COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.04.1997
COM(97) 183 final

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.

Part 3: Risk analysis

Risk analysis is a systematic procedure comprising the scientific evaluation of hazards and the probability of their emergence in a given context (risk assessment), the assessment of all measures making it possible to achieve an appropriate level of protection (risk management), and the exchange of information with all the parties concerned: decision-makers, inspectors, consumers and producers in order to explain the reasons and to justify the management measures proposed (risk communication).

Risk analysis comes within the remit of the Commission. These activities will comprise tasks falling within the competence of the different Directorates General responsible for scientific advice, for the preparation of legislative proposals and for control. Close collaboration and coordination between these departments is necessary for the performance of risk analysis. In order to achieve a high level of protection the Commission will prepare legislative proposals or adopt measures. The depth of the risk analysis undertaken will reflect the nature of the hazard identified.

Risk assessment forms the foundation of scientific advice with regard to consumer health. Scientific risk assessment offers the Commission a sound basis for proposals and measures in the field of consumer health and food safety. The Commission will aim, where appropriate, to ensure that risk assessments are made in accordance with any internationally agreed procedures. This would give a basis for the defence of Community legislation based on such risk assessments in the event that it is challenged under World Trade Organisation (WTO) rules or in the European Court of Justice.

Concerning **risk management**, the Commission will take into account available risk assessments as well as the recommendations transmitted by the Directorate General responsible for scientific advice to the Directorate General responsible for preparation of legislation. Risk management shall include the process of assessing the impact of policy alternatives in the light of the results of risk assessment and the desired level of protection.

Risk communication must be as transparent as possible. To achieve this, the Commission will assure the widest possible access to scientific advice, and will also fully inform all interested parties, including consumers, of the different steps of its development. This will include information on the reasons and the scientific grounds for proposals as well as exchange of information with interested parties at all appropriate stages. Consumer concerns in relation to possible health risks will be taken into account during the process of risk analysis which will be implemented by the Commission.

The risk analysis thus defined in respect of the protection of consumer health must enable the Commission to play an interface role between the scientific community and the political world and other elements of civil society. Here it is useful to recall that - since, there is no such thing as "zero risk" - information on the level of risk is essential for the consumer. The Commission will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists.

The Commission will, on matters relating to consumer health, and in close collaboration with the Member States, undertake a surveillance role on emerging or new hazards connected with developments in agricultural and industrial production, including data collection on possible risks. These activities will aim to identify new hazards and to anticipate rather than react to situations in proposing strategies for action for scientific research or surveillance measures. These activities will require the establishment of a network of a wide variety of disciplines and close collaboration between the services of the Commission.

PART 4: CONTROL AND INSPECTION - A NEW APPROACH

4.1 Objectives

Mission statement

The Food and Veterinary Office (FVO) will have as its principal missions the monitoring of the observance of food hygiene[2], veterinary and plant health legislation within the European Union and elsewhere, and to contribute towards the maintenance of confidence in the safety of food offered to the European consumer.

Responsibility for the implementation of Community food veterinary and phytosanitary legislation rests with Member States. The Commission, acting through its control services[3] in DG XXIV, monitors the manner in which they undertake these responsibilities. In the veterinary and phytosanitary sector, this is carried out through a programme of inspection and control missions to monitor the performance of the competent authorities, including on-the-spot inspections of individual establishments in both Member States and third countries. These may include direct interventions, such as the collection of samples for phytosanitary checks, in Member States in certain circumstances. As indicated in this paper, it is proposed to develop this approach through the introduction, where possible, of formal audit procedures to allow the performance of the competent authorities to be assessed. In doing so, this will bring inspection techniques in the veterinary and phytosanitary sectors more into line with those already in use in the food control sector. Priority will be given to the need to ensure that high levels of consumer, animal and plant health and animal welfare protection are being achieved. However, it must be recognised that the

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2 as defined in Article 2, Council Directive 93/43/EEC of 14 June 1993: "food hygiene ..... shall mean all measures necessary to ensure the safety and wholesomeness of foodstuffs"

3 comprising the Food and Veterinary Office, and a food control section, transferred from DG III, where it monitored and evaluated the equivalence and effectiveness of official food control systems operated by the competent authorities of the Member States

achievement of these objectives will be dependent upon sufficient resources being made available to the Commission services to carry out the full range of their proposed duties.

4.2 Scope of responsibilities

The control services will undertake the food, veterinary and phytosanitary inspection and control responsibilities required of the Commission in the relevant Community legislation, particularly that listed in Annex II.

In addition, a possible future expansion of the activities of the control services into additional areas of concern to consumers, or where existing controls could usefully be rationalised, will be considered. This question will be discussed with interested parties, with a view to identifying any necessary action to achieve this goal.

The Commission will aim to ensure that the responsibility of the control services for the control of the manner in which Community food hygiene, veterinary and phytosanitary legislation is operated is formally recognised in respect of both existing and future legislation.

The control services will be fully consulted on the development of veterinary, phytosanitary and food legislation as, in many cases, their expertise will be needed to ensure that legislative proposals are properly informed by the situation in Member States and third countries. The findings of the control services will be widely disseminated to other concerned services within the Commission, so that they are kept fully informed of any developments.

An internal administrative operations manual will be developed to establish the detailed rules to be followed in dealings between the control services and other parts of the Commission (including UCLAF in relation to suspect frauds) and other EU institutions

Close contacts will also be developed with consumer groups and socio economic operators to ensure that they are kept fully informed of developments (see section 8).

4.3 Improved use of existing control and inspection resources

The issues raised by the Parliament's Committee of Inquiry will not simply be resolved by the transfer of existing control and inspection resources to DG XXIV. However, operational improvements in the veterinary and phytosanitary sectors have been initiated by:

- the establishment of inspection priorities, taking into account the need to meet legislative commitments, through an informal risk assessment procedure. This will include an assessment of risk both on a country or regional basis, e.g. geography, climate, health situation, competence of official services, previous trade problems etc, and for individual production sectors, e.g. husbandry practices, presence of zoonoses, types of treatment and use of hazard analysis critical control point (HACCP) techniques in processing establishments, previous inspection reports etc

- the development and introduction of an inspection approach which follows the whole of the food production chain, and all parts of the plant health sector, through the use of multi-disciplinary, expert, inspection teams, each with a nominated team leader, with responsibility for all aspects of food production and plant health in specified geographical areas.

These changes will allow the best use of existing veterinary and phytosanitary resources, whilst confirming that the control services are committed to developing an effective system of consumer protection. They will form the basis for the future activities of the control services. It must, however, be recognised that any routine inspection programme will be subject to the over-riding need to respond to emergencies.

The food control section will continue the development and operation of existing audit-based procedures for monitoring and evaluating official food control systems in Member States. As at present, these will include controls over the manner in which rules for the prevention of economic fraud, e.g. mislabelling and misrepresentation of food quality, are operated.

As indicated above, the need to respond to emergencies will continue to be given the highest priority by the control services. Sufficient resources will be made available for these activities, even where this has an impact on more routine work. Inspectors, specially trained in epidemiology and disease outbreak control techniques, will be used to form temporary units to investigate such emergencies.

Inspection programmes will be prepared in close co-operation with the relevant Commission legislative services, and will take full account of the principles outlined above. These services will also be able to propose areas for control or inspection activities to the control services. At the same time it is necessary to recognise that certain specific control and inspection responsibilities are laid down in Community legislation, and that these will have to be taken into account in developing the programmes.

The above actions will help to allow potential or actual health problems to be rapidly identified, and socio-economic operators and consumers given early warning of hazard identification. It will also ensure that the work of the control services is integrated into the overall goals of the Commission.

Standard procedures for the performance of inspections, and the subsequent presentation of findings through standardised report proformas, will be developed. Close working links will be maintained with the legislative services and formal administrative procedures established for these contacts. As part of the administrative operations manual described earlier, procedures for the submission of inspection reports and recommendations for action by the control services, and for responses by

the legislative services, will be established through agreement between the interested parties.

Following the transfer of the Office to Ireland, a liaison section will be established in Brussels, to ensure that effective contact can be maintained with the Office, and to provide an initial inquiry point.

4.4 Need for reinforcement of resources

The Inspectorate General Service (IGS) of the Commission has reported on the reinforcement of resources needed to allow the proposed expansion of the control services to take place. A detailed account, based on the IGS report, of the resource requirements for the full and effective implementation of this reorganisation is submitted to the budgetary authorities, in the form of a supplementary and amending budget

To respond to this need, it is proposed that the recruitment process be initiated as quickly as possible. Priority will be given in the first instance to filling the inspector posts, so that training of these staff can begin without delay. The recruitment process should be completed within a short time scale, to bring staff numbers to the level where the Office can begin to take up the full range of its duties.

Sufficient support in terms of human, financial, informatics and equipment resources will have to be provided to ensure the efficient operation of the control services.

4.5 Subsidiarity, improvements in performance, control excellence

The control services will develop and introduce as quickly as possible, transparent operational systems, including a Manual of Procedures, so that Member State national authorities, the European Parliament, citizens, consumers and consumer associations, producers and producer associations and other socio-economic operators can be kept informed of their activities. In addition, they will discharge their responsibilities in a manner that respects the different roles attributed to the Commission and national authorities in the implementation of the relevant Community legislation.

An integral part of this approach in the veterinary and phytosanitary sectors will be the development by the control services of formal risk assessment procedures and audit systems, in support of the production chain controls described earlier. A small expert group will be established as quickly as possible within the control services so that an in-depth study of the action necessary to introduce these two new elements can be initiated. In conjunction with the risk analysis unit in DG XXIV, it will identify the elements to be taken into account in the risk assessment procedure, develop a hazard weighting system, and identify priorities for targeting by the control services. In addition, it will develop suitable audit procedures, and inspection and report protocols, for use in Member States and third countries, supported by the development of a system for establishing agreed corrective procedures in respect of deficiencies identified. The Manual of Procedures will be developed to ensure that these actions are implemented in a harmonised and transparent manner.

The measured introduction of this new approach, based on:

- controls over the whole food, animal and plant production chains
- formal risk assessment procedures to identify control priorities
- audit systems to monitor competent authority performance

will ensure the most cost effective use of resources, whilst respecting the principles of transparency and subsidiarity. It will also allow the operation of equivalency agreements, where the control services will be responsible for monitoring compliance, in both Member States and third countries. These developments will also be reflected in the reinforcement and expansion of the food control section to allow it to carry out its auditing activities in respect of official food control systems in Member States in an effective manner.

The overall goal will be to provide a harmonised approach to control and inspection activities for all parts of the food production chain, through a managed programme based upon the careful targeting of inspection and control resources. Sufficient financial, expertise and personnel resources must be made available if this goal is to

be achieved. However, it must be emphasised that no control system can offer zero risk in terms of consumer health protection.

Close links will be maintained with the scientific committees to ensure that inspection and control activities are kept informed of the most recent developments in the relevant fields.

A wide-ranging training programme to equip staff with the skills necessary to face the challenges posed by the expansion of the inspection and control services will be given a high priority. With a view to promoting a common approach to controls in the food, veterinary and plant health sectors, the involvement of inspection staff from Member States, the European Economic Area and Associated Countries will be encouraged.

In order to enhance controls over food safety and quality standards, and over compliance with veterinary and phytosanitary legislative requirements, the control services will, as far as possible, act in partnership with the Community's own laboratories (Joint Research Centre) in the collection of samples, e.g. for biochemical checks of foodstuffs. This control function will be developed by the Joint Research Centre in conjunction with the Community network of national research centres.

A detailed examination of the benefits of applying an externally audited quality control system (e.g. EN 45004) to the management of the control services will be undertaken. Such a system would demonstrate the Commission's commitment to openness in the operation of these services, and ensure that their management was based upon the most up-to-date principles. This was proposed by the Parliament's Committee of Inquiry in respect of a future Agency, but it is considered appropriate to consider whether such a system could usefully be applied to the existing services.

An inspector will be posted to each of a small number of EU delegations in certain third countries, to ensure that the Office can fulfil its mission in the most cost-effective and efficient manner. It will also be necessary for a contact point to be

established for dealing with these offices and with third country authorities, outside organisations etc.

4.6 Towards a Quality Assurance function

As part of its commitment to consumer protection, an expansion of the role of the Commission's control services to include the monitoring of food quality assurance systems at both Community and national level will be considered. These are important areas for consumers, and a careful analysis, including consultation with all interested parties, of the consequences for the involvement of the control services will be undertaken. It will be important that any input into these fields supplements the core health protection functions of the control services.

4.7 Independence

This concern will continue to be taken fully into account during recruitment of inspection staff into the control services, and to receive due emphasis in their introductory training. In this context, the Staff Regulations of the European Commission, to which all inspectors are subject, clearly establish the principle of the independence of officials of the European Commission.

The ability of the control services to perform their duties and to present their findings free from external influence will continue to be given the highest priority.

The Commission recalls that it submitted a proposal to Council in May 1996 for the establishment of a Veterinary and Phytosanitary Inspection Agency. In the Commission's view, efforts to establish an independent Agency should continue. In the light of recent developments and reactions from the European Parliament and the Council, and on the basis of a proper, in-depth, analysis of the best way forward, the Commission will review the existing proposal. In performing this review, the Commission will ensure that the Parliament and Council are closely involved, and that the comments of the Parliament's Committee of Inquiry into BSE are taken into account.

4.8 Confidence built upon transparency

The problems experienced because of the BSE crisis have demonstrated the need to involve in a more open fashion consumers and producers in all aspects of food production. The Commission, by bringing together the existing inspection services under a single Directorate General, with specific responsibilities for consumer interests and health protection, and through the action outlined in this paper, is contributing to this objective. To reinforce this undertaking, a number of initiatives are proposed:

- clear procedures, which will ultimately be published, will be established for external contacts between the control services and all interested parties in the food, veterinary and plant health sectors.

- through the publication of regular reports, consumers, producers, other socio-economic operators, scientists and other outside organisations will have a right of access to the findings and activities of the control services, subject to the need to respect commercial confidentiality.

- members of the public will have direct access to the control services through widely publicised telephone, fax and e-mail contact numbers. An Internet site will provide up-to-date information on the activities of the control services. Audio-visual and printed information will also be made available.

  the control services will extend the existing emergency information system to give Member States (notably the health authorities), the European Parliament, citizens, consumers and consumer associations, producers and producer associations and other socio-economic operators the maximum possible information on the identification of hazards, disease outbreaks and related emergencies.

- links will be established with consumers and socio-economic operators so that mutual understanding can be developed, and in order to encourage a two-way flow of information on food hygiene and related matters. For example, consumers will be invited to give their views on food hygiene and quality matters, so that the control services can be properly informed of their concerns.

- an outline programme of missions to be undertaken by the control services will be presented to the regulatory committees on a regular basis and made freely available to other inquirers.

ANNEX I

PRESENT MANDATES OF THE EXISTING SCIENTIFIC COMMITTEES

MULTI-DISCIPLINARY SCIENTIFIC COMMITTEE (MDSC),

Established by Commission decision establishing the committee (SEC(96) 1137). The main objectives are:

- to ensure that scientific advice on BSE given to the Commission takes into account the widest possible range of expertise;
- to provide a mechanism to obtain scientific advice from a single highly qualified committee for an issue which affects areas of competence of several DGs

SCIENTIFIC COMMITTEE ON COSMETOLOGY

The Scientific Committee on Cosmetology was established by Commission Decision n° 78/45/EEC of 19.12.1977:

The drawing up and amendment of the community rules governing the composition, manufacturing characteristics, packaging and labelling of cosmetic products involve the examination of scientific and technical problems of considerable complexity.

The objective of the Committee is to assist the Commission on any problem of a scientific or technical nature in the field of cosmetic products.

SCIENTIFIC COMMITTEE ON PESTICIDES

The Committee was established by Commission Decision 78/436/EEC. The SCP may be consulted on scientific and technical questions relating to the marketing and use of plant protection products (pesticides use in agriculture). This includes:

- physical and chemical properties;
- fate and behaviour in the environment;
- ecotoxicology;
- mammalian toxicology including operator exposure and safety;
- residues in food and animal feed;
- efficacy

SCIENTIFIC VETERINARY COMMITTEE

The Committee was established by Commission Decision 81/651/EEC.

The Committee may be consulted by the Commission on all scientific and technical problems concerning :

- Animal Health
- Veterinary Public Health
- Animal Welfare

The Committee has 3 Sections corresponding to the fields indicated below. The Section concerned with Animal Health questions shall examine in particular problems concerning the cause, nature, pathogenesis, effects, diagnosis, epidemiology, prophylasis and therapy of animal disease, including zoonoses, and with the morphology, physiology and reproduction of healthy animals and with problems of animal health in general.

The Section concerned with Veterinary Public Health questions shall examine in particular veterinary measures for the protection of the health of humans and hygiene conditions for the production, processing, handling and marketing of foodstuffs of animal origin and for the inspection of foodstuffs relative to the fixing of minimum criteria of wholesomeness and hygiene during processing, storage, distribution and preparation.

The Section concerned with Animal Welfare questions shall examine in particular measures to ensure the protection of animals, especially those relating to animal rearing, management, transport, slaughter and experimentation.

The Committee may draw the attention of the Commission to any problems in the above areas.

SCIENTIFIC COMMITTEE FOR TOXICITY AND ECOTOXICITY OF CHEMICAL COMPOUNDS

Mandate of this committee is established by the Commission Decision 78/618/EEC as lastly modified by Commission Decision 88/241/EEC and states:
"To supply the Commission with opinions, at the latter's request, on all matters relating to the examination of the toxicity and ecotoxicity of those chemical compounds the use of which is liable to have detrimental effect on human health and on the various environmental media".

SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION

The mandate is established in Commission Decision 76/791/EEC and reads as follows

1. The Committee may be consulted by the Commission on scientific and technical questions relating to the nutrition and health of animals and to the quality and wholesomeness of products of animal origin. In particular, the committee may be consulted on questions concerning the composition of feedingstuffs, processes which are liable to modify feedingstuffs, additives, and substances and products which may be considered undesirable in feedingstuffs.
2. The Committee may draw the attention of the Commission to any such problem.

SCIENTIFIC COMMITTEE FOR FOOD

The SCF was established by a Commission Decision in 1974 which was replaced by Decision 95/273/EC. Its mandate is given in Article 2 of that Decision :

- The Committee shall be consulted by the Commission whenever a legal act requires so (this currently relates to seven Community framework acts and provides the basis for most of the SCF's work).
- The Committee may be consulted by the Commission on any other problem relating to the protection of the health and safety of persons arising or likely to arise from the consumption of food.

The Committee may draw to the attention of the Commission to any such problem.

ANNEX II

MAIN LEGISLATIVE ACTS CURRENTLY REQUIRING THE COMMISSION TO MONITOR OR CONTROL THE MANNER IN WHICH THEY ARE RESPECTED IN MEMBER STATES OR THIRD COUNTRIES

NB. All acts are Council Directives unless indicated otherwise.

Veterinary

Trade and general

72/461/EEC (health controls on intra-Community trade in fresh meat)
72/462/EEC (third country - live animals, fresh meat, meat products)
80/215/EEC (health controls on intra-Community trade in meat products)
89/662/EEC (veterinary checks for animal products in intra-community trade)
90/425/EEC (veterinary checks for live animals and products in intra-community trade)
90/424/EEC (Council Decision - expenditure in the veterinary field.)
90/675/EEC (veterinary checks on products from third countries)
91/496/EEC (veterinary checks on live animals from third countries)
92/65/EEC (animals, semen, ova, embryos not in other Community legislation)
92/117/EEC (zoonoses)
92/118/EEC (animal products covered by other Community legislation)
96/43/EC (financing of veterinary inspections and controls)
96/93/EC (certification of animals and animal products)
96/239/EC (Commission Decision on BSE emergency measures)

Live animals and live animal products, e.g. semen, ova, embryos

64/432/EEC (intra-Community trade in cattle and pigs)
80/217/EEC (control of classical swine fever)
80/1095/EEC (conditions for freedom from classical swine fever)
85/511/EEC (foot and mouth disease)
92/35/EEC (African horse sickness)
92/40/EEC (avian influenza)
92/66/EEC (Newcastle disease)
92/119/EEC (certain animal diseases, including swine vesicular disease)
91/68/EEC (ovine and caprine animals)
90/426/EEC (equidae)
90/539/EEC (poultry and hatching eggs)
88/407/EEC (deep-frozen semen of domestic animals of the bovine species)
89/556/EEC (bovine embryos)
90/429/EEC (porcine semen)
90/667/EEC (disposal and processing of animal waste)
91/67/EEC (aquaculture animals and their products)
93/53/EEC (control of certain fish diseases)
95/70/EC (bivalve molluscs)

Animal products, e.g. meat milk, game etc

64/433/EEC (fresh meat)
77/96/EEC (trichinellosis testing)
77/99/EEC (meat products)
71/118/EEC (poultry meat)
91/494/EEC (fresh poultry meat)
91/495/EEC (rabbit meat and farmed game meat)
92/45/EEC (wild game meat)
94/65/EC (minced meat and meat preparations)

86/469/EEC (residues testing programmes - valid until 1.7.97)
88/146/EEC (hormonal substances - valid until 1.7.97)
92/22/EC (thyrostats, hormones ban - from 1.7.97)
96/23/EC (residues testing programmes - from 1.7.97)

89/437/EEC (egg products)
92/46/EEC (milk and milk based products)

91/492/EEC (live bivalve molluscs)
91/493/EEC (fishery products)

95/408/EC (Council Decision. prelisting of establishments)

97/198/EC (Commission-Decision. Imports of processed animal protein)
97/199/EC (Commission Decision. Imports of petfoods)

Animal welfare and zootechnics

88/166/EEC (laying hens kept in battery cages)
91/628/EEC (protection of animals during transport)
91/629/EEC (protection of calves)
91/630/EEC (protection of pigs)
93/119/EEC (protection of animals at slaughter)
94/28/EEC (zootechnical rules for importation of animals, sperm, ova and embryos)

Foodstuffs controls

89/397/EEC (official control of foodstuffs)
93/43/EEC (hygiene of foodstuffs)
93/99/EEC (official control of foodstuffs)

Plant health

69/464/EEC	(Potato Wart Disease)
69/465/EEC	(Potato Cyst Eelworm)
74/647/EEC	(Carnation leaf-rollers)
93/85/EEC	(Potato ring rot)
77/93/EEC	(organisms harmful to plants or plant products)
2251/92/EEC	(Commission Regulation on quality inspection of fresh fruit and vegetables)
92/70/EEC	(Commission Directive on recognition of protected zones)
92/76/EEC	(Commission Directive on protected zones exposed to particular health risks)
92/90/EEC	(Commission Directive on the registration of producers and importers)
92/105/EEC	(Commission Directive on plant passports)
93/50/EEC	(Commission Directive on the specification of certain plants)
93/51/EEC	(Commission Directive on movement of plants in protected zones)
94/3/EC	(Commission Directive on interception of harmful organisms)
95/44/EC	(Commission Directive on movement of harmful organisms and plants)
3763/91/EEC	(Council Regulation - agricultural products ref French overseas departments)
1600/92/EEC	(Council Regulation - agricultural products ref.Azores and Madeira)