THE ROLE OF SCIENCE IN EU REGULATORY POLICIES

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This paper discusses the role of science in policy making in the European Union (EU). Lessons from past experiences are used to provide an outlook for the future.

Key words: food safety; risk assessment; European Union (EU).

 \mathbf{F} ood crises have had a major impact on agriculture in the European Union. The establishment of a European food policy that gives priority to consumer protection and consumer health is at the forefront of the role of science in policy making within Europe.

Evolution Of European Food Policy

In 1997, the European Union adopted a new food policy which was based on the premise that complete scientific evidence should be taken into account when deciding legislative or other food safety measures. If scientific evidence was incomplete or unconvincing, full reassessment would be necessary. In addition, at all stages of the food chain there was to be clear responsibility for the safety and wholesomeness of food. Counter-measures would be taken at all critical points throughout the food chain.

At that time, the Commission informed all interested parties how it would obtain and use scientific advice, and how its food policy would be implemented through ordinary and sanitary controls and inspection services. Risk analysis, risk assessment, and scientific advice would be separated from risk management, policy, and legislation. One of the first decisions in the reform of food safety policy managed by the Commission, therefore, was the separation of responsibilities for inspections and scientific advice from responsibility for policy and legislation. This separation is consistent with the widely accepted international approach of risk analysis (e.g., see United Nations Food and Agriculture Organization [FAO] / World Health Organization [WHO], 1997). Within this approach, the work of scientific risk assessment is separated from risk management, which must also take a variety of other factors into account when establishing policy. These factors belong to the, often very complex, social, economic, and political dimensions of society.

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Within this context, the Commission has relied on scientific advice from independent advisory committees for many years. Indeed, the Scientific Committee for Food, which is one of the most important committees in the area of food safety, was established in 1974. The scientific committee system, of which the Scientific Committee for Food is a part, was completely restructured in 1997. A steering committee was set up to deal with multi-disciplinary food safety issues, including anti-microbial problems.

Transparency and Independence of Food Oversight

From 1997 onwards, scientific excellence in risk assessment is achieved by ensuring that members of the committees were selected from among the most experienced and qualified scientists in the field. Other experts were selected from an open public call for "expressions of interest" and through independent evaluation of merit against published criteria. One thousand one hundred and twenty-six expressions of interest were submitted to the Commission in 1997. One hundred and thirty-one experts were appointed to serve across the eight committees for a three-year term. These experts were drawn from the 15 member states and other countries including Norway and Israel. The three-year mandate of the eight committees is almost completed and a selection process for new members will be launched very soon.

The committees are aided in their work by extensive use of external scientists from around the world including the United States. These experts are invited to share their thoughts and pose specific questions to any of the committees.

To clarify possible conflicts of interest, all committee members are required to make annual declarations of any financial or other interests that could prejudice their views. They also have to declare such interests at the beginning of all meetings in relation to specific questions on the agenda. The transparency of the process is essential for confidence. Since June 1997, the names and affiliations of the members, as well as the draft agendas of plenary committee meetings have been available on the homepage of the Commission. The committee's opinions are also made available on the homepage, within a few days of their meetings. These opinions include any minority opinions expressed by individual members. When scientific advice concerns commercial products a balance between transparency and scientific confidentiality is found. Since November 1997 these committees have issued over 300 opinions. Some opinions are short, routine papers. Others are complex reports.

Food Safety Issues Addressed in the EU

The Scientific Committee of Food in the EU has addressed health-related effects from food contaminants. Broader assessments of risks to consumer health from anti-microbial resistance have also been made. These include consideration of food additives; microbial contaminants; pesticide residues; animal feed additives; genetically modified plants; and the safety of certain irradiated food products. Food safety issues related to animal agriculture include: animal zoonotic; solutive diseases; bovine somatotropin; animal welfare concerns; the use of hormones in meat; dioxins and viruses in food and animal feed; contamination of carcasses; and the cooling of carcasses in transportation. In addition to dealing with on-going food risks, new risks, such as anti-microbial resistance have also been the focus of concern.

The new committee system has, without doubt, improved the quality of scientific assessment, as well as the consumer's perception of the major role played by scientists in public policy. Much remains to be done, however, particularly insofar as food safety is concerned. The new Food Safety Initiative is important in this context.

New EU Food Safety Initiatives

On January 12, 2000 the European Commission adopted a white paper on food safety (European Commission [EC], 1999). The central goal of this paper was to set out how the EU might achieve the highest possible level of health protection for European consumers. A radical plan was proposed calling for legislative reform so that the European Union's "farm to table" initiative could be completed. A proposal for the establishment of a new European Food Authority (EFA) was also submitted. The establishment of the EFA is founded on the principles of best science, independence from industry and political interests, openness to rigorous scrutiny, scientific authority, and a close alliance with national scientific policy. Specific initiatives include the development of a work program to bring coherence to the European Union's legislation. This plan would cover all aspects of food products from the farm to table, with 80 separate actions on board. This comprehensive piece of legislation aims to bring all parts of the food production chain under centralized control. Other initiatives promote dialogue with consumers in order to anchor the importance of the new food safety policy and explain developments in food safety.

The European Food Authority

The Commission is in the process of defining the operation, methods, and content of the EFA. This process will act as a basis for drafting proposed legislation on, and assessing , budgetary, human, and physical resources required to bring it into existence. The question of consumer confidence is key to this initiative, and the aim of the EFA is to be fully responsive to consumers and other stakeholders.

The Commission is convinced that risk assessment, which is essentially a science driven exercise, should be functionally separated from the process of risk management which involves political choices and must take into account the broader wishes and needs of society at large. Risk management will be based on the fundamental principles of transparency, accountability, and democracy of the European Union's decision-making process. Although the central task of the Authority will be risk assessment through scientific advice, it is envisaged that the EFA will have a number of other intimately related tasks.

EFA's domain will include primary food production, food processing, storage, distribution and retailing. The Authority will also cover animal health and other areas related to the environmental and chemical sectors when there is overlap with the risk assessment of food production. The mandate of the EFA overlaps with the work currently carried out by five scientific committees. These include Scientific Committees on Food, Animal Nutrition, Animal Health, Animal Welfare, Veterinary Measures Relating to Public Health, and Plants. The current system of organization of the EU scientific committees will be reviewed in light of decisions taken about the structure of the EFA.

EFA will also be involved in information gathering and analysis. There is a pressing need to identify and use information currently available on food safety issues, both at the EU level and worldwide. The EFA is expected to play a pro-active role in developing and operating food safety monitoring and surveillance programs. A network of contacts will be established with similar agencies, laboratories, and consumer groups across the European Union and other countries.

The EFA will also inform all interested parties of its findings not only in respect of scientific opinion but also the results of its monitoring and surveillance programs. The goal is that the EFA will become the automatic first place where scientific information on food safety and nutritional issues is sent, and where all potential problems are identified. A highly visible authority with a strong proactive presence on food safety matters is seen to be key in restoring and maintaining confidence among European consumers. National policies and programs should be significantly strengthened from being part of this process.

The European Food Authority will not work in isolation. It will draw upon the expertise and knowledge available in similar bodies at the member-state level and within countries. It is envisaged that EFA will work closely with these other scientific bodies, at the center of a network of available resources. Within this context, the EFA will have to manage potential conflicts between scientific and advisory systems when relevant. Conflicts, such as the one between France and the United Kingdom over France's refusal to lift the ban on the import of UK beef, should be avoided. This conflict resulted from divergent scientific advice given by the French Food Safety Agency and the EU's Scientific Steering Committee. In principle, such differences should not occur again, not because national governments will suddenly trust the advice of the Commission, but because the European Food Authority will be at the center of a network linking the scientific base across the European Union creating convergent views.

The EFA should be in place by 2002, once the necessary legislation has been enacted. Before finalizing its proposals for the EFA, the European Commission invited all interested parties to give their views on the EFA by the end of April 2000. The results of this consultation are currently being analyzed.

Concluding Comments

This paper has focused on how the European Union has formulated its recent policy on food safety. While this paper has touched upon just one policy, namely, food safety, one can draw the following conclusions on the relationship between science and government policy. First, good policy and good science must go hand and hand. Second, the three principles of excellence, transparency, and independence must be strictly applied to the way in which scientific advice is obtained. Third, risk analysis should not be viewed and exercised as a singular activity, but rather it should be broken down into its essentials: risk assessment, risk management, and risk communication. Responsibility for risk assessment as risk management must be placed at the appropriate bodies in a well functioning system. Fourth, the importance of risk communication should not be underestimated.

The present approach of the European Commission is in line with these four principles. However, the Commission has no room for complacency. One can always learn lessons from the past in order to improve future performance. The EU's policy on the "precautionary principle" is a good example of how policy can be continually improved. Although the precautionary principle has been accepted and used for quite some time, a much better EU definition has been needed. Hence, the EU has established guidelines for its application. Input is being sought at the EU and international level. The precautionary principle should be seen as part of a structural approach to the analysis of risk and is highly relevant to the management of risk. Where action is deemed necessary, measures should be proportional to the chosen level of protection, non-discriminatory and consistent with measures already taken. They should be based on an examination of the protection benefits and costs of action, or lack of action, and subject to review in the light of new data. The use of precautionary principle is therefore an important step forward.

In conclusion, the goal of the EU is to utilize a well-organized network of scientific expertise, and to better include citizens throughout the policy making process. A good consultative mechanism is an absolute necessity. Surprises may still occur despite all efforts to apply transparency, excellence, and independence. However, understanding who takes the risks and who reaps the benefits, and the ethical implications of new technologies, should go a long way to reducing many of the food safety issues that the EU currently faces.

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