SPEECH

EFSA Conference on Nutrition and Health claims
Bologna, 8-10 November 2006

Patrick Wall
Chairman of EFSA Management Board

Closing Remarks

Ladies and Gentlemen, Mr Prodi,

It falls to me as Chairman of the EFSA Management Board to bring this conference to a close. I would like to thank all of you for your attendance and your contributions on the platform, from the floor and in the working groups. I join with you all in thanking and appreciating the time and effort all the speakers have made to deliver great presentations.

I thank Herman Koëter, the EFSA team, and their associates, involved in organising this most informative event and Albert Flynn for steering us through the past three days.

On behalf of the Management Board I would like to publicly acknowledge the work of all the EFSA staff whose commitment, enthusiasm and ability is building EFSA into a most effective organisation. I speak for the other members of the Management Board when I say we are very proud of them. EU citizens can be assured that they are being well served.

Diet related disease is not evenly distributed among EU citizens and there are huge discrepancies in the health experiences between, and within, Member States with subsets of the EU population suffering more illness than others. So the promotion of well balanced diets and healthy lifestyles

and the development of systems that enable all our citizens to adopt both easily, have to be paramount.

The burden of ill health associated with inappropriate diets continues to increase at varying rates in different Member States and collective action is required if this is to be reversed. To this end EFSA will play its part, through its scientific advice and communication activities to support the development and implementation of effective policies by the Commission and Member States.

I would like to stress that functional foods can be part of, but not a replacement for, a balanced diet. Neither are they some form of "absolution" for the health damaging consumption patterns and bizarre lifestyles that many of us practice. *We want to have three helpings of dessert but we will have a cholesterol lowering biscuit with the Cappuccino!*

Clear guidelines will be developed on the standards, and levels, of evidence and the other information acceptable, and necessary, to support an application for the different categories of claims. We will build on the work already undertaken by other agencies and bodies. The EFSA panels are composed of scientists who undertake risk assessments in addition to their day jobs and, to maximise the return for their time, industry needs to be aware of this and summit the most complete dossiers possible.

At this point in time we are not exactly sure of the assessment work load but EFSA will gauge the resource implications and put appropriate resources in place. I thank the members of the scientific panel, and working groups, for their work to date and, in advance, for the work they have yet to do. *If any company has a functional food that enables scientists to do a week's work in a day we will fast track it through the assessment process.*

In most companies the marketing people and the technologists and scientists reside in two different camps and in many companies elements of the marketing function are outsourced. While the scientists may prepare a valid dossier and receive an authorised claim that will appear on the label, through imagery, positioning, celebrity endorsement etc, the marketers can convey an impression to the consumer that the product is something that it is not. I have no doubt that the future marketing initiatives may be even more innovative than the products. Misleading the consumer can not be tolerated and consistent application of the rules across the EU is essential if this is not to occur and if there is to be a level playing field for both industry and consumers.

The issue of consumer understanding is a crucial one. It will be a challenge to communicate to consumers what this Regulation means for them and what is forbidden and what is permitted. For example certain trademarks and brand names that existed before January 1st 2005 which may convey an impression that the product has a claim which is not scientifically substantiated, can continue to be used for 15 years after the Regulation comes into force.

One factor outside the remit of EFSA which from a consumer standpoint the success of this Regulation will very much depend is whether the authorities in Member States assign adequate resources, and have the will, to enforce the Regulation especially when for many of them there are genuine threats to the public's health from poor food safety practices competing for their attention.

We are living in exciting times and foods with nutrition and health claims present definite commercial opportunities for food companies and potential benefits for EU citizens. Time will tell whether these foods make a contribution to the improvement of the health of all EU citizens or remain only on the menu of the more affluent "worried well". If the potential health gain is to be realised industry has a responsibility to reach out to all levels of society.

It is important that we keep pace with the developments outside the EU and also that both EU industry, and EU citizens, are not deprived of opportunities, and to this end we must continue to work to simplify the process.

There is much done but a lot more to do. EFSA is working closely with the Commission and will maintain dialogue with all stakeholders and in addition use the existing expertise and work undertaken to date in the Member States.

We will build on all the ideas and suggestions generated during the past three days. There are many questions yet to be answered, some for EFSA, and some for the Commission, and some for Authorities in the Member States.

We will have further discussions in a range of forums before all of the outstanding issues are resolved.

I thank you all and wish you a safe journey home. Until we meet again, stay healthy.

Italian Ministry of Health

Undersecretary of State to the Italian Ministry of Health,
Mr Gian Paolo Patta

Speech at the
"Conference on nutrition and health claims"

May I begin by thanking the Executive Director of EFSA, Catherine Geslain-Lanéelle, for her kind invitation to deliver a speech of welcome to this meeting, and by making some comments about EFSA and the issues to be discussed at this Conference.

Let me first of all express my appreciation of EFSA's work so far, in effectively and competently confronting the many challenges inherited from the past that characterised the initial years of its existence.

In January 2000, at the dawn of the new millennium, the European Commission, headed by its then President, Romano Prodi, who is now president of Italy's Council of Ministers, sowed the seeds of an important advance in the life of the European Union – namely, the modernisation of the overall approach to food safety in Europe.

The 'white paper on food safety' adopted in January 2000 contained a complex set of initiatives directed towards the establishment of a food safety system able to meet the challenges of the twenty-first century.

The aim was to improve, simplify and slim down the rules and regulations for ensuring food safety 'from farm to table' by adopting an operational plan designed to create the most sophisticated system of food safety existing anywhere in the world for the benefit of Europe's citizens.

It is surely no coincidence that the first regulatory measure implementing the strategy outlined by the European Commission was the adoption of regulation no 178/2002, which laid down the basic principles of the EU's food safety system and established the European Food Safety Authority.

Six years after the adoption of the white paper, and thanks to the hard work of the Community institutions – the Commission, Council and Parliament – as well as to the commitment of the EU's Member States, the main components of the plan outlined in that instrument have become a reality with the entry into force of many other important and innovative Community Regulations.

By virtue of these developments we now have a regulatory system that is certainly much clearer and simpler, and much more effective in maintaining not only the safety but also the quality of the EU's food products, including those of Italy, which is, as you know, particularly proud of its traditional produce.

The linchpin of this new food safety system is EFSA, a strongly science-based organisation charged by law not only with the vital task of assessing health risks but also with that of communicating them to the citizens of Europe.

In the few years since its foundation, even though it does not yet have its full staff complement and had to suffer a move from its temporary home in Brussels to Parma, EFSA has nevertheless acquired an impressive track record and vigorously established its credentials as a prestigious body. This is evident not only from the outcome of the recent legally required formal evaluation of its first three years of operation, but also from the results obtained and the high level of satisfaction of the many users of its work.

On this occasion, I am happy to be able to express the appreciation of the Italian Government, as one of these users, of EFSA's work so far.

I also wish to convey the Italian Ministry of Health's particular sense of closeness to EFSA by virtue of its vital function of protecting public health and ensuring the free movement of food in Europe.

In this connection, let me also emphasise the need for closer scientific and organisational collaboration among the individual Member States of the European Union and between these Member States and EFSA, in order fully to achieve the objectives of the white paper. Further intensification of collaboration with EFSA, by the adoption of procedures such as those provided for in article 36 of regulation no 178/2002 and other initiatives, is an essential strategic element for the future of food safety in Europe.

The other challenge faced by the European Food Safety Authority has been the assignment of a number of new functions to it by food-sector legislation adopted subsequently to Regulation n°178/2002.

This Conference is as it were a paradigm of how EFSA's functions have developed in ever more complex sectors vital to the protection of public health. In fact, the Community Regulation governing nutrition and health claims is increasingly coming to characterise EFSA's mission – with respect not just to food safety, but also to the instruments that are essential for helping consumers adapt their diets positively by providing them with a better knowledge of the nutritional and health-related properties of food products.

One point I should like to make is that many would also favour EFSA being more involved in matters concerning nutrition and in supporting innovative nutrition policies, given that the public-health repercussions of dietary excess and imbalance – that is, of nutritional errors – are much greater than those of food safety issues.

So our coming together in Bentivoglio today for this Conference is not only important in terms of finding the best ways of implementing the new Community Regulation, but will also play a vital part in the future achievement of fundamental improvements in health through the prevention of many diseases – the 'diseases of affluence' – associated with a defective diet.

These are matters to which the Italian Ministry of Health accords the greatest priority, and I intend to devote all my energy to resolving them.

Let me also express my appreciation of EFSA's initiative in undertaking its own programme in this field, involving an extensive comparison of experience in various parts of Europe, and elsewhere in the world, with regard to both scientific tests for verifying claims and nutritional profiles.

Another welcome aspect is the idea, clearly set out in the Conference programme, of allowing the various players in our societies who have an interest in the application of the new Regulation – for instance, consumers' associations and food industry concerns – to express their views.

This manifestly bears out EFSA's desire to work with a maximum of transparency and in as wide a scientific context as possible.

In conclusion, I wish you all every success in your work here, and trust that EFSA will use this conference to amass a body of knowledge, coupled with powerful motivation, that will permit the prompt implementation of the Regulation governing nutritional and health claims, which has not in fact always had a smooth passage through the various legislative stages.

EFSA CONFERENCE ON NUTRIUTION AND HEALTH CLAIMS
Bologna, 8-10 November 2006

Chairman's Summary Notes

HERMAN B.W.M. KOËTER

Deputy Executive Director
and
Director of Science

EFSA Conference on Nutrition and Health Claims

- 197 Expert participants;
- From 21 European countries, Australia, Canada, New Zealand and USA;
- From Management Board, Advisory Forum, Panels;
- From the European Parliament, Commission;
- From government agencies, institutions, academia, industry associations and consumer interest groups.

Conference Objectives

- Explain EFSA's scientific role in the context of the new Regulation;
- Listen carefully to all experts from MS, non-member countries, academia, stakeholders and Commission;
- Exchange views, experience, preferences;
- Debate and discuss issues such as the scientific substantiation of claims and profiles.

Conference Agenda

- Opening by Undersecretary of State to the Italian Ministry of Health and EFSA Executive Director;
- Setting the Scene
- Introduction to Claims
- Scientific Substantiation of Claims
- Nutrient Profiles
- Discussion in breakout Groups
- Conclusions and moving forward

EFSA Considerations

The role of EFSA and its Panel on Dietetic Products, Nutrition and Allergies (NDA) is much broader than the work coming on nutrition and health claims…..

Work areas of the EFSA NDA Panel

- Tolerable upper intake levels of vitamins and minerals;
- Safety assessment of non-GM novel foods;
- PRIs for energy, protein, fats (including saturated, polyunsaturated, monounsaturated, and trans fatty acids), carbohydrates, and dietary fibre;
- PRIs for micronutrients;
- Guidance on translation of nutrient-based recommendations into food-based recommendations.

EFSA Considerations

- EFSA welcomes the Regulation and its role as it will provide clarity to the consumer
- EFSA and its NDA Panel are prepared for the task and adequate resources will be added to this area of work;
- EFSA cannot and does not want to do it alone: input is essential from national authorities, academic researchers and all stakeholders.

EFSA Considerations

- EFSA will continue to involve all parties in the process of establishing nutrient profiles, propose claims data requirements, produce guidance and other tasks related to the Regulation;
- EFSA is concerned about the short time period (5 months) for delivering an opinion on a dossier supporting a claim;
- EFSA needs time to produce guidance on data requirements for claims dossiers and provide the scientific basis for nutrient profile requirements; meanwhile dossiers may be submitted!

General considerations

- Interpretation of the Regulation may differ between parties involved:
  - ➢« if only allowing claims on evidence (proof) we would not have folic acid supplements today »
  - ➢ « we can always withdraw a claim if it appears untrue »

General considerations

- Consumer perception of claims is an important aspect of the Regulation and should be considered when making « …a proposal for the wording of the claim… »;
- Suggested by experts in consumer behaviour:
  - o keep it simple: balance info with simplicity;
  - o define what the most important message is;
  - o put the claim on the front of the pack.

Views from Member States

- Countries covered: Finland, Netherlands, Sweden, UK, Ireland, EU general, Australia, New Zealand, USA
- European systems covered: JHCI (UK), Dutch Code of Practice, Swedish Food Sector's Code of Practice, Finnish Guide for the Control of Health Claims; PASSCLAIM;
  - All voluntary systems
  - Some are very detailed and include extensive guidance
  - Not many claims have been processed

Views from Member States

- Urgent need for action: children eat too much salt, sugar and fat and not enough fruits and vegetables;
- Build confidence in the process among all stakeholders;
- Review process: address data requirements, format, and quality;
- Presentation of the evidence: study design, criteria for cause and effect, criteria for demonstrating substantial equivalence, validated markers;
- Work on consumer understanding.

Views from Industry

- Sound scientific basis is essential for any health claims;
- Botanical products add to the complexity: relate to medicinal products regulation, cosmetics regulation and nutrition regulation;
- Worried about the options for SME's;
- System should be workable for all operators;
- Very active participant in PASSCLAIM
- Identification and validation of (bio)markers;
- Open for changes when science progresses.

Views from Consumer Interest Groups

- Healthier choices should be easier; consumers rely on claims for making food choices;
- Consumers want claims to be truthful and informative;
- Today there are too many misleading claims which make consumers sceptical about the industry's incentives;
- Appreciate the guidance given to the Panel and the transparent approach thus far; adequate resources for EFSA

Break out session outcome

- 6 questions asked on:
  - essential criteria for substantiation of claims
  - criteria the same for nutrition and health claims and for subgroups of the population and for type of claims;
  - aim and scope of nutrient profiles;
  - endpoints/health indicators for nutrient profiles;
  - how to deal with different nutritional requirements for subgroups;
  - making food choices/dietary behaviour.

Break out session outcome

- Agreement on need for **substantiation** of evidence
- Need for **criteria** for claim substantiation
- Discussion on **level of evidence**
- Cross-category or category-specific nutrient profiles?
- No *a priori* exclusions for nutrient profiles?
- Address nutrient profile of a food before or after supplementation?

Next steps

- Report of this meeting
  - Including all presentations
  - Including reports of breakout groups
- Panel and its Working Group(s) will start with its work
  - Highest priority on guidance

Next steps

- During process there will be close interaction with:
  - Commission
  - Member States Regulatory bodies
  - National experts
  - Industry
  - Consumer interest groups
- Follow up meetings are foreseen

European Food Safety Authority

Speech to Open the Conference on Nutrition and Health Claims in Bologna, November 8-10, 2006

Catherine Geslain-Lanéelle
Executive Director of EFSA

Minister, Ladies and Gentlemen, Good Morning and welcome to EFSA's conference on Nutrition and Health Claims.

This is indeed an important event for EFSA and forms part of EFSA's increasing activities in the field of nutrition with the emphasis today on nutrition and health claims. In particular I am looking forward to lively discussions on the issues of nutrient profiles and the substantiation of claims on which there are many opinions and ideas. I am indeed very grateful to the many experts from all over the world who have come to this conference to share their knowledge and experience with EFSA. I would particularly like to welcome Undersecretary Patta for agreeing to open this important Conference.

EFSA is of course occupied with many matters in the field of nutrition through the work of its scientific expert Panel on Dietetic Products, Nutrition and Allergies. Nevertheless I am committed to increasing the activities of EFSA in this field - not only through the activities linked to the implementation of the newly adopted Regulation on claims. The Management Board of EFSA has identified the development of EFSA's role in nutrition as a key priority and I am personally eager to address this work in my role as EFSA's Executive Director.

Europe faces a major public health challenge linked to diet, nutrition and lifestyle. Rates of obesity and overweight in adult have increased across Europe in the last 20 years. Of great concern, is that the rate of childhood obesity has increased sharply : 1 in 5 is overweight which means 14 million children, 3 million of which are obese. Scientific evidence clearly supports the links between the increasing problems of chronic diseases and conditions such as obesity, heart disease, type 2 diabetes, hypertension, cancer and osteoporosis. EFSA has to take its place as the authoritative European voice on food safety and nutrition in providing the scientific basis for activities at the EU level to combat this problem. To achieve this purpose, we will need close cooperation with Member States and an open dialogue with our stakeholders, Consumers, Retailers and Industry. EFSA cannot act in this respect on its own – there are many key players in this complex picture. Public authorities at national and EU level, have an important role to play as do industry, consumers, retailers, the scientific community, if we are to successfully address this difficult and important public health challenge.

European and national policy makers need to have access to the best scientific opinion, data and other information so that they are able to develop the best strategies to combat this growing problem. EFSA is uniquely placed at the European level to provide the scientific knowledge and information to guide decision makers in the development of appropriate risk management policies and specific actions to target the health problems associated with nutrition, diet and life styles. In this respect, through working closely with national authorities EFSA will be able to provide a broad overview of the scientific elements that affect the European picture.

EFSA is already active in providing scientific information to aid policy makers in this debate. For example through the work of the EFSA expert Panel on Dietetic Products,

Nutrition and Allergies we are currently working on setting Population Reference Intake levels for nutrients and certain other essential dietary components which will eventually lead to the establishment for adults and children of energy requirements needed to ensure healthy body weights and prevent obesity. EFSA will also be looking at determining recommended intakes of carbohydrates, fibre and fats – setting recommended levels for maintaining healthy body weights and reducing risks of obesity, diabetes, cardiovascular disease and certain types of cancer. We will also planning further work in looking at recommended intakes of vitamins and minerals, and if appropriate, other essential substances with a physiological effect.

EFSA is therefore capable and able to rise to the new challenges before us and in this respect I have identified three key areas:

Firstly, EFSA will increase its assistance to policy makers at EU and national level in developing strategies and setting diet-related public health targets. This will in particular be achieved by providing policy makers with the latest and most authoritative scientific advice, underpinning and supporting European Community activities. To this end, EFSA will continue to participate actively to the European Platform on Diet, Physical Activity and Health, in order to provide scientific input and guidance on diet and nutritional matters.

Secondly EFSA is in a unique position to collect and analyse dietary intake data from all EU countries and thus provide an EU picture. In January 2007, EFSA will organize with Member States the first meeting of the national food consumption database managers. This EU-wide network will enable us to set up in 2007 a European database, including dietary intake data for adults and children for 16 categories of food. This first work will be of great value both for all those who are dealing with nutrition in Europe and for exposure assessment.

And thirdly, EFSA will develop its scientific work related to the development of accurate and meaningful information on the relationship between diet and health in order to help consumers to make healthy dietary choices.

To this end today's conference is an important milestone in further developing EFSA's thinking on nutrition and health claims. I welcome the opportunity of this conference to have an in depth dialogue between experts from scientific institutes, international organizations, governmental bodies, industry, consumers and other stakeholders to look at the issue of claims and in particular to look at the development of scientific advice on nutrient profiles and the scientific substantiation of claims. EFSA and its Panels on Dietetic Products, Nutrition and Allergies are already planning and developing this work and speakers following me will address this in detail.

This conference has attracted enormous attention from experts eager to participate from all over the world. I have therefore decided to web stream the final morning of the conference so that a broader public may watch, live via the internet, the final conclusions and outcomes of the conference. There will also be further opportunities to debate these issues with our stakeholders and interested parties in the context of other conferences and meetings and through our Stakeholder Consultative Platform.

I would like to take this opportunity therefore to welcome you once again to Bologna. I look forward not only to the presentations and debates over the next three days but also with great anticipation to the conclusions and outcomes of the workshops that are planned for tomorrow. I am please that so may eminent and expert participants have agreed to participate and I wish you every success.