required

… to a new concept with adequate energy nutrient density for quality of life and a healthy life!

Content

Nutrition Related Diseases
A major Health Care issue

Diseases based on not enough

- Ca, Fe, Cu
- Lutein, Carotenoids
- Folate
- Vit A, C, etc.

Homeostasis Model

Examples

1. **Osteoporosis**
2. **AMD**
3. **Anemia**
4. **NTD (Neural Tube Defect)**
5. **(Night) Blindness**
6. **Immune Function**
7. **CHD …, etc.**

Discussion in the European Union
Education of Consumers

Consumer Information !

- Ca, Fe, Cu
- Lutein, Carotenoids
- Folate
- Vit A, C, etc.

Homeostasis Model

How to keep the body in balance

Consumer Education

1. **Consumer information on Health Maintenance**
2. **National nutrition policies**
3. **Labeling of food products**
4. **Health related consumer information**
5. **Health Claims**

Health Claim

- Definition

1 **Definition**

as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health."

2 **Scientific validity to be approved by EFSA**

Consumer Education

Health Claims – differentiation from Medicine

Health Claim → Consumer	Medicinal Products → Patients
Health Claim (Function Claim): Maintenance of Health or a Health Status Reduction of a Disease Risk	**Indication:** Curing, treating or prevention of a disease
Food Ingredient: General Claim approved by EFSA and authorized by EU Com	**Active Pharmaceutical Ingredient:** No claim granted for the API, solely for the finished product (medicine)
Food Product: Normally many ingredients	**Medicinal product:** Usually 1 API or combination product of very few APIs
Food Product → no registration: No claim approval for the finished product, claims based on approved ingredient claims	**Medicine → registration:** Product registration with approval of the medical indication
Market authorization for FS product: **No market authorization**, some countries ask for product notification Approved Health Claims are published in EU Com register	**Market authorization:** Always pre-market authorization required, indication is part of the registration and authorization process

Consumer Education

Health Claims – differentiation from Medicine

Health Claim → Consumer	Medicinal Products → Patients
Health Claim (Function Claim): Maintenance of Health or a Health Status Reduction of a Disease Risk	**Indication:** Curing, treating or prevention of a disease
Vitamin C: Vit C contributes to normal collagen formation for the normal function of teeth/gums	**Vitamin C:** X mg Vitamin C for the treatment of scurvy
Joint Health: Glucosamine plus Vitamin C Vitamin C contributes to normal collagen formation for the normal function of cartilage	**Glucosamine:** Treatment of osteoarthritis
Vitamin D: Vitamin D contributes to the maintenance of normal bones	**Vitamin D:** For the prevention of rickets or for the supportive treatment of osteoporosis
Gingko plus B-Vitamins and Choline: Zinc contributes to normal cognitive (mental) function	**Gingko Biloba:** Herbal drug to increase brain performance and blood circulation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Ginkgo + B-Vitamine + Cholin
40 Kapseln
Doppel herz®
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Ginkgo
+ B-Vitamine + Cholin
Pantothensäure als Beitrag für die normale geistige Leistungsfähigkeit
Zink für die normale kognitive Funktion
+ 100 mg CHOLIN
+ B-VITAMINE
ZUR NAHRUNGSERGÄNZUNG
Zink
Fol-säure
B12
B5
B1
1x täglich
40 Kapseln


Tebonin®
intens 120 mg
120 mg/Filmtablette
Für Erwachsene ab 18 Jahren
Wirkstoff: Ginkgo-biloba-Blätter-Trockenextrakt | EGb 761®
Pflanzlicher Wirkstoff zur Leistungsstärkung des Gehirns und zur Durchblutung
120 Filmtabletten

Key elements of the 1924/2006

1. Art. 13.1

General Health Claims: based on generally accepted scientific evidence
Health claims other than those referring to the reduction of disease risk and to children's development and health
Well understood by the average consumer

2. Art. 13.5

Any additions of claims to the list **based on newly developed scientific evidence** and/or which include a request for the protection of proprietary data shall be adopted following the procedure laid down in Art. 18

Key elements of the 1924/2006

1. Art. 14.1 claims ref. to children's development and health

… claims referring to children's development and health may be made where they have been authorized in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of this Regulation

2. Art. 14.2 disease risk reduction claim

In addition to the general requirements … **for reduction of disease risk claims** … the presentation or advertising shall also bear a statement indicating that the disease to which the claim is referring **has multiple risk factors** and that altering one of these **risk factors may or may not have a beneficial effect**.

Establishing the Art. 13 list – generally accepted claims

Procedure to establish Health Claims

- Art. 13.1. list

1. **EU Member States submit existing health claims to the EU Commission**
2. **EU Com consolidates the list of claims**
3. **Consolidated list sent to EFSA for scientific assessment**

Procedure to establish Health Claims

- The result
- 261 Health Claims

The result as of today

1	229	Art. 13.1 claims
2	6	Art. 13.5 claims
3	26	Art. 14 claims

- https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home

Education of Consumers

What is important for Consumer understanding?

Issue: How to fulfil Consumer Expectation?

Key issues for the Industry:

1. Fulfil consumer demands for new products supporting health
2. Develop innovative products
3. Communicate to consumers by giving truthful information about the benefits
4. Have an open dialog between Industry, Regulators (Governments), and consumers on innovation

CIAA Health Claims Workshop

Scientific substantiation of health claims: fulfilling the requirements of Art.13

Brussels
28th March 2006

Education of Consumers

What is important for Consumer understanding?

1. **Wording and Context of a Health Claim**
2. **Other communication elements e.g. packaging, endorsement, brand names**
3. **Consumer's motivation and ability to interpret**
4. **Personal attitudes and beliefs of consumers**

CIAA Health Claims Workshop

Scientific substantiation of health claims: fulfilling the requirements of Art.13

Prof. David P. Richardson
BSc MSc PhD

Brussels
28th March 2006

Education of Consumers

What is important for Consumer understanding?

Nutrition and Health Claims can exert an effect on consumer behavior to an extent that consumers:

1. **Are aware of the claim**
2. **Understand the claim**
3. **Make appropriate health inferences from the claim**
4. **Consider the claim credible**
5. **Attach attitudinal relevance to the claim (i.e. the claims are appealing and motivating)**
6. **Translate the claim into action, e.g. purchase intend**

CIAA Health Claims Workshop

Scientific substantiation of health claims: fulfilling the requirements of Art.13

Prof. David P. Richardson
BSc MSc PhD

Brussels
28th March 2006

Education of consumers
Scientific substantiation of Health Claims (IADSA)

IADSA report 2010

Consumers should be able to make choices based on clear and accurate information and to have confidence in the scientific and regulatory process used to support health claims

The EU Health Claims Regulation EC No 1924/2006

The EU Nutrition & Health Claims Regulation

Food Supplements Europe

Guidance for food Operators

- https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home

The EU Food Information to Consumers Regulation EC No 1169/2011

Health Claims, Food labelling, etc.

REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 25 October 2011
on the provision of **food information to consumers**, amending Regulations **(EC) No 1924/2006** and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
(Text with EEA relevance)

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&from=en

The EU Food Information to Consumers Regulation EC No 1169/2011

This Regulation applies to all information (mandatorily and voluntarily) given to consumers:

1. Product labelling
2. Information on the product
3. Advertisement of the product in all media
   - Newspapers and Journals
   - Radio and TV
   - Internet

Summary

- Key Messages

The importance of Health Claims

1. **Educated & conscious choice for consumers – I know what I buy**
2. **Consumer awareness on the benefit of product**
3. **No claim registration per product – claim per ingredient**
4. **Positive list of health claims**
5. **Flexible wording, if meaning of claim is identical**
6. **Claims are scientifically proven → EFSA assessment**

Content

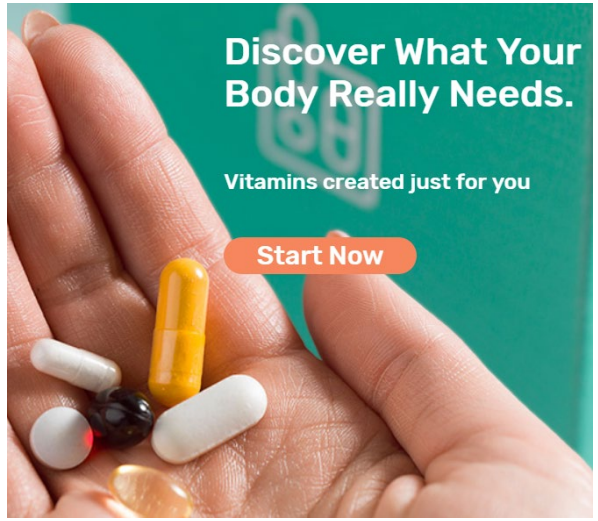
1 The Role of Functional Ingredients

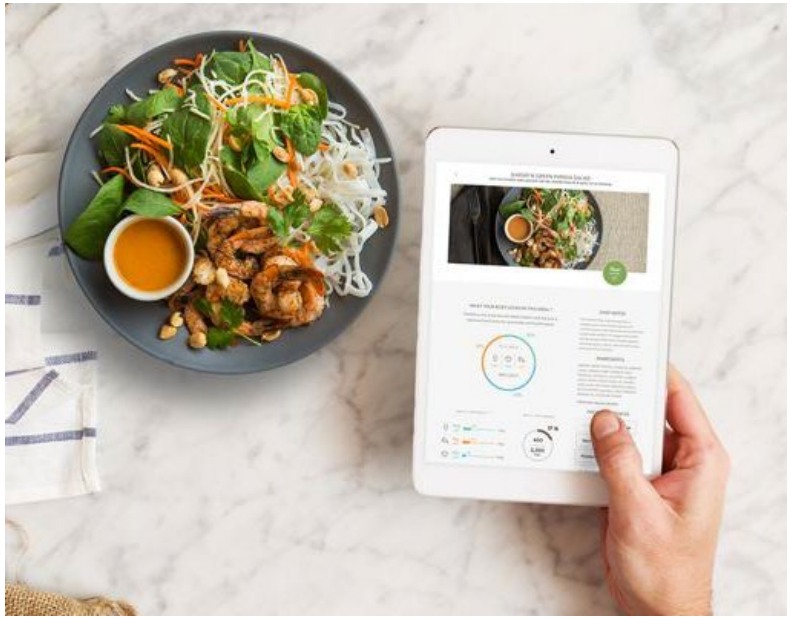
2 Benefits of Functional ingredients

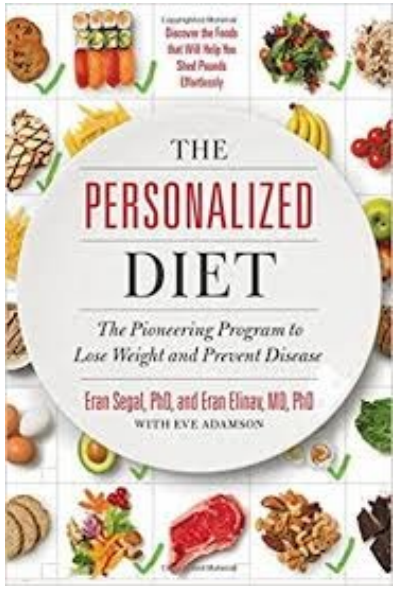
3 Consumer understanding: Labeling and Health Claims

4 Innovation, Future trends, and Personalized Nutrition

Personalized nutrition requires translating science in nutrition for health and well-being







The consumer needs guidance and less complex recommendations

Recommendations

RDA 5 a day

General dietary guidelines

Recommendations address average population

Essential & non-essential nutrients

Which **nutrients** & what amount?

Which **foods** & what amount ?

My food intake

My diet

My nutrient requirement

Sex **Age** **Height Weight** **Physical activity** **Food intolerances** **Vegetarian diet** **Genetic makeup**

university of groningen 2014 | 400 years

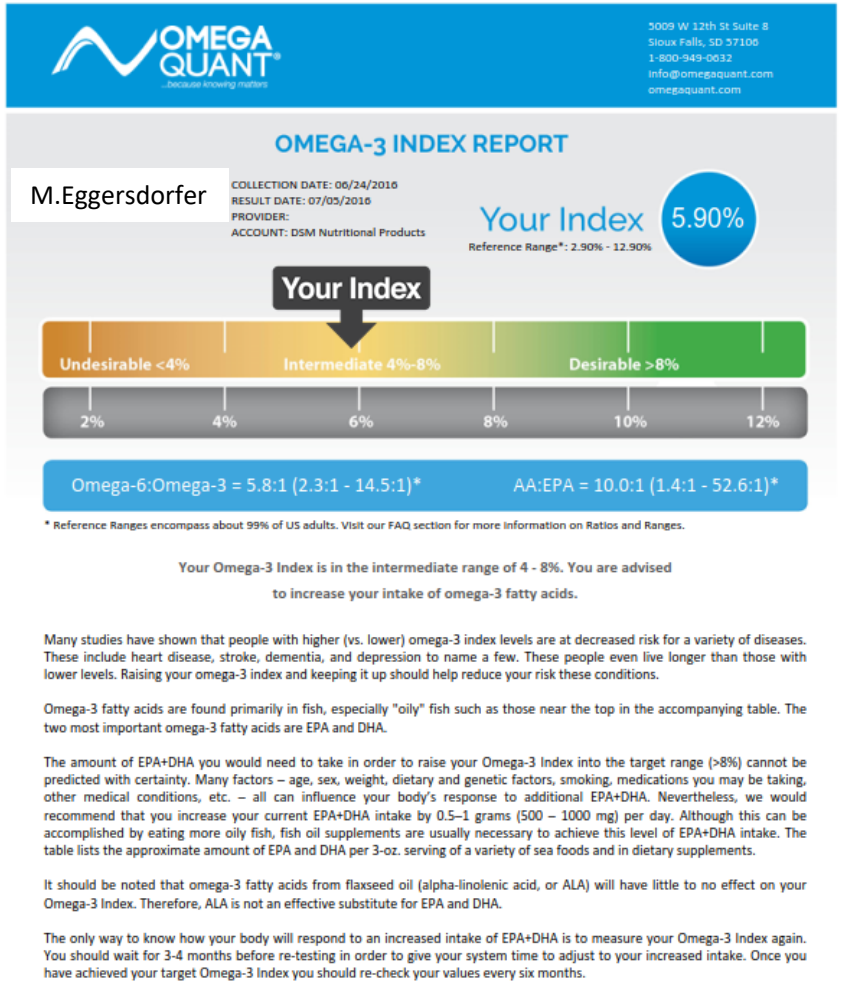
Measure personal vitamin D status and take action

- **Inadequate vitamin D often remains undiagnosed in individuals as symptoms may not manifest for several years.**
- **However, long-term suboptimal status has been linked to osteoporosis, diabetes and some cancer.**
- **Many individuals may be unaware of their status due to the lack of easy to access methods for quantifying 25(OH)D3 levels in serum.**

Vemulapati et al 2017

Measuring individual status may become the next opportunity

http://www.omegaquant.com/



OMEGA QUANT
...because knowing matters

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Sioux Falls, SD 57106
1-800-949-0632
info@omegaquant.com
omegaquant.com

OMEGA-3 INDEX REPORT

M.Eggersdorfer

COLLECTION DATE: 06/24/2016
RESULT DATE: 07/05/2016
PROVIDER:
ACCOUNT: DSM Nutritional Products

Your Index 5.90%
Reference Range*: 2.90% - 12.90%

Your Index

Undesirable <4% | Intermediate 4%-8% | Desirable >8%

2% 4% 6% 8% 10% 12%

Omega-6:Omega-3 = 5.8:1 (2.3:1 - 14.5:1)* AA:EPA = 10.0:1 (1.4:1 - 52.6:1)*

* Reference Ranges encompass about 99% of US adults. Visit our FAQ section for more information on Ratios and Ranges.

Your Omega-3 Index is in the intermediate range of 4 - 8%. You are advised to increase your intake of omega-3 fatty acids.

Many studies have shown that people with higher (vs. lower) omega-3 index levels are at decreased risk for a variety of diseases. These include heart disease, stroke, dementia, and depression to name a few. These people even live longer than those with lower levels. Raising your omega-3 index and keeping it up should help reduce your risk these conditions.

Omega-3 fatty acids are found primarily in fish, especially "oily" fish such as those near the top in the accompanying table. The two most important omega-3 fatty acids are EPA and DHA.

The amount of EPA+DHA you would need to take in order to raise your Omega-3 Index into the target range (>8%) cannot be predicted with certainty. Many factors – age, sex, weight, dietary and genetic factors, smoking, medications you may be taking, other medical conditions, etc. – all can influence your body's response to additional EPA+DHA. Nevertheless, we would recommend that you increase your current EPA+DHA intake by 0.5–1 grams (500 – 1000 mg) per day. Although this can be accomplished by eating more oily fish, fish oil supplements are usually necessary to achieve this level of EPA+DHA intake. The table lists the approximate amount of EPA and DHA per 3-oz. serving of a variety of sea foods and in dietary supplements.

It should be noted that omega-3 fatty acids from flaxseed oil (alpha-linolenic acid, or ALA) will have little to no effect on your Omega-3 Index. Therefore, ALA is not an effective substitute for EPA and DHA.

The only way to know how your body will respond to an increased intake of EPA+DHA is to measure your Omega-3 Index again. You should wait for 3-4 months before re-testing in order to give your system time to adjust to your increased intake. Once you have achieved your target Omega-3 Index you should re-check your values every six months.

I'm taking 300 mg daily!

- > 8% optimal
- 6-8% suboptimal
- 4-6% insufficient
- < 4% deficient

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Thank you!

Dr. Gert Krabichler

Food-PharmaOTC Consult, Founder & Owner

IADSA Company Council Representative of P&G Health

Member of the German CCNFSDU delegation

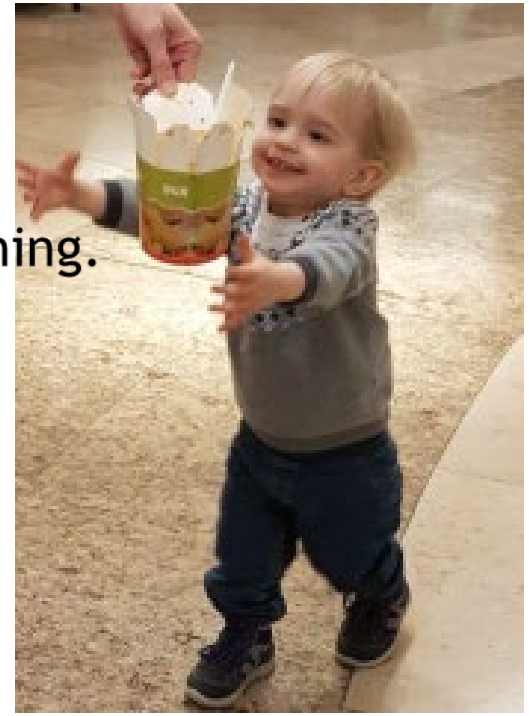
Formerly, Director Global Regulatory Policy & Intelligence and Global Head Regulatory Affairs Merck Consumer Health, R&D

gert@food-pharmaotc.com

Mob.: +49 160 97279831

Who has health has hope,
who has hope has everything.

Mark Twain



Prof. Dr. Manfred Eggersdorfer

m.l.eggersdorfer@rug.nl
m.eggersdorfer@bluewin.ch

@eggersdorferm

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