



MICHALOPOULOU  
& ASSOCIATES

Law under the microscope

# Novel Food & Nutrigenomics: the current legislative standing and the ways new technology can impact the Food industry

*Food Safety Conference • Thursday 20<sup>th</sup> June 2019 • Marousi Plaza*



# Οι Υπηρεσίες μας

Η ομάδα μας συστηματικά παρακολουθεί τις αλλαγές της νομοθεσίας και υιοθετεί ανάλογες πρακτικές με στόχο να εξασφαλίσει προσεκτική και ηθική υπηρεσία της φέροντας αδιαμφισβήτητα αποτελέσματα στον πελάτη.

15 years 2002-17  
Highlighting achievement for the Health Industry

# Law under the microscope

The first law firm in Greece to have been the member of the Pharma & Life-Sciences LawGroup



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# Technology innovation disrupts health and food categories



**TRY THE  
IMPOSSIBLE  
BURGER.**

**MEAT FROM PLANTS. WHOA.**



© New Nutrition Business

# Novel Foods

## EU Regulations 2015/2283 & 2018/456

- What is novel food?
  - Newly developed,
  - Produced using new technologies & production processes,
  - Traditionally eaten outside of the EU
  - May 15<sup>th</sup> 1997>
  - EFSA & National Focal Points
  - Consumption History: 25 years pls
  - e-submission system/portal
  - Novel Food Catalogue (Dec. 2017)

# Novel Foods

## EU Regulations 2015/2283 & 2018/456

- Provisions for authorization for use in the EU
  - ✓ it does not present a risk to public health,
  - ✓ it is not nutritionally disadvantageous when replacing a similar food,
  - ✓ is not misleading to the consumer,
  - ✓ safety assessment incl. for the authorization of the conditions of use, its designation, labelling

# Novel Foods

## EU Regulations 2015/2283 & 2018/456

- **What about Confidentiality?**

Not applicable to:

- a) the name and description of the novel food;
- b) the proposed conditions of use of the novel food;
- c) a summary of the studies submitted by the applicant;
- d) the results of the studies carried out to demonstrate the safety of the food;
- e) where appropriate, the analysis method(s)



newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of 5 years

# The future of Food is in Personalization

Personalized medicine ↔ Personalized food



Pharma Profile



Nutrition Profile

*“Let your medicine be your food and your food become your medicine”*

Ippokrates 4<sup>th</sup> century b.C.



# The future of Food is in Personalization: Fitness & Wellness Applications Legal Regime



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# The future of Food is in Personalization: Fitness & Wellness Applications Legal Regime

## ➤ **EE 2016/679-GDPR concerns:**

- Scope & Legal basis of EU citizens data processing
- Consent & Special categories of personal data
- Rights of data subject-Profiling
- Clinical/Food Trials-Secondary Processing

## ➤ **EE 2017/745-MDR & EE 2017/746-IVDR concerns:**

- any instrument, software...to be used for human beings for the medical purpose of diagnosis, prevention, prognosis...by in vitro examination of specimens from the human body, including blood and tissue donations

## ➤ **Healthcare Professionals Liability concerns**

**& national laws**

# Nutrigenomics at the heart of personalized nutrition

“What works, how well, for whom, in what setting and why?”

- Biological factors
- Behavioral factors
- Demographic and Clinical factors

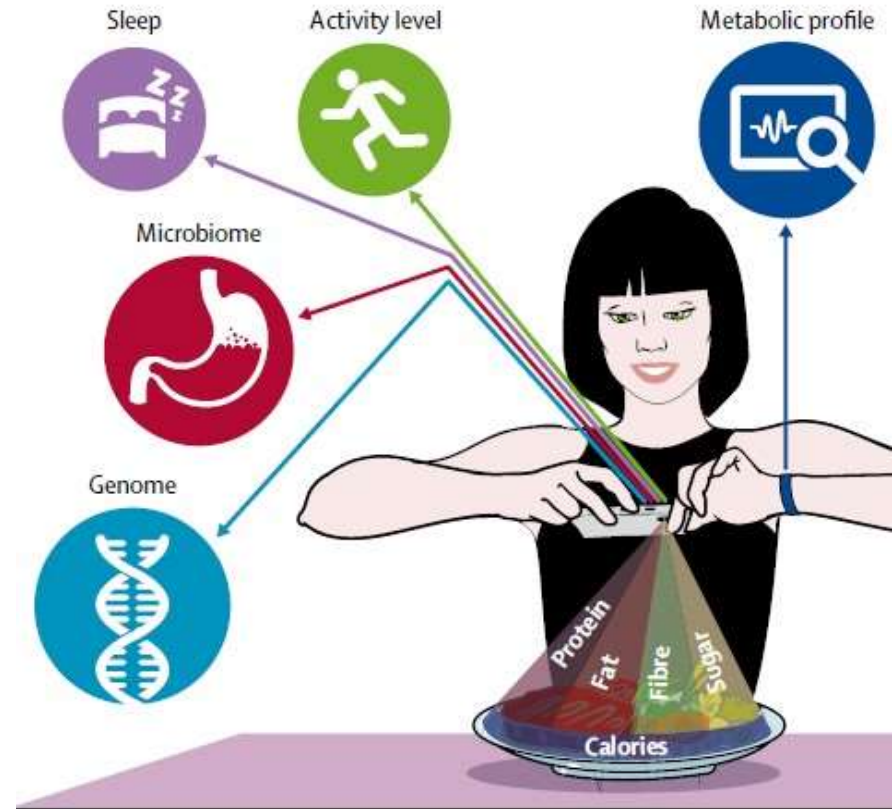


Image credit: *The Lancet* January 5, Vol 393 . *The digital nutritionist*. Hamideh et al (2019)

# DNA-based lifestyle info and advice is superior than population based

## Personalized nutrition



32%



Of adults want products:

- **Matching their personal diet**
- **Matching their nutritional needs**
- Easily available

### The 5 faces of personalized nutrition

- 1 **CONNECTED DEVICES AND NUTRITIONAL COACHING**
- 2 **PROVIDING THE RIGHT AMOUNT OF NUTRIENTS**
- 3 **3D PRINTING**
- 4 **MICROBIOME ANALYSIS**
- 5 **NUTRIGENOMICS**, a very promising and emerging discipline, that studies the interactions between genome and nutrients through the analysis of DNA in saliva (most of the available supply to date) or hair bulbs.

*Nutrigenomics: exploring how genes will dictate our food of tomorrow* | © Nutrikéo Consulting 2019



- EU level: Define a clearer and more flexible regulatory framework

- National Level: enforce safety regulations for surveillance & control & penalties to non-compliant parties



- HCPs:

- education, training & guidelines

- Consumers:

- education, training for the  
value of an ultra-personalized  
approach & consumer engagement



- Food Industry: high standards & certification mechanisms

- Clinical/Food Trials Organizations: easy & affordable solutions

- Insurances: significant player for Consumers' behavioral change

- ICT Providers: Controllers or Processors? Joint-Controllers? Define roles...

- Develop a GDPR transparent and MDR & IVDR compliant Legal Strategy!

# Thank you



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