COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION

CONSUMER HEALTH AND FOOD SAFETY

INDEX

Introduction

The aim of this Communication is to inform all interested parties, in particular the European Parliament and the Council, of the action that the Commission is taking to reinforce the manner in which it obtains and makes use of scientific advice, and in which it operates its food, veterinary and phytosanitary control and inspection services. The Commission undertakes to provide regular updates of its progress with the implementation of the approach laid down in this Communication.

In his speech before the European Parliament on 18 February 1997 President Santer made "a plea for the gradual establishment of a proper food policy which gives pride of place to consumer protection and consumer health". This communication goes hand in hand with the Green Book on food legislation in laying the foundations for such a proper food policy. It places food safety and consumer health at the core of a new political departure based on three general principles outlined in President Santer's speech:

- first, that responsibility for legislation should be separate from that for scientific consultation;
- second, that responsibility for legislation should be separate from that for inspection;
- third, that there should be greater transparency and more widely-available information throughout the decision-making process and inspection measures.

Henceforth all the relevant scientific committees and responsibility for inspection and control will be placed under the authority of the Commissioner for Consumer Policy and Health Protection. The relevant Directorate-General (DG XXIV) has been reorganised to have the particular responsibility for consumer health.

Part 1 of this communication provides a synopsis of the objectives and instruments of this new political departure. Part 2 outlines the proactive approach for scientific

advice on consumer health and the manner in which the Commission tackles its responsibilities. More time is needed for revising the mandates of the Scientific Committees. The compulsory or voluntary nature of consultations provided in existing legislation and the streamlining of the mandates without loosing sight of the often multidisciplinary nature of safety issues will need particular attention.

Part 3 explains the risk analysis approach which will be followed in the field of consumer health. Part 4 puts forward the control and inspection procedures which the Commission intends to follow. Even an improved use of existing resources will not allow a serious coverage of the wide range of about 80 legislative acts currently requiring the Commission to monitor or control the manner in which they are respected by Member States or third countries. Respecting the principle of subsidiarity, a new approach is outlined for implementation over the medium-term which identifies high risk subjects for priority inspection, raises performance and strives for control excellency. In implementing this new approach policy, the Commission will act in a spirit of openness and dialogue with citizens.

There is thus an urgent need for reinforced resources, in respect not only of the control services, but also for those involved in the preparation and the legislative follow-up of the scientific advice.

The present communication explains in detail the new approach of the Commission on "consumer health"[1] and food safety, in particular with respect to scientific advice and to control and inspection. President Santer explained in his speech before the European Parliament that the Commission has undertaken a radical reform of the departments dealing with consumer health. The Commission has in particular placed the management of all the relevant scientific committees under the responsibility of DG XXIV (the Directorate General for Consumer Policy and Consumer Health Protection), which will now also comprise the Food and Veterinary Office (FVO) and a new unit on the assessment of consumer health risks. The clear explanation of the

[1] See part 2, section 2.2 for a more detailed description of the scope of this term.

new approach unavoidably leads to a presentation in some detail of the various tasks of these and other Commission services. However, it must be stressed that the new policy in the area of consumer health and food safety involves many of the Commission's services, and that this new policy will be implemented by the Commission as a whole, acting collectively.

Part 1: Synopsis of objectives and instruments

The principal objective of the new political departure is reinforcement of the protection of consumer health. For this purpose, food safety is a necessary prerequisite. Moreover, in order to restore the confidence of the consumer and answer concerns over some models of production in which productivity is over emphasised, it is also important to protect animal and plant health and to respect animal welfare.

Recent experience has clearly demonstrated that food safety is not only of concern to the consumer, but is also at the very root of a proper functioning of the market. Food safety is therefore not only a prerequisite for protecting consumer health but will also serve the interests of producers and those involved in processing and marketing of foodstuffs and relevant agricultural products.

To achieve these objectives the Commission has reorganised and intends to reinforce three complementary instruments which will serve as a platform for an effective policy for the protection of consumers and their health: scientific advice, risk analysis, and control.

Scientific advice, on which the regulatory measures designed to protect consumer health are based, is mainly obtained from the work of the scientific committees. The re-grouping of these committees and the creation of a Scientific Steering Committee will pave the way to greater synergy and help co-ordinate their work.

The three principles which must be at the basis of the good performance of the scientific committees are, the excellence of their members, their independence and the transparency of their advice. These principles are fleshed out in the second part of this communication.

The formulation of the questions put to the scientific committees, as well as the use of these committees' advice by those responsible for preparing legislative proposals,

requires close collaboration between the Commission's services. This collaboration will have to be as flexible and as unbureaucratic as possible. Likewise the Commission will re-examine the distinction between mandatory and optional consultation of the scientific committees provided for in Community legislation in force.

Risk analysis is a three stage process, composed of the assessment, the management and the communication of the risk concerned. In the present context, risk assessment allows the identification and evaluation of hazards to consumer health, based on an estimation of the probability of their appearance in a specific situation. The essential task of risk management is to contain or reduce the level of risk identified through the assessment procedure in order to achieve an appropriate level of protection. Finally, through risk communication, information is exchanged between the parties concerned on the nature of the hazard and the measures to be taken to control it.

The new approach for **control and inspection** will be based on the following three main orientations: Firstly, in view of the wide range of areas covered by this legislation, and the limited resources available, risk assessment procedures will be introduced to allow control priorities to be established. Secondly, control activities will be reorganised to ensure that the whole of the food production chain is properly covered ("plough to plate" approach). Thirdly, the approach will be further developed through the general introduction of formal audit procedures, to allow an assessment of the control systems operated by the competent national authorities (as is already the case in the food control sector).

The principle of transparency will guide the activities of the control services in their dealings with national authorities, consumers and all other interested parties.

In using the three regrouped instruments, scientific advice, risk analysis and control, the Commission will pay particular attention to their effectiveness and practicability.

The Commission will ensure a rapid follow-up of emergencies related to consumer health. This will include action in respect of safeguard measures and the rapid alert system. Furthermore, information supplied by consumers and producers will be dealt with quickly.

Scientific advice, risk analysis and control need to be used as the basis for action in a large number of fields, notably:

- the manner in which Member States respond to recommendations made on the basis of inspection visits;
- defence of Community interests in the international context e.g. WTO, WHO, OIE and FAO;
- ensuring the respect of Community legislation;
- and most importantly, taking account of the matters covered by the three regrouped instruments in the preparation of Community legislation.

Recommendations for action will thus be based on the results of scientific advice, risk analysis or control missions. Moreover, there is a need to establish proper feedback mechanisms to ensure effective liaison between all interested parties, including monitoring the manner in which the recommended action is undertaken.

The European Union is the largest importer in the world of agricultural and food products and one of the largest exporters. In these circumstances, it is important to ensure that our internal legislation and procedures provide adequate reassurance for our trading partners and that our exports do not encounter unjustified restrictions in gaining access to the world market. The European Union can draw benefits from international agreements. Decisions on food safety are taken in the context of the rights and obligations that flow from them, in the WTO, in other international organisations and bilaterally (e.g. European Economic Area, Association Agreements and veterinary and phytosanitary equivalency agreements).

Part 2: Scientific Advice on Consumer Health: A proactive approach

2.1. Objectives and Principles

In matters relating to the health of the consumer, scientific advice is of the utmost importance at all stages of the drawing up of new legislation and for the execution and management of existing legislation. This is also the case in other areas such as animal health and animal welfare. The Commission will use this advice for the benefit of the consumer in order to ensure a high level of protection of health.

As concerns foodstuffs, the objective of the European legislative framework is to continuously improve the availability of safe and wholesome products, by ensuring that primary agricultural products, finished products and all intermediate production processes and products are analysed and evaluated for potential risks.

In reviewing its approach to scientific advice for consumer health protection the Commission will reinforce three main principles: **excellence, independence and transparency.**

Scientific advice must be of the highest possible quality. It is therefore essential that the evaluation of potential hazards is undertaken by eminent scientists (principle of excellence).

The Commission will ensure that scientists serving in the scientific bodies are free from interests which may be in conflict with the requirement to give independent advice as necessary to contribute to a high level of protection of consumer health (principle of independence).

In line with the overall policy of transparency operated by the Commission, it is necessary for interested parties, including consumers, both individuals and associations, as well as for the Institutions of the European Union and the National

Authorities to have easy access to information on the working procedures of the Committees and to their advice. In addition, the Commission will fully inform interested parties, including the consumer, about the different steps in the establishment of this advice. Communication is therefore essential in achieving these objectives (principle of transparency).

At the same time it must be recognised that scientific advice has its limits, and its use can therefore be regarded as a major factor, albeit not the only one, in the decision-making process.

2.2. Scope of responsibilities

Legislation has often, but not systematically, made scientific consultation compulsory on matters which may have an effect on public health. Several Scientific Committees were therefore established by the Commission and operated by the Directorates-General with the corresponding responsibility for drafting legislation and covered the areas of food, veterinary matters (animal health, public health and welfare), toxicology and ecotoxicology of chemicals, pesticides, animal nutrition and cosmetics and, most recently, matters linked with Bovine Spongiform Encephalopathy within the Multidisciplinary Scientific Committee. A summary of the existing mandates is given in Annex I.

Existing Scientific Committees cover matters on consumer health, animal health and welfare, plant health and environmental health resulting from certain uses of chemicals, from production and consumption of food and feedingstuffs, from the use of cosmetics or from use of chemicals in agricultural practice and food and feedingstuff production. For simplicity, these responsibilities, recently attributed to the Commissioner for Consumer Policy and Health Protection, will be referred to as "consumer health" throughout this Communication.

On several occasions in the past joint opinions have been issued by several Committees and this positive experience will be used to guide the Commission

services to set up a sufficiently flexible structure which must ensure a reliable, independent and rapid response to health concerns in order to benefit from the input of different scientific disciplines and to avoid duplication of effort and possible confusion where divergences of understanding occur between the Committees.

On the basis of the new policy orientations laid down in this Communication and the recommendations of the European Parliament, the Commission will revise and align all the mandates of the above mentioned Scientific Committees. The mandates of all Scientific Committees under DG XXIV will be the subject of a single Commission Decision to be adopted in July 1997. The mandate of the Scientific Steering Committee (previously called the Multidisciplinary Committee) will be adopted separately in May 1997.

2.3. Reorganisation of the work of the Scientific Committees.

The Commission will concentrate efforts to build a reliable and flexible structure which shall enable high quality and independent scientific advice, to ensure transparency and consideration of the scientific advice in the legislative activities of the Community Institutions.

The requests for independent scientific advice originate, in many cases, from the obligations in Community legislation. There are however several legal acts on important matters relating to food and animal health and welfare where this advice has not been made compulsory. Therefore the Commission shall examine, in co-operation with the Scientific Steering Committee, those areas where a compulsory consultation of the Scientific Committees should be introduced.

Most of the questions for scientific advice fall clearly within the current mandate of one of the Scientific Committees. However, a particular question may fall within the competence of several Committees, so that its allocation within a single Scientific Committee is not always obvious. Moreover, certain consultations have to involve the competence of several Scientific Committees.

A Scientific Steering Committee has therefore been created, which at present is composed of the Members of the multi-disciplinary committee and the chairpersons of the six other Scientific Committees. Its mandate shall include, the co-ordination of the different Committees and decisions on the involvement of several Committees in questions which need multiple expertise located within these Scientific Committees. The new Scientific Steering Committee will have eight members, in addition to the chairpersons referred to above. These eight members will advise the Commission in the selection procedure for members of the other Committees, in particular in respect of their excellence and independence.

All existing Scientific Committees dealing with consumer health need to be maintained although some of them need to be reinforced. In order to respond immediately to specific questions arising from overlapping mandates of the Scientific Committee for Food and the Scientific Veterinary Committee, a joint sub-committee will be set up on food safety questions.

When legislative acts are based on the evaluation carried out by scientists from organisations in the Member States, a consultation of the corresponding Commission Scientific Committees may in some cases be appropriate. The evaluation work carried out by these organisations in the Member States may serve as a base for peer review by the competent Scientific Committee.

Most of the procedures for risk assessment of chemical hazards established by the Scientific Committees are in full accordance with evaluation procedures established and used by both national or international bodies such as the World Health Organisation. However, development of new risk assessment procedures relating to areas such as transmissibility of animal disease to man and food-borne diseases is becoming a major task.

The Commission feels the need to have available at Community level highly specialised expertise on biotechnology. Following the suggestion of the Scientific

Steering Committee, a step by step approach will be followed. The possibility of establishing a specific working group under the Scientific Steering Committee will be examined. The Commission will come back to this issue in the context of the revision of Directive 90/220/EEC on the deliberate release of genetically modified organisms.

The new mandates will continue to ensure that the Scientific Committees may invite external experts to give advice on specialist questions. The Commission will introduce the necessary flexibility and budgetary provisions for the organisation of meetings to deal with urgent matters concerning consumer health.

2.4. The interim period.

To avoid disruption to their work, and until the new mandates of all Scientific Committees are adopted by the Commission in July 1997 all Committees in their present composition shall continue their duties based on the existing mandates (cf. Annex I). They shall continue scheduled meetings including those of their working groups in order to respond to all existing and new requests for opinions.

2.5 International relationships

The Commission, in collaboration with Member States, must maintain an active participation in international fora where recommendations, standards or guidelines concerning consumer health are elaborated, particularly with a view to ensuring that such recommendations, standards or guidelines have a sound scientific basis. The advice of the Scientific Committees in these matters has a valuable contribution to make in guiding the Commission services in this work.

As concerns international trade, the Agreement on the application of sanitary and phytosanitary measures (SPS) of the World Trade Organisation does not require its Members to change the level of protection they judge to be appropriate. The SPS Agreement provides, however, that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.

But the Member is free to decide, on the basis of a risk assessment, whether the relevant international standard, guideline or recommendation is sufficient to achieve the appropriate level of sanitary or phytosanitary protection. The activities of the Scientific Committees may therefore include an evaluation of the scientific principles upon which the Community health standards have been based. This evaluation must take into account risk assessment techniques developed by the relevant international organisations. Similarly, responsibilities flowing from other international agreements, notably the veterinary and phytosanitary equivalency agreements, may have a bearing on the manner in which such evaluations are undertaken.

2.6. Changes in legislation.

In order to implement the Commission policy concerning scientific advice on matters relating to consumer health, the Commission will propose or adopt the necessary acts to introduce, where necessary, compulsory consultation of a Scientific Committee.

In any event the Commission has the firm intention to consult the appropriate Scientific Committees on matters of particular concern related to consumer health even if Community legislation does not yet foresee compulsory consultation. In certain circumstances, however, including emergency situations or areas where the scientific situation is already clearly established, such consultation may be delayed or regarded as unnecessary.

2.7. Functioning of the Committees.

Scientific qualification and competence are the most important selection criteria for the Members of the Scientific Committees. The Commission will ensure that the selection process is transparent vis-à-vis the European Parliament, the Member States, consumer associations and other interested parties. The process may include an element of "call for expression of interest".

When appointing committee members particular attention shall be paid to their independence. The Commission will extend the existing requirements and procedures for declaration of interests of the members of all Scientific Committees.

It may not always be possible to achieve consensus amongst the Members of Scientific Committees. The reports of the scientific evaluations and records of the meetings shall accurately mention the different views expressed during evaluation. The minutes of the meeting of the Scientific Committees, including minority views, shall be made publicly available. Minority views shall be attributed to Committee Members only at their request.

Subject to the agreement of the budgetary authority, the Commission intends to attribute an indemnity to Committee Members, in addition to the usual daily allowances and travel expenses. An evaluation of the financial implications is included in the Proposal for the Supplementary and Amending budget.

Rapporteurs can be appointed by the Scientific Committees. Particular attention has to be paid to ensure that the rapporteurs are acting independently from all socio-economic pressure or personal interests. Since the rapporteurs have a particular task in gathering information, the setting up of data bases and drafting of the reports and advice, they shall receive an additional indemnity.

The role of the secretariat of the Committees will continue to be assured by the services of the Commission, according to the rules in force.

2.8. Co-ordination with legislative, official control and other functions.

Scientific advice is an essential pre-requisite for legislative proposals or measures with a potential impact on food safety and consumer protection. It is an essential safeguard and a top priority to ensure that decisions are taken with full regard to the best available scientific evidence. The Commission re-inforces this priority in its new approach towards food safety.

At the same time and without prejudice to the important role to be given to scientific advice, it has to be acknowledged that there are some inescapable limitations on its role. In some cases, there may be demands - for instance, due to ethical or environmental considerations or specific control and production methods - to go further in the area of the health protection measures than the scientific evidence suggests is necessary. Conversely, in other cases, there may be reasons to balance the scientific or identifiable risks with society's tolerance of the risks concerned - unhealthy diets and lifestyles being such examples. In still other cases, the scientific advice may not be sufficiently conclusive or complete to allow firm conclusions to be drawn. Finally, scientific advice is not infallible and is subject to change in the light of new developments and knowledge and must therefore be kept under review.

One of the primary tasks of DG XXIV will be to ensure an appropriate follow up of the advice delivered by the Scientific Committees. It will transmit the scientific advice to the Directorates General in charge of legislation. Where appropriate, it will make recommendations.

The necessary co-operation between the services must work in both directions, with other services and in particular those services responsible for preparing legislation being able to obtain scientific advice on request.

The Commissioner responsible for Consumer Policy and Health Protection shall be associated with all legal texts and proposals on matters concerning consumer health on which scientific advice is delivered.

The Commission, in discharging its political responsibilities, will make use of, where appropriate, scientific advice and the results of the risk analysis.

On the basis of the risk assessment from the Scientific Committees, the Commission shall undertake interactive exchange of information and opinions with interested parties.

In the context of its official control responsibilities, the Commission may request advice from a Scientific Committee as a follow-up to an inspection in a Member State or a third country.

Moreover, upon its own initiative, any Scientific Committee and the Scientific Steering Committee may draw the attention of the Commission to potential or emerging hazards in relation to consumer health.

The Risk Analysis Unit in DG XXIV shall fulfil a forward looking role for identifying potential or emerging hazards relating to consumer health.

DG XII, as the service responsible for science, research and development policy, will be associated in the activities of the scientific committees in particular, relating to the definition of their mandate, the selection of their members, the formulation of questions to be posed and the interpretation of the scientific advice. The Joint Research Centre, as the independent scientific body of the Commission, will provide support to the Scientific Committees, in particular with supplementary data and laboratory assistance to verify and complete information presented to the Scientific Committees by external parties. Any relevant results obtained under the Community specific research programmes will be made available to the Scientific Committees.

The Commission will also rely on scientific data generated by Member States under the arrangements for scientific co-operation established by Directive 93/5/EEC.

2.9. Public Credibility.

Consumer confidence in the legislative activities of the European Union with regard to food and animal health and welfare is conditioned by the quality and transparency of the scientific advice and its use in the legislative and control processes.

Widest possible access to the scientific advice will be guaranteed. The agenda, minutes and opinions of the Scientific Committees will be made available to Member States, particularly the health authorities, the European Parliament, citizens, consumers and consumer associations, producers and their associations and other socio-economic operators, bearing in mind the need to respect commercial confidentiality. Efforts shall be made to present information in a form which is readily understood by laymen. The opinions of the Scientific Committees shall be released shortly after adoption and made available on the Internet.

The Commission will organise regular presentations to interested parties such as the European Parliament, Member States and consumers. Special information sessions shall be held with journalists.