

COMMUNICATIONS DIRECTORATE

**Summary of the main points discussed during the
EFSA Science Forum “From Safe Food to Healthy Diets”
EU risk assessment – past, present and future
Brussels, 20-21 November 2007**

Note: Please note that this document provides an overview of the main points discussed during the Scientific Forum. Its use is purely informative and does not reflect the view of EFSA.

The scientific forum was organised on the occasion of EFSA’s five year anniversary and gave participants the opportunity to review the first five years of EFSA’s activities and to discuss future challenges.

In her welcome speech, the Executive Director, Catherine Geslain-Lanéelle reminded participants that consumer confidence in the European food safety system was low at the time when EFSA was set up in 2002. There were several food-related problems during the late 1990s, such as the BSE crisis. EFSA was established to create an independent authority providing science-based advice on food safety issues to the European Commission, European Parliament and the EU Member States to support their decision-making and risk management policies.

EFSA’s scientific excellence

In his opening address, Vittorio Silano, chairman of EFSA’s Scientific Committee, pointed out that the tasks of the Authority are performed by more than 400 scientists. In addition to their regular jobs at universities, institutes and authorities all over Europe, they participate in EFSA committees, panels and working groups. The highest standards of scientific excellence, together with the most recent data and methodologies, are the absolute reference points for their work. The selection of scientists and the process of risk assessment both take place in a transparent and independent manner. EFSA’s scientific opinions, reports and documents are readily available on its website. EFSA also carries out public consultations on key draft guidance documents, opinions and reports. EFSA’s scientists also produce declarations of interest which are available via the EFSA website.

COMMUNICATIONS DIRECTORATE

An impressive workload delivered

EFSA scientists have delivered more than 500 risk assessment opinions, guidance documents and reports on issues such as food additives, pesticides, genetically modified organisms and biological hazards. EFSA's current work addresses so-called "old" but still present risks, such as BSE and dioxins, as well as new and emerging risks, which include lifestyle-related risks, such as obesity. Another important challenge is the proactive assessment of the impact that new technologies may have on the food chain, such as animal cloning, nanoparticles in foods, or active and intelligent packaging.

Making the difference

With its achievements and efforts aimed at scientific excellence, EFSA already "makes a difference", stated Dagmar Roth-Behrendt, MEP. Nevertheless, she called on EFSA officials and scientists to remain ambitious with regard to further developments. Roth-Behrendt also stated that, in the years to come, EFSA must become the definitive food safety authority in the eyes of member states and the international arena and that, consequently, EFSA cannot afford to demand less than the "crème de la crème" of scientists.

Representing the Portuguese Presidency, Xavier Malcata, chairman of the College of Biotechnology at the Portuguese Catholic University, saw networking and the setting of priorities as the key to maintaining scientific excellence. The sharing of knowledge and resources across Europe, as well as the effective use of Europe's rich wealth of science, are crucial.

Speaking the consumer's language

EFSA's tasks include more than risk assessment and support for EU risk management policies. According to Robert Madelin, Director General for Health and Consumer Protection of the European Commission, clear and understandable communication of food safety information is also essential for gaining confidence amongst European citizens. To bridge the gap between scientific knowledge and citizens' fears and expectations, more interaction between scientists and lay people is needed. However, Catherine Geslain-Lanéelle emphasised that one single message was not enough to reach all of the EU's nearly 500 million citizens. Messages need to be "culturally appropriate"

COMMUNICATIONS DIRECTORATE

and meaningful and must adequately address public concerns.” One of the challenges for the risk assessor is to make advice more meaningful for risk managers. Robert Madelin concluded that the maintenance of close contacts between the EU institutions and individuals will be essential to EFSA's success.

Today's major challenges in food safety

Microbiological risks, chemical contamination of food and public health issues arising from an unbalanced diet were identified as some of Europe's major challenges with respect to safe food and healthy diet.

The burden of food-borne infections on public health remains substantial. Growing international trade has led to an increased risk of the transfer of microbes from one country to another. Such challenges require a transnational approach and new and emerging risks are regularly being identified, as a result of the continuing evolution of diseases and changing patterns of production and international trade. Like “wolves in sheep's clothing”, microbes tend to find new ways into new food hosts.

Robust, stable and flexible public health platforms for surveillance and investigation are important for sustained progress in diminishing the risk of human infection.

Critical attention must also be paid to the environmental impact of rearing animals and growing plants

Such issues are addressed by EFSA's Panel on Biological Hazards. This panel provides independent scientific advice on the biological hazards related to food safety and to food-borne diseases, including food-borne zoonoses and transmissible spongiform encephalopathies (BSE/TSEs). Other issues include food microbiology and waste management issues associated with food hygiene.

Consumer perception of food safety often focuses on substances added to food. Although additives, such as sweeteners, colours and flavourings perform a desired technological function, they may have a negative effect. Therefore, their use must be subject to rigorous safety assessment based on the most recent available methods and data.

COMMUNICATIONS DIRECTORATE

EFSA's activities include the evaluation of many new substances and the review of specific food additives in the light of significant new scientific evidence. Additionally, developments in the field of legislation applicable to food and feed have led to a substantial increase in EFSA's workload.

The last century has seen enormous improvements in human health, to which the amount, quality and availability of food have made a major contribution. Notwithstanding, diet and life style are both important factors to consider in addressing today's major public health concerns, such as the rise in obesity. New public health policies are being developed in Europe and EFSA is uniquely positioned to support decision-makers with the latest and most authoritative scientific advice. EFSA Opinions address issues such as the tolerable upper intake level for vitamins and minerals, Population Reference Intakes (PRIs) and the health effects of transfatty acids.

The availability of choice in regard to healthy food is indispensable. Consumer choice must be supported by accurate and meaningful information on the relationship between diet and health. EFSA is currently deeply involved in providing scientific support for the Regulation on Health Claims. Key areas of involvement include providing advice on nutrient profiles for products bearing claims and the development of a guidance document for applications containing health claims, as well as assessments of their scientific basis.

Understanding attitudes towards food, nutrition and food safety

Scientific risk assessment is an essential step for consumer protection, but it must be combined with efficient communication in order to achieve consumer confidence in food. Creation of trust depends on in-depth understanding of consumer perception of food in general and of food-related risks in particular. Prof Claude Fischler, Centre National de la Recherche Scientifique – CNRS, Ecoles des Hautes Etudes en Sciences Sociales - EHESS, France, explained that, despite apparent similarities and universal features in consumer perception of risk, differences exist and remain surprisingly consistent over time. In some Member States, for example, consumers are more concerned about chemical risks, whilst in others they are more afraid of biological risks.

Striking differences also exist in Europe with regard to eating cultures. Whereas consumers in Northern European countries regard eating as an individual affair,

COMMUNICATIONS DIRECTORATE

continental and southern countries attach greater value to the social dimension of food and of sharing a meal.

Due to our consumption and “incorporation” (i.e., “taking-into-the-body”) of food, we have a special, very sensitive relation to food and to perceived food risk. The old saying of “you are what you eat” reflects this “magical” view. Research has also shown that there is a clear tendency to perceive “naturalness” as superior and to consider that “denaturalisation” of food is more likely to result from the addition rather than from the extraction of components, with processing more important than content itself. Humans also tend to perceive plant products as safer than animal-derived foods, although food safety science does not necessarily confirm this view.

Claude Fischler also stressed the important differences in risk perception and ranking of risks by experts and the lay public. Risk is a probabilistic notion and whilst experts can assess and understand probability and the likelihood of risk, the most common way of thinking about risk is simply a “yes or no” view. For most, statistics and experience are hard to reconcile. An important point to keep in mind in communicating about risks to audiences who most likely have a much more personal and immediate view, notably with respect to risks associated with food.

Combating biological risks

The spread of pathogenic food-borne micro-organisms, such as salmonella, within the food chain poses a major challenge to food safety. Researchers have undertaken several EU-wide studies to determine the prevalence of salmonella in laying hens and in broilers, turkeys and pigs. The results support the assumption that poultry products, and table eggs in particular, are regular sources of human salmonellosis in the EU. However, they also illustrate that the prevalence of salmonella in laying and broiler flocks, and the associated human infections, can be reduced significantly. Effective surveillance and control efforts, as implemented in several EU member states, are the key to success.

At present, the priorities of food safety management are being shifted increasingly from measures of official compliance testing towards more goal-oriented systems. With regard to food-borne pathogens, researchers are developing models to predict the fate of pathogens along the food chain and estimate the associated health risks, in addition to testing for current contamination levels in given food samples. Quantitative

COMMUNICATIONS DIRECTORATE

microbiological risk assessment (QMRA) is a valuable tool for these modelling efforts. There is a growing demand for QMRA studies to support decision-making at the European level and EFSA is in a unique position to address this need.

The emergence of the bovine spongiform encephalopathy epidemic (BSE or “mad cow” disease) in the late 1990s was a serious challenge for the European food safety system. BSE belongs to the transmissible spongiform encephalopathies, which came into the spotlight of public interest when the BSE agent was found in 1996 to have the potential of being transmitted to humans to create a new type of the deadly Creutzfeldt-Jakob disease. Science-based control measures enacted in the EU and elsewhere succeeded in restricting the BSE epidemic to a continuous decline in recent years in most countries.

Keeping an eye on chemical risks

Consumers are exposed to a diversity of chemicals from all areas of life. Important groups of compounds are pesticides – according to a Eurobarometer survey, their residues in food are perceived by consumers as the top food safety risk – and dioxins, a group of contaminants resulting from environmental pollution.

About 200 dioxins, dioxin-like compounds and contaminants in food are known to exist. Of great concern to consumers, there have been several incidents of contamination from dioxins or dioxin-like compounds in food and feed in the past. More than 90% of dioxin in human bodies is derived from the food chain. Several measures have been implemented, including the setting of maximum limits, the development of early warning tools, and the improvement of the analytical capacity of the EU. Monitoring programmes have indicated that these measures have been effective and that human exposure to dioxin-like compounds has decreased considerably in the past two decades. Nevertheless, the recent dioxin contamination of guar gum powder, used as a food additive, demonstrates that such vigilance will remain necessary in the future.

For pesticide residues, models exist for both acute and chronic exposure. Such models are based both on consumption data and on residue levels measured in food. These models, together with any new developments to improve them, were critically discussed during the forum with regard to the fact that average consumption patterns do not exist in the real world. Nevertheless, further developments in methodology and analysis will lead to further improvements in food safety.

COMMUNICATIONS DIRECTORATE

Cumulative risk assessments of chemicals sharing the same mode of action currently are being developed. A set of criteria to identify common mechanisms for a group of compounds that show a dose-response relationship has been proposed. Experience in this field already exists for triazines and chloroacetanilides, as well as for carbamate and organophosphorus compounds.

Update on Food Additives and Flavourings

Key activities of the EFSA Panel on Food Additives and Flavourings (AFC) were highlighted. EFSA has received a request from the Commission to re-evaluate all presently authorised food additives. The AFC Panel has begun with the re-evaluation of food colours. The first evaluation, for the colour Red 2G which was used in breakfast sausages and burger meat, resulted in a negative assessment. As an example of the close interaction between risk assessment and risk management, the colour was immediately banned. EFSA's approach to the evaluation of smoke flavours is another example of how EFSA provides the scientific foundations for the official authorisation process.

Following the publication of a new study on the potential influence of certain food colours on hyperactivity in children, the Panel is faced with another challenge in assessment. The Panel will also seek additional expertise on behavioural issues when reviewing this study.

In case of large and sometimes diverging datasets, the “weight of evidence” approach is very useful. It examines the consistency of data, the robustness of dose response and the biological plausibility of effects. This approach was for example applied to the evaluation of the food contact material bisphenol A (BPA) when proposing a level for the current tolerable daily intake.

GMO risk assessment around the world

All over the world, authorities responsible for the assessment and surveillance of food derived from genetically modified organisms (GMO) have chosen different approaches to this task, but almost all are based on a common set of guidelines. This was developed by the “Task Force on Foods derived from Biotechnology” of the Codex Alimentarius Commission, an international body jointly established by the Food and Agriculture

COMMUNICATIONS DIRECTORATE

Organisation and the World Health Organisation of the United Nations. Ongoing activities of the Codex working group ensure that the guidelines reflect the most recent scientific knowledge. According to Codex guidelines, the underlying principle for risk assessment of GMO-derived foods is to compare the GMO food with its conventional counterpart. For this purpose, the risk assessors consider any intended and unintended effects of the genetic modification and evaluate its toxicity, allergenicity and potential impacts on nutrient levels.

However, some regulators such as Health Canada, require risk assessments for any kind of product from plants, microorganisms or animals of which the heritable characteristics intentionally have been modified, regardless of the methods used. Thus, any new plant variety and not only GMO, and the foods produced therefrom, may be subject to a risk assessment.

EFSA has established rigorous rules for risk assessments of GMO and GMO-derived foods. These rules are updated continuously in the light of the most recent scientific developments. EFSA scientists currently are evaluating methods of environmental risk assessment, which includes the evaluation of the impacts of GM plants on beneficial insects.

The Australian Office of the Gene Technology Regulator has long experience with environmental risk assessment and the monitoring of environmental impacts after market release, especially with insect-resistant GM cotton. However, this experience cannot be directly applied to European agriculture because of differences in landscape and climate. Australian authorities have recognised even some positive effects of GM cotton on non-target insects, due to reduced pesticide use on GM cotton. EFSA will use post-market environmental monitoring to detect any unintended effects of GM plants. However, even the most thorough collection and evaluation of data cannot eliminate a residual uncertainty. Dealing with this residual uncertainty is a major task for the further development of risk assessment in all areas.

At the centre of animal welfare research

Animal welfare and animal health are sensitive issues involving high ethical considerations. Risk assessment methodology helps in the formation of expert opinions based on compilations of objective scientific data. Animal welfare and animal health

COMMUNICATIONS DIRECTORATE

science are made up of four main work areas – the animal itself, animal husbandry, and societal and political aspects.

To judge from the number of publications in scientific journals, Europe is at the centre of animal welfare research worldwide. Research trends reflect the need for essential understanding of animals, in order to obtain a better understanding of animal-environment interactions and, as an indicator of how animals “feel”, of the ways in which animals respond to stress.

A major field of action will be the development of a specific, standardised methodology for animal welfare. With a view to characterising risks and laying down lines for scientific research, the need also exists for the development of robust and adequate indicators, which may be direct or indirect, of animal welfare.

The research and development of risk assessment techniques for animal welfare will form part of the basis used in advising key decision-makers and other stakeholders. Future challenges in research on animal welfare and well-being will be addressed by a stronger interdisciplinary approach, the redefinition of the concept of animal welfare and the combination of the views of natural and social scientists.

With regard to the economics of animal welfare, a clearly growing willingness exists in Europe to pay the costs of welfare improvements. Combined with continued support from consumers and politicians, such willingness has facilitated the most favourable position for the further expansion of animal welfare research in over five years.

Handling new technologies – nanotechnology in food and feed

As a twenty-first century technology, nanotechnology has enormous impact in a broad variety of areas. Nanotechnology in the food chain can be used for instance during the cultivation, production, processing or packaging of food. The impact of nanotechnology on food and feed safety and on production processes is of special interest for risk assessors worldwide.

Consumers might welcome new technologies and their benefits from nanotechnology but they also have concerns about risks for health and the environment that must be accepted

COMMUNICATIONS DIRECTORATE

and understood. "Nano is new – new is small – small is new – new is unpredictable". This is the causal chain perceived by many individuals.

NGO representatives were of the opinion that consumers should receive information in order to make an informed choice. Communication plays an important role in the debate on new technologies. Proper communication requires facts and figures provided by science and industry. A lesson learnt in the debate on genetically modified organisms is that communication must be timely and tailored to particular target groups.

Consumer acceptance and trust will depend on the perceived benefit of innovation as well as on transparent information. Europe's existing food law framework will serve as the basis for regulation of nano-products.

A major obstacle in this and future debates is certainly the lack of clear definitions. Industry representatives have different views towards what could fall under the term `nanotechnology` or `nanomaterial`. It was stressed by risk managers that industry had to inform and communicate, if already authorised materials were used in a nanoparticulated form as the substance was not identical to the product that was approved already. In addition, EC representatives confirmed that new production methods and processes are covered by the EC Novel Food Regulation.

Animal cloning - a new challenge

While still a young technology, animal cloning by somatic cell nuclear transfer (SCNT) is being publicly discussed. The birth of cloned sheep, i.e. Dolly, in early 1997 was the beginning of public debate on SCNT.

Animal cloning is a method that can be used to study genetic reprogramming, for better understanding of epigenetic changes and functional genomics and possibly for improvements in animal models used in medicine or in human therapeutic cloning, for gene banking of endangered breeds and for reproductive purposes of agricultural livestock.

During the Forum, participants discussed potential uses of animal cloning, for example, animals with resistance to diseases (including bovine BSE – already addressed

COMMUNICATIONS DIRECTORATE

successfully in a research setting in the USA – as well as mastitis, brucellosis and tropical diseases), new products with increased value (low-lactose milk, kappa-casein-rich milk, better meat from myostatin cattle), environmentally friendly animals (with lower or no greenhouse gas emissions or with low phosphate emissions), the multiplication of high producing animals adapted to given environments, and animals with potential for medical uses (xenotransplantation, pharmaceutical protein production, medical model animals).

SCNT has already been successful in a number of domesticated species. Although the overall success rate of the cloning procedure (0.5% - 20% live births, depending on species and other factors) remains relatively low, SCNT technology is evolving rapidly and the proportion of apparently healthy progeny is growing.

The composition of meat and milk or the toxicity of food and feed from animal clones or their progeny do not indicate any significant difference of products derived from sexually reproduced animals.

Animal health and welfare aspects for the surrogate dams and the clones have been investigated. Possible adverse effects on health and welfare have been identified, such as those arising from the large-offspring syndrome. In order to overcome problems of public perception and economic realities, the value of appropriately addressing public concerns cannot be overestimated. In connection with live clones, their offspring and derived products obtained from such animals, EFSA will publish a scientific opinion on food safety, animal health, animal welfare and environmental implications.

Knowing more about what we eat

The availability of reliable data on food consumption and food composition is a key tool for risk assessors working on scientifically sound intake/exposure evaluations. This is relevant when considering risk and health benefit in the areas of food safety and nutrition.

Historically, there has been wide variability in the data sets collected in different European countries. This may lead to misinterpretation and less reliable results. EFSA now acts as an important centre and clearing-house for data on European food consumption. The close collaboration between EFSA, Member States and European

COMMUNICATIONS DIRECTORATE

networks and research projects will enable better harmonisation of data collection methodologies and of the available data sets thereby. Such improvements will make it possible to assess both intake of nutrients and exposure to contaminants and will contribute significantly to a sound risk-benefit assessment.

The content of nutrient profiles, i.e. the classification of food by key nutrient contents, has been used for many years by public health authorities to develop food-based dietary guidelines and related communication and labelling tools.

With a view to categorising foods as eligible or not to bear claims, the new EU Regulation on Nutrition and Health Claims proposes the establishment of a harmonised European system of nutrient profiles. EFSA will provide a sound scientific base and will support the European Commission and Member States in implementing the regulation.

Active and intelligent food packaging

In the past, the key safety objective for materials in contact with foods was to be as inert as possible, i.e. to have a minimum of interaction between food and packaging. However, the development of “active” packaging requires a new approach to risk assessment and safety evaluation. The aim of active packaging is the improvement of food conservation, for example by absorbing oxygen, CO₂ or liquids, or by releasing desirable substances, such as vitamins or preservatives. Intelligent packaging material gives information relevant to the history and quality of the product, such as its storage temperature or its colonisation by microorganisms.

Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food provides the framework for EFSA’s safety evaluation process to help risk managers define lists of authorised substances.

At the present time, the entry of such packaging to the market is limited due to cost and acceptance issues for stakeholders in the packaging chain. Consumer acceptance and, in particular, understanding of the information provided by these new technologies will be the key to market introduction.

COMMUNICATIONS DIRECTORATE

Analysing health risks versus health benefits

Foods may contain components that have both beneficial and detrimental effects on health. Even beneficial nutrients (usually micronutrients) can produce adverse effects if consumed in high doses or by vulnerable groups, which may be defined by such factors as age (e.g. children or elderly persons) or physiological status (e.g. pregnant women). Since the mandatory fortification of foods adopts a “one size fits all” approach, the identification of at-risk groups is crucial and dosage must reflect risk and health benefit analysis when such fortification is considered.

Increasing the consumption of fruit and vegetables provides a good example of such complexity. Fruits and vegetables are a key nutritional recommendation, but their nitrate content needs to be taken into consideration. Nitrate appears to have some beneficial effects, such as aiding gastrointestinal immunity, but it is also metabolised into potentially harmful reactive nitrogen species, including nitrite, nitric oxide and n-nitroso compounds. Nitrite can react with haemoglobin and reduce its capacity to transport oxygen, which is particularly dangerous for infants. Nitroso compounds are carcinogens, especially for gastric cancer. Also, fruit and vegetables are not the only source of nitrate/nitrite that is consumed as it is formed naturally in the body and is present in water and cured meats. However, potential risks need to be weighed against the health benefits of eating vegetables and EFSA will approach its risk evaluation in this way.

Risk and health/environmental-benefit assessments may be necessary to provide citizens with the most balanced and best possible advice. Assessors must also consider other issues, such as product formulation and the susceptibilities of consumers according to age or other characteristics. For example, there is a data gap for young children.

Communicating risks: learning for the future

In the late 1990s, crises in the food chain, such as BSE and dioxins, resulted in a lack of public confidence in the ability of public authorities to fully protect consumers against potentially unsafe food. The EU food safety system was strengthened with a “farm to fork” approach to ensure the highest level of consumer protection and a clear commitment of public authorities to provide the public with more insight and access to information on food safety issues, and, in particular, to inform citizens as early and

COMMUNICATIONS DIRECTORATE

accurately as possible in the case of emerging risks associated with foods found on the market.

Openness and transparency are key principles for both risk assessors and risk managers. With the separation of risk assessment from risk management and the setting up of EFSA, an independent, European voice on food safety issues was established. The creation of risk assessment bodies at national and European levels transformed the media landscape providing a source of scientific advice on food safety issues.

Media play an important role in informing the public about food, nutrition and food safety issues. In order to reach consumers with effective messages, scientists and science communicators will have to understand each other's views and requirements as well as the values underlying public reactions to food issues. BBC journalist Nicola Carlsaw reminded participants of media's needs for "news" and how this may polarise or emotionalise information presented.

Communicating factually is of high importance, particularly in situations of food scares, and close co-operation between scientists and communicators is required to achieve both accurate and meaningful communications.

What is the most appropriate way of communicating with the public? Cultural differences make it impossible for a single message to reach all European consumers effectively. Core messages must be adapted to the needs of different audiences. EFSA seeks to do so through close co-ordination of messages with national food safety authorities in Member States, risk managers and dialogue with its stakeholders. The goal of these networks is to ensure that not only consistent messages are communicated, but also that they can be adapted by others taking into account the national audience and needs of target audiences.

Members of the Panel provided advice for further development of EFSA's communications including: the need to make scientific language accessible; the importance of responsiveness in building up trust; co-operation with both natural and social scientists to inform risk communications activities and utilising the support of competent bodies at national and local levels to reach consumers with more specific, tailored messages.

COMMUNICATIONS DIRECTORATE

Conclusions from the Scientific Forum

The two-day Scientific Forum brought together scientists from academia and industry and administrators from more than 40 countries. More than 500 participants attended the plenary sessions, scientific workshops and round table discussions.

Speakers and participants agreed that EFSA has contributed to strengthening the food safety system in Europe through its independent scientific advice and co-operation with EU Member States; preparing for future and emerging risks and developing dialogue and partnerships with stakeholders, international partners and others.

Challenges of an increasing workload

EFSA's work is continually increasing. It is crucial that EFSA has the structures and resources in place to manage this ever-growing workload to monitor its activities regularly and adjust its priorities where necessary.

EFSA will make a continuous and increasing contribution towards protecting European consumers and will maintain its vigilance. The fostering of cooperation with Member States will also be crucial.

Attention will be focused on new challenges associated with innovation in the food and feed sector. Emerging risks will be monitored and possible impacts assessed in collaboration with Member States.