Scene Setting: Food Safety (Risk Assessment, Risk Management) Consumers and Sustainability

ILSI Europe’s Annual Symposium 2017
30-31 March 2017
Thon Hotel Brussels City Centre, Brussels, Belgium

Dr Ana Canals Caballero
Spanish Agency for Consumer Affairs Food Safety and Nutrition (AECOSAN)
FROM FARM TO FORK.
The European Commission aims to assure a high level of food safety and animal & plant health within the EU through coherent farm-to-table measures and adequate monitoring, while ensuring an effective internal market.

EU FOOD POLICY COMPRISSES:
comprehensive legislation on food & animal feed safety & food hygiene
sound scientific advice on which to base enforcement & checks.
CHALLENGES

**Nutrition & Health**

How can R&I tackle obesity and malnutrition while reducing hunger?

- 2 billion people overweight or obese
- 795 million people hungry & malnourished

**Climate & Sustainability**

How can R&I reduce the CO₂ and environmental footprint of food systems while making them resilient to climate change?

- ~ 30% of greenhouse gas emissions arise from the food production supply chain

**Innovation & Communities**

How can R&I provide jobs and empower rural, urban & coastal communities?

- The EU is the world’s top food exporter
- Jobs for 4.25 million people

**Circularity & Resource Efficiency**

How can R&I increase resource efficiency and reduce food losses & waste?

- 1/3 of the all food produced is wasted
- 1.3 billion tonnes a year

**Food 2030**

Agriculture, food, fisheries & aquaculture account for 75% of the turnover of the EU’s bioeconomy (2013).
FACTS:

- 2016: 4 BILLION TONS OF FOOD PRODUCED YEARLY
- 1.3 BILLION TONS OF FOOD WASTED (33%)
- FOOD PRODUCTION = 25 % GREENHOUSE EFFECT

FACTS:

- 600 MILLION PEOPLE FOOD RELATED ILLNESS, AND 420,000 FOOD SAFETY RELATED DEATHS EVERY YEAR
- UNHEALTHY EATING CAUSE 21% OF GLOBAL DEATHS, 2,8 MILLION ANNUAL DEATHS CAUSED BY OVERWEIGHT AND OBESITY
- 795 MILLION PEOPLE CHRONIC UNDERNOURISHMENT VS TWO BILLION PEOPLE WORLDWIDE ARE OVERWEIGHT OR OBESE
HO2050: OVER 9 BILLIONS PEOPLE

IMPROVING ACCESS TO AND DISTRIBUTION OF HEALTHY FOOD AND CHANGING DIETS AND REDUCING FOOD WASTE
FOOD AND NUTRITION SECURITY

=> Nutrition: ↓ hunger & malnutrition, ↑ food safety & ↓ diet-related illnesses, and helping citizens adopt sustainable diets and healthy lives – e.g. EJP One Health

⇒ Climate: Building a climate and global change-resilient food system – e.g. PRIMA, EU/Africa

⇒ Sustainability: Implementing sustainability & circular economy principles across the whole food system – e.g. food waste, sustainable and resource-efficient food production

⇒ Innovation: ↑ market-creating innovation & investment, while empowering communities – e.g. FOOD PPP, FOOD KIC, regions and Agri-food Smart Specialisation, food in cities, synergies between funds (H2020, EFSI, RDF, etc.)
Ensuring that nutritious food and water is available, accessible and affordable for all. It involves reducing hunger and malnutrition, ensuring high levels of food safety and traceability, reducing the incidence of non-communicable diet-related diseases, and helping all citizens and consumers adopt sustainable and healthy diets for good health and wellbeing.

FOOD POLICY INSTEAD OF FOOD SAFETY?
RISK MANAGEMENT:

Regulation (EC) No 178/2002
Food law

- Competent authorities
- Food business operators

Regulation (EC) No 882/2004
General rules for official controls

Regulation (EC) No 854/2004
Specific rules for official controls on products of animal origin

Regulation (EC) No 852/2004
General rules on hygiene
- HACCP

Regulation (EC) No 853/2004
Specific hygiene rules for products of animal origin

Regulation (EC) No 2075/2005
Trichinella

Regulation (EC) No 2074/2005
Other implementing rules

Regulation (EC) No 2073/2005
Microbiological criteria
FOOD CHAIN LEGISLATION

Figure 3: EU food chain – actors and legislation (authors’ compilation)

Key: The size of the circles reflects the scope of the respective legal act – Commission legislation under chief responsibility of DG SANCO (red circles), other Commission services (blue) in charge of relevant legislation for the food chain.
32% of administrative burden due to national legislation, implementing legislation, and secondary legislation.

- More than 200 REFIT actions are being implemented since 2012 (see state of play REFIT Scoreboard 2015*)
- More than 6,100 legal acts have been repealed since 2005
- 93 legal proposals have been withdrawn in 2015 or are set for withdrawal until end 2016 and almost 400 since 2006
- Administrative burdens for businesses have been reduced by 33% in 13 priority areas since 2007 leading to savings of €41 billion
"SMARTER RULES FOR SAFER FOOD"

MAY 2013

**official controls**: how we will monitor and enforce the new rules

**animal health**: a framework for the principles of European animal health for the next 20 years

**plant health**: controls for protecting plants from disease and pests

**plant seeds**

**financial framework agri-food**
REFIT Platform

The REFIT Platform brings together the Commission, national authorities and other stakeholders in regular meetings to improve existing EU legislation.

The role, structure and working methods of the REFIT Platform

The REFIT Platform was set up by the May 2015 Better Regulation Communication to advise the Commission on how to make EU regulation more efficient and effective while reducing burden and without undermining policy objectives.

REFIT Platform members

REFIT Platform members - Chairperson
REFIT Platform members - The Government group
REFIT Platform members - The Stakeholder group

REFIT Platform meetings

Find information and documents related to the meetings of the REFIT Platform.
REFIT Platform Opinion on the submission by the Danish Business Forum on the so-called "declarations of compliance" concerning materials and articles intended to come into contact with food.

**Food Contact Materials:**
- The Danish Business Forum (DBF) suggests the establishment of common requirements for the declaration of compliance concerning articles and material to come into contact with food by introducing pre-defined templates into EU legislation. The Commission is currently undertaking a study which results will determine future possible actions.

**Traditional Herbal medicines and health claims made on botanicals used in food**
- A citizen suggests revising the Traditional Herbal Medicinal Product Directive in order to facilitate innovation and the entry into the EU market of such products and to implement the Regulation on health claims on botanicals. The Regulation on health claims is currently being evaluated under the REFIT Programme.
MORE REGULATION?

2015

Less legislative initiatives (23 vs +/- 130 previous years)

- NOT NEW RELEVANT LEGISLATION
- SECONDARY LEGAL ACTS:
  - OFICIAL CONTROL REGULATION: over 22 acts in 3 years
  - NUTRIENTS: TRANS FATTY ACIDS
  - CONTACT MATHERIALS
  - ACRYLAMIDE
  - SUPPLEMENTS; LIMITS VITAMINS, OTHER SUBSTANCES
Secondary legislation – delegated & implementing acts

Delegated acts

Commission proposes + Commission adopts

EP veto? EP revocation?

CM veto? CM revocation?

Implementing acts

Commission proposal

Examination committee

QMV

Positive opinion

Negative opinion

ADOPTION

Appeal

New draft

ADOPTION

Unless – 3 exceptions

No opinion
CAFFEINE POSITIVE OPINION EFSA

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to caffeine and increased fat oxidation leading to a reduction in body fat mass (ID 735, 1484), increased energy expenditure leading to a reduction in body weight (ID 1487), increased alertness (ID 736, 1101, 1187, 1485, 1491, 2063, 2103) and increased attention (ID 736, 1485, 1491, 2375) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

APPROVED BY PAFF APRIL 2016

- Caffeine contributes to an increase in endurance performance
- Caffeine contributes to an increase in endurance capacity
- Caffeine helps to increase alertness
- Caffeine helps to improve concentration
Parliament vetoes energy drink “alertness” claims
Plenary Session Press release - Public health – 07-07-2016 - 12:55

EU Commission plans to allow claims that sugary drinks and energy drinks containing caffeine boost “alertness” or “concentration” were vetoed by the European Parliament on Thursday. Displaying these claims on drinks cans would have led to higher sugar consumption among adolescents, who are the largest group of energy drink consumers, said MEPs in their resolution.
VETO

DELEGATED REGULATION FOR SPECIFIC COMPOSITION OF CEREAL-BASED BABY FOOD

Parlamento Europeo
2014-2019

B8-0067/2016

• Allows 30% of energy from sugars
• WHO: top 10%
European Parliament votes to scrap nutrient profiles
MOTION OF THE EUROPEAN PARLIAMENT TO REVISE SCIENTIFIC BASES OF REGULATION 1924/2006 AND DISCARD NUTRIENT PROFILES.

BEUC: INDUSTRY VS SCIENCE
POLITICS, NGO`s AND CONSUMERS
RISK ASSESSMENT:

CHALLENGES SUSTAINABILITY OF EFSA:

- RESOURCES
- NOT ENOUGH RISK ASSESSORS (CONFLICT OF INTEREST, LOW INCENTIVES, PEER REVIEW)
- ALIGNMENT BETWEEN RA NEEDS AND RESEARCH
- DIVERGENCIES
- FAST ENOUGH TO ALLOW INNOVATION?
- VISION
RISK ASSESSMENT: RESOURCES

DRAFT BUDGET & ESTABLISHMENT PLAN 2016

SCIENTIFIC ADVICE
12.2 M€  66 POSTS

15%

REGULATED PRODUCTS
23.2 M€  149 POSTS

29%

DATA & COOPERATION
22.2 M€  103 POSTS

28%

COMMUNICATION AND DIALOGUE
6.2 M€  35 POSTS

8%

GOVERNANCE, SUPPORT & COORDINATION
15.8 M€  117 POSTS

20%
RISK ASSESSMENT BY OTHER AGENCIES

ANSES - French Agency for Food, Environmental and Occupational Health & Safety

BfR
Bundesinstitut für Risikobewertung

RIKILT
Research institute
RA BASED ON SCIENTIFIC PUBLICATIONS

675 REFERENCES

Scientific Opinion on acrylamide in food

EFSA Panel on Contaminants in the Food Chain (CONTAM)

European Food Safety Authority (EFSA), Parma, Italy

913 REFERENCES

Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: Executive summary

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

312 REFERENCES

Scientific Opinion on the safety of caffeine

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)
SCIENCE AND RISK ASSESSMENT

EU RAA

Delphi study completed
Template of lead projects
Interested partners
EC Services & MS Agendas

Priorities are defined and attained collaboratively - MS together with EFSA

EU RISK ASSESSMENT AGENDA

Identify concrete activities / joint projects – translated from Delphi priority topics

Identify partners - leading and interested countries

Identify funding opportunities

Engagement with 3rd parties
SCIENCE AND RISK ASSESSMENT

Final report on ‘the identification of food safety priorities using the Delphi technique’
Gene Rowe Evaluations

**Generic**
1. Methods and systems for identifying emerging food risks (e.g. new food-borne diseases) [M E]
2. Development of standard risk-benefit assessment methods (of foods) [C E N]
3. Common data collection/surveillance scheme [C M E N]
4. Multiple contaminant impacts on the risk profile of foods [C M E N]
5. Risks/benefits of botanicals/herbals in food supplements [C N]
6. Allergenicity/food allergens in general (risk assessment and management) [C N]
7. Aggregated exposure (as per cocktail effects, but including environmental as well as food exposures) [C E N]

**Chemical**
8. Harmonisation of methods for risk assessment of chemical contaminants
9. Cumulative exposure assessment (e.g. for pesticide residues/PAHs)
10. Infant and baby food
11. Emerging contaminants

**Microbiological**
12. Systems for monitoring and characterising microbes isolated from food, environment and human illness cases
13. Improve the use of genetic data (e.g. from whole genome sequencing) for risk assessment of microbiological contaminants
14. Antimicrobial/antibiotic resistance
15. Microbial food pathogens (in general)
16. Food-borne viruses (in general) (e.g. Hepatitis A and Norovirus in fruit and vegetables)
17. Campylobacter (e.g. in poultry and ready to eat foods)
18. Zoonoses (in general, including bio-hazards, MRSA etc.)

**Environmental**
19. Improving information on the occurrence and spread of harmful organisms
20. Ribonucleic acid interference (RNAi) applied to food producing organisms as pesticide, veterinary medicine or newly expressed trait in genetically modified crops
21. Better understand biological organisms and plant substances used in crop protection (so reducing need for chemicals e.g. pesticides)
22. The impact of chemicals on the ecosystem (release of chemicals to the environment)
23. Presence/detection of environmental contaminants in food (e.g. from agricultural, industrial or household sources)
24. Cocktail effects (the health risk assessment of chemical mixtures e.g. food additives)

**Nutrition**
25. Indirect effects on human health due to modified agricultural practices (e.g. via reduction of pesticide use, changed content of mycotoxins)
26. Developing standard biomarkers of intake and/or exposure to contaminants
27. Food supplements risk/benefits (generally)
28. Determination of allergen thresholds (clinical studies), in conjunction with immunochemical measurements of allergens in foods

28 food safety risk assessment priorities
EXPERT CONSULTATION ON EFSA´s PANELS, SCIENTIFIC COMMITTEE

1. Microplastic and nanoplastic particles in food;
2. Honey bee health;
3. Foodborne viruses;
4. Risk assessment methodologies;
5. Development of European Cloud-based integrated data collection, data management, data analysis and reporting system for food safety.
PRIVATE FUNDING AND CONFLICT OF INTEREST

HORIZON 2020

The EU Framework Programme for Research and Innovation

European Commission > Horizon 2020 > Industrial Leadership

Sections navigation

Industrial Leadership

Leadership in Enabling and Industrial Technologies
Access to risk finance
Innovation in SMEs

Industrial Leadership

This pillar aims to speed up development of the technologies and innovations that will underpin tomorrow’s businesses and help innovative European SMEs to grow into world-leading companies.
OPENDATA = INTELLIGENT DATA?

**SPAIN**

### BIOLOGICAL MONITORING

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### PESTICIDES

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No change on definition of novel foods but scope clarified
Centralized risk assessment by EFSA
Centralized management by Comission
Cloned animals food, temporarily
Artificial nanomaterials
Insects
More flexible traditional food authorization
Generic authorizations but also intellectual property rights
NANOS AND FOOD

Potential applications of nanotechnology in food

Packaging
- Increased strength
- Lightweight materials
- Resistance to heat, moisture, air

Hygiene & safety
- Antibacterial coatings for cooking utensils
- Colour-changing contamination sensors

Reformulation
- More easily absorbed nutrients
- Lower fat/sugar/salt content
- Improved taste & texture

Traceability & authenticity
- Nano-barcodes for identification and tracking of food products
NANOMATERIALS:

Definition in Regulation (EU) 2015/2283: engineered nanomaterial’ means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. (the Commission shall, by means of delegated acts, adjust and adapt the definition of engineered nanomaterials to technical and scientific progress or to definitions agreed at international level)

- Need of Risk Assessment
- Need of toxicological knowledge
- Need of methodology
- Need of measurement technology
Bisphenol A: EFSA recommends lowering the Total Daily Intake (TDI) while considering that current exposure levels are without risk for human health. In 2014, following its large-scale study, EFSA submitted for consultation an interim report on the health risks of bisphenol A (BPA). ANSES contributed to the consultation by emphasizing the extensive work conducted by the European authority while pointing out certain divergences in the evaluation of how uncertainties were accounted for, as well as differences of interpretation in the analysis of available studies. Today, the European Food Safety Authority (EFSA) published the results of its work, recommending a significant reduction in the Total Daily Intake (TDI) of bisphenol A, while indicating that the current exposure levels to bisphenol A are too low to pose any risk to human health. In addition, while evaluation differences still exist in this report, EFSA and ANSES continue to pursue their collaboration on this topic, and new studies will soon be issued on the effects of low doses of BPA on health.

Bisphenol A: new immune system evidence useful but limited.

New data confirm EFSA’s previous conclusion that bisphenol A (BPA) might affect the immune system in animals, but the evidence is too limited to draw any conclusions for human health.
DIVERGENCIES IN RISK ASSESSMENT

International Agency for Research on Cancer

World Health Organization

Q&A on Glyphosate

In March 2015, IARC classified glyphosate as “probably carcinogenic to humans” (Group 2A).
Glyphosate: EFSA updates toxicological profile

EFSA and the EU Member States have finalised the re-assessment of glyphosate, a chemical that is used widely in pesticides. The report concludes that glyphosate is unlikely to pose a carcinogenic hazard to humans and proposes a new safety measure that will tighten the control of glyphosate residues in food. The conclusion will be used by the European Commission in deciding whether or not to keep glyphosate on the EU list of approved active substances, and by EU Member States to re-assess the safety of pesticide products containing glyphosate that are used in their territories.

«UNLIKELY CARCINOGENIC»

Glyphosate herbicide: don’t renew its authorisation, urge MEPs

ENVI Press release - Public health – 22-03-2016 - 14:34

So long as serious concerns remain about the carcinogenicity and endocrine disruptive properties of the herbicide glyphosate, which is used in hundreds of farm, forestry, urban and garden applications, the EU Commission should not renew its authorisation. Instead, it should commission an independent review and disclose all the scientific evidence that the European Food Safety Authority (EFSA) used to assess glyphosate, said Environment Committee MEPs on Tuesday.
Glyphosate not classified as a carcinogen by ECHA

ECHA's Committee for Risk Assessment (RAC) agrees to maintain the current harmonized classification of glyphosate as a substance causing serious eye damage and being toxic to aquatic life with long-lasting effects. RAC concluded that the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction.

17 March 2017
some panel members believed there is limited, “but suggestive,” evidence of a “positive association between glyphosate exposure and risk of NHL from epidemiological studies.”
Glyphosate: EFSA to share raw data

EFSA is to release the raw data used in the recent EU safety evaluation of glyphosate, as part of its commitment to open risk assessment.
Advisory Forum Recommended Good Practice: substantive divergence over scientific issues (Article 30 (4))

EARLY DETECTION OF POSSIBLE SUBSTANTIVE DIVERGENCIES
- COOPERATION
- EXCHANGE OF INFORMATION
- SCIENTIFIC MEETING DIALOGUE
- DOCUMENT: IDENTIFICATION OF AREAS OF DIVERGENCY AND JUSTIFICATION

EFSA explains risk assessment

Glyphosate

- What has EFSA done?
- Main findings of the assessment?
- Why do some scientists say that glyphosate is carcinogenic?
- What data was used in the EU assessment?
- How were the animal studies on carcinogenicity interpreted?
- What happens next?
- How is the safety of pesticides assessed in the EU?
- Risk assessment of glyphosate-timelines
- What do we mean by...
IARC REPORT MEATS

EFSA:
Safety of the extension of use of sodium propionate (E 281) as a food additive

Reevaluation of Nitrites Commission Regulation (EU) No 257/2010 requires that the European Food Safety Authority shall re-evaluate potassium nitrite (E 249) and sodium nitrite (E 250) by end of 2015. For this re-evaluation, EFSA shall examine the earlier opinions of the SCF and EFSA, where available, the original dossier, data submitted by the interested business operator(s) and/or any other interested party and data made available by the Commission and Member States and identify any relevant literature published since the last evaluation of each food additive.

Statement on nitrites in meat products
Panel on Food Additives and Nutrient Sources Added to Food
EFSA JOURNAL: EFSA Journal 2010
COMMUNICATING UNCERTAINTIES, PALM OIL

GLYCEROL BASED PROCESS CONTAMINANT (PALM, OIL AND OTHERS)

POTENTIAL HEALTH CONCERNS

Risks for human health related to the presence of 3- and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food

Could Nutella really cause cancer? Here's what you need to know

Hundreds of other products also contain the potentially carcinogenic ingredients

EU food safety body to look again at palm oil health risks
Cada día comemos más seguro, pero menos sano
La alimentación en nuestros días supone una gran paradoja: hay más controles pero es menos saludable
PREVALENCE OF OBESITY IN ADULTS.  
1993 - 2014

PREVALENCE OF OVERWEIGHT IN ADULTS.  
1993 - 2014

Ambos sexos

9.7 14.7 17.3 18.0 17.5 17.0

Hombres

9.5 16.0 17.0 17.0

Mujeres

28.5 29.9 28.1

54%
RISK ASSESSMENT IN NUTRITION

- Nutrient Food labelling and claims
- Health Policies:
  - nutrient intake recommendations (recommended daily intake)
  - food based dietary guidelines
- Reformulation
- Upper levels of daily intakes to prevent chronic diseases
- Upper and lower limits (nutrients, vitamins, minerals)
Sugars; there was insufficient evidence to set an upper limit
Evidence is still inconclusive on the role of the glycemic index and glycemic load in maintaining weight and preventing diet-related diseases.

higher intakes of saturated fats and trans fats lead to increased blood cholesterol levels

Intakes of fats should range between 20 to 35% of the total energy intake, with different values given for infants and young children

daily intake of 250 mg of long-chain omega-3 fatty acids for adults may reduce the risk of heart disease
Guideline:

**Sugars intake for adults and children**

- daily intake of free sugars to less than 10% of their total energy intake
- further reduction to below 5% or roughly 25 grams (6 teaspoons) per day would provide additional health benefits

The overall quality of the available evidence for changes in body weight in relation to both increasing and decreasing free sugars intake in adults was considered to be moderate; this was due to downgrading for possible biases identified in a minority of studies and potential publication bias because of the small number of trials identified (Annex 1). In children, the quality of evidence for an association between a reduction in free sugars intake and reduced body weight was similarly considered to be moderate, whereas the quality of the evidence for an association between an increase in free sugars intake and increased body weight was considered to be low (Annex 1).
REQUEST TO EFSA TO SET UP UPPER LIMITS FOR SUGAR
REDUCED [NAME OF THE NUTRIENT]
A claim stating that the content in one or more nutrients has been reduced, may only be made where the reduction in content is at least 30% compared to a similar product, except for micronutrients, where a 10% difference in the reference values, and for sodium, or the equivalent value for salt, where a 25% difference shall be acceptable. The claim "reduced sugars", and any claim likely to have the same meaning for the consumer, may only be made if the amount of energy of the product bearing the claim is equal to or less than the amount of energy in a similar product.

- DAILY INTAKE OF FREE SUGARS TO LESS THAN 10% OF THEIR TOTAL ENERGY INTAKE
REGULATION IN NUTRITION?

- INFORMATION TO CONSUMERS:
  - REG 1924/2006 NUTRITION PROFILES
  - REG 1169/2009:NUTRITION INFORMATION IN ALCOHOLIC BEBERAGES
  - TRANSFATTY ACIDS
SUMMARY

- FOOD SAFETY VS FOOD AND NUTRITION SECURITY VS FOOD POLICY
- RISK MANAGEMENT
  - SIMPLIFICATION BUT ALSO NEW LEGISLATION
  - MORE SOCIAL AND MORE POLITIZED
- RISK ASSESSMENT
  - SOSTENIBILITY OF RA
  - SYNERGIES AND COLLABORATIONS
  - ALIGMENTS
  - MORE GLOBAL
  - FASTER AND PROACTIVE TO INNOVATION
- BETTER COMMUNICATION
- IMPORTANCE OF RA IN NUTRITION
Agency for Consumer Affairs, Food Safety and Nutrition

We promote your rights, protect your health and we ensure your safety as a consumer and user.

Presentation of the Agency
Duration 6 minutes

http://www.aecosan.msssi.gob.es

Nutrición saludable, así como el papel clave de nuestros Laboratorios.

Breaking news

X Convención NAOS y IX Edición de los Premios NAOS
7 November 2016

La Agencia Española de Consumo, Seguridad Alimentaria y Nutrición incluyó en su web 53 alertas sobre productos no alimenticios durante el mes de octubre
3 November 2016