EUROPEAN PARLIAMENT

REPORT

Policy Department
Economic and Scientific Policy

# Workshop on Novel Foods Brussels, 10 September 2008

## Consolidated Texts

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| Experts invited for the Workshop | **Ottilia Saxl**, CEO of the Institute of Nanotechnology (IoN)<br>**Dr Juliane Kleiner**, European Food Safety Authority (EFSA)<br>**Prof. Giovanni Lercker**, University of Bologna, Italy<br>**Mr. Kees de Winter**, European Consumers' Organisation, BEUC<br>**Mrs. Agnès Davi**, Groupe Danone, Paris (CIAA)<br>**Ms. Ruth Chadwick**, ESRC Centre for Economic and Social Aspects of Genomics (Cesagen), Cardiff University |
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# 1. Introduction

The future adoption of a Regulation of the European Parliament and of the Council on "Novel Foods" will regulate their placing on the market. It will lay down rules for authorisation, supervision, labelling and use of novel foods. The area of novel foods is fully harmonised in the EU. Non-legislative action based, for example, on a code of good practice or guidelines could not give sufficient protection and would lack legal certainty. The safe use of novel food depends on pre-market safety evaluations and often on permitted conditions of use of these substances, therefore recommendations or self-regulations would not guarantee the protection of consumer's health. The workshop will assess the different elements mentioned in the Commission proposal COM(2007)872 on Novel Foods.

The workshop should involve experts to advice Members of the Parliamentary ENVI Committee, giving a balanced picture of the variety of views seriously considered among professionals in this field.

***Date:*** *Wednesday 10 September 2008, 15h00 - 18h30*

***Venue:*** *European Parliament, Brussels, PHS 6 B 001*

## 2. Workshop - Programme

Organised by CoMeta, together with the European Parliament's Policy Department A and the European Parliament's ENVI Committee Secretariat

# WORKSHOP
# NOVEL FOODS

10 September 2008, 15h00 - 18h30
PHS 6 B 001, European Parliament, Brussels

## Programme

15h05 **Welcome and Opening of the Workshop**, by MEP Kartika Tamara LIOTARD (GUE, NL)

15h15 **First Thematic Session: Panel of experts** (Moderated by Ms Lisa Gelhaus, Co.Meta)

1. **Ottilia Saxl**,, CEO of the Institute of Nanotechnology (IoN): *" Nanotechnology in food: dreams or reality?"*
2. **Dr Juliane Kleiner**, Acting Head of Unit of the Panel on Dietetic Products, Nutrition and Allergies (NDA) European Food Safety Authority (EFSA): *"Concerns about quality and credibility"*
3. **Prof. Giovanni Lercker**, University of Bologna, Italy: *"Chemical quality aspects of novel foods: needs and limits"*

Question and Answer Session

16h50 **Second Thematic Session: A critical assessment by stakeholders of the Commission's proposal** (Moderated by Ms Lisa Gelhaus, Co.Meta)

4. **Mr. Kees de Winter**, Head of the Food Department of the European Consumers' Organisation, BEUC: *"Consumer rights and expectations"*
5. **Mrs. Agnès Davi**, Corporate Regulatory Affairs Director - Groupe Danone, Paris, CIAA: *"The industry challenge ahead"*
6. **Ms. Ruth Chadwick**, Director, ESRC Centre for Economic and Social Aspects of Genomics (Cesagen), Cardiff University: *"The health care impacts of novel food"*

Question and Answer Session

18h15 **Closing remarks**, by MEP Kartika Tamara LIOTARD (GUE, NL)

## 3. Curriculum vitae of the experts

### 1. **Ottilia Saxl,,** CEO of the Institute of Nanotechnology (IoN)

Contact: ottilia.saxl@nano.org.uk , www.nano.org.uk

Ms. Saxl founded the Institute of Nanotechnology (IoN), in January 1997, as a follow-on to the Centre in Scotland for Nanotechnology. Since then, IoN has gained a position as the most important nanotechnology information provider in Europe. The Institute now has a database of over 65,000 individuals and provides nanotechnology information to a range of stakeholders from industry to the general public through its newsletter and website, which receives over 1.3 million hits a month. It is the lead partner in the important European NanoObservatory project, funded by the European Commission, which will provide socio-economic analyses to member states on those nanotechnologies considered to be critical to the future of Europe.

The Institute also holds at least four leading-edge nanotechnology events each year on themes of interest to business and the public, making them widely accessible via webcast and CD / DVD. Conference themes over the last 2 years have included: the Delivery of Scents and Flavours for Industry, Nanoparticle Manufacture, Scale-Up, Stabilization, Characterization and Toxicology'; Nanotechnology and Smart Textiles for Industry, Fashion and Healthcare'; 'Nano and MicroTechnologies for Foods and Healthfoods'; 'Investing in Medical Nanotechnologies', 'Nanotechnology for Security and Crime Prevention'; 'Bioinspired Nanotechnologies for Smarter Products'; 'Nanotechnology for Environmental Benefit' and most recently, 'Nanotechnology – towards reducing animal testing'.

Each year the Institute invites a nanoscientist of note to give the annual Albert Franks lecture, in memory of the IoN's first Honorary President. Recent guest lecturers included Dr Frans Kampers, a food expert from Wageningen University, Professor Sir Fraser Stoddart from the California Nanoscience Institute, and Professor James K Gimzewski from UCLA.

Ms Saxl has organised several fact finding missions to major nanotechnology centres across Europe and the USA, and she has served on several UK and EU nanotechnology panels, including DEFRA's Nanotechnology Stakeholder Panel, the European Technology Platform on NanoMedicine, the Human Performance Enhancement working group of NanoBioRaise; and contributed to both the International Risk Governance Council's White Paper on Nanotechnology Risk Governance and to the ESF publication 'Forward Look Nanomedicine', and was also editor of the important ETP in Nanomedicine's Vision Paper. She has also talked about new technologies on several radio and television programmes.

Recent IoN activities which Ms Saxl has initiated include: a business 'Club' for new nano and micro start-up companies, modelled on Rice University and NASA-Ames[1]; a nanomedicine network[2], which provides information on nanomedicine for clinicians and related professions and identifies areas of new research; and NanoChina[3], a bilingual website which is aimed at promoting nanotechnology transfer between China and other nations. Also recently launched is a new Nanotechnology Masters website[4], where potential students can easily compare the content of a burgeoning number of nanotechnology Masters Courses online, and choose the course most suited to their skills and career.

## 2. **Dr Juliane Kleiner,** Acting Head of Unit of the Panel on Dietetic Products, Nutrition and Allergies (NDA) European Food Safety Authority (EFSA)

Contact: juliane.kleiner@efsa.europa.eu

Dr. Juliane Kleiner is acting head of the Unit on Dietetic products, Nutrition and Allergies (NDA) at the European Food Safety Authority (EFSA). She is coordinating the activities of the NDA Unit dealing with health claims, novel foods, infant formulae/dietetic foods, dietary reference values and allergies. Juliane Kleiner obtained a Ph.D. degree in human biology (theoretical medicine) from the University of Marburg (DE) in 1994 and earned a Master degree in nutritional sciences from the University of Giessen (DE) in 1988. Dr. Kleiner served three years long as a secretary to the Senate Commission on Food Safety of the German Research Council (Deutsche Forschungsgemeinschaft) and after her work for the University of Giessen, Dr. Kleiner started at the European branch of the International Life Sciences Institute (ILSI Europe) for which she worked seven years as a senior scientist, responsible for the scientific management and support of the food safety programme. Since March 2004 she is employed at EFSA, where she first coordinated the Contaminants Panel, then moved as a team leader to the Scientific Committee of the Scientific Committee and Advisory Forum Unit. Sine March 2008 she is working for the NDA unit.

## 3. **Prof. Giovanni Lercker,** Dept. Food Science, University of Bologna, Italy

Email giovanni.lercker@unibo.it

***Education***

University of Bologna, Master of Science in Analytical Chemistry, 1971

University of Bologna, Bachelor of Science in Chemistry, 1970

***Professional Experience***

2006 to Present - Department Head, Department of Food Science, Agricultural Sciences Faculty, University of Bologna (Italy)

1993 to Present - Full Professor, Agricultural Sciences Faculty, University of Bologna (Italy)

[1] www.NanoMicroClub.com
[2] www.NanoMedNet.org
[3] www.NanoChina.com
[4] www.nano.org.uk/nanomasters.htm

1990 to 1993 - Full Professor, Agricultural Sciences Faculty, University of Florence (Italy)

1985 to 1990 - Full Professor, Agricultural Sciences Faculty, University of Udine (Italy)

1983 to 1984 - Associate Professor, Agricultural Sciences Faculty, University of Bologna (Italy)

1970 to 1983 - Research and Teaching Assistant, Agricultural Sciences Faculty, University of Bologna (Italy)

***Honors and Awards***

Scanno Award, Italian National Sciences Award (2004)

***Research Interests and Experience***

The research activity of the Prof. G. Lercker is focused on the field of food lipids, in particular on their composition and their degradations caused by processing and preservation. Several methods of macro-analysis have been set up, but most of his work is related to micro-analysis. Over the last few years, particular attention has been devoted to the oxidative stability problems of model and real systems. Part of these investigations has been addressed to the study of sterol oxidation products, by analyzing model systems and commercially-available products.

He is author and co-author of more than 400 publications related to these subjects.

***Teaching and Mentorship Experience***

**Classroom Teaching**

University of Bologna

Analytical Chemistry of Industrial Processes, 1994 to 1995
Agricultural Industries, 1970 to 1971, 1976 to 1978, 1990 to Present
Food Chemistry, 1984 to 1985, 1987 to 1993, 2004 to 2005
Food Technology, 1974 to 1983
Food Technology Institutions, 1984 to 1987
Oil, Fat and Fat Derivative Technology, 1973 to 1974, 1993 to 2005
Principles of General, Inorganic and Organic Chemistry, 1982 to 1983

University of Florence

Agricultural Industries, 1990 to 1993

University of Parma

Food Preservation and Cooking Techniques, 2005 to Present

University of Udine

Agricultural Industries, 1984 to 1985
Food Chemistry, 1984 to 1985
Chemical Analysis of Food Products, 1985 to 1991

**Graduate Advising**

Ph.D. Students
M.S. Students

**Other Mentorship Activities**

Visiting Scientists

***Selected Professional Recognitions and National Committee Assignments***

- Member, Academy of Georgofili (1993 to Present)
- Member of National Academy of Agricultural
- Member, CODEX ALIMENTARIUS (2000 to Present)
- Academic Member, National Academy of Olive and Oil (1992 to Present)
- Secretary, Italian Society for the Study of Lipid Substances (1988 to 1991)
- Member, Commission of the Official Analytical Methods of the Italian Health Ministry (1987 to Present)
- Scientific Advisor, Italian Society for the Study of Lipid Substances (1985 to Present)
- Member of National Academy of Food Science

***Membership in Professional Organizations***

American Chemical Oil Chemists' Society
Società Chimica Italiana
Società Italiana di Scienze e Tecnologie Alimentari
Associazione dei Ricercatori di Nutrizione Alimentare

**4.** **Mr. Kees de Winter,** Head of the Food Department of the European Consumers' Organisation, BEUC

Since May 2007 Kees de Winter has been Food Policy Advisor at BEUC, the European Consumers' Organisation. His job is to assist BEUC and BEUC's member organisations in campaigning to influence EU policies relating to food and food production in the consumer interest. From 1998 till 2007 he worked as a consultant in the area of food and life sciences. In this period he was, amongst others, active as Project Technical Assistant for the Directorate-General Research of the European Commission and prepared several courses on EU Food Law for professionals in the food sector. From 1992 till 1998 he worked as Food Officer at BEUC. Before he worked as a Civil Servant for the Dutch Ministry of Agriculture, as a Food Researcher for a Dutch Consumer Organisation, as a teacher at a teacher training College and as a researcher at the Wageningen University Research. Mr De Winter graduated as nutritionist and food technologist.

**5.** **Mrs. Agnès Davi,** Corporate Regulatory Affairs Director - Groupe Danone Paris, C.I.A.A.

**Professional experience**

*Present position*

Corporate Regulatory Affairs Director - Groupe Danone, Paris, France. Joined Groupe Danone in 1996.

Currently:

- Chair of the Novel foods expert group in the European Food Industry Federation (CIAA)
- Chair of the Novel foods expert group in the French Food Industry Association (ANIA)

*Previous positions*

1991 - 1996: Secretary General of the French Association of the Flavour Industry (SNIAA).
1985 - 1991: Scientist in Biotechnology, worked for the seed industry (Groupe Limagrain, France)

**Education**

- Diploma of Pharmacy, major in Biology (Paris)
- Master in Plant genetics and Plant breeding (Paris)
- PhD in Plant Biotechnology (Paris)

**6. Ms. Ruth Chadwick,** Director, ESRC Centre for Economic and Social Aspects of Genomics (Cesagen), Cardiff University, UK

Ruth Chadwick is Dierctor of the ESRC (Economic and Social Sciences Research Council) Centre for Economic and Social Aspects of Genomics (Cesagen), Cardiff University, UK.

She holds a Link Chair between Cardiff Law School and the School of English, Communication and Philosophy (ENCAP). She has co-ordinated a number of projects funded by the European Commission, including the EUROSCREEN projects (1994-6; 1996-9) and co-edits the journal *Bioethics* and the online journal *Genomics, Society and Policy*. She is Chair of the Human Genome Organisation Ethics Committee and has served as a member of several policy-making and advisory bodies, including the Panel of Eminent Ethical Experts of the Food and Agriculture Organisation of the United Nations (FAO), and the UK Advisory Committee on Novel Foods and Processes (ACNFP). She was editor-in-chief of the award winning *Encyclopedia of Applied Ethics* (1998), of which a second edition is now being prepared. She is an Academician of the Academy of Social Sciences and a Fellow of the Hastings Center, New York; of the Royal Society of Arts; and of the Royal Society of Medicine. In 2005 she was the winner of the World Technology Network Award for Ethics for her work on the relationship between scientific developments and ethical frameworks.

# 4. Briefings/Abstracts prepared prior to the roundtable

## 4.1. "Nanotechnology in food: dreams or reality?" by Otillia Saxl

(CEO of the Institute of Nanotechnology, IoN)

**Food Challenges.** The production, processing and marketing of food products is posing many challenges today for the food industry. These include a requirement to address social issues, such the obesity pandemic, meeting the demands of new markets (e.g. for health foods / sports drinks), all in a framework of minimizing food risks. There are also safety and sustainability issues that need to be taken into account, such as reducing food and packaging wastage, enhancing the shelf life of food, while not compromising on its quality, the detection of pathogens and prevention of tampering. Food companies also have pressures on them to increase market share through the introduction of novelty foods that excite the consumer.

**Why nano?** Nanotechnology has enabled a better understanding of how things work at the level of atoms and molecules, and why they have the properties they have. This has enabled the food industry to design in specific attributes to food products and food packaging. Nanotechnology is increasingly allowing food companies to meet the need for quality, safety and novelty in their food products, as well as incorporating other 'healthy' features, such as reduced fat and / or increased vitamin content, or new and unique taste sensations.

**NanoFoods.** Some companies are keen to promote their foodstuffs as based on nano, others are more reticent about admitting there is a nano aspect to their product, as they are unsure of public acceptance - even though many natural foods, such as milk, owe their properties to nanoscale molecules and their distribution.

Foods presently promoted as nano include 'Nanotea' - which claims to increase tenfold the amount of selenium absorbed from green tea through capsules engineered to bypass the stomach and dissolve in the lower gut. In Canola Activa Oil, nanocapsules prevent cholesterol from the digestive system entering the bloodstream, good for health and weight reduction. SlimShake chocolate is a powdered drink that uses nanotechnology to cluster the cocoa cells, and thus cut out the need for sugar.

**Risk Perception.** Food however, is a highly emotive topic. People will accept many new technologies, except in what they put into their mouths. According to Lynn Frewer of Wageningen University, the perception of risk can be classified as follows:

- An **involuntary risk** (a risk over which people have no control) is more threatening to them, e.g. GM foods.
- Potentially **catastrophic risks** concern people most: e.g. an ecological disaster related to a novel food crop.
- **'Unnatural' (technological)** risks are more threatening than 'natural' ones, e.g. gene technology, nanotechnology vs. organic production.

**Nano in Sport Nutrition.** This general rule of wariness about food may fall down when food and drink relate to high performance sport, and there are several food and drink products aimed at this market, some under the strap line: 'Compete Legally, Excel Athletically with Nanotechnology…**!'**

For example: Nutrition by Nanotech produces a vitamin B-12 Spray which is quickly absorbed as the active molecules are dispersed into nanodroplets, dramatically increasing the bioavailability of nutrients into the body. Another product is Mag-i-Cal, a nanoscale Calcium / Magnesium formulation which bypasses the processing requirements of the stomach, and can enter the cell structure the moment it is ingested.

Regarding the major food companies, Unilever and Nestlé were quoted in the Independent newspaper as 'planning to use nano-encapsulation to improve shelf life and engineer taste sensations in fat-based foods like chocolates, ice creams and spreads. This could lead to huge reductions in fats and salts in processed foods. Unilever believes it can reduce the fat content of ice cream from 15 per cent to one per cent.'

**Nanoencapsulation** is a key technology for the food industry. Nutrients, vitamins and minerals etc can be encapsulated so that anything can be added to a product without altering its colour, taste or appearance. Nanospheres containing vitamins are so small that they can pass through tissue barriers and into the blood stream. The particles can be engineered to release their contents at the required stage of digestion so that none of the nutritional benefits are lost.

Furthermore, compounds that would not mix in their natural state can be brought together by encapsulation. Mayonnaise is an emulsion which differs greatly from its separate components, egg, oil and water. Nanotechnology offers the possibilities for emulsions made from ingredients that previously wouldn't mix, giving the possibility to create a whole range of new and fantastical sauces, toppings, desserts etc.

Encapsulation can also impart a 'gee-whizz!' factor to foods and drinks; offering novelty, in terms of taste, appearance and texture New flavour delivery systems can ensure stability, lower flavour losses and maximum taste.

With regard to **packaging**, the application of nanotechnology has led to the development of smart labelling that can detect when food has ripened, or has gone off, or the product has been tampered with. Nano silvered food containers are the first of the antibacterial technologies on the market, but are similar to technology used for decades in sterilising and keeping food fresh. The addition of only 2% of nano-sized clay particles can dramatically change the properties of a packaging polymer, so it becomes heat resistant and oxygen impermeable.

**Nano vs GM.** Finally, it is useful to note the differences between nanotechnology and biotechnology (after Foley and Lardner):

- The applications of nanotechnology are far broader.
- Nanotechnology is advancing at a faster pace.
- Most of the agri-biotech products on market today are produced by a small number of large companies; whereas nanotech is far more widely distributed (corporate & academic).
- The hype quotient of nanotechnology is much higher; the emotion quotient of nanotechnology is much lower!

## 4.2. **"Concerns about quality and credibility"** by Dr Juliane Kleiner

(Acting Head of Unit of the Panel on Dietetic Products, Nutrition and Allergies (NDA)
European Food Safety Authority (EFSA))

Set up in 2002, the European food Safety Authority (EFSA) provide independent scientific advice, opinions, information, and technical support for Community legislation and policies in all fields which have a direct or indirect impact on food and feed safety - including animal health and welfare and plant protection, and nutrition in relation to Community legislation.

EFSA's risk assessments provide a sound scientific basis for defining policy-driven legislative or regulatory measures required to ensure a high level of consumer protection with regards to food safety. EFSA's risk assessments are carried out by its Scientific Committee and Scientific Panels, each composed of external experts and specialised in different aspects of food and feed safety.

The EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) is the Panel dealing with questions on dietetic products, nutrition and allergies, and other associated subjects such as Novel Food (NF). At the request of the European Commission, the NDA Panel carries out risk assessment of NF (ingredients), defined as food (ingredients) that have not been used for human consumption to a significant degree within the Community, further specified by the NF Regulation (EC) Nº 258/9.

Based on an Opinion of the former Scientific Committee for Food, the European Commission has issued Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment.

Information is required on the specification of the NF, effect of the production process, history of the organism used as the source of the NF, anticipated intake and extent of use, previous human exposure to the NF or its source, the nutritional information, microbiological and toxicological information. The requirements for individual applicants however might differ depending on the composition and the history of the NF.

On the basis of the Novel Food Regulation and the European Commissions Recommendation, the NDA Panel has so far delivered 17 scientific opinions on the safety assessment of a variety of NF such as foodstuffs with added phytosterols, substances with antioxidative properties like synthetic zeaxanthin and lycopene from various sources (*Blakeslea trispora, tomato oleoresin, synthetic)*, NF from third countries (Chia seeds, Allanblackia seed oil, Noni Juice, Noni leaves), Enova oil and vegetable oils high in unsaponifiable matter, NF ingredients with a new or intentionally modified molecular structure (α-cyclodextrin) and such to which a production process has been applied (Ice structuring proteins). Applications currently under evaluation include vitamin K2, Noni Puree and concentrate, Alfalfa (lucerne) protein concentrate, Chia seeds (2nd evaluation), Krill Oil, Glucosamine –HCl from Aspergillus niger and another lycopene product.

### 4.3. **"Chemical quality aspects of novel foods: needs and limits"** by Prof. Giovanni Lercker

(Dept. of Food Science, University of Bologna, Italy)

Some aspects about the classification, definition and analytical-chemical control of novel foods, will be discussed in depth.

Regulation (EC) No 258/97 on novel foods and food ingredients deals with food that was not consumed to a significant degree in the EU before 15 May 1997 (date of entry into force of the Regulation) and thus has to undergo a pre-market safety assessment and authorisation.

Novel foods can be divided into three categories:

- innovative food (e.g. phytosterols, salatrim reduced-energy fat, DHA-rich oil, coagulated potato protein, bacterial dextran, threhalose, egg yolk phospholipids, D-tagatose);

- traditional food from non-EU countries (e.g. noni juice);

- food produced by new processing technologies with possible impact on food (e.g. high-pressure fruit juice).

In addition, the Regulation document specifies the following aspects within the novel food definition:

1) food of animal or vegetable origin, which have been obtained from plants or animals subjected to non-traditional breeding techniques that were not used before 15 May 1997;
2) food ingredient or food subjected to new technologies and/or processing that have not been used before 15 May 1997 and that may lead to significant changes in food composition or structure, thus influencing the nutritional value, the metabolism and/or the presence of undesirable compounds.
    a) "traditional food from a non-EU country", is a new food product that has been consumed for, at least, a generation in a non-EU country and that is a representative component of the diet of a large part of the population;
    b) "experience of safe product consumption", is strictly related to the food safety and it is confirmed by data about food composition and consumption in the past and present diet of a large part of the population.

The core objective of the new regulation is to revise and update the Novel Food Regulation 258/97, in order to **ensure food safety**, **protect human health** and **secure the functioning of the internal market for food,** by streamlining the authorisation procedure, developing a more adjusted safety assessment system and clarifying the definition of novel food, including new technologies with an impact on food and the regulation's aim.

Considering all these requirements, the submission of a novel food request should be rapidly evaluated, but it will need to be well-documented, especially about the impact of new technologies and product safety.

According to the Regulation 258/97, "novel foods are foods that were not used for human consumption to a **significant degree in the EU before 15 May 1997** and thus do not have a history of food use in the EU before that date". This definition requires a better description of what a "significant degree" stands for, because the dimension of food consumption is not well delineated. In fact, several traditional minor food products from UE countries may be classified as novel food.

The Novel Food Regulation also covers newly developed foods and food derived **from new production processes and technologies** (now excluding gene technology) with a possible impact on food. When new technologies are to be utilized, it will be necessary to perform product safety assessment, so as to avoid negative effects on consumers' health.

Novel food trading should be efficiently controlled by monitoring the microbial and chemical status of the ingredients, as well as the compounds generated by processing and/or storage conditions. This operating approach will be useful to verify the actual safety and identity of the food product.

In addition, a comparison between EU food safety regulation and those of the non-European countries is of outmost importance, in order to protect and warrant EU consumers' health. For instance, China is dealing with great health problems, due to the presence of a series of undesirable compounds and microorganisms in food, such as **clenbuterol**, **chloramphenicol**, **malachite green**, **meta-chlorophenyl piperazinyl derivative (3-MCPT)**, **tetradotoxin, metaminodophos, methyl paration, *Listeria monocytogenes***, **red 2G (E128)**, **brilliant crocein (orange G), sunset yellow (E110), long-stored rice (aflatoxins)**, **benzoic acid** and **sorbic acid.** Several of these components are not legal in EU, because of their high toxicity activities.

The origin of possible problematic compounds that could be present in food are:

**a) Compounds already present in the usual food composition**

**b) Xenobiotic compounds**

Voluntary contamination

Special processing technologies

Accidental contamination

Use of chemical additives for zootechnical purposes

Use of pharmaceutical products for animal therapy

Fraudulent use of growth promoters

**c) Neo-formed compounds (in the food)**

Substances that can be reduced (LAL, biogenic amines, PAHs, …)

Substances that can be eliminated (petroleum hydrocarbons, ..)

Compounds found in food have been classified in different chemical categories (such as food additives, colours, flavours, preservatives, processing aids, contaminants, environmental contaminants, food packaging migrants, processing contaminants, residues, pesticides, veterinary medicines, animal feed additives, natural compounds, mycotoxins, marine biotoxins, plant toxins, bacterial toxins, adulterants, malicious tampering). However, unknown components should not be disregarded or underestimated.

A correct food analytical control should cover the following aspects:

a) Chemical, physical properties and molecular structure: derivatives, possible isomers and distribution in biological material;

b) Nutritional, physiological, and clinical functionality: safety, bioactivity, bioavailability, efficiency in human diet, health-related and pharmacological properties;

c) Separation technology in the laboratory and commercial production;

d) Processing: processing system and equipment, chemical, physical, and engineering properties during processing, quality control *in-situ* (during production);

e) Shelf-life: storage conditions and stability;

f) Identification techniques: HPLC, GC, MS, and NMR;

g) Standards and regulations: EC, FAO/WHO, FDA, Health Canada;

h) Utilization: applications, current and potential markets.

To protect food quality and safety, the following conditions are needed:

- Awareness of the risk level (risk assessment and management);
- In-force regulation;
- Efficient and updated control;
- Assurance and severity of penalties and sanctions.

Nowadays, food chemical control shows a high level of analytical performance, due to:

- High level of analytical chemistry;
- High sensitivity of instrumental food analysis;
- Scarce number of analytical food control operators.

4.4. **"Consumer rights and expectations"** by Mr. Kees de Winter

(Head of the Food Department of the European Consumers' Organisation, BEUC)

New foods are continuously coming on the market, with a significant number being produced using new technological processes or originating from outside the European Union.

It is critical that food safety, public health and consumer information are the overriding concerns of decision makers when revising this important piece of legislation.

Most importantly, novel foods must be subjected to a robust authorisation procedure to ensure that consumers are properly protected. There should be no danger to consumers' health should consumers ingest combinations of novel foods. Novel foods should be clearly labelled, so that consumers can make well-informed choices.

To ensure this, the Commission's proposal needs to be improved. BEUC calls for the following:

- the definition of what is meant by "novel food" should be clarified and must include a non-exhaustive list of food product considered a "novel food";
- all novel foods should be subject to post-market monitoring;
- a transparent appraisal procedure for traditional foods from third countries with no history of safe use in the EU should be applied;
- the consumers should be enabled to make informed choices regarding the use of novel foods and not be misled as to their properties.

**Definition of novel food**

Article 3 (2)(a)(i) indicates that "novel food" means food that has not been used for human consumption to a significant degree before 15 May 1997. In order to clarify the definition of 'novel food' we believe that the regulation should contain a non-exhaustive list of food products that, in all circumstances, are considered a "novel food". This list should contain food products belonging to the following categories of foods which have not until now been used for human consumption:

a) Foods with a new or intentionally modified primary molecular structure;

b) Foods consisting of, or isolated from, micro-organisms, fungi or algae;

c) Foods produced using nanotechnology and nanoscience;

d) Food products from cloned animals and from offspring of clones;

e) New strains of micro-organism with no history of food;

f) Novel foods that were approved under the so-called 'fast track procedure' of Regulation (EC) no 258/97 concerning novel foods and novel food ingredients;

g) Concentrates of substances that naturally occur in plants;

h) Food supplements other than vitamins and minerals falling within the scope of Directive 89/398/EEC, Directive 2002/46/EC or Regulation (EC) No 1925/2003.

***Offspring of clones***

Article 3 (2)(a)(ii) addresses the issue of products from animal and plant products produced using non-traditional breeding techniques, such as cloning. This Article needs to be amended to specify that the offspring of cloned animals are also classified as novel food.

***Nanotechnologies***

Article 3 (2)(a)(iii) addresses the issue of foods that have been produced using new production processes. BEUC welcomes recital 6's statement that food should be considered as novel when it is applied a production technology which was not previously used, with nanotechnology given as an example of such process. We are concerned that Article 3.1(a)(iii) does not adequately reflect this.

**Post-market monitoring**

BEUC proposes to introduce a requirement for post-market monitoring of all novel foods introduced onto the European market. This monitoring should include food safety aspects, the environmental impact and animal health and welfare aspects.

All novel foods should be reviewed every 5 years and when relevant scientific evidence becomes available.

**Traditional foods from third countries**

Article 8 allows for a simplified approach for traditional foods from third countries. It states that a food business operator has to notify the Commission that it intends to place a traditional product from a third country on the market, and has to provide documentation demonstrating the product's history of safe use in that third country. However, these proposals do not require such products to be subjected to the assessments laid down in Article 6 *(Conditions for inclusion in the Community list)* before they are placed on the market. It merely requires Member States and the EFSA to have the opportunity to raise any safety concerns within four months of the date of notification. The fact that a product has been consumed for many years in a country should not be assumed to mean it is safe. Article 8 needs to be amended to lay down a clear set of criteria for determining the "history of safe food use" which should be based on advice from EFSA.

**Labelling**

Specific labelling requirements should apply to novel foods in order to ensure that the final consumer is informed of any characteristic or food property such as: composition, nutrition value and intended use of the food which renders a novel food no longer equivalent to an existing food. The consumer should also be informed if in the novel food material is present which is not present in an existing equivalent foodstuff. We do not understand why the basic labelling requirements which exist already under the current Novel Food Regulation (Article 8) have not been taken on in the new proposal. As a minimum, these labelling requirements should be incorporated into the revised regulation.

**Authorisation process**

We welcome the fact that the safety assessment of novel foods shall be centralised within EFSA.

### 4.5. **"The industry challenge ahead"** by Mrs. Agnès Davi

(Corporate Regulatory Affairs Director - Groupe Danone, Paris (CIAA))

The revision of the Regulation should stimulate innovation in the food and drink industry, protect both the functioning of the internal market and public health, and at the same time, facilitate market access for novel food products.

CIAA welcomed the European Commission's revision of the existing European rules governing novel foods (Regulation 97/258/EC) which cover all new foods without a significant history of consumption within the European Union before 1997. CIAA maintains, however, that the following areas need to be further reviewed to ensure that the competitiveness of the food and drink industry is safeguarded and that particularly SMEs can benefit from easier procedures, thereby encouraging them to invest in innovation.

- **Establishing a more explicit link between a novel food authorization and the applicant company:** the proposal introduces a centralised authorisation procedure and includes data protection provisions for newly developed innovative foodstuffs, in order to stimulate innovation, where **a justified designation of proprietary status has been made in a novel food application.** The legislation should clarify that products comparable to the ones that have been previously granted approval cannot be marketed without also requesting an approval. The authorisation should remain available for the exclusive use of the applicant during the period of data protection as defined in the draft legislation. Other applicants must therefore provide data sufficient to substantiate new authorisations.

  The initial applicant should therefore be authorised to market the food for five years before it becomes a generic authorisation that can be used by others.

  CIAA therefore requests applicant-linked data protection so that investing companies, including SMEs are able to get a return on investment. This guarantees a system that fosters innovation over imitation.

- **Introducing a simplified notification procedure** for foods and ingredients with a history of safe use, such as foods and ingredients that are currently used in food supplements, for which extension of use in new food applications could then be requested.

  The Commission proposal makes provisions for food from third countries with a history of safe use. For such foodstuffs, the authorisation procedure is simplified. Similar simplified procedures should be foreseen for ingredients already used in Europe in traditional products such as food supplements or the use of derivates of foodstuffs with a history of safe use. Such simplified procedure would benefit in particular SMEs, allowing them to innovate.

- **Transitional mechanisms:** CIAA would like to get clarification on the status of applications for which an initial assessment has already been forwarded to the Commission under the old procedure. A pending application should be completed following the rules applicable at the time of submission in order to prevent the burden of filing a new application for the applicant business operator. Providing an appropriate transitional mechanism for pending novel food applications is essential for the food and drink industry.

  Technical guidance on how to prepare and submit an application should be available before the regulation enters into force. SMEs in particular need guidance on the procedural steps.

- **Ensuring an operable relationship between Novel Foods and Health Claims Regulation.** CIAA asks for a link between approval procedures for novel food applications (safety assessment) with the one for health claims (efficacy assessment), for novel foods to be marketed with health claims. The data protection periods for both applications should run concurrently to ensure that a Novel food can be launched with the requested claim. Otherwise products could not be marketed before their claim is approved, and this would reduce the interest of the data protection system that is limited in time.

### 4.6. **"The health care impacts of novel food"** by Ms. Ruth Chadwick

(Director, ESRC Centre for Economic and Social Aspects of Genomics (Cesagen), Cardiff University)

In considering the effects of novel foods on public health, the interpretation of the term 'public health' has to be considered. Although it might seem obvious that what is at stake is the health of 'the public' the public is constituted of different population groups that can be categorized in a number of different ways. An alternative approach might be to assess impact in terms of a number of parameters over which there are concerns, such as obesity, allergenicity, food sensitivity and so on: as a matter of fact these are prominent areas of concern at present. Issues of public awareness and choice also need to be considered as an important dimension in assessing impact, along with the foods themselves.

Other important contextual features include current trends, including the trend towards 'personalisation' of diet, as identified for example in the report of the UK Food Ethics Council, *Getting Personal.* Personalisation can also be variously interpreted, both in terms of personalised or 'tailored' advice; and personalization of responsibility. Both of these are to be found in UK policy documents. Different questions arise here: first, concerning the extent to which individuals will want personalised dietary advice. Although there have been some moves in this direction the decisions an individual makes about what to eat are arguably much more complex than the decisions about following a doctor's prescription of a drug. There is some empirical evidence, however, that 'personalisation' is found attractive, at least in pharmacogenomics.

To facilitate such personalisation would require large scale population based research, so personalisation and a population based perspective are closely connected. It is against this background that regulation of novel foods has to be considered. They have to date been assessed on the grounds of safety, and on a case by case basis. One drawback of this approach has been that the effect on the overall diet has been under represented – for example, the issues surrounding potential for over-consumption of particular ingredients. Attention has also been paid, however, to ethical principles of access and consumer choice. The issues surrounding labelling are important not only from a safety point of view but also for the promotion of such choice, although research needs to continue into the extent to which consumers read and act on labelling information. The relationship between labelling and choice also raises the issues of the link between choice and responsibility.

Where novel foods are 'functional' there is also a question of efficacy. - but surely, it might be argued, all food is functional, in some sense. This indicates the need to be more precise about what exactly is mean by 'functional'. Functional foods are those that have, or claim to have, a specific heath-promoting or enhancing effect over and above their nutritional content, such as cholesterol-lowering foods and probiotic yogurts.

There have been a number of ethical concerns associated with functional foods, arising partly from the fact that, being foods, they are tested for safety but not for efficacy, unlike drugs; they are placed in supermarkets alongside traditional products and yet they might not be suitable for all those who buy and consume them. The way in which they are advertised, moreover, is potentially misleading, using role models, for example, who are apparently not in the relevant high-risk group.

In relation to possible changes in regulation of novel foods, the potential impacts on the public health issues as identified here need to be considered: first concerning the scope and definition. The introduction of nanotechnology products, for example, raises issues as to whether there are any genuinely new questions here, or whether there are analogous issues to those in the genomics debates. The procedures for assessment need to be themselves assessed in relation to their possible effect on the perceived gaps in previous mechanisms, as regards public health: is there an appropriate balance between protecting public health and facilitating innovation and intellectual property?

When public health is at stake, public perceptions are also very important, not only in relation to awareness in order to make informed choices, but also regarding input into consultations: thus provisions on transparency and openness also have to be recognised as having a potential, possibly indirect, impact on public health.

Finally, the elements of an ethically robust policy include attention to the needs of different population groups, including research on population variation at the genomic level. It is not necessary to go down the full personalisation route in order to take into account variations at group level which significantly affect nutritional needs.

# 5. Proceedings - Summary of the workshop

## 5.1. Opening of the Workshop

**Ms. LIOTARD Kartika Tamara** MEP and Rapporteur on Novel Food for the Committee of the Environment, Public Health and Food Safety introduced the Workshop organised as follow up of the Commission's proposal. Emphasis is on certain definitions of "Novel Food": how these definitions are used in practice; what are the responses to them; and their implications. Experts from varying fields, such as health, food standards, industry, and consumer rights will touch upon key elements of the proposal.

## 5.2. Expert commentary on the topic

### 5.2.1. "Nanotechnologies in food: dreams or reality?"

**(Ms. Ottilia Saxl**, CEO, Institute of Nanotechnology, Stirling UK)

This presentation covers in particular: what nanotechnology is; what nanotechnology can offer the food industry; and some views on risk and public perception of the topic.

Nanotechnology, a sort of "smart chemistry", has enabled a better understanding of how things work at the level of atoms and molecules, and why they have the properties they have. This has enabled the food industry to design in specific attributes to food products and food packaging. Nanotechnology is increasingly allowing food companies to meet the need for quality, safety and novelty in their food products, as well as incorporating other 'healthy' features, such as reduced fat and / or increased vitamin content, or new and unique taste sensations. The best way to describe the "nano-scale" is to say that it is about the width of a DNA strand.

Risk perception can be classified as follows:

- An involuntary risk (a risk over which people have no control) is more threatening to them, e.g. GM (Genetically Modified) foods;
- Potentially catastrophic risks concern people most: e.g. an ecological disaster related to a novel food crop;
- 'Unnatural' (technological) risks are more threatening than 'natural' ones, e.g. gene technology, nanotechnology vs. organic production.

Nanoencapsulation is a key technology for the food industry. Nutrients, vitamins and minerals etc can be encapsulated so that anything can be added to a product without altering its colour, taste or appearance. Nanospheres containing vitamins are so small that they can pass through tissue barriers and into the blood stream. The particles can be engineered to release their contents at the required stage of digestion so that none of the nutritional benefits are lost.

With regard to packaging, the application of nanotechnology has led to the development of smart labelling that can detect when food has ripened, or has gone off, or the product has been tampered with.

### 5.2.2. "Safety assessment of novel foods at EFSA"

**(Ms. Juliane Kleiner,** Acting Head of Unit of the Panel on Dietetic Products, Nutrition and Allergies (NDA) European Food Safety Authority (EFSA)
EFSA risk assessments are carried out by its Scientific Committee and Scientific Panels, each composed of external experts and specialised in different aspects of food and feed safety.

The EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) is the Panel dealing with questions on dietetic products, nutrition and allergies, and other associated subjects such as Novel Food (NF). At the request of the European Commission, the NDA Panel carries out risk assessment of NF, defined as food that have not been used for human consumption to a significant degree within the Community, further specified by the NF Regulation (EC) Nº 258/9.

Based on an Opinion of the former Scientific Committee for Food, the European Commission has issued Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment.

Information is required on the specification of the NF, effect of the production process, history of the organism used as the source of the NF, anticipated intake and extent of use, previous human exposure to the NF or its source, the nutritional information, microbiological and toxicological information. The requirements for individual applicants however might differ depending on the composition and the history of the NF.

On the basis of the Novel Food Regulation and the European Commission's Recommendation, the NDA Panel has so far delivered 17 scientific opinions on the safety assessment of a variety of NF. Applications currently under evaluation include vitamin K2, Noni Puree and concentrate, Alfalfa (lucerne) protein concentrate, Chia seeds (2nd evaluation), Krill Oil, Glucosamine –HCl from Aspergillus niger and another lycopene product.

Some proposals have been made to revise the Novel Food assessment process:

- the definitions and levels may change and, as a result, toxicity testing will have to be adapted accordingly;
- the authorization process may be centralised. This means that the requests for assessment will arrive directly at EFSA, rather than passing firstly through a risk assessment made in the Member State(s). As a consequence, EFSA shall acquire expertises from Member States;
- the authorization of traditional foods from extra-EU countries should be simplified. The applicant would make a notification. Consequently EFSA would investigate the foods safeness;
- further revisions include provisions for future technologies like nanotechnologies and cloning.

### 5.2.3. "Chemical quality in novel foods: needs and limits"

**(Mr. Giovanni Lercker**, Full Professor and Head of the Department of Food Science of University of Bologna – Italy)

Aspects about the classification, definition and analytical-chemical control of novel foods are discussed. Regulation (EC) No 258/97 on novel foods and food ingredients deals with food that was not consumed to a significant degree in the EU before 15 May 1997 (date of entry into force of the Regulation) and thus has to undergo a pre-market safety assessment and authorisation.

Novel foods can be divided into three categories:

- innovative food;
- traditional food from non-EU countries;
- food produced by new processing technologies with possible impact on food.

The Regulation also specifies the following aspects within the novel food definition:

1) food obtained from plants or animals subjected to non-traditional breeding techniques that were not used before 15 May 1997;
2) food ingredient or food subjected to new technologies and/or processing that have not been used before 15 May 1997 and that may lead to significant changes in food composition or structure, thus influencing the nutritional value, the metabolism and/or the presence of undesirable compounds.
    - "traditional food from a non-EU country", is a new food product that has been consumed for at least a generation in a non-EU country and that is a representative component of the diet of a large part of the population;
    - "experience of safe product consumption", is strictly related to the food safety and it is confirmed by data about food composition and consumption in the past and present diet of a large part of the population.

The core objective of the new regulation is to revise and update the Novel Food Regulation 258/97, in order to **ensure food safety**, **protect human health** and **secure the functioning of the internal market for food,** by streamlining the authorisation procedure, developing a more adjusted safety assessment system and clarifying the definition of novel food, including new technologies with an impact on food and the regulation's aim.

Novel food trading should be efficiently controlled by monitoring the microbial and chemical status of the ingredients, as well as the compounds generated by processing and/or storage conditions. In addition, a comparison between EU food safety regulation and those of the non-European countries is of outmost importance, in order to protect and warrant EU consumers' health.

To protect food quality and safety, the following conditions are needed:

- Awareness of the risk level (risk assessment and management);
- In-force regulation;
- Efficient and updated control;
- Assurance and severity of penalties and sanctions.

### 5.2.4. Discussion and debate between Members of the European Parliament and experts.

A lobbyist remarked that Commission proposal for Regulation intends to include provisions for animals cloned for food. A Parliament resolution against cloning animals for food was adopted by a large majority in September 2008. The representative welcomed EFSA findings on health and welfare of cloned animals.

An MEP asked "**which toxicity tests are available? Are tests done on the various generations of the product?"** Mr. Lercker responded that quantity varies from molecule to molecule, due also to differing absorption levels. Different testing procedures are used for different molecules, but sometimes the quantities are so low, that toxins can in certain compositions, be considered virtually non-toxic.

There are other potential problems with testing: toxicity cannot be tested on people, but testing toxicity on cells produces different results than what actually happens in the human body, where various filters are in place to catch toxins. In cases where tests are carried out on animals, the results are not identical to what would happen in a human body.

On the topic of which tests are available, Ms. Kleiner added that there is a battery of standard toxicity tests available. EFSA follows OCD guidelines in order to apply certain tests to certain areas. In the Novel Food area it is easier to do conventional toxicity testing because we have a broad knowledge low molecular weight substances, but there are some limitations on testing bulk material.

**"Is testing performed on more than just one generation of animals and OGM products?"** Mr. Lercker answered that in some cases long term tests are done, but we know that some tumours can appear after twenty years. Tests are done on a series of short life-cycles, but it is difficult to test for long term effects and safety.

An MEP questioned the clarity of certain terms: **"In the definition of Novel Foods we speak about "significant degree". What does this mean? And what do we mean by "a large part of the population"?** And he further commented that in his opinion, the term "one generation" should be replaced with a specific number of years. On the topic of new technologies and the definition of novel food, cloning has been out ruled by the recent vote in the EP, why are we considering including it in this package? As for nanotechnology and genetically modified organisms, these are highly debated subjects in the EU at the moment. Perhaps OGM should not be included in a Novel Food package, as the population is cautious about these subjects.

To which Ms. Kleiner commented on the definition of the terms like "significant degree", also "history of safe use". These definitions depend on a certain level of common sense. When talking about a food having a "history of safe use" it is food that has been consumed by a large populous and not in an isolated group. We consider the length of a "generation" in terms of the population. That length can vary from area to area.

A lobbyist asked Ms. Kleiner to clarify the last section of her presentation, **"is it true that the burden of proof of harmfulness of a novel food has been turned around?"** Ms. Kleiner pointed out that this procedure is only applicable in the case of notification of traditional foods from third countries. A simplified procedure has been proposed exclusively for foodstuffs that have a history of safe use. In this procedure, EFSA or the Member State has to prove the unsafeness, not the safeness.

A representative of the UN asked **"how are the new definitions being integrated into the new authorisation procedure?"** Secondly, he asked, **"what can be said about the European role and international agreements"** at the WTA as well as multi-lateral conventions in areas such as biodiversity?

Some of these topics were treated by a representative of the European Commission: The last question refers to the authorization process for traditional foods from outside the EU. For this type of authorization, we foresee a speedy process. If there is a history of safe use of the food it is not necessary for the entire process to be followed. As for the second question, concerning international obligations, the proposal has already been notified and we already have comments from several countries and including several Latin-American Countries.

The Rapporteur posed a question to Ms. Kleiner about traditional foods from third countries: **"If the burden of proof has been reversed, what will the procedure be like now? Is this new procedure feasible?"** Ms. Kleiner answered that the new process is feasible, but a clear idea of which kind of documents will be delivered in the notification process must be set out. Member States and EFSA will have to provide proof of recent objections to the presumed safety of a given food.

In addition, the Rapporteur asked Ms. Saxl: Sometimes the public has an unjustified fear of nanotechnology. **"What are the real dangers of nanotechnology and how do you think we can minimise them? What sort of provisions should we include if we are going to allow nanotechnology?"** Ms. Saxl stated that according to studies most people are uninformed about nanotechnology. Nano at present is in foods the same way nature "does it". For example, we do want school children to take fish oils; we can use encapsulation techniques, so they get the element without tasting it. So the body is deluded into getting something it really needs. The food industry uses this technology to get certain elements into the body without negative health effects like excessive calories. Nanotechnology has also been used in the manufacturing process where workers are exposed to processes where foods have been heat-treated. Ms. Kleiner added that EFSA has also taken interest in nanotechnology and will be examining limitations, exposure questions and so forth. Documentation will be available for public consultation later this month.

### 5.3. A critical assessment by stakeholders of the Commission's proposal

#### 5.3.1. "Consumer rights and expectations"

**(Mr. Kees de Winter**, Food Policy Advisor - the European Consumers' Organisation, BEUC)

BEUC feels the Commission's proposal requires clarification and less ambiguous wording. Specifically:

- the definition of what is meant by "novel food" should be clarified and must include a non-exhaustive list of food product considered a "novel food";
- all novel foods should be subject to post-market monitoring;
- a transparent appraisal procedure for traditional foods from third countries with no history of safe use in the EU should be applied;
- consumers should be enabled to make informed choices regarding the use of novel foods and not be misled as to their properties.

#### 5.3.2. "The industry challenges ahead"

**(Ms. Agnès Davi**, Corporate Regulatory Affairs Director - Groupe Danone, Paris Representing the CIAA)

CIAA maintains that the following areas need to be further reviewed to ensure that the competitiveness of the food and drink industry is safeguarded and that particularly SMEs can benefit from easier procedures, thereby encouraging them to invest in innovation.

**Establishing a more explicit link between a novel food authorization and the applicant company**: the proposal introduces a centralised authorisation procedure and includes data protection provisions for newly developed innovative foodstuffs in order to stimulate innovation, where a justified designation of proprietary status has been made in a novel food application. The legislation should clarify that products comparable to the ones that have been previously granted approval cannot be marketed without also requesting an approval. The authorisation should remain available for the exclusive use of the applicant during the period of data protection as defined in the draft legislation. Other applicants must therefore provide data sufficient to substantiate new authorisations.

The initial applicant should therefore be authorised to market the food for five years before it becomes a generic authorisation that can be used by others.

CIAA therefore requests applicant-linked data protection so that investing companies, including SMEs are able to get a return on investment. This guarantees a system that fosters innovation over imitation.

**Introducing a simplified notification procedure for foods and ingredients with a history of safe use**, such as foods and ingredients that are currently used in food supplements, for which extension of use in new food applications could then be requested.

The Commission proposal makes provisions for food from third countries with a history of safe use. For such foodstuffs, the authorisation procedure is simplified. Similar simplified procedures should be foreseen for ingredients already used in Europe in traditional products such as food supplements or the use of derivates of foodstuffs with a history of safe use. Such simplified procedure would benefit in particular SMEs, allowing them to innovate.

**Transitional mechanisms**: CIAA would like to get clarification on the status of applications for which an initial assessment has already been forwarded to the Commission under the old procedure. A pending application should be completed following the rules applicable at the time of submission in order to prevent the burden of filing a new application for the applicant business operator. Providing an appropriate transitional mechanism for pending novel food applications is essential for the food and drink industry.

Technical guidance on how to prepare and submit an application should be available before the regulation enters into force. SMEs in particular need guidance on the procedural steps.

**Ensuring an operable relationship between Novel Foods and Health Claims Regulation**. CIAA asks for a link between approval procedures for novel food applications (safety assessment) with the one for health claims (efficacy assessment), for novel foods to be marketed with health claims. The data protection periods for both applications should run concurrently to ensure that a Novel food can be launched with the requested claim. Otherwise products could not be marketed before their claim is approved, and this would reduce the interest of the data protection system that is limited in time.

### 5.3.3. "Health care impacts of novel food"

**(Ms. Ruth Chadwick**, Director, ESRC Centre for Economic and Social Aspects of Genomics (Cesagen), Cardiff University)

In considering the effects of novel foods on public health, the interpretation of the term 'public health' has to be considered. An alternative approach might be to assess impact in terms of a number of parameters over which there are concerns, such as obesity, allergenicity, food sensitivity and so on: as a matter of fact these are prominent areas of concern at present. Issues of public awareness and choice also need to be considered as an important dimension in assessing impact, along with the foods themselves.

Other important contextual features include current trends, including the trend towards 'personalisation' of diet. Personalisation can also be variously interpreted, both in terms of personalised or 'tailored' advice; and personalization of responsibility.

To facilitate such personalisation would require large scale population based research, so personalisation and a population based perspective are closely connected.

It is against this background that regulation of novel foods has to be considered. They have to date been assessed on the grounds of safety, and on a case by case basis. Attention has also been paid, however, to ethical principles of access and consumer choice. The issues surrounding labelling are important not only from a safety point of view but also for the promotion of such choice. The relationship between labelling and choice also raises the issues of the link between choice and responsibility.

Where novel foods are 'functional' there is also a question of efficacy. Functional foods are those that have, or claim to have, a specific health-promoting or enhancing effect over and above their nutritional content, such as cholesterol-lowering foods and probiotic yogurts. There have been a number of ethical concerns associated with functional foods, arising partly from the fact that, being foods, they are tested for safety but not for efficacy.

In relation to possible changes in regulation of novel foods, the potential impacts on the public health issues as identified here need to be considered: first concerning the scope and definition. The introduction of nanotechnology products, for example, raises issues as to whether there are any genuinely new questions here, or whether there are analogous issues to those in the genomics debates. The procedures for assessment need to be assessed in relation to their possible effect on the perceived gaps in previous mechanisms, as regards public health: is there an appropriate balance between protecting public health and facilitating innovation and intellectual property?

When public health is at stake, public perceptions are also very important, not only in relation to awareness in order to make informed choices, but also regarding input into consultations: thus provisions on transparency and openness also have to be recognised as having a potential, possibly indirect, impact on public health.

Finally, the elements of an ethically robust policy include attention to the needs of different population groups, including research on population variation at the genomic level.

### 5.3.4. Question and Answer session (Q&A) with MEPs

A lobbyist asked "**what are the implications of application of the proposal? How will you address the fact that it is very difficult to introduce new products to the market?"** Mr. De Winter concurred that procedures must guarantee ease in going to market, but they must also guarantee food safety. There is a possibility that foodstuffs go to market resulting in health problems and consequently causing difficulties in the acceptance of new technologies. Ms. Saxl pointed out, by way of example that many techniques used in presenting foods that contain nanotechnology are adopted from those used in tradition pharmacology: delivery and encapsulation. These are old and familiar terms, approved methods of delivering nutrients and flavours. Saying there is nanotechnology involved in the food does not mean there's some strange substance in there, it simply means that work has been done on the nano scale.

The Rapporteur commented about the time frame for the procedures, as well as the administrative burden on producers. This directive must protect consumers and help producers in terms of time-to-market. **"What can we do in order to scale back the administrative burden and speed up the procedure?"** Ms. Davi answered that with a simplified requesting and authorisation process there would be more requests for NF authorisations. In her opinion, too few dossiers have been filed. The industry has not had much confidence in the procedure, and those who have filed have found the procedure painful and uncertain. Generally speaking, for a population of 500,000 inhabitants in the EU, six to seven files per year are submitted with an average of two authorisations given per year. In order to restore industry's confidence in the procedure, the procedure should be centralised and more efficient.

A lobbyist asked Ms. Kleiner to address the suggestion that there be one single set of tests to carry out in order to assure a product's safeness. **"Should it be only EFSA, or should other bodies, like industry itself, carry out this testing?"** Ms. Kleiner answered by providing some figures about the proposed centralised assessment procedure. Since EFSA inception, it has received 25 requests for opinions, out of 63 applications after the time of SCF. So EFSA has been asked for an assessment in about 40% of the applications.

This tendency is on the increase, today in about 50% of the applications, EFSA is asked to do additional assessments, based on the documents provided. Mr. Lercker added that industries are responsible for requesting authorisation and ultimately for the safety of their products.

### 5.4. Final remarks

The Rapporteur concluded by saying: "We've heard from experts, consumers, industry and EFSA, from every possible angle we have heard the same message: if we are to consume foods they must be safe. There is still a lot of work to be done".

## 6. Annex: Workshop presentations

Please refer to the CoMeta/GruppoValore workshop website at www.consorziocometa.it/novelfood for all presentations.